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Exploring the Potential of a Behavior Theory–Informed Digital Intervention for Infant Fall Prevention: Mixed Methods Longitudinal Study

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Abstract

Background: Falls are the most common hospitalized injury mechanism in children aged ≤1 years, and currently, there are no targeted prevention interventions. The prevention of falls in children of this age requires changes in the behavior of their caregivers, and theoretically informed digital behavior change interventions (DBCIs) may provide a unique mechanism for achieving effective intervention. However, user acceptance and the ability of DBCIs to effect the required changes in behavior are critical to their likelihood of success.

Objective: This study aims to evaluate a behavior theory–informed digital intervention developed following a user-centered approach for user experience, the potential for this intervention to prevent infant falls, and its impact on behavioral drivers underpinning fall risk in young children.

Methods: Parents of infants aged <1 year were recruited and asked to use the intervention for 3 months. A pre-post longitudinal design was used to examine the change in the potential to reduce the risk of falls after a 3-month exposure to the intervention. Postintervention data on behavioral drivers for fall prevention, user acceptability, and engagement with the app were also collected. Interviews were conducted to explore user experiences and identify areas for further improvement of the intervention.

Results: A total of 62 parents participated in the study. A statistically significant effect on the potential to reduce falls was observed after the intervention. This effect was higher for new parents. Parents agreed that the intervention targeted most of the target behavior drivers. The impact of behavior drivers and intervention on the potential for fall prevention had a positive correlation. The intervention demonstrated good levels of acceptability. Feedback from participants was mostly positive, and the primary area identified for further improvement was widening the scope of the intervention.

Conclusions: This study demonstrated the promise of a newly developed digital intervention to reduce the risk of infant falls, particularly among new parents. It also showed a positive influence of the DBCI on the drivers of parental behaviors that are important for fall reduction among infants. The acceptability of the app was high, and important insights were gained from users about how to further improve the app.

(JMIR Pediatr Parent 2024;7:e47361) doi:10.2196/47361
KEYWORDS
child injury; digital behavior change interventions; user experience; falls; infant fall; injury; mobile app; digital intervention; users; mixed methods longitudinal study; behavior; development; fall risk; fall prevention; acceptability; app; children; internet; parents; maternal, paternal; accidents; infancy; infant; accidental fall; accidental falls; infant behavior; longitudinal design; mixed methods; parent; mobile phone

Introduction

Children aged ≤1 year, that is, infants, have the highest rate of death owing to fall-related injury, and falls are the most common injury mechanism resulting in emergency department visits and hospitalizations during infancy. The head is the most commonly injured body part owing to infant falls [1-5], and in severe cases, these result in skull fractures, traumatic brain injuries, and long bone fractures [6].

Most of these fall events can be prevented by age-appropriate safe parenting practices and making changes in the child’s environment [7-9], but currently, there are no targeted, proven interventions specifically for infant fall prevention [10,11], and there is also evidence that fall injuries have increased in recent years [12].

To fill this gap, the research team created a behavior theory–based digital intervention for infant fall prevention following an iterative user-centered process [13]. As detailed in the first paper, the Behavior Change Wheel (BCW) [14] combined with the person-based approach [15] was used to theoretically inform and develop a user-centered digital intervention. The resulting intervention included 4 modules targeting common fall mechanisms and events occurring within the first year of an infant’s life.

The four modules consisted of (1) a safe feeding module targeting the prevention of falls related to feeding, (2) a safe furniture use module targeting infant falls related to furniture, (3) a safe use of baby products module targeting infant falls related to baby products, and (4) a safer environment module targeting stairs-related infant falls. The main features of the app include written articles (13 short articles, reading time per article approximately 3.5 min), trackable “tasks” encouraged by the articles where users can check off tasks as they complete them, a dashboard allowing users to check adherence with suggested tasks, and push notifications to remind users to engage with the app. (see the app screenshots in Multimedia Appendix 1).

The user-centered approach taken to develop this intervention inherently focused on ensuring that the target population comprehended the material provided and that the method of delivery was acceptable to users. However, as detailed in the first paper [13], this development process was undertaken iteratively with each individual module, and there is a need to ensure the acceptability of the overall app that integrates the 4 modules. Although the use of the BCW in designing the app was intended to increase the likelihood that engagement with the app would lead to the adoption of behaviors required to reduce the risk of falls among infants, this is not guaranteed, and there is also a need to evaluate whether the app is likely to have the desired impact and if this impact is consistent across all users. Finally, the app can only realize its desired effect if there is appropriate engagement by users with the app, and there remains the need to assess likely parental engagement and the scope for further improving engagement. This paper presents a 3-month longitudinal study to address these questions. The specific aims of this study were as follows:

1. To determine the overall impact of exposure to the intervention on parents’ potential to reduce the risk of infant falls and determine if this is consistent across all users.
2. To examine the behavioral drivers for falls prevention (capability, opportunity, and motivation) among parents after exposure to the intervention and examine the relationship between these factors and the impact of the intervention.
3. To determine acceptability of the app as a whole and engagement with the app.
4. To explore user experience to identify factors driving user acceptability and engagement and scope for further improving the intervention.

Methods

Study Design

This study used a pre-post longitudinal design to examine the change in the potential of parents to reduce the risk of falls after a 3-month exposure to the intervention (part 1). The postexposure survey delivered at 3 months also collected data on behavioral drivers for falls prevention (part 2), user acceptability, and engagement with the app (part 3). User experience was further studied through in-depth interviews with a subset of participants to provide insight into factors driving user acceptability and engagement and to identify the scope for further improvement of the intervention (part 4). Parts 1 to 3 were quantitative and part 4 was qualitative. A mixed methods analysis approach was then used to triangulate the user experience findings from parts 3 and 4.

Ethics Approval

Ethics approval for the study was obtained from the University of New South Wales Human Research Ethics Executive Committee (HC210494).

Study Setting and Participants

Inclusion criteria for participants taking part in this study were as follows: must be aged ≥18 years, a parent of a child aged 0 to 6 months or an expectant parent within 2 months of the due date (mother or father), living in Australia, able to speak and understand English, and have access to a smartphone (iOS or Android). The study duration was 3 months. Participants needed to be in Australia with access to an iOS or Android smartphone because of the availability of the app in relevant app stores. The study duration was selected to cover the relevance of the information within the intervention.
Recruitment
Participants were recruited from an Australian market research company’s existing consumer panel of parents between November and December 2021. A screening survey with questions to assess the inclusion criteria was emailed to the members of the consumer panel. Eligible participants who registered their interest in participating were electronically sent the main consent form to read and consent.

Within the main consent form, participants were invited to opt-in for the in-depth interviews, but a decision not to opt-in to this component did not preclude involvement in the main study. The first 10 consenting participants who opted in and provided separate consent for the in-depth interviews were selected.

The participants were given a gift voucher for Aus $100 (US $65) for completing both baseline and poststudy surveys. In addition, participants who took part in the poststudy in-depth interviews were given an Aus $40 (US $26) gift voucher.

Access to the App
Participants were provided with a link to download the app from the Google Play Store or Apple App Store depending on the smartphone they own.

Data Collection
Baseline and poststudy quantitative data were collected via a survey hosted on REDCap (Research Electronic Database Capture; Vanderbilt University) and distributed to participants electronically (Table 1). The baseline survey collected data on participant demographics (such as education level, income level, number of children, and marital status; Table 2) and questions designed to measure participants’ potential to reduce the risk of infant falls. The latter consisted of the following four questions:

1. I know how to prevent falls among young children
2. Falls in children aged ≤1 year can be prevented
3. I am confident I can take actions to reduce the risk of my child falling
4. I have taken specific actions to reduce the risk of my child falling

The same 4 questions were also included in the poststudy survey. This set of questions was designed to demonstrate whether exposure to the app had the overall desired impact and was measured using a 5-point Likert scale (strongly disagree to strongly agree). The poststudy survey also included open-ended questions designed to (1) collect data from participants on the behavioral drivers for potential to reduce the risk of infant falls (Table 3) based on the Capability, Opportunity, Motivation–Behavior (COM-B) self-evaluation questionnaire [16] and (2) collect information on user experience. The latter user experience questions were framed in terms of user acceptance and engagement with the app.

User acceptance was measured by asking participants how much they liked the app and to rate the level of agreement (Likert scale: strongly disagree to strongly agree) with the following six statements: (1) I found the app easy to use; (2) I found the information useful; (3) the advice provided was easy to follow; (4) I could act on the advice provided; (5) I like the features of the app; (6) I found the reminders or notifications helpful.

For engagement, participants were asked about their use of the app and its features and to respond to the statements “I used the app” (not at all; once; more than once but not often; often—more than once a month; frequently—more than 4 times a month); “I read all the articles” (Likert scale: strongly disagree to strongly agree); and “I used the task list feature” (Likert scale: strongly disagree to strongly agree).

Poststudy qualitative interviews were conducted with a subgroup of 10 participants to understand parents’ user experience with the app and to understand further opportunities to improve the app. In-depth interviews were conducted face-to-face using videoconferencing (Microsoft Teams). A discussion guide was used to structure interviews with each participant. The discussion guide was developed to ensure that participants understood the context of the discussion and to collect more in-depth details about the factors driving their acceptability and engagement with the app than could be collected through a quantitative survey. Similarly, it was also designed to collect more detailed insight into how the material provided in the app influenced the behaviors required to reduce the risk of falls in infants. Before conducting the interviews, the discussion guide was refined through peer-to-peer testing to optimize discussion flow and clarity. The final discussion guide used to frame the 10 in-depth interviews is provided in Multimedia Appendix 2. All the interviews were recorded and transcribed verbatim.
Table 1. Summary table of research variables.

<table>
<thead>
<tr>
<th>Aim, variable, and source</th>
<th>Data type</th>
<th>Analysis conducted</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Factors assumed related to fall prevention (secondary outcome)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Response to survey questions: I know how to prevent falls among young children (a)</td>
<td>5-point Likert scale</td>
<td>Difference between before and after using a paired Wilcoxon signed rank test</td>
</tr>
<tr>
<td>Falls in children under 1 can be prevented (b)</td>
<td>5-point Likert scale</td>
<td>Difference between before and after using a paired Wilcoxon signed rank test</td>
</tr>
<tr>
<td>I am confident I can take actions to reduce the risk of my child falling (c)</td>
<td>5-point Likert scale</td>
<td>Difference between before and after using a paired Wilcoxon signed rank test</td>
</tr>
<tr>
<td>I have taken specific actions to reduce the risk of my child falling (d)</td>
<td>5-point Likert scale</td>
<td>Difference between before and after using a paired Wilcoxon signed rank test</td>
</tr>
<tr>
<td><strong>Potential to reduce falls (primary outcome)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sum of a to d</td>
<td>Continuous variable</td>
<td>Difference in means before and after using a 1-tailed paired t test</td>
</tr>
<tr>
<td><strong>Intervention impact (“total change”—primary outcome)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calculated by postintervention potential to reduce falls minus preintervention potential to reduce falls</td>
<td>Continuous variable</td>
<td>Difference in means between different demographic groups using a 1-tailed paired t test</td>
</tr>
<tr>
<td><strong>Demographics (independent variable)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Various levels (Table 2) for relationship to child, age, experience, country of birth, household income, marital status, and education level</td>
<td>Categorical variable</td>
<td>Difference in means between different demographic groups using a 1-tailed paired t test</td>
</tr>
<tr>
<td><strong>Intervention impact (“total change”—primary outcome)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calculated by postintervention potential to reduce falls minus preintervention potential to reduce falls</td>
<td>Continuous variable</td>
<td>Linear regression used to examine influence of behavior scores on intervention impact while controlling for parental experience</td>
</tr>
<tr>
<td><strong>Capability score (independent variable)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Response to survey questions (Table 3) by Likert scales summed</td>
<td>Continuous variable</td>
<td>Linear regression used to examine influence of behavior scores on intervention impact while controlling for parental experience</td>
</tr>
<tr>
<td><strong>Opportunity score (independent variable)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Response to survey questions (Table 3) by Likert scales summed</td>
<td>Continuous variable</td>
<td>Linear regression used to examine influence of behavior scores on intervention impact while controlling for parental experience</td>
</tr>
<tr>
<td><strong>Motivation score (independent variable)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Response to survey questions (Table 3) by Likert scales summed</td>
<td>Continuous variable</td>
<td>Linear regression used to examine influence of behavior scores on intervention impact while controlling for parental experience</td>
</tr>
<tr>
<td><strong>Overall behavior score (independent variable)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calculated by the aggregate of capability, opportunity, and motivation scores</td>
<td>Continuous variable</td>
<td>Linear regression used to examine influence of overall behavior score on intervention impact while controlling for parental experience</td>
</tr>
<tr>
<td><strong>Experienced parent (confounder)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes=2 or more children; no=1 child</td>
<td>Categorical variable</td>
<td>Linear regression used to examine influence of overall behavior score on intervention impact while controlling for parental experience</td>
</tr>
<tr>
<td><strong>Aim 3</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Engagement (outcome)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Response to survey questions</td>
<td>5-point Likert scale</td>
<td>Descriptive statistics</td>
</tr>
<tr>
<td><strong>Likeability (outcome)</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Analysis conducted

Data type

Analysis conducted

Aim 4

Response to survey questions 5-point Likert scale Descriptive statistics

Barriers and enablers of the intervention

Poststudy interview Qualitative data Qualitative descriptive method

Table 2. Participant demographics (N=60).

<table>
<thead>
<tr>
<th>Relationship to child</th>
<th>Participants, n (%)</th>
<th>Total change, mean (SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mother</td>
<td>54 (90)</td>
<td>2.35 (2.17)</td>
<td>.48</td>
</tr>
<tr>
<td>Father</td>
<td>6 (10)</td>
<td>1.67 (2.80)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age (y)</th>
<th>Participants, n (%)</th>
<th>Total change, mean (SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>26-35</td>
<td>40 (67)</td>
<td>2.15 (2.34)</td>
<td>.41</td>
</tr>
<tr>
<td>36-45</td>
<td>19 (32)</td>
<td>2.68 (1.97)</td>
<td></td>
</tr>
<tr>
<td>46-55</td>
<td>1 (2)</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of children (dichotomized to a new parent and experienced parent)</th>
<th>Participants, n (%)</th>
<th>Total change, mean (SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (new parent)</td>
<td>20 (33)</td>
<td>3.15 (2.30)</td>
<td>.03</td>
</tr>
<tr>
<td>1 (experienced parent)</td>
<td>40 (67)</td>
<td>1.85 (2.08)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parent born in Australia</th>
<th>Participants, n (%)</th>
<th>Total change, mean (SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>49 (82)</td>
<td>2.20 (2.26)</td>
<td>.57</td>
</tr>
<tr>
<td>No</td>
<td>11 (18)</td>
<td>2.64 (2.11)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Household income (Aus $)</th>
<th>Participants, n (%)</th>
<th>Total change, mean (SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;Aus $100,000 (&lt;US $65,000)</td>
<td>15 (25)</td>
<td>1.81 (1.87)</td>
<td>.48</td>
</tr>
<tr>
<td>Aus $100,000-Aus $150,000 (US $65,000-97,500)</td>
<td>20 (33)</td>
<td>2.40 (2.50)</td>
<td></td>
</tr>
<tr>
<td>≥Aus $150,000 (≥US $97,500)</td>
<td>21 (35)</td>
<td>2.29 (2.33)</td>
<td></td>
</tr>
<tr>
<td>Decline to answer</td>
<td>3 (5)</td>
<td>4.00 (0)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Marital status</th>
<th>Participants, n (%)</th>
<th>Total change, mean (SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Married</td>
<td>43 (72)</td>
<td>2.28 (2.26)</td>
<td>.99</td>
</tr>
<tr>
<td>Single parent</td>
<td>3 (5)</td>
<td>2.33 (2.52)</td>
<td></td>
</tr>
<tr>
<td>De facto (common law marriage)</td>
<td>14 (23)</td>
<td>2.29 (2.23)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Education level</th>
<th>Participants, n (%)</th>
<th>Total change, mean (SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary school, secondary school, and some university or TAFE diploma</td>
<td>20 (33)</td>
<td>2.20 (1.88)</td>
<td>.66</td>
</tr>
<tr>
<td>University or TAFE graduate</td>
<td>25 (42)</td>
<td>2.08 (2.38)</td>
<td></td>
</tr>
<tr>
<td>Postgraduate degree</td>
<td>15 (25)</td>
<td>2.73 (2.46)</td>
<td></td>
</tr>
</tbody>
</table>

aN/A: not applicable.
bTAFE: technical and further education.
Table 3. The mean level of agreement with intervention impact on behavioral drivers.

<table>
<thead>
<tr>
<th>The app has improved my knowledge on (capability)</th>
<th>Values, mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The importance of getting rest</td>
<td>3.93 (0.94)</td>
</tr>
<tr>
<td>How to reduce fall risk while feeding my baby</td>
<td>4.15 (0.84)</td>
</tr>
<tr>
<td>How to reduce fall risk while my baby sleeps</td>
<td>4.12 (0.90)</td>
</tr>
<tr>
<td>How to reduce fall risk while changing my baby</td>
<td>4.40 (0.79)</td>
</tr>
<tr>
<td>How to reduce fall risk when using baby products like chairs and prams</td>
<td>4.17 (0.85)</td>
</tr>
<tr>
<td>How to reduce fall risk on stairs</td>
<td>4.30 (0.79)</td>
</tr>
<tr>
<td>Overall</td>
<td>4.18 (0.86)</td>
</tr>
</tbody>
</table>

After using the app, I feel (opportunity)

| I have the support I need to get enough rest      | 3.50 (0.98)      |
| I have everything I need to reduce fall risk while I feed my baby | 4.35 (0.60)      |
| I have everything I need to reduce fall risk while my baby sleeps | 4.38 (0.56)    |
| I have a safe place to change my baby            | 4.52 (0.68)      |
| I am able to correctly use safety straps when using baby products like chairs and prams | 4.58 (0.53) |
| I have everything I need to reduce fall risk on stairs | 4.20 (0.73) |
| Overall                                          | 4.26 (0.78)      |

After using the app (motivation)

| Remember to ask for help when feeling tired and feeding my baby | 3.90 (1.00)      |
| Have established a routine to reduce fall risk while feeding my baby | 4.08 (0.81) |
| Intend to ensure my baby always sleeps in a cot | 3.95 (1.17) |
| Believe changing my baby on the floor is the best option if I do not have access to a safe change table | 4.53 (0.77) |
| Have established the habit of correctly using safety straps when using baby products like chairs and prams | 4.42 (0.74) |
| Believe stairgates are important in areas accessed by my child | 4.68 (0.50) |
| Overall                                          | 4.26 (0.90)      |

Analysis

The R programming language (R Foundation for Statistical Computing) was used for statistical analysis. In-depth interview data were transcribed and analyzed using NVivo software (Lumivero). Sample characteristics for the 60 participants in the longitudinal study were examined using descriptive statistics. The analytical approaches varied for each part (parts 1-4) of the study. The following section describes the approach adopted for each part.

Part 1: Determining the Overall Impact of Exposure to Intervention to Reduce the Risk of Falls

The primary outcomes studied in part 1 were the change in responses to the 4 questions included in both the pre- and poststudy surveys (ie, I know how to prevent falls among young children; falls in children under 1 can be prevented; I am confident I can take actions to reduce the risk of my child falling; and I have taken specific actions to reduce the risk of my child falling) and change in overall participants “potential to reduce the risk of infant falls.” The latter was calculated from both pre- and poststudy responses by summing the Likert values for each of the 4 questions. An “intervention impact” score was then calculated by subtracting the total pre score from the total post score.

The pre-post difference in responses to the 4 questions was examined using paired Wilcoxon signed rank tests. The pre-post difference in the overall “potential to reduce the risk of infant falls” was examined using a 1-tailed paired t test.

The influence of exposure to the app on potential to reduce the risk of infant falls for different types of participants (as described by demographic variables: relationship to child, age of parent, 1 or more children, country of birth, household income, marital status, and education level) was examined by testing the difference in mean “intervention impact” between the different demographic groups. For dichotomous variables, independent 1-tailed t tests were used, and for variables with ≥2 category levels, ANOVA was used.

Part 2: Behavior Drivers for Fall Prevention After Exposure to the Intervention and the Relationship Between Behavior Drivers and the Impact of the Intervention

To examine the behavioral drivers for falls prevention (capability, opportunity, and motivation) among parents after
exposure to the intervention, the mean level of agreement with each of the capability, opportunity, and motivation statements (Table 3) was calculated across the whole sample, together with the overall mean for each group of statements across the whole sample, that is, a mean overall capability, opportunity, and motivation score.

To examine the relationship between the behavioral drivers as self-evaluated by participants and the impact of the intervention, a capability, opportunity, and motivation score was calculated for each participant by summing the level of response provided for each question in each group (Table 3), and an overall “behavioral driver” score for each participant was calculated by summing the level of agreement with each statement listed in Table 3. The association between the behavioral component scores (ie, capability, opportunity, and motivation scores for each participant) and the impact of the intervention was examined using multivariable linear regression. A second linear regression analysis was then conducted to examine the relationship between the overall behavioral driver scores and the impact of the intervention. In both regression models, demographic variables found to be significantly associated with the impact of the intervention were also controlled for parent’s experience.

Part 3: Determining Acceptability of the App as a Whole and Engagement With the App

Engagement with the app, as measured using responses to the question “I used the app,” and the number of tracked tasks per participant were examined using descriptive statistics.

The acceptability of the app as a whole was determined by calculating the mean levels of agreement for each “app-like” statement across the sample, together with the mean overall level of agreement for this group of “app-like” statements across the sample.

Part 4: Explore User Experience to Identify Factors Driving or Hindering User Acceptability and Engagement and Scope for Further Improvement

The in-depth interview data were analyzed using a qualitative descriptive method to identify barriers and enablers of the intervention in terms of user experience [17].

Sample Size

A sample size of 62 was estimated to be sufficient for the quantitative components of the study based on a power calculation to see a significant change in parents’ potential to reduce the risk of falls with an effect size of 0.4 and 80% power at the 5% level, allowing for up to 20% loss to follow-up and rounding up to the next full number.

For the qualitative poststudy in-depth interview, a sample size of 10 was chosen using a rule of thumb that this sample size should be sufficient to reach saturation and is double the minimum sample size recommended for digital intervention usability studies with a sample of 5 [18].

Results

Sample Characteristics

A total of 62 participants were recruited, downloaded the app, and completed the baseline survey, with 2 (3%) lost to follow-up. Therefore, 60 participants completed the poststudy survey. Table 2 presents the sample characteristics. In summary, 54 (90%) were mothers, 40 (67%) were aged 26 to 35 years, 20 (33%) were new parents, and 49 (82%) were born in Australia; 43 (72%) patients were married.

Part 1: Determining the Overall Impact of Exposure to the Intervention to Reduce the Risk of Falls

There was a significant improvement in each measure of the potential to reduce the risk of infant falls from after exposure to the intervention compared with before exposure. For each question, there was a significant increase in the level of agreement with the statements (Figures 1-4; \( P < .001 \)).

There was also a significant improvement in the overall potential of parents to reduce the risk of falls after using the intervention. The mean overall score among participants before exposure was 15.77 (SD 2.24; range 10-20) and 18.05 (SD 1.86; range 14-20) after a 3-month exposure to the app (\( P < .001 \)). Across the entire sample, the mean “total change” in potential to reduce the risk of falls was 2.28 (SD 2.23; range −2 to 8).

Table 2 presents the “total change” according to the different participant demographics. The only significant difference by demographics was a significantly greater “total change” in the potential to reduce the risk of infant falls among participants with only 1 child. Parents with ≥2 children had a mean “total change” of 1.85 (SD 2.08; range −2 to 5) whereas the less-experienced parents with only 1 child had a mean “total change” of 3.15 (SD 2.30; range −1 to 8; \( P = .03 \)).
**Figure 1.** Level of agreement with “I know how to prevent falls among young children”: before versus after.

![Bar chart showing level of agreement before and after intervention.](chart1)

**Figure 2.** Level of agreement with “Falls in children under 1 can be prevented”: before versus after.

![Bar chart showing level of agreement before and after intervention.](chart2)
Figure 3. Level of agreement with “I am confident I can take actions to reduce the risk of my child falling”: before versus after.

Figure 4. Level of agreement with “I have taken specific actions to reduce the risk of my child falling”: before versus after.
Part 2: Behavior Drivers for Fall Prevention After Exposure to the Intervention and the Relationship Between Behavior Drivers and the Impact of the Intervention

The mean level of agreement with each statement across the sample is shown in Table 3. As shown in Table 3, there was strong agreement with overall capability, motivation, and opportunity as self-evaluated by participants after using the app. The only aspect where there was inconsistent strong agreement was in questions related to getting enough rest where capability, opportunity, and motivation means across the sample remained <4.

Table 4 and 5 present the results of the linear regression analyses. In the univariate analysis, opportunity and motivation scores were significantly associated with the impact of the interventions, with increasing behavioral component scores associated with increasing impact scores. However, in the multivariable analysis when controlling for parent experience (which was found to be significantly associated with the impact of intervention in part 1), none of the individual behavior components were significantly associated with impact (Table 4).

As shown in Table 5, the overall behavior score was significantly associated with increasing impact scores, even when controlling for parents’ experience.

<table>
<thead>
<tr>
<th>Table 4. Regression analysis modeling the relationship between behavior drivers and intervention impact.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Univariate</strong></td>
</tr>
<tr>
<td><strong>P value</strong></td>
</tr>
<tr>
<td>Capability score</td>
</tr>
<tr>
<td>Opportunity score</td>
</tr>
<tr>
<td>Motivation score</td>
</tr>
<tr>
<td>Experienced parent (yes or no)</td>
</tr>
</tbody>
</table>

^aP<.05.

<table>
<thead>
<tr>
<th>Table 5. Regression analysis modeling the relationship between overall behavior score and intervention impact.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Univariate</strong></td>
</tr>
<tr>
<td><strong>P value</strong></td>
</tr>
<tr>
<td>BD^a score</td>
</tr>
<tr>
<td>Experienced parent (yes or no)</td>
</tr>
</tbody>
</table>

^aBD: Behavior Drivers Score.

Part 3: Determining Acceptability of the App as a Whole and Engagement With the App

Table 6 presents the mean level of agreement of app use statements across the sample of participants, including their app use, whether they read the articles, and used the task tracking feature. The mean number of completed tasks per participant was 24 (SD 24.2052).

Table 7 presents the mean levels of agreement across the whole sample for each of the “app-like” statements and the mean overall, indicating generally strong acceptability (agreement levels over 4) of the app as a whole. The lowest levels of agreement were in the response to the “I like the features of the app” and “I found the reminders/notifications helpful.”

<table>
<thead>
<tr>
<th>Table 6. Participant agreement with the use of the intervention.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>App use</strong></td>
</tr>
<tr>
<td>I used the app</td>
</tr>
<tr>
<td>I read the articles</td>
</tr>
<tr>
<td>I used the task tracking feature</td>
</tr>
</tbody>
</table>
Table 7. Participant agreement with the acceptability of the intervention.

<table>
<thead>
<tr>
<th>App-like</th>
<th>Scores, mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I found the app easy to use</td>
<td>4.20 (0.71)</td>
</tr>
<tr>
<td>I found the information useful</td>
<td>4.05 (0.79)</td>
</tr>
<tr>
<td>The advice provided was easy to follow</td>
<td>4.52 (0.60)</td>
</tr>
<tr>
<td>I could act on the advice provided</td>
<td>4.22 (0.94)</td>
</tr>
<tr>
<td>I like the features of the app</td>
<td>3.67 (0.93)</td>
</tr>
<tr>
<td>I found the reminders or notifications helpful</td>
<td>3.68 (0.89)</td>
</tr>
<tr>
<td>Overall score</td>
<td>4.05 (0.87)</td>
</tr>
</tbody>
</table>

Part 4: Exploring User Experience to Identify Factors Driving or Hindering User Acceptability and Engagement and Scope for Further Improvement (Qualitative Analysis)

General Understanding of Child Injury and Feedback on the Intervention

Parents expressed that the intervention provided them with important information, which was new. The intervention seemed to be valued more by new parents. It was evident that child injury was not an area that parents gave much attention to (“Injury is not something I had put too much thought into, I guess I just considered a baby didn’t move”). Some parents had a general understanding and personal fear about falls due to the experiences of other parents they knew. In addition, safe sleeping practices and safe change table practices were commonly identified as information parents received from antenatal classes (“one of the main ones that I sort of looked at when my first son was born was more pages like SIDS”). However, the consensus was that they had little knowledge of specific preventive actions for most of the common fall events:

I learned so much...it brought to light a lot of things that you wouldn’t think of...first I was like, you know, but then every time I would read something, I’d learn something.

Experienced parents (who had more than 1 child) also identified the importance of the intervention. Even in cases where they knew some preventive actions beforehand due to lived experiences (“it was really just some anecdotal stories of my friends babies falling off things and hurting themselves...”), they identified that the intervention was a good reminder to adhere to safe behaviors:

I can’t remember how I learned the information with my first child, but it was definitely a great reminder and easy access to find the information all in one place.

Parents liked the style of the articles, which they reported they found engaging and informative and liked that the length was not too long. They also identified that if articles were too long, parents may not bother reading them, particularly as during the first year of a child’s life a lot of information is “thrown” at parents:

I thought it was really well written. I liked the style of the way that it was written. I thought it was. It was very engaging and informative and I liked the length of it as well. But it wasn’t too long. It just made it easy to when you’re busy as a mum, sort of dip in and out of just having a bit of a look and yeah, and like getting some information quite quickly rather than reading pages and pages out. It was also quite easy to access different topics with them.

Parents also identified the importance of the tone of the intervention and appreciated the practical nature of the advice provided:

I liked it because it was really straightforward. It’s not in any way condescending. I don’t think it’s like I think sometimes you read resources and they can be like talking down to you. But I found that it was like simple language, but not in a condescending way.

Credible profiles were valued by parents. They requested more ways to show the credibility of the information such as embedded links below the articles from reputable organizations:

And I like it. It’s got the...like professors on there.... So it’s telling you that there’s experts on this.

The task-tracking and adherence dashboards were features liked by most participants. “Checking things off a list” was well liked. The adherence dashboard was found to be an incentive “to get it all green.” Parents understood the rationale of task tracking and expressed its importance in encouraging them to adhere to what was conveyed in the articles. However, there were some issues with the user experience of this feature (“I’m not finding easy to find what the ongoing ones are”). One parent requested access to the task list directly, without going through any related article. Another expressed that they could not get “100%” due to some tasks being not relevant for them. The “if-then” tasks were somewhat disliked:

I think that I think that idea of it is good, like having tasks that you can go through and say, yes, we’ve done this, but just the way it was delivered.

I quite like checking things off. At least you know this is quite satisfying to kind of get to the ending. Right. OK, well, you know, I have half a clue about what I’m doing in this area.

The notifications were found to be helpful. Parents expressed that the notifications made them come back to the app, made
them read the articles, and helped them adhere to suggested practices. However, 2 participants mentioned that they did not receive notifications:

*I liked the little reminders and I do. I do like that ‘cause I think you get busy and then you don’t think to use it. So I did like the notifications as a way from reminding to dip back in and have information.*

App aesthetics was also positively received. Parents liked that the app used real photos rather than drawings. Several “typos” within the content were noticed by the parents and were negatively received (“I’m a bit of a stickler for, you know, the text, I guess so, like typos and things, you know”).

**Feedback on 4 Modules**

Information provided in the safe feeding module was not practical for some parents. This was because it was dependent on the amount of social support available for mothers.

In addition, some mothers identified the possibility of cosleeping occurring, although this was not suggested by the module. One mother indicated that her initial evaluation of the intervention was not positive because of this inapplicability to her situation:

*I think probably this one was the least effective for me. I think like I like I mean it. I thought it was very helpful for reminding, reminding you of the importance of rest in that, that there it is risky to feed while you are tired. I think like in terms of actually making changes, it was I think the app was less helpful in doing that then the other modules because it was really around like getting support and that sort of thing, which is something that the app can’t necessarily help you with because either you have social support and you have people that can help you or you don’t work down the other modules provided more practical advice which weren’t sort of dependent on social support.*

**Get enough sleep, you know, have your partner or someone to support you to come and do that? Well,... I actually left my job after my first one, and my husband still works and he gets up at 4:00 AM. It’s unrealistic for me to expect that. But for me, the one who doesn’t work to say, Oh no, you need to get up. Or every second night you’re on duty to take over. It’s just not possible.**

Some advice was not practical for parents with more than one child, such as “sleeping while the baby sleeps,” where they have to take care of the other child at the same time (“to sleep when the baby sleeps, I thought, what about my toddler, he doesn’t nap”).

Despite these limitations, parents understood the reasons for the suggested practices. They also expressed that the module made them conscious when they were tired during night feeding and encouraged them to take action to reduce the chance of falling asleep while holding the baby. Some expressed the importance of acknowledging differences in individual experiences within the module to mitigate any negative feelings induced (“it’s one of those things where it’s like ideal situation, right. But the reality is just sometimes so different”).

The parents liked the safe furniture use module. The message “one day the baby is still, and next day they are rolling,” resonated well with the parents. Commonly, parents expressed that they practiced keeping the baby in the cot if they had to move away or “on the floor;” where they could not fall, but some parents still left their baby on a bed, when they are in the prerolling age, in the “middle of the bed”:

*I really liked this one. It made me yeah, it really made me reconsider that. Uhm, you know, even if you think either in the middle of the bed they are fine, that actually like it, they made that maybe when they roll and so it may be this. So this was helpful for me in thinking actually, although you’re tempted to put them on the bed or put them on the change table, they’re actually safer on the floor like putting them on the carpet actually safer than putting them on the bed. So this one actually really did stick with me. And that’s something that I thought about continually is actually just put him on the floor and he’s safer ’n the floor ‘cause he can’t fall anywhere.*

Parents found safe nappy change practices to be acceptable when using a change table. For some, this was aligned with the information received previously in the antenatal classes, but most mentioned that there are no safety straps in their own change tables, so keeping a hand on the baby was the applicable advice (“I don’t have a change table with straps and I do. I’m not sure that that’s a standard thing”). Changing nappies on the floor “where they can’t fall” was also liked by some, but some expressed this may be not practical in instances where the mother had a cesarean birth (“but as a mom who had two caesareans, I’m not gonna be getting down on the floor with a newborn baby”).

The module for the safe use of baby products was well received. Parents reported that the module made a difference on how they used safety straps with products. Some parents previously did not think of using straps when the baby was “very small” but reported that the module had an influence on changing the practice of using safety straps. One parent found that the information also influenced how they picked secondhand baby products, which seemed to be a common practice:

*I think it might has made me so that you always say the straps here, but I think it’s just made it. It really reinforced to me how important it is to always do it up and if they look, you know that you think are there sitting there. They look secure, already without the straps on just to make it a habit of doing them up. So that was really good reminder for me that or you always need to just do it up just to just for that safety ‘cause you never know when they’re gonna try and reach for something or rollout or slide out. I think it also made me more aware of When I was buying secondhand baby items, they saw that all of the clips and everything were usable and that and present.*

The use of a wheeled baby walker was well accepted. Parents had commonly received some information on the negatives of
baby walkers before the intervention. They understood that wheeled walkers are a fall risk and might also affect a baby’s natural ability to stand. One parent mentioned that they still used one, but the duration of use was reduced after the intervention:

No. I never did. Somewhere I read early on that they aren’t safe ‘cause they can get to places they shouldn’t be able to get to. Uh…. So I’ve never had one. I had a bouncer that didn’t move. That’s probably not great for their development, but in put them in it too much. But it wasn’t their safety thing in terms of, yeah, getting places, they shouldn’t get to.

Parents who had stairs in their homes identified the importance of the information included in the module for creating a safe home. Parents knew about using safe gates but identified the importance of other stair safety practices, but commonly, parents who did not have stairs found this module not relevant to them. They requested relevant information, such as babyproofing the environments:

We already knew that we needed to get safety gates. I’ve got friends with children. So you’re already aware of the gates. But I do find the app. Yeah. Helpful from just from the tips around stairs. So, like, sort of saying don’t step over the gate. And that’s really stuck out to me. Was like, hold onto the rails and like and making sure that you have a free hand because it’s so easy with stairs to hold baby in one hand and then be carrying a cup of tea or something else with the other hand. That is something that has changed my behavior, like making sure that I don’t have my hands full and nothing to hold onto.

**General Feedback**

Most of the interviewed parents expected more from the intervention. Even those who really liked the intervention expected more. Some thought the scope was too narrow, focusing only on falls, compared with multiple injury mechanisms, and mentioned that they may not have used it if they came across it outside the study. In addition, they felt that the intervention should have more engaging features (“It need something to keep you coming back to”). Parents had several suggestions to improve the scope of the intervention, such as providing more information relevant to older children, information on other child injury types, and prevention (babyproofing the house), including first-aid information and tapping into other relevant early childhood information:

...And I know this is sort of more a pilot, but I just wanted to see more, but I think that’s where you’re going with it. I’m, I’ve got through the modules quite quickly and I thought there’s no more. I finished it now.

Parents expressed the importance of receiving the app from reputable agents to find it valuable and for them to use it (eg, via an antenatal class):

I think if I’d been aware of it, yeah, I definitely think so. So yeah, if, yeah, if at the hospital or the midwife or if it had been in, you know, the baby bundle that you get if there’d been a little flyer. Yeah, it would be something I’d look at. And definitely if I’d known it.

Parents reported that they liked mobile apps rather than scanning through websites to obtain relevant information. Similarly, it was evident that although they tended to use social media groups (Facebook groups) to seek childcare information, they preferred reputable sources and sources where they can find professionally backed reputable information:

And sometime like when you’re looking at websites and stuff, it can get so confusing, whereas like having an app or just one place to look just makes things so much more straightforward.

I’ve recently got rid of Facebook because they’re or maybe within those groups, there tends to be lots of negativity and scaring and I would be, I think it’s taken me three kids and this long to realize that it’s probably not a space I really want to be in and without an expert moderator, I don’t wanna be there ’cause you can get too much information.

Parents felt that there is a place for digital interventions in the space of early childhood interventions. Several parents shared the opinion that the support provided by the primary health care system reduced after a while and identified the viability of digital health interventions to fill this gap. In addition, they felt that the intervention value would increase if it provided some form of opportunity to connect with a health care professional:

Because there is such limited access to midwife and nursing support after having baby now like anything you can access at home...make a difference.

You have lot of contact with the support initially, then you don’t really see anyone.

**Triangulation of Quantitative and Qualitative Data**

Triangulating the quantitative and qualitative data provided insights for where key improvements could be made to the app going forward. As shown in Table 8, where these are summarized, these largely focus on improvements that would make the app more valuable to parents.
Table 8. Areas to improve and potential improvements.

<table>
<thead>
<tr>
<th>Areas to improve</th>
<th>Potential improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broadening the scope of the intervention</td>
<td>Intervention could be broadened by including first-aid information and other injury information, including information relevant to a broader age group of children and other early childcare information. Special consideration needs to be given to make the app more valuable for experienced parents.</td>
</tr>
<tr>
<td>More autonomy for parents and reframing some advice as “suggestions”</td>
<td>Within intervention content, focus will be given to ensure the advice conveys as suggestions rather than “must follow” advice.</td>
</tr>
<tr>
<td>Improving practicality of information</td>
<td>Special consideration will be given to palpability of advice considering a range of individual circumstances of parents.</td>
</tr>
<tr>
<td>Improvements to task tracking</td>
<td>The task-tracking feature will be improved by introducing a direct way to access task lists and better ways to identify task ongoing and completion states.</td>
</tr>
<tr>
<td>Improvements to if-then plans</td>
<td>If-then tasks will be improved with giving parents a list of options that they can select from to create if-then rules.</td>
</tr>
<tr>
<td>Connecting parents to a health care professional</td>
<td>A feature where parents have ≥1 sessions with a health care professional who is experienced in child injury and early childhood could be introduced. This could also be used as a reengaging moment with the intervention for parents.</td>
</tr>
</tbody>
</table>

**Discussion**

**Principal Findings**

The findings from this study demonstrate promising potential of the intervention in terms of the impact on reducing the risk of infant falls, particularly among new parents. They also indicate promise in terms of an influence on drivers of parental behaviors important for fall reduction among infants. Acceptability of the app was high, and important insights were gained from users about how to further improve the app.

In this study, the potential to reduce the risk of falls was measured by examining the change in responses to a set of questions asked by the participants before and after the 3-month long exposure to the app. As there was no available validated measure, this set of questions was developed on the basis that knowing falls can be prevented, feeling confident that actions can be taken to prevent falls and taking action to reduce fall risk align with what was hoped would be the desired outcomes from exposure to the app. Although this is self-reported and not a validated measure, the relationship observed between this measure and the participants’ responses to questions based on the COM-B self-evaluation questionnaire provides a level of promise that the intervention may work as intended. However, confirmation of the effectiveness of the intervention requires a different methodological approach, such as randomization and use of control, and for this purpose, the use of an objective measure such as reduction in falls would be preferred. Demonstrating the promise of an intervention during the early stages is important, as this reduces the risk of unnecessarily wasting resources in a later, larger, and more resource-intensive randomized controlled trial.

For digital and mobile health interventions, acceptability, usability, and engagement are likely to be as important to effectiveness as the content. The results also demonstrate promise in this regard. Importantly, the users trialing the app appeared to like the app and found it easy to use and useful. More importantly, the feedback from the users identified some areas for further improvement that could be relatively easily actioned, such as improvements to the task-tracking and “if-then” plans, and reframing some of the advice provided to convey more autonomy. However, as identified in user testing during the development phases [13], it was clear from this longitudinal study that in the longer term, the scope of the app needs to be broadened to increase the likelihood of high levels of ongoing engagement.

Concerns raised about the practicality of advice and the relevance of all components of the intervention to all users in this longitudinal study also reflected some of the feedback received during the user testing reported in the study by Cooray et al [13]. As noted in this study [13], issues raised regarding the practicality of advice drawn from best-practice sources indicate a need for further research into practical solutions. However, it may be that it is only certain parents or parents in certain situations who have practical issues, that needs to be explored further. It is possible that the contents of the intervention could be delivered in an individually tailored manner, and this might overcome both the concern of relevance of all information to all users, as well as issues related to the practicality of some advice for certain people or situations. Digital intervention in which injury prevention information is tailored to individuals has been found to be effective in promoting the adoption of safety behaviors relevant to the use of stair gates as well as other childhood injury mechanisms [19]. The potential of this approach should be considered in conjunction with further development of the app.

The potential promise of this behavioral theory–driven app on influencing behavior relevant to falls aligns with the success of other theory-driven digital interventions targeting childhood injury in changing behavior [20-23]. However, this is the first childhood injury intervention developed using the BCW. The significant association between the “behavior score” calculated from responses to the parental COM-B self-evaluation questionnaire and the outcome measure observed in this study also appear to be the first attempt at examining the pathways through which a behavioral theory–driven childhood injury prevention intervention works. Although the approach in this study was rudimentary, consideration should be given to designing future rigorous testing of the app in such a way that the mechanistic pathways can be studied in parallel with the
overall effectiveness. The quantitative process evaluation being undertaken by Brown et al [24] in conjunction with the evaluation of their user-driven intervention to reduce the misuse of child restraints is an example of how this might be achieved. This level of evidence for the behavioral underpinnings of the success of digital interventions would further strengthen the case for designing childhood injury interventions using a behavioral theory lens.

The person-based approach to app development is likely to have influenced the high levels of usability and acceptance of the app. However, user feedback indicates that more work is required to increase engagement. The importance of engagement in digital injury prevention interventions has also been identified by other researchers. For example, Ning et al [20] cited poor engagement as a factor that may have reduced the impact of their digital intervention on reducing actual rates of injury. In their study, they measured average hours of engagement and felt that the level of engagement was relatively lower in terms of average hours of engagement than had been reported in other successful digital interventions [20]. However, no attempt has been made to directly study the level of engagement and any outcome. In contrast, Burgess et al [22] examined the direct association between their measure of engagement and an increase in knowledge and found a significant association. Including objective measures of engagement in future attempts to quantitatively evaluate processes underpinning the success of digital interventions would also appear to be useful.

The lack of an objective or quantifiable measure of engagement in this study was a limitation, and tracking engagement is something that should be added to the protocols of any future studies with this app. Other important limitations of this study are as follows: the use of an unvalidated outcome measure for the performance of the app and the pre-post design, which means no causal relationship between exposure to the app and the outcome measure can be confidently claimed. Furthermore, when reviewing the results of this study, it should be noted that recruiting participants via an internet-based panel means that the sample is possibly biased toward inclusion of only those who are already digitally active and computer literate, which may affect the generalizability of the findings. Future studies should aim to assess the intervention across a broader segment of the population. Keeping these limitations in mind, a strength of the study lies in the usefulness of the work as an intermediate step between optimization through user testing and a more resource-intensive controlled trial with a larger population-representative sample.

Conclusions
The 3-month longitudinal user-testing study has demonstrated the potential promise of the behavioral theory–driven, person-based intervention and has highlighted further scope for refinement. Overall, broadening the scope of the app appears to be the most important issue to be addressed in future work.

Conflicts of Interest
None declared.

Multimedia Appendix 1
App screenshots.
[DOCX File, 699 KB - pediatrics_v7i1e47361_app1.docx]

Multimedia Appendix 2
Interview discussion guide.
[DOCX File, 18 KB - pediatrics_v7i1e47361_app2.docx]

References


Abbreviations

BCW: Behavior Change Wheel
COM-B: Capability, Opportunity, Motivation–Behavior
Parent Perceptions of Telemedicine for Acute Pediatric Respiratory Tract Infections: Sequential Mixed Methods Study

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Abstract

Background: Since 2020, parents have had increasing opportunities to use telemedicine for their children, but how parents decide whether to use telemedicine for acute pediatric care relative to alternative sites of care is not clear. One of the most common reasons parents seek acute care for their children’s acute respiratory tract infections (ARTIs).

Objective: This study aims to examine parental expectations of care via telemedicine for pediatric ARTIs, contrasting expectations of care delivered via primary care telemedicine and direct-to-consumer (DTC) telemedicine.

Methods: We performed a sequential mixed methods analysis to examine how parents assess telemedicine for their children’s acute care. We used ARTIs as a case study for examining parent perceptions of telemedicine. First, we analyzed semistructured interviews focused on parent responses about the use of telemedicine. Each factor discussed by parents was coded to reflect whether parents indicated it incentivized or disincentivized their preferences for telemedicine versus in-person care. Results were organized by a 7-dimension framework of parental health care seeking that was generated previously, which included dimensions related to care sites (expected access, affordability, clinical quality, and site quality) and dimensions related to child or family factors (perceived illness severity, perceived child susceptibility, and parent self-efficacy). Second, we analyzed responses to a national survey, which inquired about parental expectations of primary care telemedicine, commercial DTC telemedicine, and 3 in-person sites of care (primary care, urgent care, and emergency department) across 21 factors identified through prior qualitative work. To assess whether parents had different expectations of different telemedicine models, we compared survey responses for primary care telemedicine and commercial DTC telemedicine using weighted logistic regression.

Results: Interview participants (n=40) described factors affecting their perceptions of telemedicine as a care modality for pediatric ARTIs. Generally, factors aligned with access and affordability (eg, decreased wait time and lower out-of-pocket cost) were discussed as potential incentives for telemedicine use, while factors aligned with perceived illness severity, child susceptibility, and clinician quality (eg, trustworthiness) were discussed as potential disincentives for telemedicine use. In survey responses (n=1206), primary care and commercial DTC telemedicine were rated similarly on items related to expected accessibility and affordability. In contrast, on items related to expected quality of care, primary care telemedicine was viewed similarly to in-person primary care, while commercial DTC telemedicine was rated lower. For example, 69.7% (weighted; 822/1197) of respondents anticipated their children would be comfortable and cooperative with primary care telemedicine versus 49.7% (weighted; 584/1193) with commercial DTC telemedicine (P<.001).
Conclusions: In a mixed methods analysis focused on telemedicine for ARTIs, parents expressed more concerns about telemedicine quality in commercial DTC models compared with primary care–based telemedicine. These results could help health systems better design telemedicine initiatives to support family-centered care.

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KEYWORDS

telemedicine; telehealth; acute care; acute; pediatrics; pediatric; family medicine; family-centered; child; children; parent; parents; attitude; attitudes; opinion; perception; perceptions; perspective; perspectives; expectation; expectations

Introduction

The decision to seek care for a sick child is an increasingly complex one for parents. Parents are faced with a variety of care site options, which include both in-person (ie, primary care, urgent care, and emergency department [ED]) and virtual care modalities (ie, primary care provider [PCP] telemedicine and commercial direct-to-consumer [DTC] telemedicine). In recent years, families have increased experience and opportunity to use telemedicine with both their PCP and DTC telemedicine companies [1-4]. Many studies of prior telemedicine users indicate high parent satisfaction after telemedicine use, including high satisfaction with interpersonal and technical components of these visits, while others note concerns about the quality of interpersonal interaction and concerns about misdiagnosis and privacy [5-8]. Studies of parent perceptions as they anticipate or make decisions about potential telemedicine use are fewer. Some have importantly detailed disparities in general willingness to use telemedicine by sociodemographic characteristics or technology ownership [9,10]. Beyond general willingness to use telemedicine, however, it is important to understand decision factors influencing parents toward or away from telemedicine use at the time of a specific health care need.

One common reason for problem-based visits among children is the cluster of diagnoses known as acute respiratory tract infections (ARTIs), which include viral (eg, viral upper respiratory infection and viral pharyngitis) and bacterial infections (eg, streptococcal pharyngitis and acute otitis media). Before the pandemic, ARTIs accounted for over one-third of acute pediatric primary care visits and nearly 50% of DTC telemedicine visits [4,11]. The volume of pediatric ARTI visits dropped substantially during the early pandemic but increased over time with otitis media, streptococcal sore throat, and acute upper respiratory infection remaining common acute visit diagnoses for both in-person and telemedicine care during the later pandemic period [2,12-15]. These data suggest that deciding whether to seek care for pediatric cough and cold symptoms is one of the more common care-seeking decisions faced by parents. Thus, we focus on ARTIs as an illustrative example of a reason parents may seek care for their child, providing an opportunity to examine care-seeking decision-making processes. Important prior studies uncovered factors that may influence family decision-making about ARTI care-seeking, including site accessibility (eg, timeliness and geographic) and quality (eg, interpersonal and clinical) as well as illness and family factors [16-18], but did not explore how the option of telemedicine informs these decisions. More recent qualitative studies have begun to explore ARTI care-seeking decisions in the context of the option of telemedicine [19,20]. As an example, we recently examined parents decision-making for pediatric ARTIs in the context of the option of telemedicine and identified 7 dimensions that influence parents’ decisions: perceived illness severity, perceived child susceptibility, parental self-efficacy, expected accessibility of care, expected affordability of care, expected quality of clinician, and expected quality of site [19]. By applying this framework to qualitative and quantitative data focused specifically on parent perceptions of the potential values and risks of telemedicine use, we seek now to understand how families assess individual factors to decide whether to use telemedicine for a specific ARTI care need. Understanding parent perceptions of telemedicine across these 7 dimensions is important to support health care systems in incorporating telemedicine into the acute care landscape beyond the public health emergency.

Therefore, in this analysis, we investigated current parent views regarding decision factors that potentially influence their intention to use telemedicine and other sites of acute care when their children have ARTI symptoms. Specifically, we sought to better understand parent perceptions of telemedicine models compared with in-person care for pediatric ARTIs using both qualitative and quantitative data to specifically examine potential differences in expectations of telemedicine delivered via PCPs versus telemedicine delivered via commercial DTC providers.

Methods

Overview

We performed a sequential mixed methods analysis to examine how parents approach decisions about the use of telemedicine when care-seeking for commonly experienced acute illness. We first conducted a qualitative analysis of semistructured parent interviews in which we asked parents to discuss prior care-seeking when their children were experiencing ARTI symptoms. Previous analysis of specific portions of these semistructured interviews which focused broadly on the decision to seek care published previously reported on 7 broad dimensions that parents consider when deciding whether and where to seek care for their children (perceived illness severity, perceived child susceptibility, parental self-efficacy, expected accessibility of care, expected affordability of care, expected quality of clinician, and expected quality of site) [19]. In this analysis, we examined parent responses to a specific later portion of the interviews where parents were asked to reflect specifically on the option to use telemedicine, which we analyzed to elucidate factors that might incentivize or disincentivize parents to seek ARTI care through telemedicine. Building on these qualitative findings, we fielded and analyzed
a national survey to examine pediatric telemedicine use. Prior analysis examined parent-reported use of primary care telemedicine [21]. In this analysis, we focus instead on parent expectations of the care their child would receive if they presented at each of 5 different sites of care: in-person primary care, in-person urgent care, in-person ED, PCP telemedicine, and commercial DTC telemedicine. We adhered to the standards for reporting quality research guidelines for reporting the qualitative portion of this research [22].

Semistructured Interviews
As described in greater detail elsewhere, we first interviewed 16 pediatric research and clinical professionals to establish a normative expert model of parent care-seeking. Insights from these interviews then informed an interview guide for subsequent semistructured interviews with parents. Prior to launching interviews with a full sample (n=40), we conducted 3 pilot interviews with parents to ensure clarity of our questions and definitions. The first portion of the open-ended interview guide inquired about perceived needs, desires, and care-seeking decisions when seeking care generally for a child’s ARTI, with results reported previously [19]. This paper focuses on a portion of the interview guide that inquired about the risks and benefits of telemedicine care for a child’s ARTI (“What are your thoughts on the benefits of having a provider see your child while you are in your own house?” and “When, if ever, would telemedicine feel like a good choice for a child with a cold?”) and barriers to telemedicine use (“What might make a telemedicine visit difficult for your family?”). Parents of children aged 1-5 years were recruited through a research registry of parents in Western Pennsylvania and beyond. All interviews were recorded, transcribed, and analyzed using thematic content analysis. Team members (SB, KR, and TK) independently coded each sentence in the first 5 transcripts and together reviewed and then developed a preliminary codebook of a priori and emergent codes. For each code present, we noted, when relevant, whether the factor was discussed specifically as a reason to use or avoid telemedicine. Upon achieving consensus, a codebook containing definitions and rules was finalized. The remaining transcripts were coded by a primary coder (SB), and 14 of those were cocoded by a second coder (KR or TK). Dedoose (SocioCultural Research Consultants), a qualitative research software program, was used to code interviews. In this paper, we present parental perceptions of potential factors that might positively or negatively influence their interest in the use of telemedicine organized by the previously identified 7 dimensions [19] to illustrate the degree to which these dimensions influence parental decisions to seek care from telemedicine.

National Survey
As described in greater detail elsewhere [21], we then developed a survey informed by our prior qualitative findings and fielded the survey nationally through the University of Chicago’s AmeriSpeak Panel [23], a nationally representative panel. The survey included items asking about parent priorities and expectations when seeking care for a child’s ARTI, prior telemedicine use, and sociodemographic characteristics. The survey underwent cognitive testing with 3 parents of young children and was offered in English and Spanish. Prior analysis of survey data focused on parent-report of PCP telemedicine use relative to sociodemographic characteristics of the respondent [21]. This analysis focuses on parent expectations of 21 different factors with the potential to influence their care-seeking across 5 different sites of care: in-person primary care, in-person urgent care, in-person ED, PCP telemedicine, and commercial DTC telemedicine. The order in which care sites were presented to respondents was randomized.

In the survey, PCP telemedicine was described as “a telemedicine visit with your child’s usual primary care office or clinic. This would be a virtual visit with the provider or group of providers that conduct in-person well and sick care for your child(ren) in the office or clinic.” DTC commercial telemedicine was described as “a telemedicine company or group that focuses on telemedicine visits rather than in-person care (also called DTC telemedicine). Providers in these groups do not provide care in-person and are not part of your child’s usual care team. In these visits, you connect online and see an available provider in a model that could be thought of as virtual urgent care. Some DTC telemedicine groups or companies are affiliated with health systems but are still separate from primary care clinics who might see their own patients through telemedicine.”

The survey was fielded to members of the AmeriSpeak panel, with panel members eligible if they were caregivers of children aged ≤17 years.

This analysis focused on the percentage of respondents who anticipated that the specified care site would meet their expectations “always” or “often” for each of the 21 specific items. For each of the 21 items, we calculated the weighted percentage of respondents who indicated they “always” or “often” expect that item at each site, using weights derived from panel sampling weights along with survey response rates, such that the demographics of the weighted sample align with the US Current Population Survey [24]. Surveys with missing responses to individual items were omitted from denominator for that item. We then used t statistics from weighted logistic regression models to compare responses for each item for PCP telemedicine and DTC telemedicine. Finally, we averaged responses to items within each of the 7 dimensions for PCP telemedicine and DTC telemedicine to further synthesize the differences between expectations of PCP and DTC telemedicine.

Ethical Considerations

Semistructured Interviews
The qualitative interview portion of this study was determined exempt from human participants review by the University of Pittsburgh institutional review board (IRB; STUDY20040025). Participants received an IRB-approved introductory script prior to participating in the interview informing them of the goals of the interview, potential risks and benefits, plans to protect their information, and how to contact the research team if they had questions, and they then provided verbal consent to proceed. Identifiable data collected only for payment purposes were stored separately from interview data; interview data were deidentified. Participants received a US $50 gift card through the University of Pittsburgh’s Vincent Payment Solutions.
National Survey

The survey portion of this study was determined exempt from human participants review by the University of Pittsburgh IRB and by the National Opinion Research Center at the University of Chicago IRB (STUDY21070080). The University of Pittsburgh research team only received deidentified data from National Opinion Research Center for analysis. Survey respondents were compensated for their time through AmeriSpeak, receiving the cash equivalent of $5 (equivalent of US $17.50/hour) for completing the survey.

Results

Qualitative Interview Results

A total of 40 parents participated in the qualitative interviews, of which 65% (n=26) of parents had more than 1 child, 65% (n=26) of parents had previous experience using telemedicine for a child, and 38% (n=15) of parents had children insured by a commercial or employer-sponsored insurer (Table 1).

Table 1. Demographic characteristics of participants in qualitative parent interviews (n=40).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Interview participants, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>38 (95)</td>
</tr>
<tr>
<td>Male</td>
<td>2 (5)</td>
</tr>
<tr>
<td><strong>Age group (years)</strong></td>
<td></td>
</tr>
<tr>
<td>18-30</td>
<td>12 (30)</td>
</tr>
<tr>
<td>31-40</td>
<td>23 (58)</td>
</tr>
<tr>
<td>41-50</td>
<td>5 (13)</td>
</tr>
<tr>
<td><strong>Interviewee’s children’s ages</strong>b</td>
<td></td>
</tr>
<tr>
<td>Interviewees with children &lt;1 year</td>
<td>5 (13)</td>
</tr>
<tr>
<td>Interviewees with children 1-5 year</td>
<td>40 (100)</td>
</tr>
<tr>
<td>Interviewees with children &gt;5 year</td>
<td>16 (40)</td>
</tr>
<tr>
<td><strong>Self-reported race and ethnicity</strong></td>
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</tr>
<tr>
<td>African American or Black</td>
<td>6 (15)</td>
</tr>
<tr>
<td>African American and Native American</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Hispanic or Hispanic and multiracial</td>
<td>3 (8)</td>
</tr>
<tr>
<td>White</td>
<td>30 (75)</td>
</tr>
<tr>
<td><strong>Prior telemedicine use for their child</strong></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>14 (35)</td>
</tr>
<tr>
<td>Yes</td>
<td>26 (65)</td>
</tr>
<tr>
<td><strong>Geographic location</strong></td>
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<tr>
<td>Urban</td>
<td>23 (58)</td>
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<tr>
<td>Rural</td>
<td>17 (42)</td>
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<tr>
<td><strong>Insurance type</strong></td>
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<tr>
<td>Commercial or employer based</td>
<td>15 (38)</td>
</tr>
<tr>
<td>Medicaid or federal</td>
<td>25 (63)</td>
</tr>
</tbody>
</table>

aPercentages may sum to >100% due to rounding.
bCategories are not mutually exclusive.

Dimensions Affecting Parental Perceptions of Telemedicine

Interviewees described a range of factors that affect their perceptions of telemedicine care for their children. These factors mapped onto the 7 dimensions influencing care-seeking, including dimensions related to care sites (expected access, affordability, clinical quality, and site quality) and dimensions related to child or family factors (perceived illness severity, perceived child susceptibility, parent self-efficacy) [19].

Expected Accessibility of the Site

Interviewees expressed interest in using telemedicine due to perceived opportunities to increase temporal accessibility, mitigate geographic accessibility, and maximize convenience (Multimedia Appendix 1). In contrast, some spoke about the
value of telemedicine only as a last resort option when other sites could not be accessed. One interviewee described how using telemedicine maximizes value as follows: “I honestly couldn’t see how [using telemedicine] would make anything difficult, ‘cause it’s saving me time, gas, all of that stuff” (parent 24). In contrast, some interviewees expressed concerns about digital accessibility and how telemedicine might be less optimal for their family or for other families: “You might not even have access to computer. I mean I guess everybody has a cell phone, but, you know, connecting to like a video call on your cell phone isn’t always ideal” (parent 06).

**Expected Affordability of the Site**

Interviewees favored telemedicine use if out-of-pocket costs were less than or equal to in-person options: “I mean you’re not getting that one-on-one or face-to-face time necessarily, so, I kind of feel like [telemedicine] should probably be cheaper [laughter] or free” (parent 06). Parents viewed telemedicine favorably if insurance would cover the expense and less favorably if there was a likelihood of needing further in-person evaluation contributing to a possible second visit expense or when costs for telemedicine were out-of-pocket.

**Expected Quality of the Site**

Interviewees viewed telemedicine positively when they perceived that telemedicine increased their child’s comfort level and made seeking care safer: "Well, the kids will be more comfortable on telemedicine. I mean, 'cause I know kids...they get anxious when they go to the doctor’s office, so they’re symptoms might get worse...I mean, they might also pick other stuff up when they go to the doctor’s office. So it might just be an ease, so you’re not exposing yourself to other things” (parent 39). Parents were split on whether they felt like telemedicine would allow for adequate assessment of ARTI symptoms, noting that evaluation of some symptoms (eg, ear pain) might be more difficult than others (eg, red eyes) over telemedicine without the availability of equipment with remote assessment capabilities. In contrast, some parents were less receptive to the idea of seeking telemedicine, and pointed out that a telemedicine appointment cannot provide comprehensive clinical care: “It’s kind of hard—you can’t really do immunization [on telemedicine]—I mean, ‘cause you would still have to go to the office to get those” (parent 39).

**Expected Quality of the Clinician**

Interviewees discussed intersections between telemedicine and the expected quality of clinicians. Some interviewees indicated they would be less interested in using telemedicine if they could not visit a familiar provider: “If it was doctor that...didn’t know [my child] well, I might not feel 100% comfortable. But because [pediatrician] knows him and his personality...I’d probably feel more comfortable if [telemedicine] was with her” (parent 12). Interviewees were divided on whether they perceived they would receive reassurance over telemedicine. There was a general perception among interviewees that receiving trustworthy care would be less likely over telemedicine. Additionally, parents expressed more interest in telemedicine when the provider was someone with experience in caring for children. One parent described their preference for a provider with pediatric expertise: “I don’t want, you know, like, a doctor who just got their degree last week to try and diagnose what my son has, like, with his cold and everything. I would want someone looking at it who has experience with kids” (parent 31).

**Perceived Severity of Illness of the Child**

Parent interviewees discussed perceptions of telemedicine that mapped along the following 3 primary child and parent dimensions: perceived severity, perceived child susceptibility, and parental self-efficacy (Multimedia Appendix 2). Interviewees primarily viewed telemedicine less favorably when they perceived the high severity of a child’s illness and symptom complexity. One interviewee described her care-seeking decision when her child had a cold: “I think if it’s just like a normal cold...I feel like I would be pretty comfortable doing telemedicine for that. And then if they thought it was severe enough, then I would go in” (parent 30). Parent’s perceptions of using telemedicine based on their child’s demeanor and appearance were divided, with interviewees expressing both interest and disininterest in using telemedicine when their child appeared more ill. In contrast, interviewees generally viewed the use of telemedicine favorably when prolonged persistence of their child’s symptoms was the primary driver of care seeking.

**Perceived Susceptibility of the Child**

Interviewees generally expressed less interest in telemedicine use for ARTI acute care when they perceived greater underlying susceptibility of the child, such as if they have a child with medical complexity or younger age. One interviewee described her preference for in-person care because of a perceived vulnerability to the illness of her child: “I need my child to be seen by somebody because I need them to listen to her lungs, and I need them to check her ears. Maybe if the child is not prone to having ear infections, and she’s not asthmatic, then it would be a little different” (parent 33). In contrast, interviewees showed more interest in telemedicine use when trying to avoid community-based exposure: “I’m thinking now I probably should have done [telemedicine] instead of having to take him in, and like possibly exposing him” (parent 12).

**Perceived Self-Efficacy of the Parent**

Parent self-efficacy factors identified by interviewees included achieving the goal of the visit, antibiotic expectations, and easing uncertainty, all of which interviewees generally viewed as achievable through telemedicine care. For individual interviewees, however, self-efficacy factors, such as parent health literacy and worry, were discussed as individual reasons to seek and not to seek care through telemedicine. Concerns about the ability to protect their child’s privacy (ie, information privacy and physical location privacy) and negotiate power differentials (ie, equity and patient-clinician power dynamics) contributed to parental worry about using telemedicine. One parent described these worries: “They [provider on telemedicine] could catch you at a really bad time whenever, you know, ‘cause when a kid is sick...things in the house just kind of—everything falls into chaos, so they could be seeing a snapshot and judging your entire life by that” (parent 03).
Survey Results
Survey invitations were sent to 6015 AmeriSpeak panelists, with 1599 (26.6%) of those invited completing the screener; of the 1599 individuals screened, 1297 (81.1%) met the eligibility requirements; and of the 1297 individuals who were eligible, 1206 (93.0%) completed the survey. The majority (1136/1206; 96% weighted) of respondents took the survey in English, and 60% (weighted; 714/1206) had children insured through a private employer or purchased directly (Table 2).

Table 2. Demographic characteristics of participants (n=1206) and weighted percentages in a quantitative national survey.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Survey respondents, n (weighted %)a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>786 (55.3)</td>
</tr>
<tr>
<td>Male</td>
<td>420 (44.7)</td>
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<tr>
<td>Age group (years)</td>
<td></td>
</tr>
<tr>
<td>18-29</td>
<td>158 (11.8)</td>
</tr>
<tr>
<td>30-44</td>
<td>761 (59.2)</td>
</tr>
<tr>
<td>45-59</td>
<td>258 (26.3)</td>
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<tr>
<td>&gt;60</td>
<td>29 (2.6)</td>
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<tr>
<td>Race and ethnicity</td>
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<tr>
<td>Asian, non-Hispanic</td>
<td>34 (6.4)</td>
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<tr>
<td>Black, non-Hispanic</td>
<td>109 (11.3)</td>
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<tr>
<td>Hispanic</td>
<td>375 (22)</td>
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<tr>
<td>White, non-Hispanic</td>
<td>634 (56.6)</td>
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<tr>
<td>Other, non-Hispanic</td>
<td>54 (3.7)</td>
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<tr>
<td>Census division</td>
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<tr>
<td>South Atlantic</td>
<td>233 (19.5)</td>
</tr>
<tr>
<td>Pacific</td>
<td>195 (16.7)</td>
</tr>
<tr>
<td>East North Central</td>
<td>172 (14.3)</td>
</tr>
<tr>
<td>West South Central</td>
<td>136 (13.2)</td>
</tr>
<tr>
<td>Mountain</td>
<td>129 (8)</td>
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<td>Mid-Atlantic</td>
<td>103 (11.4)</td>
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<td>West North Central</td>
<td>102 (6.6)</td>
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<td>East South Central</td>
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<td>New England</td>
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<td>Spanish</td>
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<td>Yes</td>
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<td>Child insurance type</td>
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<td>Employer or Commercial</td>
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<tr>
<td>Medicaid or federal</td>
<td>460 (37)</td>
</tr>
<tr>
<td>Uninsured</td>
<td>32 (2.8)</td>
</tr>
</tbody>
</table>

aPercentages may sum to >100% due to rounding.

Parents were asked to indicate how often they expect to find each of the 21 specific items across 5 different care sites. For most items, respondents most commonly expected to experience that item at an in-person primary care visit compared with the 4 other sites. The 2 virtual sites of care carried higher expectations than in-person primary care for items related to accessibility and not being near other sick children (Multimedia Appendix 3). For example, out of 1200 respondents answering
the item, 56.3% (weighted; n=679) expected to avoid a long wait through a primary care visit, compared with 60% (weighted; 740/1195) through commercial DTC telemedicine and 64.1% weighted (790/1200) through PCP telemedicine. The 2 virtual sites carried lower expectations than all 3 in-person sites for “being able to complete all tasks” (within the expected quality of site dimension) and “ability to care for severe symptoms” (within the perceived illness severity dimension; Table 3 and Multimedia Appendix 3).

Parents reported high expectations for PCP telemedicine across several system dimensions (Table 3), with three-quarters indicating expecting to be able to usually or always see a provider with experience caring for children (919/1195; 76.5% weighted) and to receive care in a way that protects the child’s privacy (932/1198; 76.2% weighted). Parents largely had higher expectations for PCP telemedicine than commercial DTC telemedicine for items related specifically to their perception of their child’s illness and susceptibility with 75.7% (weighted; 915/1198) always or often expecting the ability to receive care across the 0-17 years age range at PCP telemedicine (Table 4 and Multimedia Appendix 4).

Comparing expectations specifically for the 2 telemedicine options, responses were relatively similar for accessibility items and were the most discrepant for quality of clinician and child susceptibility items. For example, a similar percentage of parents expected to always or often receive care that does not disrupt their schedule for PCP telemedicine (723/1200; 60.2% weighted) and DTC telemedicine (696/1195; 59.1% weighted; P=.57), which is an item under the accessibility dimension. In contrast, parents’ expectations to often or usually receive care from a “provider who they trust to make choices in their child’s best interest” varied from 72.4% (weighted; 885/1199) for PCP telemedicine to 54.3% (weighted; 664/1192) for DTC telemedicine (P<.001). Similarly, parents’ expectations to always or often receive care from a “provider with full access to their child’s medical history” ranged from 71.3% (weighted; 857/1194) for PCP telemedicine to 46.5% (weighted; 541/1190) for DTC telemedicine (P<.001).

Survey results were averaged within each of the 7 dimensions and mapped onto the previously identified health care-seeking decision model (Figure 1), with line weight illustrating the difference in parent expectations of PCP and DTC telemedicine.

### Table 3. Percentage of caregiver respondents (n=1206) who “always” or “often” expect the factors listed relating to expected accessibility, affordability, and quality at the 2 telemedicine sites (primary care provider [PCP] telemedicine and direct-to-consumer [DTC] telemedicine).

<table>
<thead>
<tr>
<th>Factors</th>
<th>PCP telemedicine, n/N (weighted %)</th>
<th>DTC telemedicine, n/N (weighted %)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Expected accessibility</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fits schedule</td>
<td>723/1200 (60.2)</td>
<td>696/1195 (59.1)</td>
<td>.57</td>
</tr>
<tr>
<td>Minimal hassle</td>
<td>892/1199 (73.9)</td>
<td>843/1195 (70.4)</td>
<td>.045</td>
</tr>
<tr>
<td>Minimal wait</td>
<td>790/1200 (64.1)</td>
<td>740/1195 (60.0)</td>
<td>.04</td>
</tr>
<tr>
<td><strong>Expected affordability</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minimal costs</td>
<td>676/1197 (54.5)</td>
<td>553/1196 (46.2)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td><strong>Expected quality of the site</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knows child</td>
<td>726/1198 (60.5)</td>
<td>416/1196 (35.9)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Pediatric experience</td>
<td>919/1195 (76.5)</td>
<td>672/1195 (55.9)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Record access</td>
<td>857/1194 (71.3)</td>
<td>541/1190 (46.5)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Can trust</td>
<td>885/1199 (72.4)</td>
<td>664/1192 (54.3)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td><strong>Expected quality of the site</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protects privacy</td>
<td>932/1198 (76.2)</td>
<td>756/1196 (61.8)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Comprehensive tasks</td>
<td>656/1194 (56.1)</td>
<td>505/1196 (42.3)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Avoid exposures</td>
<td>890/1197 (73.4)</td>
<td>856/1192 (72.4)</td>
<td>.54</td>
</tr>
<tr>
<td>Child comfort</td>
<td>842/1197 (70.3)</td>
<td>584/1193 (50.2)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

*For each item, we calculated the weighted percentage of nonmissing responses indicating that the item was expected “always” or “often” at the specified site. We determined statistical significance using \(t\) statistics from weighted logistic regression models to compare responses for each item for PCP telemedicine and DTC telemedicine.
Table 4. Percentage of caregiver respondents (n=1206) who “always” or “often” expect the factors listed relating to perceived illness severity, perceived child susceptibility and parental self-efficacy factors at the two telemedicine sites (primary care provider [PCP] telemedicine and direct-to-consumer [DTC] telemedicine).

<table>
<thead>
<tr>
<th>Factors</th>
<th>PCP telemedicine, n/N (weighted %)</th>
<th>DTC telemedicine, n/N (weighted %)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Perceived illness severity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severity responsive</td>
<td>773/1199 (63.1)</td>
<td>585/1198 (48.3)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Duration responsive</td>
<td>792/1196 (65.3)</td>
<td>576/1194 (48.1)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Multiple symptom responsive</td>
<td>814/1199 (67.9)</td>
<td>634/1198 (51.6)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Seriousness responsive</td>
<td>762/1199 (63.3)</td>
<td>553/1196 (46.0)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Mood responsive</td>
<td>790/1196 (64.4)</td>
<td>579/1190 (47.6)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td><strong>Perceived child susceptibility</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Considers history</td>
<td>902/1193 (73.1)</td>
<td>646/1195 (52.6)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Age responsive</td>
<td>915/1198 (75.7)</td>
<td>718/1193 (58.4)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td><strong>Parental self-efficacy</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Will understand</td>
<td>892/1200 (73.1)</td>
<td>703/1198 (57.9)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Obtain doctor forms</td>
<td>754/1199 (61.8)</td>
<td>609/1198 (50.6)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

For each item, we calculated the weighted percentage of nonmissing responses indicating that the item was expected “always” or “often” at the specified site. We determined statistical significance using t statistics from weighted logistic regression models to compare responses for each item for PCP telemedicine and DTC telemedicine.

Figure 1. Percent of parents expecting each of 7 dimensions of the influence diagram of health care–seeking decisions when seeking care at primary care provider telemedicine and direct-to-consumer telemedicine. The center rectangle represents the decision “choice of care site.” Focusing on the choice to use either of the 2 studied telemedicine models (primary care telemedicine and commercial direct-to-consumer telemedicine), this choice is surrounded by dimensions affecting this decision in ovals with averaged expectations of survey respondents of primary care telemedicine (orange) and direct-to-consumer telemedicine (blue). Line weight indicates the average percentage of respondents expecting the factors within the indicated dimension always or often at the indicated telemedicine site.

Discussion

Through semistructured interviews, parents expressed positive assessments of telemedicine accessibility but voiced concerns about telemedicine quality. In a structured survey informed by these results, we found continued positive expectations of telemedicine accessibility and less concern about quality for PCP telemedicine relative to commercial DTC telemedicine. Respondents anticipated that both models of telemedicine would minimize hassle, wait time, schedule disruption, and exposure to other ill children. However, respondents had higher expectations of clinician and site quality and the ability to treat severe illness from PCP telemedicine compared with DTC telemedicine. The strengths of this analysis include a mixed methods approach with qualitative interviews conducted until
saturation was achieved followed by a large nationally representative survey, which was conducted 2 years into the COVID-19 pandemic.

These findings first provide an illustration of the applicability of our health care–seeking decision model [19], which incorporates elements represented in prior models representing both health beliefs and access to care [25,26]. By using the health care–seeking decision model as a guiding framework for the interpretation of these qualitative and quantitative data, we uncovered differences in parent perceptions of expected quality versus expected accessibility across different models of telemedicine care. The survey data further support the health care–seeking decision model, with these quantitative items showing variation across sites and dimensions.

The relatively high expectations of quality in PCP telemedicine—and the contrast to expectations in DTC telemedicine—comes at an important time for state and federal policy makers as the COVID-19 public health emergency has ended. These findings indicate that parents differentiate between primary care models of telemedicine and virtual-only telemedicine, but this is not a distinction that has made its way into all payment and policy discussions. In states and state Medicaid programs that have not adopted telehealth-supportive legislation or kept up with telemedicine policy changes in Medicare during the pandemic [27], there is a real threat to the financial sustainability of PCP telemedicine [28]. Specifically, if the majority of payers for patients within a pediatric primary care practice do not provide coverage at parity for telemedicine while the child is at home, then primary care clinicians may not be able to continue offering telemedicine to their patient panels [28]. As of June to August 2021, 63% of pediatricians reported that they were continuing to use telemedicine [29]; that number could rise or fall further depending on the ability of payers to signal and provide ongoing support for this modality of care. PCPs with concerns that patients may just as readily seek telemedicine care elsewhere may wish to take note of these results indicating that families value the continuity, pediatric expertise, and access to medical records of telemedicine through primary care practices offer.

While our data suggest that parents have the highest expectations for in-person primary care, it should be noted that parents’ expectations of PCP telemedicine approach expectations of in-person primary care for items in dimensions related to quality and even surpass in-person primary care for items related to access. In terms of virtual care options, our data suggest parents may preferentially choose PCP telemedicine for their children over DTC telemedicine, which is supported by the observation that the growth in telemedicine volume for children during the pandemic occurred almost entirely through PCP telemedicine rather than telemedicine-only providers [2]. PCP telemedicine also carries more positive expectations than urgent care or ED for access, quality, and parental self-efficacy dimensions. Thus, maintaining PCP telemedicine as an option may help families choose lower-cost options of care and maintain continuity. PCPs and health systems may also wish to ensure that patients can readily recognize and electronically engage PCP telemedicine, to ensure parents are connecting with the care and the providers that they desire.

Limitations include that results from qualitative interviews may not be generalizable to the population as this sample may over- or underrepresent certain populations when seeking care, such as female caregivers. Our research focuses specifically on how parents perceive telemedicine use in the context of seeking care for ARTI symptoms, and we note that these expectations could vary for other conditions. Interviews were conducted between April and July 2021, during a time when care-seeking decisions may have been influenced by the ongoing COVID-19 pandemic. However, the survey results were fielded in February 2022, a time when COVID-19 vaccines were available and parents had potentially 2 years of experience with telemedicine. We note also that while we had high rates of completion among those screened and determined to be eligible (1206/1297, 93%), there was a sizable number of nonresponders to the initial invitation to complete the screener, which may bias results.

In conclusion, in this mixed methods analysis of parent perceptions of telemedicine when approaching ARTI care-seeking decisions, parents expressed positive assessments of telemedicine accessibility while also voicing more concerns about telemedicine quality in commercial DTC models compared with primary care–based telemedicine. Future work is needed to help support families in making care-seeking decisions when their children are sick, by both supporting family decision-making and aligning in-person and telemedicine care options with child needs and family expectations.

Acknowledgments
This work was supported by the National Institute of Allergy and Infectious Diseases (R01AI148159; KNR) and the Health Resource and Services Administration (T32HP22240; TTD). The content is solely the responsibility of the authors and does not necessarily represent the official views of, nor an endorsement by, the National Institutes of Health (NIH) or the US Government.

Data Availability
Deidentified data will be made available on request from authors with appropriate institutional review board and data use agreements in place.

Authors’ Contributions
SKB contributed to the survey design, analyzed and interpreted the data, and drafted the manuscript. TK contributed to the design of the study and survey, supervised analysis, interpreted the results, and critically revised the manuscript. TTD and KS interpreted
the results and critically revised the manuscript. JMH, AH, and JMK contributed to the design of the study, interpreted data, and critically revised the manuscript. KNR conceptualized and designed the study and survey, acquired and interpreted the data, supervised analysis, and critically revised the manuscript. All authors approved the final version for publication and agreed to be accountable for the work.

Conflicts of Interest
None declared.

Multimedia Appendix 1
Representative quotes from parent interviews (n=40) related to system-level dimensions.
[DOCX File, 18 KB - pediatrics_v7i1e49170_app1.docx]

Multimedia Appendix 2
Representative quotes from parent participants (n=40) related to parent or child factor dimensions.
[DOCX File, 18 KB - pediatrics_v7i1e49170_app2.docx]

Multimedia Appendix 3
Results from the survey (n=1206) illustrating the percentage that caregivers “always” or “often” expect the factors listed relating to expected accessibility, affordability, and quality at each of 5 sites (in-person PCP, ED, urgent care, PCP TM, DTCTM). DTCTM: direct-to-consumer telemedicine; ED: emergency department; PCP: primary care provider; PCP TM: primary care provider telemedicine.
[PNG File, 101 KB - pediatrics_v7i1e49170_app3.png]

Multimedia Appendix 4
Results from the survey (n=1206) illustrating the percentage that caregivers “always” or “often” expect the factors listed relating to child and parent-level factors at each of 5 sites (in-person PCP, ED, urgent care, PCP TM, DTCTM). DTCTM: direct-to-consumer telemedicine; ED: emergency department; PCP: primary care provider; PCP TM: primary care provider telemedicine.
[ PNG File, 85 KB - pediatrics_v7i1e49170_app4.png]

References
Abbreviations

**ARTI**: acute respiratory tract infection  
**DTC**: direct-to-consumer  
**ED**: emergency department  
**IRB**: institutional review board  
**PCP**: primary care provider
Electronic Medical Record Data Missingness and Interruption in Antiretroviral Therapy Among Adults and Children Living With HIV in Haiti: Retrospective Longitudinal Study

Andrew M Secor¹, MPH, PhD; Kemar Célestin², MSc; Margareth Jasmin², MD; Jean Guy Honoré², MD; Anjuli D Wagner¹, PhD; Kristin Beima-Sofie¹, PhD; Jillian Pintye¹, PhD; Nancy Puttkammer³, PhD

Corresponding Author: Andrew M Secor, MPH, PhD

Abstract

Background: Children (aged 0-14 years) living with HIV often experience lower rates of HIV diagnosis, treatment, and viral load suppression. In Haiti, only 63% of children living with HIV know their HIV status (compared to 85% overall), 63% are on treatment (compared to 85% overall), and 48% are virally suppressed (compared to 73% overall). Electronic medical records (EMRs) can improve HIV care and patient outcomes, but these benefits are largely dependent on providers having access to quality and nonmissing data.

Objective: We sought to understand the associations between EMR data missingness and interruption in antiretroviral therapy treatment by age group (pediatric vs adult).

Methods: We assessed associations between patient intake record data missingness and interruption in treatment (IIT) status at 6 and 12 months post antiretroviral therapy initiation using patient-level data drawn from iSanté, the most widely used EMR in Haiti. Missingness was assessed for tuberculosis diagnosis, World Health Organization HIV stage, and weight using a composite score indicator (ie, the number of indicators of interest missing). Risk ratios were estimated using marginal parameters from multilevel modified Poisson models with robust error variances and random intercepts for the facility to account for clustering.

Results: Data were drawn from 50 facilities and comprised 31,457 patient records from people living with HIV, of which 1306 (4.2%) were pediatric cases. Pediatric patients were more likely than adult patients to experience IIT (n=431, 33% vs n=7477, 23.4% at 6 months; P<.001). Additionally, pediatric patient records had higher data missingness, with 581 (44.5%) pediatric records missing at least 1 indicator of interest, compared to 7812 (25.9%) adult records (P<.001). Among pediatric patients, each additional indicator missing was associated with a 1.34 times greater likelihood of experiencing IIT at 6 months (95% CI 1.08-1.66; P=.008) and 1.24 times greater likelihood of experiencing IIT at 12 months (95% CI 1.05-1.46; P=.01). These relationships were not statistically significant for adult patients. Compared to pediatric patients with 0 missing indicators, having all 3 indicators missing was associated with being 1.32 times more likely to experience IIT at 6 months (95% CI 1.03-1.70; P=.03), while there was no association with IIT status for other levels of missingness.

Conclusions: These findings suggest that both EMR data quality and quality of care are lower for children living with HIV in Haiti. This underscores the need for further research into the mechanisms by which EMR data quality impacts the quality of care and patient outcomes among this population. Efforts to improve both EMR data quality and quality of care should consider prioritizing pediatric patients.

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KEYWORDS
HIV; Haiti; pediatrics; combination antiretroviral therapy; electronic medical record; data quality; child; children; antiretroviral; therapy; longitudinal study; HIV diagnosis; diagnosis; HIV care; patient records; quality of care; treatment; engagement
Introduction

Despite improvements in HIV testing, care, and treatment and reduced HIV incidence over the last 3 decades, Haiti has the largest population of people living with HIV in the Caribbean, with an estimated 1.8% of the population (150,000 persons) having received a positive HIV diagnosis, including nearly 6000 children (aged 0-14 years) living with HIV [1]. Children living with HIV often have lower rates of HIV diagnosis, treatment, and viral load suppression [2]. In Haiti, children living with HIV fare worse across all steps of the care cascade, with only 63% knowing their HIV status (compared to 85% overall), 63% on treatment (compared to 85% overall), and 48% virally suppressed (compared to 73% overall) [1]. Reviews of patient records in Haiti revealed that children living with HIV were significantly less likely to initiate antiretroviral therapy (ART) in a timely manner as compared to adults, and once initiated, were less likely than adults to be retained in ART treatment [3,4].

Electronic medical records (EMRs) can improve HIV patient care and outcomes in multiple ways, including (1) directly informing individual patient care, such as tracking clinical outcomes, ART adherence and retention, as well as patient follow-up; and (2) promoting provider compliance with treatment and care guidelines [5-13]. However, these benefits are largely dependent on providers having access to high-quality data (ie, reliable, timely, and nonmissing data) [14-16]. In the context of EMRs, data missingness is both an element of quality of care (vis-à-vis noncompliance with reporting guidelines) and can itself lead to lower quality of care, as missing data cannot be used to inform clinical decision-making [17]. However, despite the importance of data quality in the value proposition of EMRs, the evidence base exploring the association between data missingness and patient outcomes is limited, especially in resource-limited settings. Although many studies of EMRs include both data quality and patient outcomes as indicators of interest, a direct association between the two is rarely assessed. In addition, no studies reviewed for this paper assessed this relationship by age cohort.

We hypothesize that data missingness will be associated with greater interruption in treatment (IIT) and that this relationship may be larger among children living with HIV. We used ART patient data extracted from the iSanté EMR system to assess the association between age group, data missingness, and IIT.

Methods

Study Design

This was a retrospective longitudinal study using patient-level routine EMR data.
**Analysis**

**Outcome Variable**

The primary outcomes of interest were IIT at the current facility at 6 and 12 months post ART initiation, defined as being more than 28 days late in picking up ART medication as of the dates 6 or 12 months after initiating ART. This definition for IIT status has been used in prior research in Haiti and other settings [39-41].

**Covariates**

Age groups were categorized as pediatric (0-14 years) and adult (>15 years) as of the time of ART initiation, following the age definition used to define pediatric care in Haiti (<15 years).

**Data Missingness**

Data missingness was defined as an indicator not being collected during the patient’s intake visit. Assessment of missingness was restricted to indicators that were shared between both pediatric and adult intake forms, indicators that were clinically meaningful for HIV care, and where missingness could be differentiated from the absence of that issue (e.g., the headache symptomology...
field may be missing due to a patient not presenting with a headache or due to the provider failing to document that issue, whereas the World Health Organization [WHO] HIV stage indicator is expected to be completed for all patients [42]. Within these stipulations, we assessed missingness for weight, current WHO HIV stage, and current tuberculosis (TB) diagnosis. As the importance and impact of missingness for particular indicators may vary by age group (eg, routine documentation of weight is generally of higher importance for pediatric patients), missingness was analyzed as individual binary outcomes (defined as missing or nonmissing) as well as through a composite score indicator (the number of indicators of interest missing), which was analyzed as both a continuous and categorical outcome.

Models

Associations between data missingness (exposure) and interruption in ART treatment at a patient’s current facility (outcome) were assessed through marginal parameters from multilevel modified Poisson models with robust error variances and random intercepts for the facility to account for clustering. Modified Poisson models have been shown to provide unbiased estimates of the risk ratio, important for nonrare binary outcomes where odds ratios estimated through logistic regression will overestimate the risk ratio and potentially lead to improper interpretation of the results [43,44]. Patient sex, facility type, ownership, patient volume, and duration of iSanté use were included as fixed effects to control for potential confounding. Models were stratified by age group to understand the relationship between data missingness and IIT status within each age group. Additional models were run with the age group as an interaction term with the continuous composite indicator to assess the statistical significance of the age group as an effect modifier in the association between missingness and IIT status.

Ethical Considerations

The secondary use of deidentified patient data from the iSanté EMR was approved by the University of Washington Human Subjects Division as nonengaged research (STUDY00016591 “Patient Risk Profiles for Interruption in Treatment among People Living with HIV in Haiti: Leveraging Health Information Systems and Prediction Models to Identify Patients at High Risk”). The research was also reviewed and approved by the Haiti Ministry of Public Health and Population’s National Bioethics Committee (reference number 2223-26).

Results

Primary Findings

In total, data were drawn from 50 facilities across 9 departments (of 10 total) in Haiti and comprised 31,457 patient records for people living with HIV. Of these, 30,151 (95.8%) were adult patients and 1306 (4.2%) were pediatric patients. The majority of patients (n=19,544, 62.1%) were female and received care at health centers (n=19,051, 60.6%) or hospitals (n=9883, 31.4%). The median duration of iSanté use at each health facility was 17.5 (IQR 15.8-18.3) years, and the median monthly patient volume was 348 (IQR 172-544). Table 1 further details participant and facility characteristics.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Patients</th>
<th>Adult (n=30,151, 95.8%)</th>
<th>Pediatric (n=1306, 4.2%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overall (N=31,457)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>19,544 (62.1)</td>
<td>18,855 (62.5)</td>
<td>689 (52.8)</td>
</tr>
<tr>
<td>Male</td>
<td>11,913 (37.9)</td>
<td>11,296 (37.5)</td>
<td>617 (47.2)</td>
</tr>
<tr>
<td>Age (years), median (IQR)</td>
<td>35 (27-44)</td>
<td>35 (28-44)</td>
<td>3 (0-9)</td>
</tr>
<tr>
<td>Facility type, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health center</td>
<td>19,051 (60.6)</td>
<td>18,319 (60.8)</td>
<td>732 (56.0)</td>
</tr>
<tr>
<td>Hospital</td>
<td>9883 (31.4)</td>
<td>9406 (31.2)</td>
<td>477 (36.5)</td>
</tr>
<tr>
<td>Dispensary</td>
<td>2523 (8.0)</td>
<td>2426 (8.0)</td>
<td>97 (7.4)</td>
</tr>
<tr>
<td>Facility ownership, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Both public and private</td>
<td>7337 (23.3)</td>
<td>7008 (23.2)</td>
<td>329 (25.2)</td>
</tr>
<tr>
<td>Private</td>
<td>11,466 (36.4)</td>
<td>11,109 (36.8)</td>
<td>357 (27.3)</td>
</tr>
<tr>
<td>Public</td>
<td>12,654 (40.2)</td>
<td>12,034 (39.9)</td>
<td>620 (47.5)</td>
</tr>
<tr>
<td>Duration of iSanté use, median (IQR)</td>
<td>17.5 (15.8-18.3)</td>
<td>17.5 (15.3-18.3)</td>
<td>18.1 (17.0-18.3)</td>
</tr>
<tr>
<td>Monthly patient volume, median (IQR)</td>
<td>348 (172-544)</td>
<td>348 (172-544)</td>
<td>408 (200-626)</td>
</tr>
</tbody>
</table>

*Facility-related characteristics are described at the patient level (eg, the proportion of patients initiating antiretroviral therapy at a health center versus a hospital or dispensary).*

https://pediatrics.jmir.org/2024/1/e51574
IIT status and indicator missingness are detailed in Table 2. Across all age groups, the proportion of patients who experienced IIT at 6 and 12 months post ART initiation were 23.8% (n=7477) and 29.3% (n=9222), respectively. Overall, the weight indicator had the highest level of missingness, with 5365 (17.1%) patient records missing weight data, while TB diagnosis had the lowest (n=1417, 4.5%). Both IIT status and data missingness were higher among pediatric patients. Pediatric patients were more likely than adult patients to be IIT at both 6 months (n=431, 33.0% vs n=7046, 23.4%; P<.001) and 12 months (n=551, 42.2% vs n=8671, 28.8%; P<.001). Only 55.5% (n=725) of pediatric patient records had no indicators of interest missing, compared to 74.1% (n=22,339) of adult patient records. Pediatric patient records were also more likely to have at least 3 (3.1%) indicators missing compared to adult records (n=401, 1.3%; P<.001). Variation in missingness across age groups was greatest for the WHO HIV stage, with 32.5% (n=425) of pediatric records missing this indicator compared to 11.1% (n=3355) of adult records (P<.001).

### Table 2

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Patients</th>
<th>P value&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overall (N=31,457), n (%)</td>
<td>Pediatric (n=1306), n (%)</td>
</tr>
<tr>
<td>IIT status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>7477 (23.8)</td>
<td>431 (33.0)</td>
</tr>
<tr>
<td>12 months</td>
<td>9222 (29.3)</td>
<td>551 (42.2)</td>
</tr>
<tr>
<td>Indicator missingness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight</td>
<td>5365 (17.1)</td>
<td>265 (20.3)</td>
</tr>
<tr>
<td>WHO&lt;sup&gt;b&lt;/sup&gt; HIV stage</td>
<td>3780 (12.0)</td>
<td>425 (32.5)</td>
</tr>
<tr>
<td>TB&lt;sup&gt;c&lt;/sup&gt; diagnosis</td>
<td>1417 (4.5)</td>
<td>79 (6.0)</td>
</tr>
<tr>
<td>Composite missingness score (number of indicators missing)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>23,064 (73.3)</td>
<td>725 (55.5)</td>
</tr>
<tr>
<td>1</td>
<td>6666 (21.2)</td>
<td>434 (33.2)</td>
</tr>
<tr>
<td>2</td>
<td>1285 (4.1)</td>
<td>106 (8.1)</td>
</tr>
<tr>
<td>3</td>
<td>442 (1.4)</td>
<td>41 (3.1)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Pearson <sup>χ</sup><sup>2</sup> test.

<sup>b</sup>WHO: World Health Organization.

<sup>c</sup>TB: tuberculosis.

Results from models exploring the association between IIT status and the composite missingness score as a continuous variable are shown in Figure 2 (full multivariable regression results can be found in Multimedia Appendix 2). Statistically significant associations were observed between higher values of the composite missingness score and a greater likelihood of experiencing IIT at both 6 and 12 months among pediatric patients. However, no such association was observed among adult patients for either outcome. Among pediatric patients, each additional indicator missing was associated with a 1.34 times greater likelihood of experiencing IIT at 6 months post ART initiation (95% CI 1.08-1.66; P=.008) and 1.24 times greater likelihood of experiencing IIT at 12 months (95% CI 1.05-1.46; P=.01). Our interaction models (not shown) revealed that the relationship between the composite score indicator and IIT status was statistically significantly larger among pediatric patients compared to adult patients at both 6 months, where pediatric patients had a 25% greater risk of experiencing IIT for each additional missing element compared to adult patients (95% CI 1.02-1.53; P=.03), and 12 months, where pediatric patients had an 18% greater risk of experiencing IIT for each additional missing element compared to adult patients (95% CI 1.01-1.38; P=.04).
Figure 2. Multivariable regression of interruption in treatment (IIT) status at (A) 6 months post antiretroviral therapy (ART) initiation and (B) 12 months post ART initiation against composite missingness score (continuous), stratified by age group.

We also assessed the composite missingness score as a categorical variable (Figure 3) to understand the estimates of excess risk in the absence of the assumption of a linear relationship between missingness and IIT status (full multivariable regression results can be found in Multimedia Appendix 2). Compared to pediatric patients with 0 missing indicators, pediatric patients with 1, 2, or 3 missing indicators were 1.59 (95% CI 1.26-2.01; \(P<.001\)), 1.74 (95% CI 1.02-2.97; \(P=.04\)), and 2.25 (95% CI 1.43-3.56; \(P=.001\)) times more likely to experience IIT at 6 months, respectively. At 12 months, pediatric patients with 1, 2, or 3 missing indicators were 1.54 (95% CI 1.34-1.78; \(P<.001\)), 1.34 (95% CI 0.82-2.20; \(P=.24\)), and 1.75 (95% CI 1.08-2.85; \(P=.02\)) times more likely to experience IIT, respectively, although this association was no longer significant for those with 2 indicators missing. Among adult patients, compared to patients with 0 indicators missing, having all 3 indicators missing was associated with being 1.32 times more likely to experience IIT at 6 months (95% CI 1.03-1.70; \(P=.03\)), while having 3 indicators missing was not associated with IIT at 12 months, and having 1 or 2 indicators missing was not associated with IIT at either 6 or 12 months.
Figure 3. Multivariable regression of interruption in treatment (IIT) status at 6 and 12 months post antiretroviral therapy initiation against composite missingness score (categorical), stratified by age group. aRR: adjusted risk ratio.

For the individual missingness indicators (Multimedia Appendix 2), only the WHO HIV stage indicator was associated with IIT status among pediatric patients, where pediatric patients with missing WHO HIV stage data on their intake form were 2.17 times more likely to experience IIT at 6 months (95% CI 1.79-2.64; \( P < .001 \)) and 1.79 times more likely to experience IIT at 12 months (95% CI 1.54-2.08; \( P < .001 \)), as compared to pediatric patients with nonmissing WHO HIV stage data. Missingness for the WHO stage data among adult patients and missingness for weight and TB status among either age group were not associated with IIT status at either 6 or 12 months.

**Sensitivity Analyses**

We hypothesized that providers at facilities with a lower proportion of pediatric patients may be less familiar with pediatric care, and therefore, less compliant with treatment and reporting guidelines, which could potentially impact the relationship between data missingness and IIT. However, neither missingness nor IIT status showed a significant association with the proportion of pediatric patients at a given facility, and an interaction model did not show any difference in the relationship between data missingness and IIT status by the proportion of pediatric patients (data are not shown). We additionally explored a more granular definition for age groups 0-9, 10-14, 15-19, 20-24, and >25 years. In age group–stratified models, the
association between the continuous composite data missingness score and IIT status at 6 months was only statistically significant for the 0-9 age group, which showed a positive association between greater missingness and likelihood of experiencing IIT (data are not shown).

Discussion

Principal Findings

In this retrospective longitudinal study of patient record data drawn from the iSanté EMR system in Haiti, we found that both data missingness and interruption in ART treatment were higher for pediatric patients compared to adult patients; nearly one-third of pediatric patients had IIT at 6 months compared to just over one-fifth of adults, and nearly half of pediatric patients had missing values for indicators of interest on their intake forms compared to just over one-quarter of adult patients. Data missingness showed a substantial and significant association with greater IIT, with adult patients being 30% more likely and pediatric patients more than twice as likely to have IIT at 6 months when all 3 indicators of interest were missing. The relationship between missingness and IIT status was stronger and more consistent among pediatric patients; pediatric patients showed statistically significantly greater likelihood of experiencing IIT at 6 and 12 months for the composite score indicator both overall (continuous) and across all levels of missingness (categorical), while for adult patients this relationship was only significant at 6 months and for the highest level of missingness in the categorical analysis. Individual indicator missingness showed little association with IIT status, except for the WHO HIV stage among pediatric patients. Within the modified Donabedian quality of care framework, our results show a link between the process of care provision (vis-à-vis compliance with reporting guidelines and data use for clinical decision-making) and patient outcomes (IIT status) after adjusting for structural elements (ie, facility characteristics), with the association being highly dependent on medical care antecedents (ie, patient age group) [21,22].

There is a rich evidence base showing the potential impact of EMR use on HIV service provision and quality of care by promoting adherence to care guidelines, enabling higher quality patient data, improving provider efficiency, and informing patient care, tracking, and follow-up [5-13]. The benefits of EMRs, however, are largely predicated on providers having access to quality data (ie, reliable, timely, and nonmissing) to inform their work, and there is a growing evidence base on the importance and impact of patient record quality (electronic or otherwise) on quality of care, care engagement, or health outcomes [14-16,29,30]. Particularly relevant to this analysis, one study of more than 6000 patient records collected from the National Clinical Audit for Rheumatoid and Early Inflammatory Arthritis found that missing baseline patient data was significantly associated with the odds of timely initiation of treatment being halved [29]. In a qualitative study of health care professionals in South Africa, participants reported viewing data quality as a critical element in the provision of quality health care services, including how poor EMR information integrity can lead “to errors that endanger patient safety or decrease the quality of care” [45]. A systematic review found that data missingness was a commonly cited barrier to the use of EMRs to inform population health efforts [12]. In another systematic review, Albagmi [11] found that EMRs were associated with both better documentation and higher quality of care, although a direct causal relationship between data quality and quality of care was not directly assessed. This limitation is common to much of the literature on EMR data quality; many studies of EMR implementation include both data quality and quality of care indicators as outcomes or indicators of interest, but few directly assess the relationship between data quality and quality of care or patient outcomes. Our results, therefore, contribute to this limited evidence base, providing evidence that EMR data quality is associated with interruption in ART treatment.

Although we have established a temporal sequence for the relationship between data quality and IIT status, the absence of measurements for other elements of quality of care makes it impossible to discern whether the observed association was due to poor data quality itself or data quality as a proxy for broader quality of care. Data quality could be a marker of lower provider competence, poorer supplies and infrastructure at the health facility, higher provider-patient ratio, lower contact time between providers and patients, or other phenomena associated with IIT status. Further research is necessary to understand the role data missingness plays in care provision.

Our finding that overall missingness was higher among pediatric patients and that the association between missingness and IIT status was stronger among pediatric patients supports our hypothesis that there may be differential quality of care among pediatric patients leading to poorer retention in care. Pediatric populations living with HIV have unique care needs, and poorer engagement for pediatric patients across the HIV care cascade is a multifaceted issue, involving behavioral, psychosocial, pharmacokinetic, and structural factors [17,46]. The literature has identified a number of key barriers to pediatric ART adherence, including stigma among caregivers to seek or continue care for children; lack of education or training for caregivers on caring for a child living with HIV; complexities inherent to a patient-caregiver-provider relationship; limited patient agency due to age and patient-caregiver power structures; patient-led treatment refusal, sometimes due to a lack of palatable formulations for younger patients; and lack of providers trained in pediatric HIV care or family-based service delivery [17,47,48]. Relevant to this analysis, prior research has shown direct links between quality of care, care engagement, and patient outcomes for this population. In their analysis of children living with HIV in Nigeria, Ojikutu et al [37] found that higher quality care—measured as a composite score exploring TB screening, adherence measurement and counseling, CD4 and weight documentation, and medication prescription—was significantly associated with a lower likelihood of pediatric and adolescent patients being lost to follow-up and mortality. Improving the quality of care for children living with HIV, including better patient record quality, is necessary to address the gaps in HIV testing and treatment among children living with HIV.
Limitations
At present, it is not possible to track patients between facilities within our analysis data. As such, it is not possible to distinguish patients who transferred to a new facility but remained on ART and those who interrupted or fully discontinued treatment. As a result, our ART retention outcome was defined as an IIT at a patient’s current facility rather than interruption overall. This outcome still fits within our causal model, with lower quality of care being feasibly associated with either an actual IIT or transfer to another facility for higher quality care, and it still represents a meaningful proxy indicator for clinical outcomes, as facility transfer may be associated with ART treatment gaps or discontinuation. Patient transfers are also not a limitation specific to this study; a systematic review of ART retention studies found that nearly 20% of patients classified as lost to follow-up had actually self-transferred to another facility [49].

Additionally, our results may be confounded if the missingness of the indicators is associated with the values of that indicator as well as our outcome. For example, if a higher WHO HIV stage is associated with both a greater likelihood of being missing and a greater likelihood of IIT, the observed association may be due to the latent WHO HIV stage rather than the data missingness. Of note, although integrated with iSanté, pharmacy data used to calculate the IIT outcome variables are collected through different mechanisms and staff. This includes greater data quality oversight, in part due to their inclusion in routine President’s Emergency Plan for AIDS Relief (PEPFAR) monitoring, evaluation, and reporting. Therefore, we do not anticipate that misclassification of the IIT outcome due to missing pharmacy data will be highly correlated with our exposure (missingness among indicators of interest), and thus, it will not present a substantial risk of bias. Finally, we were not able to assess associations with clinical outcomes (eg, viral suppression) due to data availability limitations.

Strengths
This was an observational study, and therefore, it could not assess a causal relationship between data missingness and IIT; however, our hypothesis is strengthened by the robust sample size and analytical design; strong association observed between missingness and IIT status; a dose-response relationship wherein greater missingness was associated with greater likelihood of a patient having IIT; and established temporal sequence, as the intake data are completed prior to ART initiation and the IIT outcomes.

Conclusions
Our analysis showed that both patient record data missingness for key indicators and interruption in ART treatment were common among patients, with nearly one-quarter of patients having IIT at 6 months and more than one-quarter of patients missing at least 1 indicator of interest in their patient record. Both IIT status and data missingness were more common among pediatric patients. Greater data missingness was associated with a higher likelihood of being IIT at 6 and 12 months for both pediatric and adult patients, although the association was stronger and more consistent among pediatric patients. Our findings motivate further research into the mechanisms by which EMR data quality impacts the quality of care and patient outcomes, particularly among children living with HIV. Additionally, efforts to improve both EMR data quality and quality of care should consider prioritizing pediatric patients.

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Authors’ Contributions
All authors have participated sufficiently in the work to take responsibility for the content, including participation in the conception or design of the work, or the acquisition, analysis or interpretation of data and drafting the work. AMS led on analysis design, conducted the analyses, developed the structure of the manuscript, and wrote the first draft. KC, MJ, and JGH facilitated data access and provided subject matter expertise and content review. ADW, JP, KBS, and NP provided technical review and contributed to analytic methods. NP provided project oversight. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest
None declared.

Multimedia Appendix 1
The CONSORT (Consolidated Standards of Reporting Trials) flow diagram.
[DOCX File, 123 KB - pediatrics_v7i1e51574_app1.docx ]
Multimedia Appendix 2
Multivariable regression tables.

[DOCX File, 65 KB - pediatrics_v7i1e51574_app2.docx]

References


Abbreviations

ART: antiretroviral therapy
CONSORT: Consolidated Standards of Reporting Trials
EMR: electronic medical record
IIT: interruption in treatment
PEPFAR: President’s Emergency Plan for AIDS Relief
TB: tuberculosis
WHO: World Health Organization

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Rates of Trauma Exposure and Posttraumatic Stress in a Pediatric Digital Mental Health Intervention: Retrospective Analysis of Associations With Anxiety and Depressive Symptom Improvement Over Time

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Abstract

Background: More than 2 out of 3 children and adolescents in the United States experience trauma by the age of 16 years. Exposure to trauma in early life is linked to a range of negative mental health outcomes throughout the lifespan, particularly co-occurring symptoms of posttraumatic stress (PTS), anxiety, and depression. There has been an increasing uptake of digital mental health interventions (DMHIs) among youths, particularly for anxiety and depression. However, little is known regarding the incidence of trauma exposure and PTS symptoms among youths participating in DMHIs and whether PTS symptoms impact anxiety and depressive symptom treatment response. Moreover, it is unclear whether participation in a DMHI for anxiety and depressive symptoms is associated with secondary effects on PTS symptoms among trauma-exposed youths.

Objective: This study aims to use retrospective data from youths participating in a DMHI to (1) characterize rates of trauma, PTS, and comorbid anxiety and depressive symptoms; (2) determine whether trauma exposure and elevated PTS symptoms impact the improvement of comorbid anxiety and depressive symptoms throughout participation in care; and (3) determine whether participation in a non–posttraumatic DMHI is linked to reductions in PTS symptoms.

Methods: This study was conducted using retrospective data from members (children ages 6 to 12 years) involved in a pediatric collaborative care DMHI. Participating caregivers reported their children’s trauma exposure. PTS, anxiety, and depressive symptom severity were measured monthly using validated assessments.

Results: Among eligible participants (n=966), 30.2% (n=292) reported at least 1 traumatic event. Of those with trauma exposure and elevated symptoms of PTS (n=119), 73% (n=87) exhibited elevated anxiety symptoms and 50% (n=59) exhibited elevated depressive symptoms. Compared to children with no trauma, children with elevated PTS symptoms showed smaller reductions per month in anxiety but not depressive symptoms (anxiety: F2,287=26.11; P<.001). PTS symptoms also decreased significantly throughout care, with 96% (n=79) of participants showing symptom reductions.

Conclusions: This study provides preliminary evidence for the frequency of trauma exposure and comorbid psychiatric symptoms, as well as variations in treatment response between trauma-exposed and nontrauma-exposed youths, among participants in a pediatric collaborative care DMHI. Youths with traumatic experiences may show increased psychiatric comorbidities and slower treatment responses than their peers with no history of trauma. These findings deliver compelling evidence that collaborative care DMHIs may be well-suited to address mental health symptoms in children with a history of trauma while also highlighting the critical need to assess symptoms of PTS in children seeking treatment.

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KEYWORDS

collaborative care model; telehealth; childhood trauma; DMHI; digital health; mental health; telemedicine; trauma; traumatic; pediatric; pediatrics; paediatric; paediatrics; child; children; youth; adolescent; adolescents; teen; teens; teenager; teenagers; retrospective; anxiety; depression; depressive; co-occurring; comorbid; comorbidity; comorbidities; association; associations; correlation; correlations; correlate

Introduction

More than two-thirds of children have experienced trauma, such as abuse, neglect, natural disasters, and sudden loss of a loved one, by the age of 16 years [1,2]. These rates have been exacerbated by the recent COVID-19 pandemic and associated lockdowns, which appear to have caused a significant increase in child maltreatment globally [3-6]. During the first year of the pandemic, more than 11% of US adolescents reported physical abuse and 55% reported emotional abuse—2- and 3-fold increases compared to prepandemic rates [7,8].

The far-reaching and pervasive effects of childhood trauma are well documented. Those who experience trauma, particularly in childhood and adolescence [9], are at increased risk for a number of maladaptive mental and physical health outcomes throughout the lifespan [10,11] including posttraumatic stress disorder (PTSD). PTSD and symptoms of posttraumatic stress (PTS) develop as a result of a traumatic event and include reexperiencing (eg, flashbacks or memories of the event), avoidance of reminders and feelings related to the event, and elevated arousal and alterations in cognition and mood (eg, negative emotions and feelings, blame, and isolation [12]). Recent estimates suggest that 16% of children and adolescents who experience trauma go on to develop PTSD, although symptom severity is often dependent on age and gender, as well as type, duration, and severity of the trauma experienced [13]. Those with trauma are not only at risk for developing PTSD but also a number of mental health difficulties, particularly anxiety and depression [14]. Indeed, PTS, depression, and anxiety share common symptoms, etiologies, and effective treatment modalities such as cognitive behavioral therapy (CBT) [15,16].

Youths with traumatic experiences are significantly more likely to receive mental health care from a variety of sources, including primary care physicians, therapists, psychiatrists, school counselors, and social workers [17]. With shortages of in-person mental health providers and rates of pediatric mental health disorders increasing, traditional modalities of mental health care are becoming steadily more overburdened, expensive, and inaccessible. These issues of accessibility paired with the lockdowns of the COVID-19 pandemic catalyzed widespread uptake of digital mental health interventions (DMHIs) or those facilitated by technologies such as computers and smartphones. Although a number of DMHIs are available for the treatment of pediatric PTSD [18], these interventions and associated research are limited in significant ways. First, no research has been done to characterize the rates of trauma among youths participating in DMHIs for comorbid symptoms such as anxiety and depression, which are some of the most prevalent mental health disorders among youths. Indeed, most youths who receive mental health services do so for anxiety and depressive symptoms [19-21]. Given the etiological overlap among PTS, depression, and anxiety, there is a high likelihood that many youths with PTS symptoms would experience secondary benefits when receiving mental health care for anxiety and depression. Second, there is little understanding of how traumatic experiences and PTS symptoms impact the treatment response of anxiety and depressive symptoms for youths participating in a DMHI. By exploring these 2 lines of research, pediatric DMHIs will be better equipped to adapt their care programs and modalities to the needs of users with traumatic experiences and posttraumatic symptoms.

The collaborative care model (CoCM), in which primary care providers partner with behavioral care managers (BCMs) and psychiatrists to coordinate patient-centered and measurement-based care, is widely considered the best practice for pediatric mental health care [22]. Researchers have argued that the CoCM, with its use of regular symptom measurement and individualized care, confers better outcomes, particularly for those with trauma who are exhibiting complex and comorbid symptoms of PTS, depression, and anxiety [23,24]. Early evidence indicates that DMHIs using the CoCM are associated with improvements in pediatric mental health problems, including anxiety and depression [10,25,26]. However, no research has been done to understand the use and effectiveness of collaborative care DMHIs for anxiety and depression among trauma-exposed youths.

Therefore, the purpose of this study was to use retrospective data from youths participating in a collaborative care DMHI to (1) characterize rates of trauma, PTS, and comorbid anxiety and depressive symptoms; (2) determine whether trauma exposure and elevated PTS symptoms impact improvement of comorbid anxiety and depressive symptoms throughout participation in care; and (3) determine whether participation in a non–posttraumatic DMHI is linked to reductions in PTS symptoms.

Methods

Participants

Bend Health Inc members aged 6 to 12 years (at baseline, before care started) were eligible for inclusion in the study if they (1) had their first coaching or therapy session with Bend between January 1, 2023, and October 1, 2023 (9 months), and (2) completed the trauma assessment before beginning care (N=979). To more specifically assess symptom outcomes for trauma-exposed youths.

Ethical Considerations

Study procedures were approved by the Biomedical Research Alliance of New York (Study 23-12-034-1374). All participants...
provided informed consent to their data being used for research purposes upon enrollment, and all data were anonymized and deidentified prior to analysis. Bend Health Inc members were not compensated for their participation in this retrospective research.

Treatment

Treatment with Bend Health Inc has been described previously [25]. Bend Health Inc is a DMHI for youths that uses the CoCM to implement a whole-family approach, involving caregivers in treatment. Each member is assigned a behavioral care manager (BCM) who oversees and manages the child’s individual treatment plan and works with primary care providers, psychiatrists, therapists, and coaches to determine the correct treatment plan for each member. The member then meets regularly with either a licensed therapist or a coach, depending on the type and severity of mental health symptoms the member is experiencing. To specifically target a particular symptom domain (eg, anxiety symptoms), children are assigned a care program (by their BCM) based on their symptom severity and care goals. All care programs are designed to be developmentally appropriate for the age of the member, and the primary care programs (eg, anxiety, depression, and attention-deficit/hyperactivity disorder [ADHD]) are intended to take approximately 12 weeks to complete. During sessions, coaches and therapists provide behavioral care that is informed by the components of the care program. The informational contents of all care programs are also available in a digital platform for members and their caregivers to access between sessions (asynchronously). Once a month, caregivers are asked to complete questionnaires regarding their child’s symptoms, including PTS, anxiety, and depressive symptoms.

Therapy at Bend Health Inc provides diagnostic clarity, addresses complicated history of trauma and problematic behaviors, and provides clinical treatment for mental health disorders. Coaching provides behavior change tools and improvements in self-efficacy using evidence-based best practices. When appropriate, members’ care can escalate to include both coaching and therapy for the treatment of more severe symptoms. Both coaching and therapy at Bend Health Inc are based on CBT, behavioral activation, motivational interviewing, caregiver training, and mindfulness-based practices. Depending on symptom needs and care plan, members may also meet with a psychiatrist at enrollment and throughout care for additional symptoms and medication management.

Assessments

At enrollment into care with Bend Health Inc, caregivers are asked to report their child’s demographic information, including date of birth, sex, gender, and race or ethnicity. The response options for sex are “male,” “female,” and “other.” The response options for gender are “male,” “female,” “transgender,” “nonbinary,” and “other.” From January 1, 2023, to May 26, 2023, only 1 race or ethnicity response could be selected, and the options were “White,” “Black or African American,” “American Indian or Alaska Native,” “Chinese,” “Vietnamese,” “Native Hawaiian,” “Filipino,” “Korean,” “Japanese,” “Chamorro,” “Other Asian,” “Other Pacific Islander,” “Some other race or multi-racial,” “Mexican,” “Mexican American,” “Chicano,” “Puerto Rican,” “Cuban,” and “Another Hispanic, Latino, or Spanish origin.”

To assess children’s mental health symptoms during the enrollment process, caregivers first respond to screener questions. When elevated symptoms are flagged by the responses to the screeners, caregivers are then prompted to complete fully validated assessments. To screen for PTS, caregivers are asked the question: “Has your child ever experienced a traumatic event?” If the response to this question is “Yes,” caregivers are then asked to report the nature and timing of the child’s most distressing event, and they also complete the entire Child PTSD Symptom Scale (for the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition; CPSS-V) validated questionnaire [27]. To assess the nature of the traumatic event, caregivers are asked to describe their child’s most distressing event in a free textbox. To assess the timing of the traumatic event, caregivers are asked “How long has it been since that event occurred?” with the following response options: “1-30 days,” “1-3 months,” “3-6 months,” “6-12 months,” “1-2 years,” “2-4 years,” and “4+ years.” The CPSS-V consists of 20 items, in which caregivers are asked to report how often their child exhibits behaviors consistent with PTS, such as “trying not to think about it [the distressing event] or have feelings about it” and “trouble having good feelings.” Responses to these items are made on a 5-item Likert-type scale, with responses ranging from “not at all” (score=0) to “6 or more times a week/always” (score=4).

Screener questions for anxiety and depressive symptoms are taken from the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) cross-cutting measure, which asks caregivers to report the frequency (in the last 2 weeks) that their child exhibits behaviors associated with anxiety and depression [28]. There are 3 anxiety symptom screener questions and 2 depressive symptom screener questions. Responses to the anxiety and depressive symptom screeners are made on a 5-item Likert-type scale with responses ranging from “not at all” (score=0) to “nearly every day” (score=4). If a caregiver responds to any anxiety or depressive screener question with “several days” (score=2) or more frequently, they are prompted to complete the PROMIS (Patient-Reported Outcomes Measurement Information System) anxiety assessment or PROMIS depressive assessment, respectively [29]. The PROMIS anxiety assessment includes 10 questions about common anxiety symptoms (eg, feeling worried). The PROMIS depression assessment includes 11 questions about common depressive symptoms (eg, feeling lonely). For both PROMIS assessments, caregivers report the frequency of their child’s behaviors or feelings in the last 7 days, with responses on a 5-item Likert-type scale ranging from “never” (score=1) to “almost always” (score=5). Caregivers were prompted to complete mental health symptom screeners and assessments within the web-based portal every month after enrollment to track mental health symptom severity throughout care.
Statistical Methods

Responses to all items from the CPSS-V were aggregated for a total PTS score of 0 to 80. Using standardized criteria, PTS symptom severity was determined based on CPSS-V scoring norms [27], which are as follows: minimal (scores: 0 to 10), mild (score: 11 to 20), moderate (score: 21 to 40), severe (score: 41 to 60), and very severe (score: 61 to 80). Responses to the items from the anxiety and depression PROMIS assessments were aggregated for a total anxiety score of 10 to 50 and a total depressive symptom score of 11 to 55, respectively. Then, total PROMIS scores were converted to t-scores using standardized criteria [30]. Anxiety and depressive symptom severity were then determined based on t-scores as follows: none to slight (t-score <55), mild (t-score 55-59.9), moderate (t-score 60-69.9), and severe (t-score ≥70). For PTS, anxiety, and depressive symptoms, symptom severity of moderate, severe, or very severe was considered “elevated.”

Standard descriptive statistics—including percent, mean (SD), and median (IQR)—are used throughout the “Results” section, as appropriate. For all analyses (outlined in detail below), between-group comparisons for categorical variables were performed using chi-square tests, and comparisons for continuous variables were performed using 2-tailed Wilcoxon signed rank tests or 2-tailed t tests, as appropriate based on data distribution (determined by Shapiro-Wilk test). Where between-group comparisons could not be performed given a small representation within a category of interest, only the descriptive statistics are reported.

PTS Symptoms

For all members included in the study (n=966), the rates of reported trauma at baseline (last assessment before care started) were described. For members that had a traumatic event, CPSS-V scores, PTS symptom severity, and the timing of the traumatic event were reported. Members with no traumatic event were included in the no trauma group. Members with both a traumatic event and CPSS-V scores indicating moderate or greater PTS symptoms were included in the elevated PTS symptoms group. Members with a traumatic event and nonelevated PTS symptoms were not included in the primary analyses, and thus all further analyses were applied only to members in the “no trauma” and “elevated PTS symptoms” groups (Figure 1).

Figure 1. Flowchart delineating study group formation and exclusion criteria. PTS: posttraumatic stress.

Member Characteristics and Care Use

Member characteristics and care use patterns were reported for each group. The following member characteristics were assessed: age in years (at baseline), sex (male, female, and nonbinary), gender conforming (conforming and nonconforming), ethnicity (Asian, Black or African American, Hispanic/Latino, White, and Other), and mental health diagnoses by type (anxiety disorder, depressive disorder, and ADHD). Date of birth was used to calculate age in years (at enrollment). If a member’s sex at birth and gender identity (reported at enrollment) were not identical, they were classified as gender nonconforming. Otherwise, members were classified as gender conforming. Details on the reporting of race or ethnicity are included in the Multimedia Appendix 1. Rates of elevated mental health symptoms at baseline (moderate or greater severity) were also assessed for anxiety and depressive symptoms. For care use patterns, the duration of care (months between the first session and the last session) and participation in coaching and therapy were reported only for members with at least 1 coaching or therapy session (106 excluded). Between-group comparisons were performed for the following variables of interest: age, female sex (yes or no), gender conformity (conforming or nonconforming), ethnicity (White or non-White), elevated mental health symptom (elevated or nonelevated; all types), months in care, and participation in therapy (yes or no).

Mental Health Symptom Reduction

PTS symptom reduction was assessed for members in the “elevated PTS symptoms” group. Rates of members with symptom reduction were assessed for those with at least 1 coaching or therapy session, and who completed at least one symptom assessment after starting care (37 excluded). Symptom reduction was considered a decrease in score from baseline or screening out of the last assessment. Then, the amount of total change over the duration of care was assessed by delta CPSS-V score from baseline to the last full CPSS-V assessment (no screened-out assessments), and delta scores were compared to 0 using a Wilcoxon signed rank test to assess for a significant change in score. This analysis was performed on data from members with at least 1 coaching or therapy session, and at least 1 full symptom assessment after starting care (54 excluded). To determine whether PTS symptoms decreased
over months in care, CPSS-V scores were assessed over months in care by a linear mixed effects model with a fixed effect of months in care and a random effect of member ID on the intercept. Potential covariates were added to this basic model, and if a potential covariate improved model fit (based on the likelihood ratio test [LRT]), it was included in the final model. Models with the addition of the following covariates were tested against the basic model: age (at baseline), sex (female vs nonfemale), and race or ethnicity (White vs non-White).

Anxiety and depressive symptoms were assessed over time in care and compared between groups. First, the rates of members with symptom reduction were assessed for members with elevated mental health symptoms at baseline, at least 1 coaching or therapy session, and at least 1 symptom assessment after starting care (anxiety symptoms: 576 excluded; depressive symptoms: 658 excluded). Symptom reduction was considered a decrease in t-score from baseline or screening-out of the last assessment. The rates of members with symptom reduction were compared between groups using chi-square tests. These analyses were performed on data from members with elevated mental health symptoms at baseline, at least 1 coaching or therapy session, and at least one full symptom assessment after starting care (anxiety symptoms: 626 excluded; depressive symptoms: 712 excluded). Then, the total change in t-score (delta t-score) from baseline to the last full assessment was compared between groups using a 2-tailed t test or Wilcoxon signed rank test, as determined based on sample distribution. Finally, the rate of anxiety and depressive symptom reduction was compared between groups using linear mixed effects analyses with a fixed effect of group, the interaction of the group with months (in care) and a random effect of the subject on the intercept.

For all linear mixed effects analyses, to ensure that the findings were not skewed by baseline assessments occurring very early before the start of care, members whose baseline assessment occurred greater than 1 month before the first coaching or therapy session were excluded (PTS symptoms: additional 6 excluded; anxiety symptoms: additional 10 excluded; depressive symptoms: additional 4 excluded). A single additional member (n=1) was excluded from the depressive symptom linear mixed effects analysis due to an outlier t-score. For between-group analyses of rates of symptom reduction and total change, we confirmed that each group took their last and full last assessments at approximately the same time in care by between-group Wilcoxon signed rank comparisons of assessment timing for each symptom domain.

**Results**

### PTS Symptoms

Of the 966 members included in the study, 30.2% (n=292) had experienced a traumatic event and the remaining 69.8% (n=674) did not have a traumatic event. For members with a traumatic event, CPSS-V scores were a median of 18 (IQR 9-28), with scores ranging from 0 (minimal PTS symptom severity) to 61 (very severe PTS symptoms). Of members with a traumatic event, 86 (29.5%) had minimal symptoms, 87 (29.8%) had mild symptoms, 99 (33.9%) had moderate symptoms, 19 (6.5%) had severe symptoms, and 1 (0.3%) had very severe symptoms. As such, for members with a traumatic event, 59.2% (n=173) had nonelevated PTS symptoms and 40.8% (n=119) had elevated PTS symptoms.

While 63.7% (n=186) of all members with a traumatic event reported that the event occurred 1 or more years before baseline, the timing of the event varied (Table 1). Notably, the rate of children having experienced the event within the last 30 days was nearly twice as high for children with elevated PTS symptoms (n=14, 11.8%) versus nonelevated PTS symptoms (n=10, 5.8%). For all further analyses, 674 were included in the no trauma group (no trauma reported at baseline), 119 were included in the elevated PTS symptoms group (traumatic event and elevated PTS symptoms), and 173 were not included in further analyses (traumatic event and nonelevated PTS symptoms).

### Member Characteristics

Children with elevated PTS symptoms were a median of 10 (IQR 9-11) years old, 56.3% (n=67) were female, and they were largely gender conforming (n=113, 95%; Table 2). In terms of their race or ethnicity, 44.5% (n=53) were “White” and 35.3% (n=42) were “Other” or multiracial. Compared to members with no trauma, members with elevated symptoms of PTS were older (z=-4.38; P<.001) and more predominantly female (χ²=5.33; P=.02). Rates of elevated mental health symptoms at baseline

---

**Table 1.** Timing of trauma, respective to when it was reported at baseline, reported for members in the no trauma and elevated PTS symptoms groups.

<table>
<thead>
<tr>
<th>Timing of trauma (prior to baseline)</th>
<th>Nonelevated PTS symptoms, n (%)</th>
<th>Elevated PTS symptoms, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>173 (59.2)</td>
<td>119 (40.8)</td>
</tr>
<tr>
<td>1 to 30 days</td>
<td>10 (5.8)</td>
<td>14 (11.8)</td>
</tr>
<tr>
<td>1 to 3 months</td>
<td>14 (8.1)</td>
<td>11 (9.2)</td>
</tr>
<tr>
<td>3 to 6 months</td>
<td>15 (8.7)</td>
<td>10 (8.4)</td>
</tr>
<tr>
<td>6 to 12 months</td>
<td>19 (11)</td>
<td>13 (10.9)</td>
</tr>
<tr>
<td>1 to 2 years</td>
<td>34 (19.7)</td>
<td>23 (19.3)</td>
</tr>
<tr>
<td>2 to 4 years</td>
<td>38 (22)</td>
<td>23 (19.3)</td>
</tr>
<tr>
<td>4 or more years</td>
<td>43 (24.9)</td>
<td>25 (21)</td>
</tr>
</tbody>
</table>

*PTS: posttraumatic stress.*
were higher for children with elevated PTS symptoms compared to children with no trauma. Specifically, 72.6% (n=87) of children with elevated PTS symptoms had elevated anxiety symptoms compared to 33.9% (n=228) of children with no trauma (χ²₁=63.55; P<.001). Approximately 1 in 2 children with elevated PTS symptoms also had elevated depressive symptoms (n=59, 49.6%) compared to 1 in 5 children with no trauma (n=135, 20%; χ²₁=46.21; P<.001). Children with elevated symptoms of PTS had higher rates of participation in the anxiety care program (χ²₁=7.75; P=.005) and depression care program (χ²₁=3.79; P=.05; statistical trend) and lower rates of participation in the ADHD care program (χ²₁=4.06; P=.04).

Table 2. Member characteristics reported for children in the no trauma and elevated PTS symptom groups. Between-group comparisons were performed with chi-square tests unless otherwise specified.

<table>
<thead>
<tr>
<th>Member characteristics</th>
<th>No trauma (n=674), n (%)</th>
<th>Elevated PTS symptoms (n=119), n (%)</th>
<th>Between-group comparisons</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ageᵇ (years), median (IQR)</td>
<td>9 (7-11)</td>
<td>10 (9-11)</td>
<td>-4.38ᶜ</td>
<td>&lt;.001ᵈ</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td>5.33</td>
<td>.02ᵈ</td>
</tr>
<tr>
<td>Female</td>
<td>299 (44.4)</td>
<td>67 (56.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>372 (55.2)</td>
<td>51 (42.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>3 (0.4)</td>
<td>1 (0.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender conformity</td>
<td></td>
<td></td>
<td>0.21</td>
<td>.64</td>
</tr>
<tr>
<td>Conforming</td>
<td>629 (93.3)</td>
<td>113 (95)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonconforming</td>
<td>45 (6.7)</td>
<td>6 (5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td>0.00</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Asian</td>
<td>38 (5.6)</td>
<td>4 (3.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black or African American</td>
<td>37 (5.5)</td>
<td>11 (9.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>28 (4.2)</td>
<td>9 (7.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>301 (44.7)</td>
<td>53 (44.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other or multiracial</td>
<td>270 (40.1)</td>
<td>42 (35.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elevated mental health symptom</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety</td>
<td>228 (33.9)</td>
<td>87 (72.6)</td>
<td>63.55</td>
<td>&lt;.001ᵈ</td>
</tr>
<tr>
<td>Depressive</td>
<td>135 (20)</td>
<td>59 (49.6)</td>
<td>46.21</td>
<td>&lt;.001ᵈ</td>
</tr>
<tr>
<td>Care program</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety</td>
<td>289 (42.9)</td>
<td>68 (57.1)</td>
<td>7.75</td>
<td>.005ᵈ</td>
</tr>
<tr>
<td>Depression</td>
<td>51 (7.6)</td>
<td>16 (13.4)</td>
<td>3.79</td>
<td>.05ᵉ</td>
</tr>
<tr>
<td>ADHDᶠ</td>
<td>231 (34.3)</td>
<td>29 (24.4)</td>
<td>4.06</td>
<td>.04ᵈ</td>
</tr>
<tr>
<td>Behavior</td>
<td>86 (12.8)</td>
<td>13 (10.9)</td>
<td>0.17</td>
<td>.68</td>
</tr>
</tbody>
</table>

ᵃPTS: posttraumatic stress.
ᵇBetween-group comparisons were performed with a 2-tailed Wilcoxon signed rank test.
ᶜ z value for Wilcox signed-rank tests.
ᵈ P values<.05.
ᵉ P values<.10.
ᶠADHD: attention-deficit/hyperactivity disorder.

For members in the no trauma group who began coaching or therapy, they were in care for a median of 3.03 (IQR 1.63-4.50) months; 98.8% (n=479) were in coaching and 23.7% (n=115) were in therapy. For members in the elevated PTS symptoms group that began coaching or therapy, they were in care for a median of 3.03 (IQR 1.89-4.67) months, and 100% (n=102) were in coaching and 25.5% (n=26) were in therapy. The duration of care did not differ between groups (z=−1.08; P=.28), and the rates of members in therapy also did not differ between groups (χ²₁=1.27; P=.26).
Mental Health Symptom Reduction

The rates of reduction in anxiety and depressive symptoms from baseline to the last assessment did not differ between groups (anxiety: $\chi^2_{1}=1.33; P=.25$ and depressive: $\chi^2_{1}=0.28; P=.59$), with 84.3% (183/217) of all members exhibiting a reduction in anxiety symptom severity and 86.7% (117/135) of all members exhibiting a reduction in depressive symptom severity (Table 3). The amount of change (delta t-score) from baseline to the last full assessment also did not differ significantly between groups (anxiety: $z=-0.35; P=.73$ and depressive: $t_{51.23}=0.19; P=.85$). Specifically, for all children, anxiety t-scores decreased by a median of 5 points (IQR –9 to 0) and depression t-scores decreased by a mean of 3.77 (SD 7.54) points. The number of months between baseline and the last assessment and the last full assessment did not differ between groups for anxiety and depressive symptoms (all $P>.05$).

Table 3. Change in anxiety and depressive symptoms from baseline. Rates of members with a reduction in symptom severity from baseline to their last assessment and the change in t-score from baseline to the last full assessment are reported for each group.

<table>
<thead>
<tr>
<th>Mental health symptom</th>
<th>No trauma</th>
<th>Elevated PTS symptoms</th>
<th>Between-group comparisons$^b$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Anxiety, n/N (%)</td>
<td>130/158 (82.3)</td>
<td>53/59 (89.8)</td>
</tr>
<tr>
<td></td>
<td>Depressive, n/N (%)</td>
<td>80/94 (85)</td>
<td>37/41 (90)</td>
</tr>
<tr>
<td>Delta t-score (baseline to last full assessment)</td>
<td>Anxiety$^c$</td>
<td>$-5.0$ (–9 to 0)</td>
<td>$-5.0$ (–8 to –2.5)</td>
</tr>
<tr>
<td></td>
<td>Participants, n</td>
<td>116</td>
<td>51</td>
</tr>
<tr>
<td></td>
<td>Depressive$^e$</td>
<td>$-3.65$ (7.70)</td>
<td>$-4.00$ (7.35)</td>
</tr>
<tr>
<td></td>
<td>Participants, n</td>
<td>55</td>
<td>26</td>
</tr>
</tbody>
</table>

$^a$PTS: posttraumatic stress.

$^b$Between-group comparisons were performed with chi-square tests, unless otherwise specified.

$^c$Between-group comparisons performed with a 2-tailed Wilcoxon signed rank test.

$^d$z value for Wilcoxon signed rank test.

$^e$Between-group comparison were performed with a 2-tailed t test.

$^f$t value for t test.

In the linear mixed effects model of anxiety symptom severity, the main effect of the group was not statistically significant ($F_{1,155}=2.52; P=.11$), indicating that the no trauma and elevated PTS symptoms groups did not differ in anxiety symptom severity. The interaction of the group with months (from care start) was significant ($F_{2,285}=26.11; P<.001$), such that children with no trauma had larger anxiety symptom reduction per month (mean $–1.23$, SD 0.19) than children with elevated PTS symptoms (mean $–1.12$, SD 0.31). For depressive symptom severity, the main effect of the group was not statistically significant ($F_{1,74}=2.39; P=.13$). The interaction of the group with months approached significance ($F_{2,112}=2.86; P=.06$), as children with elevated PTS symptoms had slightly larger depressive symptom reduction per month (mean $–0.65$, SD 0.44) than children with no trauma (mean $–0.64$, SD 0.34).

For those with elevated PTS symptoms, 96.3% (79/82) exhibited PTS symptom reduction from baseline to the last assessment, with the last assessment having a median of 2.33 (IQR 1.04-3.89) months after the start of care. For members who took the full CPSS-V after beginning care (n=65; median 2 months, IQR 1.03-3.50 after the start of care), CPSS-V scores decreased significantly from baseline (median change score –13 points, IQR –19 to –6; $z=-6.35; P<.001$). Results from the linear mixed effects model of PTS symptoms, which included a fixed effect of age (LRT: $\chi^2_{1}=3.97; P=.046$) and female sex (LRT: $\chi^2_{1}=4.92, P=.03$), showed that CPSS-V scores decreased significantly over months in care ($F_{1,140}=67.11; P<.001$) by an estimated mean of 3.37 (SD 0.41) points per month (Figure 2). The main effects of age ($F_{1,54}=2.07; P=.16$) and female sex ($F_{1,54}=1.42; P=.24$) were not statistically significant.
Discussion

Principal Findings

The purpose of this study was to use retrospective data from youths participating in a collaborative care DMHI to (1) characterize rates of trauma, PTS, and comorbid anxiety and depressive symptoms; (2) determine whether trauma exposure and elevated PTS symptoms impact the improvement of comorbid anxiety and depressive symptoms throughout participation in care; and (3) determine whether participation in collaborative care DMHI is linked to reductions in PTS symptoms. We found that trauma, PTS, and psychiatric comorbidity are common among youths participating in a DMHI, and comorbid PTSD is associated with variations in rates of improvement for anxiety and depressive symptoms. Moreover, participation in a collaborative care DMHI is linked to improvements in PTS symptoms for most participants. These findings offer valuable preliminary insights into the clinical characteristics and sequelae among trauma-exposed youths participating in a DMHI.

Nearly 1 in 3 members participating in care for depressive, anxiety, or ADHD symptoms had experienced trauma. Many trauma-exposed youths reported symptoms of elevated PTS (n=119, 41%), and children with a traumatic event and elevated PTS had higher rates of elevated anxiety (n=87, 73%) and depressive symptoms (n=59, 50%) than children with no trauma. These observed rates of PTS, which are higher than previous estimates among trauma-exposed youths [13], paired with the high—albeit expected [31]—co-occurrence of anxiety and depression, highlight an acute need for DMHIs to provide both PTS screening and evidence-based treatment for youths with complex trauma-related symptomatology [32]. A slight majority (n=67, 56%) of those with elevated PTS were female, suggesting a limited role of sex in this sample’s PTS symptoms. Recent estimates suggest that more than twice as many women develop PTSD in adulthood as men [33], a discrepancy that remains largely consistent when controlling for trauma type [34]. However, these sex-based differences in PTSD prevalence may not arise until adolescence, during which pubertal changes catalyze developments in fear-related neurocognitive processing [35]. Incidence of sexual violence in adolescence may also contribute to sex-based differences in PTS: the majority of youths who experience sexual violence are between 12 and 17 years, and 82% of all sexual assault and abuse victims younger than 18 years are female [36]. Given the relatively young age of our sample, it is understandable that we did not identify such stark sex-based differences in PTS severity. Nevertheless, DMHIs should take into account sex-based differences in trauma and PTS risk factors when providing pediatric mental health care.

PTS symptom severity significantly impacted treatment response for anxiety. Youths with elevated PTS symptoms showed smaller reductions in anxiety symptoms compared to those without PTS symptoms. This is understandable, given the particularly close symptom overlap and etiology of PTS and anxiety [37,38]. Anxiety symptoms may be particularly related to PTSD in the form of anxiety sensitivity or the fear of anxiety-related sensations [39], with previous research suggesting that anxiety sensitivity is both retrospectively and prospectively related to PTSD severity [40,41]. PTS symptoms can also interfere with mental health treatment by exacerbating anxiety and other mental health symptoms, increasing feelings of overall distress, and decreasing receptivity to treatment [42,43]. It should be noted that youths with elevated PTS symptoms showed larger reductions in depressive symptoms; however, this effect was small and was not statistically significant. Given the small effect size paired with the limited sample, this finding requires additional study and replication before we interpret it further. In sum, these results suggest that among youths receiving digital mental health care for anxiety and depressive symptoms, screening for and consideration of PTS symptoms are crucial, as PTS may impact the timing and magnitude of treatment response. These findings also emphasize

Figure 2. CPSS-V score over months in care for members with elevated PTS symptoms. CPSS: Child PTSD Symptom Scale; PTS: posttraumatic stress.
Although the intervention did not directly target PTS symptoms, most participants showed significant decreases in PTS symptoms throughout care. This finding likely points to the shared treatment targets (eg, emotion regulation [44]) and evidence-based methods (eg, CBT [15]) across PTS, anxiety, and depressive symptoms. Several DMHIs exist for the treatment of pediatric PTSD [18,45]; however, a recent review found that most are of poor quality and lack evidence- and measurement-based practice in the formation and implementation of the intervention [45]. As the usage of DMHIs for child mental health continues to increase, this study indicates that collaborative care DMHIs, which include high-quality evidence- and measurement-based care, are linked to secondary improvements in PTS symptoms via behavioral health care for depression, anxiety, and other mental health concerns (eg, ADHD). Taken together, these preliminary findings suggest that collaborative DMHIs may confer improvements in symptoms that are related to but outside the scope of treatment targets. Importantly, further experimental research is necessary to compare these effects with active and nonactive controls.

**Limitations and Future Directions**

Although illuminating, these findings are limited by several notable factors. First, the retrospective nature of the study design limits us from drawing causal conclusions from our results. Further experimental research comparing the current DMHI with a randomized controlled group will offer more conclusive evidence for the effectiveness of the current intervention above and beyond another type of mental health treatment. Another consequence of the retrospective study design is that our results may be biased by participants self-selecting into care, given that nontreatment factors associated with mental health care use may also underlie symptom improvements (eg, family support, increased parental education, and perceived need [46]). Future studies should include a more rigorous study design with a randomized controlled group and data from long-term members.

This study did not address whether particular behavioral intervention methods—including coaching versus therapy and specific symptom target (eg, anxiety or depression)—may be more or less beneficial to mental health outcomes than other methods. Instead, we assessed outcomes associated with participation in the DMHIs regardless of intervention methods. In future studies, identification of the behavioral interventions that are most beneficial to mental health outcomes in the context of DMHIs would greatly enhance the quality and efficacy of DMHIs in addressing PTS and comorbid anxiety and depression. Given the relatively small sample size of children with trauma and elevated PTS symptoms, we were not able to gauge whether the nature of the participants’ trauma exposure (eg, type and timing) may have predicted their outcomes. A large body of research suggests that the development of PTS and comorbid psychiatric symptoms following trauma exposure is heavily correlated with the nature of the trauma [11,47]; as such, our analyses are missing a potentially significant covariate. While we reported the timing of trauma for members with an event, we could not assess timing as a potential covariate in further analyses. Future research should continue to assess whether the nature of a child’s exposure to a traumatic event may affect their outcomes and symptom trajectory within the context of a DMHI. Nonetheless, the high correlation between participants experiencing a traumatic event and exhibiting elevated PTS symptoms suggests that the trauma measure accurately reflected traumatic exposure.

**Conclusions**

This study provides preliminary evidence for the frequency of trauma exposure and comorbid psychiatric symptoms, as well as variations in treatment response between trauma-exposed and nontrauma-exposed youths, among participants in a pediatric collaborative care DMHI. Youths with traumatic experiences may show increased psychiatric comorbidities and slower treatment responses than their peers with no history of trauma. These findings deliver compelling evidence that collaborative care DMHIs may be well-suited to address mental health symptoms in children with a history of trauma while also highlighting the critical need to assess symptoms of PTS in children seeking treatment.

**Authors’ Contributions**

LGH and DLS contributed to the conceptualization, methodology, formal analysis, writing the original draft, manuscript reviewing and editing, and visualization of this study. ABB contributed to the writing of the original draft and editing. MR edited the paper and acquired funds. AP and RG reviewed and edited the paper. JH contributed to the conceptualization, writing the original draft, manuscript reviewing and editing, and supervision of this study.

**Conflicts of Interest**

All authors are employed by Bend Health Inc, which delivered the treatment used in this retrospective study. However, authors’ employment status and salary are not dependent upon the results of their research.

**Multimedia Appendix 1**

Additional details regarding the categorization and analysis of race or ethnicity demographic question responses.

[DOCX File, 13 KB - pediatrics_v7i1e55560_app1.docx ]
References


https://pediatrics.jmir.org/2024/1/e55560

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(page number not for citation purposes)


Abbreviations

ADHD: attention-deficit/hyperactivity disorder
BCM: behavioral care manager
CBT: cognitive behavioral therapy
CoCM: collaborative care model
CPSS: Child PTSD Symptom Scale
DMHI: digital mental health intervention
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
LRT: likelihood ratio test
PTS: posttraumatic stress
PTSD: posttraumatic stress disorder

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Review

Exploring Maternal and Infant Health App Development and Effectiveness Research: Scoping Review

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Abstract

Background: Globally, high rates of maternal and infant mortality call for interventions during the perinatal period to engage pregnant people as well as their loved ones in care. Mobile health technologies have become ubiquitous in our lives and in health care settings. However, there is a need to further explore their safety and effectiveness to support and improve health outcomes locally and globally.

Objective: The aim of this study was to review and synthesize published literature that described the development process or effectiveness evaluations of maternal and infant apps.

Methods: We applied a methodological framework for scoping reviews as well as the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) guidelines; in addition, the systematic review platform Covidence (Veritas Health Innovation Ltd) was used to facilitate the review of included studies. Search terms were developed collaboratively, and health sciences–associated databases were searched for studies conducted between January 1, 2000, and February 4, 2022. We excluded studies about apps that only gathered or tracked data or targeted care providers.

Results: A total of 1027 articles were included for title and abstract screening, of which 87 (8.47%) were chosen for full-text screening. Of these 87 articles, 74 (85%) were excluded with reasons, and 19 (22%) were included. Four articles were added at data extraction from hand searching and 2 others were excluded. Thus, we reviewed and synthesized data from 11 unique studies reported in 21 articles published between 2017 and 2021. The included studies represented 8 different countries. Most of the apps (8/11, 73%) were in English, although apps were also developed in Arabic, Bahasa Indonesia, and Nepali. The articles reviewed revealed the early stage of development of the field of maternal and infant health apps, with modest evidence of app use and achievement of study outcomes. Only 1 (9%) of the 11 apps was endorsed by an independent health care provider society. App development and evaluation processes emerged, and specific app features were identified as vital for well-functioning apps. End-user engagement occurred in some, but not all, parts of app research and development.
Conclusions: Apps to improve maternal and infant health are being developed and launched in enormous numbers, with many of them not developed with mothers’ needs in mind. There are concerns about privacy, safety, and the standardization of current apps as well as a need for professional or institution-specific guidelines or best practices. Despite challenges inherent in currently available apps and their design processes, maternal and infant app technology holds promise for achieving health equity goals and improving maternal and child health outcomes. Finally, we propose recommendations for advancing the knowledge base for maternal and infant apps.

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KEYWORDS
maternal and child health; smartphone; mobile health; mHealth; eHealth; app development; app evaluation; app effectiveness; maternal and infant app; pregnancy, postpartum; mothers; mobile phone; artificial intelligence; AI

Introduction

Overview

Achieving the global health goal of health for all requires engaging and empowering individuals, families, and communities for increased social participation and enhanced self-care and self-reliance in health, in addition to universal health coverage (UHC) and primary health care (PHC) [1-4]. Globally, high rates of maternal and infant mortality call for interventions during the perinatal period to engage pregnant people as well as their loved ones to ensure that they remain in care during pregnancy and the postpartum period [5-10]. As mobile health (mHealth) technologies such as smartphone apps emerge and become ubiquitous in our lives and in health care settings, there is a need to further explore their potential to support and improve health outcomes locally and globally. The COVID-19 pandemic demonstrated the capacity for widespread uptake of mHealth technologies in every aspect of life [11,12]. Before the COVID-19 pandemic, there were numerous smartphone apps being developed to support many diverse health goals [7-9,12-14]. However, many maternal and infant health apps are short lived or constrained to specific health care systems or networks, and few of them are evaluated for effectiveness in improving health outcomes for the mother, their children, and families or endorsed or reviewed by health professionals or organizations independent of app development teams [14-19]. Despite the existence of a plethora of apps to support parents, especially during the perinatal and postpartum periods, documented scientific data remain meager. The limited peer-reviewed published evidence about the development process and effectiveness of apps in supporting mothers or parents with the challenges they face during the perinatal or postpartum period makes the content of the available apps questionable, which may influence their efficacy.

Background and Significance

Apps to Prevent Maternal and Infant Morbidity and Mortality

Numerous apps have been developed to support and improve maternal and infant health, including during pregnancy and the postpartum period. These apps can be an efficient means of providing information for parents, and the number of apps is rapidly increasing [20,21]. However, most apps lack the information needed and searched for by mothers with low income and non–English-speaking mothers with low income belonging to minority groups. It is well documented that people with low income, those with low income belonging to minority groups, and non–English-speaking people have a lower rate of pregnancy app use [22,23]. Most maternal and infant apps are not designed for women with low income and culturally diverse non–English-speaking women [24-26]. In the United States, it is estimated that most women (92%-95%) aged between 18 and 34 years own a smartphone [27]. This large proportion of smartphone users may have easy access to apps during pregnancy and the postpartum period when they could benefit from app-based maternal and infant health information. Evidence is emerging that maternal and infant apps have been developed and tested in resource-constrained settings and for use in humanitarian crises [7-9,14,28]. However, most existing pregnancy apps lack commercial regulation and standardization, making their content questionable [29]. Potential harm from several pregnancy mHealth intervention apps have been identified by health professionals [30]. Many apps have not been evaluated for content accuracy, making it difficult for users to assess the reliability of the information presented in them [31,32]. Many apps currently lack information that would be most helpful for women during pregnancy [33,34]. Neither medical nor health care societies have issued guidelines for mHealth apps [18,19,29,35,36]. Few studies exist that report on the outcomes from the use of such apps [29].

Regulatory agencies are constrained under current regulatory frameworks to provide effective and efficient regulation of apps that can be classified as software as medical device (SaMD) [17-19,35]. The US Food and Drug Administration (FDA) takes the position that the regulation of apps needs to be tailored to the risk and benefit profiles of the apps but has no standards for apps [35]. The FDA “oversees apps intended to treat, diagnose, cure, mitigate, or prevent diseases or other conditions as medical devices under federal statute” [35]. The FDA seeks to empower patients and clinicians through innovation, including the creation of regulatory frameworks that instill confidence in the performance and reliability of apps [35]. The International Organization for Standardization (ISO) has articulated assessment processes and quality requirements for health apps [17]. There are international standards for product safety and lifecycle processes that are applicable to health apps. However, because of the time investment involved, most health-related apps are not evaluated [17]. This lack of effective regulatory oversight has led to calls for user-centered reforms to improve the accuracy, usability, accessibility, and privacy protection features of apps, especially health apps [18,19].
The current research and regulatory landscape offers little data or regulatory guidance to inform people about the effectiveness of available apps that aim to improve health outcomes among mothers, especially mothers with low income, mothers with low income belonging to minority groups, and non–English-speaking mothers. The lack of regulatory frameworks and guidelines for the development of safe and effective maternal and infant apps limits the confidence of patients and clinicians and may lead to harms derived from the use of currently available apps [18,19,35,36]. Increasing knowledge in this area is important because the population of people with low income and those with low income belonging to non–English-speaking minority groups continues to grow, and these groups tend to have poorer maternal and infant health outcomes. In addition, there is an increased need for maternal and infant apps in languages other than English.

**App Searches**

Mobile apps are downloaded by end users on their smartphone. However, there are little data on why people search for apps, although major life events seem to be drivers for mobile app installations [37]. People experiencing major life events—change in marital status, moving, job change, pregnancy, or the birth of a child—install 2.5 times more apps than those without any significant life changes. There are studies reporting how end users find apps [37]. More than half of app users (55%) found apps based on recommendations from friends, family members, and colleagues [37]. In addition, 1 in 3 consumers found apps through app store recommendations; searching in an app store; and advertisements on the web, social media, and television. Most consumers (74%) downloaded apps after viewing mobile advertisements for them [38]. There are little data documenting that consumers’ app searches and downloads are based on scientific recommendations [38,39].

**Brief Overview of Currently Available Parent and Infant Health Apps**

An extensive review of currently available maternal and infant apps is beyond the scope of this review. In 2018, a total of 5276 Android maternal and child health (MCH) apps and 877 iOS MCH apps were identified [40,41]. There are estimated to be >350,000 health apps available worldwide, and it is estimated that 250 new health apps are released every daily [42].

**Positionality Statement**

Our scoping review team includes professionals and researchers with a variety of perspectives that inform our evaluation of the literature reviewed. We represent multiple cultural backgrounds, migrant statuses, sexes, and genders. In addition, our multiple academic disciplines include computer technology and IT, communications, human rights law, informatics, speech-language pathology, medicine, and maternal and child nursing. We have team members from multiple contexts globally. Our varied lived experiences and knowledge support analysis of the literature reviewed from a wider perspective of world views to inform future development of computer-mediated technologies, such as smartphone apps, to improve the health of mothers, their infants, families, and communities.

**Objectives**

The purpose of this scoping review study was to review and synthesize published literature that described the development process or effectiveness evaluations of maternal and infant health apps, with a specific emphasis on determining the use of the apps by the target population; provided evidence of outcomes with mothers, fathers, infants, or children; and explained whether the apps have been reviewed or endorsed by a health care provider. The research question guiding this scoping review study was as follows: what evidence exists that describes the development and effectiveness evaluation of maternal and infant health apps?

**Methods**

**Scoping Review Approach**

Because of the scarce evidence of apps being systematically evaluated for effectiveness, we used a scoping study methodology to review and synthesize the existing literature. The scoping review approach was originally described by Arksey and O’Malley [43] and has since been adapted by Islam et al [44], Levac et al [45], and Westphaln et al [46]. The original scoping review method included 5 steps: identifying the research question (step 1); search strategy (step 2); study selection (step 3); charting the data (step 4); and collating, summarizing, and reporting the results (step 5). Two additional steps were added subsequently: consultation (step 6) [45,46] and quality assessment (step 7) [44]. We used the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) guidelines to enhance transparency in our approach to the scoping study [47]. The PRISMA-ScR guidelines checklist is available in Multimedia Appendix 1.

**Steps Taken**

The identification of the research question (step 1) and the development of our search strategy (step 2) were developed collaboratively during team meetings. The research question addressed by the scoping study was as follows: what evidence exists that describes the development and assessment of the development and effectiveness of parent and infant health apps? Specifically, we sought to identify extant studies that described the use of the apps by the target population; provided evidence of outcomes with mothers, infants, or children; and explained whether the apps have been reviewed or endorsed by a health care provider or health care provider society (eg, American Academy of Pediatrics). Our search strategy included literature published between January 1, 2000, and February 4, 2022. The search terms included “((mother* OR mom* OR matern* OR pregna* OR parent* OR postpart*) AND (infan* OR newborn OR neonat* OR prenat* OR perinat* OR postnat* OR bab*) AND (app OR mobile app OR apps OR mobile device applications OR mobile apps OR smartphone) AND (health*)).” The search resulted in 1895 citations being identified. The search process commenced on January 27, 2022, with a preliminary search of Academic Search Complete (EBSCO), Bibliography of Indigenous Peoples in North America (EBSCO), CINAHL, Communication Source (EBSCO), Education Source (EBSCO), and Global Health (EBSCO). The citations identified from this
search (163/1895, 8.6%) were imported into the systematic review platform Covidence (Veritas Health Innovation Ltd) [48]. MEDLINE (Ovid) was also searched on January 27, 2022, and the citations identified (398/1895, 21%) were imported into Covidence [48]. Citations from Scopus (64/1895, 3.38%), PubMed (656/1895, 34.62%), and Web of Science (614/1895, 32.4%) were identified in an additional search on February 4, 2022, and added to Covidence [48]. Of the 1895 citations, after screening, 892 (47.07%) duplicates were removed.

Study selection (step 3); charting the data (step 4); and collating, summarizing, and reporting the results (step 5) were facilitated using Covidence [48]. Study selection occurred in 2 stages: title and abstract screening and full-text screening. All articles at each stage were reviewed by at least 2 team members. Any conflicts were resolved during team meetings for title and abstract screening. During full-text screening, any conflicts were resolved by team members who had differing opinions about inclusion discussing their differences and coming to an agreement about whether to include a citation for data extraction. Inclusion and exclusion criteria (Textbox 1) were specified during team meetings and adapted as needed through team consensus. All team members had the opportunity to participate in title and abstract screening, which aligns with our approach to consultation (step 6) that was inclusive of the multiple perspectives of our team members.

Textbox 1. Literature review inclusion and exclusion criteria.

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
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<tbody>
<tr>
<td>Published primary research article (eg, completed studies)</td>
</tr>
<tr>
<td>Review article (eg, systematic review or scoping review)</td>
</tr>
<tr>
<td>Apps for pregnant people (people), parents (include fathers if they are part of the app’s target audience), postpartum people (people), infants and children, and mothers and infants</td>
</tr>
<tr>
<td>Language: app in any language; articles limited to publications in English</td>
</tr>
<tr>
<td>Any country</td>
</tr>
<tr>
<td>Article describes app development process or how effectiveness was determined (eg, randomized controlled trial or evaluation)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study or app focused on pathology or psychopathology (eg, gestational diabetes mellitus, preterm or premature birth, anxiety, and depression)</td>
</tr>
<tr>
<td>Study protocols</td>
</tr>
<tr>
<td>Thesis or dissertation</td>
</tr>
<tr>
<td>Commentaries, editorials, and letters to the editor</td>
</tr>
<tr>
<td>Apps for health care or community services workers only</td>
</tr>
<tr>
<td>Apps for data gathering or tracking</td>
</tr>
<tr>
<td>Computer-mediated platforms: websites, communication platforms (eg, WhatsApp, Facebook Messenger, and FaceTime), and social media or social networking platforms (eg, Twitter, Facebook, and Reddit)</td>
</tr>
</tbody>
</table>

Our team developed a data extraction tool for charting the data (step 4). This instrument was then entered into Covidence to facilitate data extraction. Three authors (JCP, JH, and SZ) completed data extraction. All other team members had access to the data extraction outputs in Covidence [48]. The final outputs of the data extraction process—the charted data—were shared with all team members for review and discussion at a team meeting. Collating, summarizing, and reporting the results (step 5) were completed using the PRISMA-ScR process [47]. To ensure rigor in reporting our findings, we used a 3-stage process [45]. First, we provide numerical summaries of key aspects from the reviewed studies (eg, country where app was designed to be used, app language, and study population). Second, narrative summaries, tables, and figures are used to present our findings and facilitate comparisons between, and contrasts across, the reviewed studies. Finally, in the Discussion section, we elaborate on the implications of our findings for the future research and development of maternal and infant apps. We also propose recommendations for improving the development, usability, end-user uptake, evaluation, quality assessment, as well as policies for funders and regulators in the field.

Consultation (step 6) was incorporated into this scoping review by including the multiple personal and professional perspectives of the members of our diverse and inclusive team, which is briefly described in the Positionality Statement subsection. We did not consult outside our research team for conducting this scoping review study. Our future research endeavors will include wider community consultations to include the experiences and perspectives of the people who use maternal and infant apps. Quality assessment (step 7) is a potentially fraught process for scoping review studies, but efforts are underway to develop an appraisal tool for them [49]. Some researchers have included this step to enhance scoping review quality [44]. For the purposes of our review and given the early developmental stages of the science regarding the development and effectiveness evaluations of smartphone apps, quality assessment was not part of the inclusion criteria for this study. The assessment of the selected studies will be made in a separate study after
recommendations for the critical appraisal of scoping reviews have been more formalized [49].

**Results**

**Overview**

Of the 1889 studies identified, after removing 862 (45.63%) duplicates, 1027 (54.37%) articles remained. Of these 1027 articles, 940 (91.53%) were excluded during the title and abstract screening. Of the remaining 87 articles that were assessed for eligibility during full-text screening, 74 (85%) were excluded for reasons stated in the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) diagram (Figure 1 [50]), resulting in 19 (22%) articles reporting on 13 distinct studies that were included for data extraction. At data extraction, 4 articles [51-54] describing aspects of 1 (8%) of these 13 studies were added from a hand search of the literature, yielding a total of 23 articles for data extraction. Of the total 23 articles, 2 (9%) were excluded at data extraction; 1 (4%) was excluded because the app is limited to podcasts, which may not offer a range of engagement opportunities and communication modalities for app users and has less potential for use with multiple languages [55]; and 1 (5%) was excluded because the study tested a model of care that included an encrypted digital app that facilitated text-based communication between patients and their care team, not an app with multiple functionalities [56]. Each of these excluded articles reported on a study, which yielded the final total of 11 studies reported in 21 articles included. Of these 11 studies, 2 (18%) were reported in multiple articles, 1 (9%) was reported in 3 (14%) of the 21 articles [7-9], and 2 (18%) studies were each reported in 5 (24%) of the 21 articles [51-54,57-62]. Ultimately, we reviewed and synthesized data from 11 unique studies reported in 21 articles, published between 2017 and 2021.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram.

**Characteristics of Included Studies**

Table 1 summarizes characteristics across the 11 included studies. The lead authors of the included studies represented 8 different countries, with Australia (3/11, 27%) [57,59-64] and the United States (3/11, 27%) [16,65,66] having the greatest representation. The other represented countries included Indonesia (1/11, 9%) [28], Jordan (1/11, 9%) [14], Morocco (1/11, 9%) [67], Nepal (1/11, 9% study reported in 3/21, 14% of the articles) [7-9], and Singapore (1/11, 9% study reported in 5/21, 24% of the articles) [51-54,58]. The health discipline of the primary authors varied, with the most common being medicine (3/11, 27%) and nursing (3/11, 27%). The other disciplines included public health (2/11, 18%), followed by computer technology fields: computing and informatics (1/11, 9%), IT (1/11, 9%), and biomedical engineering (1/11, 9%). Most of the apps were in English (8/11, 73%); other app languages included Arabic (1/11, 9%) [14], Bahasa Indonesia (1/11, 9%) [28], and Nepali (1/11, 9% study reported in 3/21, 14% of the articles) [7-9]. English-language apps were developed for use in Australia (3/11, 27%), the United States (3/11, 27%), Morocco (1/11, 9%), and Singapore (1/11, 9%).
<table>
<thead>
<tr>
<th>Country (language); authors and year</th>
<th>Studies (n=11), n (%)</th>
<th>Articles (n=21), n (%)</th>
<th>Disciplines</th>
<th>Endorsed by independent HCP&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Australia (English)</strong></td>
<td>3 (27)</td>
<td>7 (33)</td>
<td>Anthropology, media, communications, and health (health, arts, and design)</td>
<td>No</td>
</tr>
<tr>
<td>Dalton et al [64]; 2018</td>
<td></td>
<td></td>
<td>Medicine, nursing, social work, IT, computer science, and business</td>
<td>No</td>
</tr>
<tr>
<td>Meedya et al [63]; 2021</td>
<td></td>
<td></td>
<td>Medicine, nursing, IT, dietetics, public health, and population health</td>
<td>No</td>
</tr>
<tr>
<td>Scott et al [57]; 2021</td>
<td></td>
<td></td>
<td>Medicine, nursing, IT, dietetics, public health, and population health</td>
<td>No</td>
</tr>
<tr>
<td>White et al [59]; 2016</td>
<td></td>
<td></td>
<td>Medicine, nursing, IT, dietetics, public health, and population health</td>
<td>No</td>
</tr>
<tr>
<td>White et al [60]; 2018</td>
<td></td>
<td></td>
<td>Medicine, nursing, IT, dietetics, public health, and population health</td>
<td>No</td>
</tr>
<tr>
<td>White et al [61]; 2016</td>
<td></td>
<td></td>
<td>Medicine, nursing, IT, dietetics, public health, and population health</td>
<td>No</td>
</tr>
<tr>
<td>White and Scott [62]; 2019</td>
<td></td>
<td></td>
<td>Medicine, nursing, IT, dietetics, public health, and population health</td>
<td>No</td>
</tr>
<tr>
<td><strong>United States (English)</strong></td>
<td>3 (27)</td>
<td>3 (14)</td>
<td>Nursing</td>
<td>No</td>
</tr>
<tr>
<td>Bush et al [65]; 2017</td>
<td></td>
<td></td>
<td>Nursing, public health, and business administration</td>
<td>No</td>
</tr>
<tr>
<td>Cawley et al [66]; 2020</td>
<td></td>
<td></td>
<td>Medicine, social work, computer science, and trained health workers (prenatal care coordination providers)</td>
<td>No</td>
</tr>
<tr>
<td>Chaudhry et al [16]; 2019</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Indonesia (Bahasa Indonesia)</strong></td>
<td>1 (9)</td>
<td>1 (5)</td>
<td>Medicine and computer science</td>
<td>No</td>
</tr>
<tr>
<td>Wiweko et al [28]; 2019</td>
<td></td>
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<tr>
<td><strong>Jordan (Arabic)</strong></td>
<td>1 (9)</td>
<td>1 (5)</td>
<td>Medicine, international development agencies, UNRWA&lt;sup&gt;b&lt;/sup&gt;, and World Bank</td>
<td>No</td>
</tr>
<tr>
<td>Nasir et al [14]; 2020</td>
<td></td>
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<tr>
<td><strong>Morocco (English)</strong></td>
<td>1 (9)</td>
<td>1 (5)</td>
<td>Medicine, computer science, and biomedical science</td>
<td>Yes</td>
</tr>
<tr>
<td>Sardi et al [67]; 2020</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Nepal (Nepali)</strong></td>
<td>1 (9)</td>
<td>3 (14)</td>
<td>Social work, IT, and computer science (female community health volunteers were part of the sample studied)</td>
<td>No</td>
</tr>
<tr>
<td>Kayastha et al [7]; 2021</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mueller et al [8]; 2020</td>
<td></td>
<td></td>
<td>Social work, IT, and computer science (female community health volunteers were part of the sample studied)</td>
<td>No</td>
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<tr>
<td>Mueller et al [9]; 2020</td>
<td></td>
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<tr>
<td><strong>Singapore (English)</strong></td>
<td>1 (9)</td>
<td>5 (24)</td>
<td>Nursing and psychiatry</td>
<td>No</td>
</tr>
<tr>
<td>Shorey et al [58]; 2017</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Shorey and Ng [51]; 2019</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shorey et al [52]; 2019</td>
<td></td>
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<td></td>
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<td>Shorey et al [53]; 2021</td>
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<td></td>
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<tr>
<td>Shorey et al [54]; 2018</td>
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</table>

<sup>a</sup>HCP: health care provider.

<sup>b</sup>UNRWA: United Nations Relief and Works Agency for Palestine Refugees in the Near East.
The studies included a variety of study designs, including randomized controlled trial (2/11, 18% studies reported in 3/21, 14% of the articles) [51,57,58], observational study (1/11, 9%) [66], multisite cross-sectional study (1/11, 9%) [14], diagnostic test accuracy study (1/11, 9%) [16], mixed methods study (1/11, 9%) [63], case study methodology report of a pilot study (1/11, 9%) [65], app development reports (2/11, 18%) [28,67], and qualitative articles with participants from the main study (4/11, 36%) [51,53,54,60]. Of the 11 apps, 4 (36%) were designed for use in resource-constrained settings: Indonesia [28], Morocco [67], Nepal (reported in 3/21, 14% of the articles) [7-9], and Palestine refugee camps in Jordan [14].

All studies reviewed reported that they had funding to conduct the research for the study. Of the 11 studies, 7 (64%) were funded by a governmental agency, whereas 1 (9%) was funded by a state Medicaid office [65], 1 (9%) was funded by the United Nations Relief and Works Agency for Palestine Refugees in the Near East (UNRWA) [14]; 1 (9%), reported in 5 (24%) of the 21 articles, was funded by a university [51-54,58]; and 1 (9%) was funded by a health system [66]. Funding specific for app development was reported in 5 (46%) of the 11 studies reported in 7 (33%) of the 21 articles [7-9,28,65-67]. Funding to support app sustainability was not specifically reported in any of the studies but could be assumed in 3 (27%) of the 11 studies [14,16,65]. It was not clearly specified whether app development and sustainability funding were obtained for 2 (18%) of the 11 studies [14,16].

Evidence of Apps’ Use, Outcomes, or Endorsement

Characteristics of the study populations from the reviewed studies are summarized in Table 2, and evidence use of the apps by the target population is presented in Table 3. Sardi et al [67] described an app in development and proposed a study to evaluate the effectiveness of the app they developed in collaboration with postpartum people. Evidence of outcomes with mothers, fathers, infants, and children was limited and is summarized in Table 3. Evidence that apps have been reviewed or endorsed by a health care provider is presented in Table 1. Although all studies reviewed included health professionals or health care providers as members of their research and development teams, only 1 (9%) of the 11 apps was endorsed by an independent health care provider or health care provider society not involved in the app’s development or evaluation [67].
### Table 2. Participant characteristics.

<table>
<thead>
<tr>
<th>Authors</th>
<th>Population description</th>
<th>Recruitment method</th>
<th>Sample size, n</th>
<th>Sample characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sardi et al [67]</td>
<td>Physicians and nurses (app for puerperal women)</td>
<td>Hospital</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Wiweko et al [28]</td>
<td>Pregnant and nonpregnant people</td>
<td>Clinic patients</td>
<td>205</td>
<td>Age: 20-36 y</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ethnicity: African American (69, 67%); Hispanic (19, 11%); White (29, 22%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Education: ≤high school (69, 67%); college (39, 33%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Income: US $0-US $30,000/y</td>
</tr>
<tr>
<td>Chaudhry et al [16]</td>
<td>Prenatal care coordination providers, social workers,</td>
<td>Clinic patients</td>
<td>9</td>
<td>Age: 20-36 y</td>
</tr>
<tr>
<td></td>
<td>and women</td>
<td></td>
<td></td>
<td>Race or ethnicity: Asian; European; Middle Eastern; White</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Education: NR</td>
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<td></td>
<td></td>
<td>Income: &gt;US $6000/mo</td>
</tr>
<tr>
<td>Meedya et al [63]</td>
<td>Pregnant people</td>
<td>News platform, paper flyers, and social media</td>
<td>7</td>
<td>Age: 20-36 y</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Race or ethnicity: Asian; European; Middle Eastern; White</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Education: NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Income: &gt;US $6000/mo</td>
</tr>
<tr>
<td>Bush et al [65]</td>
<td>Pregnant people</td>
<td>Grass roots referrals</td>
<td>85</td>
<td>Age: 20-36 y</td>
</tr>
<tr>
<td>Shorey et al [58]</td>
<td>Couples (mothers and fathers)</td>
<td>Clinic patients</td>
<td>250 (126/250, 50% [63 couples] received education support via app, whereas 124/250, 50% [62 couples] were in the control group)</td>
<td>Age: 26-42 y</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ethnicity: Chinese; Malay; other</td>
</tr>
<tr>
<td>Shorey and Ng [51]</td>
<td>Couples (mothers and fathers)</td>
<td>Clinic patients</td>
<td>250 (126/250, 50% [63 couples] received education support via app, whereas 124/250, 50% [50 couples] were in the control group)</td>
<td>Education: NR</td>
</tr>
<tr>
<td>Shorey et al [52]</td>
<td>Couples (mothers and fathers)</td>
<td>Clinic patients</td>
<td>250 (126/250, 50% [63 couples] received education support via app, whereas 124/250, 50% [50 couples] were in the control group)</td>
<td>Income: &gt;SG $6000 (US $4367)/mo</td>
</tr>
<tr>
<td>Shorey et al [53]</td>
<td>Couples (mothers and fathers)</td>
<td>Clinic patients</td>
<td>250 (126/250, 50% [63 couples] received education support via app, whereas 124/250, 50% [62 couples] were in the control group)</td>
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<td>Clinic patients</td>
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<td>Ethnicity: Chinese; Malay; other</td>
</tr>
<tr>
<td>Nasir et al [14]</td>
<td>Parents (mothers and fathers)</td>
<td>Clinic patients</td>
<td>1042</td>
<td>Age</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Mothers: 23-33 y</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td>Fathers: 29-39 y</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ethnicity: Palestinian (refugees)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Education: NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Income: US $0</td>
</tr>
<tr>
<td>Cawley et al [66]</td>
<td>Postpartum mothers</td>
<td>Mail</td>
<td>567</td>
<td>Age: 20-36 y</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Race or ethnicity: Asian (74/567, 13%); Hispanic (46/567, 8%); White (360/567, 63%); other (87/567, 15%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Education: ≤high school (82/567, 14%); college (482/567, 85%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Income: US $0-US $70,000/y (276/567, 49%); &gt;US $70,000-US $150,000/y (201/567, 35%)</td>
</tr>
</tbody>
</table>

https://pediatrics.jmir.org/2024/1/e46973
<table>
<thead>
<tr>
<th>Authors</th>
<th>Population description</th>
<th>Recruitment method</th>
<th>Sample size, n</th>
<th>Sample characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scott et al [57]</td>
<td>Expecting couples (mothers and fathers)</td>
<td>Clinic patients</td>
<td>1426</td>
<td>• Age</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Mothers: 33-34 y</td>
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<td></td>
<td></td>
<td></td>
<td>• Fathers: NR</td>
</tr>
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<td></td>
<td></td>
<td>• Race or ethnicity: African or Middle Eastern (64/1426, 4%); Asian (84/1426, 6%); Australia or New Zealand (724/1426, 51%); United Kingdom or Ireland (129/1426, 9%); other (72/1426, 5%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Education: ≤high school (409/1426, 29%); college (663/1426, 46%)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Income: NR</td>
</tr>
<tr>
<td>White et al [59]</td>
<td>Expecting couples (mothers and fathers)</td>
<td>Clinic patients</td>
<td>1426</td>
<td>• Age</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Mothers: 33-34 y</td>
</tr>
<tr>
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<td></td>
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<td></td>
<td>• Race or ethnicity: African or Middle Eastern (64/1426, 4%); Asian (84/1426, 6%); Australia or New Zealand (724/1426, 51%); United Kingdom or Ireland (129/1426, 9%); other (72/1426, 5%)</td>
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<td></td>
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<td>• Income: NR</td>
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<td>Clinic patients</td>
<td>1426</td>
<td>• Age</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
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<td></td>
<td></td>
<td>• Fathers: NR</td>
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<td>• Income: NR</td>
</tr>
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<td>Expecting couples (mothers and fathers)</td>
<td>Clinic patients</td>
<td>1426</td>
<td>• Age</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Mothers: 33-34 y</td>
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<tr>
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<td></td>
<td></td>
<td>• Fathers: NR</td>
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</tr>
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<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Income: NR</td>
</tr>
<tr>
<td>White and Scott [62]</td>
<td>Expecting couples (mothers and fathers)</td>
<td>Clinic patients</td>
<td>1426</td>
<td>• Age</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Mothers: 33-34 y</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Fathers: NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Race or ethnicity: African or Middle Eastern (64/1426, 4%); Asian (84/1426, 6%); Australia or New Zealand (724/1426, 51%); United Kingdom or Ireland (129/1426, 9%); other (72/1426, 5%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Income: NR</td>
</tr>
<tr>
<td>Authors</td>
<td>Population description</td>
<td>Recruitment method</td>
<td>Sample size, n</td>
<td>Sample characteristics</td>
</tr>
<tr>
<td>--------------------</td>
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<td>----------------</td>
<td>-------------------------------------------------------------</td>
</tr>
<tr>
<td>Kayastha et al [7]</td>
<td>Men and women</td>
<td>By referrals</td>
<td>71</td>
<td>NR</td>
</tr>
<tr>
<td>Mueller et al [8]</td>
<td>Men and women</td>
<td>By referrals</td>
<td>71</td>
<td>NR</td>
</tr>
<tr>
<td>Mueller et al [9]</td>
<td>Men and women</td>
<td>By referrals</td>
<td>71</td>
<td>NR</td>
</tr>
</tbody>
</table>
| Dalton [64]        | Pregnant people        | Clinic patients    | 124            | • Age: 19–41 y
|                    |                        |                    |                | • Ethnicity: Australian White (103/124, 83%); other (21/124, 17%) |
|                    |                        |                    |                | • Education: high school (83/124, 67%); college (41/124, 33%)|
|                    |                        |                    |                | • Income: NR                                                |

*NR: not reported.*
Table 3. Target group involvement, app use, and outcomes.

<table>
<thead>
<tr>
<th>Authors</th>
<th>Target group</th>
<th>Involvement</th>
<th>App use</th>
<th>Outcomes reported</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sardi et al [67]</strong></td>
<td>Mothers and infants</td>
<td>App development</td>
<td>N/Aa (app in development phase)</td>
<td>• Clinical staff examined app features and functionalities.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• A future study with mothers is planned.</td>
</tr>
<tr>
<td><strong>Wiweko et al [28]</strong></td>
<td>Mothers</td>
<td>Implementation phase</td>
<td>Mothers</td>
<td>• App provides pregnant people directions to nearest health centers, access to medical staff, and saves patient’s medical records to easily obtain professional help needed immediately.</td>
</tr>
<tr>
<td><strong>Chaudhry et al [16]</strong></td>
<td>Mothers and infants</td>
<td>App development</td>
<td>Pregnant people</td>
<td>• Low use by both providers and mothers.</td>
</tr>
<tr>
<td><strong>Meedya et al [63]</strong></td>
<td>Mothers</td>
<td>App development</td>
<td>Breastfeeding mothers</td>
<td>• App was piloted with, and revised based on, mothers’ feedback.</td>
</tr>
<tr>
<td><strong>Bush et al [65]</strong></td>
<td>Pregnant people NRb</td>
<td></td>
<td>Pregnant people</td>
<td>• There was a statistically significant increase in the completion of prenatal visits (P=.02).</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• There was an association between the use of the app and lowered incidence of low birth weight infants (P=.06).</td>
</tr>
<tr>
<td><strong>Shorey et al [58]</strong></td>
<td>Postnatal mothers and fathers</td>
<td>Research process</td>
<td>Postnatal mothers and fathers</td>
<td>• There was an increase in the parenting confidence of new parents, better perceived social support (parents were encouraged to proactively seek help), and greater parenting satisfaction.</td>
</tr>
<tr>
<td><strong>Shorey and Ng [51]</strong></td>
<td>Postnatal mothers and fathers</td>
<td>Research process</td>
<td>Postnatal mothers and fathers</td>
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</tr>
<tr>
<td><strong>Shorey et al [52]</strong></td>
<td>Postnatal mothers and fathers</td>
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<td>Postnatal mothers and fathers</td>
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</tr>
<tr>
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</tr>
<tr>
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<td>Postnatal mothers and fathers</td>
<td>Research process</td>
<td>Postnatal mothers and fathers</td>
<td>• There was an increase in the parenting confidence of new parents, better perceived social support (parents were encouraged to proactively seek help), and greater parenting satisfaction.</td>
</tr>
<tr>
<td><strong>Nasir et al [14]</strong></td>
<td>Pregnant people and mothers</td>
<td>No community involve- ment</td>
<td>Pregnant people and mothers</td>
<td>• The number of participants who downloaded the app was reported.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Having other apps (OR 6.17; P&lt;.01), staff knowledge of the app (OR 11.82; P&lt;.01), using the Internet as a source of medical information (OR 1.63; P=.01) and having internet access at home (OR 1.46; P=.05) were associated with app download.</td>
</tr>
<tr>
<td><strong>Cawley et al [66]</strong></td>
<td>Mothers and infants</td>
<td>Research process</td>
<td>Pregnanat people</td>
<td>• The app provided access to personalized and evidence-based health information.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• The app was associated with an increase in healthy behaviors and health knowledge.</td>
</tr>
<tr>
<td><strong>Scott et al [57]</strong></td>
<td>Mothers and fathers</td>
<td>Research process</td>
<td>Fathers</td>
<td>• The study did not demonstrate a measurable impact of father-focused support for breastfeeding.</td>
</tr>
<tr>
<td><strong>White et al [59]</strong></td>
<td>Mothers and fathers</td>
<td>Research process</td>
<td>Fathers</td>
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<tr>
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<td>• The study did not demonstrate a measurable impact of father-focused support for breastfeeding.</td>
</tr>
</tbody>
</table>
The studies reviewed revealed several approaches to app development. Some of the studies (4/11, 36%) used systematized app development strategies, including software requirements specification [67], rapid iterative testing and evaluation [16,57], and persuasive system design model and principles [63]. Most of the studies (9/11, 82%) included formalized evaluation processes. Standardized approaches to the evaluation of the apps included the Computer System Usability Scale [16], the Mobile Application Rating Scale [57,59,61], and investigator-developed evaluation instruments or processes [7-9,14,59].

**App Development and Evaluation Processes**

The studies reviewed revealed several approaches to app development. Some of the studies (4/11, 36%) used systematized app development strategies, including software requirements specification [67], rapid iterative testing and evaluation [16,57], and persuasive system design model and principles [63]. Most of the studies (9/11, 82%) included formalized evaluation processes. Standardized approaches to the evaluation of the apps included the Computer System Usability Scale [16], the Mobile Application Rating Scale [57,59,61], and investigator-developed evaluation instruments or processes [7-9,14,59].

**App Features**

Each app included features intended to improve the end users’ experience. A full list of app features described in the studies is beyond the scope and purpose of this scoping review report. Textbox 2 summarizes the key features and functionality reported across the reviewed studies.

**End-User Engagement**

End-user engagement in app development was reported in 5 (45%) of the 11 studies, which were reported in 8 (38%) of the 21 articles [7-9,16,28,63,64,67]. Mothers were involved in app development in 7 (64%) of the 11 studies, which were reported in 4 (19%) of the 21 articles [16,28,63,67]. Fathers were involved in app development in 1 (9%) of the 11 studies, which was reported in 3 (14%) of the 21 articles [7-9]. End users were engaged in the research process in 3 (27%) of the 11 studies, which were reported in 11 (52%) of the 21 articles [51-54,57-62,66]. Of the 11 studies, 2 (18%) included mothers and fathers in the research process, as reported in 10 (48%) of the 21 articles [51-54,57-62]; and 1 (9%) included postpartum mothers in the research process [66]. Of the 11 studies, 1 (9%) included pregnant and nonpregnant people in the implementation phase of app development [28], whereas 2 (18%) did not report including end users in any aspect of the study [14,65].

**Discussion**

**Principal Findings**

**Overview**

Our scoping review is consistent with what has been previously reported in the literature. Apps have been developed for, and used in, a variety of settings globally. There are little data and regulatory guidance to inform people about the effectiveness of available apps that aim to improve health outcomes among mothers, especially mothers with low income, mothers with low income belonging to minority groups, and non–English-speaking mothers. This includes geographic locations with constrained resources and humanitarian crises (both human-made and natural disasters) [7-9,14,28]. The studies we reviewed reinforce the importance and usefulness of maternal and infant health apps to support global PHC objectives and confirm that they can be useful tools to facilitate the achievement of UHC [1-4]. However, our findings highlight...
several research gaps and challenges for the effective and sustainable development, implementation, and evaluation of maternal and infant health apps.

**App Development Process**

Currently, the development of maternal and infant health apps (including for use during pregnancy and the postpartum period) is on the rise; however, as documented in the literature and the results of this scoping review study, evaluation is lacking. Consistent with previous research, these apps are an efficient means of providing a wide range of health and safety information, and most women and parents, regardless of background or language, own a smartphone [7-9,14,20,21,28]. In fact, >85% of the world’s population in advanced economies [68] and >67% of the global population own a smartphone, with >90% owning a mobile phone [69,70]. Smartphone ownership makes health information on pregnancy and perinatal periods easily accessible through maternal and infant health apps. However, as seen in our study, maternal and infant health apps lack commercial regulation and standardization, making their content questionable, which has been previously documented [29]. As there is a lack of regulation and standardization, potential harm has been identified by health professionals with several pregnancy mHealth intervention apps [18,19,30,35]. Our review as well as other studies have found that many apps have not been evaluated for content accuracy, making it difficult for end users to assess the reliability of the information presented in them [31,32]. Some apps also lack information that would be most helpful for women and their families during the perinatal period [33,34]. No medical society has issued guidelines for mHealth apps [29], although the ISO and FDA offer guidance to support further development of guidelines [17,35], and legal scholars have proposed a framework for user-centered approaches to improve the safety and security of all apps, including mHealth apps [18,19].

In this scoping review study, we found that the outcomes reported demonstrated slight increases in behavior and knowledge [9,52,58,63,65,66], whereas other studies reported low use [14,16,64] or were in the development stages with no outcomes reported [28,67]. This is similar to other studies reporting on outcomes regarding the reasons why most apps developed are targeted at English-speaking White women without regard for women of other cultures and non–English-speaking people [8,14,22,23,28,29]. This has been attributed to a lack of app development designed for culturally diverse non–English-speaking women [25,71]. Few studies with culturally diverse women with low income and their use of mHealth apps have been reported or have examined language and cultural issues as potential barriers to app use [8,14,72,73]. Our study indicated that most of the apps (8/11, 73%) were in English. However, our scoping review study documents emerging evidence to support the use of maternal and infant health apps in other languages and cultures [7-9,14,28,51-54,58,67]. Studies have reported high uptake and use of linguistically and culturally tailored apps [74,75].

The findings of our study help in assessing similar conclusions in other recent studies that women using maternal and infant health apps during pregnancy and the postpartum period prefer greater and immediate access to information that is relevant to their local health care context, which includes support offered by health care professionals [25,76].

**App Features**

A summary of key features to include in future apps are described in **Textbox 2**. Key features for inclusion in apps include health status tracking, care support and access to information, usability, health data and privacy protection, data transfer, communication with health care providers, and behavior change techniques. Health status tracking facilitates recording various health indicators that can be monitored over time. Care support and access to information build knowledge to improve health outcomes. Usability enhances the end users’ experience when using an app. Health data and privacy protection protects the end users’ health data gathered by, or shared through, the app. Data transfer allows for sharing information between patients and health care or social services providers. Communication with health care providers facilitates dialogue and communication between patients and health care or social services providers. Behavior change techniques can be embedded in apps to support the achievement of health-promoting or risk behavior reduction goals. Additional information regarding app features is provided in a literature review conducted by Sardi et al [77].

In resource-constrained settings, such as Nepal [7-9], the app served multiple purposes to achieve public health and safety objectives, including maternal health and disaster preparedness. In addition, in refugee settings, an app based on the *Maternal and Child Health Handbook* contains basic MCH information and promotes care-seeking behaviors, improves the continuum of care, and increases users’ health-related behaviors [14]. This is evidence that apps can serve multiple health-related objectives, which has been documented in other settings during the COVID-19 pandemic [11,12]. In the context of health and humanitarian crises, the adoption of mHealth apps may be a wise use of scarce resources to address multiple public health–related and safety objectives simultaneously.

Potential risks related to mHealth and privacy exist and have been documented in the literature; for example, apps with the capacity to gather and store health data from end users need to have policies and protocols in place to ensure that the privacy of these data is maintained. These policies and protocols need to be transparent so that end users can be aware of who has access to their health data and for what purposes. In addition, algorithms, artificial intelligence, and machine learning can be used with the data gathered from apps. People who use these apps need to be aware of how these technologies are used with the data they share in apps [36]. Finally, risks can occur related to end users’ capability and capacity to read and understand content embedded in apps, even if the app is developed in the end users’ native language.

**End-User Engagement**

A fundamental feature of PHC that effective maternal and infant mHealth apps can offer is engaging people in their health care through empowerment and opportunities for enhanced self-care and self-reliance [1-4]. End-user engagement ought to be an
essential part of the development of all maternal and infant health apps as well as other mHealth apps. Including end users in all stages of app development, implementation, scale-up, evaluation, and research across all stages is critical to the sustainability of apps and may enhance app longevity. Strategies for how to engage end users of apps in research have been described previously [78]. None of the studies included in this scoping review included participants in all aspects of app research and development. Most of the studies (9/11, 82%) included end users in part of the app research and development process, including app development, reported in 7 (33%) of the 21 articles [7-9,16,63,64,67]; the implementation of the app [28]; and the research process, reported in 11 (52%) of the 21 articles [51-54,57-62,66].

Quality Appraisal and Risk of Bias
The current state of the science for app development and evaluation limits the ability to evaluate the published studies for risk of bias [49]. Furthermore, there is debate about whether and how to review study quality and risk of bias in scoping reviews [49,79]. As our scoping review included a variety of different research approaches or app development reports, it was difficult to conduct a thorough quality appraisal of the potential for risk of bias, especially because we did not exclude any study based on quality appraisal or risk of bias. Our finding that the current literature may not meet criteria specified in many quality appraisal and risk-of-bias tools aligns with the challenges in the field of mHealth app development and evaluation with which regulatory and standards agencies are currently grappling [18,19,35].

Strengths and Limitations of the Review
This scoping study used a methodological approach that has demonstrated success in other settings. In addition, we used the PRISMA-ScR guidelines to guide our study, which increases the transparency of the processes used to conduct the study. The limitations of this review include the fact that we may have missed some studies by only searching English-language literature. As we excluded studies with a primary focus on mental health outcomes, we may have missed some studies that reported on apps that have demonstrated efficacy and have begun to surmount the concerns with regard to quality and reliability as well as the accuracy, usability, accessibility, and privacy protection features of apps [18,19,35].

Conclusions
In conclusion, this is one of the few studies reviewing the research regarding apps for maternal and infant health. These apps are increasingly being developed and launched in the marketplace in enormous numbers with little to no evaluation criteria in place. Many of the current maternal and infant health apps being launched are not developed with the pregnant person or mother’s needs in mind. Although the use of maternal and infant apps in health research is a relatively new area, there are concerns about the safety of these apps for end users. Future initiatives are needed to support health researchers to navigate the landscape of maternal and infant health apps and evaluate the impact of their efforts to develop effective and sustainable apps. Given the concerns related to safety and standardization, future research needs to focus on providing additional direction to health researchers on how to set policies in place. This could include the development of professional or institution-specific guidelines or the development of best practices. Furthermore, there is a need for research to determine the influence and implications of the integration of apps within health care information systems. The integration of apps into health care information systems architecture and environments may pose unique challenges that directly influence the acceptability and usability of these apps for end users and may limit an app’s utility, uptake, and sustainability. Despite challenges inherent in currently available apps and their design processes, maternal and infant health app technology holds promise for achieving health equity goals and improving MCH outcomes.

Recommendations
Funders should consider strategies to support the sustainability of effective apps that achieve their stated purpose and are accessible, acceptable, safe, and secure for their end users. This will facilitate the sustainability of apps that have demonstrated effectiveness among pregnant people, parents, and their families. This implies that a quality appraisal or effectiveness evaluation of apps would need to be built into the app development, implementation, and scale-up processes.

We advocate for regulation to ensure that maternal and infant apps support the needs of mothers, fathers, and others who use them to improve health outcomes for mothers, infants, and their families. The regulatory framework proposed by Knox and Tenenbaum [18,19] would be useful to inform and guide regulatory advances in the field, as would the inclusion of strategies to protect the private information of people who use apps [18,19,36]. One aspect of this recommendation is for funders and policy makers to consider requiring end-user engagement in all aspects of app development and research that is consistent with the principles of PHC and UHC [1-4].

Researchers, policy makers, and patient advocates should advocate for the safe and wise use of new technology advances such as the artificial intelligence chatbots ChatGPT and Bard. These technologies may further advance opportunities for computer-mediated approaches that support improvements in MCH. These technologies hold tremendous potential to revolutionize health care but must be used to support goals for improved health outcomes, not for nefarious purposes.

Acknowledgments
The authors are grateful to the participants and researchers whose lives and work formed the basis for this scoping review study.
Data Availability

All data analyzed in this study are cited in this paper and available in the public domain. Data extraction tables are available from the corresponding author.

Conflicts of Interest

None declared.

Multimedia Appendix 1

PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist.

[DOCX File, 84 KB - pediatrics_v7i1e46973_app1.docx]

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Abbreviations

- FDA: Food and Drug Administration
- ISO: International Organization for Standardization
- MCH: maternal and child health
- mHealth: mobile health
- PHC: primary health care
- PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
- PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews

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**SaMD**: software as medical device

**UHC**: universal health coverage

**UNRWA**: United Nations Relief and Works Agency for Palestine Refugees in the Near East

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A Risk Assessment and Planning Tool to Prevent Sudden Unexpected Death in Infancy: Development and Evaluation of The Baby Sleep Planner

Abstract

Background: Successful national safer sleep campaigns in the United Kingdom have lowered the death rates from sudden unexpected death in infancy (SUDI) over the past 3 decades, but deaths persist in socioeconomically deprived families. The circumstances of current deaths suggest that improvements in support for some families to follow safer sleep advice more consistently could save lives.

Objective: This study aimed to develop and evaluate a risk assessment and planning tool designed to improve the uptake of safer sleep advice in families with infants at increased risk of SUDI.

Methods: A co-design approach was used to develop the prototype interface of a web-based tool with 2 parts: an individual SUDI risk assessment at birth and a downloadable plan for safety during times of disruption. The advice contained within the tool is concordant with national guidance from the Lullaby Trust, the United Nations International Children’s Emergency Fund (UNICEF), and the National Institute for Health and Care Excellence. User testing of the prototype tool was conducted by inviting health visitors, midwives, and family nurses to use it with families eligible for additional support. Qualitative interviews with health professionals and families allowed for iterative changes to the tool and for insights into its function and influence on parental behavior.

Results: A total of 22 health professionals were enrolled in the study, of whom 20 (91%) were interviewed. They reported appreciating the functionality of the tool, which allowed them to identify at-risk families for further support. They felt that the tool improved how they communicated about risks with families. They suggested expanding its use to include relevance in the antenatal period and having versions available in languages other than English. They reported using the tool with 58 families; 20 parents gave consent to be interviewed by the research team about their experiences with the tool. Families were positive about the tool, appreciated the trustworthy information, and felt that it was useful and appropriate and that the plans for specific infant sleeps would be of benefit to them and other family members.

Conclusions: Our tool combines risk assessment and safety planning, both of which have the potential to improve the uptake of lifesaving advice. Refinements to the tool based on these findings have ensured that the tool is ready for further evaluation in a larger study before being rolled out to families with infants at increased risk.
Safer sleep; parent education; co-design; process evaluation; sudden infant death syndrome; SIDS; sleep; baby; babies; infant; infants; prototype; interface; develop; development; sleeping; pattern; tool; parent; infant mortality; risk; risks; assessment; death; mortality; parents; parenting; risk assessment; sudden unexpected death in infancy; SUDI; approach; antenatal; postnatal; user testing; user experience; web-based; experience; experiences; attitude; attitudes; opinion; perception; perceptions; perspective; perspectives

Introduction

Background

Recent data from the National Child Mortality Database show a strong link between known risks in the sleep environment (eg, infant prone sleeping and hazardous cosleeping) and sudden unexpected death in infancy (SUDI) in 2020, with at least 1 known factor present in 75% of the deaths [1]. These data also show the scale of inequalities, with a significantly larger proportion of unexplained deaths of infants living in the most deprived neighborhoods (42%) than of those in the least deprived neighborhoods (8%), a 5-fold increase. In 2017, a consensus process (based on the James Lind Alliance Priority Setting model) in identifying research priorities to reduce SUDI rated “developing and evaluating new ways to make safe sleep interventions more effective” as the top priority in the United Kingdom [2]. More recently, the Child Safeguarding Practice Review Panel has called for further efforts to increase the uptake of safer sleep advice in families in which the risks of SUDI are much higher than in the general population [3]. The Baby Sleep Planner was designed in response to recommendations to target support and resources to those families with infants most at risk, provide tailored and personalized risk information, and facilitate planning for infant safety during times when the normal routine is disrupted [3]. Risk assessment calculators for SUDI at the time of birth have not been widely used before in the United Kingdom, but the shift to increased prevalence among families living in the most deprived neighborhoods makes this more viable. The tool comprises 2 parts: a risk assessment at birth showing infant risk based on background and neonatal characteristics and a sleep environment planning section that provides an individualized plan for safety that can be downloaded as an image and shared with family and friends. Currently, most safer sleep advice and guidance in the United Kingdom is given by midwives, health visitors, and specialist nurses. Message delivery is often compounded by limited time and conflicting advice from multiple sources [4]. Health professional resources aim to increase parental knowledge of SUDI risks, and recent qualitative interviews with them suggest that they would welcome a targeted approach for families with infants at the greatest risk using parental input to come up with realistic strategies during disrupted routines [3,5]. A recent review of interventions to increase the uptake of safer sleep advice in families of infants at increased risk concluded that approaches moving away from “information giving” toward “information exchange” may be more effective for this group [6]. Using the detailed evidence we collected in Bristol and working closely with families whose infants are at higher risk to understand parental decision-making, we had a unique opportunity to derive a targeted intervention [4,7].

Objectives

This paper describes the development and evaluation of a web-based tool that aimed to improve the uptake of safer sleep advice in families with infants at increased risk of SUDI. The Baby Sleep Planner was designed together with health professionals, families, other academics, and a team of software developers. The objectives of this study were as follows:

1. To use a co-design approach to develop a prototype web-based interface that the target group can use
2. To conduct user testing of the tool, including training and data capture of tool answers
3. To conduct qualitative interviews with health professionals and family members who have used the tool to understand how the tool works in real-world conditions and refine it for testing in a future study

Theory-Based Approach

The Medical Research Council’s guidance on the development and evaluation of complex interventions puts developing and testing theory as a core concept [8]. By using previous research on the influences on behavior of our priority group, we hope to provide a transparent theoretical underpinning that can be tested in a future study.

The risk assessment and planning tool is based on a Capability, Opportunity, and Motivation–Behavior (COM-B; behavior change) model that considers the sources of behavior along with the behavior change techniques likely to work on the target behaviors [9]. The COM-B model proposes that capability, opportunity, and motivation interact to predict behavior and that intervention designers should consider how to influence these constructs. Our previous studies have provided the basis for identifying the behavioral targets for intervention and their corresponding behavior change techniques [4,5,10,11]. The goal of our intervention is to enable parents with infants at most risk of SUDI to consistently provide a safe sleep environment for their infants, especially during disrupted routines. We chose techniques that focus on increasing capability by providing information about their baby’s risk; opportunity by using their environmental context and resources to develop realistic strategies for providing a safe sleeping environment; and motivation through planning, goal setting, and increasing confidence (Table 1).
Table 1. Model of the intervention showing the Capability, Opportunity, and Motivation–Behavior (COM-B) model using Theoretical Domains Framework (TDF) domains and corresponding behavior change techniques.

<table>
<thead>
<tr>
<th>COM-B construct and subconstruct</th>
<th>TDF domain</th>
<th>Finding or problem</th>
<th>Corresponding behavior change technique</th>
<th>Proposed mechanism of action of the Baby Sleep Planner</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capability</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical capability</td>
<td>Physical skills</td>
<td>Advice interpreted differently or misunderstood</td>
<td>Instruction on how to perform the behavior</td>
<td>Increased confidence to provide a safer sleep environment</td>
</tr>
<tr>
<td>Psychological capability</td>
<td>Knowledge</td>
<td>Safer sleep advice too generic and not individualized</td>
<td>Information about health consequences</td>
<td>Increased understanding of their own infant’s risk status and prioritizes safety over convenience</td>
</tr>
<tr>
<td></td>
<td>Cognitive and interpersonal skills; memory, attention, and decision processes</td>
<td>Disruption to the routine can create unplanned risky situations</td>
<td>Behavior substitution</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Behavioral regulation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opportunity</td>
<td>Environmental context and resources</td>
<td>Poor-quality accommodation makes following advice harder</td>
<td>Restructure the physical environment</td>
<td>Increased confidence to maintain safety in nonstandard situations</td>
</tr>
<tr>
<td>Social opportunity</td>
<td>Social influences</td>
<td>Burden of following advice loaded on primary carer or mother</td>
<td>Social support</td>
<td>Sharing the plans with wider family and friends reduces burden and increases safety when the infant is cared for by others</td>
</tr>
<tr>
<td>Motivation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reflective motivation</td>
<td>Social or professional role and identity</td>
<td>Trusted sources provide impactful information “Just this once” mentality puts infants at increased risk during times of disruption</td>
<td>Credible source Goal setting Behavioral contract</td>
<td>Health professionals become trusted, and advice increases in credibility and increased confidence to follow a personalized plan for safety</td>
</tr>
<tr>
<td></td>
<td>Beliefs about capabilities; optimism</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Beliefs about consequences; intentions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Goals</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Automatic motivation</td>
<td>Reinforcement Emotion</td>
<td>Fear of SUDI(a) can be stressful and overwhelming</td>
<td>Reduce negative emotions</td>
<td>Increased confidence that the plan is achievable and realistic</td>
</tr>
</tbody>
</table>

\(a\)SUDI: sudden unexpected death in infancy.

Methods

Ethical Considerations

The full study protocol was reviewed and given a favorable ethical opinion by the London – Chelsea Research Ethics Committee and granted Health Research Authority approval on June 21, 2022 (reference 22/PR/0445). Interview participants were compensated for their time with shopping vouchers.

Professional Advisory Group

A group of experts was consulted to make sure that the content and advice within the tool supported the national advice for safer sleep. These experts comprised a professor of neonatology; a professor of midwifery and nursing; a professor of anthropology; a chief executive of a national SUDI charity; and a specialist health visitor for Gypsy, Roma, and Traveler families. Their input was sought during the development of the tool in conjunction with our co-design meetings.

Co-Design Meetings

Before developing the tool, we engaged a family advisory group made up of 15 families with infants at risk of SUDI or who were affected by SUDI. The group met regularly both before and during the evaluation phase to influence the concept and design of the tool. Members of this group were invited to join via local health visitors, family nurses, and our study website and social media accounts as well as through Little Lullaby, a branch of the Lullaby Trust specifically for young parents. Figure 1 shows the overall process of tool design, including the influence of the co-design team and evaluation activities.
Health Professional Recruitment
A total of 3 health professional roles were included in our process evaluation of the tool: midwives, health visitors, and Family Nurse Partnership (FNP) nurses. The midwives were all from a single community-based team for vulnerable and high-risk families. FNP nurses work solely with mothers aged ≤19 years, and 1 team from Bristol was invited to take part. Health visitors working with vulnerable families in 3 local areas (Bristol, North Somerset, and South Gloucestershire) were asked to volunteer to take part in the study by their managers. Study information sheets detailed all aspects of the research and included information on data security. Written consent to use the tool and take part in an interview was collected before participating in the study. All data collection for the evaluation followed the UK policy framework for health and social care research [12], including adhering to strict data protection guidance. Data were stored on secure university servers only accessible to members of the study team.

Health Professional Training
A training package comprising a handbook, video presentation, Microsoft PowerPoint (Microsoft Corp) slide show, and 30-minute session with a member of the study team was provided to each health professional. The handbook included information on the background of the tool, the evidence base, how it was developed, the structure of the tool, and details about how to use it with families. The video presentation covered both the structure and use of the tool and was presented at a 30-minute training session attended by every health professional. Completion of the training was a prerequisite for being sent the link to the tool. Health professionals were supported throughout the study with dedicated email and phone contact.

Health Professional Interviews
Semistructured interviews with health professionals provided insights at each stage into the conditions of delivery, including adoption of the tool (how it was used, which resources were used, how families were chosen, and which family members
engaged), appropriateness and acceptability (response from professionals and ease of use), and fidelity (the details of implementation into practice vs what we envisaged). Health professionals were also asked about scope for widening the tool beyond safer sleep, for their suggestions for how to do this, and which other infant health or well-being topics would be relevant to their work with families experiencing poverty. The interview topic guide was developed with input from our professional advisors, and iterations were made as the interviews progressed.

Family Interview Recruitment
Consent to be shown the tool was given verbally to the health professionals during initial conversations on safe sleep. Separate consent was also embedded into the tool to allow researchers to view the responses. Thus, it was possible to consent to be shown the tool without collecting any data or participating in an interview. Consent to be contacted regarding a possible interview about their experience using the tool was passed on to the research team via the health professional for follow-up. A member of the research team contacted each family member with a study information sheet and consent form. Recruitment took place via telephone, email, or SMS text message depending on participant preference.

User Testing (Health Professionals Using the Tool With Families)
The link to the Baby Sleep Planner was provided for a period of 12 weeks to allow enough time for each health professional to use the tool with 5 to 6 families. Once health professionals had recruited enough families, they took part in a qualitative interview. At the end of the user testing phase, the data were downloaded. Where consent was given, the tool collected data on each answer to the risk assessment and planning sections and which plan options were chosen. All questions were multiple choice, no personal details could be entered into the tool, and no responses were stored locally on any device to prevent accidental data breaches or identification of any participants.

Family Interviews
Qualitative telephone interviews used a topic guide with families focused on acceptability (engagement with the tool and ease of use), appropriateness (language and literacy access and perceived targeting by professionals), and evidence of influence on behavior (experiences with using the plan and spreading awareness to other parents or carers). The interview topic guide was developed with input from our family advisory group, with iterations as the interviews progressed. Individuals aged <16 years, anyone who lacked the cognitive capacity to consent, and anyone unable to complete an interview in English were not eligible to take part in the study.

Interview Analysis
The interviews took place via telephone or face-to-face. The audio recordings were transcribed, anonymized, coded, and investigated using a framework analysis allowing for a systematic approach to generating themes [13]. An initial analytical framework of codes was developed inductively using the first 5 transcripts, agreed upon by 3 team members, and then applied consistently (deductively) across the remaining transcripts. Separate frameworks were developed for family and health professional interviews. Team members coded transcripts using double coding across 50%, and discrepancies were resolved through team discussion.

Results
Objective 1: Co-Design of the Tool Interface
Overview
Our family advisory group, together with the research team, developed a model for delivering risk information (Figure 2) to caregivers of infants involving five stages: (1) being honest about the risks, (2) giving reasons for the risks and feedback on reducing them, (3) showing options for reducing the risks (using other families’ real experiences), (4) asking what would work and support planning, and (5) making it shareable for other caregivers. Using this input, we worked together with the software development team and a graphic designer to make the tool meet each of those 5 stages. We adapted the planning option wording and images based on the recommendations of the family advisory group and included advice specific to a wider range of families thanks to their focus on the realities of infant care, such as nonstandard housing and looking after more than 1 baby at a time.

Following the co-design meetings, we produced a flowchart of tool functions showing the questions and functions for each stage. This flowchart was refined through further family advisory group meetings and with feedback from our professional advisory group members. Decisions were made based on the complexity of the tool, the costs of the design, and how well it enabled each of the behavior change techniques.

During this process, we kept the risk assessment and sleep environment planning sections separate, with an option to complete them together if suitable. Feedback from professionals in our advisory group suggested that the separate risk assessment could be a useful stand-alone tool for professionals working with families to know who to target with additional support for safer sleep and to complete before using the tool with a family. The risk assessment is based on nonmodifiable family background and birth characteristics, whereas the sleep environment section is based on modifiable behavior.

An initial prototype of the tool interface was available for feedback from our professional advisors, after which any final refinements were made. Table 2 shows example changes made throughout the co-design process. The family and professional advisory groups also reviewed the training materials.
Figure 2. Risk communication model designed by the co-design team.

Table 2. Example changes from the co-design process and professional advisory groups.

<table>
<thead>
<tr>
<th>Feedback, question, or wording in tool</th>
<th>Change</th>
<th>Reason and example</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Which one best describes your relationship to the baby?”</td>
<td>Add in an option for “both parents or caregivers”</td>
<td>Feedback from health professional advisor—if they are talking to both parents at the same time (e.g., in midwifery clinic)</td>
</tr>
<tr>
<td>“Babies in larger families, especially if the mother is young, are nearly three times more at risk of SIDS.”</td>
<td>Change to the following: “Babies in families with 2 or more children, especially if the mother is young, are nearly three times more at risk of SIDS.”</td>
<td>Feedback from professionals and family advisors that 2 children is not really a “large” family</td>
</tr>
<tr>
<td>Feedback that the nonmodifiable nature of the risks feels unfair</td>
<td>Add in the following: “Your baby’s background risk is fixed and often not something you can control. You can have control over your baby’s sleep environment and reduce their risk greatly by following the advice.”</td>
<td>Feedback from family members; this change may help give families a feeling of acknowledgment that their baby’s risk status is not within their control and empower them to reduce risks by following safer sleep advice</td>
</tr>
<tr>
<td>Things to think about if answered “sheets or blankets”: “Make sure sheets and blankets can’t cover the baby’s face.” Putting the baby at the bottom of the space can stop them wriggling under blankets.”</td>
<td>Change to the following: “Make sure sheets and blankets can’t cover the baby’s face. If baby is in a cot, putting their feet at the bottom of the cot can stop them wriggling under blankets.”</td>
<td>Feedback from family advisors so that people do not interpret “bottom of the space” as the bottom of an adult bed</td>
</tr>
<tr>
<td>Question: what will be covering the baby?</td>
<td>Add in options for “nothing.” If “nothing” is selected, add the following text: “If it is very hot in the room where the baby will sleep, it may be best not to use any bedding. You can also try to cool the room, please visit this site for more advice: [link to relevant Lullaby Trust web page]”</td>
<td>Feedback from health professionals and families during a heat wave to accommodate hot weather scenarios</td>
</tr>
<tr>
<td>Add in more detail when “blankets” is chosen. “Make sure sheets and blankets can’t cover the baby’s face. If baby is in a cot, putting their feet at the bottom of the cot can stop them wriggling under blankets.”</td>
<td>Change to the following: “Make sure sheets and blankets can’t cover the baby’s face. If baby is in a cot, putting their feet at the bottom of the cot can stop them wriggling under blankets. Make sure sheets and blankets don’t make the baby too hot—for advice about temperature please visit: [link to relevant Lullaby Trust web page]”</td>
<td>Feedback from health professional advisors to add information about thermal regulation and room temperature</td>
</tr>
<tr>
<td>Details about the risks of smoking</td>
<td>Added in a link to relevant Lullaby Trust web page.</td>
<td>Requested by professionals to support conversations about smoking cessation</td>
</tr>
</tbody>
</table>
The Baby Sleep Planner Intervention

The Baby Sleep Planner (Figure 3) is a web-based risk assessment and planning tool with 2 sections that can be completed together or separately. The risk assessment tool includes 8 questions about the background characteristics of the infant, usually delivered shortly after birth, and assigns a score based on an algorithm [14]. These questions include maternal age, number of children, smoking during pregnancy, partner support, partner smoking, infant sex, birth weight, and neonatal unit admission. A total of 7 other nonmandatory questions are asked to inform the research, including infant age, gestation, multiple births, ethnicity, relationship to the baby, whether this is the first time using the tool, and whether there is a health professional present. Each question is categorical, with 3 levels of risk assigned: lower, slightly higher, and higher risk. The information in the results is tailored to the risks present in each infant. The results are presented with information about research evidence and a key message that risks can be substantially lowered by following safer sleep advice.

Figure 3. Final design of the Baby Sleep Planner.

The planning tool includes 6 questions about the infant’s sleep environment, including room sharing, sleep location (eg, cot or adult bed), sleeping position, items in the sleep space, coverings (eg, blankets or sleeping bag), and feeding method. The results of these questions comprise 3 categories: things going well, things to think about, and things to change. Feedback includes links to further information from a national advice charity, the Lullaby Trust. Users are then given 14 “plan options” comprising images with safety messages and asked to pick between 2 and 4 to create their own baby’s plan. The plan can be downloaded to a device (eg, mobile phone) as an image that can be shared with wider family and friends.

The intervention includes training for health professionals, a 30-minute web-based session with a member of the research team to explain the background, theory, and use. For this evaluation, the tool was only available for use as part of a conversation with a health professional, and the link to the website was not shared directly with families. Although the tool is under development, we wanted to make sure that the content and interpretations were as intended.

Objective 2: User Testing, Including Tool Use Database Development

The tool and associated training were completed by 22 health professionals: 9 (41%) midwives, 8 (36%) health visitors, and 5 (23%) family nurses. In total, health professionals reported using the tool with 58 families, and the tool database recorded 55 uses of the tool. Of these responses, 48 (87%) were for the combined risk assessment and planning tool, 5% (3/55) were for the risk assessment tool only, and 7% (4/55) were for the sleep planner only. It was not possible to match tool use to a particular user because of data security, so we do not know whether the database responses are from real conversations with families or health professionals trying out the tool. We also do not know whether the tool was completed more than once per participant, although the reports from the health professionals suggest that it was not completed more than once. Health professionals reported that all the families they spoke to consented to seeing the tool, and the majority also consented to the research team seeing their answers. However, as we were unable to match the database responses, we could not quantify
how many refused to provide information to the researchers, although it is thought to be a small number.

**Objective 3: Qualitative Interviews**

**Health Professional Interviews**

A total of 22 health professionals volunteered to take part in the process evaluation (Table 3), were recruited for the study, and attended either over the web or face-to-face training. In total, 9% (2/22) of the health professionals subsequently withdrew, both going on long-term sick leave. In total, 20 health professionals, comprising 9 midwives, 8 health visitors, and 3 family nurses, were interviewed.

<table>
<thead>
<tr>
<th>ID</th>
<th>Role</th>
<th>Training in person or over the web (n=11 in person and n=11 over the web)</th>
<th>Families shown the tool (n=58), n (%)</th>
<th>Took part in an interview? (n=20)</th>
</tr>
</thead>
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<tr>
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<td>In person</td>
<td>2 (3)</td>
<td>Yes</td>
</tr>
<tr>
<td>MW2</td>
<td>Midwife</td>
<td>In person</td>
<td>5 (9)</td>
<td>Yes</td>
</tr>
<tr>
<td>HV1</td>
<td>Health visitor</td>
<td>Over the web</td>
<td>4 (7)</td>
<td>Yes</td>
</tr>
<tr>
<td>HV2</td>
<td>Health visitor</td>
<td>Over the web</td>
<td>3 (5)</td>
<td>Yes</td>
</tr>
<tr>
<td>HV3</td>
<td>Health visitor</td>
<td>Over the web</td>
<td>1 (2)</td>
<td>Yes</td>
</tr>
<tr>
<td>HV4</td>
<td>Health visitor</td>
<td>Over the web</td>
<td>4 (7)</td>
<td>Yes</td>
</tr>
<tr>
<td>HV5</td>
<td>Health visitor</td>
<td>Over the web</td>
<td>5 (9)</td>
<td>Yes</td>
</tr>
<tr>
<td>FNP1</td>
<td>Family nurse</td>
<td>In person</td>
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<td>Yes</td>
</tr>
<tr>
<td>FNP2</td>
<td>Family nurse</td>
<td>In person</td>
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<td>No—off sick</td>
</tr>
<tr>
<td>FNP3</td>
<td>Family nurse</td>
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<td>0 (0)</td>
<td>No—off sick</td>
</tr>
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<td>Family nurse</td>
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</tr>
<tr>
<td>MW4</td>
<td>Midwife</td>
<td>In person</td>
<td>5 (9)</td>
<td>Yes</td>
</tr>
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<td>HV6</td>
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<td>HV7</td>
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<td>6 (10)</td>
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<td>Yes</td>
</tr>
<tr>
<td>MW6</td>
<td>Midwife</td>
<td>In person</td>
<td>4 (7)</td>
<td>Yes</td>
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<tr>
<td>MW7</td>
<td>Midwife</td>
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<td>1 (2)</td>
<td>Yes</td>
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<tr>
<td>MW8</td>
<td>Midwife</td>
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<tr>
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<td>Midwife</td>
<td>Over the web</td>
<td>3 (5)</td>
<td>Yes</td>
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<tr>
<td>FNP5</td>
<td>Family nurse</td>
<td>Over the web</td>
<td>1 (2)</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Practical Use and Engagement**

Health professionals found the tool easy to use and appreciated its ability to engage parents in conversations regarding the risk of SUDI. They commented on its simplicity, plain language, and visual design. Some commented that it took a little bit of time to get used to using it, and some had difficulties accessing the internet while with the families:

…it was really good, and parents really engaged with it, because it was very much tailored to them, and so compared to other sleep conversations they were much more engaged and interested in it. [HV7]

With anything it takes a little bit of getting used to, but it was easy enough once you have done it once with a family. You were both learning at the same time really with the first family I did it with. [HV1]

**Communicating About Risk**

Health professionals appreciated the balance between being honest and up-front with families while being careful to avoid making parents feel anxious or judged. They described using the tool to support conversations that empower parents with knowledge about their individual infants, which then supports the need for the safer sleep messages:

What I liked about the tool is that directness about it…it gave me support, because often I feel like as a practitioner I was saying this stuff and can come across a little bit naggy...Whereas this was a really helpful tool to back up what we’re asking of families. [FNP5]

...you need to understand a certain level of risk, but it wasn’t making people feel worse going through the questions, and going through the outcomes, it didn’t
make parents feel more anxious about the situation. [HV6]

**Beyond the Messages**

Advice given to families is often didactic, and health professionals commented that the tool allowed them to go further than just giving out the safer sleep messages. They liked that it supported a conversation rather than just telling families what to do. They described being able to get more information across, feeling that parents were more involved in the conversation, and being able to delve into specific messages that parents wanted to discuss:

...she has some learning difficulties as well, so I was quite surprised she could focus throughout the whole thing really. It felt like that they were being involved, rather than just being told, and also I think what it was did was it meant we talked about it for longer. [FNP1]

...she could then ask questions just about little other areas, just talking about when can they have a pillow, what age? And it facilitated a little bit more of a wider discussion around safe sleep really. [FNP5]

So engaging with people, listening to what they have to say, and then maybe just bringing it up more in conversation than this is what I’m telling you to do. [MW9]

**Wider Family Support**

Advice about safer sleep is often given solely to the primary carer of the infant, and some health professionals described how they used the tool to encourage mothers to share their plans with their wider friends and family. Some found it difficult to send the image to the mother’s device and would have preferred a printed option; however, there was a consensus that supporting how mothers communicate about safer sleep with their families is important:

We used it to help her communicate what was important to her with the paternal family, so that she could ensure her baby was safe, and those steps that she was taking at home could be continued in a different environment. [FNP5]

We find this with a lot of our clients’ parents in that they’re giving a lot of advice themselves, so it’s important that they are given the up to date advice so they can support the mum in making decisions. [FNP1]

**Barriers to Use and Changes Suggested**

Health professionals cited time as a limiting factor in tool use as well as internet access problems and battery issues with work laptops. The timing of use was also raised, with some seeing value in repeating the process and starting sleep planning conversations during the antenatal period. They described seeing the value of the tool for all parents, not just those with infants at increased risk. Some suggested a variety of options for sharing the sleep plan image with the family, including printing it off for those without mobile devices. Changes suggested included versions in languages other than English, more information on the risks associated with smoking, rethinking our description of larger families, information on ideal room temperature, and more details on blanket use:

For some people having a visual maybe on the fridge printed off, that’s what I intended to do but it got lost in the ether when I downloaded it on my phone and I couldn’t find where it had downloaded to. For others, their phones break every week, and getting new numbers, something printed like that would be ideal. [MW1]

More about smoking around the baby or smoking in the same room as baby? [HV2]

Would you need a different tool for antenatal to look at the risk factors, and you could discuss those risk factors then with them? [HV4]

The girl had only had two children, but it came up with a message at that point from babies from larger families are more at risk, and I wouldn’t class two children as a larger family. [MW3]

**Scope for Future Work**

Health professionals were asked about other topics they thought would be of benefit to the families they worked with, and they raised a variety of issues. The limited capacity for home visits and relationship building owing to heavy workloads was a constant problem. Some had ideas for widening the scope of the Baby Sleep Planner to be able to use it during pregnancy and with non-English speakers, and 1 health visitor suggested adding reminders that could be sent via email to parents to support the changing needs of infants over the first year, for example, at 6 months, when babies can potentially be moved into a room of their own. Several suggested including more detail in the existing tool focusing on use of substances, both prescribed and illicit, to increase awareness of the risks associated with co-sleeping when parental responses may be impaired. Another health professional suggested incorporating a planning aspect into stressful parenting situations, for example, planning activities to reduce stress and potential injury to the infant, similar to ICON (a program to reduce abusive head trauma in infants). Finally, 1 family nurse suggested an intervention focused on domestic abuse, in particular on the effects of coercive control on parenting capacity:

Something about domestic abuse? Domestic abuse like to care and control, and neglect, of them not being able to focus and care for their babies, because of stuff going on in their relationship. [FNP1]

More information about smoking or strong painkilling medication that might make someone sleepy. [MW3]

In the future would it send parents reminders and things at all if they signed up for this planner and things? I think that would be good. As health professionals we don’t see them as often as we can do, but just if they signed up they could get a text or whatever about sleeping, or if it was an app you would get a notification wouldn’t you about remember these things, it’s really important, your baby is 6 months, they can move into their own room, but they...
still can’t have a pillow or duvet, that kind of thing. [HV1]

Family Member Interviews

Health professionals sent contact details for 32 family members who had agreed to be contacted about a research interview. All were invited to take part in an interview except for 1, whose contact details were sent to the research team after data collection had been completed and recruitment was closed. A total of 20 families gave consent to be interviewed and completed a telephone interview (Table 4). In total, 4 interviews included both the mother and the mother’s partner. Joint interviews were analyzed together, and 1 mother was still pregnant at the time of the interview. Risk scores (using the algorithm for interview participants’ infants) ranged from 0 to 153 (mean 58.7, SD 49.5). A total of 3 of the infants had risk scores of >115, indicating increased risk of sudden infant death syndrome using our recently developed algorithm.

Table 4. Families interviewed, with corresponding infant risk status.

<table>
<thead>
<tr>
<th>ID</th>
<th>Relationship to baby</th>
<th>Maternal age (y)</th>
<th>Infant sex</th>
<th>Birth weight (g)</th>
<th>NICU admission</th>
<th>Parity</th>
<th>Smoking during pregnancy</th>
<th>Partner support</th>
<th>Partner smoking</th>
<th>Infant risk assessment score</th>
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<tbody>
<tr>
<td>01</td>
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<td>Male</td>
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<td>Yes</td>
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<tr>
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<td>15</td>
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<tr>
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<td>≥2500</td>
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</tr>
</tbody>
</table>

aNICU: neonatal intensive care unit.

N/A: not applicable.

Tool as a Trusted Source

Parents commented on how they felt that they could trust the information they received from the tool and that this was supported by its delivery from a health professional and alignment with national advice. They appreciated the wording as “factual” and not judgmental. Some liked that it was interactive and tailored to their baby, whereas others felt that they knew the information already and this was just a useful reminder:

I thought it was presented very simply, but not in a patronising way. It just the imagery and the just

having a few words around it just made sense, and made it a bit more engaging. [ID04]

...it’s not judgemental but straight down the middle factual, but not trying to ward people off. I think the wording was fine for me. [ID03]

...as a first time mum it was very useful, because I wouldn’t have...people tell me stuff, but to hear it from somebody professional who actually knows was a lot more helpful. [ID02]

The hospital went over it when I was discharged, and my community midwife, but that was about it...They
were the same but they weren’t in as much detail as your survey. [ID07]

I think it’s good when they come across the whole planner about it, because I think a lot of people would like to go through it just so that they’ve got all the information they need as well. [ID20]

**Risk Assessment Process**

Lower-risk parents reported feeling reassured by the results of the risk assessment, whereas higher-risk parents described it as unsurprising and supportive in that it encouraged them to follow the advice. Some described difficult feelings regarding the algorithm risks being unchangeable or related to things that they did not have any control over:

So yeah it was reassuring to know that as far as anyone can predict we are at lower risk. So that I found quite helpful. [ID04]

I believe it came out that I was high risk, that it was high risk, but with doing everything that I’m doing she said it was okay, do you know what I mean? [ID15]

The difficult one about with the single parent is unsupported partner. That’s the one thing that was difficult for me was you’re three times higher risk with SIDS, what can I really do about that? That was difficult. Tilted cot, fine I can change that, but I can’t change a supportive partner thing. [ID12]

Yeah, and I think at the end when you get your risk as well and it’s like you’re at this much of a higher risk, it opens your eyes and you’re like wow and you’re like okay, do you know like...yeah. [ID20]

**Sleep Planning Process**

Parents had mostly positive things to say about the sleep planning process, commenting that it included all the information they would need and appreciating that it explained the reasons for the advice without just telling them what to do. Most of the parents had answered the sleep environment questions remembering a real sleep that had taken place recently or with what they normally did. Changes to this part of the tool may be required to encourage parents and caregivers to use the sleep planning process to imagine what might happen in times when the normal routine is disrupted, for example, when staying away from home overnight. Several of the parents commented that they did not receive their plan image from their health professional:

Because as well the idea is that it doesn’t just tell you what to do or what you should do, it tries to explain why. [ID15]

I think we’ve been quite realistic with our plan, so I think we could stick to it most nights, depending on how things go with the baby, things could change in terms of feeding patterns and that kind of thing. But I generally it would be quite straightforward to stick to. [ID03]

One mother shared how she had used the sleep planning tool and downloaded the plan as a picture to share with her family members who were responsible for her baby’s overnight care once a week:

This is what we done, we took a picture so then we could send it to them, because I thought it would be more helpful to them, whereas if they don’t have him as much, so they’re not...they don’t know him as well in his sleep than what I would do. So I thought it would help them a lot more. [ID01]

**Changes Since Using the Tool: Potential Impact**

Several parents described things that had changed as a result of using the tool with their health professionals. These changes included, taking items out of the Moses basket, tucking blankets in, using age-appropriate sleeping bags, and keeping unsupervised pets away from sleeping babies. Others felt that they were doing everything they could but still appreciated the reassurance that this gave them:

...it was nice that there was something on there that I hadn’t considered. I felt a little bit nervous about the fact that he’s been sleeping with a slant, but it was only for seven to ten days, and I’ve rectified that now. [ID12]

I didn’t know that you didn’t have to...you weren’t allowed anything in the Moses basket. [ID07]

...a lot of things we were doing already, and it was good to get the advice about tucking the blanket under the mattress, because that bit we had been like oh how do we keep it secure so it doesn’t go over his face? So yeah, no it was useful. [ID09]

**Barriers to Use and Changes Suggested**

Some of the barriers included not being able to access the plan images and preferring to go through the tool on their own without their health professional present. Some suggested having more links to click through for more in-depth explanations of how the messages protect infants. Several parents felt that the way in which the risks were explained could be better, using pictures or comparators that were known to them. One parent commented that there could be more emphasis on the ways in which they can lower the risks and less on things that they cannot change:

...perhaps being able to click on something and go through to a bit more information. So as you were saying about the feet to foot of the bed, so if you want to know more about it you can click on the icon and go through and have a bit more information about why that’s the recommended sleeping position and those sorts of things. [ID04]

I suppose the only thing that would be easier to use would be something digitally, like an app, or something that could be sent through to you to do rather than being shown two you on another laptop. [ID11]

...having this baby here that I need to look after on my own all night with no support from his dad, and then to look at that statistic it was like oh no, and what can I do about that apart from bring down all
the other risks? That’s the only feedback I would have in terms of there was no okay well what can I do to make sure that I’m lowering that risk in that way. [ID12]

Discussion

Principal Findings

This study developed a risk assessment and planning tool that is pragmatic for use in a real-world setting. It has the potential to be used in clinical practice for the identification and support of high-risk infants and for families to use to reduce proven risk factors in the infant sleep environment. Interviews with users demonstrated how the tool could enable enhanced support to reach those most at risk while also reducing the burden of work for health professionals. Health professionals reported that they found the tool more conversational and less didactic, and families reported that they appreciated this approach.

Comparisons With Existing Literature

Our findings align with those of other research into behavior change for this group, including a recent COM-B analysis of interventions to improve the uptake of safer sleep that found that, although increasing capability by passing on information about risks was common, more effective interventions incorporated motivational factors such as goal setting and making plans [11]. The risk assessment and planning tool incorporates motivational factors within the planning part of the tool, asking about where and how the baby will sleep, providing feedback on a variety of answers, and inviting users to prioritize their goals for safety in an individualized safety plan. In our study, families appreciated the approach to bed sharing taken in the tool, aligning with recently updated advice from the National Health Service in England to acknowledge that bed sharing occurs in planned and unplanned ways and offering advice to reduce the risks in bed-sharing situations [15]. In a 2016 review of behavioral interventions, Moon et al [16] suggested that interventions should be multilevel, incorporating contextual factors into the design, as we have attempted to do in this study. They also recommended formal process evaluations and future studies that can measure effectiveness as needed to support wider implementation [16]. Other reviews have found similar issues with measuring effectiveness and concluded that creative methods may be needed, as well as interventions that include the wider family and peers [17].

Strengths and Limitations

The inclusion of a theory-based approach incorporating co-design elements, along with the evidence for behavioral influences that work for this group, gives this intervention a solid basis for effectiveness. Findings from the interviews support the theory that sharing individual risk status information (ie, “information about health consequences”) may increase parental understanding of their own infant’s safety needs. Sharing achievable and realistic plans may increase social support for following safer sleep advice, and having personalized conversations about safer sleep with health professionals as credible and trusted sources may enhance parental confidence and decision-making, especially during times of disruption to the normal routine. Integrating feedback from both health professionals and family members into the design and function of the tool meant that we were able to align the needs of both groups by ensuring that the tool provides evidence-based information in a way that supports the individual needs of each family. Testing the prototype intervention under real-world conditions provided insights into implementation and highlighted necessary changes. Issues with accessing the downloaded plan image meant that some families were not able to use this aspect of the tool, and this needs further consideration, with options for printing where possible. There were promising signals from the evaluation that understanding the risks to their baby and planning for safety during times of disruption may influence decision-making regarding the sleep environment, prioritizing safety at all times. The finding that some families found the unchangeable risks difficult to hear prompted further work to investigate how the risk assessment results can be presented as honest but not hopeless, providing more emphasis on how safer sleep planning can reduce the risks as much as possible even for an already higher-risk infant. It may be that the decision to describe infants as “higher risk” is unhelpful, and this should be explored in future work. This wording is currently used based on advice from our family advisors that being honest about the risk status of infants is important, as shown in the model in Figure 2. Most of the suggestions for changes to the tool were mainly minor, and we were able to incorporate them fairly quickly (see Table 2 for examples). Other changes, such as non–English language versions, will take longer. This was a small evaluation study using a prototype intervention. Our original aim included the development of a stand-alone tool that families could use independently but studies that can collect more data on the safety and appropriateness of the tool to be used in this way will be required first. The risk status of the infants referred to the research team was also lower than we had expected; only 15% (3/20) of the families had infants at increased risk of SUDI, although every family except 1 had at least 1 risk factor present. We were also only able to include English-speaking families in this study, and future work to translate the tool for use in other languages should be included as part of future evaluations. Challenges with health professional recruitment because of current National Health Service pressures led to delays in data collection, resulting in health professionals using the tool with any families they thought suitable rather than those with higher-risk infants only. We were also unable to analyze the background tool data in this study as we were not able to discern “real” conversations with families from health professionals practicing with the tool. Improvements to tool background data collection have been made to make it possible to use these data to understand the characteristics of the families using the tool in future studies. We have also changed the wording of our “data usage” question to prevent this problem in future studies. To test the tool in “real-world” conditions, we did not restrict health professionals in terms of who they used the tool with, and some of them reported that they appreciated being trusted to use the tool with whom they thought best, including anxious parents with low-risk infants who would be reassured by the results. The implications of tool use for this population should

https://pediatrics.jmir.org/2024/1/e49952
be included in future evaluations without undermining the focus on families with infants at increased risk.

**Conclusions**

The Baby Sleep Planner was designed with involvement from families and key stakeholders and shows promise as a useful tool for health professionals having conversations about safer sleep with caregivers of infants. The web-based tool was acceptable to family members, midwives, health visitors, and FNP nurses. Further work should investigate whether the uptake of this intervention will significantly reduce known risk factors in the infant sleeping environment associated with sudden infant deaths and whether this algorithm can identify families with infants at risk of other causes of death.

**Acknowledgments**

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**Data Availability**

The data sets generated during and analyzed during this study are available at the University of Bristol data repository, data.bris [18].

**Conflicts of Interest**

AP is the chair of the Lullaby Trust Scientific Advisory Group and a member of the grants committee.

**References**


Abbreviations

COM-B: Capability, Opportunity, and Motivation–Behavior
FNP: Family Nurse Partnership
SUDI: sudden unexpected death in infancy

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Chinese Women’s Concept of Childbirth Based on the Social Media Topic “What Does Childbirth Mean to a Woman”: Content and Thematic Analysis

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Abstract

Background: In recent years, women’s fertility desire has attracted increasing attention in China.

Objective: This study aims to detect attitudes toward giving birth among young female users on Douban, a very popular Chinese social media platform.

Methods: A total of 2634 valid posts from 2489 users discussing the topic “What does childbirth mean to a woman” on Douban were crawled and retained for analysis. We utilized content and thematic analysis methods to capture users’ concepts of childbirth.

Results: The findings reveal that a significant majority of users conveyed generally neutral (1060/2634, 40.24%) or negative (1051/2634, 39.90%) attitudes toward childbirth, while only about one-fifth of users expressed positive (523/2634, 19.86%) sentiments. Notably, posts with negative attitudes garnered more replies and likes, and the proportion of posts expressing negativity exhibited fluctuations over time. Health risk (339/2634, 12.87%) emerged as the most frequently cited aspect of childbirth cost, with subjective happiness and the fulfillment of mental needs identified as primary benefits. Surprisingly, only a minimal number of posts (10/2634, 0.38%) touched upon the traditional objective benefits of raising children for old-age care. Thematic analysis results suggest that discussions about fertility on social media platforms might contribute to an exaggerated perception of health risks among women. Additionally, a lack of knowledge about childbirth was observed, partially attributable to longstanding neglect and avoidance of communication on these matters, likely influenced by traditional cultural biases. Moreover, there is a prevailing assumption that women should naturally sacrifice themselves for childbirth and childcare, influenced by the idealization of the female figure. Consequently, women may harbor hesitations about having a baby, fearing the potential loss of their own identity in the process.

Conclusions: The results indicate a shift in the perception of childbirth among modern Chinese women over time, influenced by their increasing social status and the pursuit of self-realization. Implementing strategies such as public education on the health risks associated with pregnancy and delivery, safeguarding women’s rights, and creating a supportive environment for mothers may enhance women’s willingness to undergo childbirth.

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KEYWORDS
childbirth willingness; social media; risk perception; childbirth cost; childbirth benefit

Introduction

The academic community in demographics has centered its attention on fertility issues, and China is currently grappling with a significant challenge in population development due to its low fertility rate. In August 2020, the National Health Commission of the People’s Republic of China issued a document highlighting that the low fertility rate has emerged as a major risk impacting the balanced development of the country’s population. To mitigate the consequences of population aging and the decline in demographic dividends resulting from the low fertility rate, China introduced the “Universal Two-Child Policy” in January 2016, followed by the “Three-Child Policy” in May 2021. The implementation of these policies has elevated individual childbirth willingness as a crucial factor influencing the childbirth rate [1]. The determinants of childbirth are multifaceted and intricate; past research indicates that cultural norms and values play a substantial role in shaping both the concept and behavior associated with childbirth [2,3]. Research on the willingness to have a second child among Chinese women has indicated that cultural concepts play a pivotal role in influencing the decision to pursue a second child [4]. In the context of a highly “mediatized” modern societal culture, where the media not only exerts influence but also, to some extent, shapes cultural attitudes [5], it appears that women’s fertility desires are more significantly impacted by media exposure compared with men [6].

In contemporary society, the internet has emerged as one of the foremost cultural media. As of June 2022, the number of internet users in China had surpassed 1.051 billion, with an adoption rate of 74.4% [7]. Serving as a crucial platform for individuals to articulate their perspectives, the internet fosters cultural diversity and the expression of values. This, in turn, influences personal attitudes toward marriage, inspiring individuals to seek independence, personal happiness, and a heightened awareness of emotional connection and respect for individuality [8]. The evolution of the internet is concurrently driving a shift in the concept of gender roles among rural residents, transitioning from traditional to modern perspectives. This influence is evident in both men and women, with a notably more pronounced effect on women compared with men [9]. Social media, as a novel form of online communication, provides users with an extensive platform for active participation. It embodies features such as engagement, openness, real-time communication, community-building, and connectivity [10]. Social interaction serves as a crucial mechanism by which media can shape fertility behaviors and concepts [11]. Consequently, the utilization of social media can influence people’s perceptions of fertility and their intentions regarding it. Examining discussions about fertility on social media becomes valuable in gaining insights into the collective understanding of fertility among the populace.

In recent years, a growing number of women have been actively sharing comments on childbirth-related topics, including discussions about the “2-child” and “3-child” policies, expressing their personal insights and thoughts on the matter. A notable distinction is that the majority of discussions on foreign social media platforms exhibit a predominantly positive attitude toward childbirth [12,13]. Nevertheless, the discourse on fertility in China’s social media landscape is characterized by a prevalence of antifertility sentiments [14]. On the one hand, the textual information available on the internet partially mirrors the childbirth concepts held by contemporary women. On the other hand, public opinion expressed on social media platforms may exert an influence on women’s perceptions of childbirth, potentially diminishing their willingness to pursue childbirth [15,16]. In this study, content analysis was used to delineate the predominant attitudes evident in posts within a social media topic focused on childbirth. Additionally, the analysis aimed to identify the costs and benefits associated with childbirth that garnered attention and concern among the participants. Furthermore, thematic analysis was utilized to reveal the underlying childbirth themes embedded in the posts under this particular topic.

Methods

Selection of Research Platform

This paper selected Douban (Beijing Douwangle Co. Ltd.) as the source platform for data collection based on the considerations outlined in Textbox 1.

Textbox 1. Considerations for data collection.

1. To identify suitable social media data for the study, the research team conducted a screening of childbirth topics across various popular platforms in China, such as Weibo (Weibo Corporation), WeChat (Tencent Holdings Limited), TikTok (ByteDance), Bilibili (Bilibili Inc.), and Douban. It was observed that the feature settings of Douban and Weibo rendered them more conducive to text analysis. However, on Weibo, no topics closely aligned with our research objective were found, and the word count and content quality of Weibo posts were found to be inferior to those on Douban.

2. Douban stands out as a popular social media platform, particularly among young women of childbearing age. As per data from the “Qianfan” query platform, which serves as a digital economy market information and data terminal, Douban boasts a monthly active user base of 10.51 million. Notably, within this user demographic, women constitute a significant majority at 63.3%. In comparison to other social media platforms such as Weibo and WeChat, Douban exhibits a higher proportion of female users. The bulk of Douban’s user demographic falls within the childbearing age range, with 30.07% aged under 24 years, 24.83% aged 24-30 years, and 24.25% aged 30-35 years. Additionally, 49.14% of users originate from first-tier or new first-tier cities. This demographic profile underscores that a significant proportion of Douban users are urban women of childbearing age. Consequently, their discussions on childbirth have the potential to reflect the attitudes and concerns toward childbirth among Chinese women to a considerable extent. It is noteworthy that many studies focusing on Chinese women have selected Douban as their research platform (Figure 1, [17-20]).
Selection of Research Topic

Among the numerous childbirth-related topics on Douban, this paper selected the one most pertinent to women’s concept of childbirth and with the highest number of posts. Specifically, the chosen topic is “What does childbirth mean to a woman.” Initiated in June 2020, this discussion has garnered significant engagement, accumulating 3655 posts as of August 5, 2022. Notably, the most popular post on this topic received 5596 likes. The substantial quantity and the evident quality of the posts led us to conclude that they met our inclusion standards.

Selection of Posts Under the Research Topic

This study focused on analyzing the discussions within the topic “What does childbirth mean to a woman,” and data were collected by crawling posts from June 10, 2020, to July 16, 2022. A total of 3403 raw posts from 2838 users were gathered, encompassing information such as post time, content, and likes. Additionally, permanent residence details were obtained for 2128 users. Recognizing the contextual nature of replies below the posts and the challenges associated with their identification and categorization, we opted to solely crawl the original posts. Replies beneath the posts were not included in the data collection process, acknowledging the potential complexity in comprehending their content without the necessary context from the original posts.

The crawled posts underwent a standardized screening and cleaning process, which unfolded in 2 steps. Initially, 2 categories of invalid data were systematically removed. The first category encompassed elements such as emojis, symbols, pictures, and blanks, which were deemed unsuitable for text analysis. The second category included irrelevant posts or those with an ambiguous attitude toward childbirth, such as advertisements, personal life records, ambiguous sentences, questions, and posts from men, among others. Following these criteria, a total of 460 posts were eliminated in the first step of the cleaning process. In the second step, for users who posted more than once, we analyzed their attitude toward childbirth. If all posts from the same user exhibited a consistent attitude, the post with the highest number of likes was retained. In cases where posts had the same number of likes, the one with the greater word count was preserved, and any remaining posts were eliminated. This approach aimed to distill the most representative content from users with multiple posts on the same topic. If a user’s attitude toward childbirth changed, the post with the highest number of likes under each different attitude was retained. For instance, if a user’s attitude shifted from positive to neutral and then to negative, 3 posts would be retained. Adhering to this criterion, a total of 309 posts were sequentially eliminated. Importantly, to maintain the focus on women’s concepts of childbirth, all posts where the posters identified as male were removed. While the data did not explicitly specify the gender of the posters, given the topic’s nature, the predominant female user base on Douban, and the thorough data cleaning process, it is argued that most of the retained posts after elimination originated from women. In the end, 2634 valid posts from 2489 users were retained for analysis.

Ethics Approval

To safeguard user privacy, this study used the practice of using the first letter of each word in the username to replace the full name. For English usernames, the first 3 letters were utilized. Additionally, the post time was appended after each post. The study adheres to ethics code H15009 and obtained approval from the Institutional Review Board at the Institute of Psychology at the Chinese Academy of Sciences.

Content Analysis Procedure

Content analysis aims to describe the prevailing attitudes of people toward childbirth and their concerns about the costs and benefits associated with childbirth. We referenced the methods from MacPherson et al [21] and Liu et al [22]. Two investigators (TY and YHW), with an in-depth understanding of Douban’s cultural environment, conducted the content analysis. Initially, the 2 researchers read 10% (340/3403) of the posts and then engaged in discussions to generate coding criteria for attitudes toward childbirth, the costs of childbirth, and the benefits of childbirth (Tables 1, 2 and 3). Subsequently, they randomly selected 50 posts to verify the saturation of the coding criteria.
Following that, both researchers independently coded all the data based on the coding criteria. During this process, they conducted regular cross-checks to ensure the consistency of their coding results, and any disagreements were adjudicated by the third researcher (NH). After that, quantitative descriptive results concerning childbirth attitudes, childbirth costs, and childbirth benefits were obtained.

Table 1. Coding criterion for attitudes toward childbirth.

<table>
<thead>
<tr>
<th>Category and definition</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Negative</strong></td>
<td></td>
</tr>
<tr>
<td>• Willingness not to give birth or regret to give birth</td>
<td>• If I had known that childbirth would deprive the freedom to live an unconstraint life, to cook, to attend an exhibition, and to sleep late at weekends, to improve myself and play at night, I truly would not have a baby. [Poster and Time: CC, June 23, 2020, 16:21:08]</td>
</tr>
<tr>
<td>• Negative effects of childbirth</td>
<td>• It means my belly not going back to how it was before I was pregnant, anterior pelvic tilt, fat saddlebags, diastasis recti abdominis, sagging breasts and no freedom. [Poster and Time: LTGZ, October 12, 2020, 15:02:29]</td>
</tr>
<tr>
<td>• Sharing of personal experiences or stories that makes researchers feel subjective negative attitudes toward childbirth</td>
<td>• Today, a colleague returned to work after maternity leave. Her office cubicle was no longer available in the department. I asked if there was a need to register in new financial software for her, while the manager said he didn’t know. Then, the leader said to seal her employment separation certificate. What a sad story! [Poster and Time: PSH, April 27, 2021, 21:12:27]</td>
</tr>
<tr>
<td><strong>Neutral</strong></td>
<td></td>
</tr>
<tr>
<td>• A view that agrees with both giving and not giving birth</td>
<td>• It means freedom and rights. As a woman, getting married or having children is only one of the choices. Whether to get married or not, whether to have children or not is our own choice. [Poster and Time: WZHYLDN, June 11, 2020, 15:07:05]</td>
</tr>
<tr>
<td>• Positive or negative effects of childbirth with no indication of personal willingness</td>
<td>• Having a baby means the loss of your own life. Isn’t taking care of children a part of your life? There is no accounting for tastes. Opportunities and costs are everywhere and need to be chosen. [Poster and Time: MISS, October 15, 2020, 08:43:17]</td>
</tr>
<tr>
<td>• Sharing of personal experiences or stories does not make researchers feel subjective attitudes toward childbirth</td>
<td>• I don’t have a child, but I have a friend who already has a baby. I see her state, there are gains and losses. What childbirth means to women may depend on their own state of mind/family attitudes. [Poster and Time: QHCD, November 28, 2020, 23:44:33]</td>
</tr>
<tr>
<td><strong>Positive</strong></td>
<td></td>
</tr>
<tr>
<td>• Willingness to give birth</td>
<td>• Most likely, because my own family is incomplete, I personally want to get married and have children to start a new family. [Poster and Time: NKWKBBKN, June 13, 2020, 04:31:45]</td>
</tr>
<tr>
<td>• Positive effects of childbirth</td>
<td>• For me, I am very happy, I have a sense of responsibility, one more person I care about, more maturity and stability. It is like a seed, growing with my care, and I have a sense of achievement and pride. [Poster and Time: XYCDXWB, June 11, 2020, 12:18:34]</td>
</tr>
<tr>
<td>• Sharing of personal experiences or stories makes researchers feel subjective positive attitudes toward childbirth</td>
<td>• I chatted with my friend last night, who was the same age as me. Her daughter is five years old, and I thought she would become complaining, grumpy and anxious like other mothers, but she doesn’t. She has a strong ability of introspection and awareness to change and adjust her state of mind. [Poster and Time: YYSH, June 17, 2020, 10:12:49]</td>
</tr>
</tbody>
</table>
Table 2. Coding criterion for the costs of childbirth.

<table>
<thead>
<tr>
<th>Category</th>
<th>Posts (N=2634), n (%)</th>
<th>Definition</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health risks</td>
<td>339 (12.87)</td>
<td>Severe reactions during pregnancy, physical pain of childbirth, sequelae of childbirth, and postpartum depression</td>
<td>After giving birth, I still feel pains in some part of my body. The arms, knees and heels feel cold even in summer, so that I have to wear socks to sleep every day. As the mother of two daughters, I hope that they will choose not to marry and be infertile in the future. [Poster and Time: QQWDBB, June 18, 2020, 10:14:30]</td>
</tr>
<tr>
<td>Constraint on freedom</td>
<td>232 (8.81)</td>
<td>Constraint on freedom and the lack of self-personality caused by childbirth</td>
<td>It means losing freedom and self within an uncertain period. [Poster and Time: LSSJL, July 17, 2020, 22:08:34]</td>
</tr>
<tr>
<td>Energy investment</td>
<td>162 (6.15)</td>
<td>Energy investment during pregnancy and parenting, such as the inability to sleep due to breastfeeding</td>
<td>After being a mother, 24 hours a day is not enough. I don’t want to sleep more, just want to fight for more time of my own. [Poster and Time: CXMY, July 19, 2020, 08:50:38]</td>
</tr>
<tr>
<td>Influence on occupation</td>
<td>159 (6.04)</td>
<td>Workplace discrimination and the impact of childbirth on occupation</td>
<td>Having a baby means your career will be forced to stagnate for 3 to 5 years. The tiredness and concern for children are really a major cost for women in the workforce. [Poster and Time: BBQDJXK, April 18, 2021, 02:02:55]</td>
</tr>
<tr>
<td>Parenting responsibility</td>
<td>84 (3.19)</td>
<td>Responsibility for childbirth and education of children</td>
<td>I don’t know why. But when I see the topic, the first thought coming into my mind is responsibility, being responsible for myself and for my baby. If I can’t do it well, I will not give birth. I don’t yearn for giving birth. And I will not regret if I don’t have any children. [Poster and Time: CGJ, June 11, 2020, 19:31:50]</td>
</tr>
<tr>
<td>Influence on appearance</td>
<td>84 (3.19)</td>
<td>Influence of appearance, figure, scar, etc</td>
<td>After giving birth, it is easy to welcome the coming of a new baby but is difficult to face with the linea nigra, stretch marks on the thighs and flabby belly. [Poster and Time: LKNT, May 1, 2021, 02:53:04]</td>
</tr>
<tr>
<td>Family relationship</td>
<td>69 (2.62)</td>
<td>Negative effects of family relationships caused by childbirth</td>
<td>Many spouses will engage in emotional abuse. I have seen numerous examples around me, where after the wife gave birth, the husband became particularly distant and cold towards her. [Poster and Time: DY, November 20, 2020, 01:38:22]</td>
</tr>
<tr>
<td>Financial investment</td>
<td>33 (1.25)</td>
<td>Financial investment due to childbirth</td>
<td>My baby is 16 weeks old. I need to have the Down syndrome screening, Mediterranean anemia test, and an ultrasound. These tests will cost 953 yuan, which is really expensive..... [Poster and Time: PTR, December 30, 2021, 09:31:21]</td>
</tr>
</tbody>
</table>
Table 3. Coding criterion for the benefits of childbirth.

<table>
<thead>
<tr>
<th>Category</th>
<th>Posts (N=2634), n (%)</th>
<th>Definition</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parenting experience</td>
<td>196 (7.44)</td>
<td>Well-being, love, and happiness felt in the parenting process</td>
<td><em>It is lucky for a woman to be able to deliver a baby, because only by giving birth can you know how happy it is to be a mother. A little baby who is as small as a meat ball can grow up after your care. And every progress he achieved will let you feel happy. I think companion is the best moment in the world.</em> [Poster and Time: HL, June 13, 2020, 17:37:32]</td>
</tr>
<tr>
<td>Self-growth</td>
<td>115 (4.37)</td>
<td>Growth of knowledge, the reconstruction of world outlook and values, and the maturity of self-character</td>
<td><em>I think giving birth is an opportunity for a woman and a man to grow up. The deeper life goes, the greater the difference and the resistance to seeking common ground. Because of children, we have the desire to seek common ground, so the creativity to overcome resistance is stronger and the vitality is also stronger.</em> [Poster and Time: KGDZM, June 30, 2020, 17:09:09]</td>
</tr>
<tr>
<td>Continuation of life</td>
<td>38 (1.44)</td>
<td>The social value of propagation of the race and the significance of the personal continuation of life</td>
<td><em>I chose to have children just because I think child is still a continuation of our blood in this world when my husband and I died, which can prove that we have been here. It is beautiful to think about it, isn’t it?</em> [Poster and Time: NL, June 16, 2020, 08:14:36]</td>
</tr>
<tr>
<td>Children’s company and psychological support</td>
<td>23 (0.87)</td>
<td>Children’s daily company, psychological sustenance, etc</td>
<td><em>Parents accompany you in the first half of your life, and children do the same in the second half of your life. People will feel reassured when there is always a person accompanying you in your life.</em> [Poster and Time: TK, June 23, 2020, 12:18:10]</td>
</tr>
<tr>
<td>Complete life</td>
<td>22 (0.84)</td>
<td>The integrity of personal values and life experiences</td>
<td><em>I think childbirth has completed a transformation from being a woman to a mother for me. It lets me realize the greatness and selflessness of my mother. It also makes my life as a woman more complete.</em> [Poster and Time: HX, June 15, 2020, 21:01:44]</td>
</tr>
</tbody>
</table>

Thematic Analysis Procedure

Thematic analysis aims to explore more intricate childbirth concepts, providing an exploratory theoretical explanation for the results of content analysis. More specifically, the results of the thematic analysis can provide explanations and insights into why there is a widespread prevalence of negative childbirth attitudes, why some childbirth costs are of particular concern, and what kind of support individuals require from the government and society. While content analysis helps identify themes based on frequency, thematic analysis reveals potential themes within the data that can present a more nuanced perspective [23]. This study utilized the thematic analysis approach with the 5 phases outlined by Braun and Clarke [23]. In the first phase, the authors immersed themselves in the data through repeated readings and viewing, critically contemplating the meanings within the content of the posts. In the second phase, the research team identified initial codes. Moving into the third phase, the authors shifted from identifying codes to identifying themes, interconnecting the codes logically to form themes. The fourth phase involved reviewing each theme’s relation to the data overall and to the other themes to determine the boundaries of each theme. In the fifth phase, the research team defined, named, and elaborated on each theme and extracted illustrative examples of the final themes [24].

Results

Content Analysis

Basic Attitude

In the content analysis, we identified coding criteria related to attitudes toward childbirth, and Table 1 illustrates specific criteria and examples. The basic classification of the attitude toward childbirth showed that 1051/2634 (39.90%) posts had a negative attitude, 523/2634 (19.86%) posts had a positive attitude, and 1060/2634 (40.24%) posts had a neutral attitude. This indicates that the public attitude toward childbirth is generally neutral or negative, with fewer instances of a positive outlook. By extracting and classifying the top 10 most-liked posts, we found that there were 5 posts with a negative attitude (50%), 2 posts with a positive attitude (20%), and 3 posts with a neutral attitude (30%). The negative ratio was higher, but it was basically consistent with the whole distribution. From the word count, the posts with a positive attitude are the longest, but the number of likes is the lowest. By contrast, the posts with a negative attitude are the shortest, but the number of likes is the highest (Table 4).

If the factor of time is taken into account and the changes in the proportion of childbirth attitudes in different periods are analyzed, it can be found that the proportion of posts with a negative attitude fluctuates to rise, the proportion of posts with a neutral attitude fluctuates to decline, and the proportion of...
posts with a positive attitude has small fluctuations and shows a downward trend (Figure 2).

Table 4. Distribution of childbirth attitude of posts.

<table>
<thead>
<tr>
<th>Category</th>
<th>Posts (N=2634), n (%)</th>
<th>Top 10 most-liked posts, n (%)</th>
<th>The average number of words in 1 post</th>
<th>The median number of words in 1 post</th>
<th>The average number of likes in 1 post</th>
<th>The median number of likes in 1 post</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>1051 (39.90)</td>
<td>5 (50)</td>
<td>277.64</td>
<td>103</td>
<td>41.27</td>
<td>4</td>
</tr>
<tr>
<td>Neutral</td>
<td>1060 (40.24)</td>
<td>3 (30)</td>
<td>352.87</td>
<td>101</td>
<td>28.48</td>
<td>3</td>
</tr>
<tr>
<td>Positive</td>
<td>523 (19.86)</td>
<td>2 (20)</td>
<td>415.86</td>
<td>158</td>
<td>26.26</td>
<td>3</td>
</tr>
</tbody>
</table>

Figure 2. Changes in the proportion of three childbirth attitudes with time.

---

**Childbirth Costs and Childbirth Benefits**

In the content analysis, we identified coding criteria for the costs and benefits of childbirth, and the proportions in Tables 2 and 3 refer to the proportion of posts mentioning this category in the total number of posts. It should be noted that the content of posts under research topics varies in length. Some posts involve multiple categories, while others only indicate attitudes without involving any categories. Therefore, the total proportion of categories related to childbirth benefits and costs does not equal 100%.

Among all the categories related to childbirth cost, health risk is the most common category, including severe reactions during pregnancy, physiological pain during childbirth, sequelae of childbirth, and postpartum depression. In addition, limited freedom, energy input, negative influence on the workplace, parenting responsibility, and appearance change are the childbirth costs that people are more concerned about.

Among all the posts, the parenting experience is generally recognized as the greatest childbirth benefit, which includes happiness and love felt in the process of parenting. Compared with childbirth costs, childbirth benefits are mostly subjective feelings and spiritual needs, such as parenting experience, the continuation of life, companionship of children, and the integrity of life. There were only 10/2634 posts (0.38%) that mentioned the objective benefits of bringing up children for the purpose of being looked after in old age.

**Thematic Analysis**

**Overview**

Results of thematic analysis generated 4 childbirth concepts from all posts: (1) amplified perception of childbirth risk; (2) hidden childbirth experience and childbirth knowledge spread through informal channels; (3) gender equality and childbirth trap; and (4) the deification of the mother figure. Each theme is presented with detailed descriptions and illustrative examples from the posts.

**Amplified Perception of Childbirth Risk**

In the discussion under the topic, the frequency of mentioning childbirth costs is much higher than that of childbirth benefits, and the explanation of the former makes it easier to attract the attention of the audience and get more likes. Taking the cost of health risks as an example, many users share their personal childbirth experiences, and the real delivery process highlights the physiological pain of childbirth.

*I felt regular contractions at two o'clock in the morning when I gave birth to my daughter. When my cervix dilated to about 2cm, I was extremely painful. When it dilated to about 3cm, I couldn’t bear it, so I asked for painless childbirth. After the injection of epidural, I felt tired and breathless without any...*
energy. My head went blank and I couldn’t help to trembling. There was no way but call an anesthesiologist to stop the epidural. Then, I couldn’t feel anything but the pain of contractions. On the second day after I was discharged from the hospital, my lateral incision broke along the suture and became inflamed, so it had to be sutured twice. It was my second time in the delivery room. But this time, I had to have a suture without anesthetic. It was so painful that I even wanted to die and would never forget that feeling in my life. [Poster and Time: XXXXAX, November 1, 2020, 13:42:03]

These negative posts may make many unmarried and childless women fear giving birth and then show resistance to childbirth. In addition to the pain and discomfort of pregnancy and childbirth, the complications of pregnancy strengthen the negative perceptions of netizens about childbirth.

Some worries include severe morning sickness during pregnancy, frequent urination at night, a sense of breathlessness as the stomach gets bigger, overwhelming back pain after sitting or standing for a long time in class, too much or too little fetal movement... [Poster and Time: LLL, September 29, 2020, 20:09:01]

Pregnancy makes pelvic floor muscles loosen and natural labor will cause bladder prolapse, which takes a long time to heal. [Poster and Time: QSXX, June 24, 2022, 14:02:12]

After childbirth, reactions and recovery processes after childbirth are common experiences for pregnant women, and these symptoms vary in different pregnancy periods and for different individuals. However, many posts emphasize that childbirth will inevitably bring significant health effects and attribute some individuals’ postpartum health changes to childbirth.

Childbirth is a gamble, and it is common to make you get out of shape and have urinary incontinence. Apart from that, you may suffer from some lifelong diseases such as diabetes and eclampsia. Two of my relatives and friends have systemic lupus erythematosus (SLE) after delivery. [Poster and Time: MDAY, October 29, 2020, 00:46:09]

Childbirth is a gambling which risks a mother’s life to deliver a baby. Even if it is a successful delivery process, the harm to women is irreversible. My mother used to be a long-distance runner, who is even stronger and healthier than most men. But now this 50-year-old woman still feels cold in winter even when we use many ways to get her warm by opening air conditioner and underfloor heating. [Poster and Time: PER, June 21, 2020, 09:46:47]

By browsing so many negative posts listed under this topic, viewers are inclined to think that “childbirth must be painful and will bring negative effects to the body.” In addition to physical health, limited freedom and influence on occupation are important childbirth risks. Without correct guidance, these posts will increase viewers’ perception of childbirth risk to a certain extent and then prevent their willingness from giving birth. Of all the posts, 34/2634 (1.29%) posts mentioned the negative impact of browsing this discussion.

I feel very scared when I view this topic by accident. It seems that I fear marriage and childbirth. I suddenly want to withdraw my couple seeking post. Well, it’s fine to just live alone. [Poster and Time: JDXJ, February 7, 2021, 21:21:59]

Whenever I have doubts and shake my faith in marriage and childbirth, I will find this topic to see the advice of my predecessors, and I think I will be safe without marriage and childbirth. [Poster and Time: WAQDZ, April 15, 2022, 18:38:57]

**Hidden Childbirth Experience and Childbirth Knowledge Spread Through Informal Channels**

On the one hand, the deviation in viewers’ perception of childbirth risks, especially health risks, comes from the influence of the spread of network information, and on the other hand, it is due to the lack of systematic, complete, and scientific childbirth knowledge. In the posts, many users expressed their lack of relevant knowledge, suggesting that the popularization of childbirth knowledge in schools and society, especially women’s childbirth health, is still insufficient.

There are countless books on the market that teach people how to have a healthy and intelligent child from conception, but few books tell people what damage childbirth will cause to women’s bodies and how to minimize this damage as much as possible. China’s policymakers attach great importance to prenatal and postnatal care. There are all-around and multilevel support means from card establishment during pregnancy, and prenatal care check-ups to breastfeeding and pediatric health care after delivery. But there is almost no means of support for the physical and mental health of mothers. I think this is a result caused by the whole society, paying too much attention to children and neglecting mothers. [Poster and Time: OYSS, July 17, 2020, 11:43:46]

Childbirth is an important event that most women in China will experience, and its specific process and health risks rarely appeared in the public field in the past. From the perspective of older females in traditional society, they were ashamed to discuss the childbirth process and its sequela. Moreover, because every woman in society has to experience this kind of pain, there is no need to emphasize it. Therefore, women are less likely to get relevant experience from relatives and older individuals.

Until the moment I give birth, I never know what it means to my body. Before this, no relatives and friends who become mothers around me have talked about this topic with me. I remembered that in college, I asked my cousin-in-law who gave birth to a child this question and she replied: I feel like I have grown up all of a sudden. When I was a graduate student, I asked my cousin, and she replied: You will know the answer when you deliver a baby—maybe she is shy.
There are various reasons why women lack knowledge about health risks during pregnancy and delivery. For a long time, the whole society has had an insufficient understanding of women’s childbirth, as pointed out by some posts.

For a long time, we have not been allowed to talk about our bodies in public, and some details and experiences including the physiological period, pregnancy and childbirth, are regarded as taboo. But, if we don’t talk about it, we can’t communicate with each other, let alone attract a public concern in society. And if we don’t pay attention to our own body and mind, no one will. [Poster and Time: MMJ, December 13, 2020, 17:16:08]

**Gender Equality and Childbirth Trap**

With the progress of modernization, a growing number of women have gained access to education, actively participated in employment, and started to seek fair labor remuneration and equalized social status. All these factors combined have led to the rise of feminism. Feminism strives to attain gender equality and promote equal rights, opportunities, social recognition, and space for development for all family members, irrespective of gender. The most significant biological difference between men and women lies in the distinct reproductive function of women. Women’s reproductive behavior is a key factor contributing to inequality between men and women, manifesting in various aspects such as access to educational resources, career opportunities, and labor remuneration. Consequently, in the online public opinion environment, discussions related to feminism are often sparked by the topic of childbirth.

Under the research topic, 172/2634 (6.53%) posts mentioned content related to feminism, covering aspects such as unequal reproductive responsibilities between men and women, protection of women’s rights, gender discrimination, abortion rights, and reproductive rights. Among these, 115 posts expressed a negative attitude toward reproduction. In these posts, the reproductive function was no longer perceived as a biological advantage or a gift to women but rather as a negative factor hindering women from pursuing personal development and achieving self-fulfillment. The reason is that the career development of many professional women often comes to a standstill during childbirth, especially during the postpartum period. After giving birth, their incomes suffer as well because a significant portion of their energy has to be invested in caregiving. This has a notable negative impact on those who seek freedom, equality, and socioeconomic status as modern, independent females.

*Childbirth has made me a complete feminism and understand the plight of women who can only fight back by not having children. At least at this stage, feminism and childbirth are still at odds with each other. The enormous amount of energy and time required to bear and raise a child is an exponentially increasing workload that has been placed on women for a long time as a ‘punishment for motherhood’. Women are tied to unrecognized labor, and their status is naturally inferior. In addition, there is no security. Now the only option for women to achieve equal economic status is not to have children, not to take on this unrecognized part of the work, but to fight for rightful social status.* [Poster and Time: TTZ, October 15, 2021, 17:53:04]

In addition to the reality of career stagnation and the unrecognized value of domestic work, the collected posts argued that childbirth can have other negative spiritual effects. These include the identity shift after reproduction, which can confuse women’s self-perception and a lack of self-subjectivity. Moreover, in some cases, childbirth even becomes a tool for society to discipline women.

Marriage and childbirth mean disciplining and reshaping women. The gender concept tends to be traditional, and what once believed, insisted on, and pursued may be annihilated in the trivialities of life and other people’s demands. I fear that kind of change is irresistible, and the fear of losing a part of myself makes me resistant to marriage and childbirthing. [Poster and Time: YSBG, July 13, 2020, 00:36:04]

Some posts even expressed the belief that childbirth has become a kind of original sin for women, and it does not bring any benefits to them.

*Having children is a life choice. In a male-dominated society, childbearing is a disaster for women.* [Poster and Time: WT, October 7, 2020, 21:10:08]

*A pair of bulging breasts and a uterus is the sole source of modern female woe, in a society marinated in misogynistic thinking.* [Poster and Time: PLPLB, June 27, 2022, 14:22:05]

Admittedly, many of the posts were, to some extent, radical. However, it is essential to consider that the subject of female fertility discourse has been historically obscured for so long that, once people gain the right to free speech, they may resort to language for a thorough emotional release. While women are expressing their repressed feelings, the court of public opinion can influence women who are not married or pregnant, leading to negative evaluations of marriage and fertility.

These feminism-related posts intensively conflict with traditional concepts. In agricultural societies, reproduction and fertility are among the most important values attributed to women in the family. Although modern women are gradually finding new sources of value from education, careers, and society, and to some extent, detaching their self-worth from reproduction, traditional cultural evaluations are slow to change. Many posts also indicated that fertility behavior is subject to social and family pressure.

*For a woman who is about to enter her 30 s, the real feeling is that no one (especially the elders) cares about what you want to do in the future, whether you are happy with your life or what your career plan is, but only when you are going to prepare for pregnancy? When are you going to have a baby? It*
My mother’s classic quotes are ‘A woman is not complete without a child; hearing no child is a waste of womb; at least have one child, otherwise there is no point in living: a woman will definitely be miserable if she does not have a child…….’ In the eyes of traditional women like my mother, the major prerequisite for a woman to have value is that she must have children, otherwise she will not be happy in any way. [Poster and Time: SAN, October 4, 2020, 19:39:56]

The Deification of the Mother Figure

The image of motherhood is often perceived by society as great, loving, and sacrificial. Becoming a mother is also a process of self-growth for many women. Self-growth is one of the most frequently cited childbirth benefits under the topic, and it includes the maturation of character, usually embodied in the shift from self-centeredness to child-centeredness. However, this shift can sometimes be overdone and give rise to a lack of self.

Childbearing means that henceforth she will literally become a so-called attachment to the family in the eyes of the world; it means that henceforth she is better off realizing her value as a virtuous wife and mother than as an independent human being in the eyes of the world. [Poster and Time: HEL, November 21, 2020, 23:23:08]

In a life of constant reinforcement, people take the phenomenon that a mother gives 100% of her love and care her children for granted. However, the truth is that the independence of the woman herself has been overlooked. Imagine you are going to visit a friend who recently gave birth to a baby, will you prepare a gift for the baby? [Poster and Time: DHAXX, November 22, 2020, 10:39:39]

It is not difficult to see that this neglect of the mother’s subjectivity is socially structured, with all the attention from the mother herself to family relatives and even society revolving around the child. The lack of maternal subjectivity is based on the cultural notion that it is obligatory and common for mothers to sacrifice for their children. When a family accommodates a child, the child becomes the most important being in the family. When a woman becomes a mother, society expects her to become a great mother. Being shackled by such an expectation, the woman’s sacrifices become deserved and her feelings become secondary.

A woman who is married and has children is taken away from the immunity of making mistakes and is by default an indestructible file. She is supposed to understand everything and bear all the hardships. Those who have experienced it know that it is anguished, but she is not allowed to cry out in pain. [Poster and Time: LHQ, February 21, 2021, 20:17:02]

The deification of the mother figure is also reflected in society’s belief that women should do their best in all aspects of the childbirth process for the good of their children and that it is common to sacrifice a mother’s time, energy, and even health to do so.

I think society has a very strong tendency towards perfectionism in the mother-infant relationship. Anytime you see contents like mom’s hands make the best supplements (what about dad’s or grandparents’ hands?) Even if it’s just bottle-feeding, it’s believed that mom ought to do it herself (does it truly have that much of a negative impact if someone else does it?) As a woman, I think we need to realize that these requirements may not actually be very scientific. Most people grew up with a handful of 100 in examinations, so how is possible that when you get to raise a child you suddenly become perfect at everything? [Poster and Time: AHJM, August 15, 2021, 19:32:23]

The high expectations of society for mothers may be internalized and transformed into high standards for themselves. Admittedly, it has a positive impact from this aspect, as mothers would actively seek to grow if they want to take better care of their children or use themselves as role models.

I myself do not truly like little kids, but after becoming a mother, I always want to set an example so that my baby feels that his mother is also an awesome person. [Poster and Time: DAR, June 23, 2020, 22:17:02]

After you lost your temper and lashed out at your child, you are likely to think you are not a competent mom after calming down, and cringe at not being able to control yourself. Then, you will naturally want to be better in order to be a role model for your child. As a mother of a three-and-a-half-year-old kid, childbirth for me was something I needed to become stronger, better, and more mature. [Poster and Time: Sayly, August 1, 2020, 14:17:49]

While such high standards can promote women’s self-growth to some extent, these standards may bring about negative emotions, such as anxiety, if they are too high to meet. For example, some posters indicated that they would feel guilty for not loving their children enough or for not prioritizing them above all else.

I was recently reading The House on the Slope, and I clearly remembered that the main character, Risako, faced the challenge of not having enough breast milk after becoming a new mother. The idea of exclusive breastfeeding instilled in her by people around her made her feel less confident, doubt, and deny herself. There was even one time she became tired of parenting and only wanted to escape. Is it true that if you cannot breastfeed exclusively, you are not a good mother and therefore not worthy of being a human being? [Poster and Time: XRK, September 29, 2021, 12:28:33]

I don’t want to be a mother anymore. It’s too hard. I always unintentionally hurt my child, such as underdressing her, overlooking her, holding her hands?) Even if it’s just bottle-feeding, it’s believed that mom ought to do it herself (does it truly have that much of a negative impact if someone else does it?) As a woman, I think we need to realize that these requirements may not actually be very scientific. Most people grew up with a handful of 100 in examinations, so how is possible that when you get to raise a child you suddenly become perfect at everything? [Poster and Time: AHJM, August 15, 2021, 19:32:23]

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incorrectly, accidentally bumping her, and not being able to give her a comfortable living environment. She cries, and in many cases, I don’t even know why. [Poster and Time: TJDSXJ, December 8, 2020, 21:03:02]

The unreasonably high standards dissuade women who are not married or pregnant. Many of the users posting are not afraid of bearing children but are apprehensive about not being able to be a “perfect” mother and not being able to take responsibility for their children’s upbringing and education.

I don’t have confidence that I can provide a good enough life for him, that I have enough patience to educate him, and that I can give up something for him without regret. [Poster and Time: YKDGJ, May 5, 2021, 23:56:59]

Discussion

Principal Findings

Based on the representative topic of childbirth, this study analyzed the ecology of online public opinion on childbirth using a mixed method of content and thematic analyses. It has been found that women’s attitudes toward childbirth were generally neutral (1060/2634, 40.24%) or negative (1051/2634, 39.90%), with only a few showing a positive stance (523/2634, 19.86%). Messages with negative attitudes received more follows and likes. This finding is consistent with existing Chinese literature analyzing childbirth willingness from online texts [25, 26]. Previous studies showed that there are often more negative posts on fertility-related topics on Weibo [14], TikTok [27], WeChat [28], and other social media platforms in China. By analyzing the trend of women’s attitudes toward childbirth, we found that the proportion of posts expressing a negative attitude fluctuates and rises over time. According to previous reports [26, 29, 30] and the analysis of this study, we believe that both environmental factors and personal subjective factors interact to affect women’s attitudes toward childbirth. On the one hand, environmental factors, including rising housing and living costs, intense competition in child education, and the job market, as well as increased work pressure, lead young people to choose to have fewer children. On the other hand, from the perspective of subjective factors, the need for self-realization has motivated women to pursue higher education and success in their careers, leading to a delay in the age of marriage and childbirth, and a choice to have fewer children [31].

Childbirth costs and benefits are common concerns for women. In this study, health risk, restricted freedom, and energy input were the most frequently mentioned aspects in the broad topic of childbirth costs. This finding differs from Gao [25], who used textual analysis on childbirth-related content crawled from other social media. In our study, health risks were discussed more frequently and received more attention, whereas Gao [25] found that economic impacts such as financial investment were more important. The difference may be attributed to the fact that different social media have different audiences and public opinion climates. Compared with other social media such as Weibo and WeChat, Douhan’s users have a higher proportion of female users. Currently, Chinese families generally have more financial responsibilities borne by men, while most of the users posting under the topic of childbirth are women. Therefore, the collected posts were mostly generated from women’s perspectives, which naturally include health risks, restricted freedom, and energy input. Turning our attention to childbirth benefits, we found that posters focused on spiritual needs and subjective feelings, such as parenting experience, self-growth, and the continuation of life. However, only 10/2634 posts (0.38%) mentioned the objective benefits of bringing up children for the purpose of being looked after in old age. It shows that the childbirth concept of urban women has gradually changed from the traditional ones of “passing on the family line” and “bringing up children for the purpose of being looked after in old age” to the modern ones of “emotional experience,” “spiritual needs,” and “the pledge of love.” This finding is consistent with the findings of previous studies investigating childbirth motivation and childbirth willingness [4].

Concept of Childbirth

Childbirth was described as a painful process in social media. Some women have pregnancy complications. Physical pain during childbirth is a major source of fertility fear for young women [32]. Some social media users vividly describe their childbirth experience in detail. It makes viewers feel like they went through the same situation personally. Negative events could be widely spread on the internet and attract public attention [33]. This negativity can affect social media users through emotional contagion [34]. In line with previous findings on the relationship between social media and risk perceptions [28], this paper concludes that social media indeed increase women’s childbirth risk perceptions. Taking a step further, this paper also provides specific examples for the expansion of women’s risk perception.

This study also finds that many women lack comprehensive and scientific knowledge about the health risks of pregnancy and delivery. Without systematic and scientific health knowledge, many women are not only unable to properly cope with potential health risks but also have a misleading perception or wrong expectations of childbirth risks, thereby increasing their anxiety about childbirth due to the information received through informal channels. At present, the internet has become an essential means for women to gather knowledge about childbirth health [35, 36]. However, most of them did not discuss the information they retrieved from the internet with their health care professionals [37, 38]. Social media such as Twitter, Reddit, and Facebook provide forums for private citizens to freely express their views, including those about medicine and health care. Yet, the content disseminated through websites and online communities is largely unregulated [39]. This situation highlights that the internet, as an informal communication channel, may unfavorably bias women’s fertility perceptions. Currently, network information has become a crucial means for people to acquire knowledge about childbirth, with some blogs focused on the popularization of childbirth knowledge and sharing childbirth experiences gaining widespread attention on the internet. Under this topic, among the top 20 posts, 3 (15%) are about personal health changes and sharing information about breast milk. This reflects the prevalence of personal blogs.
discussing childbirth health knowledge and also underscores the demand for this type of information among the audience.

The discussions on the topic of childbirth illustrate that modern women are influenced by both traditional and modern fertility concepts. On the one hand, women seeking independence and equality are easily swayed by internet trends, believing that childbirth contributes to gender inequality and impedes personal self-fulfillment, leading to resistance to marriage and childbirth. On the other hand, they face significant pressure from traditional family values, as mentioned earlier. The collected posts reflect that the value of childbirth to women has become ambiguous and contradictory as the approaches to women’s self-worth have broadened. Zhang et al [27] also pointed out the ambivalent mindset of the new generation of women regarding childbirth and self-evaluation. This shift in gender concepts often has a negative impact on fertility [40].

In addition, the shift in women’s family identity brought about by childbirth leads many of them to feel a lack of subjectivity. The image of motherhood is often perceived by society as great, loving, and sacrificial. Most women believe that motherhood is a rite of passage for women, characterized by the transition from a selfish child to a selfless adult [41]. The maternal norms constructed by society embody characteristics of self-sacrifice. All mothers are expected to adhere to the moral standards of being a “good” mother. These norms make some mothers feel uncomfortable and distressed [42,43]. This kind of sacrifice has also faced criticism from some feminists because sacrifices made for children and partners might perpetuate oppressive gender norms, burdening women and further relinquishing their freedom [44,45].

This article reveals that the elevated social expectations imposed on mothers can be internalized, leading to the establishment of high standards for themselves. While this motivation drives them to pursue self-growth, it simultaneously triggers anxiety about parenting. These heightened social expectations have the potential to not only induce anxiety in mothers who have experienced childbirth but also instill fear among those who have not given birth.

**Strengths and Limitations**

To our knowledge, only a limited number of previous studies have explored the influence of social media on women's perceptions of childbirth. Among them, even fewer have delved into the analysis of user-generated text on social media platforms. Instead, some studies opted to assess the sentiments of their study participants through questionnaires and interviews. In this study, we conducted a thorough analysis of the posts and discussions shared by users on Douban, a social media platform known for attracting a large population of highly educated young individuals. This user base contributes to the clarity, completeness, and rationality of the points expressed in the discussions. The chosen research method enables us to gain new insights, particularly highlighting how the deification of the mother figure may result in elevated public expectations, pressuring women to sacrifice themselves to attain the ideal of a perfect mother. Women may be hesitant to become mothers as they fear losing their sense of self. Another noteworthy insight is that longstanding social and cultural biases in China may have hindered open discussions on the childbirth process and its health implications, consequently contributing to a lack of comprehensive childbirth knowledge among young women.

The findings of this study should be considered in light of certain limitations. The majority of Douban users reside in urban areas, limiting the generalizability of the results to rural women who may have different perspectives on childbirth. Future research on the attitudes and concepts of childbirth among rural women is warranted. However, previous studies have indicated that the internet's development also influences the gender role concepts of rural residents, transitioning from traditional to modern, with women being significantly more affected than men [9]. The suggestion is made that the influence of cultural concepts via the internet is present in both urban and rural areas, and analyzing urban women’s concepts is valuable for understanding those of rural women. Additionally, the gender of all users in this study could not be determined. However, based on the content of the topic and the detailed study of part of the selected sample, it is considered that the majority of the sample consisted of females. While it cannot be ruled out that a few users might be male, it is considered that this would not significantly alter the analysis results and findings.

**Conclusion and Suggestions**

This study discovered that users generally held neutral or negative attitudes toward childbirth, with fewer expressing a positive stance. Additionally, posts with a negative attitude garnered more attention and likes. Moreover, there was an observed increase in posts with negative attitudes in recent years compared with earlier years. A significant number of young women lack comprehensive and scientific knowledge about the health risks associated with pregnancy and delivery. They tend to rely on the internet to gather relevant information. However, the internet, functioning as an informal communication channel, may inadvertently skew women’s perceptions of fertility. As women’s socioeconomic status has elevated, there is a redefinition of the value attached to childbirth. In Chinese society, women often encounter greater restrictions on their freedom and are required to invest more energy in childcare compared with men, leading them to hesitate or even resist childbirth [46,47]. Moreover, the structural neglect of mothers’ needs and desires in Chinese society creates a perception among women that they might lose themselves due to childbirth and child-rearing, contributing to their hesitation or resistance to giving birth.

The study findings highlight the importance of monitoring public expressions on the internet, offering guidance to women seeking information on pregnancy and delivery, and assisting them in developing a scientific understanding of childbirth. Furthermore, enhancing the public childcare system, safeguarding women’s rights, and creating a supportive societal environment for mothers could potentially contribute to an increase in women’s fertility desires.
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Authors’ Contributions
TY and TL participated in the study design, data collection, and qualitative analysis, as well as the drafting and editing of the manuscript. YW and NH participated in the study design, drafting, and critical revision of the manuscript.

Conflicts of Interest
None declared.

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Abstract

Background: Studies have highlighted significant challenges associated with the transition from pediatric to adult health and social care services for youth living with childhood-acquired disabilities and their caregivers. Patient navigation has been proposed as an effective transitional care intervention. Better understanding of how patient navigation may support youth and their families during pediatric to adult care transitions is warranted.

Objective: This study aims to describe the preferred adaptations of an existing web-based platform from the perspectives of youth with childhood-onset disabilities and their family caregivers to develop a web-based peer-patient navigation program, Compassionate Online Navigation to Enhance Care Transitions (CONNECT).

Methods: A qualitative descriptive design was used. Participants included youth living with childhood-acquired disabilities (16/23, 70%) and their caregivers (7/23, 30%). Semistructured interviews and focus groups were conducted, digitally recorded, and transcribed. Thematic analysis was used to analyze the data and was facilitated through NVivo software (Lumivero).

Results: Participants desired a program that incorporated (1) self-directed learning, (2) a library of reliable health and community resources, and (3) emotional and social supports. On the basis of participants’ feedback, CONNECT was deemed satisfactory, as it was believed that the program would help support appropriate transition care through the provision of trusted health-related
information. Participants highlighted the need for options to optimize confidentiality in their health and social care and the choice to remain anonymous to other participants.

**Conclusions:** Web-based patient navigation programs such as CONNECT may deliver peer support that can improve the quality and experience of care for youth, and their caregivers, transitioning from pediatric to adult care through personalized support, health care monitoring, and health and social care resources. Future studies are needed to test the feasibility, acceptability, usability, use, and effectiveness of CONNECT among youth with childhood-onset disabilities.

**KEYWORDS**

youth; patient navigation; web-based intervention; peer support; transition; childhood disability; caregiver; transitional care intervention; social support; usability; program; children; pediatric; disability; digital health; eHealth; web-based support; web-based health

**Introduction**

**Background**

Young people with childhood-onset disabilities (e.g., acquired brain injury and cerebral palsy) are living longer than previous generations owing to advances in medical knowledge and clinical management [1,2]. Research and advocacy efforts have focused on ensuring continuous access to health, education, and social services for youth transitioning from pediatric to age-appropriate and developmentally appropriate adult health care services, to support autonomy and maximize independence in society for capable youth [3-7]. Many youths who age out of pediatric services experience a gap in services designed to meet their adult health and social needs [6,8-12]. Furthermore, finding and accessing the appropriate adult care providers and services is often challenging [8,12,13]. Adult health care providers often lack training related to aging with a childhood-onset disability and supporting the unique health and psychosocial needs of young adults [7,14-16].

Youth and young adults living with disabilities acquired in childhood often have chronic health issues that require frequent health care visits, and yet, few receive the comprehensive services and support they need [8,12,17]. Without seamless, accessible, and appropriate services, health concerns may remain poorly managed or undetected, increasing the risk of preventable secondary health complications and comorbidities in young adulthood [18-21], which may lead, in turn, to increased or inappropriate reliance on acute health services (e.g., hospitalizations) [7,13,22]. For example, young adults with disabilities aged between 19 and 27 years, including cerebral palsy, spina bifida, and acquired brain injuries, visit physicians and are admitted to the hospital, on average, 9 times more than that among the general population [17,23]. Results from studies conducted in Alberta, Canada, indicate that individuals providing care for children or adolescents with complex care requirements frequently experience feelings of being overwhelmed, fearful, and isolated [24]. Collectively, this evidence highlights gaps in appropriate care for a growing population of transition-age young adults with disabilities (e.g., aged 18-30 y) and their caregivers [7]. Closing this gap and ensuring the successful transition from pediatric to adult services is vital to improve the health and well-being of youth and young adults living with disabilities.

Despite the critical importance of successful transition, there is limited evidence about effective transitional care interventions for young adults with childhood-onset disabilities. Most evaluation studies have been descriptive in nature [7], lack rigor in design [25], and often do not use instruments that are valid and reliable for meaningful evaluation [26]. Furthermore, high variability across practice settings and the siloed nature of health and social services have led to issues with transferability to practice settings and community contexts [7]. Previous evidence syntheses in this area, including a systematic review [25], and clinical guidelines [27] have focused mainly on managing chronic medical diagnoses and failed to address the specific and additional needs of the youth with disabilities. It is important to address this gap, as young adults with disabilities may have diverse requirements as they prepare to transition to adult care settings [28,29]. Thus, there exists a pressing need to develop and implement culturally sensitive, accessible, effective, and fiscally sustainable approaches to youth transition. Cost-effective transitions for young adults with childhood-onset disabilities can be expected to have positive, far-reaching impacts on health and social care systems [30].

Although case navigation is a recognized effective transition intervention [31], a recent systematic review found no studies of peer navigation for transition-age youth with childhood-acquired disabilities [7]. Patient navigation emerged in the 1990s as a model of transitional support across health care settings [32,33]. Patient navigation has been defined as a partnership among the patient; family; members of the care team; and patient navigator, who facilitates timely access to health or community resources and fosters self-management and autonomy through education and emotional support [34]. Patient navigators can be peer (lay) navigators (e.g., peers with lived experience) or professional navigators (e.g., nurses) [32]. Although patient navigation has historically been implemented in the context of adults with cancer, recent programs have focused on children and youth with complex, chronic conditions [35,36]. Patient navigation has been posited as an intervention for youth and young adults with disabilities by reducing barriers to access and integrating various services in a timely, coordinated manner, thus facilitating seamless transitions in care [37]. For example, NaviCare/SoinsNavi is a professional patient navigation center in Canada that is specifically designed to provide support and assistance to children, youth, and their families who are dealing with complex care needs [38]. Patient
navigation centers such as NaviCare/SoinsNavi play a crucial role in helping individuals and families navigate the complex health care system by offering guidance, information, and coordination of care [38]. Peer navigation is generally defined as an advantageous interaction between a peer navigator and a patient and traditionally involves a trained peer who provides education and support to a patient to promote recommended health care use behaviors (eg, health screening, attending the recommended care events, and adhering to treatment or follow-up care) with the goal of optimizing care [39,40]. Specifically, through the provision of emotional, informational, and appraisal support, peer navigators can increase patient self-efficacy and, consequently, promote the achievement of recommended health behaviors. However, so far, it is not well known whether and how peer navigation can contribute to the delivery of integrated care for youth with childhood-acquired disabilities transitioning to the adult health care system and community services. Thus, studies of the role that patient navigators may have in assisting during these transitions and specific components of such an intervention are needed.

The NexJ Health Wellness Platform is a web-based platform that has been previously used to build peer navigation programs for adults with chronic illness (eg, cancer [41]). The profile and dashboard display users’ personal information that they wish to share with their circle of care members (eg, peer navigators, health care providers, and families). The profile also includes contact information such that the youth or care team can connect with one another via the platform. The dashboard is adaptable, such that the youth can personalize it with their own background or goals. Points are assigned as individuals meet their goals. The care plan is also where navigators can note any action item that youth should be taking to manage their health (eg, medications to take). Related to this aspect, there is a scheduling feature on the program, which is very similar to a digital calendar, where the clients can set up an appointment with their care team members, who will receive this request and schedule the appointment. Reminders of appointments will be facilitated through the scheduling feature. The health library contains resources provided by the study team that are verified by health care professionals and organized into different categories according to conditions, disabilities, mental health, socialization, mindfulness, and health needs. In phase 1, we received initial ideas about how the platform should be modified to build the Compassionate Online Navigation to Enhance Care Transitions (CONNECT) platform, which are presented as part of phase 2, as described in the following sections.

Objective
This study aimed to describe the preferred adaptations of this existing web-based platform from the perspectives of youth with childhood-onset disabilities and their family caregivers to develop a web-based peer-patient navigation program called CONNECT. CONNECT aims to be a web-based tool in peer-patient navigation for youth with childhood-acquired disabilities transitioning to adult health care and community services. The development of an evidence-based, patient and family–informed, web-based peer navigation intervention for young adults with childhood-onset disabilities holds the potential to improve transitional care experiences and outcomes [42].

Methods

Study Design
We conducted a qualitative descriptive study using semistructured interviews and web-based focus groups [43,44]. Qualitative description is a commonly used methodology in health care research, whereby the primary goal is to describe a complex construct by staying close to the data elicited from the perspectives and in the words of participants with lived experiences [45]. A qualitative descriptive approach is based on individuals' experiences and points of view—in this case, on peer navigation [38]. We have reported our methods as per the COREQ (Consolidated Criteria for Reporting Qualitative Research) [46].

Ethical Considerations
The protocol for this study was approved by the (University Health Network Research Ethics Board REB 22-5023). Informed verbal and written consent were obtained from all participants.

Setting
The study was conducted in Ontario, Canada, where peer navigation has recently emerged as a novel model of pediatric care provincially [47] but where little is known about patient navigation in the context of transition-age youth with disabilities.

Sampling and Recruitment
A convenience sampling strategy that combined criterion and snowball sampling was used to recruit English-speaking youth, aged between 19 and 30 years with cerebral palsy, intellectual disabilities, or acquired brain injury, and their caregivers [48]. Individuals who were unable to communicate in English were excluded from the study. The recruitment process primarily involved 2 health care organizations that maintain email lists of clients interested in research projects related to youth living with disabilities. The research coordinator used the email list to send invitations to individuals, and in addition, administrators at these organizations verbally promoted the study during group support sessions. Furthermore, social media advertisements were used to reach a wide audience of eligible participants. As part of the snowball sampling approach, at the end of the interview, participants were encouraged to actively inform their peers about the study, facilitating the expansion of our participant network. Eligible participants were subsequently contacted by a study coordinator to obtain informed verbal and written consent. It is important to note that none of the participants had previous affiliations or associations with the research team, ensuring impartiality in data collection.

We initially set a predetermined sample size goal of 15 to 25 participants, which was informed by existing guidance for qualitative research, where the aim is to reach a point of saturation at which new data no longer significantly contribute to the emergence of additional themes or insights [49,50].

Data Collection and Analysis

Overview
Data collection and analysis occurred in 2 phases. Phase 1 aimed to obtain insight about the initial, desired characteristics of a
web-based patient navigation program. Before phase 2, we incorporated the findings from phase 1 into the CONNECT program. Phase 2 aimed to obtain feedback about the preferred adaptations of an existing web-based platform to further develop the CONNECT intervention. We also collected information about sociodemographic characteristics to help contextualize the interview data.

**Phase 1**

Semistructured interviews were conducted using an interview guide developed by the research team (refer to Textbox 1 for a sample interview guide). Before the interview, participants were provided with a definition of patient navigation to help orient them to the topic area. Then, 2 experienced qualitative researchers (KMK and TSJL) conducted all interviews over the phone. Each participant completed a single interview ranging between 30 and 75 minutes. Interview were audio recorded and professionally transcribed verbatim. Immediately following each interview, the interviewer wrote reflexive memos about the interview. In total, 61% (11/18) of youths and 39% (7/18) of caregivers participated in the interviews (phase 1).

**Textbox 1.** Sample interview questions.

If money/resources were no object, what would the “ideal” patient navigation intervention look like to you?
- Not applicable

Thinking about your experience as you transitioned from pediatric to adult health and social care services, how might a patient navigation program have been helpful when you/or your family member transitioned (ie, to adult healthcare, community resources/services)?
- What benefits do you think such a program would provide to patients and family caregivers that current support, training, resources, programs, services, etc. you receive do not?

From your perspective, what are the ideal components of a patient navigation intervention?
- In what ways, specifically, do you think a patient navigator could help provide education and support?
- What can/should the navigator do?
- What information can/should the navigator provide?
- What information about the program is needed to inform people who are taking part in the intervention?
- What kind of training is needed for the navigators?

Interview data were thematically analyzed, whereby preliminary themes were derived from ongoing data collection and analysis through a coding process [51,52]. First, all transcripts were reviewed for accuracy by author, KMK, who compared the audio files with the transcript. During this process, any preliminary thoughts about the data were recorded. Next, all transcripts were reviewed independently by 3 investigators (KMK, TSJL, and SEPM) and coded using open coding procedures. Discussions around key ideas and codes in the data occurred through a series of weekly meetings to reach consensus on a codebook [51]. This codebook was then applied to the transcripts by 2 researchers (KMK and TSJL), under the guidance of the senior author (SEPM). The coded data were reviewed by the research team, who at least once weekly to discuss similarities and differences across and within the coded data. This process occurred until preliminary themes were identified. Full-team meetings helped to refine the themes and their content [51]. The full research team comprised content and methodological experts (ie, experts in disabilities, health care transition research, health system research, and qualitative methods). Interviews were stopped when theme saturation was believed to have been achieved, as consistent redundancy was evident in the themes derived from participant experiences [51,53,54]. Data from these interviews were shared with technology developers of the NexJ Health Wellness program to inform the customization of the existing program. An existing web-based program, NexJ Health Wellness, was previously designed to support the monitoring and coaching of chronic diseases in adults.

**Phase 2**

Web-based focus groups were conducted where participants were introduced to the initial features of CONNECT that had been incorporated based on the feedback provided in the interviews (ie, phase 1). However, owing to scheduling difficulties (ie, unable to gather participants on the same day), we also offered participants individual interviews if they preferred. Of the 18 participants who were interviewed and had consented to be contacted for focus groups, 3 (17%) participated in the focus groups and 2 (11%) participated in individual interviews. Some participants who participated in the initial interviews did not participate in the follow-up focus groups or interviews; reasons included the following: their phone or email was not working, and thus, they were unreachable by the research coordinator, and time constraints (eg, work schedules and family obligations). Then, 6 new participants (ie, individuals who did not participate in the original interviews; n=1, 17% caregivers and n=5, 83% youths) were also recruited. Of these participants, 3 (50%) participated in a focus group and 3 (50%) were interviewed individually. These individuals also completed the sociodemographic questionnaires. Overall, 2 focus groups, with 3 participants per focus group, and 5 individual interviews were conducted.

The focus groups lasted approximately 90 minutes and were facilitated by 2 experienced qualitative investigators (KMK and SEPM). A focus group guide (Textbox 2), informed by the preliminary analysis of and reflexive memos from the interviews, was developed by the first and senior authors. During
the focus groups, the qualitative investigators strived to ensure that participants had equal opportunity to share their thoughts by using probes to ask individuals their own thoughts. A research assistant took field notes and memos during and after the focus groups [55]. As in phase 1, the research team explored the emergence of new themes as we conducted additional interviews and focus groups. When we reached a point where new interviews did not yield substantially new insights or themes and, instead, reinforced the existing ones, we made the informed decision to conclude the data collection phase.

**Textbox 2. Sample focus group guide.**

From your perspective, what qualities make an effective peer navigator (especially with the view to promoting quality of life and increased participation/integration in the community)? We are defining effective as a program that would help you in promoting quality of life and increased participation/integration in the community.

- What training should a peer navigator have to be effective?
- How often should the touch-points with peer navigators be?

Now thinking about the platform you’ve just seen/reviewed, what components/features here would you like/be helpful in your peer navigator program (or the program for your family member)? Why?

- What components would you dislike/not be helpful (and be helpful to you as a family member)? Why?
- Has the platform captured the issues that are important to you (i.e., that you described before)?
- Are there any components not included that you would like to see?

We are interested in building an online peer navigation program that focuses on compassionate care. Do the features presented here promote the description of compassionate care you hold? Why or why not?

- If not, what could be added/amplified?

Is the platform easy to use and understand in terms of its eg, wording and the interface? Why or why?

- Are there ways that we could improve on these areas?

The individual interviews were conducted by the same 2 interviewers who led the focus groups, using the same guide. All focus groups and interviews were audio recorded and transcribed verbatim. Phase-2 data (i.e., interviews and focus groups) were analyzed using the same thematic analysis process as the interviews [51,52]. Following this process, a more critical review of both the interview themes and focus group themes was conducted. Similarly, the coded data from both data sets were combined. Once completed, a side-by-side comparison of the individually coded transcripts was conducted during a team meeting. To help identify the major themes across the data, 3 research team members (KMK, TSJL, and SEPM) led the analysis by individually reviewing the coded transcripts, meeting minutes, and memos. The full investigation team then reviewed the preliminary major themes to reflect about salient ideas, which resulted in full-team discussion and subsequent follow-up discussions to clarify ideas. Hence, investigator and data triangulation were used to ensure the trustworthiness of the data [56,57].

**Positionality of the Research Team**

Qualitative researchers are urged to consider how their background and position affect the design, analysis, and reporting of their study [58]. The research team consisted of Canadian researchers with various backgrounds (e.g., cultural) and education (e.g., trainees, health care professionals, and researchers). Throughout the data collection and analysis process, the research team had frequent discussions to remain cognizant of their own positions and reflect about how these could influence the design of the intervention and the findings. This was the first time the research team had worked with the technology partner. None of the investigators experienced living with cerebral palsy. Throughout the data collection process, we upheld reflexivity by consistently engaging in critical self-reflection and modifying our interview and focus group guides accordingly. This iterative approach empowered us to enhance our questioning techniques and remain responsive to the emergence of new themes and valuable insights.

**Results**

**Overview**

In total, 24 participants participated in this study, with 5 (21%) participating in both phase 1 and phase 2. Of these 24 unique participants, 8 (33%) were caregivers (all women) and 16 (67%) were youths (n=11, 69% young women; n=5, 31% young men). Most of the caregivers (7/8, 88%) were mothers to a youth with a childhood-onset disability, and a participant was an aunt. Characteristics of the youths and caregivers are reported in Table 1. To secure anonymity, quotations include only the participants’ group (i.e., youth or caregiver), sex, diagnosis, and participant ID number. We have synthesized the findings from phase 1 and phase 2 in Figure 1 and Table 2.
Table 1. Characteristics of the participants (N=24).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Youths (n=16), n (%)</th>
<th>Family caregivers (n=8), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>11 (69)</td>
<td>8 (100)</td>
</tr>
<tr>
<td>Male</td>
<td>5 (31)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Age (y)</td>
<td>3 (23)</td>
<td>7 (58)</td>
</tr>
<tr>
<td><strong>Living environment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>15 (94)</td>
<td>8 (100)</td>
</tr>
<tr>
<td>Rural</td>
<td>1 (6)</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Highest level of education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obtained high school</td>
<td>9 (56)</td>
<td>4 (50)</td>
</tr>
<tr>
<td>Obtained college or university</td>
<td>7 (44)</td>
<td>4 (50)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>4 (25)</td>
<td>2 (25)</td>
</tr>
<tr>
<td>White</td>
<td>11 (69)</td>
<td>4 (50)</td>
</tr>
<tr>
<td>South Asian</td>
<td>1 (6)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Southeast Asian</td>
<td>0 (0)</td>
<td>2 (25)</td>
</tr>
<tr>
<td><strong>Primary diagnosis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intellectual disability</td>
<td>8 (50)</td>
<td>N/A*</td>
</tr>
<tr>
<td>Cerebral palsy</td>
<td>5 (31)</td>
<td>N/A</td>
</tr>
<tr>
<td>Acquired brain injury</td>
<td>3 (19)</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Primary diagnosis of care recipient</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cerebral palsy</td>
<td>N/A</td>
<td>6 (75)</td>
</tr>
<tr>
<td>Acquired brain injury</td>
<td>N/A</td>
<td>1 (13)</td>
</tr>
<tr>
<td>Intellectual disability</td>
<td>N/A</td>
<td>1 (13)</td>
</tr>
</tbody>
</table>

*N/A: not applicable.

Figure 1. Summary of key findings categorized based on the phase. CONNECT: Compassionate Online Navigation to Enhance Care Transitions.
Table 2. Summary of themes.

<table>
<thead>
<tr>
<th>Phases and themes</th>
<th>Description</th>
</tr>
</thead>
</table>
| Phase 1                                  | **Advantages of web-based programs**                                                                 • In this theme, participants expressed the advantages of a web-based program over in-person support, citing time-saving benefits and independence in navigating web-based resources. Some participants, especially caregivers, acknowledged limited technology knowledge and concerns but saw the potential for enhanced accessibility, particularly for non–health-related goals, through a web-based program.  

**Benefits of peer support**                                                                 • Participants highlighted the benefits of peer support within the proposed program. They emphasized the importance of the peer navigator being trained in individualized, client-centered care and possessing knowledge about regional health and social services. Furthermore, participants stressed the significance of training the navigator in mental health support to aid in transitions from pediatric to adult services.  

**Core components of a navigation program**                                                                 • Participants expressed their desires for several core components of a navigation program:  

- Patient education: Participants emphasized the importance of patient education to enhance their understanding of their condition and treatment options. They believed that this knowledge would empower them with the confidence to actively engage in shared decision-making regarding their health care.  

- Care coordination: Participants stressed the need for care coordination to enable collaborative, patient-centered, and team-based care across various health care settings. This aspect was seen as essential for ensuring seamless transitions in care.  

- Monitoring and coaching: Participants desired remote and mobile support for self-management of their health conditions. They expressed the need for ongoing monitoring and coaching from the research team to help them navigate their health care effectively.  

Phase 2                                                                

**Logistical considerations for CONNECT**                                                                 • Participants discussed various logistical considerations for the CONNECT program. They emphasized the importance of specific aspects:  

- Navigator characteristics: Participants expressed a preference for peer navigators with similar life experiences and disabilities.  

- Value of appraisal support: Participants highlighted the need for the navigator to provide appraisal support, including feedback and evaluation. They suggested regular opportunities for participants to provide feedback and suggestions, with input reviewed by trained health care professionals to enhance the program.  

- Necessary infrastructure for accessibility: Participants discussed the importance of accommodating the differences in abilities when using CONNECT.  

**Balancing youth confidentiality with caregiver involvement**                                                                 • Both youth and caregivers highlighted the importance of personalized control over the information shared via CONNECT. Participants believed that navigators could help facilitate discussions with caregivers. Caregivers also wanted control over specific platform functions to prevent unintended actions, suggesting additional confirmation steps for certain actions owing to concerns about unintentional changes.  

**Value of multimodal communication**                                                                 • Participants valued the program’s multimodal communication options, including phone calls, instant messaging, email, and video calls, with the ability to initiate contact themselves. Digital text-based communication was seen as providing fast access to psychosocial support and enhanced privacy for sensitive discussions.  

**Holistic and developmentally appropriate care needs**                                                                 • Participants emphasized the importance of holistic and developmentally appropriate care within the CONNECT program:  

- Developmentally appropriate care: Participants believed that receiving care through CONNECT should consider their unique developmental stages, life events, and personal goals, making their participation in the program meaningful.  

- Point system: Many youth participants did not find value in the point system incorporated into the generic program, especially if points were not linked to tangible outcomes or rewards.  

- Health library: Participants responded positively to the health library, viewing it as a trusted and credible source of health information and comparing it with a more reliable version of a Google search.  

- Forums: Regarding the community forum, participants discussed the issue of anonymity and its impact on their ability to connect with peers. They believed that not remaining anonymous could lead to the potential for meaningful peer connections, providing additional opportunities for mentorship during transitions in care.  

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*CONNECT: Compassionate Online Navigation to Enhance Care Transitions.*
Phase 1: Development

Overview
During the phase-1 interviews, participants described their desires for a web-based patient navigation program. The research team worked with participants during the interviews to identify features for the first iteration of the novel, web-based CONNECT program. Phase 1 consequently identified themes related to the advantages of a web-based patient navigation program facilitated by peer support and the core categories desired in a web-based peer navigation program.

Phase 1—Theme 1: Advantages of Web-Based Programs
Several participants explained that a web-based program would be advantageous in comparison with in-person support owing to time-saving benefits related to not needing to travel. Many participants indicated that they would feel comfortable in navigating the web-based navigation program, whereas some caregiver participants highlighted having limited knowledge about technology and associated worries of being unable to support their care recipient:

I think if you can, implement the program using technology as best as you can because that way, I can do it on my own time without finding a drive and I can do all the things that I need to do online independently without assistance. If I do need help, then it’s okay, but I always do it independently when tech. issues come up. [Youth 10; female; cerebral palsy]

I guess, not too many families struggle with technology I have, but I don't know how to fix things. Like, as a single mom, working full-time, I have a child with very, very severe disabilities, not really able to use technology like this. So, I'll need to learn how to use it to help him. [Caregiver 2; female; cerebral palsy]

Although participants reported working with various care providers to support and maintain their health during transitions in care, many were unfamiliar with opportunities for self-management and support for non–health-related goals. Youth believed that that a web-based program would make such services more accessible:

I wish the services, specifically life skills and things like that were more easily accessible, because they're only in a couple of places right now and you have to have the time available to go to certain sessions wherever they're happening. And I wish they were more frequent or accessible maybe online and just to be able to talk to people even just for five minutes if you have a question about a goal rather than having to book an appointment a year in advance to see five different people at the same time. It's not always the best way to get the help that you need, so the program should help with that by being online with one peer. [Youth 8; female; cerebral palsy]

Phase 1—Theme 2: Benefits of Peer Support
Participants noted that, in addition to being a peer, the navigator should be someone who is trained in individualized, client-centered care with knowledge about the existing health and social services in the region, if possible. Participants also highlighted the importance of training the navigator in mental health support to facilitate the transitions from pediatric to adult services.

Participants highlighted numerous components to be considered for the program. Considerations included resources that provided feedback about disability-related symptoms or treatments; opportunity for self-directed learning; library of vetted health and community resources; and ability to allow for human connection including ongoing communication, compassion, and understanding. Participants validated the notion of peer navigators as being ideal to provide compassionate, appropriate care because they can provide information and emotional support and facilitate health care navigation from a lived experience perspective. Participants also highlighted a general need for support from their navigator with managing personal goals of care and nonmedical transitions (eg, desire to find employment).

Despite consensus on these preferences, participants highlighted that a degree of personalization would be required in the navigator’s approach. Participants believed that the peer navigator is uniquely positioned to provide this individualized support. There was no consensus among participants about the duration for or frequency in which an individual would want to interact with their peer navigator or use the CONNECT program. Thus, participants highlighted that the program should be available for as long as the individual felt that they needed to be enrolled, as transitions can range in time. A participant shared the following:

But maybe 6-12 months or 12-18 months for 2 hours. The reason I say two hours is because there are a lot of things that you have to learn and express, right? If people get the hang of it somewhere, I guess they can go on their own. But if they still have problems with it, or like accessing it even, they can stay longer. Every individual is different, so I would like to see it tailored to their own individual needs. [Youth 2; male; cerebral palsy]

Phase 1—Theme 3: Core Components of a Navigation Program
Participants described desiring the following: education to improve the understanding of their condition and treatment options for信心 in shared decision-making; care coordination to enable collaborative, patient-centered, team-based care across multiple care settings; and monitoring and coaching to provide remote and mobile support to help self-management, until they were built into a functioning prototype. Participants also described desiring multiple channels and modes of communication to support participants in achieving their health and wellness goals, whereby the peer navigator is the first point of contact for participants.
Phase 2: Feedback About the Features of the Initial CONNECT Program

In this section, we have outlined the key themes related to the logistics, parental control, multimodal communication, and varied needs for support regarding the use of CONNECT. Figure 1 presents the collective learnings across phase 1 and phase 2.

Phase 2—Theme 1: Logistical Considerations for CONNECT

Overview

Participants described a wide range of logistical considerations related to the CONNECT program. These included the training of the patient navigator, value of appraisal support, and infrastructure needed for CONNECT. We have illustrated these changes in an updated image of the CONNECT system in Figure 2.

Figure 2. Updated Compassionate Online Navigation to Enhance Care Transitions platform.
Subtheme 1: Navigator Characteristics

Participants described their ideal peer navigator as someone with similar life experiences and disabilities. Participants described that they would prioritize someone with these similar experiences over someone of the same age or sex. An individual shared the following:

As a person of colour, and as a self-identifying woman, I would feel more comfortable if someone my age and my demographic were to provide me information, compared to, let’s say just purely an example, of a cis white man. [Youth 19; female; intellectual disability]

Another youth participant described this by sharing the following:

It’s just nice to have a person who lived through that experience, and know that somebody has been through it. Actual lived experience is very good versus just a doctor telling you some theoretical things, versus a real person. [Youth 14; male; acquired brain injury]

Another caregiver shared the following:

I prefer my son connect with a person who has the same condition. Especially in my son’s case, it’s a little bit different because he’s underweight, he is suffering from dysphasia and he has a G-Tube inserted in his stomach...So, when you have these resources and connect with other persons who have the same condition, it would be very helpful for me and my son both in critical and non-critical situations.

[Caregiver 7; female; cerebral palsy]

Having time to meet the navigator before receiving care or advice from them was reported as an important facilitator to developing a trusting relationship.

Subtheme 2: Value of Appraisal Support

Participants also highlighted the importance of and need for the navigator to assist with appraisal support (ie, evaluation and feedback), particularly in providing feedback to the navigator and other health care providers. A participant shared the following:

I think also maybe just giving them the option to provide feedback and suggestions as needed so maybe having it once a week, or two weeks, or something where a form goes out for them to provide feedback or if they would provide any suggestions. I guess that would be helpful on your side as well when creating it and making the program a bit better so having that going out once every month or so, just so that they know that their suggestions are being heard. [Youth 5; female; intellectual disability]

Participants shared that this feedback could be reviewed with trained health care professionals who could provide the navigator with strategies for improvement. Many youths suggested that these strategies should be provided by someone who is trained in mental health care. A youth shared the following:

I think counsellors and therapists, for example, are a very good role model to draw upon these professional qualities from. I think people who are trained in mental health aspects do hold the qualities it takes to create an environment where the participant would feel safe talking about their issues.

[Youth 19; female; intellectual disability]

Subtheme 3: Necessary Infrastructure for Accessibility

Upon reviewing the existing platform, participants highlighted that owing to accessibility concerns, different hardware may be needed to accommodate the differences in abilities when using CONNECT. Examples of hardware mentioned included laptops, desktops, iPads or tablets, and cellular phones. A caregiver described the following:

[My son] cannot use a computer because both of his are closed. Even now, he uses the computer, but I have to open it and set everything up and put the camera in front of him. But also, the iPad, yeah, sometimes is much better because he has hand control movement, so yeah, the iPad is much better for my son, but it’s different for other people. [Caregiver 1; female; has a son with cerebral palsy]

Regardless of the technology, almost all participants noted that the device should allow for features such as control over the size of font, brightness, and speech-to-text functions. To serve the multicultural population of Canada, participants emphasized that the program had to be available in English, French, and other languages that may be spoken by users.

Some participants identified the barriers to the use of CONNECT for individuals who may not have access to internet. A participant said the following:

I would say that perhaps having the program in an online program might not work for everyone. They might not be able to access a computer or access the internet. But I think it’s really important to figure out a way to make sure that these individuals are still included in the program and are still able to be supported through the program. [Youth 13; female; acquired brain injury]

Phase 2—Theme 2: Balancing Youth Confidentiality With Caregiver Involvement

Many youths raised concerns over their parents accessing the information they shared via CONNECT. Youth described that all aspects of the program (ie, communication among the care team and progress posts) should be personalized such that the youth can control who can view their personal health information. Confidentiality came up as an important factor regarding youth feeling comfortable with using CONNECT, particularly in the context of discussing sexual and reproductive health issues or medical concerns with the navigator (eg, impact of the disability on reproductive health). Moreover, youth thought that the navigator could help them with discussions with their caregivers about their role in their care. A youth shared the following:
Thinking of sexual health concerns and like if someone wants their parents to know. Because I know that there are youths who are already basically independent at a very young age, and so they can easily bring up this conversation with their parents because they just have that type of dynamic. Some other youths might have a different dynamic with their parents, such that it’s like, they’ve relied upon them for medical issues and things like that; so they don’t really know how to go about bringing conversations other than, hey, I kind of want to do this. I think in that case, having a navigator would definitely help to express next steps to the youth. [Youth 19; female; intellectual disability]

At the same time, caregivers wanted to be able to control the functions their care recipient could access. A caregiver shared the following:

My point is some of the features I don’t want him to play with like canceling appointments. I want to prevent him from doing that on his own. All the features we have on the platform will be absolutely necessary. It’s like in the bank account you have to have it joint with certain people so you can do it. Because if he makes it, sometimes I can’t change it or something. I have to make up the time to make it right back, right? So, that’s what I worry about.

[Caregiver 7; female; has a son with cerebral palsy]

Another caregiver described that owing to the nature of some disabilities, many of the features on the program should have “an extra layer of clicks or click/confirm options” such as a need to click a second button or confirm button to make the action happen:

My son is 20 years old and he has uncontrolled movement for his hand. Sometimes he pushes the button and makes a mistake. So, what should I do in this case? For my son, he clicks very fast. So, the thing is I want a lock, so both of us to be there, so we can make it available.

[Caregiver 1; female; cerebral palsy]

Phase 2—Theme 3: Value of Multimodal Communication

All participants appreciated that the program allowed for multiple modes of communication. Participants responded favorably to having the option to communicate with the navigator on one’s own terms (ie, phone call, instant messaging, email, and video call), with the contact being initiated by the youth. Simultaneously, participants believed that digital communication (ie, SMS text message) could lead to fast access and more prompt management of their psychosocial issues. Some youths found that not having to communicate verbally provided an added sense of privacy, for example, if they were discussing issues that they did not want others to hear (eg, in the community forum or through messaging their patient navigator). Moreover, caregivers noted that this option may help accommodate youth with nonverbal communication abilities.

Moreover, youth believed that being able to contact the navigator when they wanted could help them better access services for a variety of health and nonhealth issues. For example, a participant shared the following:

My main goal is to be able to be in a place where I can live in an apartment and go to work every day and not necessarily have to think about how my disability will impact me after I’ve already troubleshooting it for long enough that I have a routine. So I also just want to talk about that and get support with that. Just living life when something comes up. [Youth 8; female; cerebral palsy]

Participants emphasized that the navigator should be available to the youth, caregivers, and care providers beyond standard business hours (eg, Monday to Friday from 9 AM to 5 PM), through a toll-free number, email, or messenger functions on the platform. Participants described wanting to reach a navigator that they trusted with a specific concern or a general need for emotional support during a crisis. Participants suggested having alternative navigators available to support the provision of 24/7 care. A participant stated the following:

Like, because people that will go through health issues, and they need support, but you don’t know when they need the support. You can’t just have it, have someone that’s a registered person be present only from nine to five, or like, I don’t know, eight to four, or something like that. Sometimes going through something right now, like my...like, I’m talking fine right now, but at night I’ll be like, crying in my bed. So, you need to have people there, and someone to talk to at all times. Even at two in the morning, three in the morning. That’s the key, I believe, when you’re building something to support someone. Because our struggles happen all the time, not just during the day and sometimes we have no one who understands us to talk to....So, having a main person from nine, from eight, or whatever, and then having a couple of people at night to, just to...you know, just there. Even though people...even if people don’t need it, you know, you want to be there in case someone wants it, right?

[Youth 15; female; intellectual disability]

Phase 2—Theme 4: Holistic and Developmentally Appropriate Care Needs

Overview

Participants indicated that the CONNeCT program should provide health education and support that is developmentally appropriate. Youth perceived that receiving care through CONNeCT should account for their unique developmental needs, life events, and personal goals, therefore making participation in the program meaningful. Participants operationalized developmentally appropriate care as care that could be personalized to their abilities including up-to-date health information that was written in lay terms and care that could promote self-management.
Subtheme 1: Point System

Many youth participants did not value the point system that is a part of the generic program, especially if the points were not linked to outcomes such as a prize. A participant described the following:

I don’t know, a little reward or something tangible, that is motivational, but just having the points itself might not be worth anything to someone who isn’t a child. [Youth 18; female; intellectual disability]

Subtheme 2: Health Library

Participants responded positively to the health library, often comparing the program with a Google search that was more trusted or credible. A participant described the following:

So, if I had someone recommending things to me that would be incredible. When it’s on an app for healthcare, it’s already you would trust it a lot more as a rule I would think. [Youth 16; female; intellectual disability]

However, participants noted that the health library should be expanded beyond physical health, to include mental health and information about accessible hobbies (eg, sport centers), restaurants, and transportation options.

Subtheme 3: Forums

Regarding the community forum, participants discussed the issue of anonymity. By not remaining anonymous, participants felt that there would be the potential to meet other peers. The potential to meet more peers with lived experiences was an attractive possibility to many of the youths as it would provide additional opportunities for mentorship through transitions in care. A participant described the following:

I feel like people can actually make friends out of this. Because some people might be going through the same thing, and they might be, eventually, buddies down the road. So, I feel like definitely this is something...especially patient-to-patient. There will be a connection. Like, oh, she or he is going through the same thing as I am. And they will feel like they’re not alone, in case they want to make a decision. I definitely understand why you guys did anonymous, and it’s definitely a good option to still keep anonymous, but there should be...if people want to share their name, it’s okay to share their name, so that they can make friends that way. [Youth 15; female; intellectual disability]

Participants appreciated the information vetting (eg, using peer navigators as moderators) that would occur in the forums, such that the advice provided by peers would likely be considered legitimate and safe.

Discussion

Principal Findings

We have presented the findings from the development process of a web-based patient navigation program that highlighted the preferred adaptations of an existing web-based platform from the perspectives of youth with childhood-onset disabilities and their family caregivers that will be incorporated into a web-based peer-patient navigation program called CONNECT. Participants desired a program that included (1) information about disabilities, (2) self-directed learning, (3) a library of reliable health and community resources, and (4) emotional and social supports. Upon obtaining feedback, we found that participants perceived that CONNECT could help support holistic and developmentally appropriate care needs. Participants also desired a program that was accessible to people with various physical disabilities. Moreover, as with other peer support literature [59-61], we found that for peer navigation to be most meaningful, the navigator should have similar life experiences as the user.

Our findings suggest that youth wanted their personal health information to remain confidential and preferred options of personalized caregiver involvement. Confidentiality is a major factor affecting youth’s decision to access health care services [62]. When health care professionals can assure confidentiality and a trusting relationship, youth are more likely to communicate regarding their needs, engage with follow-up, and develop skills to navigate the health care system [62]. Having a navigator with the same disability and similar life circumstances was viewed as important by participants, as it can help foster trusting relationships. A study of an existing web-based peer navigation program for adult cancer care also found that participants wanted to be matched with a peer navigator who shared common characteristics, particularly the same language and sexual orientation [41]. Optimal Matching Theory, a well-cited theory in the peer support literature that informed CONNECT, suggests that living with a disability or illness creates the need for social support across many aspects of care (eg, physical and occasional) [63]. Matching the support desired with the support provided can enhance outcomes including improved friendship formation, reduced social isolation, and improved mental health [63]. Incorporating simple screening questions regarding language, disability, and sexual orientation may be helpful. It may also be helpful to incorporate specific areas where youth are seeking support, such as emotional, informational, or practical support; their preferred mode of communication; specific modes of web-based delivery; and when and how much the intervention should be delivered. Taken together, these considerations or adaptations may serve to enhance the overall benefits of the CONNECT intervention.

Although there are many definitions of patient navigation [64], implicit in most definitions is the notion that a patient navigator works to meet the health needs of individuals and their families [32]. Our study found that patient navigation should address psychosocial, educational, recreational, and vocational considerations and physical health considerations. In addition to health information, participants also desired information that could facilitate their day-to-day lives such as locating restaurants that are accessible for people with disabilities. Moreover, an important finding from this study was that despite the positive views about having peer support offered in various ways (eg, forum and via the navigator), participants also wanted the information shared and discussed to be vetted by a trained professional. Thus, opportunities for peer navigators to routinely
work alongside health care professional navigators may be worth considering in future studies and programs, as current interventions often include solely lay or professional navigators, rather than both [65,66]. For example, youth desired emotional support during times of crises, indicating an example of where care can be better facilitated through trained professionals. Future studies should begin to explore navigation programs that include a combination of professional and peer support and programs that have professional oversight of peer navigators to determine whether and how they can be effectively integrated into transitional support interventions to optimize peer navigation delivery for youth with childhood-acquired brain injury, intellectual disabilities, and cerebral palsy and their families. Our findings provide the preferred requirements for a web-based peer navigation program for youth with childhood-acquired disabilities transitioning from pediatric to adult care. Future studies focused on refining the CONNECT program have the potential to improve the transitional experiences and outcomes of youth living with childhood-acquired disabilities and their families. The age and developmental variations among youth with complex care needs complicate the logistics of patient engagement with the intervention, as tailored approaches are essential owing to diverse cognitive and communication abilities [67,68]. Therefore, addressing these logistical challenges while maintaining a patient-centered, coproduced approach is paramount in the refinement of the CONNECT program.

In a meta-analysis of randomized controlled trials to determine the effects of patient navigation on health care use outcomes, Ali-Faisal et al [69] determined that compared with usual care, patients who received patient navigation were significantly more likely to access health screening and attend a recommended follow-up. Peer-patient navigation was also associated with increased adherence to cancer care follow-up treatment and obtaining early diagnoses [69]. Moreover, data from published studies reporting telehealth solutions for people living with illness or disability suggest the delivery of patient-centered care, relationship building between professionals and patients [68], and supporting medication adherence and health system cost savings [70]. Future directions for this program of research will include evaluating the effectiveness and health economic impacts of an optimized CONNECT intervention in a large-scale, pragmatic, randomized controlled trial. Benefits of the CONNECT program could include increasing participants’ knowledge, skills, and confidence in managing health care transitions and health-related quality of life. The results of a future randomized controlled trial may help determine the potential of CONNECT for wide dissemination and public health impact, if it demonstrates effectiveness.

We acknowledge that implementing CONNECT in real-world clinical practice entails multifaceted challenges. Successful implementation of patient navigation programs within health care systems necessitates planning, funding, multidisciplinary engagement, workflow establishment, communication mechanisms, knowledge user support, appropriate caseload management, and in-kind resource allocation [71]. Thus, to ensure a fit with existing health and social care systems, careful consideration must be given to how the CONNECT system aligns with established health care workflows, processes, and roles [72,73]. Future implementation studies are required to determine who will provide the initial instructions to both users and administrators and are essential for successful adoption. In addition, addressing the provision of ongoing technological support is vital to resolving any technical issues promptly and ensuring seamless operation of CONNECT in the community setting (ie, home) [74]. Thoughtful planning regarding these aspects will play a pivotal role in the effective implementation and sustainability of the system within the complex landscape of health care practices.

**Limitations**

This study had some limitations. Most notably, participant selection was biased toward individuals who had high-speed internet and telephone service, as they were more likely to participate in the interviews and focus groups. As such, the needs of individuals living in rural and remote areas, who may be without high-speed internet, and individuals without access to necessary hardware should be considered [75]. Moreover, our study was limited to individuals who could verbally communicate in English, excluding youth with certain communication impairments or disabilities. Moreover, we only recruited individuals with cerebral palsy, acquired brain injury, and intellectual disabilities. All participants in this study were from Ontario, Canada. As such, the preferences and perceptions of the participants may not be transferable to the desires and perceptions of a broad community of youth living with childhood-acquired disabilities [76]. Beginning our intervention development with an existing platform (ie, iterating on an existing platform) may have limited the opportunity to meaningfully co-design the CONNECT program. Finally, our participants explored the existing platform without actual interactions with the peer navigator. By deploying the patient navigation intervention, future studies could also assess its ecological validity [77].

**Conclusions**

This study describes the development of CONNECT, a web-based peer-patient navigation intervention for youth with childhood-acquired disabilities to support transitions from pediatric to adult care. Our findings reveal that youth desire receiving peer support from an individual with similar life experiences through multimodal communication techniques and with assurance of confidentiality. At the same time, participants highlighted that for web-based patient navigation to be age appropriate and developmentally appropriate, it must involve trusting relationships and vetted information. Future studies are needed to further refine CONNECT before determining its effectiveness in real-life settings. To the best of our knowledge, this study is the first to explore the desires of youth and their caregivers regarding web-based patient navigation and a codeveloped potential technology solution; however, additional studies are needed to expand the knowledge about the benefits of web-based patient navigation for youth with childhood-acquired disabilities to support transitions from pediatric to adult care.
Conflicts of Interest

MP received research funding from Autism Speaks, unrelated to this work, and has done paid consulting work with the Province of Nova Scotia, unrelated to this work. SEPM is the Editor-in-Chief of JMIR Rehabilitation and Assistive Technologies and a Guest Co-Editor of Healthcare Transitions.

References


Abbreviations

CONNECT: Compassionate Online Navigation to Enhance Care Transitions
COREQ: Consolidated Criteria for Reporting Qualitative Research
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Guiding Principles for Adolescent Web-Based Portal Access Policies: Interviews With Informatics Administrators

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Abstract

Background: Web-based patient portals are tools that could support adolescents in managing their health and developing autonomy. However, informatics administrators must navigate competing interests when developing portal access policies for adolescents and their parents.

Objective: We aimed to assess the perspectives of informatics administrators on guiding principles for the development of web-based health care portal access policies in adolescent health care.

Methods: We interviewed informatics administrators from US hospitals with ≥50 dedicated pediatric beds. We performed a thematic analysis of guiding principles for developing and implementing adolescent portal access policies.

Results: We interviewed 65 informatics leaders who represented 63 pediatric hospitals, 58 health care systems, 29 states, and 14,379 pediatric hospital beds. Participants described 9 guiding principles related to three overarching themes: (1) balancing confidentiality and other care needs, (2) balancing simplicity and granularity, and (3) collaborating and advocating. Participants described the central importance of prioritizing the health and safety of the adolescent while also complying with state and federal laws. However, there were differing beliefs about how to prioritize health and safety and what role parents should play in supporting the adolescent’s health care. Participants also identified areas where clinicians and institutions can advocate for adolescents, especially with electronic health record vendors and legislators.

Conclusions: Informatics administrators provided guiding principles for adolescent portal access policies that aimed to balance the competing needs of adolescent confidentiality and the usefulness of the portal. Portal access policies must prioritize the adolescent’s health and safety while complying with state and federal laws. However, institutions must determine how to best enact these principles. Institutions and clinicians should strive for consensus on principles to strengthen advocacy efforts with institutional leadership, electronic health record vendors, and lawmakers.

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KEYWORDS
adolescent; patient portal; electronic health records; policy; ethics; portal; portals; adolescents; youth; health record; health records; EHR; EHRs; perspective; perspectives; policies; administrator; administration; informatics; information system; information systems; guidelines
Introduction

Web-based patient portals are widely available tools that can improve patients’ sense of control [1-4], adherence [1], and medical understanding [2,3,5]. Portals represent an opportunity to engage adolescents in health care and support their developing autonomy. However, adolescents could experience emotional distress or frustration when reviewing results or clinical notes through the portal, especially if they receive difficult news such as a cancer diagnosis. These portals also risk divulging confidential information to parents that an adolescent has shared with a clinician [6,7]. Adolescents are less likely to communicate transparently with clinicians if they have concerns about confidentiality [8,9]. These concerns could lead adolescents to forgo sensitive medical care that could result in serious health repercussions, such as sexually transmitted infections, unplanned pregnancies, or poor mental health. However, parents often play an important role in managing the adolescent’s health, and US public opinion supports parental access to adolescents’ health care records [10]. Additionally, most adolescents rely on their parents’ support to manage or comanage their health care, especially if the adolescent has a chronic illness [11]. To provide ethical and effective access to adolescent portals, institutions must strive for ideal strategies that balance confidentiality and usefulness [12-14].

The 21st Century Cures Act mandates that US health care systems allow patients access to their electronic health record (EHR) data, typically through web-based patient portals [15]. We previously found that pediatric institutions have used widely varying policies for adolescent portal access across the United States [16]. Although most studies of adolescent portal use have been performed in the United States [17], other countries are similarly providing portal access to adolescents and their parents [18,19]. Variations in portal policy are driven, in part, by adolescent confidentiality laws that vary by state [20]. Each state has unique confidentiality laws with categories of protected information that generally include information about reproductive health, substance use, sexually transmitted illnesses, and mental health [21,22]. However, even within states, health care systems have interpreted the same laws differently, leading to different access policies [16]. Similarly, regulations vary in other countries. For example, the General Data Protection Regulation of the European Union requires a patient to be 16 years old to provide digital consent. The 21st Century Cures Act mandate for transparency has encouraged institutions to further reevaluate these adolescent portal access policies and their interpretation of laws.

Few studies have engaged administrators to understand their perspectives on guiding principles for developing and implementing adolescent portal access policies following the 21st Century Cures Act. Several professional medical societies have published guidelines and policy statements about adolescent portal policies and focused mainly on preserving confidentiality [13,14,23,24]. However, it is essential to understand the perspectives of administrators who are charged with developing and implementing these policies because they have rich experiential insights into the challenges of administering adolescent portal access in the US health care system. In the United States, these administrators often work in teams that include technical staff and clinicians with informatics expertise. These groups also collaborate with risk management and legal counsel to develop adolescent portal access policies that they perceive to be compliant with state and federal laws. We interviewed 65 informatics administrators from multiple health systems across the United States. Our prior analysis of these interviews characterized the varying adolescent portal policies across the United States [16], as well as approaches to engaging adolescents in using the portal [25]. In this analysis, we aimed to identify guiding principles to inform the development of these policies in the future.

Methods

Overview

We report these findings following the Standards for Reporting Qualitative Research (SRQR) checklist [26] (Multimedia Appendix 1).

Participants and Recruitment

We performed structured interviews with informatics administrators who oversaw adolescent portal access policies. Informatics administrators were eligible if they were involved in developing or implementing adolescent portal policies and if they oversaw a US children’s hospital with ≥50 dedicated pediatric beds. Specialty and rehabilitation hospitals were ineligible. We identified children’s hospitals using the Children’s Hospital Association (CHA) database in January 2022. Of 232 children’s hospitals, we excluded specialty or rehabilitation hospitals (n=37), non-US hospitals (n=7), and hospitals with <50 pediatric beds (n=9), yielding 179 eligible hospitals. We recruited participants through 2 email groups of informatics administrators and simultaneously identified contact information for informatics administrators through publicly available data. These email groups included informatics administrators across the United States who opted into the list to communicate with fellow informatics leaders. After initially sending recruitment materials through these email groups and receiving some responses, we then sent targeted emails to administrators at each remaining children’s hospital listed in the CHA database. We emailed administrators at every eligible children's hospital to request interviews. We also included administrators from US hospitals with which the authors were affiliated, given the importance of capturing representative data across the United States.

Data Collection

We identified the number of pediatric beds from the CHA database, supplemented with information from hospital websites. We developed a structured interview guide that explored adolescent portal policies, factors influencing the development and implementation of policies, and approaches to engaging adolescents through portals (Multimedia Appendix 2). We specifically asked for advice from other informatics administrators and guiding principles for developing adolescent portal access policies. This interview guide was developed through a literature review and engagement with informaticists. We revised the interview guide with a stakeholder advisory
board and 3 informatics administrators. This advisory board included 4 physicians with expertise in informatics, primary care, adolescent medicine, and endocrinology, as well as an adolescent with chronic illness and their parents. In the interview guide, we indicated which questions were essential and which questions could be skipped if insufficient time. However, we were able to ask each pertinent question for the current analysis in every interview. BAS conducted interviews between February and July 2022 via telephone or videoconferencing software. Interviews were audio-recorded and professionally transcribed. Interviews ranged from 12 to 43 minutes.

**Data Analysis**

Our overall qualitative analysis adhered to the Total Quality Framework, a comprehensive approach that ensures the accuracy, credibility, analyzability, transparency, and usefulness of qualitative findings [27,28]. We used thematic analysis [29] of guiding principles for developing and implementing adolescent portal policies. BAS and ALA developed the codebook. BAS is a pediatric oncologist, ethicist, and communication researcher with training in qualitative research. ALA is an organizational psychologist and ethics researcher with experience and training in qualitative research. Coding involved multiple iterative steps: (1) read transcripts to familiarize themselves, (2) descriptively coded 5 transcripts to formulate preliminary codes, (3) grouped codes into categories and collapsed categories into representative themes, and (4) refined definitions for themes through 3 cycles of independent coding and consensus meetings. After reviewing 25 transcripts, we reached saturation for representative themes. Using this final codebook, BAS, CB, and ME independently coded all transcripts, using these codebook definitions to ensure consistent and reliable application of codes. These authors then reviewed the other’s application of codes, marked disagreements, and resolved disagreements through discussion. We used Dedoose (SocioCultural Research Consultants) qualitative software.

**Ethical Considerations**

The institutional review board at Washington University determined this study was exempt. We obtained verbal informed consent. All transcripts were deidentified prior to analysis.

**Results**

**Participant and Health Care System Characteristics**

We identified 179 eligible pediatric hospitals and contacted an informatics administrator at every eligible center. We interviewed 65 informatics experts representing 63 hospitals across 58 health care systems. Thus, participants represented 35% of all US children’s hospitals with more than 50 dedicated pediatric beds. EHRs from all participating health systems had web-based health portals in pediatrics. The number of dedicated pediatric beds in participating hospitals ranged from 51 to 664 (median 189, IQR 107-313) beds. In total, participants represented systems with 14,379 dedicated pediatric beds across 29 states plus Washington, District of Columbia (Table 1). The majority of health care systems used Epic EHR systems.
Table 1. Characteristics of participants and represented health care systems.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Professional role of participant (n=65), n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Chief medical information officer</td>
<td>34 (52)</td>
</tr>
<tr>
<td>Clinical informaticist</td>
<td>15 (23)</td>
</tr>
<tr>
<td>Chief information officer&lt;sup&gt;a&lt;/sup&gt;</td>
<td>3 (5)</td>
</tr>
<tr>
<td>Other&lt;sup&gt;b&lt;/sup&gt;</td>
<td>13 (20)</td>
</tr>
<tr>
<td><strong>Type of electronic health record (n=58), n (%)</strong></td>
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</tr>
<tr>
<td>Epic</td>
<td>41 (70)</td>
</tr>
<tr>
<td>Cerner</td>
<td>9 (16)</td>
</tr>
<tr>
<td>Multiple</td>
<td>5 (9)</td>
</tr>
<tr>
<td>Allscripts</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (3)</td>
</tr>
<tr>
<td><strong>Pediatric-specific informatics team (n=58), n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>31 (53)</td>
</tr>
<tr>
<td>No</td>
<td>27 (47)</td>
</tr>
<tr>
<td><strong>Pediatric-specific instance of EHR&lt;sup&gt;c&lt;/sup&gt; (n=58), n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>20 (34)</td>
</tr>
<tr>
<td>No</td>
<td>38 (66)</td>
</tr>
<tr>
<td><strong>Number of dedicated pediatric hospital beds (n=58)</strong></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>51-664</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>189 (107-313)</td>
</tr>
<tr>
<td><strong>Age of adolescent access (years; n=58), n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>No access provided</td>
<td>8 (15)</td>
</tr>
<tr>
<td>10</td>
<td>1 (2)</td>
</tr>
<tr>
<td>11</td>
<td>2 (3)</td>
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<td>12</td>
<td>14 (24)</td>
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<td>13</td>
<td>21 (36)</td>
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<td>7 (12)</td>
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<td>15</td>
<td>2 (3)</td>
</tr>
<tr>
<td>16</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Unsure</td>
<td>2 (3)</td>
</tr>
<tr>
<td><strong>Are parents permitted proxy access? (n=58), n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>55 (95)</td>
</tr>
<tr>
<td>No</td>
<td>3 (5)</td>
</tr>
<tr>
<td><strong>Are adolescents permitted access? (n=58), n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>43 (74)</td>
</tr>
<tr>
<td>No</td>
<td>8 (14)</td>
</tr>
<tr>
<td>Unsure</td>
<td>7 (12)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Includes 1 participant who identified as a director of health information systems.

<sup>b</sup>Other roles included pediatric service line lead, director of nursing informatics, director of quality, certified analyst, adolescent physician, director of clinical analytics, medical director of informatics, chief medical officer, and clinician champion.

<sup>c</sup>EHR: electronic health record.
Guiding Principles and Advice for Developing Adolescent Portal Access Policies

Overview

Participants described 9 guiding principles related to three overarching themes: (1) balancing confidentiality and other care needs, (2) balancing simplicity and granularity, and (3) collaborating and advocating. We describe each of these themes and principles in Table 2 and subsequent sections.

Table 2. Subtheme definitions for guiding principles for developing and implementing adolescent portal policies.

<table>
<thead>
<tr>
<th>Themes and subthemes</th>
<th>Representative excerpts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balancing confidentiality and other care needs</td>
<td>Compliance with laws and regulations was noted as an essential requirement for any portal policy. The overarching goal of improving transparency was shared by nearly all administrators, but there were differences in how to achieve this transparency in ethically and legally acceptable ways. Administrators described the vagueness of these laws and several instances with state and federal laws are in conflict. As a result, administrators described the importance of developing a productive, collegial working relationship with the institutional compliance office and legal counsel.</td>
</tr>
<tr>
<td>Prioritize adolescent health and safety</td>
<td>Administrators strongly believed that all policies should aim to ensure the health and safety of the adolescent. However, health and safety could sometimes be in conflict. For example, some adolescents might need parental involvement to help them manage complex disease. Other adolescents might be unsafe if their parents see sensitive information, such as drug use, gender identity, or sexual activity.</td>
</tr>
<tr>
<td>Preserve clinician-adolescent relationship</td>
<td>Administrators highlighted the importance of ensuring that portal policies support rather than strain the clinician-adolescent relationship. Clinicians especially needed to honor their promises of confidentiality or they would risk losing the adolescent’s trust.</td>
</tr>
<tr>
<td>Support adolescent’s developing autonomy</td>
<td>Although administrators had disagreements about what level of access is appropriate or mandated for parents, most administrators expressed that adolescents should have access to as much of their own information as possible. Not only do adolescents have a right to learn about their own health, but administrators believe that this access could support the adolescent’s development into adulthood and self-management.</td>
</tr>
<tr>
<td>Balancing simplicity and granularity</td>
<td>Administrators generally agreed that some granularity in the ability to determine which information is shared with parents versus adolescents is ideal. Some described an ideal in which adolescents could determine each type of information that is shared with their parents. However, technological limitations created barriers for differential sharing, especially at centers with smaller pediatric populations.</td>
</tr>
<tr>
<td>Ensure the end product is useful for families</td>
<td>Administrators urged vendors and institutions to ensure the user interface was user-friendly and provided meaningful information for parents and adolescents. They also described how it was important to make sure information was understandable to families. Simply providing access was not sufficient. Additionally, administrators urged against the view of the portal as a panacea for all communication and information challenges.</td>
</tr>
<tr>
<td>Collaborating and advocating</td>
<td>Administrators emphasized the importance of engaging with leadership, informatics workforce, legal or compliance officers, clinicians, frontline staff, parents, and adolescents in developing and implementing access policies. Additionally, they encouraged the ongoing engagement of these parties after implementation to ensure the system continues to meet all parties’ needs.</td>
</tr>
<tr>
<td>Engage key stakeholders within the institution</td>
<td>Given the uncertainty and vagueness of state and federal laws, administrators encouraged other administrators to communicate with colleagues at other institutions to understand the variety of approaches to adolescent portal access. This collaboration was especially important to understand how other hospitals in the same state were interpreting the laws.</td>
</tr>
<tr>
<td>Collaborate with colleagues at other institutions</td>
<td>Many of the conditions influencing adolescent policies originated outside of the institution, especially state laws, federal policies, and EHR© functionality. It is imperative for health care institutions to advocate with these external parties to support safe and transparent sharing of adolescent medical information through portals.</td>
</tr>
</tbody>
</table>

aEHR: electronic health record.

Balancing Confidentiality and Other Care Needs

Provide Appropriate Transparency While Complying With State and Federal Laws

State-level confidentiality laws varied widely across states, leading to policies that varied in the amount of authority parents have to access their child’s medical information through the portal. The federal mandate against information blocking did not specify how this mandate applied to adolescent health, and the federal law specifically defers to state laws in these matters. Furthermore, federal and state laws were written vaguely, and some perceived the state and federal laws to be in conflict. For a detailed analysis of state-by-state variability, see Sharko et al [22]:

It was a lesson learned how really poorly written state laws are. Whether it’s state or federal or regulations, you think it would spell out exactly what you need to do, but it’s not that way at all. That 1,250-page
Participants described how adhering to state laws was a critical foundation for any portal access policy for adolescents:

“We have an affirmative requirement to protect certain information and not violate the state laws of [our state]. That is, obviously, something we take extremely seriously.” [Participant #176, chief medical information officer]

Given the complexity, variation, and vagueness of state laws, participants expressed the essential role of institutional legal and compliance officials:

“There are many regulations that are conflicting, and it’s really important to ensure that you are looping in your compliance and legal folks...because ultimately, there’s just laws that are in conflict.” [Participant #26, chief information officer]

However, the recommended approaches to complying with confidentiality laws varied. While participants described the need to balance transparency and confidentiality, some participants emphasized the importance of prioritizing the adolescent’s confidentiality over transparency and limiting access for both parents and adolescents because this was the “path of least resistance” (participant #78, clinical informaticist), technically easier, and satisfied the concerns of legal and compliance administrators. Additionally, some participants expressed their beliefs that state laws provided protection if they opted to restrict information from both parents and adolescents:

“We have not increased access for adolescents...We would defend it based on state laws about confidentiality. If there’s state laws that supersede some of the Cares Act, we can seek protection behind those.” [Participant #78, clinical informaticist]

Conversely, others emphasized the importance of transparency:

“I think that the default assumption should be that teens can access all their own information, and that parents can access all of their kids’ information, except that that’s protected by adolescent health laws.” [Participant #153, chief medical information officer]

Some participants also described the “importance of parents knowing what’s going on with their [adolescent]” (participant #93, chief medical information officer).

“We can’t disconnect the parents from the non-confidential information. I think it’s so important and key for them to be able to continue to meaningfully provide care and safely provide the care that’s required for their adolescent. Disconnecting them from that information, I think, is just the wrong thing to do.” [Participant #172, chief medical information officer]

However, this point was discussed less frequently than the importance of preserving transparency. Some participants recommended that adolescents should be empowered to determine this balance of transparency and privacy by determining what level of access their parents are permitted: “I think having it be in the adolescent’s hands to determine what their parents have access to and to be the ones in control of that I think is the right approach” (participant #119, chief medical information officer). Participants in other states, however, explained that such an approach might conflict with their state laws that provided parents with rights to access these data.

**Prioritize Adolescent Health and Safety**

In addition to adhering to the law, participants described how the adolescent’s health and safety must be the other central guiding principle for portal access policies: “To me, the guiding principle is always what’s the safety of the patient and what’s in their best interest” (participant #26, chief information officer). Furthermore, some participants described the need to prioritize the adolescent’s health needs over the legal concerns of the institution:

*Focus on the patient, not on the lawyers. If we can, again, try and stay focused on what is gonna help us take care of the patients, why do we want to be transparent with this information, understand that nobody is out to get us...Frankly, the government doesn’t have the resources to do any kind of investigation anyway.* [Participant #112, chief medical information officer]

However, there were differing beliefs about how to prioritize health and safety. For some participants, supporting health requires transparent disclosure of high-quality information to both adolescents and their parents.

*Information is powerful. Information helps improve communication, helps improve health outcomes, helps improve quality.* [Participant #57, chief medical officer]

Additionally, some participants reiterated the need to incorporate parents in the adolescent’s health care, especially for adolescents with serious illness:

*I do think for other health conditions, we want to be careful not to set barriers to where the parents can be helpful in helping that adolescent manage those conditions. It’s very much a balancing act.* [Participant #176, chief medical information officer]

Others, however, described how limiting parental access might be necessary to ensure the adolescent’s safety, for example, if they were at risk of abuse from parents following disclosure of sensitive information:

*At the very top of the pyramid is patient. All of our decisions, we try to keep that in mind. That’s where, even though I may get frustrated that sometimes there’s access that’s decreased for my parents, if it means that it’s providing the actual patient a little bit more security and privacy, then I’m able to appreciate that this is really what’s best for them.* [Participant #38, chief medical information officer]
Still, others were uncertain about how to determine what portal policy is best for adolescents:

_Yeah. I think it should be about patient—what’s best for the patient. I think that should be—to me, it’s pretty simple. Now, that’s a complex part, right? How much information do you divulge? What do they keep from their parents? What’s the right thing to do? The more ethical issues there, which I don’t have an answer to but, I think, at the end of the day, what’s gonna promote the best health for child and adult?_ [Participant #140, chief medical information officer]

**Preserve Clinician-Adolescent Relationship**

Participants advised clinicians to recognize that adolescents have a right to their own relationship with their clinician:

_At the end of the day, we wanna protect their information and their relationship with their provider…I struggle because, as a parent, I want to have access to my child’s information, but I also realize it’s their relationship as well, so, I guess, just protecting their—I don’t know—right to have that relationship with a provider._ [Participant #167, chief medical information officer]

The trust established in this relationship is essential to engaging adolescents in their care and bolstering the long-term clinical relationship: “I think if [trust is] fractured, then it’s difficult to have an ongoing good relationship with that teenager” (participant #20, chief medical information officer). This trust relies on clinicians honoring their promises of confidentiality:

_If we tell them that a conversation is private, it truly is private and that we honor that, and that there is a mechanism for that to truly be information that we do not share without their consent. Otherwise, they’re just never going to trust us. They’re not gonna trust giving us that information or really feeling comfortable engaging with a portal._ [Participant #172, chief medical information officer]

**Support Adolescent’s Developing Autonomy**

Supporting and developing the adolescent’s autonomy were also goals of many participants:

_Patient access to patient portals has a lot of positives, and I think one that gets overlooked is patients taking ownership of their own health care because the portal allows them to learn about themselves at an earlier age, learn what their diagnoses are, what their medications are, who their providers are…I think it’ll help patients understand more about themselves, communicate better with health care professionals, and make them an active participant in their health care._ [Participant #57, chief medical officer]

They viewed portals as a teaching tool to support the independence of the adolescents:

_The portal, I think for the adolescent group, is a way to increase engagement and to, hopefully, teach some of these skills that are going to be lifelong skills. This is like a really pivotal time, and I think we’re missing the opportunity, from that perspective._ [Participant #10, clinical informaticist]

However, the role of the adolescent must be adapted to their level of development and interest:

_We can’t expect a 14-year-old to manage their Type 1 Diabetes or their own Inflammatory Bowel Disease, but I do think that by giving them access, it does kind of help them take that next step in owning the management of their current diseases._ [Participant #138, clinical informaticist]

In addition, policies should not force responsibilities on the adolescent if they are not ready or willing to manage their health:

_For adolescents that truly want to manage their own health care and want to be engaged to that degree, then they should be the primary user of the portal, with the parent being in a supporting role. On the flip side, if you have a parent and a child relationship where the parent really is managing everything, then they need to retain that._ [Participant #181, chief medical information officer]

Some participants described the importance of guidance and guardrails to ensure adolescents remain safe. For some participants, the ideal guardrail is comanagement of care between the parent and adolescent, with graduated responsibility for the adolescent over time. Without this support, adolescents might be unable to sufficiently manage their health care:

_Is a 13-year-old ready to make their own medical decisions? There’s probably a handful who are, but there’s probably a lot more who struggle with that. I know certainly my kids at 13 wouldn’t have been able to manage their own care._ [Participant #133, chief medical information officer]

**Balancing Simplicity and Granularity**

**Strive for Appropriate Granularity in Differential Sharing of Health Information**

Many participants described the need for technological advancements that will permit differential sharing of information between the parent and adolescent:

_Technology needs to evolve so that parents can be engaged, and teens have the ability to actively, through portals, decide what they’re gonna share and not share because every relationship between a teen and their parents is different and can change on a moment’s notice._ [Participant #176, chief medical information officer]

The adolescent would ideally control this access, perhaps through widgets on their portal that do not require clinician actions:

_I would put the widgets for access right on the portal for the adolescent to control in addition to re-upping. I would also make it more autonomous that they can manage the access independently. They don’t have to go through us._ [Participant #60, chief medical information officer]
Some participants believed that adolescents with complex needs might need different or modified privacy settings to ensure that the child’s medical problems are sufficiently managed:

*I think that we try to make it as simple as possible, and this is a rather complex issue. I think that we probably need another type of access for those patients with chronic medical care needs, or if we could pick and choose more easily which things a child was letting their parent see, I think that would make it a little bit easier, and I think I would be more satisfied with it.* [Participant #116, chief medical information officer]

With this granular sharing, however, some participants worried that allowing the adolescent to censor certain health information might be considered information blocking or might conflict with state laws that consider the medical record to be the parent’s property: “When you cross over into that world where you’re now blocking certain elements from the parent, then you possibly fall into information blocking” (participant #98, clinical informaticist). Another participant further elaborated:

*I think that to be fully compliant with the Cures Act and the need to prevent information blocking, we should really only be selectively not sharing that information with the proxy, the third party [and adolescents should retain access to this information]. Right now, at least in our system, we only really have the ability to either have it appear in the portal or not appear in the portal [for both the adolescent and proxy]...That seems unfair to adolescents ‘cause those may be the things they most care about.* [Participant #119, chief medical information officer]

Conversely, other participants worried that more granular sharing was required to comply with the Cures Act because many health care systems were withholding information from adolescents. To achieve this granularity, a participant encouraged other administrators to “figure out your needs, and then design backwards from that” (participant #52, chief medical information officer).

**Ensure End Product Is Useful for Families**

In addition to the focus on portal access and privacy issues, participants also emphasized the importance of focusing on the user experience to ensure the portal is useful. Participants noted that registration processes needed to be simplified and streamlined to encourage portal use:

*Making our consent form electronic. Instead of having to come in and sign a piece of paper, that process is now online. You can sign up for a patient portal account through an electronic form. You can upload a picture of your driver’s license, and that has made all the difference in helping people get enrolled with a patient portal account.* [Participant #167, chief medical information officer]

However, many of the barriers to streamlined enrollment were related to identity verification to ensure parents were not registering for their adolescent’s account. Furthermore, some participants described the need to engage adolescent end users to ensure the interfaces are user-friendly:

*In general, I’m not sure if people have set about to do studies from the patient perspective, on how difficult or easy it is to use any of these personal health records or the portals that they have, so there’s a lot of improvement that could be done in terms of making these user-friendly.* [Participant #116, chief medical information officer]

**Collaborating and Advocating**

**Engage Key Stakeholders Within the Institution**

When developing policies, participants stressed the importance of engaging multiple stakeholders within the health care institution, clinical teams, and families to ensure the policies were responsive to the needs of these parties and as broadly acceptable as possible: “Communication, communication, communication, get everybody involved early and speak to all the people who were involved” (participant #121, clinical informaticist). Stakeholders included teens, parents, legal and compliance teams, clinicians, informaticists, information technology support staff, and other frontline staff involved in registration and enrollment. Participants advised multiple approaches to engaging families, including advisory boards, open forums, and satisfaction surveys:

*If you don’t have a family advisory board or a teen advisory board, that is really key. Then I also think just having open forums to hear what people say because we’re not perfect.* [Participant #167, chief medical information officer]

Yet, some participants felt that the adolescent voice was lacking at their institution:

*I don’t think there’s any adolescent voices being represented. I think there’s a lot of parental voices being represented, but I don’t think in our situation, I don’t think that there’s any—there’s ever been a teen at the table in adolescent practices even in creating clinic culture.* [Participant #144, clinician]

Within the clinical team, participants advised administrators to consider differences in practice patterns and patient populations when developing and implementing policies:

*We had to have a working group with legal, with experts in adolescent care, and really with care providers from different venues. Outpatient versus ED, versus urgent care, versus inpatient are all very different sets of episodes of care, and information types. The needs and perspectives, the providers are also gonna be different.* [Participant #153, chief medical information officer]

One participant described the need to continue tracking the expected and unexpected outcomes of policies after implementation:

*Put this on your agenda regularly. How are we accomplishing this, and what are our gaps? For our organization, I feel like we—and how are we gonna...*
continually assess it? We are not successfully doing that. [Participant #163, chief medical information officer]

Another important aspect was collaborating with hospital administration to understand organizational priorities to most effectively advocate for adolescents:

Know what your state laws are but also know what are your guiding principles as an organization with respect to adolescent health. Those might be in conflict. Then you have to determine what is your risk tolerance when it comes to that. [Participant #20, chief medical information officer]

Collaborate With Colleagues at Other Institutions

Given the multiple challenges inherent in developing and implementing portal policies for adolescents, participants emphasized the importance of collaborating and sharing best practices with colleagues. Additionally, some participants noted how institutions within the same state are implementing very different policies. As such, some participants called for institutions within states to strive toward consensus on a common approach, even though consensus would be difficult to reach:

I would say that to the extent you can within your state, come together across institutions and try to at least discuss a common approach...I think some uniformity agreements which is straight in will never get there, but it’s great to strive for. [Participant #180, chief medical information officer]

Furthermore, institutions should share their best practices with other institutions:

Then I would encourage institutions to share best practice. If something’s working put it out there so that other people that are using the same EHR can see what you’re doing and learn from it as well. [Participant #37, clinical informaticist]

Finally, a participant from an integrated health system advised informatics leaders from major academic pediatric hospitals to consider smaller pediatric centers with fewer resources when recommending standards and policies:

The big pediatric institutions in the country, I would ask that they really think about where and how a lot of pediatric care is delivered in the country...How do we help the great work that’s happening at some of the big, pediatric centers from that standpoint really get into these other places in the country that are providing lots of pediatric care? [Participant #36, clinical informaticist]

Advocate With External Parties for Adolescent and Pediatric Issues

Participants described the need to pressure EHR vendors to develop necessary technical functions in the EHR, especially related to granular differential sharing of content between adolescent and proxy portals. Currently, each health system has to modify its EHR instance to meet these unique sharing needs, and the capacity to differentially share information between proxy and adolescent portals is limited:

I think the other thing is to continue to pressure the vendors to make this easier to do out of the box, and that’s really where the CEOs have the ear of the leads of the vendor, EHR vendors, and so really to push that this is something that needs to be really addressed at the vendor level. It’s crazy for us all to be doing our own build on this. [Participant #155, chief medical information officer]

Additionally, participants described the need to advocate and lobby legislators to improve laws and regulations by adding specificity around the type of sharing required, age of adolescence, and parental and adolescent rights: “Encourage Uncle Sam [United States Government] to write rules that make sense specific to the pediatric population” (participant #109, chief medical information officer). One participant described the importance of engaging with legal counsel that was external to the hospital, to avoid being “stuck in an institutional echo chamber” (participant #158, clinical informantist). To support these advocacy efforts, 1 participant called for guidance from national organizations:

It would be really great if one of our professional organizations would come forward, like the [American Academy of Pediatrics] and say like, “This is what we believe,” in the context of information blocking and the Cures Act...If you could refer to some external expert body...I think it would really lend that extra weight. [Participant #90, chief medical information officer]

Discussion

Informatics administrators described guiding principles that aimed to maximize transparency while complying with laws, respecting parental roles, protecting the adolescent’s health and safety, and ensuring that the portal remains a useful tool. These overarching guiding principles align well with prior policy statements from professional organizations, providing an evidence base to support these statements. For example, the American Academy of Pediatrics advised health care institutions to ensure medical teams are “aware of state and federal requirements and to assist them in complying with standards, rules, and regulations” [23]. The Society for Adolescent Health and Medicine described the crucial importance of institutions determining which information will be shared with patients and proxies, as well as ensuring this information sharing complies with the 21st Century Cures Act Final Rule. This organization specifically recommended that clinicians and institutions know and abide by state and federal laws and advocate on behalf of the adolescent with key stakeholders within and outside of the institution [24]. The American College of Obstetrics and Gynecology similarly called for awareness and compliance with pertinent laws, while ensuring adolescents have the ability to have private, confidential communication with their obstetrician-gynecologists. Additionally, they advised clinicians to be aware of their institution’s policies and capabilities...
Regarding confidentiality when they are documenting sensitive information [14].

While we observed general agreement on many of these overarching principles, these goals can be conflicting when put into practice. For many adolescents with chronic illness, for example, providing parents with information is essential to support that child’s complex care needs. Yet, technological limitations and interpretations of state laws led many institutions to limit parental access to information that is essential to support the adolescent [16]. Furthermore, the usefulness of portals is greatly diminished when institutions limit available information. For example, we previously found that some institutions shut down the portal completely during adolescence for parents and adolescents, and other institutions only provide minimal information such as vaccination status and vital signs [16]. Contrarily, other adolescents might need information withheld from their parents to protect them from abuse or harm. Inadvertent disclosure of sensitive information can subvert the adolescent’s right to privacy, diminish trust in clinicians, and decrease the adolescent’s transparent engagement with the health care system [6,8,9,30]. Furthermore, some adolescents might forgo sensitive care (ie, sexually transmitted infections, pregnancy, and drug abuse) if they are not guaranteed confidentiality. Some participants described how adolescents should be empowered to decide on this balance between confidentiality and usefulness by determining how much access they will permit their parents. Yet, some institutions considered this practice to be in conflict with their state’s laws.

While it is important to ensure adolescent’s confidentiality, the role of parents in supporting adolescents must not be ignored. Most adolescents rely on their parents for medical management, insurance and financial support, transportation, assistance in decision-making, emotional support, and consent to treatment [11]. Furthermore, some adolescents have limited interest in using portals, scheduling appointments, filling prescriptions, and managing other aspects of care. For adolescents with serious or debilitating illness, this reliance on parents can be even greater. Depending on each adolescent’s unique situation, protecting privacy can either be essential to providing safe and effective health care or a major barrier to health and safety. When developing policies, the beneficial role of parental involvement must be weighed against the potential harms of inadvertent disclosure. To the extent possible, administrators should leverage available technology to minimize these disclosures while also allowing adolescents to involve parents in their health care to the extent desired or required by law.

These data highlight several targets for ongoing advocacy efforts, further supporting prior calls for advocacy in this area [24]. Within each institution, pediatricians can advocate with institutional leaders to ensure policies are informed by the adolescent’s best interests and the voices of key stakeholders. To address technological limitations, institutions can advocate with EHR companies to develop tools and workflows to permit differential sharing of information to the adolescent and proxy. Pediatricians and pediatric institutions can also advocate with lawmakers at the state and federal levels to support legislation that is informed by the experiences of adolescents, parents, and clinicians. Future studies should aim to capture the perspectives of adolescents and parents to better inform these advocacy efforts. To strengthen these advocacy efforts, health care institutions within and across states should attempt to align policies and priorities to the extent possible. While many participants described myriad challenges to gaining a national consensus, intrastate consensus should be more feasible, since all institutions are responding to the same state laws.

This study has limitations that should be considered. We limited enrollment to hospitals with at least 50 dedicated pediatric beds, which could underrepresent the challenges of hospitals in integrated health systems with a smaller pediatric presence. Our results could be biased toward larger pediatric hospitals, which could limit the representativeness of our data. Also, participants could have moderated their responses during interviews due to social desirability bias. Furthermore, we did not design this study to evaluate specific characteristics of different EHR platforms, which could have provided additional practical information.

Informatics administrators provided guiding principles for adolescent portal access policies that aimed to balance the competing needs of adolescent confidentiality and the usefulness of the portal. As bedrock principles, these policies must prioritize the adolescent’s health and safety while complying with state and federal laws. The main limiting factors in balancing these priorities were technological limitations and institutional interpretations of laws. Although most participants agreed on broad principles, we observed disagreements about how to specify the principles into policies. Institutions and clinicians should strive for consensus on principles to strengthen advocacy efforts with institutional leadership, EHR vendors, and lawmakers.

Acknowledgments

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Authors’ Contributions

BS participated in the conceptualization, design, and implementation of the study; participated in formal analysis; drafted the initial manuscript; and reviewed and revised the manuscript. CB and ME participated in the design of the study, facilitated the acquisition of data, participated in formal data analysis, and critically reviewed and revised the manuscript. ALA, FB, and JD participated in the conceptualization, design, implementation of the study; participated in formal analysis; and reviewed and
revised the manuscript. All authors approved the final manuscript as submitted and agreed to be accountable for all aspects of the work.

Conflicts of Interest
None declared.

Multimedia Appendix 1
Standards for Reporting Qualitative Research (SRQR) checklist.
[DOCX File, 21 KB - pediatrics_v7i1e49177_app1.docx]

Multimedia Appendix 2
Interview guide.
[DOCX File, 20 KB - pediatrics_v7i1e49177_app2.docx]

References


Abbreviations

CHA: Children’s Hospital Association
EHR: electronic health record
SRQR: Standards for Reporting Qualitative Research

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The Report of Access and Engagement With Digital Health Interventions Among Children and Young People: Systematic Review

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Abstract

Background: Digital health interventions are increasingly used to deliver health-related interventions for children and young people to change health behaviors and improve health outcomes. Digital health interventions have the potential to enhance access to and engagement with children and young people; however, they may also increase the divide between those who can access technology and are supported to engage and those who are not. This review included studies that reported on the access to or engagement with digital health interventions among children and young people.

Objective: This review aims to identify and report on access and engagement in studies involving digital health interventions among children and young people.

Methods: A systematic review following the Joanna Briggs Institute methods for conducting systematic reviews was conducted. An electronic literature search was conducted for all studies published between January 1, 2010, and August 2022, across sources, including MEDLINE, CINAHL, and PsycINFO. Studies were included if they examined any aspect of access or engagement in relation to interventions among children and young people. The quality of the included papers was assessed, and data were extracted. Data were considered for meta-analysis, where possible.

Results: A total of 3292 references were identified using search terms. Following the exclusion of duplicates and review by inclusion criteria, 40 studies were independently appraised for their methodological quality. A total of 16 studies were excluded owing to their low assessed quality and flawed critical elements in the study design. The studies focused on a variety of health conditions; type 1 diabetes, weight management and obesity, mental health issues, and sexual health were the predominant conditions. Most studies were conducted in developed countries, with most of them being conducted in the United States. Two studies reported data related to access and considered ethnicity and social determinants. No studies used strategies to enhance or increase access. All studies included in the review reported on at least 1 aspect of engagement. Engagement with interventions was measured in relation to frequency of engagement, with no reference to the concept of effective engagement.

Conclusions: Most digital health interventions do not consider the factors that can affect access and engagement. Of those studies that measured either access or engagement or both, few sought to implement strategies to improve access or engagement to address potential disparities between groups. Although the literature to date provides some insight into access and engagement and how these are addressed in digital health interventions, there are major limitations in understanding how both can be enhanced.
to promote equity. Consideration of both access and engagement is vital to ensure that children and young people have the ability to participate in studies.

**Trial Registration:** PROSPERO CRD42020170874; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=170874

**KEYWORDS**
access; engagement; digital health technology; mobile phone; children

**Introduction**

**Background**
Worldwide, access to many public services including health information and service provision is available through digital platforms [1]. The COVID-19 pandemic has accelerated the digital shift and highlighted the value it can bring to enabling access to health services and enhancing social connectedness [2]. However, equitable distribution of resources crucial for engaging with digital platforms—such as access to equipment, financial support for connectivity, and digital literacy—is uneven among populations. Consequently, certain groups have greater access to digital services than others [3,4]. It is crucial to focus on equity concerning access to digital health services, ensuring that the gap between those who can and cannot access these services is not widened further [5].

A plethora of literature exists on equity in health and health care; however, the key principles remain the same: that there should be equal access to health care for those in equal need of health care; equal use of health care for those in equal need of health care; and equal (equitable) health outcomes, for example, quality-adjusted life expectancy [6,7]. Equal access for equal need requires horizontal equity, conditions whereby those with equal needs have equal opportunities to access health care [8].

Health care providers are increasingly using digital technologies such as smartphones, websites, or SMS text messaging to communicate information to address health needs and in the delivery of health interventions [9]. Digital health interventions are programs that provide information and support for physical and mental health using digital technologies [10,11]. These interventions can be automated, interactive, and personalized, using user input or sensor data to shape feedback, treatment decisions, and treatment delivery [12].

Digital health interventions for children are increasing because of rapid technological advancements and the increasing interest of children and young people in technology [13]. Digital health interventions have been proposed to create opportunity to increase access to health care [14-16]. However, unless access to health care is equitable so that children and young people as consumers of health care within wider communities can use appropriate services in proportion to their need, inequities will create a divide in outcomes [17,18].

Although there is evidence for the effectiveness of digital health interventions developed for children and young people [19,20], understanding how issues related to access and variations by individuals, families, and communities are areas that have not been reviewed and require further discussion.

**Objective**
This review aimed to identify the reports of access to, and engagement with, digital health interventions among children and young people. The review includes a report of data on access and engagement in studies that report on the effectiveness of digital health interventions as well as evaluations of strategies to increase access and engagement.

**Methods**
The review followed the Joanna Briggs Institute (JBI) methodology for systematic reviews [21] in design and was conducted according to the PROSPERO protocol (CRD42020170874). The review was conducted in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement.

**Search Strategy**
A scoping search was conducted to identify key papers and search terms to inform the search strategy. This included the key terms and medical subject headings engagement or equity of access or access to health care and digital health or mobile health or electronic health.

The search strategy was reviewed and refined by a research librarian. The base search strategy was developed on CINAHL. A total of 4 web-based databases, including CINAHL, MEDLINE, PsycINFO, and Embase, were searched for English language publications between January 2010 and August 2021 and updated in August 2022. A manual search in Google Scholar was also conducted. Gray literature sources including OpenGrey, ProQuest Dissertation and Theses (ProQuest), and Google and Google Scholar were also searched to identify unpublished studies. Multimedia Appendix 1 provides the full search strategy. EndNote (Clarivate) was used to remove duplicate citations before screening.

**Inclusion and Exclusion Criteria**
The review included studies that reported data on access or engagement when reporting the effectiveness of digital health interventions for children and young people. The participants included school-aged children and young people aged 5-18 years. Parents or caregivers of children receiving health services were also included; however, studies that only reported the parent experience were excluded. Studies reporting on health interventions involving 1-way and 2-way communication including web-based platforms, mobile apps, videoconferencing, and SMS text messaging on access or engagement outcomes were included. Qualitative and quantitative studies were included in this review.

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(page number not for citation purposes)
Studies that included children aged ≤4 years and ≥19 years were excluded. Studies that reported health professionals, such as nursing staff, medical personnel, health care management and administrators, or researchers, as the primary users of the digital health intervention were excluded. Studies reporting a telephone-based intervention with no additional technological function or where the intervention focused on health records such as patient portals or personal health records were excluded.

**Screening**

The titles, abstracts, and full papers of the selected records were screened independently by 2 reviewers (SR and MJ) using the abovementioned inclusion and exclusion criteria. Any discrepancies were discussed, and disagreements were resolved by a third reviewer (LW). The reference lists of all included studies were reviewed to identify relevant papers that were not found in the electronic search.

**Assessment of Methodological Quality**

The quality of the screened papers was critically appraised independently by reviewers (SR and LW) using the appropriate standardized critical appraisal instruments from JBI, including the Checklist for Randomized Controlled Trials, Checklist for Quasi-Experimental Studies, Checklist for Cohort Studies, Checklist for Analytical Cross Sectional Studies, and the Checklist for Qualitative Research [21].

**Data Extraction**

Data were extracted from the included studies using an adapted version of the standardized data extraction tool from JBI [22]. Two reviewers (SR and MJ) extracted the data from the included papers, and a third reviewer (LW) verified the accuracy of the extracted data, with any disagreement resolved through discussion.

The extracted data included specific details about the study setting and context; the aim and objectives of the study; study design; the sampling of participants, sample size, and the characteristics of the study sample; and details about the interventions and engagement and access outcomes. All data were extracted following a thorough reading of the text to identify qualitative or quantitative findings relevant to the objectives and questions for the review. A second reviewer checked all the data extracted from each paper to enhance certainty.

**Data Synthesis**

Owing to the heterogeneity between the studies on outcome measures, research design, and the intervention, a meta-analysis was not possible. The findings have been presented in narrative form including tables and figures to aid in data presentation. The process of data synthesis followed the JBI approach of meta-aggregation. The meta-aggregative approach is sensitive to the practicality and usability of the findings extracted and does not seek to reinterpret these findings. A strong feature of the meta-aggregative approach is that it enables the generation of statements in the form of recommendations that can guide researchers, practitioners, and policy makers. In this way, meta-aggregation contrasts with meta-ethnography or the critical interpretive approach to qualitative evidence synthesis, which focuses on reinterpretation and theory generation rather than aggregation.

**Results**

**Study Inclusion**

In total, 3292 references were identified using the search terms. The addition of secondary searches of reference lists and gray literature resulted in the identification of no further references. The exclusion of 1143 duplicates resulted in 2149 references. The titles and abstracts of the references were independently reviewed to determine if they met the inclusion criteria, and 2032 references were excluded. The remaining 117 references were retrieved in full text papers and reviewed by 3 reviewers (SR, MJ, and LW) using the inclusion criteria. A total of 77 studies were excluded as they did not meet the inclusion criteria. Of the 77 studies, 45 (58%) were excluded because the age of the child was outside the inclusion range, 27 (35%) did not report on access or engagement, 2 (3%) did not include a digital intervention, and 3 (4%) were opinion pieces or letters to the Editor. A total of 40 studies met the inclusion criteria (Figure 1).
**Methodological Quality**

A total of 40 studies that met the inclusion criteria were independently appraised for their methodological quality. A total of 16 studies were excluded where the quality of the studies was assessed as low and critical elements of the study design were flawed (Tables 1-5). A cutoff was applied for each research design. A total of 5 randomized controlled trials (RCTs) were excluded because they were unclear or did not report on ≥6 items out of 13 items (Table 1). In addition, 7 quasi-experimental studies were excluded because they were unclear or did not report on ≥4 out of 9 (Table 2). All qualitative studies were retained (Table 3). The 1 cohort study was excluded because it did not meet 5 of the 11 items (Table 4). One cross-sectional study was excluded because it did not meet 4 of the 8 criteria (Table 5). Of note, the mixed methods study was assessed using the criteria for RCTs and qualitative studies for the relevant sections as per JBI guidance.
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<th>Participants blind to treatment assignment</th>
<th>Those delivering treatment blind to treatment assignment</th>
<th>Outcome assessors blind to treatment assignment</th>
<th>Treatment groups treated identically other than the intervention of interest</th>
<th>Follow-up complete and if not, were differences between groups adequately described and analyzed</th>
<th>Participants analyzed in the groups to which they were randomized</th>
<th>Treated outcomes measured in the same way for treatment groups</th>
<th>Treated outcomes measured in a reliable way</th>
<th>Appropriate statistical analysis used</th>
<th>Was the trial design appropriate, and any deviations from the standard randomized controlled trial</th>
<th>Percentage of items assessed as met</th>
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\(^{a}\)N/A: not applicable.
Table 3. Quality assessment. Qualitative studies.

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<th>Congruity between the research methodology and the research question</th>
<th>Congruity between the research methodology and the methods used to collect data</th>
<th>Congruity between the research methodology and the representation and analysis of data</th>
<th>Congruity between the research methodology and the interpretation of results</th>
<th>Statement locating the researcher culturally or theoretically</th>
<th>Influence of the researcher on the research, and vice-versa</th>
<th>Adressed</th>
<th>Participants and their voices adequately represented</th>
<th>Research ethical according to current criteria or, for recent studies</th>
<th>Conclusions drawn in the research report flow from the analysis and interpretation, of the data</th>
<th>Percentage score</th>
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<td>Unclear</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>55</td>
</tr>
</tbody>
</table>

Table 5. Quality assessment. Analytical cross-sectional studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Were the criteria for inclusion in the sample clearly defined?</th>
<th>Were the study subjects and the setting described in detail?</th>
<th>Was the exposure measured in a valid and reliable way?</th>
<th>Were objective, standard criteria used for measurement of the condition?</th>
<th>Were confounding factors identified?</th>
<th>Strategies to deal with confounding factors stated</th>
<th>Outcomes measured in a valid and reliable way</th>
<th>Follow-up complete, and if not, were the reasons for loss to follow-up described and explored</th>
<th>Strategies to address incomplete follow-up used</th>
<th>Percentage score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dowshen et al [55], 2015</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>50</td>
</tr>
<tr>
<td>Piatkowski et al [56], 2020</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>88</td>
</tr>
</tbody>
</table>

Characteristics of the Studies

Of the 24 studies included in the review (Table 6), 7 (29%) used an RCT design, 12 (50%) were quasi-experimental studies, and 3 (13%) used a qualitative study design. One study used an analytical cross-sectional study design and 1 used a mixed methods design.
<table>
<thead>
<tr>
<th>Study</th>
<th>Health condition</th>
<th>Aim and objectives</th>
<th>Country</th>
<th>Study setting</th>
<th>Study design</th>
<th>Type of digital intervention</th>
<th>Age</th>
<th>Gender</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anderson et al [33], 2018</td>
<td>Sickle cell disease</td>
<td>To examine the feasibility of the Intensive Training Program (ITP), a mobile health intervention for youths with sickle cell disease to promote disease knowledge, adherence, and patient-provider communication.</td>
<td>United States</td>
<td>Pediatric sickle cell disease clinic</td>
<td>Quasi-experimental</td>
<td>Mobile app</td>
<td>Children: mean age of children 13 (SD 3.33) years</td>
<td>Children: 16 (50%) children were female</td>
</tr>
<tr>
<td>Beaudry et al [34], 2019</td>
<td>Children transitioning from pediatric to adult care with chronic illness</td>
<td>To test the feasibility of a texting platform aimed at increasing engagement among teenagers while teaching essential self-care skills while transitioning to adult focused care.</td>
<td>United States</td>
<td>Pediatric inflammatory bowel disease, cardiology, and type 1 diabetes specialty clinics</td>
<td>Quasi-experimental</td>
<td>Text message</td>
<td>Children: mean age of children 15 years; 2 aged 14 years; 1 aged 15 years; 9 aged 16 years; and 1 aged 17 years</td>
<td>Children: sex of children not provided</td>
</tr>
<tr>
<td>Bergner et al [22], 2018</td>
<td>Type 1 diabetes</td>
<td>To evaluate the acceptability and feasibility of Check It! a positive psychology intervention to improve adherence in adolescents with T1D.</td>
<td>United States</td>
<td>Outpatient pediatric diabetes clinic</td>
<td>Mixed method (RCT and qualitative)</td>
<td>Text message</td>
<td>Children: mean age of adolescents 14.8 (SD 1.5) years</td>
<td>Children: 63 (52.5%) female participants and 57 (47.5%) male participants</td>
</tr>
<tr>
<td>Brown et al [35], 2016</td>
<td>Sexual health</td>
<td>To evaluate a behavior change intervention targeting sexual health service uptake among young people delivered using digital media.</td>
<td>United Kingdom</td>
<td>Secondary schools</td>
<td>Quasi-experimental pretest posttest design</td>
<td>Website and mobile app</td>
<td>Children: mean age at baseline 15.7 (SD 1.51) years</td>
<td>Children: at baseline 158 (55%) female and 129 (45%) male participants; at follow-up 94 (41%) female 134 (59%) males</td>
</tr>
<tr>
<td>Bunnell et al [23], 2017</td>
<td>Mental health</td>
<td>To examine access and completion of a web-based disaster mental health intervention in adolescents and their caregivers affected by the spring 2011 tornadoes in Missouri and Alabama.</td>
<td>United States</td>
<td>Community</td>
<td>Quasi-experimental; pretest posttest design</td>
<td>Website</td>
<td>Children: mean age of rural children was 14.5 (SD 1.76) years; mean age of urban children was 14.6 (SD 1.74) years; parents or caregivers: mean age of rural caregivers was 45.0 (SD 9.54) years; mean age of urban caregivers was 45.4 (SD 9.38) years</td>
<td>Children: 329 (49%) rural female participants and 347 (51%) rural male participants; 658 (50%) urban females and 663 (50%) urban males; parents or caregivers: 493 (72.9%) rural caregivers were female and 183 (27.1%) were male; 980 (74.2%) urban care givers were female and 341 (25.8%) were male</td>
</tr>
<tr>
<td>Galy et al [37], 2019</td>
<td>Overweight and obesity</td>
<td>To investigate a technology-based program combining education, objective measures of PA, and self-assessment of goal achievement delivered to Pacific adolescents.</td>
<td>New Caledonia</td>
<td>School</td>
<td>Quasi-experimental pilot study</td>
<td>Mobile app and wearable tracker device</td>
<td>Children: mean age of children 11.9 (SD 0.57) years; age ranged from 12 to 14 years</td>
<td>Children: sex not provided</td>
</tr>
<tr>
<td>Hiliard et al [25], 2020</td>
<td>T1D</td>
<td>To test the feasibility and acceptability of a behavioral intervention delivered to parents of adolescents with T1D via mobile-friendly web app.</td>
<td>United States</td>
<td>Diabetes clinic in the hospital</td>
<td>RCT</td>
<td>Mobile app</td>
<td>Children: mean age of children 15.3 (SD 1.5) years; parents: not provided</td>
<td>Children: 47 (59%) female participants and 33 (41%) male participants; parents: 64 (80%) female and 16 (20%) male</td>
</tr>
<tr>
<td>Study</td>
<td>Health condition</td>
<td>Aim and objectives</td>
<td>Country</td>
<td>Study setting</td>
<td>Study design</td>
<td>Type of digital intervention</td>
<td>Age</td>
<td>Gender</td>
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<tr>
<td>Kosse et al [40], 2019</td>
<td>Medication self-management asthma</td>
<td>To explore the use and the effective engagement of adolescents aged 12-18 years with the Adolescent Adherence Patient Tool</td>
<td>The Netherlands</td>
<td>Community</td>
<td>Quasi-experimental</td>
<td>Mobile app</td>
<td>Children: mean age of children 15.0 (SD 2.0) years</td>
<td>Children: 48 (55%) female participants and 39 (45%) male participants</td>
</tr>
<tr>
<td>LeRouge et al [51], 2016</td>
<td>Weight management (overweight)</td>
<td>To investigate the use of animated avatars and virtual agents to deliver computer-based interventions for chronic weight management in adolescents</td>
<td>United States</td>
<td>Camp Jump Start</td>
<td>Qualitative</td>
<td>Virtual avatars</td>
<td>Children: mean age of adolescents not provided</td>
<td>Children: sex of children not provided</td>
</tr>
<tr>
<td>Lopez et al [53], 2020</td>
<td>Substance use and HIV</td>
<td>To evaluate a technology-based approach to delivering culturally tailored, integrated substance use disorder and HIV risk behavior prevention programs to African American female youths</td>
<td>United States</td>
<td>School and community</td>
<td>Qualitative</td>
<td>Telemedicine</td>
<td>Children: age ranged from 13 to 18 years</td>
<td>Children: all (100%) female participants</td>
</tr>
<tr>
<td>March et al [42], 2018</td>
<td>Mental health (anxiety)</td>
<td>To examine program adherence, satisfaction, and changes in anxiety with a publicly available online, self-help iCBT&lt;sup&gt;d&lt;/sup&gt; program (BRAVE Self-Help)</td>
<td>Australia</td>
<td>Community</td>
<td>Quasi-experimental</td>
<td>Website</td>
<td>Children: mean age of children 12.9 (SD 2.97) years</td>
<td>Children: 2938 (66.4%) female participants and 1406 (31.8%) male participants; 81 (1.8%) participants identified as another gender category</td>
</tr>
<tr>
<td>McGill et al [44], 2019</td>
<td>Diabetes type 1</td>
<td>To evaluate an SMS text messaging intervention in teenagers with T1D assessing factors associated with text responsiveness and glycemic benefit</td>
<td>United States</td>
<td>Outpatient clinic</td>
<td>Quasi-experimental</td>
<td>Text message</td>
<td>Children: mean age of children 14.9 (SD 1.3) years</td>
<td>Children: 76 (52%) female participants and 70 (48%) male participants</td>
</tr>
<tr>
<td>Palermo et al [24], 2020</td>
<td>Chronic pain</td>
<td>To evaluate effectiveness and implementation of a digital health delivered psychological intervention for children aged 10-17 years with chronic pain</td>
<td>United States</td>
<td>Pain clinics</td>
<td>Stepped-wedge cluster randomized trial</td>
<td>Mobile app</td>
<td>Children: mean age of children 14.5 (SD 1.9) years</td>
<td>Children: 117 (81.8%) female participants and 26 (19.2%) male participants</td>
</tr>
<tr>
<td>Piatkows-ki et al [56], 2020</td>
<td>Obesity</td>
<td>To examine user characteristics and parenting practices associated with adolescents' initial use of the Aim2Be app; a health behavior modification intervention</td>
<td>Canada</td>
<td>Community</td>
<td>Analytical cross-sectional study</td>
<td>Mobile app</td>
<td>Children: mean age of children 14.9 (SD 1.5) years</td>
<td>Children: 184 (49.6%) female participants and 187 (50.4%) male participants</td>
</tr>
<tr>
<td>Sousa et al [47], 2015</td>
<td>Overweight and obesity</td>
<td>To evaluate the effectiveness of an e-therapeutic platform (Next,Step), aiming to promote weight management skills and the adoption of health-promoting lifestyles</td>
<td>Portugal</td>
<td>Pediatric obesity clinic</td>
<td>Quasi-experimental</td>
<td>Website</td>
<td>Children: mean age of children 14.2 (SD 1.51) years</td>
<td>Children: 48 (51.1%) female participants and 46 (48.9%) male participants</td>
</tr>
<tr>
<td>Tolou-Shams et al [53], 2019</td>
<td>Mental health and substance abuse</td>
<td>To examine the acceptability of a dyadic (youth and caregiver) SMS text messaging intervention to enhance treatment engagement of the youths attending face-to-face community-based treatment, as referred by probation staff</td>
<td>United States</td>
<td>Community-based Juvenile Probation Department and community-based provider organization</td>
<td>Qualitative</td>
<td>Text message</td>
<td>Children: mean age of children was 17.0 years; caregiver: age ranged from 35 to 265 years.</td>
<td>Children: 6 (75%) female participants and 2 (25%) male participants; caregiver: 4 (80%) female and 1 (20%) male</td>
</tr>
<tr>
<td>Study</td>
<td>Health condition</td>
<td>Aim and objectives</td>
<td>Country</td>
<td>Study setting</td>
<td>Study design</td>
<td>Type of digital intervention</td>
<td>Age</td>
<td>Gender</td>
</tr>
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</tr>
<tr>
<td>Tu et al [48], 2017</td>
<td>Overweight and obesity</td>
<td>To determine whether adolescent and parental adherence to components of an e-health intervention resulted in change in adolescent BMI and waist circumference (WC) z-scores in a sample of overweight/obese adolescents</td>
<td>Canada</td>
<td>Children’s Hospital Endocrinology and Diabetes Clinic and Center for Healthy Weights program in British Columbia and by other sources</td>
<td>Quasi-experimental</td>
<td>Website</td>
<td>Children: mean age of children 13.2 (SD 1.8) years; parents: mean age of parents 45.8 (SD 6.2) years</td>
<td>Children: 91 (57.2%) female participants and 68 (42.8%) male participants; parents: 135 (84.9%) female participants and 24 (15.1%) male participants</td>
</tr>
<tr>
<td>Voss et al [28], 2019</td>
<td>Autism</td>
<td>To evaluate the efficacy of Superpower Glass, an artificial intelligence–driven wearable behavioral intervention for improving social outcomes of children with ASD</td>
<td>United States</td>
<td>Home environment</td>
<td>RCT</td>
<td>Wearable glasses</td>
<td>Children: mean age of 8.4 (SD 2.46) years</td>
<td>Children: 8 (11%) female participants and 63 (89%) male participants</td>
</tr>
<tr>
<td>White et al [29], 2013</td>
<td>Type 1 diabetes</td>
<td>To compare the demographic and clinical characteristics of young people with T1D on recruitment, participation, and satisfaction with eHealth programs</td>
<td>United States</td>
<td>Clinical sites</td>
<td>RCT</td>
<td>Website</td>
<td>Children: mean age of 8.4 (SD 2.46) years</td>
<td>Children: 177 (55.3%) female participants and 143 (44.7%) male participants</td>
</tr>
<tr>
<td>Widman et al [30], 2017</td>
<td>Sexual health</td>
<td>To assess the feasibility and acceptability of Project HEART providing sex education focusing sexual communication skills to reduce the risk of HIV/STDs and unplanned pregnancy among youths</td>
<td>United States</td>
<td>High schools</td>
<td>RCT</td>
<td>Website</td>
<td>Children: mean age of 12.3 (SD 1.1) years</td>
<td>Children: 107 (100%) female participants</td>
</tr>
<tr>
<td>Wingo et al [49], 2020</td>
<td>Children with physical disabilities</td>
<td>To test the usability and preliminary efficacy of an eHealth and telecoaching intervention compared with telecoaching alone</td>
<td>United States</td>
<td>Pediatric rehabilitation medicine clinics</td>
<td>Quasi-experimental</td>
<td>Website</td>
<td>Children: mean age of 11.3 (SD 3.3) years; parents: mean age of parents not provided</td>
<td>Children: 29 (58%) female participants and 21 (42%) male participants; parents: 45 (90%) female participants and 5 (10%) male participants</td>
</tr>
<tr>
<td>Ybarra et al [31], 2019</td>
<td>HIV prevention</td>
<td>To determine whether technology is an appropriate delivery mechanism for adolescent-focused HIV preventive programming in South Africa</td>
<td>South Africa</td>
<td>Schools</td>
<td>RCT</td>
<td>Text message</td>
<td>Children: mean age of 17.5 (SD 1.2) years</td>
<td>Children: 647 (63.7%) female participants and 368 (36.3%) male participants</td>
</tr>
<tr>
<td>Yen et al [50], 2019</td>
<td>Mental Health (suicidal behavior)</td>
<td>To examine feasibility, acceptability, and clinical outcomes of a positive affect skills–based technology–assisted program in an acute setting</td>
<td>United States</td>
<td>Adolescent inpatient psychiatric unit</td>
<td>Quasi-experimental</td>
<td>Text message</td>
<td>Children: mean age of 15.9 (SD 1.5) years</td>
<td>Children: 15 (75%) female participants and 5 (25%) male participants</td>
</tr>
</tbody>
</table>
The studies focused on a variety of health conditions; type 1 diabetes (4/24, 17%), weight management and obesity (5/24, 21%), mental health issues (4/24, 17%), and sexual health (3/24, 13%) were the predominant conditions (Table 6). Most studies (23/24, 96%) were conducted in developed countries. Most studies (15/24, 63%) were conducted in the United States.

Of the 24 studies included in the review, 10 (42%) recruited participants from outpatient clinics, 1 (4%) recruited from the hospital setting, 4 (17%) recruited in schools, and 8 (33%) within community settings. One study recruited participants from both a school and a community setting.

In more than half of the studies (16/24, 67%), more females were recruited than males. In 3 studies, the gender of the child was not provided [23,33,51].

### Type of Digital Interventions

Overall, 38% (9/24) of the digital health interventions were web based, 21% (5/24) of the interventions were mobile apps, 29% (7/24) of the interventions used SMS text messaging, 4% (1/24) of the interventions used a website and a mobile app, 4% (1/24) of the interventions were a telemedicine intervention with participants logging in on their home computer or tablet, and 8% (2/24) of the digital interventions combined a website and digital wearable glasses and an app and wearable tracker (Table 6).

### Access and Engagement

#### Access to Digital Health Interventions

The 2 studies that reported access and digital health interventions included 1 that reported on access related to race and ethnicity and access by income and 1 that reported on gender differences in accessing services (Table 7).
Table 7. Report of access and engagement.

<table>
<thead>
<tr>
<th>Study</th>
<th>Number of participants enrolled</th>
<th>Intervention period</th>
<th>Data reported on access</th>
<th>Engagement: logged in; or interacted at least once</th>
<th>Engagement: frequency; average per day or week</th>
<th>Engagement: intensity of engagement</th>
<th>Engagement: completion of the course</th>
<th>Engagement: acceptance satisfaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anderson et al [33], 2018</td>
<td>32 children completed the baseline survey</td>
<td>90 days (6 weeks) participants to enter medication daily</td>
<td>No data reported</td>
<td>28 (87%) participants logged in</td>
<td>Participants logged in average 18 of the 30 days (60% of participants logged in each day)</td>
<td>37% tracking daily entry</td>
<td>27 (84%) participants completed track an entry of medication each day</td>
<td>Ranged from 41.7% to 91.7%</td>
</tr>
<tr>
<td>Beaudry et al [34], 2019</td>
<td>13 children enrolled</td>
<td>24 weeks—weekly text messages sent</td>
<td>No data reported</td>
<td>13 (100%) children responded to the chatbot</td>
<td>97% responded to weekly text message</td>
<td>Responses rates ranged from 85% to 100% response to the text message each week</td>
<td>13 children, 100% responded to the last text of the study period. 12 (92%) children completed the final survey</td>
<td>Satisfaction was not measured on the survey. Children reported being motivated to respond to the texts because of its “ease of use” and because they were “friendly.”</td>
</tr>
<tr>
<td>Bergner et al [22], 2018</td>
<td>120 parent child dyads enrolled</td>
<td>8 weeks; intervention group to answer weekly text message</td>
<td>No data reported</td>
<td>Information not provided</td>
<td>14% teenagers answered weekly phone reminders (control group) vs 67% in the text (intervention) group (t=7.97; P&lt;.001)</td>
<td>No other measurement provided</td>
<td>89% of the adolescents and 92% of the parents completed the 3-month follow-up survey</td>
<td>Adolescents and their parents were satisfied with the study, with &gt;87% noting a positive experience.</td>
</tr>
<tr>
<td>Brown et al [35], 2016</td>
<td>287 children enrolled at baseline</td>
<td>6 weeks</td>
<td>A digital intervention approach had a significant positive effect on psychological barriers to and antecedents of service access among females. Males reported greater confidence in service access than females.</td>
<td>Information not provided</td>
<td>100%</td>
<td>No measured</td>
<td>At follow-up, all participants reported having accessed the website or web app at least once. 45% had visited 22 main intervention pages. 36% indicated that they had not visited any of the core website pages and 21% indicated that they had visited only one of the 19 main intervention pages.</td>
<td>Not measured</td>
</tr>
<tr>
<td>Bunnell et al [23], 2017</td>
<td>2000 families (parent child dyad)</td>
<td>Intervention period not provided</td>
<td>No data reported</td>
<td>485 (36.7%) urban adolescents and 223 (33.0%) rural adolescents accessed the resource. 503 (38.1%) urban caregivers and 233 (34.5%) rural caregivers accessed the resource.</td>
<td>Not measured</td>
<td>Not measured</td>
<td>384 (79.2%) urban adolescents and 170 (76.2%) rural adolescents completed the course. 313 (62.2%) urban and 128 (54.9%) rural caregivers completed the course.</td>
<td>Not measured</td>
</tr>
<tr>
<td>Study</td>
<td>Number of participants enrolled</td>
<td>Intervention period</td>
<td>Data reported on access</td>
<td>Engagement: logged in; or interacted at least once</td>
<td>Engagement: frequency; average per day or week</td>
<td>Engagement: intensity of engagement</td>
<td>Engagement: completion of the course</td>
<td>Engagement: acceptance satisfaction</td>
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</tr>
<tr>
<td>Galy et al [37], 2019</td>
<td>24 adolescents</td>
<td>4 weeks to 8 one-hour modules</td>
<td>No data reported</td>
<td>24 (100%) adolescents used the electronic tracking device</td>
<td>24 (100%) adolescents wore the electronic tracking device daily</td>
<td>Not measured</td>
<td>21 (84%) adolescents completed the program.</td>
<td>95% of the adolescents rated their satisfaction with the modules as “fun.”</td>
</tr>
<tr>
<td>Hilliard et al [25], 2020</td>
<td>80 families enrolled. At baseline randomized to 55 family’s intervention and 25 families usual care control</td>
<td>3 to 4 months</td>
<td>No data reported</td>
<td>All 55 (100%) intervention arm families (parents) downloaded the app and logged in at least one time</td>
<td>53 participants (parents; 96%) logged in at least 1 additional time. 91% of parents used the app ≥ 2 days per week on average. 79.9% of parents logged in each day.</td>
<td>96% of the participants used the strengths tracking section of the app. 90% of the participants viewed the strengths summaries.</td>
<td>78 families (98%) completed follow-up</td>
<td>Intervention participant responses (n=50) on the USE® questionnaire indicated high acceptability of the intervention. Feedback from 48 parents was positive.</td>
</tr>
<tr>
<td>Lopez et al [52], 2020</td>
<td>58 African American adolescents</td>
<td>S 11 weekly; 1-hour group sessions with youth participants and 1 20-minute individual session with each parent of participants at some point between weeks 5 and 9 (totaling 12 weeks)</td>
<td>No data reported</td>
<td>53 (91%) adolescents completed the baseline</td>
<td>—</td>
<td>39 (67%) completed the intervention</td>
<td>100% would recommend the program to a friend</td>
<td></td>
</tr>
<tr>
<td>Kosse et al [40], 2019</td>
<td>103 patients enrolled</td>
<td>6 months</td>
<td>No data reported</td>
<td>87 (84%) patients logged in to the app. 16% of the patients did not download the app.</td>
<td>86 adolescents used the app 1975 times between October 2015 and April 2017. The median app use per person was 17 times.</td>
<td>51% watched at least 1 movie. 65 (75%) adolescents sent or received ≥ 23 chat messages. 18 adolescents used the peer chat.</td>
<td>26 (weekly) reminders sent to complete the app—individual completion of the app 10 times.</td>
<td>Not measured</td>
</tr>
<tr>
<td>Study</td>
<td>Number of participants enrolled</td>
<td>Intervention period</td>
<td>Data reported on access</td>
<td>Engagement: logged in; or interacted at least once</td>
<td>Engagement: frequency; average per day or week</td>
<td>Engagement: intensity of engagement</td>
<td>Engagement: completion of the course</td>
<td>Engagement: satisfaction</td>
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</tr>
<tr>
<td>LeRouge et al [51], 2016</td>
<td>70 adolescents</td>
<td>Intervention period not provided</td>
<td>A structured protocol of questions including general background questions (ie, age, technology access questions, level of avatar, or virtual agent experience) and then reviewed midfidelity mock-ups of 7 types of graphical embodiments of the character, for the virtual self-avatar or virtual agent.</td>
<td>70 (100%)</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Not measured</td>
</tr>
<tr>
<td>March et al [42], 2018</td>
<td>4425 young people enrolled</td>
<td>20 weeks with 10 sessions</td>
<td>No data reported</td>
<td>3467 (78.4%) completed the first session</td>
<td>Not measured</td>
<td>48.05% (2126/4425) of the registered participants completed only 1 or 2 sessions.</td>
<td>3.6% (163/4425) completed all 10 sessions</td>
<td>The mean total satisfaction rating was 17.72 (SD 5.16) out of a maximum 25</td>
</tr>
<tr>
<td>McGill et al [44], 2019</td>
<td>151 young people enrolled</td>
<td>18 months</td>
<td>No data reported</td>
<td>147 (97%) young people received the SMS text messaging intervention. Received a daily text message to check blood glucose levels.</td>
<td>Over 18 months, 49% of young people responded with ≥1 blood glucose result on ≥50% of days. Declined over time (0 to 6 months 60% response—7 to 12 months 50% daily response); 13 to 18 months 43% daily response</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Not measured</td>
</tr>
<tr>
<td>Palermo et al [24], 2020</td>
<td>143 youths enrolled: 73 youths assigned to the treatment group and 70 youths to the control group</td>
<td>8 weeks</td>
<td>No data reported</td>
<td>68 (97%) youths downloaded the app and 54 youths (74%) completed at least 1 module of the intervention.</td>
<td>Not measured</td>
<td>Youths completed an average of 3.1 modules; range 5 (0 to 8)</td>
<td>20 (27%) youths completed the intervention program.</td>
<td>85.7% of youths and rated the WebMAP program as moderately to highly acceptable on the Treatment Evaluation Inventory</td>
</tr>
<tr>
<td>Study</td>
<td>Number of participants enrolled</td>
<td>Intervention period</td>
<td>Data reported on access</td>
<td>Engagement: logged in; or interacted at least once</td>
<td>Engagement: frequency; average per day or week</td>
<td>Engagement: intensity of engagement</td>
<td>Engagement: completion of the course</td>
<td>Engagement: acceptance satisfaction</td>
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<tr>
<td>Piatkowski et al [56], 2020</td>
<td>371 adolescents and parent dyads enrolled and completed the baseline assessment</td>
<td>Not provided</td>
<td>No data reported</td>
<td>294 (79.2%) adolescents used the app</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Not measured</td>
</tr>
<tr>
<td>Sousa et al [47], 2015</td>
<td>94 adolescents enrolled (48 adolescents enrolled in the experimental group and 46 adolescents enrolled in the control group)</td>
<td>24 weeks</td>
<td>No data reported</td>
<td>25 (52.1%) adolescents in the experimental group logged in to the website.</td>
<td>On average, accessed the platform 10.68 times (SD 18.92)</td>
<td>On average analyzed 7.9 (SD 9.25) resources and read 31.8 (SD 47.56) messages from the forums during the 24-week period.</td>
<td>13.7% of the adolescents in the experimental group completed the activities.</td>
<td>Satisfaction was not measured.</td>
</tr>
<tr>
<td>Tolou-Shams et al [53], 2019</td>
<td>8 youths</td>
<td>6 months</td>
<td>No data reported</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Not measured</td>
<td>7 (87.5%)</td>
<td>Not measured</td>
</tr>
<tr>
<td>Tu et al [48], 2017</td>
<td>159 (90%) adolescent parent dyads participated</td>
<td>8 months</td>
<td>No data reported</td>
<td>15 (9.4%) adolescents and 50 parents (31.5%) did not log in to the intervention website during the entire study period.</td>
<td>Over the 33-week intervention adolescents logged into the website an average of 13.4 weeks, and parents logged into the website an average of 7.5 weeks.</td>
<td>Adolescents mean percentage of web pages viewed per week, where a total of 83 and 78 pages could be viewed in the first and last 4 months, respectively (typically there were 4-5 pages per week to view).</td>
<td>Satisfaction was not measured.</td>
<td></td>
</tr>
<tr>
<td>Voss et al [28], 2019</td>
<td>71 families enrolled; 40 (56.3%) were randomly assigned to the treatment and 31 (43.7%) to the control group</td>
<td>6 weeks; 20-minute sessions at home 4 times a week</td>
<td>No data reported</td>
<td>27 (67.5%) of the 40 treatment families engaged with the Superpower glasses.</td>
<td>Families used the glasses 12.1 times over the 6 weeks.</td>
<td>Families used each of the 3 engagement activities at least once, used the device at home for 20 min 3 times per week. Participants played guess the emotion in 39.8%, capture the smile 23.8%, and unstructured free play 36.4%.</td>
<td>24 (60%) families completed the intervention</td>
<td>Satisfaction was not measured.</td>
</tr>
<tr>
<td>Study</td>
<td>Number of participants enrolled</td>
<td>Intervention period</td>
<td>Data reported on access</td>
<td>Engagement; logged in; or interacted at least once</td>
<td>Engagement; frequency; average per day or week</td>
<td>Engagement; intensity of engagement</td>
<td>Engagement; completion of the course</td>
<td>Engagement; acceptance satisfaction</td>
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</tr>
<tr>
<td>White- more et al [29], 2013</td>
<td>320 youths enrolled; 167 were allocated to TeenCope intervention and 153 were allocated to managing diabetes intervention.</td>
<td>5 sessions</td>
<td>Black, Hispanic, or mixed-race and ethnicity youths with type 1 diabetes were less likely to enroll in digital health interventions than White and higher-income youths</td>
<td>148 (90.3%) youths who received the intervention logged in</td>
<td>Not measured</td>
<td>Not measured</td>
<td>250 (78.1%) youths completed at least 4 of 5 sessions. The mean number of sessions completed was 4.08 (SD 1.64) across both groups. 39 (12.2%) completing 1 to 3 sessions, and 31 (9.7%) completing no sessions.</td>
<td>Satisfaction was high with mean satisfaction score was 3.97 (SD 0.71) for TEENCOPE (1 is not at all satisfied and 5 is very satisfied)</td>
</tr>
<tr>
<td>Wid- man et al [30], 2017</td>
<td>107 participants randomly assigned to the intervention group and 115 participants assigned to the control group.</td>
<td>1 session; 45 minutes to complete</td>
<td>No data reported</td>
<td>107 (100%) participants interacted with the website</td>
<td>Not measured</td>
<td>Not measured</td>
<td>107 (100%) participants completed the intervention</td>
<td>Participants found the program to be highly acceptable with 79% of participants reported they would come back to the website again, 88% would recommend the program to a friend, and 94% plan to use the information they learned in the future</td>
</tr>
<tr>
<td>Wingo et al [49], 2020</td>
<td>65 parent and child dyads consented and randomized and a total of 32 dyads randomized to the eHealth group and 33 to the telephone only group.</td>
<td>12 weeks</td>
<td>No data reported</td>
<td>24 (75%) eHealth group received the intervention; 26 (78.7%) telephone only group received the intervention.</td>
<td>Not measured</td>
<td>Mean days journal entry: 45.6 food, 46.1 water, and 42.1 physical activity</td>
<td>17 (67%) in the eHealth group compared with 23 (92%) of telephone only group completed the intervention.</td>
<td>Participants indicated they valued phone calls more than the eHealth platform</td>
</tr>
<tr>
<td>Ybarra et al [31], 2019</td>
<td>303 youths; 150 intervention and 153 control</td>
<td>8-10 daily text messages sent over 5-week period</td>
<td>No data reported</td>
<td>98% of the intervention participants sent or received a text message</td>
<td>Not measured</td>
<td>Not measured</td>
<td>93% of the intervention participant said they somewhat or strongly agreed that they liked the program. The intervention was described as good or excellent by &gt;90% of the parents and 100% of the adolescents</td>
<td></td>
</tr>
<tr>
<td>Yen et al [50], 2019</td>
<td>20 (83%) adolescents enrolled</td>
<td>4 weeks</td>
<td>No data reported</td>
<td>100% responded</td>
<td>Not measured</td>
<td>Not measured</td>
<td>19 adolescents completed the intervention.</td>
<td></td>
</tr>
</tbody>
</table>
Engagement With Digital Interventions

Overview

Engagement with the digital health intervention was measured by the frequency and intensity of engagement, satisfaction with the digital health intervention, and changes in knowledge or behavior. Of the studies that reported on engagement, most used system use data to capture how the intervention was used by each participant. The studies reported on various aspects of use data including initial log-in, frequency, intensity, and duration of engagement with the program, as described in Table 7.

Initial Log-In

Once enrolled in a digital health intervention, most participants logged in and engaged with the intervention. The percentage of enrolled participants logging in at least once to the digital intervention ranged from 35.6% [23] to 100% [30,34,35,37,50]. One study did not provide this information [22]. In 16 studies, more than three-quarters of the participants logged on at least once to the digital intervention (Table 7).

Frequency of Engagement

Frequency of engagement was measured by the log-in data, number of log-ins recorded per participant, average log-ins per unit of time or total for intervention duration, visits to the site, number of visits per participant, average per unit of time, or total time of visits. Overall, 42% (10/24) of the studies reported the average number of log-ins per unit of time. The measurement of frequency varied across the studies with either daily or weekly measurement with the unit of measurement dependent on the study aims and the frequency of the delivery of the intervention.

Overall, 21% (5/24) of the studies reported on engagement on a daily basis with between 49% [44] to 100% [37] of the participants engaging daily with the intervention. Moreover, 29% (7/24) of the studies reported weekly engagement with the digital health intervention, 13% (3/24) of the studies reported monthly engagement, and 13% (3/24) of the studies reported the percentage of participants engaging weekly, and 17% (4/24) of the studies reported the average weekly engagement with the website or app.

The most frequent measurement of the frequency of engagement was daily or weekly response to text messages by participants as reported in 6 studies.

Zhang et al [32] found that adolescent sex was significantly related to engagement (t=2.42; P=0.02), with boys demonstrating higher response rates (88%) than girls (67%). However, Whittemore et al [29] found no significant gender difference in enrollment and participation in an eHealth program for adolescents with type 1 diabetes.

Intensity of Engagement and Type of Behavior

The intensity of engagement was measured by pages viewed, modules viewed, number of emails sent, number of posts, and number of experts accessed. Three studies measured the number of log-ins per participant and reported the number of times an app or web page was visited. Zhang et al [32] reported that race

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**Table 7: Data on initial log-in for studies included in the review**

<table>
<thead>
<tr>
<th>Study</th>
<th>Number of participants enrolled</th>
<th>Intervention period</th>
<th>Data reported on access</th>
<th>Engagement: logged in; or interacted at least once</th>
<th>Engagement: frequency; average per day or week</th>
<th>Engagement: intensity of engagement</th>
<th>Engagement: completion of the course</th>
<th>Engagement: acceptance satisfaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zhang et al [32], 2018</td>
<td>48 adolescents; 24 adolescents and their caregivers</td>
<td>8 weeks</td>
<td>No data reported</td>
<td>87% responded</td>
<td>The mean response rate was 76 to the 4 to 5 text messages per week overall. Responses waned over the 8-week period, from 87% in week 1 to 81% in week 5 and 62% in week 8.</td>
<td>Not measured</td>
<td>Not measured</td>
<td>Not measured</td>
</tr>
</tbody>
</table>

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**Note:**

- USE: Usefulness, Satisfaction, and Ease of use.
- Data not reported.

**Race and Ethnicity**

Equity of service use based on race and ethnicity was explored in 1 study. Whittemore et al [29] reported that Black, Hispanic, or mixed-race youths with type 1 diabetes were less likely to enroll in digital health interventions than White and high-income youths. However, once enrolled, youths of diverse races and ethnicities with type 1 diabetes were as highly satisfied with the eHealth programs as White youths. The results suggest that eHealth programs have the potential to reach diverse youth groups and to be relevant to them; however, considerations relating to access need to be addressed in the study design.

One study reported on access related to gender. Brown et al [35] reported that the digital intervention had a significant positive effect on psychological barriers to and antecedents of service access among females. Males reported greater confidence in service access than females and significantly increased service access by the second follow-up.

Equity of service use based on income was explored in 1 study. Whittmore et al [29] reported that low-income youths were less likely to participate, possibly because of access. However, once enrolled, youths of diverse races and ethnicities and low-income youth with type 1 diabetes were as highly satisfied with the eHealth programs as White youths and those with higher income.
and ethnicity were significantly related to engagement ($t=3.48$; $P=.04$), with White, non-Hispanic youths responding to more messages (80%) than youths in racial and ethnic minority groups (45%).

One study measured functions used stating the number and percentage of participants who used the 5 functions within the intervention platform [40].

**Completion of Modules and Courses**

Most studies measured either completion of modules or completion of the course, with completion rates ranging from 3.6% to 100%, with most studies reporting >80% of participants completing modules or the course. Completion of modules, web pages, and courses were measured in 16 studies. In the study with the lowest completion rate [42], completion of all 10 sessions was low (3.6%), but 48% of the participants completed some sessions [40]. Although completion rates were reported in 16 studies, understanding whether these were higher or lower than expected or in direct comparison to face-to-face or other nondigital intervention approach was not clear. Completion of the intervention sessions was high in several studies (Table 7); for example, 84% of the participants completed the intervention in 2 studies [33,37], 95% of the participants completed the intervention in another study [50], to 100% of the participants completing the intervention [37]. The results did not provide insight into whether the digital nature of the intervention increased, decreased, or had a neutral impact on completion rates.

**Satisfaction**

Satisfaction was measured in 14 studies, with satisfaction measurement methods varying across the studies (Table 7). Of the 14 studies that assessed satisfaction, participants were generally satisfied with the digital intervention, and in 1 study [49] participants were more satisfied with telephone calls than the digital alternative. When reported, satisfaction rates were high, ranging from 42% [33] to 93% [31].

**Discussion**

**Principal Findings**

This review found that few studies have reported on how they addressed access and engagement of children and young people in digital health interventions. Most studies (23/24, 96%) included in the review were conducted in developed countries, mainly the United States. Only 2 studies reported data related to access, and no study reported the use of strategies to enhance or increase access. All studies included in the review reported on at least 1 aspect of the engagement of children and young people in interventions. Engagement was assessed in relation to frequency but did not consider whether the level of engagement achieved could be considered effective.

Access to health care includes both the availability of services and the ability of individuals and populations to access services. Inequities in access to health care tend to affect the most susceptible people in our communities and those with the most complex health care needs [17,57]. Until now, the examination of young people's access to digital health interventions has primarily focused on reviewing their engagement after enrollment in the study. However, there has been minimal consideration of equity issues regarding access before enrollment or engagement after enrollment among different groups. There is much work to be done in carefully mapping the factors that may affect access within a population during the conception of a study and planning for how to improve equity in relation to access before recruitment begins. The World Health Organization [58] has developed a framework for planning, developing, and implementing youth-centered digital health interventions. The framework provides guidance on the key considerations at each stage, including whether a digital solution is the best approach and consulting with young people. Examples of considerations for researchers and others to deliberate include ownership of, and access to, digital devices; connectivity in a geographical area; and community consultation to understand the cultural, social, family, and individual beliefs and behaviors related to technology, health, and behavioral change to create a user-centered designed intervention.

Variability in the measurement of engagement with digital health interventions reflects the diversity, complexity, and multiple aims of the digital health interventions. Although there is variability in the measurement of engagement, most young people in the studies included in this review engaged with the digital health interventions once enrolled. The measurement of engagement with interventions was based on use data, frequency and intensity of engagement, and user satisfaction data. There has been no exploration of the relationship between engagement with the digital intervention and the outcome measures. The concept of “effective engagement” [19] was not explored in the papers included in the review. The concept of promoting effective engagement rather than simply more engagement is an area that could yield valuable insights into how to support young people to achieve the goals and intended outcomes of a digital health intervention. Exploring and recognizing the combination of measures to promote and support “effective engagement” is an area for development with the potential to test multidimensional models of engagement [1,59].

The digitalization of health has the potential to improve health outcomes by empowering young people to become active custodians of their own health. There is the potential to improve access and health outcomes for traditionally underserved groups where smartphone ownership and use are higher than the general population [60,61]. However, caution has been advised regarding the digitalization of health, as it tends to favor certain groups while potentially having negative impacts on others. Although there has been exponential growth in the use of the internet, access to health information remains unequal [61].

Equal use for equal need requires conditions whereby those who have an equal need for health care make equal use of health care. Compared with equal access for equal need, this equity principle requires more proactive efforts. Areas related to fiscal and social policy, that influence education, housing conditions, and nutrition, are highly influential and speak to fundamental determinants of health. To promote access and engagement, researchers must first recognize the importance and value of considering these factors and preempt, plan, and document their efforts to make progress.
The limitations of this review include the search for, and inclusion of, papers published in English only. The heterogeneity of the papers meant that a meta-analysis was not possible and a narrative summary was completed. The review included studies that reported on either access or engagement or both; however, improving or addressing these concepts was not the primary aim of the studies. Where the 2 concepts are fundamental to the design and effectiveness of digital interventions, a strength of the review lies in the inclusion of all studies that report on the consideration of access and engagement.

**Conclusions**

The review identified several gaps and raised important questions for further investigation. Most of the studies reporting on access or engagement, did not seek to improve access to digital technology and focused on the frequency of engagement. Future work should explore how access and engagement can be considered preemptively and assessed throughout the intervention, with the goal of improving the equity of access and effective engagement with digital interventions.

**Acknowledgments**

The authors would like to acknowledge Lisa Munro, a subject librarian at Edith Cowan University, for her support with the search strategy. Funding to support the research assistant role was provided by the School of Nursing and Midwifery, Edith Cowan University. The funder had no role in the design of this study and did not have any role in its execution, analyses, interpretation of the data, or preparation of the manuscript.

**Data Availability**

Data are presented in the manuscript and Multimedia Appendix 1.

**Authors’ Contributions**

LW, EM, and DA were involved in conceptualization, methodology, screening, and bias assessment and wrote the review. MJ and SR were involved in study methodology, literature search, screening, data extraction, data analysis, and bias assessment and wrote the review.

**Conflicts of Interest**

None declared.

Multimedia Appendix 1

Search strategy.

[DOCX File, 13 KB - pediatrics_v7i1e44199_app1.docx ]

Multimedia Appendix 2

PRISMA checklist.

[PDF File (Adobe PDF File), 66 KB - pediatrics_v7i1e44199_app2.pdf ]

**References**


complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.
Review

Young Children and the Creation of a Digital Identity on Social Networking Sites: Scoping Review

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Abstract

Background: There is limited understanding of the concept of the digital identity of young children created through engagement on social networking sites.

Objective: The objective of this scoping review was to identify key characteristics of the concept of digital identity for children from conception to the age of 8 years on social networking sites.

Methods: This scoping review was conducted using the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) guidelines. The key databases searched were EBSCO, Web of Science, ProQuest ERIC, and Scopus. Gray literature sources (National Grey Literature Collection, ProQuest Dissertations and Theses, and Google Scholar) were also searched to identify unpublished studies. Articles were selected if they were published in English and reported data on the digital identity of children in relation to social networking sites.

Results: The key terms used in the literature were sharenting, followed by digital footprints and children’s identities. Our study revealed 2 approaches to the creation of digital identity: social digital identity and performative digital identity. The articles in this review most commonly used the term sharenting to describe the behavior parents engage in to create digital identities for children on social networking sites. Motivations to post information about children differed among parents; however, the most common reasons were to share with friends and family and create digital archives of childhood photos, termed social digital identity. The second motivation was categorized as performative digital identity. The risk of digital kidnapping and identity theft associated with the creation of digital identities also influenced parents’ behaviors.

Conclusions: The creation of a digital identity for children is an emerging concept. Our review develops a deeper understanding of sharenting behaviors that can be used to better support parents and their children in creating a digital identity with children and awareness of the potential future impact. We recommend that future studies explore the perspectives of children as key stakeholders in the creation of their digital identity.

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KEYWORDS
digital identity; children; social networking sites; sharenting; scoping review; perspectives
Introduction

Background

Every post made on social networking sites contributes to the development of a digital identity. For some, this occurs naturally through their engagement with social networking sites, and for others, the process is planned or curated. Children and vulnerable populations can be represented on social networking sites without control over the creation of the digital identity developed on their behalf [1-7]. Children’s digital identities are often created before the child is born [8,9]. The creation of a child’s digital identity can start with parents sharing information about their soon-to-be-born or newly born child on social networking sites [3,10-12]. Digital identity development continues beyond the initial post as images, events, and milestones are shared with or without the permission of the child.

One of the major limitations of the literature on children and social networking sites is the underrepresentation of the voice of the younger child. There is little information available on social networking sites and their use and impact on children and even less from the perspective of children [13-16]. The lack of research with children is mainly attributed to the minimum age requirement for a child to register an account. Each social media site and app has its own criteria for minimum age requirements, which range from 13 to 16 years (13 with parental consent). It is common for parents to either post on behalf of their children or post (knowingly or unknowingly to the child) about their children between conception and the age of 8 years [17].

Although literature on the digital identity of children is emerging [8,12,18,19], evidence on the digital identities of adults has grown rapidly over the past 2 decades [20-25]. Despite the increase in the literature that explores adults’ digital identity, the key concepts related to processes and outcomes have not been established [1,20]. Approaches to define digital identity often draw on existing theories, such as the theory of self-presentation by Goffman [26,27]. Goffman [26] describes identity as performative and the world as a stage on which the act is taking place. The performance cannot take place without an audience who is there to validate the social performance [26]. Social networking sites are often seen as a stage in which one is actively trying to manage their impression or performance to be liked by others [28].

Research on adolescents’ digital identity (development) also draws on the theory by Goffman [26] and identity development theories such as the stages of psychosocial development were developed by Erikson [29], the identity status theory by Marcia [30], and the concept of networked publics by Boyd [31]. Identity development theories describe the adolescent years as the most important phase of identity development, and little is theorized about young children’s identity development [20,29,32]. However, Schachter and Ventura [33] argue that identity formation starts before adolescence and that parents play an active role in their children’s identity formation and later identity development. This aligns with the early formation of “digital” identities, which often starts with parents posting about their children on social networking sites.

Objectives

There is limited understanding of the concept of digital identity for young children [21,34]. The purpose of this scoping review was to explore key characteristics in the literature on the concept of digital identity for children from conception to the age of 8 years on social networking sites. The review question was as follows: “What are the key concepts, definitions, and characteristics related to the concept of digital identity as generated through engagement with social networking sites for children from conception to the age of 8 years?”

Methods

Overview

A preliminary search of the Cochrane Database of Systematic Reviews and JBI Evidence Synthesis was conducted, and no current systematic or scoping reviews on the topic were identified. The updated methodological guidance for conducting a Joanna Briggs Institute scoping review was used in tandem with the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) to guide this review [35]. The completed PRISMA-ScR checklist can be found in Multimedia Appendix 1. A scoping review was assessed as the most appropriate method, where the purpose of this review was to identify and clarify concepts [36] regarding the digital identity of children. The scoping review protocol was registered with the Open Science Framework and can be retrieved via the web (see the reference for a link to the protocol) [37].

Search Strategy

Relevant databases were searched using a constructed Boolean strategy with subject headings and keywords to reflect the inclusion criteria (the search strategy can be found in Multimedia Appendix 2). The first search was conducted between July 2022 and September 2022, and the second search was conducted between February 2023 and April 2023. The strategy was developed in conjunction with a specialist librarian. The search strategy, including all identified keywords and index terms, was adapted for each included database or information source. The databases EBSCO, Web of Science, ProQuest ERIC, and Scopus were searched. The reference lists of the included studies were cross-checked with search outcomes to identify studies not previously identified. Gray literature sources such as the National Grey Literature Collection, ProQuest Dissertations and Theses, and Google Scholar (the first 200 results) were also searched to identify unpublished studies.

The search terms were as follows: child OR children OR infant OR toddler OR preschooler (population) AND (digital AND identity) OR “digital identity” OR (online AND profile) OR “online profile” OR (social AND presence) OR “social presence” OR sharenting (concept) AND social media OR Facebook OR Instagram OR Twitter OR Snapchat OR Tumblr OR “social networking” (context).
Inclusion and Exclusion Criteria

Overview

Studies of any research design that included the presentation of findings on digital identity in relation to children from conception to the age of 8 years on social networking sites were included if a full text could be retrieved. The viewpoint within the studies could be of the young person, family, health professionals, peers, and others. Further inclusion criteria were articles that were peer reviewed, written in English, and published between January 2000 and April 2023 inclusive. Gray literature was included if research findings were reported. No restrictions on the inclusion of studies were applied in relation to the geographic location or setting of the studies except for the generation of the data on social networking sites.

Participants

Social media related to children from conception to the age of 8 years was included. Data related to family members who posted about their children were also included.

Concept

The concept explored was digital identity on social networking sites in relation to children from conception to the age of 8 years. This review focused on web presence on social networking sites, and therefore, literature on digital identity that was purely data generated was excluded. Data-generated identities include, for example, log-ins, personal information saved on websites for identification purposes, and data saved while using apps and playing games. This type of digital identity is discussed elsewhere [38].

Types of Sources

This scoping review included both qualitative and quantitative studies. Quantitative study designs including experimental and quasi-experimental study designs, randomized controlled trials, nonrandomized controlled trials, before-and-after studies, interrupted time-series studies, analytical observational studies (prospective and retrospective cohort studies), case-control studies, and analytical cross-sectional studies were considered for inclusion. This review also considered descriptive observational study designs including case series, individual case reports, netnography, and descriptive cross-sectional studies for inclusion.

Screening

Following the search, all identified references were imported into EndNote (version 20.1; Clarivate Analytics) for the identification and removal of duplicates and then exported to the Joanna Briggs Institute System for the Unified Management, Assessment, and Review of Information (Ovid) for a second identification of duplicates and the independent screening of titles and abstracts against the inclusion criteria by 2 reviewers [39]. Any differences between the reviewers regarding the inclusion or exclusion of articles for full-text review were discussed, and if not resolved, they were referred to a third reviewer. The full texts of the retained articles were independently assessed by 2 reviewers. Any differences between the reviewers were discussed and, if not resolved, they were referred to a third reviewer. The reasons for excluding studies at the full-text review stage were recorded. The study selection, screening, and reasons for exclusion at the full-text review stage are reported in the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) diagram [35] in Multimedia Appendix 1.

Charting the Data

Data extraction tables were developed with the team and used to ensure a uniform data extraction process. Data extraction was undertaken by a minimum of 2 reviewers. The selected studies were analyzed to identify the key characteristics, such as study design, aim, country of study, setting and context, participant characteristics (the age and gender of the children and their families), and sample size. Key terms and concepts related to children’s digital identity were identified, and themes and trends were charted. Where required and possible, the authors of the papers were contacted to request missing or additional data for clarification.

Analysis and Presentation of Results

All articles in this scoping review were searched for key terms used in relation to the concept of digital identity. If the term was mentioned ≥2 times, it was included in the count. Key terms were included if they appeared in the main text, titles, abstracts, or keywords but not in references, footnotes, or headers.

Where variations of the term existed, all variations were analyzed as related to the core term. For example, for the core term children’s identities, variations such as children’s identity, child’s identity, the identity of the child, or their (children’s) identity were included. Similarly, variations of sharenting such as oversharing, anti-sharenting, and grand-sharenting [40] were analyzed as related to the core term sharenting.

The search was carried out using the PDF reader Nitro (Nitro Software, Inc), and words were copied and pasted into the search bar to avoid spelling mistakes. The search strategy included terms such as identit to quickly identify all terms related to identity, such as online identity, digital identity, and social identity (identity on its own was not counted).

Data were presented in tabular form, which allows for easy comparison between articles. A graphic was chosen as a way to demonstrate the relationships between key terms. Quantitative and qualitative data were extracted into tables to compare the studies, and qualitative data were sorted into key themes. Key trends are discussed in the Results and Discussion sections.

Results

Overview of Results

The search produced a total of 2573 abstracts, 1764 references from database and register searches, and 809 references from searches using other methods (refer to Multimedia Appendix 1 for the PRISMA flowchart [40]). Of the 1764 references, 652 (36.96%) were identified as duplicates, leaving 1112 (63.04%) references. There were no duplicates in the 809 references from other search methods. After title and abstract reviews were completed on all remaining references, 93.53% (1040/1112) of the articles were excluded from the database references and 99% (801/809) were excluded from the references from other...
search methods. This left 72 articles, of which 1 (1%) was
excluded as there was no way to retrieve the full text and there
were no contact details for the corresponding author [41]. Of
the remaining 71 articles, after the full-text review, 50 (70%)
were excluded, with the most common reasons being ineligible
phenomena of interest (n=20, 40%), age (n=14, 28%), and the
article not being about the child or children (n=8, 16%). This
resulted in 21 articles. An additional hand search in March 2023
and April 2023 identified 7 articles for full-text review, of which
6 (86%) were included and 1 (14%) was excluded as it was not
about the child or children. This resulted in a total of 27 articles
included in this scoping review [7,9,10,17-19,40,42-61].

Characteristics of the Studies

Participants

Overview
The total reported number of participants in this scoping review
was 8643, comprising mothers (n=1768), fathers (n=585),
grandparents (n=1), and participants reported collectively as
parents (n=1841). In total, 4% (1/27) of the articles reported
data from child participants (n=68) [59]. The remaining 4263
participants were not identified further. Overall, more female
participants (n=4158) than male participants (n=1753) were
reported in the articles.

The sample size of the included studies ranged from 1 [18] to
3472 [57] participants. Notably, 30% (8/27) of the articles did
not provide sample characteristics [7,43-45,47,48,52,54]. This
was due to the study context (eg, content analyses of social
networking site posts and photos) [7,43-45,47,48,52,54] and
the nature of the articles, such as books or reviews [54] (Table
1).
<table>
<thead>
<tr>
<th>Study, year</th>
<th>Study aim</th>
<th>Study design</th>
<th>Country</th>
<th>Setting and context</th>
<th>Identity type</th>
<th>Participants</th>
<th>Age</th>
<th>Sex</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ammari et al [19], 2015</td>
<td>To investigate how parents decide what to disclose about their children on SNSs&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Qualitative</td>
<td>United States</td>
<td>Sharearenting and the shared responsibility of parents in managing their children’s online identities</td>
<td>SDI&lt;sup&gt;b&lt;/sup&gt;</td>
<td>102 parents</td>
<td>Data unavailable</td>
<td>Male and female</td>
</tr>
<tr>
<td>Bare [43], 2020</td>
<td>To provide an overview of the images of children being posted to Instagram by parents under the hashtag #letthembelittle</td>
<td>Qualitative</td>
<td>United States</td>
<td>Content analysis of Instagram posts of children with the hashtag #letthembelittle.</td>
<td>SDI and PDI&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Unspecified</td>
<td>Data unavailable</td>
<td>Data unavailable</td>
</tr>
<tr>
<td>Benevento [44], 2022</td>
<td>To understand how photographs shared on social media connect and express values regarding childhood</td>
<td>Narrative inquiry</td>
<td>Not specified</td>
<td>Analyzing Instagram postings and comments on photos of children on 2 hashtags—#let-thekids and #fashionkids</td>
<td>SDI</td>
<td>Not specified</td>
<td>Data unavailable</td>
<td>Data unavailable</td>
</tr>
<tr>
<td>Bezakova et al [45], 2021</td>
<td>To identify the extent of the problem of sharing content on minors with family members on social media (sharearenting), identify legal solutions to the problem, and point out the importance of adequate social mechanisms (media and marketing) to raise awareness of the issue</td>
<td>Analytical-synthetic and comparative research methods</td>
<td>Not specified</td>
<td>Analyzing sharearenting of sensitive data on social media, comments, reviews, blogs, web portals, and emails. Identifying legal solutions to protect children.</td>
<td>SDI</td>
<td>Not specified</td>
<td>Data unavailable</td>
<td>Data unavailable</td>
</tr>
<tr>
<td>Briazu et al [46], 2021</td>
<td>To investigate how the risks and benefits alongside psychosocial variables affected the Facebook sharearenting behavior of mothers of young children</td>
<td>Mixed methods</td>
<td>United Kingdom</td>
<td>Facebook sharearenting behaviors of mothers</td>
<td>SDI</td>
<td>190 mothers of young children</td>
<td>62.6% were aged between 25 and 34 y</td>
<td>Female</td>
</tr>
<tr>
<td>Brosch [10], 2016</td>
<td>To learn about parents’ habits regarding their children on Facebook, especially how much and what kind of information about their children they share</td>
<td>Social media ethnography</td>
<td>Poland</td>
<td>Sharearenting on Facebook. Exponential nondiscriminative snowball recruiting.</td>
<td>SDI</td>
<td>168 parents with a child or children aged &lt;8 y</td>
<td>Data unavailable</td>
<td>Data unavailable</td>
</tr>
<tr>
<td>Choi and Lewallen [47], 2018</td>
<td>To examine how children are represented on Instagram and how children are depicted in relation to traditional stereotypes</td>
<td>Mixed methods</td>
<td>United States</td>
<td>Content analysis of 510 photos of children on Instagram on children’s gender and racial representations on social media</td>
<td>SDI and PDI</td>
<td>Not specified</td>
<td>Data unavailable</td>
<td>Data unavailable</td>
</tr>
<tr>
<td>Study, year</td>
<td>Study aim</td>
<td>Study design</td>
<td>Country</td>
<td>Setting and context</td>
<td>Identity type</td>
<td>Participants</td>
<td>Age</td>
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<tr>
<td>Cino and Dalledonne Vandini [40], 2020</td>
<td>To investigate how boundaries of children’s social media presence are understood and experienced within interacting systems regarding the relationship between MILs and DILs</td>
<td>Literature review and qualitative study</td>
<td>United States</td>
<td>Digital dilemmas on their children’s digital footprints, privacy, and social media presence created by members external to the family, such as the child’s teacher. Analysis of parents’ posts on a BabyCenter community, a web-based parenting forum.</td>
<td>SDI</td>
<td>300 parents</td>
<td>Most were female. Specific data are unavailable.</td>
<td>Data unavailable</td>
</tr>
<tr>
<td>Dobson and Jay [18], 2020</td>
<td>This paper explored the representation of children and family life, with an emphasis on the “image of the child” that exists on Instagram.</td>
<td>Qualitative</td>
<td>Australia</td>
<td>Perspectives and experiences of an influencer parent sharing children’s photos on Instagram</td>
<td>SDI and PDI</td>
<td>1 mother</td>
<td>Data unavailable</td>
<td>Female</td>
</tr>
<tr>
<td>Er et al [48], 2022</td>
<td>To investigate sharenting during the early COVID-19 pandemic and quarantine periods</td>
<td>Qualitative</td>
<td>Turkey</td>
<td>Sharenting during the pandemic and quarantine period. Descriptive content analysis of the Instagram profiles of the parents—401 posts from Instagram</td>
<td>SDI</td>
<td>Unspecified</td>
<td>Data unavailable</td>
<td>Data unavailable</td>
</tr>
<tr>
<td>Fox et al [50], 2022</td>
<td>To explore first-time fathers’ vulnerabilities and decisions to engage in sharenting, especially given that marketers seek to connect with new parents on social media via engagement tactics that prompt sharenting</td>
<td>Mixed methods</td>
<td>United States</td>
<td>First-time fathers’ willingness to sharent on social media and their level of perceived sensitivity to their children’s information. Web-based survey on Amazon Mechanical Turk using Prime Panels and grounded theory.</td>
<td>SDI</td>
<td>75 first-time fathers</td>
<td>Aged 20 to 40 y</td>
<td>Male</td>
</tr>
<tr>
<td>Fox and Hoy [49], 2019</td>
<td>Study 1: to explore mothers’ expressions of vulnerability and how these relations can be linked to their motivations for sharing children’s PII on social media. Study 2: to explore mothers of young children in a Twitter chat and the extent to which they post children’s PII, as well as the mother’s vulnerability.</td>
<td>Mixed methods</td>
<td>United States</td>
<td>Qualitative: interaction of consumer vulnerability of the mother and the reasons and decision to post about their children on social media. Quantitative: interaction of a brand—Carter’s, Inc and Children Apparel—with the engagement of mothers on Twitter.</td>
<td>SDI</td>
<td>Study 1: 15 mothers; study 2: 122 participants</td>
<td>Study 1: aged 24-40 y; study 2: data unavailable</td>
<td>Study 1: female; study 2: data unavailable</td>
</tr>
<tr>
<td>Hashim et al [51], 2021</td>
<td>To investigate the trends, motives, or purposes behind sharenting by Malaysian parents and their awareness (or lack thereof) of its related privacy issues</td>
<td>Qualitative</td>
<td>Malaysia</td>
<td>Mothers’ motives to sharent and the type of content they post frequently and like to update their status with or post on social media</td>
<td>SDI</td>
<td>40 mothers</td>
<td>52.5% were aged between 31 and 40 y</td>
<td>Data unavailable</td>
</tr>
<tr>
<td>Holiday et al [52], 2022</td>
<td>To identify how parents self-present in their sharenting posts</td>
<td>Qualitative</td>
<td>United States</td>
<td>Self-representation on Instagram posts about their children</td>
<td>SDI and PDI</td>
<td>Unspecified</td>
<td>Data unavailable</td>
<td>Data unavailable</td>
</tr>
<tr>
<td>Study, year</td>
<td>Study aim</td>
<td>Study design</td>
<td>Country</td>
<td>Setting and context</td>
<td>Identity type</td>
<td>Participants</td>
<td>Age</td>
<td>Sex</td>
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<tr>
<td>Jorge et al [17], 2022</td>
<td>To explore how Cristiano Ronaldo, his partner, and his mother shared information about his children on Instagram between 2018 and 2020</td>
<td>Qualitative</td>
<td>Portugal</td>
<td>Sharenting of a celebrity, Cristiano Ronaldo, and his family members. The digital identity of Cristiano Ronaldo’s children analyzed through sharenting by Ronaldo, his partner, and his mother on Instagram.</td>
<td>SDI and PDI</td>
<td>3 participants (mother, father, and grandmother)</td>
<td>Data unavailable</td>
<td>Data unavailable</td>
</tr>
<tr>
<td>Kopecky et al [53], 2020</td>
<td>To investigate the type of content that parents publish about their children and compare this behavior between Czech and Spanish parents</td>
<td>Quantitative study</td>
<td>Czech Republic and Spain</td>
<td>Comparing sharenting content, extent, and behaviors in 2 countries. The study was conducted on the web (Google Forms distributed through Facebook, Instagram, email, and WhatsApp channels)</td>
<td>SDI</td>
<td>1093 Czech parents and 367 Spanish parents</td>
<td>Czech parents aged 25 to 64 y; Spanish parents aged 21 to 61 y</td>
<td>Men and women</td>
</tr>
<tr>
<td>Kumar and Schoenebeck [9], 2015</td>
<td>To gather mothers’ narratives and experiences about sharing baby photos on Facebook. To show how identity performance allows mothers to enact—and receive validation of—good mothering.</td>
<td>Qualitative study</td>
<td>United States</td>
<td>Attitudes, opinions, and experiences of sharing baby photos on Facebook and mothers’ perceptions of Facebook and other sites</td>
<td>SDI</td>
<td>22 mothers</td>
<td>Aged 25 to 39 y</td>
<td>Female</td>
</tr>
<tr>
<td>Kumar [54], 2021</td>
<td>To investigate how power works through 3 fields of discourse that govern parents’ social media conduct</td>
<td>Review and qualitative study—“thinking with theory” method</td>
<td>United States</td>
<td>Governmentality and parents’ conduct in sharenting</td>
<td>SDI</td>
<td>Unspecified</td>
<td>Data unavailable</td>
<td>Data unavailable</td>
</tr>
<tr>
<td>Latipah et al [55], 2020</td>
<td>To describe the sharenting model by millennial parents as a process of exchanging information between parents in parenting, mentoring, education, and child development</td>
<td>Phenomenological approach</td>
<td>Indonesia</td>
<td>Motives, impact, and ways of sharenting. Interview was completed via the web.</td>
<td>SDI and PDI</td>
<td>10 parents</td>
<td>Aged 24 to 35 y</td>
<td>5 female and 5 male</td>
</tr>
<tr>
<td>Leaver [7], 2020</td>
<td>To investigate how exactly the digital communication and sharing of and by parents about their children can be balanced with children’s rights to privacy both in the present and, more challengingly, in the future</td>
<td>Critical review of parenting practices through examples</td>
<td>Australia</td>
<td>Sharenting children’s sensitive information on Instagram, Facebook, wearables, and apps (Owlet Smart Sock and Peakaboo Moments); web safety; and children’s rights to opt out</td>
<td>SDI and PDI</td>
<td>Unspecified</td>
<td>Data unavailable</td>
<td>Data unavailable</td>
</tr>
<tr>
<td>Marasli et al [56], 2016</td>
<td>To investigate the use frequency and the content of social media sharing and investigate the information a group of parents shared on the web about their children via content analysis</td>
<td>Mixed methods</td>
<td>Turkey</td>
<td>Sharenting on Facebook</td>
<td>SDI</td>
<td>219 parents</td>
<td>41.7% were aged 31 to 40 y</td>
<td>Data unavailable</td>
</tr>
<tr>
<td>Study, year</td>
<td>Study aim</td>
<td>Study design</td>
<td>Country</td>
<td>Setting and context</td>
<td>Identity type</td>
<td>Participants</td>
<td>Age</td>
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<tr>
<td>Mascheroni et al [62], 2023</td>
<td>To investigate the patterns of sharing among a nationally representative sample of parents of children aged 0 to 8 y. To identify the presence of recurrent sharenting styles. To examine the relationship between sharenting styles and parents' sociodemographic information and between sharenting styles and parental practices of privacy management adopted to govern their children's social media presence.</td>
<td>Quantitative</td>
<td>Italy</td>
<td>Sharenting styles, extent of sharenting, and parents' privacy management practices</td>
<td>SDI</td>
<td>1000 Italian parents</td>
<td>Aged 18 to 54 y</td>
<td>Male and female</td>
</tr>
<tr>
<td>Minkus et al [57], 2015</td>
<td>To measure adults’ sharing of children’s PII in web-based social networks, namely, Facebook and Instagram</td>
<td>Mixed methods</td>
<td>United States</td>
<td>Analysis of images shared on Facebook and Instagram</td>
<td>SDI</td>
<td>2383 Facebook users and 1089 Instagram users</td>
<td>≥18 y</td>
<td>Women and men</td>
</tr>
<tr>
<td>Morris [58], 2014</td>
<td>To provide insights into the types of child-related content that mothers of infants and toddlers are willing to share on SNSs</td>
<td>Mixed methods</td>
<td>United States</td>
<td>How mothers of young children use Facebook and Twitter and mothers’ perceptions on the appropriate site on which to share photos of their children. Survey was completed on the web.</td>
<td>SDI</td>
<td>412 mothers</td>
<td>Aged 19 to 46 y</td>
<td>Female</td>
</tr>
<tr>
<td>Sarkadi et al [59], 2020</td>
<td>To investigate children’s thoughts about sharenting</td>
<td>Quantitative</td>
<td>Sweden</td>
<td>Children’s views on sharenting. Survey was completed on the web.</td>
<td>SDI</td>
<td>68 children</td>
<td>Aged 4 to 15 y</td>
<td>Two-thirds were boys, and one-third were girls</td>
</tr>
<tr>
<td>Turgut et al [60], 2021</td>
<td>To investigate what factors affect what parents share on social media about their children</td>
<td>Qualitative study</td>
<td>Turkey</td>
<td>Sharenting and its associated factors and parents’ views on legal liability</td>
<td>SDI</td>
<td>88 parents</td>
<td>Aged 22 to 45 y</td>
<td>Data unavailable</td>
</tr>
<tr>
<td>Wagner and Gasche [61], 2018</td>
<td>To investigate what factors parents consider when disclosing personal information about their children on SNSs and what strategies they apply</td>
<td>Qualitative</td>
<td>Germany and Austria</td>
<td>Parents’ thoughts on drivers and inhibitors of disclosing children’s photos on SNSs</td>
<td>SDI</td>
<td>220 mothers</td>
<td>Data unavailable (mean age 31.1 y)</td>
<td>Data unavailable</td>
</tr>
</tbody>
</table>

aSNS: social networking site.  
bSDI: social digital identity.  
cPDI: performative digital identity.  
dMIL: mother-in-law.  
eDIL: daughter-in-law.  
fPII: personally identifiable information.  

**Study Origin**  
Of the 27 studies, 11 (41%) were conducted in the United States [9,19,40,43,47,49,50,52,57,58], 3 (11%) were conducted in Turkey [48,56,60], and 2 (7%) were conducted in Australia [2,18], followed by 1 (4%) study conducted in both the Czech Republic and Spain [52], 1 (4%) conducted in Germany and Austria [61], and 1 (4%) from each of the following countries:  

https://pediatrics.jmir.org/2024/1/e54414

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the United Kingdom [46], Malaysia [51], Poland [10], Sweden [59], Italy [62], Indonesia [55], and Portugal [17]. The remaining 7% (2/27) of the studies did not name the country of data origin [44,45].

**Context**

The main social networking sites used were Instagram and Facebook. A total of 26% (7/27) of the studies focused on Instagram [17,18,43,44,47,48,52], and 15% (4/27) of the studies focused on Facebook [9,10,46,56]. The remaining studies focused on social media more broadly.

**Study Design**

In total, 48% (13/27) of the studies used a qualitative approach [9,10,17-19,43,44,48,51,52,55,60,61]. A total of 26% (7/27) of the studies used a mixed methods approach [46,47,49,50,56-58]. In total, 11% (3/27) of the studies used a quantitative design [30,53,59]. A total of 7% (2/27) of the studies used both qualitative and literature review methodologies [40,54], and 4% (1/27) of the articles were book chapters [7].

**Key Terms and Concepts Used to Describe Digital Identity**

In this first part of the Results section, we explore key terms and concepts used in relation to the concept of the digital identity of children on social networking sites. We then explore the concept of digital identity in relation to 2 types of behaviors that underpin the development of young children’s digital identity.

**The Key Term Sharenting**

**Overview**

The term sharenting was the most commonly used term in the literature (21/27, 78% of the articles) on the development of children’s digital identities [7,10,17,40,44-54,56,59,60]. Of the 27 studies, 5 (19%) studies discussed the term in more detail and provided a definition of sharenting [40,45,47,49,50]. Bezakova et al [45] explained the term sharenting as “the overuse of social media by parents or legal guardians who share photos or various home videos of minors with the virtual community,” whereas Brosch [10] defined sharenting as “the practice of a parent to regularly use the social media to communicate a lot of detailed information about their child” and drew upon the Collins dictionary definition. All authors appeared to share a similar understanding of the term sharenting. Thus, the definition of sharenting is widely accepted and used frequently in the context of the digital identities of children on social networking sites.

**Digital Footprint**

A total of 48% (13/27) of the articles referred to the concept of digital footprint(s) [7,9,10,19,40,45,46,48,50,53,54,60,62]. The term digital footprints was sometimes used interchangeably with the term digital identity. It often came down to the authors’ preference for wording to describe the creation of digital identities for children. For example, Brosch [10] and Bezakova et al [45] explained that children’s digital footprints are mostly created by parents early in their child’s life, sometimes before or just after the birth of the child or during infancy [10,45]. Brosch [10] further explained that 10.7% of Polish parents in their sample created digital footprints for their unborn children by posting sonogram images, and 8.3% shared photos of the expectant mother on Facebook. As illustrated by this example, the term digital footprints was used synonymously with the term digital identity.

When the risks of sharing children’s content on the web were discussed, the term digital footprints was often chosen. Kumar and Schoenebeck [9] discussed the risk of mothers creating digital footprints for their children in relation to the benefits of receiving validation. Mothers in their study were hesitant and uncertain about how their photo-sharing behavior might affect their children’s online identity later and restricted their sharing to pictures that were cute and funny and showed milestones. Nevertheless, they found that the benefits of receiving validation via shared content outweighed the mothers’ concerns about digital footprints and oversharing. The authors introduced a new term, privacy stewardship, to describe “the responsibility mothers take on as they consider what kinds of baby photos are appropriate to share and the implications for their children’s digital footprint.” In line with this, Cino and Dalledonne Vandini [40] described the pressure and responsibilities of motherhood as mothers are eager to and expected to actively manage their children’s digital footprints. The literature suggests that the management of children’s digital footprints and identities is mostly considered to be the responsibility of parents, especially mothers [7,9,40,62].

**The Use of the Term or Concept of Identity**

The different types of identities that were mentioned in relation to children’s digital identities on social networking sites are discussed in the following sections.

**Children’s Identities**

The term children’s identities or variations of this term (eg, child’s identity) was used in 44% (12/27) of the articles [7,9,17,19,43,44,48,52-54,56]. The term children’s identities was used to represent a broad concept that often encompassed other subterms or concepts related to identity. A total of 26% (7/27) of the articles that included the term children’s identities further discussed the concept of online identity [9,17,19,43,45,53,60], and 15% (4/27) of the articles discussed the term digital identity [17,54,60,62].

**Online Identity**

All articles that used the term online identities discussed how parents were the creators of their children’s identities on the web [9,17,19,43,45,53,60]. Similar to the other concepts related to the digital identity of children, online identity could often be used interchangeably with the term digital identity. However, the context in which online identity was used differed from that in which the other terms were used. Of the 27 studies, 5 (19%) studies discussed children’s online identities in the context of children’s rights and agency over their online identity and the missing consent from children to allow their parents to post about them on the web [17,19,43,45,53].
Digital Identity
The literature did not generate an accepted definition of digital identity; however, some authors briefly discussed the concept and its relationship with sharenting. Kumar [54] linked the concepts of digital identity and sharenting: “sharenting is potent thanks to the concept of a ‘digital identity,’ also called a digital persona, profile, legacy, trail, footprint, or presence” and “Sharenting discourse portrays the creation of a digital identity as a choice, one best left to the child.”

Mascheroni et al [62] also linked the 2 terms by discussing the consequences of sharenting on children’s digital identity: “Generally speaking, almost half of the parents are reportedly aware of the consequences of sharenting for children’s digital identity, but regular sharers show a lower average value, suggesting a lower degree of awareness.”

Jorge et al [17] discussed the term digital identity in more detail by exploring how celebrity sharenting contributes to the construction of children’s digital identities. They found that the parents shared information and photos that aligned with the theme of happy and grateful parenthood and that the family posts represented the children as the extended selves of the father, stepmother, and grandmother.

Thus, there is an understanding that the digital identities are created by parents through sharenting. Here, sharenting is seen as the action (sharing information about the child), and the digital identity is described as the consequence or outcome of the sharenting behavior. Although sharenting was well defined, definitions for children’s digital identity were not provided in the articles.

Other terms or concepts that included the word identity were used less frequently; for example, relational identity was mentioned in 7% (2/27) of the articles, whereas the terms identity performance, mediated identity, private identity, social identity, social media identity, and moral identities only appeared each in 4% (1/27) of the articles. Overall, most articles (19/27, 70%) in this review discussed some form of identity in relation to children’s presence on social networking sites.

Sharenting is the behavior that parents engage in when sharing information about their children on social networking sites. This creates long-lasting digital footprints on the web that form children’s digital identities. The literature has identified a number of risks related to the creation of children’s digital identities on social networking sites, such as digital kidnapping and identity theft, especially if the information that was shared contained personally identifiable information. These areas will be explored in relation to the concept of the digital identity of young children.

Safety: Digital Kidnapping
A total of 11% (3/27) of the articles in this review discussed the concept of digital kidnapping [43,48,51]. The terms identity theft, personally identifiable information, and privacy stewardship were used in 7% (2/27) of the articles in this review [9,46,49-51,54]. The term digital kidnapping is defined as “people who steal a child’s identity and photo on social media and pass the child off as their own” [48]. Digital kidnapping is described as one of the risks of creating digital identities for children by sharing images, especially those that include personal information about the child and reveal the child’s face [43,48]. Hashim et al [51] found that Malaysian mothers were concerned about digital kidnapping and identity theft and, therefore, were conscious of not sharing locations in their posts and actively hid information regarding places and their children’s names and dates of birth.

Children’s Digital Identity as an Extension of Parents’ Digital Identities
A total of 7% (2/27) of the articles discussed the concept of extended self [17,52]. These 2 articles also discussed the term relational identity. In the article by Holiday et al [52], the authors discussed the theory of the “extended self” and applied it to the concept of sharenting. The authors described parents’ engagement in sharenting as fundamental to their identity as parents, which the authors argue says more about the parent as an individual than about the depicted child. Following this thought, sharenting is seen as a form of parents’ self-presentation that includes children as a component in the definition of the self.

Jorge et al [17] also described parents’ representation of children on social networking sites as the extended selves of family members. When children’s digital identities on social networking sites are interpreted as extensions of their parents’ or family members’ identities, parents’ and family members’ identities form part of the child’s digital identity. Accordingly, some articles in this review (4/27, 15%) discussed the digital identity of parents, mothers, and families in relation to the child’s digital identity [9,49,54,62].

Overall, the review of the key term and concepts related to digital identity shows that there is limited research defining key terms such as children’s digital identity and digital footprints, whereas sharenting is a commonly used and widely accepted term that is clearly defined.

Content and Image Analyses
The Development of Social and Performative Digital Identities
The synthesis of the data generated through content and image analyses generated 2 types of digital identity: “social digital identity” and “performative digital identity.” Children’s social digital identity creation involves parents who create their children’s digital identity by sharing information such as everyday activities and milestones without links to commercial products or promotion of their children. Parents’ motivation to create social digital identities for their children is most often to share with family and friends and keep a digital diary [9,10,51,52,54,61], whereas children’s performative digital identity is created when parents promote or market their children, often for their own benefit, for example, to promote their clothes and brands [18,44,52]. This means that parents post information and photos of their children to convey a picture of the child that can deviate from the actual identity of the child. These posts often present the child in a neat and fashionable way and can include links to products that parents obtain a financial share of. For example, “mummy” or fashion bloggers

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(eg, #fashionkids) create performative digital identities for their children that mostly benefit them and often disregard the needs of the child [18,63].

**The Use of Social and Performative Digital Identities in the Literature**

**Overview**

Most articles (18/27, 67%) discussed social digital identities exclusively [9,10,19,40,42,45,46,48-51,53,54,56-58,60,61], whereas 30% (8/27) discussed performative digital identities [7,17,18,43,44,47,52,55]. Social digital identities were mostly created on Facebook or discussed in a social media context in general, whereas performative digital identities were mostly created on Instagram. A summary of the types of posted content is presented in Table 2. The percentages indicate the proportion of articles that discussed the different topics.

**Table 2.** Analysis of posted content related to children on social networking sites (N=27).

<table>
<thead>
<tr>
<th>Content</th>
<th>Total articles, n (%)</th>
<th>Activity or leisure time, n (%)</th>
<th>Events (birthdays or family), n (%)</th>
<th>Posing or influencing making income, n (%)</th>
<th>Developmental stages or milestones, n (%)</th>
<th>Family holidays or outings, n (%)</th>
<th>Embarrassing or cute, n (%)</th>
<th>Face visible, n (%)</th>
<th>Name or DOB, n (%)</th>
<th>Nudity, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social DI&lt;sup&gt;a&lt;/sup&gt;</td>
<td>18 (67)</td>
<td>11 (61)</td>
<td>13 (72)</td>
<td>1 (6)</td>
<td>6 (33)</td>
<td>3 (17)</td>
<td>8 (44)</td>
<td>6 (33)</td>
<td>7 (39)</td>
<td>5 (28)</td>
</tr>
<tr>
<td>Performative DI</td>
<td>8 (30)</td>
<td>7 (88)</td>
<td>2 (25)</td>
<td>6 (75)</td>
<td>1 (12)</td>
<td>1 (12)</td>
<td>2 (25)</td>
<td>3 (38)</td>
<td>2 (25)</td>
<td>3 (38)</td>
</tr>
</tbody>
</table>

<sup>a</sup>DOB: date of birth.

<sup>b</sup>DI: digital identity.

Social digital identities were often created through images of events such as birthdays and family gatherings, whereas most of the studies that demonstrated a performative digital identity (8/27, 30%) included images and descriptions of children posing for photos, and in some cases, the family made an income from these posts [7,17,18,43,44,47,52,55].

In the following sections, we explain what information (including text and photos) parents typically share when creating social and performative digital identities for children and what motivates them to share this information.

**Social Digital Identities**

**What Parents Share When Creating Social Digital Identities for Their Children**

Most studies (10/27, 37%) reported that parents created social digital identities for their children by sharing their happy moments. Brosch [10] found that these happy moments were often recorded during daily life activities, outings, and special events (95.6%). Similarly, most of the mothers in the study by Briazu et al [46] shared information about special days (72.7%) or social activities (52.6%), and some shared information about health (6.7%) or educational issues (5.2%). Brosch [10] found that many parents revealed private information about their children by sharing posts containing images of their children's birthday parties (23.2%), baby videos, birth certificates, kindergarten diplomas, or art (32.7%), as well as sonogram images (10.7%). Information about the child was also shared via posts containing information such as the child’s name and date of birth (48.2%). Brosch [10] also found that some of the posts contained embarrassing photos (eg, nude or seminude pictures of the child during bathing or at the beach), photos in which children were in distress (eg, crying or angry), or photos in which children were covered in food after dinner (eg, chocolate on their faces).

Kopecky et al [53] surveyed parents from the Czech Republic and Spain and found that these parents shared photos of celebrations, family moments, holidays, important milestones, and photos that parents considered to be cute or funny. Most parents reported sharing content in which the child could be identified (by face) but did not include sexual content (81.7%). One-fifth of parents shared photos in which the child was partially exposed to the extent that the identity of the child could be determined. A small proportion (3.5%) of parents from the Czech Republic reported sharing nude photos of their young children.

Er et al [48] investigated sharenting behaviors at the beginning of the COVID-19 pandemic. They found that mothers posted more often than fathers and that most posts contained photos and some contained videos of the children. Of the 226 posts they analyzed, 207 included the children’s faces, with a limited number of parents blurring their children’s faces (n=17). In line with the other studies, the posts were generally happy, for example, expressing the joy of spending time with children and love toward children and showing how children and the family happily played games, cooked, or learned together. The daily lives of the children were also posted, including birthdays, vacations, and anniversaries. A smaller proportion of posts expressed unpleasant situations during the COVID-19 pandemic, such as boredom, complaints, and unhappiness with quarantine.

Cino and Dalledonne Vandini [40] explored the digital identities that are created for children by the mothers’ mothers-in-law and the conflict that this raises with the mothers. The content is either shared before the birth of the child (eg, pregnancy status of the mother, gender reveal, or labor) or afterward (eg, daily life activities) and usually against the will or knowledge of the mother.

Fox et al [50] investigated first-time fathers’ sharenting behavior and found that fathers tried to avoid posting sensitive information (eg, their naked child). However, they did post about everyday activities such as going to the park, playing, birthdays, and firsts (eg, first tooth). Fathers were aware of
security risks and, therefore, hid their children’s faces and names.

Hashim et al [51] found that parents mostly shared social events (eg, vacations, events, family activities, and outings; 29.3%), moments (eg, good, funny, happy, important, or special moments; 25.3%), day-to-day activities (13.3%), memories of their children (12%), school activities (10.6%), food (4%), antics (2.6%), and milestones (2.6%) about their children.

Kumar and Schoenebeck [9] interviewed mothers about their sharenting experiences. Mothers described the photos that they shared about their children as cute and funny and explained that the photos often contained family or friends and developmental milestones of the children.

Marasli et al [56] found that the most common theme parents shared about on Facebook was special days (81.4%), such as birthdays, graduations, and year-end shows, followed by social activities (54.98%) and educational issues (30%). Less commonly shared themes included sports and arts activities (18.96%), play activities (17.54%), health issues (12.8%), and recommendations about products for children and informatics (12.32%). Most parents in this study (63.77%) also reported that they liked sharing pleasant things about their children.

Hashim et al [51] found that the most common theme parents shared about on Facebook was special days (81.4%), such as birthdays, graduations, and year-end shows, followed by social activities (54.98%) and educational issues (30%). Less commonly shared themes included sports and arts activities (18.96%), play activities (17.54%), health issues (12.8%), and recommendations about products for children and informatics (12.32%). Most parents in this study (63.77%) also reported that they liked sharing pleasant things about their children.

Minkus et al [57] used a web-based application programming interface called Face++ to analyze Facebook and Instagram photos. The software identified children via age estimates based on the faces in the photos. Over 25% of the photos on Facebook and 16% of the photos on Instagram with children aged 0 to 7 years had comments that revealed the children’s names, and 2.7% (Facebook) and 5% (Instagram) included the word birthday. The authors were also able to infer the children’s last names from the parents’ last names. Overall, 5.6% of Facebook accounts and 19% of Instagram accounts with child photos revealed the name and date of birth of the children, which is enough information to identify them. By further linking the parents’ Facebook accounts with public records (eg, voter registration records), the authors were also able to identify the address of the parents and children.

Parents’ Motivation to Create Social Digital Identities for Their Children

In this section, we explore mothers’, fathers’, and mothers-in-law’s motivations for creating social digital identities for their children on social networking sites. Briazu et al [46] found that mothers’ motivations or perceived benefits of posting about their children were to build connections, gain practical benefits such as asking for parenting advice, gain emotional benefits (eg, pride and joy from their children), and help others, and some mothers did not identify any benefits.

Fox and Hoy [49] found that the desire to be a “good” mother motivated mothers’ sharenting behavior. Mothers used sharenting as a coping strategy. They shared their experiences as mothers and information about their children to seek affirmation and social support from others. The authors also explored mothers’ motivations not to post about their children. Mothers focused on portraying the “right” image of the child and avoided posts that potentially could have made them look like a “bad” parent. It was also important to mothers in this study that their children would not be upset or embarrassed by their posts later in life.

Kumar and Schoenebeck [9] found that most mothers in their study used Facebook as an archive for their children’s photos. It was important to these mothers to portray their children and themselves in a favorable light and to receive validation and support as mothers.

Wagner and Gasche [61] investigated German and Austrian mothers’ decision-making processes and strategies when sharing about their children. Most mothers indicated that the costs of sharing photos of their children on the web outweighed the benefits, and therefore, more than half of the mothers (60%) never shared photos of their children on social networking sites. The mothers’ main motivation to share was social participation (to inform others, to keep others up to date, and to document the children’s development), followed by showing how proud they are of their children and the need to be liked, approved of, and accepted by others.

Fox et al [50] found that fathers’ motivation to share was not to gain support from others but rather to express humor or spotlight themselves as fathers. Overall, fathers made fewer sharenting decisions, and the main responsibility of sharenting most often lay with the mothers [50].

Hashim et al [51] found that the most common motivation (42.8%) for Malaysian parents to share about their children was to save memories of them. Social networking sites served as an archive or journal for them to refer to at a later stage. The second most common motivator (31.6%) was the desire to share their experiences, information, activities, and feelings about raising children. Other motivations included being influenced by other social media users; staying connected and engaged with others; and motivating, encouraging, and inspiring other parents. In line with this, Turgut et al [60] described parents’ motivation to post about their children as related to keeping in touch with others (eg, relatives and friends) and recording and memorizing their children’s development. Brosch [10] found that the number of Facebook friends was a significant predictor of sharenting.

Cino and Dalledonne Vandini [40] investigated the motivation of mothers-in-law to post about their grandchildren. They reported that grandmothers’ motivation stemmed from a desire to show excitement for the grandchild, which was often at the cost of the parent’s desire for agency over their children’s digital identities. However, it was noted that grandparents might be less knowledgeable about the internet and web safety and are potentially naiver about sharing information about their grandchildren on the web.

Performative Digital Identities

What Parents Share When Creating Performative Digital Identities for Their Children

Posts that contribute to a child’s performative digital identity creation are usually well planned out to present the child in a fashionable or favorable way. Benevento [44] investigated posts with the #letthekids and #fashionkids hashtags. These are often used by parents who create performative digital identities for their children by sharing well-prepared posts that have been

https://pediatrics.jmir.org/2024/1/e54414 JMR Pediatr Parent 2024 | vol. 7 | e54414 | p.169 (page number not for citation purposes)
planned out. The hashtag #letthekids emerged as a counter to the more established hashtag #fashionkids; it stands for “let the kids dress themselves.” The author found that #fashionkids photos often show the child alone during structured activities outdoors. Children are often displayed smiling or with still expressions posing with their possessions (eg, clothing and accessories). The attention is drawn to the child and their outfit rather than the location or activity. The background locations include well-maintained spaces such as parks, backyards, and playgrounds as well as home settings (eg, bedrooms and kitchens). Although children are often presented as posing with a focus on their clothes, these are most often casual.

In contrast, #letthekids photos often show the child during unstructured activities, such as during play, eating in their home environment, or in nature (eg, forest). This hashtag often displays children acting on their own, for example, while playing with their toys in their room, but also sometimes includes family members. The children in the #letthekids hashtag often look away or are shown from behind, as if they are not aware of the photo being taken. Interestingly, #letthekids posters upload more professional photographs than #fashionkids posters and more naked or seminaked pictures of their children than #fashionkids posters [44].

Choi and Lewallen [47] investigated children’s gender representations on Instagram and found that parents posted more about their female children than about their male children and generally presented both their female and male children with positive emotions in white or gender-typical (ie, pink and blue) clothes. Children on Instagram were often displayed as playing or having fun in indoor settings by themselves. Girls were found to be frequently displayed as engaging in fashion.

Holiday et al [52] explored how parents self-presented in their children’s presentation on Instagram. The authors identified 3 presentational categories: polished, promotional, and intimate. Photos in the polished category displayed children as visually appealing and suggested that parents invested time and effort in the post to portray an idealized image of the child. The parents were presented as favorably themselves, with possessions including the child. The attention was often directed toward the parents, not the children (via the text or image). Children in this category served as accessories (eg, in the parents’ arms or on the side of the photo). Parents typically presented themselves as their “ideal self” in this category. The promotion category included posts in which parents used their children to promote their own skills, competencies, services, or products. Finally, the intimate category portrayed children more realistically without perfectioning of the image. With a strong focus on the child in the intimate category, more information is revealed about the child, which adds to the child’s digital identity [52].

Jorge et al [17] explored celebrities’ creation of their children’s digital identities through sharenting. The authors analyzed Cristiano Ronaldo’s family’s sharenting practices and the portrayal of the children as the parents’ extended selves. The results showed that celebrity sharenting contributes to digital identities through the themes of happy and grateful parenthood and the representation of children as the extended selves of the father, stepmother, and grandmother. Finally, Latipah et al [55] found that millennial parents shared content about their children related to everyday activities that are perceived as fun and that are often displayed as esthetically pleasing, with some posts including the promotion of products.

Parents’ Motivation and Motives for Creating Performative Digital Identities for Their Children

Parents who engage in performative digital identity creation for their children have several motives for sharenting. Some parents want to pass on knowledge and educate other parents by providing advice, products, and insights into their daily life activities [18,55], whereas others’ motive is to primarily promote their products or clothes [44,52]. In the promotion category in the study by Holiday et al [52], the motivation behind posting was often to promote products or services to other parents, whereas parents’ motivation in the intimate category was often to preserve memories, which is in line with our findings on the motivation to create social digital identities.

Dobson and Jay [18] found that the motive of their case study was to connect with others as the family lived in a rural area. The mother reported that she had made friendships on the web and that followers empathized with her posts and offered support and a sense of community.

In the study by Latipah et al [54], parents’ motivation to share about their children was to receive affirmation and social support and to demonstrate the ability to care for their children, social participation, and documentation.

The only study that included children as participants could not be classified as either “performative” or “social” digital identity. In this study, children were asked for their opinion on sharenting [58]. Children aged 4 to 15 years indicated that it is not OK for parents to post photos of their children (them) on social networking sites, whereas sending the photos to relatives was more accepted by the children in the study. The lowest (least acceptable) scores were found among the youngest children (aged 4-6 y) in the study. Irrespective of the participants’ age, children wanted to be asked before their parents took or shared photos of them, and they wanted their answers to be listened to.

Discussion

Summary of Principal Findings

Overview

This scoping review identified 27 studies. Participants included mothers and fathers (collectively reported as parents) and grandparents. On the basis of the analysis of the key terms and concepts used in the literature, the following description of how these relate to one another was developed. The creation of a child’s digital identity is developed through the behaviors of parents, most referred to as sharenting. The behavior of parents through the decisions on the web they make creates a digital identity that can be described as social digital identity or performative digital identity. We found that much of the literature on the concept of the digital identity of children reports on parents, especially mothers, and their sharenting behavior on social networking sites. The most used terms related to digital
Identity in the literature are sharenting, followed by digital footprint and children’s identity. The term sharenting is well defined and popular among researchers and the media, whereas the term digital identity was less commonly used. We found that the term digital footprint was more commonly used than digital identity; however, clear definitions were also lacking in the articles in this review. Common across all terms was parents making decisions about what to share about their children, mostly without the children’s consent.

The term digital identity is more commonly used in the literature on adults [20-25,64,65]. However, we expect a rise in the term digital identity in relation to children in the coming years as there has been a steep increase in research that focuses on the consequences and risks of sharenting [50,66,67]. The use of digital identity terms often depends on authors’ preference for words. We found that digital footprints, children’s identity, online identity, and digital identity were used interchangeably by authors. Together with sharenting, these 4 constructs were the most used terms across the articles, suggesting that they are closely related.

Digital Identity Creation: What and Why

We found that most of the content shared by parents was related to social digital identity and included sharing special events such as birthdays and family gatherings, as well as everyday activities and leisure time. In the performative digital identity category, posts also included content about everyday activities and leisure time but with a focus on children who were posing for a photo, with some posts contributing to the posters’ income (eg, influencers). In the performative digital identity category, the motives of some parents were to sell products or promote themselves and their children. The content posted appeared carefully prepared and polished. The literature on the digital identity of children frequently made reference to the concepts of safety on the internet and the rights of the child, and these 2 areas will be explored further with reference to the findings of this review.

Safety Risks: Digital Footprints

Although some awareness among parents of the potential risks of creating digital footprints via sharenting and the creation of their children’s digital identities was noted, there is still uncertainty about the exact impact and consequences of parental sharing behavior. One of the potential risks, digital kidnapping, was considered by some parents; however, the benefits of sharing were described as outweighing the risks of creating digital footprints and identities [9]. The perceived risks of sharenting may differ depending on the parents’ cultural background. For instance, in the study by Wagner and Gasche [61], 60% of German and Austrian mothers reported never having shared a photo of their children on the web. In an Australian study, participants refrained from posting about their children on social media as a strategy for privacy [68]. Other researchers suggest that parents who perceive web-based social networks as a source of support are highly likely to sharent [69,70].

To make an informed decision about whether to share children’s content on the web, parents need to receive information and guidance. Researchers and policy makers have started to develop new policies and guidelines for parents. Although there is a need to update existing policies to reflect the addition of online identities [71-73], the focus of many of these guidelines and policies is on children’s screen time exposure and not on children’s digital identity development or children’s right to their digital identity and footprints [71,74,75]. Therefore, we recommend more rigorous research on parents’ attitudes toward privacy and the factors influencing their sharing of children’s photos and information on the web. Findings from such studies could inform efforts and emerging policies directed at mitigating sharenting behaviors that are associated with web-related risks.

Children’s Rights and Privacy

The process of children’s digital identity creation most often takes place without the child’s permission or input [10,17-19,43,45,52-54,62]. No studies in this review investigated young children’s creation of their own digital identities on social networking sites. A study in this review asked children for their opinion on their parents’ sharenting behavior [59], and very few of the studies in this review (4/27, 15%) addressed the agency of the child [18,19,54,59]. When digital identities are created early for the child without the input of the child, their right to create their own digital footprint or identity is taken away, leaving them without a voice and choice [45,54,60]. Where possible, children should be involved in the development of their digital identity. Research to identify how this can be achieved and to give voice to the experiences of young children is needed to better understand this important and fast-moving area [19]. Future studies should explore the perspectives of children as key stakeholders in the creation of their digital identity [19,76].

Strengths and Limitations

To our knowledge, this is the first scoping review to map out the literature published on the creation of digital identities among young children through social networking sites. We strove to apply rigorous methods to search and select articles and chart the data. Owing to our strict age range exclusion criteria, we did not review articles that discussed the digital identity of children aged ≥9 years on social networking sites. The use of search terms and the selected databases may not have been exhaustive, and the omission of social networking sites such as YouTube is a limitation. The search was only valid up to April 2023. In the same vein, most of the included studies were conducted in the Western world, with only 7% (2/27) of the studies conducted in Asia and none conducted in Africa or South America. The interpretation of the findings should consider this geographical bias.

Conclusions

Digital identities on social networking sites are created when photos and information about a person are shared. The digital identities of children on social networking sites from conception to the age of 8 years are most often created by their parents (without the children’s permission). Children’s digital identities can be grouped into 2 categories: social and performative. Parents use the web environment to capture moments that matter to them while also creating positive narratives around the child’s
The content that is shared for each type of identity and the motivation behind the creation of such identities differ. Research into young children and the digital world has focused on areas such as the effects of screen time and child development and digital safety [77-81]. We urge greater attention to the important area of how the digital identity is created, the impact of this, and how young children can be involved in important decisions that affect their lives.

Acknowledgments
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Data Availability
The data sets generated during and analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest
None declared.

Multimedia Appendix 1
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist and flowchart of the study selection and inclusion process.

Multimedia Appendix 2
Search strategy.

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Abbreviations

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews

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Building a Sustainable Learning Health Care System for Pregnant and Lactating People: Interview Study Among Data Access Providers

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Abstract

Background: In many areas of health care, learning health care systems (LHSs) are seen as promising ways to accelerate research and outcomes for patients by reusing health and research data. For example, considering pregnant and lactating people, for whom there is still a poor evidence base for medication safety and efficacy, an LHS presents an interesting way forward. Combining unique data sources across Europe in an LHS could help clarify how medications affect pregnancy outcomes and lactation exposures. In general, a remaining challenge of data-intensive health research, which is at the core of an LHS, has been obtaining meaningful access to data. These unique data sources, also called data access providers (DAPs), are both public and private organizations and are important stakeholders in the development of a sustainable and ethically responsible LHS. Sustainability is often discussed as a challenge in LHS development. Moreover, DAPs are increasingly expected to move beyond regulatory compliance and are seen as moral agents tasked with upholding ethical principles, such as transparency, trustworthiness, responsibility, and community engagement.

Objective: This study aims to explore the views of people working for DAPs who participate in a public-private partnership to build a sustainable and ethically responsible LHS.

Methods: Using a qualitative interview design, we interviewed 14 people involved in the Innovative Medicines Initiative (IMI) ConcePTION (Continuum of Evidence from Pregnancy Exposures, Reproductive Toxicology and Breastfeeding to Improve Outcomes Now) project, a public-private collaboration with the goal of building an LHS for pregnant and lactating people. The pseudonymized transcripts were analyzed thematically.

Results: A total of 3 themes were identified: opportunities and responsibilities, conditions for participation and commitment, and challenges for a knowledge-generating ecosystem. The respondents generally regarded the collaboration as an opportunity for various reasons beyond the primary goal of generating knowledge about medication safety during pregnancy and lactation. Respondents had different interpretations of responsibility in the context of data-intensive research in a public-private network. Respondents explained that resources (financial and other), scientific output, motivation, agreements collaboration with the pharmaceutical industry, trust, and transparency are important conditions for participating in and committing to the ConcePTION LHS. Respondents also discussed the challenges of an LHS, including the limitations to (real-world) data analyses and governance procedures.

Conclusions: Our respondents were motivated by diverse opportunities to contribute to an LHS for pregnant and lactating people, primarily centered on advancing knowledge on medication safety. Although a shared responsibility for enabling real-world data analyses is acknowledged, their focus remains on their work and contribution to the project rather than on safeguarding
Introduction

Background

In many areas of health care, learning health care systems (LHSs) are seen as a promising method for learning from real-world experiences [1,2]. In an LHS, health care and research are aligned to accelerate research and outcomes for patients and have the potential to develop scientific knowledge based on health information and research data by directly implementing new insights from analyses to the clinical practice [3].

For some patient populations, an LHS approach may be considered one of the most promising ways forward, for example, the group of pregnant and lactating people, who are often excluded from controlled clinical research studies and for whom there is still a poor evidence base for medication safety and efficacy. In real life, numerous medications, which are key to the health of the pregnant person, have been used safely and effectively in pregnancy with minimal risk to the fetus and pregnant person, but we do not systematically learn from these experiences [4-8]. Current information on medications used during pregnancy and lactation is fragmented and spread across different countries and data sources, including pregnancy or medicine cohorts, registries, research groups, and the pharmaceutical industry [9]. Examples of such data sources are the European system for the evaluation of safety of medication use in pregnancy in relation to risk of congenital anomalies (EUROmediCAT), the European Network of Teratology Information Services (ENTIS), and national population registries or regional cohorts. Accessing and analyzing these unique data sources in a system of continuous learning could help more effectively clarify how medications impact pregnancy outcomes.

In general, a remaining challenge of data-intensive health research, which is at the core of an LHS, has been obtaining meaningful access to data. A way to impact the field of pregnancy and lactation is through collaborations between various organizations (including public-public and public-private). These organizations, known as data access providers (DAPs), often possess or have access to vast amounts of routine (health care) data, which reflect routine health care encounters and processes, and they have valuable expertise in managing large data sets. Collaborating with private organizations can also be beneficial, as they also possess relevant data and resources. In addition, private organizations, such as medicines marketing authorization holders, require evidence on the effects of medications during pregnancy to comply with regulatory requirements and to update product information. Public-private partnerships present their own set of challenges, such as ownership, benefits and effectiveness, impact on public interest, and achieving a social license, all of which have been discussed in the literature on public-private partnerships [10,11]. In addition, frequently discussed in the context of LHS development is the challenge of establishing a sustainable collaboration capable of consistently facilitating the processes of data collection, analyses, and dissemination of research results [2,12-14].

At the same time, there is a growing expectation for these DAPs as data controllers and processors to extend their focus beyond regulatory compliance and actively safeguard the privacy and appropriate use of data. The General Data Protection Regulation (GDPR) includes various rules and principles for data controllers to ensure transparency and adherence to principles, such as fairness, purpose limitation, data minimization, accuracy, storage limitation, integrity and confidentiality, and accountability, while granting certain rights to persons whose personal data are being processed (GDPR, Articles 5 and 6) [15]. Ultimately, DAPs are viewed as moral agents who must respect ethical principles such as transparency, trustworthiness, responsibility, and community engagement [16].

To realize a sustainable and ethically responsible LHS, it is important to know whether people working for these organizations acknowledge their role and responsibility in safeguarding the responsible use of data and the dissemination of research outcomes to the public. Rising expectations with respect to DAPs’ responsibility for the ethical use of data and data ownership do not necessarily mean that each of these organizations has a dedicated governance structure to safeguard these principles or that people working for DAPs feel as if they are a moral actor in an LHS. Moreover, apart from the obvious differences in management and reward systems among DAPs [17], these organizations may also have different motivations for collaborating in an LHS. Furthermore, their perspectives on the sustainability of an LHS and their roles once the project phase concludes may also diverge.

Objectives

In this study, we aimed to explore the views of people working for DAPs who participate in public-private partnerships to build a sustainable LHS. We were especially interested in the views of DAPs contributing to the Innovative Medicines Initiative (IMI) ConcePTION (Continuum of Evidence from Pregnancy Exposures, Reproductive Toxicology and Breastfeeding to Improve Outcomes Now) project, which aims to build an LHS for pregnant and lactating people [18]. Using a qualitative interview design, we hoped to identify, better understand, and juxtapose people’s views and interests in collaborating in an ecosystem that uses routine health data to generate new knowledge for pregnant and lactating people and their doctors. By providing insight into the views and interests of people representing DAPs in this particular LHS, this study intends to inform a governance framework for LHSs and, in turn, to help
facilitate the development of a sustainable LHS in which public and private organizations collaborate. Moreover, this study aims to contribute to the ongoing discourse on moral responsibilities associated with responsible data handling and dissemination of research findings, particularly by exploring whether DAPs themselves perceive and articulate this moral responsibility.

**Methods**

**Design**

We conducted a qualitative study to collect the views and interests of people who work for organizations and who act as a DAP in the Conception project. This qualitative interview study is a substudy of the IMI Conception project (Textbox 1). IMI Conception was used as the primary case study during the interviews and as the source for participation selection. The study was reported following the COREQ (Consolidated Criteria for Reporting Qualitative Research) [19]. We conducted semi-structured interviews with a topic list (refer to the general topic list in Textbox 2). The topic list was based on the topic list used for another qualitative interview study, in which we asked women during preconception, pregnancy, and nursing what they thought about an LHS for pregnant and lactating women [20]. The topic list was also based on an analysis of the challenges of public-private partnerships, LHSs, and responsible data sharing [1,10,21], as well as discussions among the research team. To mitigate the potential for socially desirable responses from our respondents, it was determined that the topic of moral responsibility regarding the use of data and the dissemination of research findings would not be included in the general topic list. Instead, an opportunity for spontaneous or organic discussion of the topic was provided during the course of the interview. Moreover, it was expected to be, for example, discussed under topic 2: “expertise and dual roles.” This topic provided an opportunity for DAPs to elucidate their roles and responsibilities concerning their primary organization; their involvement in the Conception consortium; and in certain instances, their clinical obligations.

Textbox 1. Description of the initiation, aim, and composition of the Innovative Medicines Initiative (IMI) Conception (Continuum of Evidence from Pregnancy Exposures, Reproductive Toxicology and Breastfeeding to Improve Outcomes Now) project.

In April 2019, the IMI Conception project was launched, which aims to establish a trusted ecosystem that can efficiently, systematically, and in an ethically responsible manner generate and disseminate reliable evidence-based information regarding the effects of medications used during pregnancy and breastfeeding to women and their health care providers. The Conception consortium consists of European public and private stakeholders, including national public health institutes, the European systems for the evaluation of safety of medication use in pregnancy in relation to risk of congenital anomalies (EUROmediCAT), the European Network of Teratology Information Services (ENTIS), research institutes, universities, and pharmaceutical companies. The Conception consortium is currently a public-private partnership; however, the approach of Conception to collect and learn from real-world data on the safety of medicines during pregnancy and breastfeeding is similar to what may also be called a learning health care system [6].

Sample and Setting

To capture a wide range of interests and perspectives (contrast maximization), a variety of people from different types of organizations and different countries were identified. We aimed to include people working as DAPs in partnering organizations and third parties in the Conception project. To be able to invite people working for different DAPs, we distinguished between private (pharmaceutical companies and private centers) and public organizations (universities, teratology information centers, public health services, and hospitals), countries, regions, collaborative partnerships, and occupations. Respondents were recruited using purposeful sampling with the help of colleagues from the Conception consortium. The respondents were approached via email. Most of the interviews started with an introductory question related to the work of the respondent and the process of data collection, storage, and analysis within their organization. We then used the topic list to continue with the interview. Although the approach of Conception is similar to that of an LHS, we used the terms ecosystem and network interchangeably. This is because the term ecosystem is commonly used within the consortium and is more familiar to the respondents. The interviewer (MJH) created a safe space for respondents and invited them to share their views and experiences by emphasizing (1) the privacy and confidentiality arrangements, (2) their autonomy during the interview (eg, regarding answering questions, stopping the interview, and asking for clarification), and (3) the option to review the transcript before analysis. These points were emphasized by the interviewer before seeking verbal consent. The interview allowed respondents to introduce or emphasize new issues that they considered relevant. Therefore, it is important to emphasize that the results reflect personal views and do not represent the views of the entire organization for which the respondents work.

Textbox 2. General topic list used during the qualitative study to guide the interviews.

**Topic list**

- Willingness to participate
- Expertise and dual role
- Future (after consortium agreement ends)
- Conditions for working for the Conception (Continuum of Evidence from Pregnancy Exposures, Reproductive Toxicology and Breastfeeding to Improve Outcomes Now) learning health care system
- Added value
### Data Collection

The interviews were conducted by MJH (trained qualitative researcher, female) using the topic list. The topic list was refined after 2 pilot interviews. Furthermore, according to the technique of constant comparative analysis, the interview topics evolved as the interviews progressed alongside data analysis [22]. Data were collected from November 2021 to February 2022. The interviews were conducted in English and Dutch and took place via a secure communication platform. The interviews took 33 to 60 minutes, with an average duration of 43.8 (SD 75) minutes. In 12 out of 14 interviews, there had been no previous contact between the interviewer and the respondent. In 2 out of 14 interviews, the interviewer and the respondent had contacted each other before for project-related work. During and after the interview, MJH made notes to enhance the data and to provide a clear context for data analysis. The interviews were audiotaped, transcribed verbatim, coded, and stored anonymously. Verbal consent was obtained from all the respondents. One respondent requested to read the transcript before analysis.

### Data Analysis

After transcription, we analyzed the interviews according to the thematic analysis method and by using a backward and forward approach between data collection and analysis to develop codes [22]. An initial coding list was developed based on the topic list. Subsequently, the transcripts were coded. The coding list was evaluated and adapted, and all interviews were coded using NVivo 12 software (Lumivero). To enhance the validity of our results, an intern (medical student, Bachelor of Science) also read and coded 8 randomly chosen interviews out of 14 pseudonymized interviews to check for consistency of the thematic framework and critically read the coding list. In the course of the analysis, codes were adapted, and additional codes were added to the coding list where necessary. A meaning pattern was identified across the data set, leading to the formulation of interpretative higher-order themes. The themes capture the views and interests of the DAPs regarding the ConcePTION ecosystem. The themes represent both topics that were often discussed by respondents and a variety of views that are helpful in the development of a sustainable ecosystem of continuous learning. The findings, including the coding list and formulated higher-order themes, were discussed by the complete research team (MJH, RvdG, MCJMS, and JJMvD). Thematic saturation was reached when additional data did not lead to any new emergent themes after 14 interviews [23]. Furthermore, a member check was executed during the last phase of data analysis. A draft version of the manuscript was sent to all respondents, inviting them to provide feedback and discuss the accuracy and interpretation of our results [24].

### Ethical Considerations

The research protocol, including the procedure for obtaining informed consent, was reviewed by the institutional research support office at UMC Utrecht. As no intervention was imposed on the participants, this study was exempt from ethics review under the Dutch law. All participants were provided with a letter of information and gave their verbal consent for participation and recording as required under the Dutch law that implements the GDPR (uitvoeringswet algemene verordening gegevensbescherming). Each participant was assigned a study ID number to protect their privacy and confidentiality. Furthermore, their names, the names of their workplace, and other names of the consortium members mentioned in the interviews were redacted by the interviewer MJH. The participants were not compensated for participating in the study.

### Results

#### Overview

Of the 23 DAPs that were approached, 14 agreed to participate in the study, 4 declined, and 5 did not respond. A total of 14 semistructured interviews were conducted with 18 people involved in IMI ConcePTION. A total of 2 DAPs were represented by 2 employees of the same organization or research collaboration. The interview respondents worked in different organizations, including universities, public health centers, hospitals, teratology information centers, pharmaceutical companies, and private centers. Table 1 shows the respondents’ characteristics. We could not share all details to ensure the privacy of the respondents.

Because of the constant comparative analysis during the qualitative study, we enhanced our interview guide. During the first couple of interviews, the subject of (moral) responsibility was not (always) organically discussed. Therefore, we added to the second topic “expertise and dual roles,” the possibility of asking DAPs directly about their sense of responsibility and to whom that responsibility was directed, if relevant. We still decided to leave the answers open and not steer too much in the direction of the sense of moral responsibility regarding the use of health data and dissemination of research findings to avoid socially desirable answers.

On the basis of the interviews, we formulated 3 main themes characterizing the views and reflections of DAPs on the development of a knowledge-generating ecosystem for pregnant and lactating people. These themes emerged consistently across all interviews. We provide representative quotations to illustrate these themes (Table 2).
Table 1. List of characteristics of the respondents, categorized based on the respondent number, type of organization, whether it is a public or private organization, and the general location of the organization.

<table>
<thead>
<tr>
<th>Respondent number</th>
<th>Type of organization</th>
<th>Public or private organization</th>
<th>General location of the organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>R01</td>
<td>University</td>
<td>Public</td>
<td>Southern Europe</td>
</tr>
<tr>
<td>R02</td>
<td>Research institute</td>
<td>Public</td>
<td>Southern Europe</td>
</tr>
<tr>
<td>R03</td>
<td>Pharmacoepidemiologic research institute</td>
<td>Public</td>
<td>Central Europe</td>
</tr>
<tr>
<td>R04</td>
<td>Research institute</td>
<td>Public</td>
<td>Northwestern Europe</td>
</tr>
<tr>
<td>R05</td>
<td>Hospital</td>
<td>Public</td>
<td>Central Europe</td>
</tr>
<tr>
<td>R06</td>
<td>University</td>
<td>Public</td>
<td>Northern Europe</td>
</tr>
<tr>
<td>R07</td>
<td>University</td>
<td>Public</td>
<td>Western Europe</td>
</tr>
<tr>
<td>R08</td>
<td>Pharmaceutical company</td>
<td>Private</td>
<td>Central Europe</td>
</tr>
<tr>
<td>R09</td>
<td>Public health service</td>
<td>Public</td>
<td>Middle East</td>
</tr>
<tr>
<td>R10</td>
<td>Pharmaceutical company</td>
<td>Private</td>
<td>Western Europe</td>
</tr>
<tr>
<td>R11</td>
<td>University</td>
<td>Public</td>
<td>Northwestern Europe</td>
</tr>
<tr>
<td>R12</td>
<td>Hospital</td>
<td>Public</td>
<td>Northwestern Europe</td>
</tr>
<tr>
<td>R13</td>
<td>Health center</td>
<td>Private</td>
<td>Middle East</td>
</tr>
<tr>
<td>R14</td>
<td>University</td>
<td>Public</td>
<td>Northwestern Europe</td>
</tr>
</tbody>
</table>
### Theme 1: Opportunity and Responsibility

<table>
<thead>
<tr>
<th>Quotation and respondent number</th>
<th>Representative quotations (Q) from the respondents (R) used to illustrate the identified themes.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Theme 1:</strong> opportunity and responsibility</td>
<td>“It was another opportunity for us to exchange data on a wider basis. ...share with one another might be an interesting experience.” [R09]</td>
</tr>
<tr>
<td>Q1</td>
<td>“The first thing to remember, is that we want to be important. We want to continue being bold. Because at the end, it’s big; ConcePTION. It has a lot of power. We want to be there. Not for, only for some type, scientific purposes. But the main one is, to include our data.” [R02]</td>
</tr>
<tr>
<td>Q2</td>
<td>“Think it’s two things. One is we feel the obligation, because we have a large database, so it’s a moral obligation I think—or we think. And the other one is also because we like working in this team.” [R03]</td>
</tr>
<tr>
<td>Q3</td>
<td>“I’m excited to be in this field, because you can help people improve their health whether it’s women or children, doing this study, or in other types of study we do. I’m not sure I’d use the word responsible in that context, but definitely it’s a motivating factor.” [R14]</td>
</tr>
<tr>
<td>Q4</td>
<td>“Then we would have some safeguards that we are the ones who say ‘Yes, this data can be used,’ or the results. We have obligations to the data providers; we need that these are full in. So the problem is if we have like one day to review the results and then something is published, we will kind of have problems with our obligations.” [R03]</td>
</tr>
<tr>
<td>Q5</td>
<td>“To be sure that at least we have one [person] working on this. And that it is a very stable income. Because otherwise we are looking for the calls [tenders] and running for them. And yeah, it takes a lot of time, and when we spend time on this, we don’t spend time on thinking about the research we’re performing.” [R07]</td>
</tr>
<tr>
<td>Q6</td>
<td>“We are a research institute, and we get evaluated every seven years, and we are measured on publications mostly. So, research is a value for us and publications is important for us, and especially also first and last authorships. So we need to focus our resources on getting some publications.” [R03]</td>
</tr>
<tr>
<td>Q7</td>
<td>“There needs to be some rules, an agreement about our participation and how much pharma can affect the processes and how much pharma can receive from this and every package actually, so it should be in some agreement written down.” [R13]</td>
</tr>
<tr>
<td>Q8</td>
<td>“What I would want is to have more time to discuss things like double programming and also to decide like decisions implicitly made.” [R03]</td>
</tr>
<tr>
<td>Q9</td>
<td>“In many countries that are strict data privacy rules and when for a given observation, there are like less than four observations, the results are masked. …that means that I cannot use the data when combining data from several studies. So one thing that I think would be beneficial is to see if there would be data privacy rules that would be lifted for pregnancy studies.” [R08]</td>
</tr>
<tr>
<td>Q10</td>
<td>“So, but it’s a big assumption. Because academia is involved, you know, …taking care of [the governance; the data privacy]. And …they will handle the trust part. I trust them or [when academia] are taking the lead in this project, I’m like: ‘okay I think they will take care of everything.’ …They [academic partners] are extra careful, and that extra carefulness is making collaborating complex and difficult.” [R10]</td>
</tr>
<tr>
<td>Q11</td>
<td>“But here one of the biggest questions is the sustainability. So how this platform will be, I’m saying platform and it’s not the exact quote, but how this platform will be sustained after ConcePTION.” [R08]</td>
</tr>
<tr>
<td>Q12</td>
<td>“In the end, you’re going to need a person who understands the data and to analyze [the data] how is the meaning of the data? Because if you are, at the end, just a numbers situation. You are not thinking about this biological play. Classical or not. Or if it makes sense with your kind of population.” [R02]</td>
</tr>
<tr>
<td>Q13</td>
<td>“In [In] the end, you’re going to need a person who understands the data and to analyze [the data] how is the meaning of the data? Because if you are, at the end, just a numbers situation. You are not thinking about this biological play. Classical or not. Or if it makes sense with your kind of population.” [R02]</td>
</tr>
</tbody>
</table>

### Theme 2: conditions for participation and commitment

<table>
<thead>
<tr>
<th>Quotation and respondent number</th>
<th>Representative quotations (Q) from the respondents (R) used to illustrate the identified themes.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Theme 2:</strong> conditions for participation and commitment</td>
<td>“In [In] the end, you’re going to need a person who understands the data and to analyze [the data] how is the meaning of the data? Because if you are, at the end, just a numbers situation. You are not thinking about this biological play. Classical or not. Or if it makes sense with your kind of population.” [R02]</td>
</tr>
<tr>
<td>Q14</td>
<td>“In [In] the end, you’re going to need a person who understands the data and to analyze [the data] how is the meaning of the data? Because if you are, at the end, just a numbers situation. You are not thinking about this biological play. Classical or not. Or if it makes sense with your kind of population.” [R02]</td>
</tr>
<tr>
<td>Q15</td>
<td>“In [In] the end, you’re going to need a person who understands the data and to analyze [the data] how is the meaning of the data? Because if you are, at the end, just a numbers situation. You are not thinking about this biological play. Classical or not. Or if it makes sense with your kind of population.” [R02]</td>
</tr>
</tbody>
</table>

### Theme 3: challenges for a knowledge-generating ecosystem

<table>
<thead>
<tr>
<th>Quotation and respondent number</th>
<th>Representative quotations (Q) from the respondents (R) used to illustrate the identified themes.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Theme 3:</strong> challenges for a knowledge-generating ecosystem</td>
<td>“In [In] the end, you’re going to need a person who understands the data and to analyze [the data] how is the meaning of the data? Because if you are, at the end, just a numbers situation. You are not thinking about this biological play. Classical or not. Or if it makes sense with your kind of population.” [R02]</td>
</tr>
<tr>
<td>Q16</td>
<td>“In [In] the end, you’re going to need a person who understands the data and to analyze [the data] how is the meaning of the data? Because if you are, at the end, just a numbers situation. You are not thinking about this biological play. Classical or not. Or if it makes sense with your kind of population.” [R02]</td>
</tr>
<tr>
<td>Q17</td>
<td>“In [In] the end, you’re going to need a person who understands the data and to analyze [the data] how is the meaning of the data? Because if you are, at the end, just a numbers situation. You are not thinking about this biological play. Classical or not. Or if it makes sense with your kind of population.” [R02]</td>
</tr>
</tbody>
</table>
Besides articulating a responsibility toward pregnant and lactating people, their offspring, and their doctors, the respondents of the private industry also explained that they need to generate knowledge because it is a requirement from the European Medicines Agency and Food and Drug Administration. As they are required to research medication safety among pregnant people, this was considered to be another type of obligation and, with that, a different type of willingness to participate.

A few respondents also expressed feeling a responsibility for enabling research and the quality of the data analyses, and because of that, they wanted to be involved in the decision-making regarding the development and testing of analytical scripts within the research ecosystem.

Finally, 1 respondent also mentioned their responsibility and obligations toward other data providers. Some organizations receive data from other organizations, such as health insurance providers. Because of these obligations, they wanted to remain in control of some of the review processes in terms of data programming and analyses (quotation 5). However, challenges in this regard were also discussed stemming from time and financial constraints as well as short research deadlines. None of the respondents discussed their role as data controllers, which involves the responsibility to determine the purpose and manner in which personal data are processed.

**Theme 2: Conditions for Participation and Commitment**

Respondents explained that their willingness to collaborate within the ConcePTION LHS depends on certain conditions that need to be in place.

**Resources and Support**

In all interviews, financial resources were discussed as an important condition. Interestingly, financial resources were mentioned as important for reasons beyond the immediate need to cover resource costs associated with participation in a project. Financial resources were discussed in the following ways: (1) as a stable flow of income, preferably contracted for an extended period and covering all the planned activities, and (2) as a source of funding. A stable flow of income is beneficial for attracting and training more employees in this area of work and will help with distributing tasks and becoming more specialized and efficient in the field of pharmacoepidemiology. Agreements on financial support are also necessary for planning and being less dependent on other sources to keep "the system running" (ie, tendering; quotation 6). Regarding sources of funding, some respondents specifically stated that they cannot receive funding from the private industry. They believe that because they are independent (public) institutions, there would be a conflict of interest.

Other respondents mentioned that besides financial resources, they also need IT and computational resources to perform the actual analyses and to ensure that they can keep up with the heavy computational work, which is necessary for sustaining the data analyses.

Some respondents mentioned that they are not used to writing certain types of protocols or experience challenges when receiving ethics approval for studies. Some respondents suggested that ConcePTION could benefit from having a permanent staff to provide support and address questions about timelines, deadlines, funding, ethics, and events.

**Scientific Output and Motivation**

The importance of scientific output was emphasized during the interviews. Some respondents worked in academic institutions whose aim was to produce scientific publications (quotation 7). Therefore, their willingness to participate in an ecosystem is also affected by whether they get to perform and design studies within the ConcePTION LHS and publish the results in scientific journals. Some respondents also emphasized the need to ask more scientific questions and implement more scientific methods within the network. They mentioned that working within the ConcePTION ecosystem should be different from tendering for projects from pharmaceutical companies. Finally, respondents also wanted to feel motivated to commit to the ConcePTION ecosystem. According to them, motivation is stimulated in different ways, but most importantly, by scientific interest in the project, autonomy regarding work, respect for expertise, and good working relationships. A few respondents also emphasized the importance of offering valuable and easily accessible knowledge to pregnant and lactating people as well as health care providers as a prerequisite for contributing to the ecosystem. They felt that generating valuable information for these stakeholders is the most important goal of an ecosystem such as ConcePTION.

**Safeguards**

Safeguards were also mentioned as a condition for working for the ConcePTION ecosystem. A few respondents were hesitant regarding the role of the pharmaceutical industry in the processes of formulating research questions, cowriting protocols, and analyzing results (quotation 8). According to them, industry involvement could conflict with the primary goal of the research, or they considered it challenging to align the goals of private and public industries. Other respondents, who worked for pharmaceutical companies, regretted this view and argued that collaboration is very much needed and possible because of independently determined regulations that govern both public and private organization research into the effects of medicines.

They stressed that trust and open-mindedness toward each other are important for a good collaboration. Another safeguard mentioned by some respondents was related to transparency. They argued that in a large network and with a developing ecosystem, it is important to be able to track every step and decision made regarding techniques and methods. One respondent explained how several decisions are made in the process of data analyses, which can influence the quality and value of the results (quotation 9). A few respondents also mentioned that to safeguard the quality of data analyses, especially in the developmental phase of the ecosystem, decisions about technical aspects such as programming and writing scripts for analyses need to be transparent for all DAPs. In this way, DAPs can perform their own quality checks, if desired, and provide valuable feedback.
Theme 3: Challenges for a Knowledge-Generating Ecosystem

When asked about their perspective on the development of a knowledge-generating ecosystem, respondents talked about the challenges they have experienced thus far and which, according to them, are relevant when building the ecosystem.

Data (Is Not Information)

Some respondents explained that there were challenges in harmonizing the databases and executing studies because of the heterogeneity of the data across all databases. Some respondents also mentioned that it may be challenging to generate reliable information based on such heterogenic data, databases, and IT systems. Most importantly, data are not (yet) information or knowledge. To overcome this challenge, respondents discussed 3 types of solutions. First, to be able to interpret data and develop valuable information, many respondents emphasized the need to involve experts who know the data and the real-life health care context of the persons whose personal data are being processed and data points represented in the different data sets (quotation 10). Second, respondents mentioned the need for security and quality assessments to ensure that analytic scripts fit the data and are run correctly at every organization. Third, a few respondents preferred to work in small teams so that they could exchange experiences with scripts, data analyses, and research questions. According to them, working in small teams creates a better overview of the possibilities and limitations of data.

Governance

Some respondents experienced challenges owing to governance procedures. On the one hand, it was mentioned that these procedures are challenging because countries have different data privacy rules, which sometimes complicate the ability to perform observational studies (quotation 11). On the other hand, it was mentioned that these procedures are challenging because their own company or organization restricts certain (research) activities. Some respondents argued that in academia, people exert extreme caution regarding governance, which creates an additional barrier to collecting, sharing, and analyzing data. One respondent assumed that the involvement of academic institutions in the consortium implies that matters such as data handling, privacy and confidentiality, and trust were adequately addressed. However, according to the respondent, this also led to an increase in bureaucratic steps, making collaboration more intricate and challenging (quotation 12). Furthermore, respondents agreed that having fragmented governance procedures led to slow processes and unfulfilled opportunities. According to these respondents, a clear overview of what can be done with the data could be of great help.

Concerning governance, some respondents discussed the need for trust between all collaborators, especially regarding the aim of the ecosystem and methods used within the ecosystem. It was also mentioned that people need to trust the decisions made by people taking a more leading role in the ecosystem and that trust between the public and private participants is necessary to ensure that robust knowledge is going to be generated transparently within the ecosystem. Finally, many respondents emphasized the need for a good sustainability model for the ConcePTION LHS (quotation 13).

Discussion

Principal Findings

The results of our analysis indicate that respondents felt responsible to participate in an LHS for pregnant and lactating people. Although respondents emphasized the professional opportunities that come with participating in a large public-private partnership, many respondents collaborated because they wanted to help develop an ecosystem that can transform real-world data into new knowledge on medication safety and efficacy.

Moral Responsibility

From our interviews, it seems that people mainly reflect upon their views and responsibilities from the perspective of their professional role as a data analyst or pharmacoepidemiologist. As a result, most answers were linked to the more technical side of realizing a system in which real-world data can be used, together with a sense of moral responsibility toward the quality of their data, databases, and data analyses (under theme 1 and as mentioned in quotation 5). On the one hand, technological responses are not surprising because of the expertise of our respondents. On the other hand, our respondents work at the core of data processing and analysis, which means that their role is also to handle the data ethically. Some respondents mentioned that they assume that compliance with rules and regulations is being taken care of by other departments of their organization or other people within the LHS, and therefore, they did not worry so much about the ethical handling of data. However, compliance with rules and regulations is a narrow understanding of handling data ethically because it often solely refers to protecting the privacy and confidentiality of persons whose personal data are being processed—an aspect extensively discussed in the interviews and sometimes perceived as a complicating factor for research. Although many respondents viewed contributing to ConcePTION as an opportunity to generate new information for pregnant and lactating people, there appears to be a lack of widespread moral responsibility toward handling data from the perspective of pregnant and lactating people. Some respondents also considered pregnant and lactating people themselves to be disconnected from the work they are responsible for. However, during the member check, some respondents expressed that they did not feel accurately represented in the portrayal of their views on this topic. For them, it was important to recognize that they feel responsible for contributing to the ConcePTION project [25].

Trust and Transparency

Interestingly, trust and transparency were discussed as important aspects of the relationship between the participating organizations. Respondents explained that trust and open-mindedness are important conditions for working toward a common data model and getting everyone to share the same vision for the LHS. In the literature on public-private partnerships, big data research, and data-intensive research in health care, trust is also often mentioned as a crucial principle.
for effective collaboration [10,26,27]. During the interviews, there was hesitancy among respondents about the prospects of public-private collaboration. Some respondents mentioned that they believe they are officially constrained by their institution to closely collaborate with the pharmaceutical industry or cannot share any data (pseudonymized or not) with the pharmaceutical industry. This constraint challenges the effectiveness of the collaboration and, as a result, might complicate the development of a sustainable LHS as a public-private partnership. Interestingly, the ConcePTION project currently operates as a consortium under a consortium agreement, making reference to the European Network of Centers for Pharmacoepidemiology and Pharmacovigilance code of conduct (2010) [28]. The European Network of Centers for Pharmacoepidemiology and Pharmacovigilance code of conduct aims to maximize transparency and promote scientific independence. Furthermore, a consortium agreement typically addresses the issues of a conflict of interest by making agreements on ownership and intellectual property, obligations and rights of the participating parties, and third-party agreements. It seems that although many of the concerns of our respondents are addressed in the consortium agreement, they are not aware of these arrangements or they still experience dilemmas regarding the collaboration and their own interests, which can lead to a continued lack of trust between the public and private industries. It might be worthwhile to close this gap between the consortium agreements and the experiences of collaborators by ensuring that everyone understands the consortium structure. In the literature on large research consortia, it has been argued that transparency is important for realizing an appropriate governance framework for these types of complex collaborations. Here, transparency refers to the accessibility and visibility of the governance structures. For example, within a consortium, good governance requires that those internal or external to the project know what governance structures and procedures are in place, what mechanisms for legitimate decision-making have been adopted, and where the authority and responsibility for different types of actions are located in the consortium [17]. Our interviews underline the importance of transparency in the context of governance of an LHS with public and private organizations. One solution is the installation of a separate independent body, especially when the contractual agreement of the consortium has ended. Some scholars have suggested a Data Access Committee that can help protect persons whose personal data are being processed from foreseeable harm, stimulate social value, and mandate clear lines of accountability, terms of reference, and membership [29].

Public Trust

The above-described perceptions of trust are of course important; however, both the literature and our previous interview study with women during preconception, pregnancy, and nursing show that public trust is also of crucial importance for the development of an LHS [20]. In the literature, it is emphasized that it is important to meet the public expectations for transparency when developing an LHS, which in turn will strengthen or maintain trust in not only the LHS but also the institutions working within the LHS [26]. People anticipate that their voluntary contribution of data will be used to enhance the care for others and they expect that their good faith will not be taken advantage of. Therefore, much depends on the extent to which uses of personal data are seen as serving the public interest and conducted by those with a public interest orientation. It is of great importance that in an LHS, public interest is considered to realize transparency, increase responsibility, and earn the trust of the public. Interestingly, some of our respondents seem to expect that others in their organization are taking care of these principles that are important for public trust or are, again, not fully aware of the governance and arrangements within the organization or the collaboration.

Future of an LHS for Pregnant and Lactating People

Many respondents viewed the ability to conduct scientific research within a broader context as a crucial opportunity. Engaging with a diverse range of organizations can not only enhance the quality of data analyses but also improve the integrity of individual databases. Although research is essential in a knowledge-generating ecosystem, the implementation of research within the health care system is equally important. Respondents affiliated with academic institutions emphasized the significance of publishing new findings in scientific journals, as this is a key aspect of their professional responsibilities. In an LHS, it is imperative to move beyond the conventional practice of publishing primarily in scientific journals and instead prioritize the ethical integration of learning within the delivery of care [30]. This approach would allow for the continuous improvement of care through the application of new insights, while also ensuring the proper management of data. Pharmaceutical companies have already applied this method to a certain extent by generating evidence and translating findings onto product labels and educational materials for health care providers. Perhaps, the dissemination of new insights is an area in which these parties should work together and learn from each other. As LHSs mature, it is crucial that all stakeholders recognize and embrace the system’s necessity and value, extending beyond the project phase to include patients, physicians, scientists, institutional boards, pharmaceutical companies, governments, and other relevant parties.

Limitations

Our study had several limitations. First, we have tried to purposefully include both public and private industry partners; however, we have received more responses from people working in public organizations. Thus, we were not able to include people working in the eastern part of Europe, which challenges the generalizability of our findings, as Eastern European organizations might reflect a different culture and attitude toward an LHS. Second, although we wanted to avoid socially desirable responses, the topic of moral responsibility regarding data handling was not always organically discussed during the interviews. To address this topic, the interviewer directly asked some respondents about their sense of responsibility for specific aspects of their work. Openly discussing the topic could have influenced the initial position of the respondent. We would also like to emphasize that we spoke to individuals who represent their organization in the context of the consortium; however, they do not represent the views of their organizations. Therefore, their views were subjective and might differ from those of other

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(page number not for citation purposes)
people working in the same organization. It would be interesting to understand the views of DAPs outside the context of pregnancy. As mentioned in the Introduction section, in many areas of health care, LHSs are seen as a promising way to learn from real-world data. To establish a successful LHS, more research is needed on the perspectives of the stakeholders involved.

Conclusions
To conclude, people working for DAPs have different reasons for contributing to a project such as IMI ConcePTION, which aims to build an LHS for pregnant and lactating people. The most common motivation was opportunity. The opportunities included creating knowledge on medication safety during pregnancy, examining medication safety in the European context, collaborating with and learning from other experts, stimulating scientific research, presenting their database, and securing financial support. Although many respondents expressed a responsibility to enable real-world data analyses, their focus was primarily on their work and contribution to the project rather than safeguarding ethical data handling from the perspective of pregnant and lactating people. The results of our interviews underline the importance of a transparent governance structure that addresses decision-making processes, authority, responsibility, and accountability. Trust is crucial for the success and sustainability of a public-private LHS, relying on the relationship between DAPs and public trust. For an LHS, it is essential that all relevant stakeholders recognize and embrace the need for and added value of the system itself.

Acknowledgments
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Data Availability
The data sets generated and analyzed during this study are not publicly available because individual privacy could be compromised. In addition, no permission was obtained from the participants for public availability. The data set is available from the corresponding author (MJH) upon reasonable request.

Authors' Contributions
MJH, RvdG, MC, and MCJMS were responsible for the concept and design of the study. MJH was responsible for recruiting participants. MJH was responsible for data collection, initial drafting of the manuscript, and conducting the thematic analysis, to which RvdG, MCJMS, and JJMvD provided substantial input along the way. RvdG, MCJMS, MC, and JJMvD revised the manuscript critically. All authors approved the final version of the manuscript.

Conflicts of Interest
MCJMS is leading a department that conducts regulatory-required research for COVID-19 vaccine manufacturers based on the European Network of Centers for Pharmacoepidemiology and Pharmacovigilance code of conduct and is the project coordinator of Innovative Medicines Initiative ConcePTION (Continuum of Evidence from Pregnancy Exposures, Reproductive Toxicology and Breastfeeding to Improve Outcomes Now).

References


Abbreviations

ConcePTION: Continuum of Evidence from Pregnancy Exposures, Reproductive Toxicology and Breastfeeding to Improve Outcomes Now
COREQ: Consolidated Criteria for Reporting Qualitative Research
DAP: data access provider
ENTIS: European Network of Teratology Information Services
GDPR: General Data Protection Regulation
IMI: Innovative Medicines Initiative
LHS: learning health care system
Mobile App/Web Platform for Monitoring Food Oral Immunotherapy in Children: Longitudinal Clinical Validation Study

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Abstract

Background: Milk and egg allergies significantly impact the quality of life, particularly in children. In this regard, food oral immunotherapy (OIT) has emerged as an effective treatment option; however, the occurrence of frequent adverse reactions poses a challenge, necessitating close monitoring during treatment.

Objective: This study aims to evaluate the ability of a new mobile/web app called OITcontrol to monitor milk and egg OIT.

Methods: Patients undergoing milk or egg OIT were recruited and divided into 2 groups: the active group used the OITcontrol app in conjunction with standard written monitoring methods, whereas the control group relied solely on written diaries. Investigators documented hospital doses, hospital reactions, and administered treatments on the website. Patients recorded their daily allergen home-dose intake, home reactions, and administered treatments using the app. The following variables were compared between both groups: number and severity of hospital and reported home reactions, patient’s adhesion to the OITcontrol app or written diary or both in terms of daily home-dose intake and home reactions recording, and treatment and dose adjustment compliance at home in case of reaction.

Results: Sixteen patients were assigned to be monitored using the OITcontrol app along with additional written methods (active group), while 14 patients relied solely on a written paper diary (control group). A similar distribution was observed in terms of sex, age, basal characteristics, allergen treated in OIT, premedication, and sensitization profile. Active patients reported a comparable number of hospital and home reactions compared with the control group. In terms of recording system usage, 13/16 (81%) active patients used the OITcontrol app, while 10/14 (71%) control patients relied on the written diary. Among active patients, 6/16 (38%) used both methods, and 1 active patient used only written methods. However, control patients recorded home reactions more frequently than active patients ($P=.009$). Among active patients, the app was the preferred method for recording reactions (59/86, 69%), compared with the written diary (15/86, 17%) or both methods (12/86, 14%; $P<.001$). Treatment compliance in home-recorded reactions was similar between both groups ($P=.15$). However, treatment indications after an adverse reaction were more frequently followed ($P=.04$) in reactions recorded solely in the app (36/59, 61%) than in the written diary (29/71, 41%) or both systems (4/12, 33%). Moreover, compliance with dose adjustments after a moderate-severe reaction in home-recorded reactions was higher in the active group than in the control group ($P<.001$). Home reactions recorded only in the app (16/19,
Food allergies are increasingly prevalent worldwide, particularly within the European population [1]. Children, in particular, often experience allergies to common foods such as eggs and milk, which can lead to severe reactions [2]. Notably, these allergies constitute a significant factor in causing anaphylaxis during early childhood [3]. Research indicates that approximately 50% of children with allergies naturally outgrow their milk and egg allergies. However, a substantial number of patients do not experience spontaneous resolution of these allergies [4,5]. The prevailing method for treating food allergies involves the complete avoidance of the allergen. However, with milk and egg allergies, which are found in numerous everyday foods, steering clear of the allergen is challenging. Consequently, over 20% of children and adolescents who experience anaphylaxis are already aware of the allergen, necessitating avoidance [3]. Indeed, food allergies in children significantly impact the quality of life for parents and caregivers, particularly in terms of the self-management of the condition [6].

Oral immunotherapy (OIT) for food, involving the oral administration of allergens to induce tolerance, has proven to be an effective treatment for persistent food allergies in children, despite the occurrence of frequent adverse reactions [7-9]. In typical OIT protocols, incremental doses of the allergenic food are administered in a hospital setting, and once tolerated, these doses are continued daily at home. This daily allergen consumption continues until the target food dose is reached, marking the completion of the buildup phase [10]. Subsequently, the established target dose is maintained at home to sustain the acquired tolerance, marking the beginning of the maintenance phase. Although most reactions typically occur during the hospital-based buildup phase, it is noteworthy that reactions can also manifest during the maintenance phase, after home dose intake [11,12]. Patients undergo education on avoiding potential cofactors and managing potential reactions at home [13]. Furthermore, it is crucial to adjust the prescribed allergen dose in the event of a reaction [14] or if patients are experiencing an intermittent disease [10]. This information, along with specific treatment guidelines for addressing reactions at home, is typically conveyed verbally and in writing to caregivers and patients undergoing OIT treatment. Indeed, the management of OIT necessitates vigilant oversight both from the medical staff during hospital-based doses and from patients and their families during home-based doses.

Certain studies have reported an enhancement in the quality of life for patients treated with OIT at the culmination of the buildup phase [15-19]. However, contrasting findings exist, with some studies demonstrating no discernible differences [20] and others even describing a decline in the quality of life for certain patients following OIT treatment [21]. It has been suggested that the absence of improvement in quality of life after OIT could be linked to the numerous hospital visits required during the up-dosing phase [22] and the frequent occurrence of adverse reactions [23].

To assist patients in managing home doses and provide targeted information in conjunction with OIT treatment, a web platform designed for health staff and a hybrid mobile app for patients, named OITcontrol (University of Navarra, Pamplona, Spain), have been developed. OITcontrol enables medical staff to record doses and reactions in the hospital, and caregivers/patients can use it to log information regarding doses and reactions while at home. OITcontrol serves as a reminder for the timing and administration instructions for daily home doses. Additionally, it provides guidance on specific treatments following a reaction and offers evidence-based dose adjustment instructions through dedicated algorithms [24-26].

The objective of this study was to assess the effectiveness of the OITcontrol app in monitoring patients undergoing food OIT treatment, with a focus on (1) evaluating its capability to document adverse reactions occurring at home, and (2) examining patient adherence to specific recommendations regarding home adverse reactions, including prescribed treatment and adjustments for the next day’s dose.

**Methods**

**Study Population**

This study was conducted in Spain, specifically at the Hospital Universitario Donostia in Donostia-San Sebastián and Hospital Ramón y Cajal in Madrid. The participants were patients aged either 2 years and older for those diagnosed with milk allergy or between 5 and 18 years old for those diagnosed with egg allergy. The diagnosis was established through immunoglobulin E (IgE)–derived clinical history and positive skin prick tests, IgE sensitization to the allergenic food, or both. These patients were invited to undergo OIT treatment in accordance with the
Spanish OIT guidelines [10], with the study period spanning from April 2019 to April 2021. Parents of patients or their legally authorized representatives, and in the case of a mature minor, the children themselves, were provided with comprehensive information regarding the risks and benefits associated with the OIT treatment. Those patients who opted for OIT and reported the use of smartphones were extended an invitation to participate in the study. The participants were monitored until they completed the OIT buildup phase or until the predetermined conclusion of the study in April 2021.

Ethics Approval

Before participation, written informed consent was acquired from all involved patients, adhering to the prevailing ethical-legal regulations, as outlined in the Helsinki Declaration. The study protocol received approval from the ethics committees of all participating hospitals (2018.199 University of Navarra; PI2017053, Euskadi; Hospital Universitario Ramón y Cajal).

Allergy Diagnosis

For patients undergoing milk or egg OIT, a skin prick test was conducted using commercial extracts of milk, alpha-lactalbumin, beta-lactoglobulin, and casein for milk allergy, whereas white and yolk egg, ovomucoid, and ovalbumin were used for evaluating egg allergy. Measurements of wheal and flare sizes were taken 15 minutes after the test, and wheals with a diameter equal to or greater than 3 mm were deemed positive [27]. The determination of specific IgE levels for the entire extract (milk or white and yolk egg) and its components (alpha-lactalbumin, beta-lactoglobulin, and casein for milk or ovomucoid and ovalbumin for egg) was conducted using fluorescence enzyme immunoassay with ImmunoCAP (Thermo Fisher). Specific IgE values equal to or exceeding 0.35 kUA/L were classified as positive.

Food OIT Treatment Protocols

Patients underwent treatment with initially grouped dosing schedules at the hospital, in accordance with the Spanish OIT guidelines [14]. Subsequently, weekly increments in hospital doses were administered. The allergen dose that was tolerated at the hospital was then maintained daily at home between hospital visits. For milk OIT, ultra-high temperature milk was used until, whenever feasible, the final dose of 200 ml milk was reached. For egg OIT, the process involved the use of lyophilized egg white powder (ovo-des; Cantabria Labs Nutrición Médica), pasteurized egg white, or boiled whole egg until the target of 4000 mg of egg white powder, 30 ml of pasteurized liquid egg white, or 1 boiled whole egg was achieved, respectively, where possible [14].

Intervention

Before commencing OIT, patients were consecutively recruited, ensuring a balanced distribution between the control group (PaperPRO group) and the active group (OITcontrol group). The medical staff provided oral and written general recommendations to all patients and caregivers (referred to as patients hereafter). All patients were given detailed explanations and written instructions regarding various aspects, including how to administer the allergen dose, a list of cofactors to avoid, guidelines for treating different types of home reactions, and instructions for dose adjustment following a moderate/severe reaction or in the presence of altered basal conditions (axillary fever of ≥38°C, asthma, or gastroenteritis; Figure 1) [8-10]. Patients underwent training to manage home reactions, which included the use of specific medication tailored to each type of reaction (Table S1 Multimedia Appendix 1) [24]. Furthermore, within the category of severe reactions, written recommendations for patients outlined 2 additional severe reactions: anaphylaxis, which was considered when 2 or more symptoms distinct from oral allergy syndrome (OAS) were reported, and anaphylaxis with bronchospasm, when bronchospasm was one of the symptoms accompanying anaphylaxis. For these scenarios, prescriptions of epinephrine and a combination of epinephrine and bronchodilator (salbutamol) were provided, respectively. The term “anaphylaxis” is used in the “Results” section to describe an anaphylactic reaction, irrespective of the presence of bronchospasm. The severity of reactions was categorized based on Sampson’s severity classification into mild, moderate, and severe reactions [28].

Patients were instructed to maintain a daily record of the allergen dose taken and any reactions experienced, noting the type of reaction and the administered treatment, in a paper-based diary as part of patient-reported outcomes (PaperPRO). Furthermore, individuals in the active group were provided training on the utilization of the OITcontrol app on their smartphones to document home doses and reactions. These patients were also encouraged to concurrently use the written diary (OITcontrol group).
OITcontrol App

OITcontrol is a mobile app designed for patients, available on Google Play (Google LLC) or Apple Store (Apple Inc.) [29], and a website for health staff [30], accessible through 3 distinct user interfaces: (1) The doctor’s interface for prescribing allergen and rescue treatment, accessible as a website platform recommended for use on a computer; (2) the interface for nurses or health personnel responsible for administering food/medication doses, accessible as a website platform intended for use on a tablet; and (3) the patient interface, available as a mobile app, accessible exclusively through the log-in credentials provided by the doctor (Figure 2).

Within OITcontrol, when a doctor prescribes an OIT treatment for a patient, the app allows for the prescription of allergen dose increases, scheduled step rises following the OIT protocol, and outlines home/hospital treatment procedures in the event of a reaction (doctor’s credentials are necessary for access). Once the treatment commences, the app provides daily reminders for the patient’s dose, indicates the observation time, and incorporates an algorithm outlining actions and treatments to be used in the case of a home reaction, contingent on the type of reaction [24] (Table S1 Multimedia Appendix 1). Each symptom is associated with a specific indication in the app. In addition, the app computes 2 additional severe reactions: anaphylaxis, identified when 2 or more symptoms distinct from OAS are reported, and anaphylaxis with bronchospasm, recognized when anaphylaxis occurs alongside symptoms of bronchospasm, mirroring the written recommendations. The app provides general recommendations on how to take the daily dose, including guidance on avoiding cofactors, taking the dose at a consistent time, and the need for observation and rest after dose intake. These recommendations align with those provided in writing to every patient.

The platform/app is designed to retain the last tolerated allergen dose on a daily basis. It does not automatically prescribe increases in allergen dose. However, it is programmed to automatically decrease the dose in 2 specific situations:

- When the basal condition is linked to a reaction, such as in the presence of gastroenteritis, fever, or an asthma attack, the app automatically decreases the dose to half of the scheduled amount [8,10].
- In the event of a moderate/severe reaction, the app adjusts the dose for the next day [8,26] (Figure 1).

OITcontrol facilitates guiding the patient through home treatment and enables medical staff to closely monitor the patient, even when they are at home.

For the health staff, OITcontrol serves several functions:

- It accumulates the complete OIT history of the patient, including protocol modifications, allergen doses linked to reactions, and cofactors involved in reactions. This information is provided by the patient at home and by the health staff during hospital visits. These data are accessible in real-time, constituting an electronic data capture system.
- It serves as an electronic prescription tool for drugs and allergen doses, allowing doctors to prescribe electronically.
- It sends real-time notifications about the patient’s reactions. In the case of a severe reaction, a second notification is dispatched via email.
- It facilitates the management of hospital dose administrations, covering both the multiple-dose initial phase and the unique-dose weekly increase. It generates a summary of the hospital visit, which can be integrated into any digital history system. The app allows for the export of structured text containing patient-specific data for seamless integration.
- It conducts an anonymous analysis of clinical data from hospital patients, considering factors such as the type of reactions, age, sex, and assigned protocol.
Data Collection

The OIT buildup phase was organized into weekly hospital visits with interhospital home doses. Investigators documented hospital doses, the type of reactions that occurred during hospital visits, and the administered treatment. At home, all patients were encouraged to record daily outcomes in a written diary, including the amount of the daily allergen dose taken, instances of reactions, the type of symptoms experienced, and the treatment administered. Moreover, active patients were encouraged to use the OITcontrol app to document comparable information. The use of the OITcontrol app or a written diary was deemed effective when at least five consecutive home doses had been registered or when 1 reaction had been recorded during the follow-up. The medical staff documented the information in the digital clinical history regarding home dose intakes and home reactions reported verbally by the patients during weekly hospital visits.
Users’ Satisfaction Questionnaire

An anonymous electronic satisfaction questionnaire regarding the use of the OITcontrol app was distributed to the initial 10 patients in the OITcontrol group. Additionally, 11 previous patients were included in the survey to verify the correct performance and use of the app before initiating the validation study. These participants were recruited from both the Hospital Universitario Donostia in Donostia-San Sebastián and Hospital Ramón y Cajal in Madrid. The same questionnaire was administered after the first and fourth week of app use. The questionnaire included a few demographic questions and inquired about the general impression of the app, the assessment of texts and screens, and the evaluation of terminology. The respondents provided ratings on a scale ranging from 1 (poor) to 5 (good) or from 1 (poor) to 9 (good) for the 22 items included in the questionnaire.

Statistical Analysis

The distribution of variables was assessed for normality using the Shapiro-Wilk test. Normally distributed quantitative values were presented as mean and SD, while nonnormally distributed quantitative values were described as medians and IQRs (Q1-Q3). Qualitative values were reported as frequencies (percentages). Proportions were compared using the chi-square test or Fisher exact test when the expected frequencies were below 5. Quantitative variables were analyzed using the Student t test or Mann-Whitney U test based on normality. The clinical statistical analysis was conducted using Stata IC 12.0 (StataCorp LLC). Differences with a P value <.05 were considered statistically significant.

Results

Baseline Characteristics of the Sample

Thirty participants were enrolled in the study, with 16 patients monitored using both written methods and the OITcontrol app (ie, the OITcontrol group) and 14 patients monitored solely through a written paper diary (ie, the PaperPRO group). A comparable distribution was observed concerning sex, age, basal characteristics (bronchial asthma/previous anaphylaxis with OIT food), the allergen used in OIT, premedication, and sensitization profile (Table 1).

No significant differences (P=.07) were observed in terms of follow-up time between PaperPRO patients (median 146.5 days, Q1-Q3 98-213 days) and OITcontrol patients (median 196.5 days, Q1-Q3 147.5-336.5 days). However, it is worth noting that 5/14 (36%) PaperPRO patients and 13/16 (81%) OITcontrol patients (P=.01) underwent OIT treatment during the COVID-19 pandemic. In fact, a similar number of hospital dose increases were observed between PaperPRO patients (mean 9.9, SD 6.4) and OITcontrol patients (mean 14, SD 9.5; P=.18). Likewise, the number of home OIT days was comparable between the PaperPRO group (median 128, Q1-Q3 89-192) and the OITcontrol group (median 167.5, Q1-Q3 135-287.5; P=.11).
Table 1. Baseline characteristics of the sample.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>PaperPRO group (n=14)</th>
<th>OITcontrol group (n=16)</th>
<th>P value</th>
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<tr>
<td>Female, n (%)</td>
<td>5 (36)</td>
<td>10 (63)</td>
<td>.14</td>
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<td>Age (years), mean (SD)</td>
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<td>7.6 (3.7)</td>
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<td>5 (36)</td>
<td>7 (44)</td>
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<td>Previous anaphylaxis with OIT(^a) allergen, n (%)</td>
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<td>13 (81)</td>
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<td>8 (50)</td>
<td>.70</td>
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<td>.70</td>
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<td>Omalizumab premedication, n (%)</td>
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<td>1 (6)</td>
<td>.92</td>
</tr>
<tr>
<td>Total immunoglobulin E value (kU/L), median (Q1-Q3)(^b)</td>
<td>494.5 (120-858)</td>
<td>258 (87-931)</td>
<td>.57</td>
</tr>
<tr>
<td><strong>In egg OIT patients</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OIT with egg, n (%)</td>
<td>8 (57)</td>
<td>8 (50)</td>
<td>.70</td>
</tr>
<tr>
<td><strong>Specific immunoglobulin E (kUA/L), median (Q1-Q3)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Egg white</td>
<td>7.7 (2.2-13.8)</td>
<td>9 (5.7-16.2)</td>
<td>.56</td>
</tr>
<tr>
<td>Egg yolk</td>
<td>1.9 (0.5-4.4)</td>
<td>3 (1.1-7.6)</td>
<td>.40</td>
</tr>
<tr>
<td>Ovalbumin</td>
<td>4 (0.6-8.8)</td>
<td>4.9 (1.4-9)</td>
<td>.67</td>
</tr>
<tr>
<td>Ovomucoid</td>
<td>4.1 (0.5-14.1)</td>
<td>8.1 (4.5-17.3)</td>
<td>.21</td>
</tr>
<tr>
<td><strong>Prick test diameter (mm), median (Q1-Q3)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Egg white</td>
<td>7 (3-9.7)</td>
<td>8 (6-5-11)</td>
<td>.46</td>
</tr>
<tr>
<td>Egg yolk</td>
<td>5 (2.2-7.5)</td>
<td>6.5 (3-8)</td>
<td>.67</td>
</tr>
<tr>
<td>Ovalbumin</td>
<td>6.2 (2.7-10)</td>
<td>9 (6-10)</td>
<td>.53</td>
</tr>
<tr>
<td>Ovomucoid</td>
<td>5.5 (4.2-9.7)</td>
<td>9.5 (7-15)</td>
<td>.19</td>
</tr>
<tr>
<td><strong>In milk OIT patients</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OIT with milk, n (%)</td>
<td>6 (43)</td>
<td>8 (50)</td>
<td>.70</td>
</tr>
<tr>
<td><strong>Specific immunoglobulin E (kUA/L), median (Q1-Q3)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Milk</td>
<td>5.9 (3.9-7.8)</td>
<td>8.6 (3.8-19.8)</td>
<td>.70</td>
</tr>
<tr>
<td>Alpha-lactalbumin</td>
<td>1.1 (0.4-3.2)</td>
<td>0.4 (0.1-9.8)</td>
<td>.30</td>
</tr>
<tr>
<td>Beta-lactoglobulin</td>
<td>0.7 (0.4-1.4)</td>
<td>0.5 (0.2-0.9)</td>
<td>.52</td>
</tr>
<tr>
<td>Casein</td>
<td>3.7 (1.6-9.4)</td>
<td>2.8 (0.8-13.6)</td>
<td>.56</td>
</tr>
<tr>
<td><strong>Prick test diameter (mm), median (Q1-Q3)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Milk</td>
<td>4.7 (3-5)</td>
<td>4.7 (3.5-10.2)</td>
<td>.56</td>
</tr>
<tr>
<td>Alpha-lactalbumin</td>
<td>5.5 (4.5-6)</td>
<td>3 (0-7)</td>
<td>.49</td>
</tr>
<tr>
<td>Beta-lactoglobulin</td>
<td>6.7 (5.5-9.5)</td>
<td>7 (3.5-9.2)</td>
<td>.43</td>
</tr>
<tr>
<td>Casein</td>
<td>7.5 (3-9)</td>
<td>3.7 (1-12)</td>
<td>.56</td>
</tr>
</tbody>
</table>

\(^a\)OIT: oral immunotherapy.

\(^b\)Q1-Q3: first quartile-third quartile.

**OIT Adverse Reactions**

PaperPRO patients experienced 5 hospital reactions, while OITcontrol patients experienced 19 hospital reactions. Table 2 summarizes hospital reactions. In the PaperPRO group, the 5 hospital reactions were experienced by 5 different patients (1 reaction per patient), whereas in the active group, the 19 reactions were experienced by only 3 patients (the first patient had 1 reaction, the second had 3 reactions, and the third had 15 reactions). No differences were observed regarding the number of hospital reactions per patient, the number of hospital reactions per hospital dose given, the type of reactions, or the severity of the reactions between both groups of patients.

Concerning home reactions, PaperPRO patients reported 56 home reactions, while OITcontrol patients reported 97 home reactions (P=.70). Table 3 summarizes home reactions. More than one-half of all patients included in the study (19/30, 63%)...
experienced a home reaction. Globally, only moderate home reactions were more frequently reported by PaperPRO patients than OITcontrol patients ($P=.047$). However, no differences were observed regarding the specific type of reaction between both groups of patients.

**Table 2.** Hospital reactions.

<table>
<thead>
<tr>
<th>Reactions</th>
<th>PaperPRO group (n=14)</th>
<th>OITcontrol group (n=16)</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital reactions, n</td>
<td>5</td>
<td>19</td>
<td>.45</td>
</tr>
<tr>
<td>Hospital reaction/hospital visit, median (Q1-Q3$^a$)</td>
<td>0 (0-0.1)</td>
<td>0 (0-0)</td>
<td>.18</td>
</tr>
<tr>
<td>Patients with hospital reactions, n (%)</td>
<td>5 (36)</td>
<td>3 (19)</td>
<td>.29</td>
</tr>
<tr>
<td>Hospital reaction/patient, median (Q1-Q3)</td>
<td>0 (0-1)</td>
<td>0 (0-0)</td>
<td>.45</td>
</tr>
</tbody>
</table>

**Type of hospital reaction**

- **Mild reactions, reactions (affected patients), n**
  - Mild OAS$^b$
    - Relevant OAS (lip edema/perioral urticaria)
    - Facial urticaria/angioedema
    - Mild gastrointestinal symptoms
  - 2 (2) vs. 5 (2), $P> .99$
  - 0 (0) vs. 1 (1), $P=.35$
  - 1 (1) vs. 2 (1), $P=.96$
  - 1 (1) vs. 0 (0), $P=.29$
  - 0 (0) vs. 2 (1), $P=.35$

- **Moderate reactions, reactions (affected patients), n**
  - Acute generalized urticaria
    - 1 (1) vs. 1 (1), $P=.92$
  - Rhinoconjunctivitis
    - 2 (2) vs. 6 (1), $P=.52$
  - 3 (3) vs. 7 (1), $P=.31$

- **Severe reactions, reactions (affected patients), n**
  - Severe gastrointestinal symptoms
    - 0 (0) vs. 7 (2), $P=.18$
    - 0 (0) vs. 1 (1), $P=.35$
    - 0 (0) vs. 3 (1), $P=.35$
  - Bronchospasm
    - 0 (0) vs. 3 (1), $P=.35$
  - Anaphylaxis
    - 0 (0) vs. 0 (0), $P>.99$
  - Anaphylactic shock
    - 0 (0) vs. 0 (0), $P>.99$

$^a$Q1-Q3, first quartile-third quartile.

$^b$OAS: oral allergy syndrome.
Table 3. Reported home reactions.

<table>
<thead>
<tr>
<th>Reactions reported</th>
<th>PaperPRO group (n=14)</th>
<th>OITcontrol group (n=16)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home reactions, n</td>
<td>56</td>
<td>97</td>
<td>.70</td>
</tr>
<tr>
<td>Home reactions/home doses, median (Q1-Q3)</td>
<td>0 (0-0.06)</td>
<td>0 (0-0.07)</td>
<td>.76</td>
</tr>
<tr>
<td>Patients with home reactions, n (%)</td>
<td>9 (64)</td>
<td>10 (63)</td>
<td>.12</td>
</tr>
<tr>
<td>Home reactions/patient, median (Q1-Q3)</td>
<td>3 (0-5)</td>
<td>2.5 (0-11.5)</td>
<td>.70</td>
</tr>
<tr>
<td>Mild reactions, reactions (affected patients), n</td>
<td>38 (6)</td>
<td>73 (8)</td>
<td>.53</td>
</tr>
<tr>
<td>Mild OAS(^b)</td>
<td>12 (3)</td>
<td>37 (7)</td>
<td>.17</td>
</tr>
<tr>
<td>Relevant OAS (lip edema/perioral urticaria)</td>
<td>11 (3)</td>
<td>6 (4)</td>
<td>.95</td>
</tr>
<tr>
<td>Facial urticaria/angiœdema</td>
<td>7 (3)</td>
<td>3 (3)</td>
<td>.72</td>
</tr>
<tr>
<td>Mild gastrointestinal symptoms</td>
<td>8 (3)</td>
<td>27 (5)</td>
<td>.47</td>
</tr>
<tr>
<td>Moderate reactions, reactions (affected patients), n</td>
<td>13 (6)</td>
<td>2 (2)</td>
<td>.047</td>
</tr>
<tr>
<td>Acute generalized urticaria</td>
<td>3 (3)</td>
<td>1 (1)</td>
<td>.23</td>
</tr>
<tr>
<td>Rhinoconjunctivitis</td>
<td>10 (4)</td>
<td>1 (1)</td>
<td>.09</td>
</tr>
<tr>
<td>Severe reactions, reactions (affected patients), n</td>
<td>5 (3)</td>
<td>22 (6)</td>
<td>.21</td>
</tr>
<tr>
<td>Severe gastrointestinal symptoms</td>
<td>1 (1)</td>
<td>8 (3)</td>
<td>.32</td>
</tr>
<tr>
<td>Oropharyngeal discomfort</td>
<td>3 (2)</td>
<td>9 (4)</td>
<td>.42</td>
</tr>
<tr>
<td>Bronchospasm</td>
<td>1 (1)</td>
<td>0 (0)</td>
<td>.28</td>
</tr>
<tr>
<td>Anaphylaxis</td>
<td>0 (0)</td>
<td>5 (3)</td>
<td>.09</td>
</tr>
<tr>
<td>Anaphylactic shock</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>&gt;.99</td>
</tr>
</tbody>
</table>

\(^a\)Q1-Q3: first quartile-third quartile.

\(^b\)OAS: oral allergy syndrome.

Home Data Recording

In the OITcontrol group, 81% (13/16) of patients used the OITcontrol app, while in the PaperPRO group, 71% (10/14) used the written diary (P=.53). As mentioned previously, patients in the OITcontrol group were advised to record daily taken allergen doses and home reactions using both methods: the written paper and the app. Following these recommendations, 38% (6/16) of OITcontrol patients used both methods. One active patient used only the written diary without using the OITcontrol app. Interestingly, none of the patients collected all daily dose intakes, regardless of the monitoring method used.

When analyzing reported reactions, every home reaction experienced in the PaperPRO group was recorded in the written diary (56/56, 100%), while 89% (86/97 reactions) of the home reactions experienced in the OITcontrol group were recorded (P=.009). Active patients preferred using only the app (59/86, 69%) rather than the written diary (15/86, 17%) or both methods (12/86, 14%) to record home reactions (P<.001). These data are summarized in Figure 3. Every reaction recorded by the OITcontrol group in both recording methods, written diary and OITcontrol app, was documented using the same description regarding allergen dose, type of symptoms, and administered treatment.
Figure 3. Summary of reported and recorded home reactions in both study groups, including the number of reactions documented, the treatment compliance and the dose adjustment performed after a moderate or severe reaction in recorded reactions through written diary, OITControl® app, or a combination of both monitoring systems. * Percentage of recorded reactions among reported reactions for each severity grade in each group. ** Percentage of reactions that followed indicated treatment among recorded reactions for each severity grade in each group. *** Percentage of reactions that follow dose adjustment after a moderate-severe reaction among recorded reactions for each severity grade in each group.

<table>
<thead>
<tr>
<th></th>
<th>PaperPRO group (n=56)</th>
<th>OITcontrol group (n=86)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reported Reactions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>38 (67.2%)</td>
<td>73 (85.3%)</td>
</tr>
<tr>
<td>Moderate</td>
<td>13 (23.2%)</td>
<td>2 (2.3%)</td>
</tr>
<tr>
<td>Severe</td>
<td>5 (9.1%)</td>
<td>22 (25.9%)</td>
</tr>
<tr>
<td><strong>Recorded Reactions</strong></td>
<td>36 (66.1%)</td>
<td>68 (78.8%)</td>
</tr>
<tr>
<td>Treatment Compliance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P=0.04</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dose Adjustment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P=0.001</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

App Assistance Evaluation

Treatment compliance in home-recorded reactions was analyzed between both groups and the monitoring method used. The indicated treatment was followed in 23 of the 56 (41%) recorded reactions in the PaperPRO group and in 46 of the 86 (53%) home-recorded reactions in the OITcontrol group (P=.15). Analyzing the monitoring system used, treatment was observed to be followed more frequently (P=.04) in reactions recorded only in the app (36/59, 61%) than in the written diary (29/71, 41%) or both systems (4/12, 33%; Figure 3). In general, treatment compliance was observed more frequently (P<.001) in mild reactions (61/100, 61%) than in moderate (5/15, 33%) and severe reactions (3/27, 11%). However, it is worth noting that in recorded mild reactions, treatment compliance was quite high, possibly because no treatment was indicated for the frequently reported mild OAS (every recorded mild OAS was correctly managed in both groups: 12 in the PaperPRO group and 31 in the OITcontrol group). In fact, mild reactions excluding mild OAS (18/57, 32%), moderate (5/15, 33%), and severe reactions (3/27, 11%) followed treatment prescription correctly in similar rates (P=.11). Interestingly, in most of the reactions where prescribed treatment was not followed, the common attitude among patients was not to apply any treatment, which was consistent across both groups. Detailed data are provided in Tables 4-6.

Dose adjustments after a moderate-severe reaction in home-recorded reactions were analyzed between both groups and the monitoring method used. Among the 18 doses that should have been adjusted after a moderate-severe reaction in the PaperPRO group, only 3 (17%) were adjusted. By contrast, among the 24 recorded doses requiring adjustment after a moderate-severe reaction in the OITcontrol group, 18 (75%) were correctly adjusted (P<.001). In general, dose adjustment was more frequently performed (P<.001) in those reactions recorded only in the app (16/19, 84%) than in those recorded in the written diary (3/20, 15%) or in both methods (2/3, 67%). The severity of reactions was associated with better compliance, as adjustments were made after severe reactions (19/27, 70%) more frequently (P<.001) than after moderate reactions (2/15, 13%). Data are summarized in Figure 3.
Table 4. Comparison of the adequacy of the treatment applied in recorded reactions of written diary users from both groups of patients.\textsuperscript{a}

<table>
<thead>
<tr>
<th>Written diary (indicated treatment)</th>
<th>Treatment applied</th>
<th>None</th>
<th>\textsuperscript{b}AH</th>
<th>\textsuperscript{c}AH and CST</th>
<th>\textsuperscript{d}EPI</th>
<th>\textsuperscript{e}EPI and BD</th>
<th>\textsuperscript{f}BD</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td></td>
<td>14\textsuperscript{f}</td>
<td>0</td>
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<td>0</td>
</tr>
<tr>
<td>AH</td>
<td></td>
<td>33</td>
<td>14</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>AH and CST</td>
<td></td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>EPI</td>
<td></td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>EPI and BD</td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

\textsuperscript{a}The number of reactions among both groups of patients is represented by comparing the treatment applied and indicated treatment in written diary-recorded reactions.

\textsuperscript{b}AH: antihistamine.

\textsuperscript{c}CST: corticosteroid.

\textsuperscript{d}EPI: epinephrine.

\textsuperscript{e}BD: bronchodilator.

\textsuperscript{f}Italicized values indicate the number of patients that followed the prescribed treatment correctly.

Table 5. Comparison of the adequacy of the treatment applied in recorded reactions of OITcontrol app users from both groups of patients.\textsuperscript{a}

<table>
<thead>
<tr>
<th>Written diary (indicated treatment)</th>
<th>Treatment applied</th>
<th>None</th>
<th>\textsuperscript{b}AH</th>
<th>\textsuperscript{c}AH and CST</th>
<th>\textsuperscript{d}EPI</th>
<th>\textsuperscript{e}EPI and BD</th>
<th>\textsuperscript{f}BD</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td></td>
<td>27\textsuperscript{f}</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>AH</td>
<td></td>
<td>8</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>AH and CST</td>
<td></td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>EPI</td>
<td></td>
<td>10</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>EPI and BD</td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

\textsuperscript{a}The number of reactions among both groups of patients is represented by comparing the treatment applied and indicated treatment in the OITcontrol app–recorded reactions.

\textsuperscript{b}AH: antihistamine.

\textsuperscript{c}CST: corticosteroid.

\textsuperscript{d}EPI: epinephrine.

\textsuperscript{e}BD: bronchodilator.

\textsuperscript{f}Italicized values indicate the number of patients that followed the prescribed treatment correctly.
Table 6. Comparison of the adequacy of the treatment applied in recorded reactions of OITcontrol app and written diary users from both groups of patients. 

<table>
<thead>
<tr>
<th>Written diary and OITcontrol (indicated treatment)</th>
<th>Treatment applied</th>
<th>None</th>
<th>AH</th>
<th>AH and CST</th>
<th>EPI</th>
<th>EPI and BD</th>
<th>BD</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td></td>
<td>2 f</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>AH</td>
<td></td>
<td>5</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>AH and CST</td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>EPI</td>
<td></td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>EPI and BD</td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

The number of reactions among both groups of patients is represented by comparing the treatment applied and indicated in both OITcontrol app– and written paper–recorded reactions.

AH: antihistamine.

CST: corticosteroid.

EPI: epinephrine.

BD: bronchodilator.

Italicized values indicate the number of patients that followed the prescribed treatment correctly.

Users' Satisfaction Questionnaire

A total of 15 users answered the questionnaire in the first week, and 11 responded in the fourth week. Among the 15 users answering in the first week of app use, 7/15 (47%) were females, with most aged between 35 and 44 years (8/15, 53%); 5/15 (33%) were between 45 and 54 years and 2/15 (13%) were between 25 and 34 years; 9/15 (60%) of them reported very frequent use of a smartphone (1=no use to 5=very frequent use: 3/15, 20%, rated the use 4/5; 2/15, 13%, rated the use 3/5; and 1/15, 7%, rated the use 2/5). In general, the app received positive ratings, being considered easy to use in most functions and screens, with suitable text. However, there were suggestions that error messages could be clearer. The questionnaire results are summarized in Tables 7-9.

Table 7. Results of the usability questionnaire after 1 week and 4 weeks of use of the OITcontrol app: general opinions.

<table>
<thead>
<tr>
<th>Questions and rating</th>
<th>Results at 1 week of use</th>
<th>Results at 4 weeks of use</th>
</tr>
</thead>
<tbody>
<tr>
<td>OITcontrol app is</td>
<td></td>
<td></td>
</tr>
<tr>
<td>l=terrible to 5=wonderful, mean (SD)</td>
<td>3.9 (0.7)</td>
<td>4.3 (0.6)</td>
</tr>
<tr>
<td>l=frustrating to 5=easy, mean (SD)</td>
<td>4.1 (0.7)</td>
<td>4.3 (0.6)</td>
</tr>
<tr>
<td>l=boring to 5=exciting, mean (SD)</td>
<td>3.6 (0.8)</td>
<td>3.8 (0.9)</td>
</tr>
<tr>
<td>l=difficult to 5=easy, median (Q1-Q3)</td>
<td>5 (4-5)</td>
<td>5 (4-5)</td>
</tr>
<tr>
<td>l=too slow to 5=too fast, mean (SD)</td>
<td>3.3 (1)</td>
<td>3.2 (0.9)</td>
</tr>
<tr>
<td>l=unreliable to 5=highly reliable, median (Q1-Q3)</td>
<td>3.9 (3.9-4.4)</td>
<td>3.9 (2.8-4.4)</td>
</tr>
<tr>
<td>l=noisy to 5=noiseless, mean (SD)</td>
<td>4.4 (0.6)</td>
<td>4.7 (0.5)</td>
</tr>
</tbody>
</table>

Q1-Q3: first quartile-third quartile.
Table 8. Results of the usability questionnaire after 1 week and 4 weeks of use of the OITcontrol app: opinion about how easy/difficult is to use different functions.

<table>
<thead>
<tr>
<th>Questions</th>
<th>Rating</th>
<th>Results at 1 week of use</th>
<th>Results at 4 weeks of use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Know I should take the dose</td>
<td>1=difficult to 5=easy, median (Q1-Q3)</td>
<td>5 (5-5)</td>
<td>5 (5-5)</td>
</tr>
<tr>
<td>Know how to take the dose</td>
<td>1=difficult to 5=easy, median (Q1-Q3)</td>
<td>5 (4-5)</td>
<td>5 (4-5)</td>
</tr>
<tr>
<td>Know indications after reaction</td>
<td>1=difficult to 5=easy, mean (SD)</td>
<td>4.6 (0.5)</td>
<td>4.6 (0.5)</td>
</tr>
<tr>
<td>Record the dose intake and its additional information</td>
<td>1=difficult to 5=easy, mean (SD)</td>
<td>4.6 (0.5)</td>
<td>4.8 (0.4)</td>
</tr>
<tr>
<td>Receive the alarm at the dose intake time</td>
<td>1=difficult to 5=easy, mean (SD)</td>
<td>3.9 (1)</td>
<td>4 (1.2)</td>
</tr>
<tr>
<td>Consult past dose intake record</td>
<td>1=difficult to 5=easy, median (Q1-Q3)</td>
<td>5 (4-5)</td>
<td>5 (4-5)</td>
</tr>
<tr>
<td>Consult the next hospital visit</td>
<td>1=difficult to 5=easy, median (Q1-Q3)</td>
<td>5 (4-5)</td>
<td>5 (4-5)</td>
</tr>
<tr>
<td>To correct mistakes</td>
<td>1=difficult to 5=easy, mean (SD)</td>
<td>3.5 (0.9)</td>
<td>3.5 (1.2)</td>
</tr>
</tbody>
</table>

Table 9. Results of the usability questionnaire after 1 week and 4 weeks of use of the OITcontrol app: opinions about text and screens.

<table>
<thead>
<tr>
<th>Questions</th>
<th>Rating</th>
<th>Results at 1 week of use</th>
<th>Results at 4 weeks of use</th>
</tr>
</thead>
<tbody>
<tr>
<td>The texts on the screen are...difficult or easy to read?</td>
<td>1=difficult to 9=easy, median (Q1-Q3)</td>
<td>8 (7-9)</td>
<td>8 (7-9)</td>
</tr>
<tr>
<td>Is the information highlighted helpful?</td>
<td>1=absolutely not to 9=of course yes, median (Q1-Q3)</td>
<td>8 (7-9)</td>
<td>8 (7-9)</td>
</tr>
<tr>
<td>Is the transition from one screen/information to another confusing or clear?</td>
<td>1=confuse to 9=clear, median (Q1-Q3)</td>
<td>8 (7-8)</td>
<td>7 (6-8)</td>
</tr>
<tr>
<td>Does the use of terms...encourage or discourage its use?</td>
<td>1=discourage to 9=encourage, mean (SD)</td>
<td>5.9 (2.3)</td>
<td>5.8 (2.5)</td>
</tr>
<tr>
<td>Does the use of terms encourage or discourage learning?</td>
<td>1=discourage to 9=encourage, mean (SD)</td>
<td>6.2 (2.5)</td>
<td>6.3 (2.1)</td>
</tr>
<tr>
<td>Error messages...are they confusing or clear?</td>
<td>1=confuse to 9=clear, mean (SD)</td>
<td>6.6 (1.7)</td>
<td>5.5 (2.5)</td>
</tr>
<tr>
<td>The messages that appear on the screen...Are they difficult or simple?</td>
<td>1=difficult to 9=simple, mean (SD)</td>
<td>7.9 (1.1)</td>
<td>8.2 (0.9)</td>
</tr>
</tbody>
</table>

Discussion
Principal Findings
This study demonstrates that OITcontrol, a patient advisor app incorporating medical algorithms, goes beyond serving as an electronic report and is an effective method for monitoring home OIT. Moreover, our findings suggest that OITcontrol emerges as an appealing method for overseeing OIT treatments, as it has been predominantly used by the active group. Additionally, instructions provided by the app have been adhered to more consistently than the written indications regarding treatment and dose adjustments following a reaction.

eHealth technology has seen widespread adoption in recent years, particularly in the context of respiratory allergy [31-33]. Conversely, the application of eHealth technology in food allergy has primarily focused on the development of mobile apps designed to complement patient care. These apps often provide features such as allergen-free product searches, meal planners, or tools for locating allergy-adapted restaurants [34,35]. OITcontrol aligns with the objectives of eHealth apps, serving not only the beneficial purposes for patients with allergies but also catering to the needs of clinicians and researchers [36]. It exemplifies the use of health informatics by automating physician orders [37].

Previous reports have indicated that as few as 20% of patients are genuinely compliant with paper-based diaries [38]. In our sample, reporting compliance was remarkably high. PaperPRO patients exhibited perfect adherence in recording home reactions, surpassing the OITcontrol group. In the OITcontrol group, patients displayed a preference for recording home reactions within the app. This observation may be due to the control group’s potentially better performance when using only 1 monitoring system, as opposed to the active group using 2 systems. Alternatively, it could be indicative of underreporting of home reactions by the control group, possibly trivializing or forgetting to report reactions when using standard methods compared with having an additional monitoring intervention.

Indeed, a previous electronic web-based reporting system implemented for OIT, which focused on dose and home reactions reporting, demonstrated higher adherence than that observed in our sample. However, the rate of reported home reactions was quite similar to our data [39]. Nevertheless, Nachshon et al [39] highlighted some limitations of this monitoring web-based system, including challenges related to...
the patient’s description of reactions. In this regard, OITcontrol provides a tabulated selection of reactions rather than an open-ended description box. It appears that these predefined reactions are effectively described, as treatment compliance and dose adjustment after a reaction were more successful, particularly for those reactions recorded in the app.

Home reactions documented in the OITcontrol app were more consistently treated correctly compared with those recorded in the written diary, despite the fact that treatment compliance was notably low, particularly among patients experiencing moderate and severe reactions. It is worth noting that epinephrine is underused in cases of anaphylaxis, even among well-informed and trained parents familiar with the use and indications of autoinjectors. This could be attributed to reasons such as the unavailability of the autoinjector, difficulty in recognizing anaphylaxis, and concerns about potential adverse effects [40-45]. In our limited sample, patients who required self-injectable epinephrine rarely used it, irrespective of whether they followed written or electronic recommendations. However, the correct treatment in mild reactions was more frequently adhered to. Further, a larger sample of patients is needed to assess whether the OITcontrol app could enhance treatment compliance for home reactions and contribute to adjusting home doses after moderate-severe reactions. Our data, albeit based on a limited number of reactions, suggest that OITcontrol app recommendations regarding dose adjustment were followed more consistently than written recommendations.

Conclusions
In conclusion, the OITcontrol app appears to enhance treatment and dose adjustment compliance in home reactions, although further studies are needed to confirm the efficacy of the app in this regard. As a monitoring system, the OITcontrol app is deemed a suitable method in OIT treatment for recording daily dose intakes and home reactions during the buildup phase.

Acknowledgments
The authors extend their gratitude to Maite Lacunza for technical support, Paola Quan for her assistance with figure design, and Jorge Nuñez Córdoba for providing statistical advice. Funding for the development of the OITcontrol app and its clinical validation was generously provided by the Navarra Government (Economic development grants: 2016/PI041 and 2017/PI065) and the Sociedad Española de Alergología e Inmunología Clínica (SEAIIC) in 2018. Additionally, this work received support from the Redes de Investigación Con Objetivos en Salud (RICORS)-Red De Enfermedades Inflamatorias (REI)—RD21/0002/0028, Instituto de Salud Carlos III, Madrid, Spain, and the Fundación Tecnología y Salud de Instituto de Investigación Sanitaria de Navarra (IdisNA).

Conflicts of Interest
None declared.

Multimedia Appendix 1
Supplementary Table S1: Clinical description, classification, and treatment of reactions.

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30. OITcontrol medical staff access. OITcontrol. URL: https://tool.oitcontrol.com/#/personal-medico/citas [accessed 2023-12-01]


Abbreviations

AH: antihistamine
BD: bronchodilator
CST: corticosteroid
EPI: epinephrine
IgE: immunoglobulin E
OAS: oral allergy syndrome
OIT: oral immunotherapy
Mobile App/Web Platform for Monitoring Food Oral Immunotherapy in Children: Longitudinal Clinical Validation Study

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An Electronic Teen Questionnaire, the eTeenQ, for Risk Behavior Screening During Adolescent Well Visits in an Integrated Health System: Development and Pilot Implementation

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Abstract

Background: Screening for risk behaviors is a routine and essential component of adolescent preventive health visits. Early identification of risks can inform targeted counseling and care. If stored in discrete fields in the electronic health record (EHR), adolescent screening data can also be used to understand risk behaviors across a clinic or health system or to support quality improvement projects.

Objective: Goals of this pilot study were to adapt and implement an existing paper adolescent risk behavior screening tool for use as an electronic data capture tool (the eTeenQ), to evaluate acceptance of the eTeenQ, and to describe the prevalence of the selected risk behaviors reported through the eTeenQ.

Methods: The multidisciplinary project team applied an iterative process to develop the 29-item eTeenQ. Two unique data entry forms were created with attention to (1) user interface and user experience, (2) the need to maintain patient privacy, and (3) the potential to transmit and store data for future use in clinical care and research. Three primary care clinics within a large health system piloted the eTeenQ from August 17, 2020, to August 27, 2021. During preventive health visits for adolescents aged 12 to 18 years, the eTeenQ was completed on tablets and responses were converted to a provider display for teens and providers to review together. Responses to the eTeenQ were stored in a REDCap (Research Electronic Data Capture; Vanderbilt University) database, and for patients who agreed, responses were transferred to an EHR flowsheet. Responses to selected eTeenQ questions are reported for those consenting to research. At the conclusion of the pilot, the study team conducted semistructured interviews with providers and staff regarding their experience using the eTeenQ.

Results: Among 2816 adolescents with well visits, 2098 (74.5%) completed the eTeenQ. Of these, 1811 (86.3%) agreed to store responses in the EHR. Of 1632 adolescents (77.8% of those completing the eTeenQ) who consented for research and remained eligible, 401 (24.6%) reported someone they lived with had a gun and 172 (10.5%) reported having had a stressful or scary event that still bothered them. In addition, 157 (9.6%) adolescents reported they were or wondered if they were gay, lesbian, bisexual, pansexual, asexual, or other, and 43 (2.6%) reported they were or wondered if they were transgender or gender diverse. Of 11 staff and 7 providers completing interviews, all felt that the eTeenQ improved confidentiality and willingness among adolescents to answer sensitive questions. All 7 providers preferred the eTeenQ over the paper screening tool.

Conclusions: Electronic capture of adolescent risk behaviors is feasible in a busy clinic setting and well accepted among staff and clinicians. Most adolescents agreed for their responses to risk behavior screening to be stored in the EHR.

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KEYWORDS
electronic data capture; data capture; privacy; security; adolescent health; risk behavior screening; screening; acceptance; primary care; adolescent; adolescents; electronic health record; risk behavior; risk; risky; behavior; behaviors; behaviour; behaviours; digital health; eHealth; teenage; teens; teen; teenager; teenagers; children; young adults; youth; online health; web data; online data; user experience; interview; interviews; qualitative
**Introduction**

Adolescence is a period of rapid and complex transitions. Biological maturity often precedes psychosocial maturity, and the choices made during this period can have both immediate and long-term health consequences. While many adolescent risk behaviors are transient or experimental, habits and unhealthy coping strategies with origins in adolescence may persist into adulthood [1,2]. In addition, limit-testing behaviors explored during adolescence can increase risk for injury and can contribute to long-term morbidity and mortality [3].

Routine risk behavior screening of adolescents is an important part of providing comprehensive and equitable care to this age group and is a recommended best practice by the American Academy of Pediatrics [4,5]. Early recognition and response to high-risk adolescent behaviors can help to maintain youth on a healthy trajectory. Standardized questionnaires assessing adolescent risk behaviors have been found to help shift the focus of primary care visits from data gathering to discussion and counseling around sensitive topics. Furthermore, use of standardized questionnaires can improve organization and efficiency during the visit [6].

Many primary care practices rely on paper adolescent screening tools. However, these tools are often not completed by patients and results of the paper screening are inconsistently recorded in the electronic health record (EHR), making it difficult to monitor individual or population-level risk behaviors over time [7]. Electronic data capture for adolescent risk behavior screening has several potential advantages over paper screening and is generally preferred by adolescents [8-10], including those engaging in high-risk behaviors [9,11].

Nevertheless, barriers to adoption of electronic risk behavior screening tools remain, including clinical and institutional inertia and concerns regarding confidentiality of patient-reported risk behaviors collected on electronic tablets or similar devices [12]. In addition, risk behavior screening in primary care through paper or electronic methods may prolong visits and crowd out time for addressing other acute health issues.

In this pilot project, we adapted a paper-based adolescent risk behavior screening tool, the Adolescent and Young Adult Teen Questionnaire [13], which was developed by the Minnesota Department of Health and is currently in use in our health system as a paper screening tool at all primary care clinics, for use as an electronic data capture tool, the eTeenQ. We then pilot-tested the eTeenQ at 3 primary care clinics within our large, integrated, Midwestern health system, with goals of evaluating patient and clinician acceptance of the eTeenQ and describing the prevalence of selected adolescent risk behaviors as reported through the eTeenQ.

**Methods**

**Adaptation of the Paper Risk Screening Tool for Electronic Data Capture as the eTeenQ**

The multidisciplinary project team, which included 2 primary care physicians, 1 project manager, and 2 members of the HealthPartners Institute software engineering team, applied an iterative process over a 4-month period to adapt a paper risk behavior screening tool, the Adolescent and Young Adult Teen Questionnaire, for use as an electronic data capture form to be completed at the point of care on an electronic tablet. Two unique data entry forms were created with attention to (1) user interface and user experience (UI/UX), (2) the need to maintain patient privacy, and (3) the potential to transmit and store data for future use in clinical care and research. Additional considerations that affected the overall design of the eTeenQ included the need for the system to be stable, process responses quickly, and require limited ongoing maintenance. The overall architecture of the eTeenQ is shown in Multimedia Appendix 1.

The first electronic, web-based form created allowed clinic staff at check-in to enter the patient medical record number (MRN) and then to confirm the patient identity (Multimedia Appendix 2). The GetPatientDemographics application programming interface (API) from Epic Systems was used to identify the correct patient. The second electronic, web-based form created enabled adolescent patients to complete the 29-item fixed-response questions on safety, physical activity, diet and body image, school, self-harm, gender identity, sexual identity, and sexual activity that comprise the Adolescent and Young Adult Teen Questionnaire (Multimedia Appendix 3). The second form contained additional questions for adolescents to consent for their survey responses to be used for research and stored in the EHR, as described below. The eTeenQ forms were developed in REDCap (Research Electronic Data Capture; Vanderbilt University). REDCap is a secure web application used for building and managing online databases and surveys [14].

At the point of care, responses to the eTeenQ are converted to a provider display and adolescents and their primary care providers review responses together on the tablet during the visit. As shown in Multimedia Appendix 4, the provider display highlights eTeenQ “positive screens” or responses requiring attention during the visit. In real time, eTeenQ responses are stored in a REDCap secure external database [14]. For patients who consented to have their data stored in the EHR, after completing the eTeenQ and pressing Submit, a copy of their eTeenQ responses was automatically saved. The SetSmartDataValues API from Epic Systems was used to securely transfer the data from REDCap to custom discrete data elements created in the EHR for the project.

Additional security was integrated to the build of the tool to prevent the use of the tool outside the health system’s intranet. Software use and data transfer were closely monitored throughout the project, and the tablet firmware was maintained.

**Setting and Population for Pilot Implementation**

HealthPartners Care Group includes a multispecialty group practice of more than 1800 physicians, 8 hospitals, 55 primary care clinics, 22 urgent care locations, 24 dental clinics, and numerous specialty practices in Minnesota and western Wisconsin. The care group uses a common EHR (Epic; Epic Systems Corporation). Adolescents aged 12 to 18 years receive primary care within the care group from physicians trained in...
pediatrics, family medicine, or internal medicine, as well as from advanced practice providers, including nurse practitioners and physician assistants.

In June 2018, all 55 primary clinics within HealthPartners Care Group implemented comprehensive screening for well-being and risk behaviors among adolescents aged 12 to 18 years during well visits. At the time of check-in, patients and their parents were each handed a letter that described policies related to confidential care for adolescents and notified them that the adolescent would be completing a paper questionnaire for teens (based on the Adolescent and Young Adult Teen Questionnaire [13] developed by the Minnesota Department of Health). The letter provided at check-in also advised the adolescents and their parents that during the visit the parent would be asked to leave the room so the provider could review responses to the paper questionnaire in private with the adolescent. After the visit, the paper questionnaire was shredded, and it was at the discretion of the clinician to document any patient responses or discussion related to the risk behaviors identified in the EHR.

This pilot implementation of the eTeenQ took place at 3 clinics within the HealthPartners Care Group. Clinic A, located in a small town in Minnesota, had 27 pediatricians participate during the period from January 18, 2021, to August 27, 2021; clinic B, located in a metropolitan area of St Paul, Minnesota, had 5 pediatricians participate during the period from January 18, 2021, to August 27, 2021; clinic C, located in a Minneapolis suburb, had 3 pediatricians and 8 family medicine clinicians participate during the period from August 17, 2020, to August 27, 2021.

All patients aged 12 to 18 years and presenting for a preventive health or well visit with a participating primary care provider at a pilot site during the study period were eligible to participate. Eligible visits were identified through current procedural terminology (CPT) codes for these preventive health visits: 99384, 99394, 99385, and 99395; they were also identified through the International Classification of Diseases, 10th Revision—Clinical Modification (ICD-10-CM) codes Z00.121, Z00.129, Z00.00, and Z00.01.

Training and Support
All staff and providers at the 3 pilot sites attended lunchtime in-person or virtual training(s) regarding the pilot test and points of contact for the research team. Throughout the pilot period, the study primary investigator (SN) conducted brief in-person or virtual semistructured interviews with participating clinic providers and staff to understand their experiences using the eTeenQ. Questions for clinic staff included the following: “How did this pilot go?” “How did it work to hand out the tablets at the front desk to adolescents to complete the eTeenQ before the visit?” “Can you tell me about any difficulties with the technology or workflow?” “What ideas do you have about improvements we should make to the workflow or technology before spreading across primary care?” and “Do you have any additional feedback regarding this pilot?”

Questions for providers included the following: “How did this pilot go?” “Can you tell me about any difficulties with the technology or workflow?” “How did it work to review the Teen Questionnaire on a tablet?” “As compared to prior to the pilot, how did use of the eTeenQ impact visit quality of care?” “As compared to prior to the pilot, how did use of the eTeenQ impact adolescent clinician communication?” “As compared to prior to the pilot, how did use of the eTeenQ impact parent-clinician communication?” “Did you make changes to clinical care or documentation as a result of the data reviewed on the tablet during the visit?” “Were you able to find the results of the eTeenQ in Epic, after the visit?” “How satisfied are you with adolescent patient, the tablet was handed to the patient along with instructions to complete the eTeenQ on their own, without input from parents or other guardians (Multimedia Appendix 2). After completing the eTeenQ, patients completed 2 additional questions regarding permission to import the eTeenQ data into the EHR and permission for responses to the eTeenQ to be accessed for research. Patients were instructed to hand the electronic tablet to the rooming staff so it could be reviewed by the clinician in advance and discussed during the confidential portion of the visit.

Prior to entering the patient room, the clinician reviewed the data on the tablet. Any survey responses that would generally require attention during the visit were highlighted on the provider display in order to facilitate efficiency (Multimedia Appendix 3).

Evaluating Use of the eTeenQ and Responses
Use of the eTeenQ was assessed by comparing the total number of adolescent preventive health visits at the 3 participating sites during the pilot period to the number of completed eTeenQ surveys stored in the REDCap database. For those consenting for their data to be used in research, eTeenQ responses were linked to administrative data (eg, age, sex, race/ethnicity, and insurance type) as recorded in the EHR. Selected responses were compared by age group (12-14 years vs 15-18 years) with the chi-square test with a 2-sided \( P < .05 \) as the threshold for significance. All analyses were conducted in SAS (version 9.4; SAS Institute).

Obtaining Feedback From Providers and Clinic Staff at Pilot Sites
At the conclusion of the pilot, the study primary investigator (SN) conducted brief in-person or virtual semistructured interviews with participating clinic providers and staff to understand their experiences using the eTeenQ. Questions for clinic staff included the following: “How did this pilot go?” “How did it work to hand out the tablets at the front desk to adolescents to complete the eTeenQ before the visit?” “Can you tell me about any difficulties with the technology or workflow?” “What ideas do you have about improvements we should make to the workflow or technology before spreading across primary care?” and “Do you have any additional feedback regarding this pilot?”

Questions for providers included the following: “How did this pilot go?” “Can you tell me about any difficulties with the technology or workflow?” “How did it work to review the Teen Questionnaire on a tablet?” “As compared to prior to the pilot, how did use of the eTeenQ impact visit quality of care?” “As compared to prior to the pilot, how did use of the eTeenQ impact adolescent clinician communication?” “As compared to prior to the pilot, how did use of the eTeenQ impact parent-clinician communication?” “Did you make changes to clinical care or documentation as a result of the data reviewed on the tablet during the visit?” “Were you able to find the results of the eTeenQ in Epic, after the visit?” “How satisfied are you with
electronic capture of eTeenQ data on a tablet?” (3-point scale for responses) and “Do you have a preference for how adolescent risk behavior screening should be administered at your clinic in the future?”

The study primary investigator took notes during the semistructured interviews. These notes were reviewed by the full study team to identify common themes regarding perceptions, preferences, and actual use of the eTeenQ.

**Ethical Considerations**

This study was reviewed and approved by the HealthPartners Institutional Review Board (A19-123). Implementation of the eTeenQ at pilot sites was approved with a waiver of informed consent. Adolescent consent for eTeenQ survey responses to be used for research and to be stored in the EHR was obtained as described below.

Adolescents consented for their eTeenQ responses to be used for research by reading the following prompt and then answering the consent question on the tablet:

> We are asking all teens who complete the Teen Questionnaire on a tablet for permission to group their answers together in a large database. This data will be used to better understand the health of teens in our clinics and to improve care for teens in the future. We will not include your name or other information about you in the database. This study is voluntary. That means you can tell us that you do not want us to use your answers to the questionnaire for research. This will not affect your care today or in the future. We expect up to 1000 adolescents to participate in this study.

Adolescents consented for their eTeenQ responses to be stored in their EHR by reading the following prompt and then answering the consent question on the tablet:

> The information in this questionnaire is confidential. It will be used by the doctors and nurses taking care of you to provide the best care possible. In the occasion that your parent or guardian requests a copy of your entire medical record, it is possible they may see the answers you provided on this form. If you report that you intend to harm yourself or to harm others, we are required to intervene on your behalf.

> Do you give permission to save this information in your medical record so that it can be used to help take care of you at future medical appointments?

**Results**

**Evaluating Use of the eTeenQ**

During the pilot period, among 2816 eligible adolescents with well visits, 2098 (74.5%) completed the eTeenQ. Of the 2098 adolescents who completed the eTeenQ, 1653 (78.8%) consented to have their data used for research and 1811 (86.3%) agreed to have their data stored in the EHR. After excluding 21 responses due to incorrect MRN linkage to the EHR or because the patient had an a priori research opt-out recorded in their EHR, the final analytic sample included 1632 adolescents; 818 (50.1%) were female and the mean age was 14.5 (SD 1.8) years. (Figure 1, Table 1)
Figure 1. Flowsheet of study eligibility and consent for data to be used in research. EHR: electronic health record; MRN: medical record number.
Table. Characteristics of sample (n=1632).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Site, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Clinic A</td>
<td>997 (61.1)</td>
</tr>
<tr>
<td>Clinic B</td>
<td>231 (14.2)</td>
</tr>
<tr>
<td>Clinic C</td>
<td>404 (24.8)</td>
</tr>
<tr>
<td><strong>Age (years), mean (SD)</strong></td>
<td>14.5 (1.8)</td>
</tr>
<tr>
<td><strong>Sex, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>818 (50.1)</td>
</tr>
<tr>
<td>Male</td>
<td>814 (49.9)</td>
</tr>
<tr>
<td><strong>Race/ethnicity, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>1224 (75)</td>
</tr>
<tr>
<td>Black/African American</td>
<td>139 (8.5)</td>
</tr>
<tr>
<td>Asian</td>
<td>72 (4.4)</td>
</tr>
<tr>
<td>Native Hawaiian or Pacific Islander</td>
<td>60 (3.7)</td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>4 (0.3)</td>
</tr>
<tr>
<td>Other (or multiple)</td>
<td>74 (4.5)</td>
</tr>
<tr>
<td>Unknown</td>
<td>59 (3.6)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>70 (4.3)</td>
</tr>
<tr>
<td><strong>Insurance type, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Commercial</td>
<td>1284 (78.7)</td>
</tr>
<tr>
<td>Public</td>
<td>340 (20.8)</td>
</tr>
<tr>
<td>Missing</td>
<td>8 (0.5)</td>
</tr>
</tbody>
</table>

Overall data quality was good. Of 1632 respondents in the analytic sample, 1562 (95.7%) responded to all 29 questions in the eTeenQ. The most common question skipped was “How often do you use marijuana?” but this was only left incomplete for 10 (0.6%) respondents.

Across all 1632 teen respondents, 1472 (90.2%) reported having an adult they can really talk to and 1510 (92.5%) reported feeling safe in their community, yet 401 (24.6%) reported someone they lived with had a gun and 172 (10.5%) reported having had a stressful or scary event that still bothered them. In addition, 263 (16.1%) reported missing 7 or more days of school and 196 (12%) reported their grades were worse than they used to be. In addition, 157 (9.6%) responded they were or wondered if they were gay, lesbian, bisexual, pansexual, asexual, or other, and 43 (2.6%) reported they were transgender or gender diverse. Risk behaviors were more common among older adolescents (aged 15-18 years; n=774) as compared to younger adolescents (aged 12-14 years; n=858). For example, 137 (17.7%) of older adolescents reported ever having had any kind of sex (with anyone of any gender) as compared to 9 (1%) of younger adolescents (P<.001). Similarly, 133 (17.2%) of older adolescents reported ever having used alcohol and 94 (12.1%) reported ever having used marijuana, as compared to 25 (2.9%) and 11 (1.3%), respectively, reporting use among younger adolescents (P<.001 for comparisons by age group).

Feedback From Providers and Clinic Staff at Pilot Sites

Across the 3 pilot clinics, 18 providers and clinic staff provided feedback through semistructured interviews. All felt that their adolescent patients liked using the tablets for completing the eTeenQ. They believed that patients were more honest with their responses using the tablet and noted more “positive screens” than when screening for adolescent risk behaviors on paper. They felt the tablets enhanced privacy and they particularly liked the provider display on the tablet that highlighted the “positive screens” or topics to address during the visit.

Challenges with the eTeenQ reported during interviews included isolated interruptions of Wi-Fi connectivity and confusion about which tablet belonged to which adolescent when 2 or more siblings with well visits were in the same examination room. In addition, adolescents occasionally clicked past the provider display screen, and the provider was then unable to review the eTeenQ responses on the tablet. Despite these occasional minor difficulties, primary care providers felt that the eTeenQ improved the quality of care they were able to provide and enhanced adolescent confidentiality. When asked their screening preference going forward, paper vs electronic, all respondents chose electronic.
Discussion

Principal Results
In this pilot study conducted in 3 busy community-based clinics within a large health system, we demonstrated that a paper adolescent risk screening tool can be converted for use as an electronic form; that adolescents were generally adherent to completing electronic risk screening on tablets at the time of preventive health visits, with a majority agreeing to have their responses stored in the EHR; and that implementation of the eTeenQ was feasible and well accepted by providers. Furthermore, the conversion of adolescent questionnaire responses to an intuitive provider display may have improved identification of risk behaviors requiring attention or further discussion during the visit. Storage of eTeenQ responses in a discrete field in the EHR can allow clinicians or researchers to evaluate adolescent risk behaviors across a clinic or geographic region, and ultimately can be used to design and implement targeted quality improvement projects.

Limitations
Several limitations to this pilot study should be noted. First, the participating clinics were not randomly selected. These clinics were motivated sites and had site champions who were engaged partners throughout the pilot. The successful adaptation and implementation of the eTeenQ at our pilot sites may not be generalizable to other clinics or health systems. A second limitation was that while adolescents complete several questionnaires at their preventive health visits, due to limitations in scope and budget, in our pilot only the eTeenQ was completed electronically. Thus, teens were filling out forms both electronically and on paper, which was cumbersome for staff and patients. Third, as a pilot project, we were not able to optimize all aspects of UI/UX, and the transfer of the data from REDCap to the EHR required a manual trigger following patient consent. If widely implemented, we would encourage additional modifications to the display and updates to the architecture to allow eTeenQ responses to flow seamlessly, in real time, into the EHR, and the incorporation of all adolescent screening tools for completion through electronic data capture. Further enhancements should also support completion of risk behavior screening in the days prior to preventive health visits. Fourth, as a small pilot study, our assessment of provider and staff acceptance of the eTeenQ was based on brief semistructured interviews and did not include formal qualitative analyses.

Comparisons With Prior Work
Findings from this pilot study were consistent with prior research, which has demonstrated that adolescents appear to more accurately report and be more willing to disclose sensitive information when questioned electronically vs on paper or in person [15,16]. In a pilot study conducted in 2015 in an academic adolescent clinic in Seattle, teens aged 13 to 18 years reported they preferred an electronic screen to a paper version. Prior studies have also noted that adolescents also perceive their visits as more confidential, feel they are listened to more carefully, and report they are more satisfied with their visit when computerized screening is used, as compared to other approaches to adolescent risk behavior screening [17]. Our study adds to the literature, as we conducted this work outside of an academic setting in 3 community-based clinics.

A potential benefit of electronic data capture is that forms can be easily modified and can include additional skip patterns or branching logic to support additional targeted data collection. For example, for those responding “yes” or “sometimes” to the eTeenQ single screening question regarding gender identity, “Are you or do you wonder if you are transgender or gender diverse?” in future iterations additional questions could then display allowing the patient to specify their gender identity [18].

We are not aware of prior research on adolescent preferences for storing sensitive information in the EHR. Prior to conducting this pilot, health system leaders had assumed that adolescent patients would not want their responses to adolescent risk screening stored in the EHR, as there would be a potential risk for disclosure to parents or others accessing their medical records. As such, we were surprised to find that 86% of adolescents consented to store their eTeenQ responses in the EHR. Recording of eTeenQ responses in discrete fields in the EHR is critical for follow-up of risk behaviors at future visits. If not documented, important health information revealed through risk behavior screening may be lost and not available at a patient’s next medical encounter. In addition, adolescents may assume that communication between care teams occurs in the EHR and may not reveal vital sensitive information during a subsequent visit.

Conclusions
The use of electronic data capture for adolescent risk screening in primary care is feasible for collecting sensitive information in busy, community-based primary care settings. Most adolescents were agreeable to having their data stored in the EHR, and staff and primary care providers preferred electronic to paper screening. Providers felt that electronic screening enhanced confidentiality and that the eTeenQ improved the quality of care overall.

Acknowledgments
This research was supported by the HealthPartners Institute internal grants program. HealthPartners Institute is a 501c(3) nonprofit organization dedicated to conducting high-quality, public-domain health research, often in collaboration with other academic and research organizations throughout the world. The funder was not involved in the study design; conduct of the study; collection, management, analysis, or interpretation of the data; preparation, review, or approval of the manuscript; or the decision to submit the manuscript for publication. We would like to thank the participating clinicians and staff at the following pilot sites: Park Nicollet Clinic Bloomington, HealthPartners Clinic Stillwater, and HealthPartners Clinic St Paul.
Conflicts of Interest

None declared.

Multimedia Appendix 1
Architecture of the eTeenQ and data transfer.
[PNG File, 1069 KB - pediatrics_v7i1e47355_app1.png]

Multimedia Appendix 2
Check-in workflow for the eTeenQ.
[PNG File, 68 KB - pediatrics_v7i1e47355_app2.png]

Multimedia Appendix 3
First 7 questions of the eTeenQ for adolescents to complete, as displayed on a tablet.
[PNG File, 130 KB - pediatrics_v7i1e47355_app3.png]

Multimedia Appendix 4
Provider display of eTeenQ responses, with positive results highlighted in blue.
[PNG File, 512 KB - pediatrics_v7i1e47355_app4.png]

References


13. Adolescent and young adult health questionnaire. Minnesota Department of Health. URL: www.health.state.mn.us/people/childrenyouth/cte/teenhlth.html [accessed 2023-10-09]


Abbreviations

API: application programming interface
CPT: current procedural terminology
EHR: electronic health record
ICD-10-CM: International Classification of Diseases, 10th Revision–Clinical Modification
MRN: medical record number
REDCap: research electronic data capture
UI/UX: user interface and user experience

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Screening and Retaining Adolescents Recruited Through Social Media: Secondary Analysis from a Longitudinal Clinical Trial

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Abstract

Background: Social media has become a popular method to recruit participants, particularly for studies with hard-to-reach populations. These studies still face challenges in data quality and, for longitudinal studies, sample retention. However, in addition to aiding in recruitment, social media platforms can help researchers with participant verification and tracking procedures during the study. There is limited previous research describing how longitudinal studies can use social media to screen and retain participants.

Objective: This paper describes strategies implemented to screen and retain a nationwide sample of sexual minority youth who were recruited through social media platforms for a longitudinal study testing a drug abuse prevention program.

Methods: Our screening strategies for participants included collecting necessary demographic information (name, phone, email, and social media accounts), verifying this information using publicly available web-based records, and sending confirmation emails to ensure working email addresses and correct dates of birth. Retention strategies included communications designed to develop positive participant relationships, incentives for survey completion, regular updating of participant contact information, targeting hard-to-reach participants, and using social media as an alternative means of contacting participants.

Results: During enrollment, although the only demographic data required were a phone number and an email address, 87.58% (1065/1216) of participants provided their Instagram as an alternative means of contact. This form of alternative communication remains the most preferred with 87.40% (1047/1198) of participants continuing to provide an Instagram username as of January 2023, about 3 years after recruitment began. In comparison, other alternative means of contact (eg, Facebook and alternative email) were provided by only 6.43% (77/1198) to 56.18% (673/1198) of participants. Direct messaging on Instagram was used to successfully confirm participant identity, remind participants to take annual follow-up surveys, and update lost participant contact information. Screening and retention strategies used in the study have helped achieve 96.30% (1171/1216) to 96.79% (1177/1216) sample retention across 3 waves of data collection.

Conclusions: Though social media can be a helpful tool to recruit participants, attrition and participant authenticity difficulties may be associated with this method. Screening and retention strategies can be implemented to improve retention. Internet searches are effective for screening youth to ensure they meet eligibility requirements. Additionally, social media—Instagram in this study—can help to track and locate participants who do not respond to traditional contact methods.

Trial Registration: ClinicalTrials.gov NCT03954535; https://clinicaltrials.gov/study/NCT03954535

(JMIR Pediatr Parent 2024;7:e47984) doi:10.2196/47984
KEYWORDS
adolescents; attrition prevention; Instagram; LGBQ; online recruitment; retention; screening; sexual minority; social media; youth

Introduction

With the rise in social media popularity, web-based recruitment methods for clinical trials have become increasingly popular. Social media allows researchers greater access to nationwide samples [1]; adolescents [2-6]; and hard-to-reach populations [7,8], such as sexual minority individuals [9-13] and people who use substances [14-16]. However, some research has associated web-based recruitment with lower retention rates than in-person recruitment methods [17,18]; researchers have theorized that web-based recruitment lacks the connection and commitment from participants that come from in-person recruitment [18]. Further, there is a greater opportunity in longitudinal studies to lose participants over time due to changes in contact information or the desire to no longer participate in the study [19]. Thus, longitudinal studies that recruit through social media are at high risk for participant attrition. Despite these challenges, researchers have identified methods to increase retention rates of samples recruited on the web, including frequent communication between surveys [20], financial incentives [21], and building positive rapport with participants [21,22]. Previous research has been able to maintain high retention rates after recruiting participants on social media. One study recruited youth aged between 12 and 25 years using advertisements on social media, Google, Craigslist, and a web-based neighborhood forum; they found retention rates of 78.11% at the 3-month follow-up and 72.18% at the 6-month follow-up [23]. Another study recruited using a similar method of advertising on social media, a collaborating website, and a newsletter and found a retention rate of 88.4% at the 2-week follow-up [24]. Our previous research has used social media (eg, Facebook advertisements) to recruit youth for 2 longitudinal web-based drug abuse prevention programs that maintained retention rates of 97% at the 1-year follow-up [25] and 84.75% at 3-month follow-up [13]. Much of what researchers know about using social media recruitment strategies comes from reports using Facebook. Several studies and systematic reviews have confirmed that advertising on Facebook is more cost-effective and time-efficient than in-person recruitment [7,8,14,15,26,27]. Facebook has also been a valuable tool for locating and communicating with participants in longitudinal studies [28,29]. However, trends in social media have shifted in recent years, especially among younger demographics. In 2015, 71% of teenagers reported using Facebook, while only 52% reported using Instagram [30]. This was notably different in 2022 when 32% of teens reported using Facebook, while 62% reported using Instagram [31]. Instagram has already been used as a successful tool in recruiting sexual and gender minority adolescents and young adults [32-38]. Thus, in 2020, we used Facebook and Instagram to recruit for Free2b, a nationwide 5-year web-based drug abuse intervention program for sexual minority youth (ClinicalTrials.gov NCT03954535). Though recruiting on social media is cost-effective, timely, and grants access to large and diverse samples, it does not guarantee the authenticity of participants that in-person recruitment allows [39,40]. Social media recruitment requires a thorough screening process to confirm and ensure the legitimacy and eligibility of potential participants. However, thorough screening processes may lead to a more committed sample that can withstand attrition typically seen in longitudinal studies recruited on the web. Throughout the Free2b study, we also used Facebook and Instagram to verify youth’s identities, maintain contact with participants, and locate hard-to-reach participants. To date, little has been published on the use of social media to screen and retain participants in a longitudinal study. This paper describes how thorough screening processes using internet searches and social media, Instagram in particular for sexual minority youth samples, along with a range of retention strategies, help maintain retention in longitudinal clinical trials for youth recruited through social media.

Methods

Social Media–Based Recruitment

We used Facebook ads and Instagram promoted posts to recruit participants for a longitudinal trial of a drug abuse prevention program called Free2b. By clicking an ad or post, youth were taken to the study recruitment website. This website contained a brief consent video about study procedures, duration, compensation, and eligibility criteria (English speaking; aged 15 years or 16 years; US resident; access to the internet through computer or tablet; and identifying as lesbian, gay, bisexual, queer, or questioning [LGBQ]). At the conclusion of the video, youth who were still interested in participating could connect to a web-based informed assent quiz. The quiz assessed youth’s knowledge of study aims, procedures, risks, protections, and compensation. Youth who passed the quiz were then allowed to consent to study participation. Consented youth were asked to provide demographic information: first name, last name, sexual orientation, date of birth, primary and alternative email, primary and alternative phone number, social media handles (Instagram, Facebook, Twitter, and alternative social media), zip code, and alternate contact information (optional). Youth were expressly told that the alternate contact would only be used if their other forms of contact no longer worked. IP addresses were automatically collected upon form submission.

Eligibility Screening and Enrollment

The process to screen consented youth was systemized for research assistants (RAs). RAs were trained to use the steps outlined in Figure 1 to help ensure the authenticity of consenting youth. First, we removed youth who did not meet eligibility requirements: aged between 15 and 16 years, identify as LGBQ or questioning, reside in the United States, and have a phone number and email address. We then removed duplicate names, phone numbers, email addresses, and IP addresses.
To the extent possible, the demographic data from youth who had consented were cross-referenced with information from web-based searches and the social media handles the youth provided. Google searches of names with zip codes often confirmed their existence, location, and age. For example, high school athletes may have profiles showing their names and grades in school. Social media accounts could confirm age and location. Instagram and Twitter bios frequently contained age, high school, and city. Posts and tagged posts were also useful when they referenced birthday celebrations. Confirming sexual orientation was not a required element of screening as many adolescents have not publicly disclosed their sexual orientation and because sexual orientation often changes during adolescence [41]. However, when a lesbian, gay, bisexual, trans, queer, or questioning [LGBTQ] symbol or post was present on youth’s social media, it was noted as a point of authenticity; the lack of such content did not exclude youth from the study. For youth with private or limited social media accounts or no web-based presence, we used other methods to help confirm their identities. For instance, an IP address, cell phone area code, and zip code that correlated helped verify a youth’s authenticity; sometimes an email address included a birth year that matched their provided age or included a name that matched their provided first and last name.

Once youth cleared the aforementioned steps, we sent them an email asking them to reply back confirming the contact information they provided after consenting and we asked them to provide us with their birthdate. Only youth who replied to this email and who accurately confirmed the birthdate they provided during consent were enrolled in the study and randomly assigned to a study condition.
Building Positive Relationships With Participants

Building rapport with participants is important in longitudinal studies to help maintain retention [42,43]. RAs were trained to use a friendly and appreciative communication style to communicate with participants through phone calls, text messages, emails, and direct messages (DMs) on social media. The language used in messages and calls was positive, supportive, understanding, and appreciative of participants’ time. For example, RAs frequently started messages with language that acknowledged participants’ busy schedules (eg, “I know it’s the beginning of the school year and things are probably pretty hectic right now.”) to convey an understanding that the study surveys were unlikely to be their priority.

Given our understanding that participants were busy, we maintained the philosophy that no participant is “lost” unless we have no working contact information. However, even when a participant met the standards to be considered “lost,” they...
were not removed from the study. This allowed us to recover participants who may have chosen to skip a survey one year, but then chose to take the next year’s survey.

We also built positive relationships by honoring when participants requested needing more time to complete a survey (eg, during finals week). Annual holiday and birthday texts and emails (Figure 2) helped maintain contact but also served to build rapport. Email correspondence encouraged participants to contact us with questions or concerns and included the study phone number and the principal investigator’s phone number and email to facilitate this contact.

Figure 2. Examples of holiday and birthday messages sent to participants throughout the study.

Communication Strategies

Given the importance of sample retention to longitudinal research, timely communication with participants is essential. Project email and social media accounts were checked regularly; RAs were expected to respond immediately to participants’ texts, phone calls, emails, or DMs on social media. Each interaction was logged in a shared database to record contact history. This record helped determine the best methods of contact for a participant. Before making contact, RAs read through a participant’s contact log for previous successful contacts (eg, a participant might respond to texts more often than calls). RAs were also instructed to vary their contact methods, switching between text, email, voicemail, or social media. These methods increased the chances of participants seeing our communication attempts. We also made an effort to send messages with different wording or images (eg, for holiday cards each year) to participants, rather than repeatedly sending the same template message. This helped our communication come across as individually tailored, rather than as an automated message to all participants.

Finally, RAs were instructed to maintain frequent communication and reminders without overwhelming participants. As described earlier, they often started texts and phone calls with understanding language. Additionally, most reminders to take surveys included a link so participants would not have to go through their inbox to find the original survey reminder. When talking to participants on the phone, RAs always offered to send a follow-up text or email with the survey link. Finally, if a participant had not taken a survey after numerous reminders, or they mentioned that they are busy with other activities, we offered to pause communications and asked them when they would like us to check back.

Update Contact Info Surveys

To minimize the likelihood of losing participants between annual surveys due to changes in their contact information, we attempted to update participant contact information quarterly. We provided participants with their phone number or phone numbers; email address or email addresses; social media account handles; zip code; and if they have provided one, their alternate contact’s phone number in a brief web-based form. If all of their contact information was up to date, they simply clicked “correct,” or they could update their information if necessary. Youth could also continue to provide no alternate contact, add an alternate contact, remove the alternate contact they had provided, or change the one they provided.

Inevitably, some participants are lost over time due to frequent changes in contact information, competing priorities for time, or loss of interest in continuing in the study [44]. If we reached out to a participant more than 10 times with no response, they were considered “hard-to-reach.” RAs were trained on standard protocols for contacting hard-to-reach participants (Figure 3). Once a participant became “hard-to-reach,” we took a break from contacting them for several weeks. We then conducted an internet search and used social media to try to reconnect. In the rare instance that a cell phone and email was no longer working, and we were confident we were no longer reaching the participant, we discreetly reached out to their alternate contact without disclosing the purpose of the study. Youth who were considered “hard-to-reach” were always asked if they would like to be removed from the study or take a break from participation so that we did not bother them unnecessarily or
needlessly spend time trying to collect survey data. Though some youth who did not respond to our survey reminders may no longer have wished to participate, we did not make this decision for them.

Figure 3. Flowchart of steps taken to contact hard-to-reach (HTR) participants and remind them to complete annual surveys.

Ethical Considerations

Study procedures were approved by the Columbia University Institutional Review Board (IRB-AAAR5072). A waiver of parental permission was granted to reduce risks; such waivers may also increase participation from adolescents who are not out to their parents [45]. Because our sample could be considered a vulnerable population, a detailed data and safety and monitoring plan was also established, and a Data and Safety Monitoring Board met no less than once a year. A primary charge for the Data and Safety Monitoring Board in year 1 was to review Institutional Review Board–approved recruitment and informed consent procedures.

After completing the aforementioned consent processes, participants received US $30, US $35, US $40, US $45, and US $50 for each of the 5 waves of data collection (pretest; posttest; and 1-, 2-, and 3-year follow-up, respectively). Participants were able to choose from several e-gift card options. As soon as a survey was completed, participants were notified that they would receive their e-gift card within 36 hours. Sending e-gift cards in a timely manner showed our appreciation and helped maintain positive relationships with participants. We also reminded participants to redeem their gift cards when they were close to expiring.

Results

Rates of Provided Participant Contact Information

All participants were required to provide a primary email and phone number in order to be enrolled in the study, but 11.76% (143/1216) also provided an alternative phone number and 51.23% (623/1216) provided an alternative email. At the time of recruitment, 87.58% (1065/1216) of enrolled Free2b participants provided an Instagram account as part of their contact information, as compared to 19.98% (243/1216) providing an alternate contact (eg, family or friends), 15.13% (184/1216) providing a Facebook account, and 29.03% (353/1216) providing an alternative social media account (eg, Twitter, Tumblr, or TikTok). Only 10.61% (129/1216) provided no form of alternate contact or social media accounts (Table 1). The percentage of participants with an Instagram account has remained relatively stable in the approximately 3 years since recruitment. Throughout the study, Instagram has remained the most commonly provided alternative method of contact. As of
January 2023, a total of 87.40% (1047/1198) of Free2b participants have provided Instagram handles, while only 22.37% (268/1198) of participants have provided an alternate contact with a cell phone number, 19.37% (232/1198) have provided a Facebook account, 30.47% (365/1198) have provided an alternative social media account, 6.43% (77/1198) have provided an alternative phone number, and 56.18% (673/1198) have provided an alternative email.

Table 1. Number of participants who provided each type of alternative contact information at enrollment and 3 years after recruitment.

<table>
<thead>
<tr>
<th>Type of contact information</th>
<th>At enrollment (2020; n=1216), n (%)</th>
<th>Currently (January 2023; n=1198), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alternate contact</td>
<td>268 (22.37)</td>
<td>268 (22.37)</td>
</tr>
<tr>
<td>Alternative email</td>
<td>673 (56.18)</td>
<td>673 (56.18)</td>
</tr>
<tr>
<td>Alternative number</td>
<td>77 (6.43)</td>
<td>1047 (87.40)</td>
</tr>
<tr>
<td>Facebook</td>
<td>232 (19.37)</td>
<td>232 (19.37)</td>
</tr>
<tr>
<td>Instagram</td>
<td>117 (9.77)</td>
<td>365 (30.47)</td>
</tr>
<tr>
<td>No alternate contact number or social media</td>
<td>353 (29.03)</td>
<td></td>
</tr>
</tbody>
</table>

Direct Messaging and Locating Hard-to-Reach Participants Through Social Media

If participants have not taken their surveys after multiple automated reminders, they are added to a “call list” to receive personalized communication from RAs. First, RAs attempt to contact them through traditional contact methods (phone calls, text messages, and emails); if this is not effective, they begin adding social media contacts (eg, direct messaging on Instagram) in addition to traditional methods. Of the 17 participants on the call list for Survey 1 who completed the survey, 100% received only traditional contacts, and 0% received a combination of traditional and social media contacts. Of the 102 participants on the call list for Survey 2 who completed the survey, 71.6% (73/102) received only traditional contacts and 28.4% (29/102) received a combination of traditional and social media contacts. Of the 100 participants on the call list for Survey 3 who completed the survey, 77% (77/100) received only traditional contacts and 23% (23/100) received a combination of traditional and social media contacts. Finally, of the 121 participants on the call list during Survey 4 who completed the survey, 81.8% (99/121) received only traditional contacts and 18.2% (22/121) received a combination of traditional and social media contacts (Table 2).

Table 2. The percentage of participants who were on the call list and then took the survey after traditional contact (phone and email) versus a combination of traditional and social media (eg, Instagram direct messages) contacts.

<table>
<thead>
<tr>
<th>Survey number</th>
<th>Combination of traditional and social media contacts, n (%)</th>
<th>Traditional contacts (phone and email), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survey 1 (n=17)</td>
<td>0 (0)</td>
<td>17 (100)</td>
</tr>
<tr>
<td>Survey 2 (n=102)</td>
<td>29 (28.4)</td>
<td>73 (71.6)</td>
</tr>
<tr>
<td>Survey 3 (n=100)</td>
<td>23 (23)</td>
<td>77 (77)</td>
</tr>
<tr>
<td>Survey 4 (n=121)</td>
<td>22 (18.2)</td>
<td>99 (81.8)</td>
</tr>
</tbody>
</table>

Social Media Versus Traditional Contact Methods for Survey Reminders

Both Instagram and Facebook offer a direct messaging feature. However, unlike our attempts to communicate with participants through Facebook DMs, communication through Instagram DMs was frequently successful. As seen in the left screenshot in Figure 4, an anonymized recreation of an interaction with a study participant, Instagram DMs resulted in direct replies or liked messages. Instagram also notified us when the participants read our DMs by displaying “seen” under read messages. Moreover, success of Instagram survey reminders was evidenced by the completion of surveys soon after DM reminders: of the participants who received social media contacts, 41% (12/29) completed Survey 2, 39% (9/23) completed Survey 3, and 27% (6/22) completed Survey 4 within 48 hours of being sent a reminder through DM. In particular, Instagram proved to be a useful method for contacting hard-to-reach participants, who otherwise did not respond to calls, texts, and emails to take follow-up surveys. Attempts to contact participants on Facebook did not yield similar results.

Instagram was also a helpful tool for finding lost participants for whom we had no working contact information. When a participant was “lost,” we used Google to search for the participant’s new social media accounts. Both Facebook and Instagram were used to DM lost participants, but only Instagram resulted in successful participant discoveries (middle and right screenshots in Figure 4). Despite the success that these examples indicate, there were still instances where our Instagram DMs were ignored, never seen, or we were simply unable to send messages to participant accounts.
Retention Strategies

Our incentives increased in value as the study continued and ranged from US $30-US $50. These incentives are almost always claimed by the participants: 99.59% (1208/1213) claimed their Survey 1 gift card, 99.41% (1170/1177) claimed their Survey 2 gift card, and 99.32% (1168/1176) claimed their Survey 3 gift card. Of the few participants who did not claim their gift cards, only 1 or 2 participants per survey explicitly stated that they did not want their gift card.

Our success in developing and maintaining positive relationships with participants has been demonstrated by the messages we occasionally receive from participants expressing their appreciation for the project:

Example 1:

Hi Free2b folks, I just wanted to send a message that the project has seen me through a lot of change (both with time and otherwise)...Thank you for providing this space.

Example 2:

I appreciate you [sic]. I am glad to be apart [sic] of this after so many years (it's very exciting).

Example 3:

Thank you! I’m not sure if this is a no-reply kind of thing, but in the case that it’s not, I want to show my gratitude! Thank you for the opportunity to be in this study, it really means a lot to me. I am very excited to see the impact this will have! And the money has helped me so much, I was able to pay for my first binder with it! I am eternally grateful.

Example 4:

Good morning to whoever is reading this!!! Hi I’m ______ and I’m a part of the Free2b program and I want to say thank you! Your website has really allowed me to open up with those around me, as a bisexual and proud young female.

Such messages from participants frequently express gratitude, that the study is helpful for them, interest in the outcome of the research, or that the project has had a positive impact on how they feel about their sexual orientation.

Finally, 3 Update Contact Info Surveys were sent in between each study survey. Participants were not incentivized to complete these surveys, but still, 87.14% (1057/1213) of participants completed at least 1 Update Contact Info Survey between Survey 2 and 3 and 84.17% (1021/1213) completed at least 1 between Survey 3 and Survey 4.

Retention Rates

Our Instagram and Facebook recruitment and screening techniques allowed us to verify and enroll 1216 participants in the Free2b study. Retention at the first survey after enrollment was 99.75% (1213/1216). The second survey, taken about 4 months later, was completed by 96.79% (1177/1216) of participants. We were able to maintain similarly high retention at 96.71% (1176/1216) in the 1-year follow-up survey (Survey 3) and 96.30% (1171/1216) in our 2-year follow-up (Survey 4). Of the participants who did not take Survey 2, a total of 28% (10/36) were recovered in Survey 3. Of the participants who took Survey 2 but not Survey 3, a total of 9% (1/11) were recovered in Survey 4. Additionally, of the participants who did not take Surveys 2 or 3, a total of 17% (5/30) were recovered in Survey 4. Overall, since the end of the recruitment period, we have only lost 6 participants (<1%), as defined by a participant not completing any follow-up surveys to date and having zero working contact information. Despite the difficulty in reaching these participants, they are still invited to participate in each survey, and we contact them each year.

The 3 participants who did not take Survey 1 were exited from the study, and 15 participants asked to exit the study after the first survey. After Survey 2, one additional participant asked to be exited, bringing our total exited participants to 19.
Discussion

Principal Findings

Due to the increased popularity of social media and other messaging platforms, researchers have more opportunities to identify and communicate with participants in longitudinal clinical trials. This paper reports on the use of social media to aid participant screening and retention in a longitudinal study for sexual minority youth. Our findings suggest that a sample recruited through social media platforms can achieve minimal attrition with certain screening and retention strategies. Our results confirm the effectiveness of commonly published retention strategies [42,43,46] and offer new methods, such as using social media to maintain contact with participants. Study findings further suggest that Instagram is an effective method for communicating with and finding potentially lost participants over Facebook for sexual minority youth. This points to the importance of researchers following social media trends to meet their potential or enrolled participants where they are.

Overall, the various retention and screening strategies used in this study have shown promising results, with retention rates ranging from 96.30% (1171/1216) to 96.79% (1177/1216) in follow-up surveys. Our retention rates are somewhat higher than other studies with sexual minority youth. In a study of sexual minority youth whose sample included minors, retention rates at each study wave ranged from 82% to 90% [47]. Another study of sexual minority youth aged between 18 and 19 years found retention rates ranging from 85.9% to 89.5% [48].

Sexual minority youth are a hard-to-reach population, making it difficult to recruit using in-person methods [49]. However, social media has presented an accessible way to reach this demographic [1,2,5,6]. We used Instagram and Facebook to recruit a large nationwide sample of sexual minority youth. But studies that use web-based recruitment can be vulnerable to poor data quality as eligibility is harder to verify compared to in-person methods [40]. A common strategy in web-based recruitment is the use of eligibility screening questions to remove ineligible applicants [39,50]. However, screening questions do not guarantee authentic answers. Moreover, when studies such as ours compensate participants, duplicate or fraudulent enrollees are common [51]. Therefore, the benefits of web-based recruitment can be offset by risks to sample validity and data integrity. There is limited literature outlining the extent of these threats and how to mitigate them [40].

By cross-referencing demographic data provided by the participant with publicly available information and confirming participant birthdates through email, we improved the overall quality of this study data. If we had not validated their email by asking for their birthday confirmation, we may have enrolled people in the study who provided inactive email addresses and who were not 15-16 years old. Without collecting sufficient contact information at the study’s onset—primary and alternative phone numbers, primary and alternative emails, social media handles, and an optional alternate contact—sample retention would likely have been lower.

As seen in Table 1, Instagram was consistently the most common alternative contact method youth provided. This is unsurprising given the popularity of Instagram among our age demographic [31]. This may also be due to our recruitment methods through Instagram. Many participants had already interacted with us on Instagram—through DMs, comments, and likes—and thus may have been more comfortable sharing their handle. We have continued to use Instagram to reach participants throughout the duration of the study given its continued popularity among the sample. During survey data collection, reminders through Instagram DM were successful, as seen through the participants who took the survey within 48 hours of receiving a reminder DM. Instagram DMs were also useful to help update participant contact information. Understanding the most popular form of social media among a recruited demographic may help researchers to remain in contact with hard-to-reach participants.

The retention strategies used in this study include those traditionally used in longitudinal clinical trials as well as new methods that reflect the current shifts in social media trends. Traditional methods include survey incentives, building positive relationships with participants, and regularly updating participant contact information [42,43,52]. The incentives for each survey were popular as evidenced by the high number of gift card acceptances after each survey. Training RAs to have consistent communication standards and demonstrate respect for participants’ time helped us build rapport. Evidence of our success at building these positive relationships includes when they frequently thanked us for their birthday or holiday messages or upon receipt of their gift card.

Worth noting are the examples of participant messages outlined in our results. Sometimes participants were unsure if they were emailing a “real person” (eg, “not sure if this is a no-reply kind of thing”). This concern likely resulted from the use of templates for mass emails related to surveys or gift cards. Though we personalized these emails with first names, the concerns voiced by some participants is an important reminder that adolescents are savvy and able to detect when correspondence is mass generated versus individually written. Researchers may benefit from ensuring they have a mix of automated and individualized messages, as we did, to maintain positive relationships.

Throughout the study we reached out to participants to update their contact information through a brief survey. This task required minimal effort on behalf of the participant. The ease of use of the survey likely contributed to the high rates of completion. In turn, the correct contact information minimized attrition. These surveys may have also helped us to maintain positive relationships with our participants as we were able to note changes in names, pronouns, and gender identities, thereby minimizing the chance to use a deadname or misgender a participant, which can be detrimental when maintaining rapport with sexual minority youth [53].

Tracking lost participants and finding alternative methods to contact hard-to-reach participants are both crucial to prevent attrition. Throughout the study, we used Instagram to reach out to hard-to-reach participants as an alternative contact method when calls, texts, and emails were ineffective. Social media
contacts were successful as seen when participants took their survey within 48 hours of receiving a DM reminder from us. This success is likely attributable to participants’ frequent use of the app; those who were active on the platform may have been more likely to see our DMs over calls, texts or emails which can be deemed spam.

When tracking lost participants, we implemented multiple strategies. Researchers have commonly used multiple forms of web-based methods to track participants: search engines (eg, Google) and fee-based directories (eg, White Pages) are 2 common examples [54]. Though search engines are useful to locate participants, they often do not provide new methods of contact. Therefore, we used social media to locate and DM potentially lost participants. Social media platforms, primarily Facebook, have also been used by researchers to search for participants. Despite the reported success shown on tracking through Facebook [28,54,55], we have primarily used Instagram over Facebook due to its higher popularity among our sample (Table 1).

Unless requested to be exited, no participant was considered lost from the study. We used social media to “recover” participants whom we lost contact with due to changes in their contact information. After finding a profile on Instagram that matched their demographic information, we reached out to participants regarding their participation in the study (middle screenshot in Figure 4). In some instances, we were also able to use old accounts to update contact information. After attempting to reach some participants through Instagram, we found that their accounts were no longer active, but they had added a link to their new account in their bio through which we were able to reach them (right screenshot in Figure 4). Overall, Instagram has been useful as an alternative contact method for survey reminders, to track down lost participants, and to build positive relationships with participants.

Limitations
A limitation of using Instagram to screen and maintain contact with participants is that Instagram frequently changes its policies, including how DMs can be sent. In March 2021, Instagram announced it would be banning adults from direct messaging teenagers under the age of 18 years who do not follow the adult’s account [56]. This may affect retention efforts when using Instagram as a contact method in a sample of youth. It is unclear how this policy will change in the future. Moreover, people can easily change their profile handle names, preventing us from finding previously provided accounts. An additional limitation of using social media as a method to recover participants is that these methods are more effective with participants who have uncommon names, as it was very difficult to find participants on social media if there were hundreds or thousands of users with the same name. Finally, efforts to communicate or contact participants through social media were likely less effective for participants who were not out or did not want to be publicly associated with our Instagram account.

Conclusion
This paper demonstrates effective screening and retention methods to conduct a longitudinal clinical trial for sexual minority youth. Social media, particularly Instagram, was found to be useful both in the screening process and in maintaining contact with participants throughout the study. Through the use of similar thoughtful screening and retention strategies, others may be able to replicate our high retention rates. Future research is needed to determine the efficacy of individual strategies, as well as to test these strategies in different populations and on new social media platforms as they gain popularity.

Acknowledgments
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Conflicts of Interest
None declared.

References

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XSL-FO RenderX


Abbreviations

DM: direct message
LGBTQ: lesbian, gay, bisexual, trans, queer, or questioning
LGBQ: lesbian, gay, bisexual, queer, or questioning
RA: research assistant

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The Finnegan Score for Neonatal Opioid Withdrawal Revisited With Routine Electronic Data: Retrospective Study

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Abstract

Background: The severity of neonatal abstinence syndrome (NAS) may be assessed with the Finnegan score (FS). Since the FS is laborious and subjective, alternative ways of assessment may improve quality of care.

Objective: In this pilot study, we examined associations between the FS and routine monitoring data obtained from the electronic health record system.

Methods: The study included 205 neonates with NAS after intrauterine (n=23) or postnatal opioid exposure (n=182). Routine monitoring data were analyzed at 60±10 minutes (t–1) and 120±10 minutes (t–2) before each FS assessment. Within each time period, the mean for each variable was calculated. Readings were also normalized to individual baseline data for each patient and parameter. Mixed effects models were used to assess the effect of different variables.

Results: Plots of vital parameters against the FS showed heavily scattered data. When controlling for several variables, the best-performing mixed effects model displayed significant effects of individual baseline-controlled mean heart rate (estimate 0.04, 95% CI 0.02 - 0.07) and arterial blood pressure (estimate 0.05, 95% CI 0.01 - 0.08) at t–1 with a goodness of fit ($R^2_m$) of 0.11.

Conclusions: Routine electronic data can be extracted and analyzed for their correlation with FS data. Mixed effects models show small but significant effects after normalizing vital parameters to individual baselines.

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KEYWORDS
data science application; neonatology; Finnegan score; neonatal opioid withdrawal syndrome; mixed models; neonate; neonatal; abstinence; opioid; withdrawal; substance abuse; postnatal; pediatrics; electronic health record; EHR; monitoring; health record; finnegan; neonatal abstinence syndrome; NAS; opioid withdrawal

Introduction

When exposure to opioids ends, neonates may develop withdrawal symptoms [1]. Neonatal abstinence syndrome (NAS), also referred to as neonatal opioid withdrawal syndrome, can be subdivided into primary NAS due to prenatal opioid abuse by (or treatment of) the mother, and iatrogenic NAS (iNAS) when neonates are treated with opioids. Primary NAS may develop in more than 90% of infants after intrauterine opiate exposure [2]. Occurrence and severity vary interindividually and are influenced by several factors, such as prematurity [3], breastfeeding [4], and multisubstance exposure, which results in more severe symptoms and worse outcomes than exclusive exposure to a single substance [5]. Though primary NAS is typically understood as abstinence from opioids, neonates can also develop withdrawal symptoms after exposure to other substances or medication such as tobacco [6], alcohol [7], cocaine [8], selective serotonin reuptake inhibitors and other antidepressants [9], benzodiazepines [10], and a combination of opioids and other substances [5].

Many neonatal intensive care units monitor withdrawal symptoms using the Neonatal Narcotic Abstinence Scoring System, also called the Finnegan score (FS), which is composed of 32 clinical signs, each scored between 0 and 5 (maximum score 46) [11]. The FS was originally designed to assess withdrawal in otherwise healthy-term infants from mothers abusing opioids [11,12]. Thus, the validity of the FS in other patients receiving neonatal intensive care is unclear, particularly in preterm or term neonates experiencing iNAS [11,12]. The implementation of electronic patient data management systems (PDMSs) alongside the availability of digital data on vital signs allows using data science algorithms to reevaluate clinical scoring systems and to facilitate clinical decision-making using decision support algorithms [13]. Having provided the first examples in adult medicine, these methods have shown promising results in neonatology. For instance, algorithmic
analysis of heart rate characteristics is used to generate the Heart Rate Observation score—an estimate of the risk of developing sepsis [14]. Other approaches for early detection of sepsis use more variables and extensive machine learning algorithms but have not yet been validated in prospective settings [15]. Other studies have attempted to use data science algorithms to predict neonatal mortality [16]. Regarding opioid exposure, the PoPPI (Procedural Pain in Premature Infants) trial assessed the possibility of minimizing procedural pain in neonates receiving morphine treatment [17]. These data have allowed for the successful establishment of models predicting whether cardiorespiratory instability occurs after morphine administration and whether it requires intensified treatment [17,18].

Considering the subjectivity and the effort in generating an FS, the exploration of data-driven alternative ways of monitoring withdrawal symptoms appears necessary. In this pilot trial, we analyzed the association between electronic health data—mostly continuously and routinely monitored vital parameters—and the FS as a measure of the severity of NAS. Strong associations would allow an objective and less laborious NAS assessment based on routinely available data.

**Methods**

**Ethical Considerations**

The institutional review board of the Charité – Universitätsmedizin Berlin approved the study (EA2/104/21). Due to the retrospective nature of the study, the need for patient consent was waived.

**Data Export and Inclusion and Exclusion Criteria**

Continuously and routinely monitored vital parameters were extracted from the electronic health systems and harmonized for further analysis.

Data were exported for all patients admitted to the clinic between January 1, 2013, and February 1, 2022. The data set was then refined on the basis of the following inclusion criteria, and all calculations were later performed within the refined data set. To include all patients with continued clinical suspicions of withdrawal symptoms but to exclude those with one-time-only suspicions or accidental documentation, we performed the export by selecting patients with at least 3 documented FSs, since a pharmaceutical intervention was usually not initiated on the basis of a single scoring result. We cross-referenced this export selection with patients classified as having NAS in accordance with ICD-10 (International Statistical Classification of Diseases, Tenth Revision) criteria for quality control purposes. We categorized patients into subgroups of primary NAS and iNAS based on opioid medication, history of surgery, and time after birth before documenting the first FS for each patient.

Primary NAS was coded when at least 1 FS was documented before any opioid medication was administered, any surgery was performed, and the patient had not yet approached postpartum day 8. iNAS was coded when any opioid medication was administered before the patient’s first FS regardless of postnatal age. Patients with documented FS who did not meet any of these criteria were excluded. To design a sensitivity analysis, the analytic code was also applied to total study population without exclusion due to unclear NAS classification.

**Review of Hospital Data Structure**

Each variable was checked for availability within the hospital information system (SAP/Cerner) as well as the PDMS (COPRA) used in the neonatal wards (levels 1 - 3).

**Medication Data**

Medications were not named consistently; hence, their names had to be preprocessed manually. We exported all unique medication entries from the PDMS and categorized them manually. The complete list of medication categories is provided in Multimedia Appendix 1.

**Variables**

To evaluate patients’ demographics, we recorded their sex, gestational age at birth, birth weight, mode of delivery, number of documented FSs, and whether a time frame for individual baseline calculation was available and, if so, whether data were available within this time frame for the abovementioned vital parameters (including heart rate, respiratory rate, peripheral oxygen saturation, and mean blood pressure).

We calculated means for all variables listed below within specified time periods (t–1 and t–2, see the Time Periods section): heart rate, respiratory rate, peripheral oxygen saturation, and blood pressure.

Additionally, we generated an individual baseline for each patient by calculating the mean for each variable in a period of up to 5 days before documenting the first FS, which we defined as the relevant beginning of withdrawal (Figure 1). When calculating the individual baseline, we excluded spacer periods immediately post partum to minimize effects from postnatal adaptation and those immediately before documenting the first FS to minimize the effects of early-onset withdrawal. We set this spacer period to 1 day for patients with primary NAS and 3 days for those with iNAS (Figure 2). The sensitivity analysis was carried out with both spacer periods for the whole collective.

We introduced the difference between this individual baseline and the mean of the respective vital parameter within the specified period before documenting any FS as a new variable to use as an alternative to the mean of the vital parameters and henceforth referred to this variable as the “baseline-controlled mean” (Figures 1 and 2).
Figure 1. Schematic representation of the calculation of an individual baseline-controlled mean of a given vital parameter—heart rate. To reduce the scattering of data in (A), we calculated the mean of the vital parameter for each patient (denoted with a green triangle, a blue dot, and a gray square) during the individual baseline period (B). The definition of this period is illustrated in Figure 2. We then calculated the difference from the baseline for each vital parameter of each patient, as shown in (C). When plotting this difference (D), we obtained individual baseline-controlled means for vital parameters plotted on a scale around zero and with a more linear grouping of all measurements, irrespective of patient identity.
Figure 2. Time periods for the calculation of individual baselines (timeline not to scale). We defined a period to calculate an individual baseline for each patient of up to 5 consecutive days. After birth and before documenting the first Finnegan score, we introduced a spacer. The spacer has a length of 1 day for patients with primary neonatal abstinence syndrome (NAS) and 3 days for those with iatrogenic NAS. For all measurements within this period, we calculated a mean that is used to baseline-control measurements during every t–1 and t–2 for the respective patient; this baseline-control approach is illustrated in Figure 1.

Body temperature was assessed in variable patterns, and we calculated the mean and baseline-controlled mean body temperature within 1 day before documenting each FS and used these data for both time periods (t–1 and t–2).

Furthermore, we included the following variables. (1) The pharmacodynamics of buprenorphine—the first-line pharmacotherapy for NAS—is highly complex, and data on transferability to neonates are limited [19,20]. Hence, we did not attempt to estimate pharmacodynamics in neonates but considered the time between the last documented opioid medication and each FS instead. As these hours since medication can only be recorded for patients who have been administered any opioids before documenting the respective FS, either because of iNAS or because of treatment of any type of NAS, we used the date of birth as the date of the last opioid medication for infants with primary NAS if no opioid medication was documented more recently. (2) The last body weight measure before documenting each FS was considered as a percentage of the individual’s birth weight. (3) The current gestational age at each FS documentation was recorded.
Time Periods

All graphs and models were created for 2 time periods. With the goal of exploring options for predicting withdrawal symptoms, we focused on time periods before each FS. The first time period, t–1, was set to 1 hour±10 minutes before each FS, resulting in a 20-minute period from 10 minutes before until 10 minutes after the time point of 1 hour prior of each FS documentation. The second time period was set in the same manner to 2 hours±10 minutes before the respective FS, resulting in an earlier time period, t–2. The time periods are visualized in Figure 2.

Data Analysis Software

Data analysis was carried out using RStudio (version 2022.07.1+554) and R (version 4.2.1; 2022-06-23 ucrt) [21,22] using the following packages and their dependencies in addition to the function included in R, RStudio, and the ::base-package R during data extraction and harmonization: cli [23], data.table [24], dplyr [25], lubridate [26], tibble [27], and tidyverse [28]. We used the consort package to generate Figure 3 [29]. Table 1 was created using the tableone package; significance was tested using chi-square tests for categorical variables, Wilcoxon tests for skewed variables and t tests for normally distributed metric variables [30]. Skewness was assessed using the summary-function from tableone in accordance with tableone documentation [30]. We generated graphs with ggplot2 [31] and fitted our mixed effects models using lme4 [32]. Goodness of fit parameters of the mixed effects models was calculated using MuMIn [33]. Table output from RStudio was facilitated using flextable [34]. All code is has been published previously [35].
Figure 3. Patient allocation and numbers. NAS: neonatal abstinence syndrome.
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Total</th>
<th>Primary NASb</th>
<th>Iatrogenic NAS</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants, n</td>
<td>205</td>
<td>23</td>
<td>182</td>
<td>N/Ac</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>&gt;.99d</td>
</tr>
<tr>
<td>Female</td>
<td>72 (49.7)</td>
<td>8 (47.1)</td>
<td>64 (50.0)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>73 (50.3)</td>
<td>9 (52.9)</td>
<td>64 (50.0)</td>
<td></td>
</tr>
<tr>
<td>Median gestational age at birth in weeks (IQR)</td>
<td>37±1 (32±4 to 39±1)</td>
<td>38±4 (37±1.75 to 40±1.5)</td>
<td>37±0 (31±5 to 39±1)</td>
<td>.02e</td>
</tr>
<tr>
<td>Birth weight (g), median (IQR)</td>
<td>2663 (1758-3243)</td>
<td>3140 (2583-3366)</td>
<td>2585 (1695-3200)</td>
<td>.01e</td>
</tr>
<tr>
<td>Mode of delivery, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>&lt;.001d</td>
</tr>
<tr>
<td>Cesarean section</td>
<td>114 (55.6)</td>
<td>3 (13.0)</td>
<td>111 (61.0)</td>
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<tr>
<td>Vaginal delivery</td>
<td>74 (36.1)</td>
<td>19 (82.6)</td>
<td>55 (30.2)</td>
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</tr>
<tr>
<td>Data not available</td>
<td>17 (8.3)</td>
<td>1 (4.3)</td>
<td>16 (8.8)</td>
<td></td>
</tr>
<tr>
<td>Median number of documented Finnegan scores (IQR)</td>
<td>23 (10-47)</td>
<td>7 (5-14)</td>
<td>26 (12-50.75)</td>
<td>&lt;.001e</td>
</tr>
<tr>
<td>Time frame for individual baseline, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>.004d</td>
</tr>
<tr>
<td>Definable</td>
<td>172 (83.9)</td>
<td>14 (60.9)</td>
<td>158 (86.8)</td>
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</tr>
<tr>
<td>Not definable</td>
<td>33 (16.1)</td>
<td>9 (39.1)</td>
<td>24 (13.2)</td>
<td></td>
</tr>
<tr>
<td>Individual baseline data for heart rate, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>.005d</td>
</tr>
<tr>
<td>Available</td>
<td>166 (81.0)</td>
<td>14 (60.9)</td>
<td>152 (83.5)</td>
<td></td>
</tr>
<tr>
<td>Not availablef</td>
<td>6 (2.9)</td>
<td>0 (0)</td>
<td>6 (3.3)</td>
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</tr>
<tr>
<td>Individual baseline data for respiratory rate, n (%)</td>
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<td></td>
<td></td>
<td>.005d</td>
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<tr>
<td>Available</td>
<td>164 (80.0)</td>
<td>14 (60.9)</td>
<td>150 (82.4)</td>
<td></td>
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<tr>
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<td>8 (3.9)</td>
<td>0 (0)</td>
<td>8 (4.4)</td>
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</tr>
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<td>Individual baseline data for peripheral oxygen saturation, n (%)</td>
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<td></td>
<td></td>
<td>.005d</td>
</tr>
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<td>14 (60.9)</td>
<td>151 (83.0)</td>
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<tr>
<td>Not availablef</td>
<td>7 (3.4)</td>
<td>0 (0)</td>
<td>7 (3.8)</td>
<td></td>
</tr>
<tr>
<td>Individual baseline data for mean blood pressure, n (%)</td>
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<td></td>
<td></td>
<td>.004d</td>
</tr>
<tr>
<td>Available</td>
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<td>14 (60.9)</td>
<td>148 (81.3)</td>
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</tr>
<tr>
<td>Not availablef</td>
<td>10 (4.9)</td>
<td>0 (0)</td>
<td>10 (5.5)</td>
<td></td>
</tr>
</tbody>
</table>

aAll values rounded to integers except for pH.
bNAS: neonatal abstinence syndrome.
cN/A: not applicable.
dCategorial variables were assessed using the chi-square-test.
eMetric variables were assessed using the Wilcoxon–Mann-Whitney U test.
fNumber of patients, for which a time interval for individual baseline calculation was definable but no data for the respective vital parameters were available within this interval.

**Graphs**

We visualized data availability in a clustered bar plot, reporting the number of data points per variable available for each patient within each period (Figure 4). By computing 2 statistical measures for each of the 4 vital parameter variables in each of the 2 time periods, we obtained a total of 16 graphs (see Multimedia Appendix 1). To visualize data distribution, we generated heat map plots. The color of each tile is set by the number of data points weighted by the number of measurements generating the data point so that data points based on more observations contribute more to the color scale. Hence, 2 data points based on 1 observation each and 1 data point based on 2 observations both result in the same color of the respective tile.
**Mixed Effects Models**

We developed several mixed effects models. The models were fitted to descriptively analyze the relationship between the FS and vital parameters as well as NAS type, the time elapsed since the last opioid medication, gestational age, and the percentage of birth weight reached by the most recent body weight measurement. We controlled for interindividual differences by including the patient identifier as the random effect. We generally selected one set of vital parameter variables mixing neither means or individual baseline-controlled means nor the time periods of different vital parameters within a single mixed effects model. The models were not fitted to predict the FS; therefore, neither cross-validation nor bootstrapping were applicable. The regression equation for the full model was as follows, where “mean” could be substituted with “baseline-controlled mean” and “t–1” with “t–2” throughout the equation:

\[
\text{Value of Finnegan-Score} \sim \text{Intercept} + \text{Mean heart rate in the t–1 period} + \text{Mean peripheral oxygen saturation in the t–1 period} + \text{Mean respiratory rate in the t–1 period} + \text{Mean of the mean arterial blood pressure in the t–1 period} + \text{Mean body temperature}
\]
within 1 day before documenting the FS + Hours between the last medication as specified and documentation of the FS + Percentage of birth weight + Gestational age + NAS type + (1 / patient identifier)

We evaluated the goodness of fit again for models with a simplified set of variables, excluding variables with small effects (estimates of <0.05) and high degree of missingness (>30% missing values). Goodness of fit was determined using the Akaike information criteria (AIC), Bayesian information criteria (BIC), and $R^2_m$ and $R^2_c$ and is listed in Multimedia Appendix 1.

For the sensitivity analysis, we excluded the NAS-type variable from the full model. The model’s results and goodness-of-fit data from the sensitivity analysis can be found in Multimedia Appendix 2.

Results

Patient Characteristics and Data Composition

Patient demographic data are provided in Table 1, and patient allocation is demonstrated in Figure 3. Out of 205 neonates with NAS, 78 (38%) had been ICD-10–coded. Abstinence after intrauterine exposure (P96.1) was coded in 17.4% (n=4) of patients who were classified as having primary NAS and 5.5% (n=10) of patients who were classified as having iNAS. Abstinence after therapeutic exposition (P96.2) was coded in 21.7% (n=5) and 34.6% (n=63) of the respective patient groups.

We obtained 7050 FS data points and calculated the baseline-controlled mean for up to 166 (81%) infants (Table 1). Two reasons prevented us from doing so in the other cases: no definable time period (as illustrated in Figure 2) or no data points within the time period to calculate upon.

Visual Interpretation

As shown in Figure 4, heart rate measurements showed the highest data density and mean blood pressure measurements showed the lowest. Heart rate measurements were the only variable for which at least 5 data points within a time period were commonly available, the only other variable being mean arterial blood pressure in very rare instances.

The plots show a widely distributed pattern for mean and baseline-controlled mean heart rate (Figure 5) and mean arterial blood pressure (Figure 6), each plotted against the FS. The tile color and different ranges shown in the color legends illustrate differences in the density of data available for heart rate and mean arterial blood pressure measurements; this corresponds to the data density described above and is shown in Figure 4. While there was no direct relationship between the FS and the respective parameters visible, the graphs for the baseline-controlled version of each parameter showed a narrower spectrum on the x-axis. In particular, the baseline-controlled blood pressure shows a discernible trend of greater-than-zero values, indicating a rise in blood pressure in neonates in comparison with that before withdrawal assessment. However, this rise in baseline-controlled blood pressure does not clearly increase with an increase in the FS.
Figure 5. Heat maps of mean heart rate and baseline-controlled mean difference in heart rate during the t–1 time period (60±10 minutes before documenting the Finnegan score [FS]), values of children with iatrogen neonatal abstinence syndrome. Left: the x-axis shows the mean heart rate in beats per minute (bpm); right: the x-axis shows the baseline-controlled mean difference in heart rate in bpm. Each tile has a width of 2 bpm and a height of 1 FS point; the opacity is generated from the amount of data points within the area of the respective tile weighted by the number of heart rate observations that each of those data points is calculated from.
Regression Analysis of Vital Parameters in Fitted Models

Estimates for vital parameters stayed either positive or negative across all fitted models and varied only in the corresponding SEs, CIs, and P values. Among all models, the model containing all variables, using the later time period of t–1 and the baseline-controlled mean as the statistical measure, yielded the highest $R^2_c$ and $R^2_m$ and second-lowest AIC and BIC (Table 2). This model was fitted on 357 observations obtained from 84 infants.
An increasing individual baseline-controlled heart rate (estimate 0.04, 95% CI 0.02 to 0.07) and an increasing arterial blood pressure (estimate 0.05, 95% CI 0.01-0.08) correlated significantly with an increased FS.

Furthermore, a decreasing individual baseline-controlled peripheral oxygen saturation (estimate –0.09, 95% CI –0.19 to 0.01), decreasing gestational age (estimate –0.06, 95% CI –0.18 to 0.06) as well as increasing individual baseline-controlled respiratory rate (estimate 0.00, 95% CI –0.02 to 0.03), increasing hours since the last medication (estimate 0.00, 95% CI 0.00-0.00), increasing baseline-controlled body temperature (estimate 0.33, 95% CI –0.63 to 1.28), increasing percentage of birth weight (estimate 0.00, 95% CI 0.00-0.00), increasing baseline-controlled blood pressure, which underlies heavy scatter and is only revealed corrected for various variables. These models supported the hypothesis that opioid withdrawal measured by FS is associated with vital parameter readings if big data sets are considered.

The irregularity and scarcity of blood pressure measurements in neonatal standard care resulted in missing values for the individual baseline-controlled mean arterial blood pressure and thereby reduced the amount of complete data on which the model could be fitted. Due to the large number of missing values (mean blood pressure unavailable for >90% of FS), imputation was not applicable. When blood pressure was not included—thereby reducing the complexity of the model but increasing the number of complete observations—all measures for goodness of fit decreased (worst model with blood pressure [\(R^2_m=0.08, \text{ AIC}=2345\)]; best model without blood pressure [\(R^2_m=0.07, \text{ AIC}=25,992\]). On excluding the NAS type from our sensitivity analysis, these results were confirmed. Including previously excluded patients and using spacer periods of the same length for all patients during baseline calculation resulted in similar results (Multimedia Appendix 2).

The abovementioned estimated effects are small and may seem clinically irrelevant. However, due to the nomenclature of mixed effects models, the estimates refer to 1-unit changes of the respective variable. This implies that a heart rate increase of 10 beats per minute from the individual baseline would coincide with an FS increase of 0.4 and a 10-mm Hg increase (increase of 0.6) in the mean arterial blood pressure assuming that all other values remained constant.

**Discussion**

This pilot study shows a measurable association between withdrawal assessment based on FS and heart rate and blood pressure, which underlies heavy scatter and is only revealed when controlling for several other influencing variables in regression analysis. The unfiltered correlation between FS values and vital parameters was weak, and the analysis revealed heavily scattered data. Thus, we fitted mixed effects models that corrected for various variables. These models supported the hypothesis that opioid withdrawal measured by FS is associated with vital parameter readings if big data sets are considered. Multiple analyses revealed robust estimates with a small magnitude for the association of increasing FS with an increased heart rate and arterial blood pressure (Table 2) but not with the respiratory rate. However, even in the model exhibiting the best goodness of fit (\(R^2_m=0.11; \text{ Table 2}\)), this association was found to be weak, likely because of heavily scattered input data. Notably, our analysis only revealed an association with the FS, which, while being the currently and widely used assessment tool for withdrawal, can only be understood as a resemblance of the latter, not withdrawal itself.

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**Table .** Results of the mixed model using baseline-controlled means as statistical measures, t–1 as time period, and a complete set of variables (\(R^2_m=0.11; \text{ AIC}=1999.36; \text{ Bayesian information criterion}=2045.89; 84 patients; 357 Finnegan scores).  

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Estimate</th>
<th>SE</th>
<th>95% CI</th>
<th>(P) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Intercept)</td>
<td>9.31</td>
<td>2.88</td>
<td>3.51 to 14.92</td>
<td>.002</td>
</tr>
<tr>
<td>Individual baseline-controlled heart rate in the t–1 period</td>
<td>0.04</td>
<td>0.01</td>
<td>0.02 to 0.07</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Individual baseline-controlled peripheral oxygen saturation in the t–1 period</td>
<td>–0.09</td>
<td>0.05</td>
<td>–0.19 to 0.01</td>
<td>.09</td>
</tr>
<tr>
<td>Individual baseline-controlled respiratory rate in the t–1 period</td>
<td>0.00</td>
<td>0.01</td>
<td>–0.02 to 0.03</td>
<td>.84</td>
</tr>
<tr>
<td>Individual baseline-controlled mean arterial blood pressure in the t–1 period</td>
<td>0.05</td>
<td>0.02</td>
<td>0.01 to 0.08</td>
<td>.005</td>
</tr>
<tr>
<td>Individual baseline-controlled body temperature within 1 day before documenting the Finnegan score</td>
<td>0.33</td>
<td>0.49</td>
<td>–0.63 to 1.28</td>
<td>.51</td>
</tr>
<tr>
<td>Hours between last medication as specified and Finnegan score</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00 to 0.00</td>
<td>.46</td>
</tr>
<tr>
<td>Percentage of birth weight</td>
<td>0.00</td>
<td>0.00</td>
<td>–0.01 to 0.00</td>
<td>.19</td>
</tr>
<tr>
<td>Gestational age</td>
<td>–0.06</td>
<td>0.06</td>
<td>–0.18, to 0.06</td>
<td>.35</td>
</tr>
<tr>
<td>Iatrogenic (vs primary) neonatal abstinence syndrome</td>
<td>–0.27</td>
<td>1.64</td>
<td>–3.41 to 2.92</td>
<td>.87</td>
</tr>
</tbody>
</table>

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https://pediatrics.jmir.org/2024/1/e50575
The use of electronic monitoring data and health records may become an attractive source for clinical decision-making (eg, for identifying the risk of sepsis) or multivariable predictive models (eg, for neurodevelopmental impairment) in neonatology [36-39]. While more conservative models perform similarly on the task of predicting sepsis in neonates, advanced machine learning techniques exhibit better performance in case of heterogeneous big data pipelines [40].

Conceptually, it is appealing to develop such a big data–based prediction strategy, particularly if it can be validated by using a clinical scoring system. Since opioid withdrawal symptoms considered in the FS rely on the accuracy of reporting, detecting, and describing symptoms, adding monitoring or laboratory data might improve subsequent clinical decisions. However, items in the FS may be too complex per se for fitting common models of analyzing big data from electronic health records. In this regard, the density of electronic monitoring data, such as arterial blood pressure, was surprisingly low in our cohort. Other easily accessible data such as intrauterine growth restriction and maternal tobacco or multisubstance abuse also failed to sufficiently predict NAS severity in previous studies [41]. Success in using continuously monitored electronic data for decision-making in care of neonatal opioid withdrawal, however, may critically depend on the granularity of these data. At our institution, the heart rate may have been recorded with very low data granularity, for example (Figure 4), as these readings were previously summarized to means for storage capacity reasons. This is not unusual as hospital systems regularly do not save the highest available data frequency to reduce the required data storage space, all the while limiting its use for research at later stages [40]. Thus, we applied specific periods (t–1 and t–2; Figures 1 and 2) and identified an individual baseline of vital parameters to compile data with varying temporal resolution. Of note, temporal cross-correlation of vital parameters might have resulted in an improvement in predictive values on the severity of FS, as previously shown in other cohorts of preterm infants with sepsis, necrotizing enterocolitis, or retinopathy [38,42,43].

To date, our data did not offer sufficient temporal resolution to cross-correlate vital parameter data strings. However, based on the most the recent study by Poppe et al [38], we suggest that continuously logged electronic data sampled preferentially at 1 Hz should be obtained. For model development, such high-frequency data may also be obtained during prospective trials. For model validation, real-world data are required at a later stage. High temporal resolution also allows models to reach high levels of goodness of fit and significance with the use of relatively basic sets of variables, as demonstrated for both instability and requirement of treatment after morphine analgesia based on documented episodes of apnea, profound oxygen desaturation, the average heart and respiratory rates, and the postmenstrual age [18]. While our models based on our limited temporal resolution data did not show significant effects of changes in the respiratory rate, the addition of respiratory signals to heart rate characteristics also improved the performance of sepsis prediction models. The resulting model features an especially strong negative predictive value, and we suggest validating this model with larger cohorts [44]. Further research is necessary to not only validate the effects we observed in other cohorts but also analyze associations between high-frequency data and withdrawal, potentially using measures obtainable within these data, such as heart rate characteristics and variations. Most recently, our institution has begun to archive vital parameter data in real time and with high resolution, enabling us to pursue this path.

Our data do not allow considering the different (substance or dose) pharmacologic interventions for neonatal opioid withdrawal and variations in the half-life of such substances when computing the time elapsed since the last administration and the next FS. The complex metabolism of buprenorphine in neonates [19,20] may also affect the analytical mixed models' performance and be relevant for strategies using artificial intelligence for future clinical decision-making.

Despite these limitations, the discrepancy between the FS and data from electronic monitoring may also reflect an inherent weakness of the clinical score. Since the FS has been reported to be subjective, resulting in low interrater reliability, our study indirectly supports the “Eat, Sleep, Console” approach for neonatal opioid withdrawal as successfully shown in the recent cluster-randomized controlled trial of the ACT NOW Collaborative [45].

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Conflicts of Interest
FB reports receiving grants from the German Federal Ministry of Education and Research, the German Federal Ministry of Health, the Berlin Institute of Health, personal fees from the Elsevier Publishing, grants from the Hans Böckler Foundation, support from the Robert Koch Institute for attending meetings and travel, grants from the Einstein Foundation, grants from the Berlin University Alliance, personal fees from Medtronic, and personal fees from GE Healthcare outside of the submitted work.

Multimedia Appendix 1
Extented set of figures on vital parameters and tables showing mixed effects model results.

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(page number not for citation purposes)
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Abbreviations

AIC: Akaikes information criterion
BIC: Bayesian information criterion
FS: Finnegan score
ICD-10: International Statistical Classification of Diseases, Tenth Revision
iNAS: iatrogenic neonatal abstinence syndrome
NAS: neonatal abstinence syndrome
PDMS: patient data management system
PoPPI: Procedural Pain in Premature Infants

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Correction: Caregivers’ Perceptions, Needs, and Data Sharing Concerns in mHealth Research on Pediatric Asthma: Cross-Sectional Survey Study

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Related Article:
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(JMIR Pediatr Parent 2024;7:e56046) doi:10.2196/56046

In “Caregivers’ Perceptions, Needs, and Data Sharing Concerns in mHealth Research on Pediatric Asthma: Cross-Sectional Survey Study” (JMIR Pediatr Parent 2023;6:e49521) the authors noted one error.

In the original publication, Figure 2 included the correct caption but the image was a reproduction of Figure 1. This has been corrected, and Figure 2 will appear as attached.
Figure 1. Caregivers’ perceptions on the use of data through mHealth for research. N/A: not applicable.

The correction will appear in the online version of the paper on the JMIIR Publications website on January 12, 2024 together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

Conflicts of Interest
None declared.