

Evaluating the Picterus Jaundice Pro Application in Parental Use: a prospective mixed-methods study

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Abstract

Background: Undiagnosed severe neonatal jaundice, caused by hyperbilirubinemia, can lead to irreversible brain damage. The Picterus® Jaundice Pro application (Picterus JP) is a mobile health app developed for use by healthcare professionals and parents to screen for neonatal hyperbilirubinemia. Yet, parental experiences with the Picterus JP remain largely unexplored.

Objective: To evaluate the usability and user-friendliness of Picterus JP when used and evaluated by parents.

Methods: Between August 2023 and January 2025, we conducted a prospective mixed-methods study at three maternity care settings: the maternity wards of two hospitals in the Netherlands and one hospital in Israel. Parents were invited to participate if their infant was term-born, at least 12 hours old, but still in the first week of life. Parents used Picterus JP once according to the manufacturer's instructions. Immediately afterwards, usability was evaluated using the validated mHealth App Usability Questionnaire (MAUQ) and open-ended questions. A subset of parents and nurses participated in semi-structured interviews and focus groups.

Results: In total, 123 participants completed the questionnaire. The median [IQR] MAUQ-score was 6 [5-7] out of 7. Ninety-seven (88%) parents indicated they would use Picterus JP at home. Parents reported they found the app easy, quick and convenient, although sixty-seven (56%) reported a failure on the first try. Some parents struggled to find or interpret the instructions, but most (75%) who tried again obtained a bilirubin estimate. The thematic analysis identified three themes that were considered important for the usability of Picterus JP: intention to use Picterus JP, infant wellbeing and instruction and guidance.

Conclusions: Parents rated Picterus JP highly in terms of usability, despite encountering difficulties during initial use. Technical improvements and more proactive guidance seem important to support successful parental use. Nonetheless, both parents and nurses are positive about the Picterus JP potential for home screening of severe neonatal jaundice. Clinical Trial: N/A

This study was registered in PaNaMa (ID 10763), the internal research registry of the University Medical Center Groningen (UMCG). Formal trial registration in a WHO-recognized trial registry was not required because the study did not fall under the

Dutch Medical Research Involving Human Subjects Act (WMO).

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Original Manuscript

Evaluating the Picterus® Jaundice Pro Application for Neonatal Jaundice Screening by Parents: prospective mixed-methods study

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Abstract

Background: Undiagnosed severe neonatal jaundice, caused by hyperbilirubinemia, can lead to irreversible brain damage. The Picterus® Jaundice Pro application (Picterus JP) is a mobile health app developed for use by healthcare professionals and parents to screen for neonatal hyperbilirubinemia. Yet, parental experiences with the Picterus JP remain largely unexplored.

Objective: To evaluate the usability and user-friendliness of Picterus JP when used and evaluated by parents.

Methods: Between August 2023 and January 2025, we conducted a prospective mixed-methods study at three maternity care settings: the maternity wards of two hospitals in the Netherlands and one hospital in Israel. Parents were invited to participate if their infant was near term-born, at least 12 hours old, but still in the first week of life. Parents used Picterus JP once according to the manufacturer's instructions. Immediately afterwards, usability was evaluated using the validated mHealth App Usability Questionnaire (MAUQ) and open-ended questions. A subset of parents and nurses participated in semi-structured interviews and focus groups.

Results: In total, 123 participants completed the questionnaire. The median [IQR] MAUQ-score was 6 [5-7] out of 7. Ninety-seven (88%) parents indicated they would use Picterus JP at home. Parents

reported they found the app easy, quick and convenient, although sixty-seven (56%) reported a failure on the first try. Some parents struggled to find or interpret the instructions, but most (75%) who tried again obtained a bilirubin estimate. The thematic analysis identified three themes that were considered important for the usability of Picterus JP: intention to use Picterus JP, infant wellbeing, and instruction and guidance.

Conclusions: Parents rated Picterus JP highly in terms of usability, despite encountering difficulties during initial use. Technical improvements and more proactive guidance seem important to support successful parental use. Nonetheless, both parents and nurses are positive about the Picterus JP potential for home screening of severe neonatal jaundice.

Keywords: hyperbilirubinemia; jaundice detection; mobile health

Introduction

Background

Undiagnosed and untreated severe neonatal hyperbilirubinemia (SNH) can lead to irreversible brain damage: kernicterus. This is a preventable condition that leads to sensorineural hearing loss, vertical gaze paralysis, dystonia or more subtle forms of kernicterus spectrum disorders.(1)

Neonatal jaundice, a yellowish discoloration of the skin and sclerae, occurs in the first days of life due to excessive levels of total serum bilirubin (TSB).(2) Neonatal jaundice affects 60-80% of term newborns and is generally self-limiting.(3) However, in four to nine percent of near term newborns, treatment with phototherapy is necessary to prevent neonatal jaundice progressing to SNH.(4) Therefore, it is paramount to detect within the large group of jaundiced children, those who develop potentially dangerous levels of TSB.

The gold standard for diagnosing hyperbilirubinemia is quantification of TSB levels through blood sampling.(5) The common practice of early postnatal discharge after in-hospital births often occurs before the physiological peak in TSB levels. They peak around the fourth day of life. In some countries, a pre-discharge TSB or transcutaneous bilirubin (TcB) screening is performed to ensure appropriate follow-up of neonatal jaundice. Other strategies encompass the use of risk factors to predict the risk of developing SNH.(6-8) Once at home, visual inspection is widely used by health care professionals (HCPs) to assess the severity of jaundice. This has shown to be unreliable.(9) HCP visits are typically scheduled on just a few occasions in the first week of life. This implies that an opportunity for timely detection of imminent SNH is limited to only a few occasions. As a result, many infants may develop SNH unnoticed, putting them at risk of kernicterus and requiring intensive treatment that could often have been prevented.(10)

To support timely diagnosis and treatment, several novel devices to screen for SNH have been developed.(11-16) One of these devices is the Picterus® Jaundice Pro (Picterus JP), a mobile health app developed to estimate bilirubin levels non-invasively. The app showed high sensitivity (94%) in detecting SNH and has obtained European Conformity marking (CE marking).(17, 18) By enabling parents to use the app at home, Picterus JP could facilitate more frequent screening at any time. Yet, parental experiences with the Picterus JP remain largely unexplored.

Therefore, this study aimed to determine the usability and user-friendliness of the Picterus JP when used and evaluated by parents.



Methods

Study design

We evaluated the usability and user-friendliness through a prospective mixed-methods study by using the validated mHealth App Usability Questionnaire (MAUQ), open ended questions, interviews and focus groups.

Setting and Participants

This study was part of the IDjaundice@home project, conducted under the Transforming Health and Care Systems (THCS) program (project number: 1477).(19) Participants were recruited at three distinct real-world newborn care settings: the maternity wards of two hospitals in The Netherlands (Frisisus Medical Center Leeuwarden (FMC) and University Medical Center Groningen(UMCG)) and one in Israel (Shamir Medical Center (SMC)). This study was initially conducted in the Netherlands from August to December 2023 (period 1) and extended to Israel from October 2024 to January 2025 (period 2). To ensure comparability, the study was also repeated in the UMCG in Netherlands in the second period.

Parents and/or caregivers were invited by researchers to participate if their neonate was healthy with a gestational age of ≥ 35 weeks and between the age of 12 hours and 7 days. At least one parent was required to have sufficient proficiency in Dutch (in The Netherlands) or Arabic or Hebrew (in Israel). Researchers had no prior clinical relationship with the parents, who were aware that the researchers had experience in both clinical pediatrics and research.

Definition of variables

Parental education level was classified into three categories according to self-reported highest attained education: (1) basic education (elementary school), (2) intermediate education (high school and vocational training), and (3) advanced education (college or university degree).

Postnatal age was recorded in 24-hour intervals (e.g., 24–48 hours, 48–72 hours) based on the time of birth. Daily check-ins with the study team were conducted to confirm whether parents had used the app within the previous 24 hours. Exact age in hours was not documented. Infants younger than 12 hours were not enrolled due to the informed consent reflection period.

Additional demographic and clinical variables collected from infants and parents were: neonatal sex,

birth weight, gestational age, maternal parity, and country and hospital of recruitment. These variables were collected as per standard clinical documentation. Limited information on healthcare providers was collected, including age, years of work experience, and the number of times they had observed the use of the app.

Intervention

Parents were asked to use Picterus JP at least once during hospital stay. Immediately afterwards parents answered questions about their experience. The app could only be used by parents during hospital stay for practical and safety considerations. All participating neonates received standard care to ensure safe practice. This included visual inspection for signs of jaundice, TcB, and/or TSB measurements as deemed necessary by the attending physicians or midwives. The use of Picterus JP app did not affect standard care.

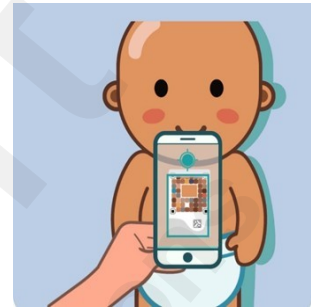


Figure 1. Intended use of Picterus JP. Figure used with permission from Picterus AS.

All parents received a Picterus® calibration card, a download link and the same instructions for using Picterus JP at their convenience. Instructions consisted of a brief verbal explanation, textual instructions (via the patient information letter or app), and pictograms, which were included in the app and printed out.(20) The study team did not provide explicit demonstrations or guidance before and during app use. Parents either installed the app on their own smartphones (Netherlands) or used a Samsung Galaxy A50 provided by the researchers (Israel).

When starting the Picterus JP, users were instructed to place the square, colorful Picterus® calibration card on the infants' bare chest (see Figure 1). Picterus JP then guided users onscreen on how to correctly position their smartphone (i.e., angle, distance). Once the app detected that the conditions were appropriate (i.e., correct placement of the calibration card, positioning of the smartphone, and sufficient ambient light) it would then automatically proceed to take six photos: three with flash and three without.

After capturing the images, the app either displayed a bilirubin value (in $\mu\text{mol/L}$ or mg/dL , depending on the setting) or issued an error message. If an error occurred, the app would either state that the measurement was unsuccessful or, if possible, provide a reason (e.g., insufficient ambient light or shadows rendering the photo's unsuitable for analysis). During the photo-taking phase, the

app attempted to correct suboptimal conditions by offering simple on-screen instructions to the user. If image quality remained insufficient, Picterus JP would either delay image capture until instructions were correctly followed, and/or take additional photos, and ultimately abort the measurement attempt, providing an error message when possible.



Data collection

Quantitative Data Collection

The MAUQ was used to evaluate Picterus JP usability. This is a validated instrument specifically designed to evaluate the usability of mHealth apps.(21)

The MAUQ consists of 18 statements, divided into three subscales: ease of use, interface & satisfaction, and usefulness (Multimedia Appendix, Table A1). One statement (#17) was omitted from the original MAUQ version, because it assessed offline functionality, which did not apply. MAUQ was scored from 1 (strongly disagree) to 7 (strongly agree) on statements in favor of the device. Statements were translated from English to Arabic, Dutch and Hebrew, and verified by independent back-translation.

Qualitative Data Collection

All parents were asked to answer four open-ended questions about their experiences with the app to elaborate on the following topics: such as their general experience, child comfort, possible malfunctioning of the app, and additional comments.

Semi-structured interviews and focus groups were conducted using a topic list covering four categories: general experience, instruction and guidance, possible app malfunctions, and perceived future use and suggestions for improvement. The topics contained two to five questions that the researcher could use to elicit further responses if participants provided limited information. The topic list can be found in the Multimedia Appendix 1.

A subset of parents was invited to participate in semi-structured interviews. The interviews lasted between 5-15 minutes and were conducted either in person or over the phone by local members of the study team. Interviews were generally audio-recorded and transcribed, while phone interviews were documented through detailed notes.

Registered nurses in the Netherlands shared their observations on parental app usage in focus groups. Focus groups were led by two researchers (FT and TdV) and were recorded and transcribed. Each

session lasted between 15-25 minutes.

Ethical considerations

This study was conducted in accordance with the Declaration of Helsinki. In the Netherlands the study was approved by the Central Ethics Review Board for non-WMO studies of the University Medical Center Groningen (CTc UMCG, Research Register Number 10763). The study was classified as a non-WMO study, falling outside the scope of the Medical Research Involving Human Subjects Act (WMO). Local feasibility was confirmed by the Regional Ethics Review Committee (RTPO) at the Frisius Medical Center (reference RTPO 1160). In Israel the study was approved by Shamir Helsinki Committee (approval number 264-23-ASF).

Informed consent was obtained from the parents of all participating neonates.

Data analysis

Sample size

A convenience sample of 120 participants was targeted across two study periods, with 30 participants per participating center in each time period.

Quantitative data

The Likert-scale data of the MAUQ questionnaires was summarized by medians and interquartile ranges [IQR] given the skewed data distribution as visually assessed by histograms. Other categorical data was represented as relative distribution (frequencies and percentages) per item. Demographic variables were assessed for normality and reported as means with standard deviations, or medians with IQRs, or range depending on distribution. No formal hypothesis testing was performed; all analyses were descriptive. Microsoft Excel and IBM SPSS Statistics for Windows, version 28 (IBM Corp., Armonk, N.Y., USA) were used for all analyses.

Qualitative data

Qualitative data from focus groups, in-depth interviews, and four open-ended survey questions were analyzed and systematically coded using thematic analysis.(22) Participant responses were summarized as codes (i.e., keywords). Codes with similar meanings were grouped into overarching

topics. These topics are either facilitators or barriers to the use of Picturus JP.

Topics (i.e., barriers and facilitators) were subsequently organized into themes. These themes could follow the structure of the open-ended questions (deductive) or emerge from the data itself (inductive). This approach allowed for a comprehensive and integrated analysis of all qualitative sources.

Coding was independently performed per country by local researchers. One researcher (FT) coded all datasets of both countries to ensure consistency across contexts. Codes merged into topics. Another researcher (TdV) reviewed a sample of the coded data and confirmed agreement with the chosen topics and thematic structure.

Results

Participants

In total, 123 parents completed the MAUQ questionnaire and open-ended questions. Table 1 shows participant characteristics. The sample included both first-time and experienced parents, with a relatively high proportion (63%) of participating parents having completed higher education. Sixteen parents were approached for in-depth interviews: after two reminders, twelve participated. The two focus groups included twelve nurses, all Dutch and female. Table 2 shows nurse characteristics. Notably, they had a young age range and few years of work experience.

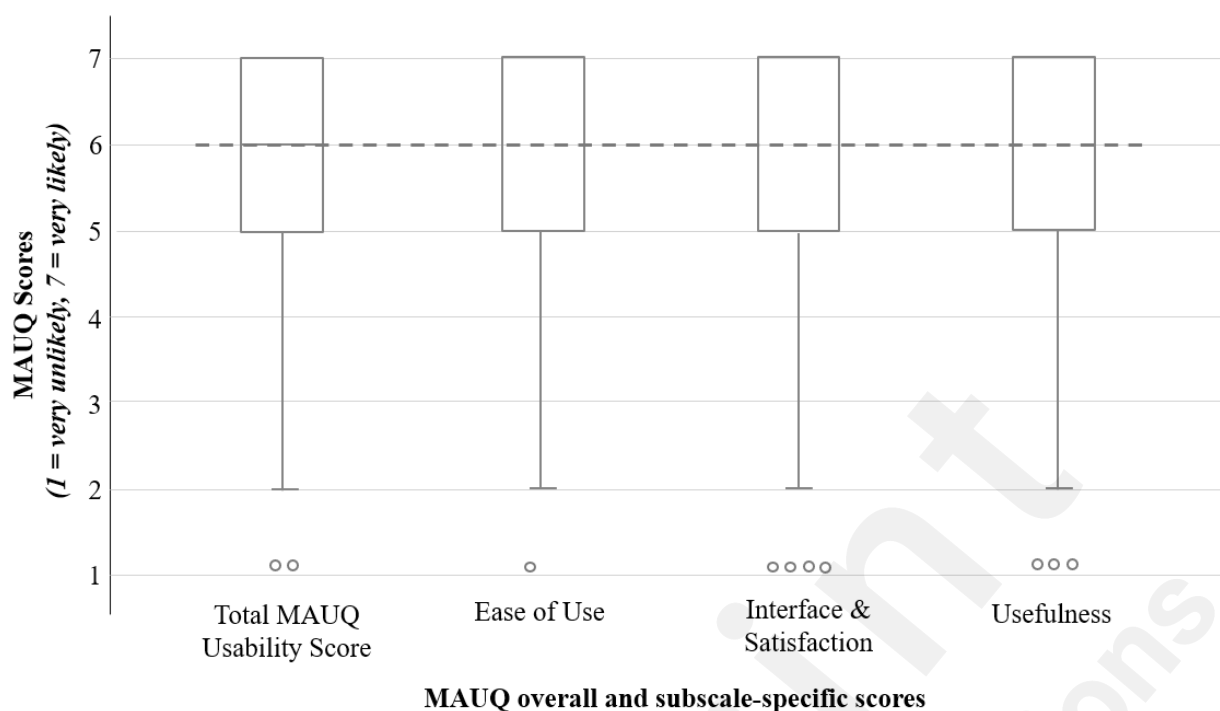


Figure 2. Total parental mHealth app Usability Scores (MAUQ).

The overall MAUQ scores and scores within the three subscales are shown. The median is marked by the horizontal dotted line. The boxes are limited by the 25th and 75th percentiles. The whiskers ($\perp$) represent the lowest and highest irradiance within 1.5 interquartile distance below the box. Extreme outliers ($\circ$) indicate participants who gave the lowest possible rating (median = 1) on the statements.

mHealth app usability questionnaire

Figure 1 shows the median [IQR] score of 6 [5-7] on a scale from 1 to 7 of the total mHealth usability score of the MAUQ. Similarly, the median [IQR] scores for the subscales of ease of use, interface & satisfaction, and usefulness were 6 [5-7]. There were no differences in overall median MAUQ scores or MAUQ scores per subscales between the two countries, between the three hospitals, or between both time periods.

Parents expressed the most positive attitudes toward the statements that Picterus JP was easy to learn and improved their access to healthcare, with a median [IQR] MAUQ score of 7 [6-7]. All other statements had a median MAUQ score of 6. Figure 2 displays the distribution of parental ratings of the usability score in percentages. Table 2 in the Multimedia Appendix shows all 17 MAUQ statements and the corresponding medians [IQR].

Table 1. Participant characteristics (neonate and parent dyads).

Characteristic	Netherlands (n= 93)	Israel (n= 30)
Hospitals	2	1
Time period		
2023	62	0
2024/2025	31	30
Interviews, parents (n)	6	6
Gestational age, weeks, median [IQR]	39 [38-40]	39 (38-40)
Median postnatal age, grouped in hours(h) (range)	24-48 (12-144)	24-48 (12-120)
Birth weight, grams, mean (SD)	3466gr [$\pm$ 570]	3552 ($\pm$ 339)
Female, n (%)	44 (47%)	14 (47%)
Maternal parity		
First	14 (15%))	11 (37%)
Second	48 (52%)	7 (23%)
Third or more	31 (33%)	12 (40%)
Educational level parents		
Basic education	1 (1%)	0
Intermediate education	25 (27%)	4 (13%)
Advanced education	56 (60%)	22 (73%)
Unknown	11 (12%)	4 (13%)

Table 2. Participant characteristics of registered nurses

Focus group (N=12)	Group 1 N=5 (41,7%)	Group 2 N=7 (58,3%)
Location	Frisius medical center, Leeuwarden, The Netherlands	University Medical Center Groningen, The Netherlands
Female n (%)	5 (100%)	7 (100%)
Age, in years Median (range)	24 (21-39)	27 (19-35)
Work Experience, in years Median (range)	0,5 (0,3-15)	5 (0-12,5)
Frequency of witnessing Picterus® app being used by parents:		
1 Time	1	4
1-5 Times	2	3
5-10 Times	1	0
≥10 Times	1	0

Qualitative results

Themes, facilitators and barriers

Table 3 shows the results of the thematic analysis. Three themes were identified: “Intention to use Picterus JP”, “Neonatal Wellbeing” and “Guidance & Instructions”. The first two themes were deductive, corresponding to two open-ended questions, whereas the last theme was inductive and emerged from the interviews and focus groups but was also supported by the responses to the open-ended survey questions. Within these themes 13 facilitators and 10 barriers were identified.

Table 3. Facilitators and barriers to using the Picterus JP app: insights from parents and nurses^{a-c}

Theme	↑ Facilitator ↑	P	I	N	↓ Barrier ↓	P	I	N
Intention to use Picterus JP	Easy and simple to use	P	I	N	Difficulties obtaining measurements	P	I	N
	Home Access	P	I		Doubts about relevance		I	N
	Feeling in control	P	I	N	Doubts about reliability	P	I	
	Reassuring for extra monitoring	P	I		Reminders needed		I	N
Infant Wellbeing^b	Quick	P		N	Prolonged undress	P	I	
	Comfortable	P			Neonate too upset	P	I	
	Safe	P			Camera flash	P	I	
	Minimally intrusive	P						
	Usable at own convenience	P	I					
Guidance & Instructions	Easy to understand	P	I	N	Unclear for parents what to do when a problem occurs	P	I	N
	Self-explanatory	P	I	N	Uncertain for parents what to do with results	P	I	N
	Quick to explain	P		N	In-app guidance easy to miss	P	I	N
	In Person explanation		I	N				

^aThis figure presents perceived facilitators and barriers (topics) to using the Picterus JP app. Topics are grouped into three themes. Within themes, topics are ordered from most to least frequently mentioned.

^bThe theme ‘Infant Wellbeing’ reflects factors related to the infant’s comfort and safety, as perceived by parents, but does not indicate actual clinical risk that was reported during the study.

^cTopics emerged from three types of qualitative data: **P** = Parents, responses from the survey (N=123); **I** = Interviewed parents (N=12); **N** = Nurse who participated in focus groups (N=12).

Open-ended questions

Table 4 presents the four open-ended questions for parents. In response to the first question, *"Would you use the app?"*, 97 parents (88%) responded affirmatively. For the second question, 96 parents (81%) reported no concerns about their infant's comfort while using the app. A common facilitator for both questions was that Picterus JP was *"easy, simple, and quick to use"*. Common barriers included difficulty obtaining a valid measurement and specific concerns about their baby, particularly when using the app took longer than expected. Parents worried that prolonged undressing might result in hypothermia or cause the neonate to become upset. Of 23 parents who expressed concerns, 20 (87%) reported having encountered difficulties using the app.

For the third question, *"Did you encounter any difficulties using the app?"*, 67 parents (56%) reported having experienced an issue. Table 5 shows reasons for difficulties, which varied between study periods and countries and were either device-related or user-related issues. Device-related difficulties referred to issues where parents reported having received an error message. For example, when the photo quality was insufficient for analysis, the Picterus JP could display a message such as 'ambient light insufficient' or 'difficulty focusing'.

User-related difficulties included cases where the infant was too 'uncooperative' to obtain sufficient photos, or where parents acknowledged incorrect use of Picterus JP (e.g., displacing the calibration card).

In the first period in the Netherlands (2023), 36 out of 62 parents (58%) primarily encountered device-related difficulties to various reasons. In the second period in the Netherlands (2024), 10 out of 31 parents (32%) reported difficulties, which were primarily user-related. Whereas in Israel (2025) 23 out of 30 parents (77%) reported difficulties and these were mostly device-related. In Israel, 7 of these 23 parents (30%) indicated an issue where ambient light was insufficient. Multiple attempts were made to improve ambient light. Retrospective analysis of these photos indicated that the issues in these cases were often related to the quality of the camera and the save files format of the specific phone model being used.

Of 105 parents who attempted the measurement again, even though this was not required within the scope of the study, 79 (75%) reported that they were able to get a bilirubin estimate. Likewise, 21 (70%) of Israeli parents reported a successful measurement after further attempts.

Missing responses were not included and were limited to 9 (7%), 3 (2%), and 2 (2%) out of 123 for the three respective questions.

The fourth question, *'Do you have any additional comments?'*, resulted in 50 responses that were integrated into the thematic analysis (Table 3). Some comments addressed misunderstandings and

suggestions regarding the instructions and in-app guidance (i.e., correct use of the calibration card), while others expressed uncertainty about interpreting the results. Additionally, satisfaction with the Picterus JP was expressed. All emerging topics were closely aligned with findings from other survey questions, interviews, and focus groups.

Table 4. Open-ended questions

		Yes	No
<i>Would you use the app?</i>	N=119	97 (88%)	13 (12%)
Concerned about neonates comfort?	N=121	23 (19%)	96 (81%)
<i>Did you encounter any difficulties using the app?</i>	N=121	67 (56%)	53 (44%)
<i>Do you have any other comments?</i>	N=123	50 (41%)	73 (59%)
<i>*Missing data was excluded from analysis</i>			

Table 5. Parental difficulties when using Picterus JP app for the first time^a

Theme	Device-related	User-related
Identified topics	Issue with focusing and/or ambient light	Baby factors (i.e., upset or moving)
	Miscellaneous error messages (i.e., freeze, calibration card not recognized)	Found instructions unclear
	Unknown error	Used the calibration card incorrectly
	Phone was not compatible	Miscellaneous parental factors (i.e., hand tremors)

^a**Topics are organized by frequency, from most to least frequent.**

Focus groups & Interviews

The identified topics in focus groups with nurses and in-depth interviews with parents supported and further contextualized the topics reported by parents in the questionnaires. They led to the identification of three additional topics (Table 3). An additional identified facilitator was the perceived value of receiving an in-person explanation or demonstration of the app. There were two additional barriers. First, parents needed reminders to use the Picterus JP app. Another issue was that in-app guidance could easily be missed, which delayed or disrupted the process. All three topics were mentioned by both nurses and parents. Table 3 in the multimedia Appendix presents supporting quotes from nurses.

Intention to Use Picterus JP

Consistent with questionnaire findings, ease of use was frequently mentioned as a facilitator by parents and nurses (quote 1). However, more unique to this part of the data collection, both nurses and parents noted that reminders to use Picterus JP were often necessary (quote 2).

Parents appreciated the ability to monitor their neonate for jaundice themselves but questioned its added relevance alongside regular healthcare visits. Parents stated that it had to be very clear for them what they had to do with the results. In the interviews they emphasized the need for clear guidance. Nurses acknowledged the relevance as well, noting that their clinical experience and recognition of early signs of jaundice served as important reminders for parents (quote 3).

Neonatal Wellbeing

Similar to the answers from parents, nurses mentioned that taking a photo with Picterus JP was perceived as quick and non-distressing for the neonate. Similar to the questionnaire, parents expressed a preference for additional warnings about the camera flash to remind them to cover their neonates' eyes (quote 4). Nurses expressed no concerns about infant wellbeing during the use of Picterus JP when asked about disadvantages or improvements that could be made.

User Guidance & Instructions

User guidance and instructions were most prominently discussed during interviews and focus groups. Oral explanations were preferred over written instructions, even though in general the latter were considered clear (quote 5). Nurses found the instructions easy to explain, and often parents agreed that understanding what to do was straightforward (quote 6).

Interestingly, as was often reported in the survey and also shown in Table 5, when parents were unsuccessful in obtaining a measurement, it was not always clear to them what went wrong (quote 7). Some parents admitted in hindsight that they had not fully paid attention to the in-app guidance or that they had misunderstood the instructions (quote 8). Some nurses reported that, at times, they were unsure why a measurement had failed. In contrast, others stated that the cause of failure was often clear to them as observers, whereas parents appeared to have overlooked the in-app guidance (quote 9).

Overall nurses in the focus groups were positive about the potential parental use of Picterus JP in the

home setting (quote 10).



Discussion

Principal results

We determined how parents perceived the usability and user-friendliness of Picterus Jaundice pro, a novel smartphone app to allow for early detection of imminent severe SNH. Our results show that parents rated Picterus JP highly on usability, supported by a median mHealth App Usability score of 6 out of 7. Parents described Picterus JP as easy, simple and quick to use.

A considerable number of parents reported either technical difficulties or movement of their baby as reasons for failing to obtain a result on the first use of Picterus JP.

Technical difficulties reported by users may be partly explained by the variation in smartphone devices used across study sites despite that these devices passed Picterus JP's compatibility check. Yet, some phones, e.g., budget models, may still be more sensitive to ambient lighting conditions. In Israel, all parents used the same mid-range phone provided by the study team, whereas in the Netherlands varied personal devices were used. This difference may explain the lower incidence of technical difficulties in the Netherlands compared to Israel. Furthermore, within the Dutch site, technical difficulties decreased during the second study period, possibly due to ongoing software improvements of Picterus JP.

In addition to technical difficulties, some parents (19%) expressed concerns regarding neonatal wellbeing during app use. Frequent topics were concerns about the infant becoming cold or upset. The majority of these parents (87%) reported having encountered difficulty using Picterus JP on their first attempt. This may suggest a possible connection between prolonged attempts and parental concerns, but this was not formally studied.

Although parents and nurses found the Picterus JP instructions clear, they reported that instructions could be overlooked or misunderstood. It is possible that in some cases, unsuccessful attempts were related to skipped or misunderstood instructions, rather than technical failure alone. Picterus JP offers multiple instructions: symbols on calibration cards and the app launch screen, online text, and in-app pop-ups. It is tempting to speculate that passive instructional methods may not fully support parents in busy post-partum settings.

Nonetheless, the majority of parents (88%), even among those who encountered technical difficulties

or had concerns, stated that they would use the app at home. This implies that, despite initial barriers, overall acceptability and perceived usefulness of Picterus JP in a home setting are high, which are both essential prerequisites for its implementation.

Notably, the nurses participating in focus groups were young and had limited work experience, reflecting the composition of junior and senior staff typically present during shifts. Demographic characteristics, with younger nurses potentially being more tech-savvy, may influence generalizability but also improve comparability with similarly aged parents.

Nevertheless, all nurses had experience with SNH screening and regarded Picterus JP as relevant and useful. They emphasized that parents engaged more with Picterus JP when its relevance was clear for parents too. Moreover, insights from nurses helped contextualize parental responses as they frequently observed parents during the use of Picterus JP. This underlines the importance of incorporating multiple perspectives in usability studies.

Comparison with Prior Work

Our findings are consistent with the two prior studies to date in which the use of Picterus JP was assessed by HCPs. HCPs perceived Picterus JP as an easy-to-use, useful, and time-saving tool in the management of neonatal jaundice.(23, 24) Our study builds on previous work by including the perspectives of both HCPs and parents in high-income countries.

Despite the widely recognized need for accessible screening tools to detect SNH, few clinically validated alternatives currently exist. Although non-invasive screening can be performed with TcB devices, these devices are rather costly and currently generally not available in home settings.(12) To save costs, two- and multicolor icterometers, i.e., the Bilistrip™ and the Bili-ruler™, respectively, have been developed with rather acceptable screening performances and interrater reliability.(11, 15) In parallel with these icterometers, other smartphone applications to optically estimate hyperbilirubinemia have been developed and studied throughout the past years.(12-14) Except for Picterus JP, to our knowledge none have currently published usability results, or reached a clinical implementation phase and obtained a CE or Food and Drug Administration (FDA) certification.

Usability studies are a relevant step for implementation, given that apps that are considered easy to use have yielded higher acceptability and satisfaction ratings.(25) However, studies linking app usability to clinical outcomes in pediatrics remain scarce, and are mainly focused on chronic disease

management.(26, 27) The MAUQ is a validated and reliable instrument specifically developed to evaluate mobile health applications used by patients and HCPs, unlike more general instruments such as the System Usability Scale (SUS) and the Post-Study System Usability Questionnaire (PSSUQ). (21)

MAUQ has increasingly been adopted in recent years and been used for studies across diverse healthcare settings all over the world.(28) High MAUQ scores have been associated with proper test performance in another mHealth screening app.(29) This suggests that high usability scores, as measured by MAUQ, could be a relevant indicator for evaluating feasibility of a screening mHealth tool like Picterus JP.

Limitations

This study has several limitations. Firstly, we used convenience sampling, which may limit representativeness, although saturation was observed in the open-ended responses in the interviews and focus groups. Secondly, the design may have led to selection bias: Participants were motivated to participate, comfortable with smartphone use and noticeably highly educated on average. Although this may limit generalizability, we did not observe a clear association between education level and MAUQ score or parental experience, i.e., failure to measure.

Lastly, the app was typically used for only one measurement with limited instruction with the purpose to generalize the outcomes. The intended repeated daily use of Picterus JP might influence user experience differently. Though repeated use might expose the user to other user- and device-related difficulties, familiarity through guidance and practice may also enhance perceived parental usability of the app.

Strengths

To our knowledge, this is the first study to assess the usability of a smartphone-based bilirubin screening tool from the perspective of both parents and HCPs. Furthermore, the multicenter and multicultural setting, spanning two countries and three hospitals, adds to the potential generalizability of the results of different health and care systems, as similar usability patterns emerged across diverse user groups. In addition we used a validated instrument (MAUQ) to evaluate usability, which enhances the reliability and comparability of our findings.

Conclusion

Our findings show that parents and nurses highly appreciated the Picterus app, despite some device- and user-related difficulties. Our findings highlight the importance of ongoing technological improvements, clear user guidance, and proactive support to improve usability and user experience to successfully facilitate the implementation of parental use of Picterus JP in neonatal jaundice management.

If future studies confirm the clinical accuracy and reliability of parental use of Picterus JP in different populations and health and care systems, daily non-invasive home screening could become feasible. As such, use of Picterus JP may enable earlier detection of imminent SNH, allowing timely intervention for at-risk neonates, reducing the emotional and logistical burden on families, and supporting clinical decision-making by HCPs.

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FJ Terpstra conceptualized the study, conducted the focus groups, collected most of the data, analyzed all data, and wrote the manuscript.

A Hazan and E Kohn contributed to data collection and analysis.

TJ de Vries contributed to the study design, facilitated and reviewed the focus groups, cross-checked the coding and thematic analysis, supervised the study, and provided critical feedback throughout the research process.

PH Dijk and CV Hulzebos contributed to the study design, supervised the study, and provided critical feedback throughout the research process.

All authors contributed to interpretation of the findings in addition to the reviewing and approving of the manuscript.

Conflicts of Interest

We received free calibration cards from Picterus AS. Picterus AS is member of the THCS consortium ID Jaundice @ Home. However, the company had no role in the study design, data collection, analysis, or interpretation of the results. The authors declare no other conflicts of interest.

Abbreviations

CE = European Conformity

CTc = Central Ethics Review Board

EMC = Erasmus Medical Center

FDA = Food and Drug Administration

FMC = Frisius Medical Center

HCP = Health Care Provider

IQR = Interquartile range

MAUQ = mHealth App Usability Questionnaire

mHealth = Mobile Health

Non-WMO = falling outside the scope of the Medical Research Involving Human Subjects Act

Picterus JP = Picterus Jaundice Pro

PSSUQ = Post-Study System Usability Questionnaire

RTPO = Regional Ethics Review Committee

SD = Standard deviation

SMC = Shamir Medical Center

SNH = severe neonatal hyperbilirubinemia

SUS = System Usability Scale

TcB = transcutaneous bilirubin

THCS = Transforming Health and Care Systems

TSB = total serum bilirubin

UMCG = University Medical Center Groningen

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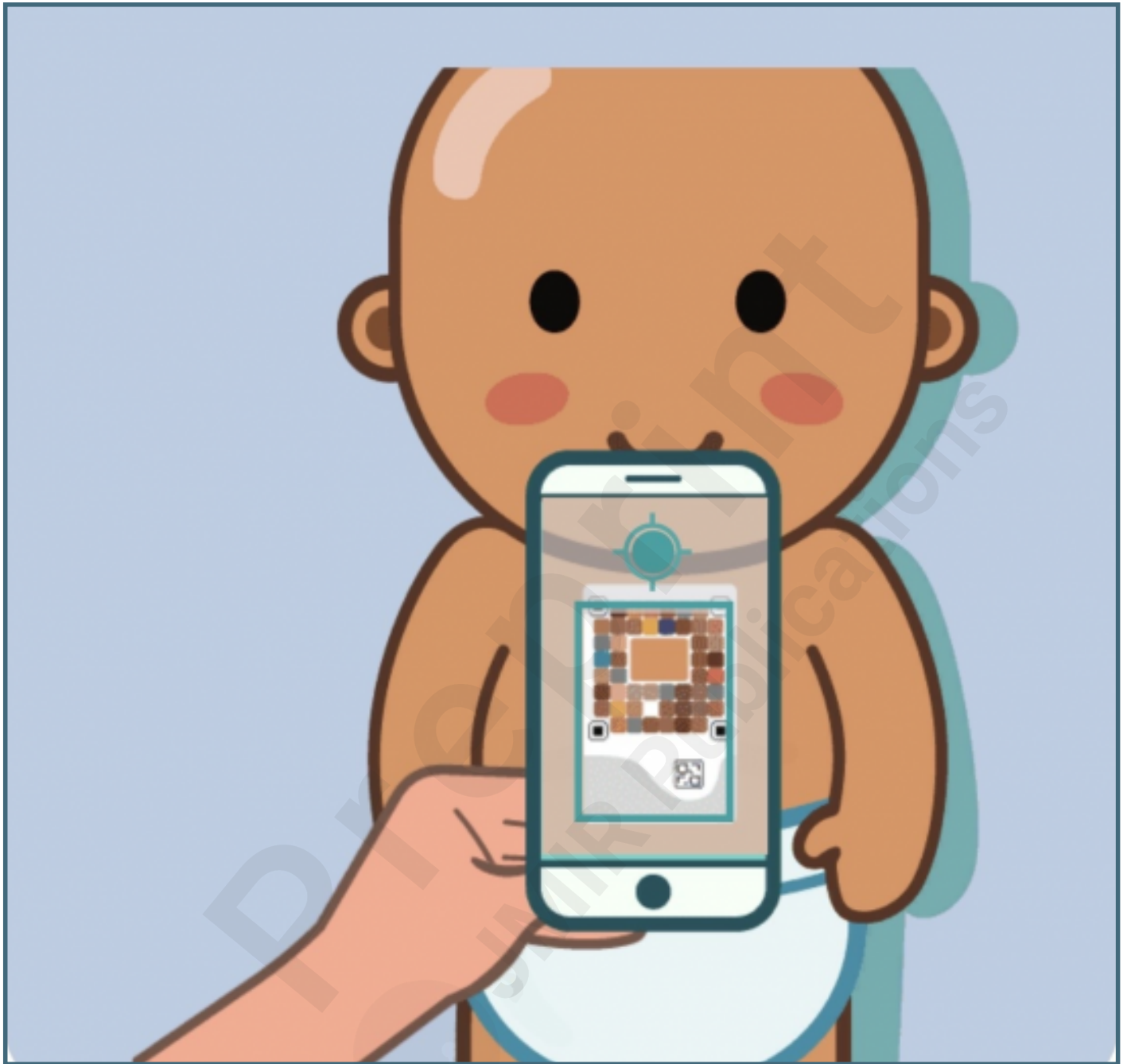
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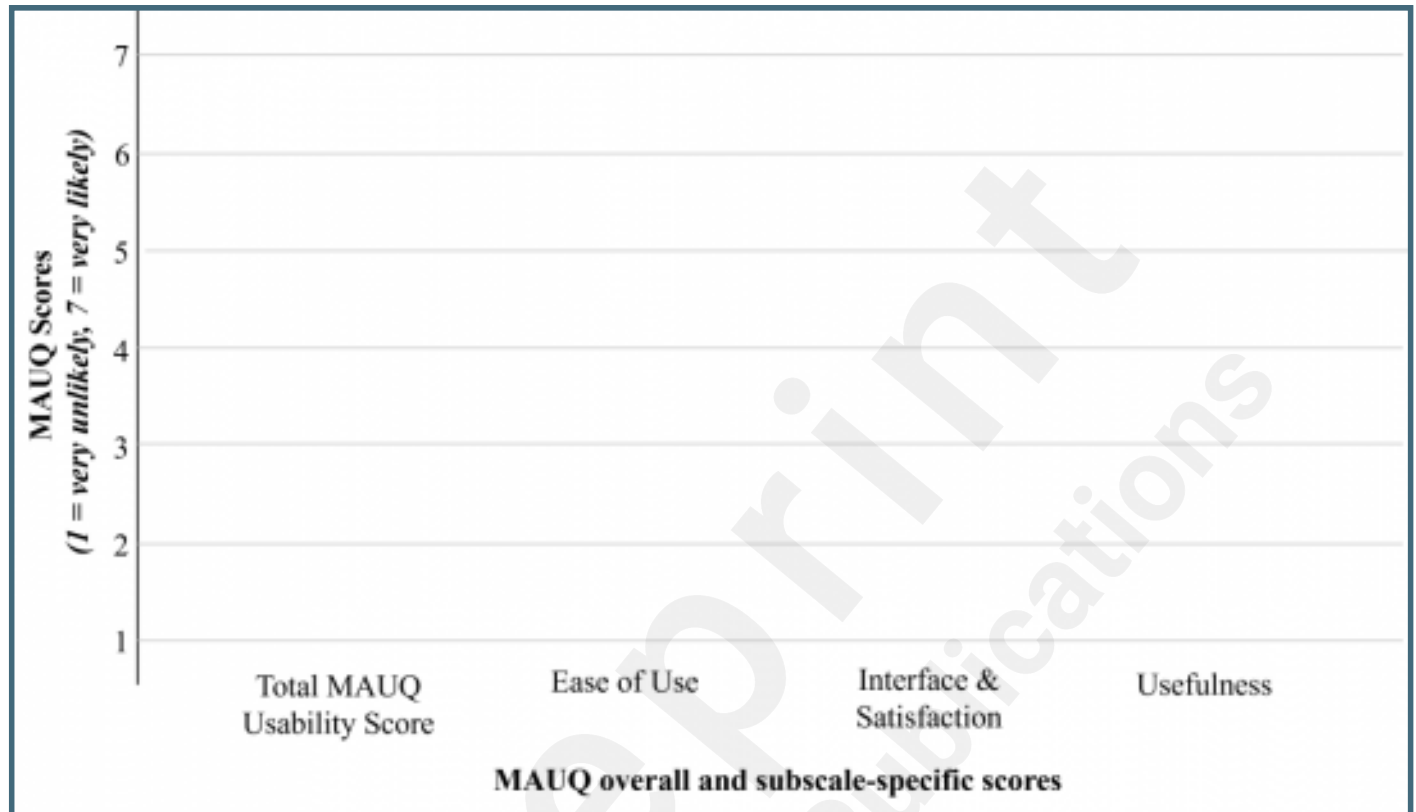
Supplementary Files

Figures

Intended use of Picterus JP is show. Figure 1 is used with permission from Picterus AS.



Overall parental mHealth app Usability Scores (MAUQ) and MAUQ scores within the three subscales are shown. The median is marked by the horizontal dotted line. The boxes are limited by the 25th and 75th percentiles. The whiskers (?) represent the lowest and highest irradiance within 1.5 interquartile distance below the box. Extreme outliers (?) indicate participants who gave the lowest possible rating (median = 1) on the statements.



Multimedia Appendixes

The topic list used for interviews and focusgroups.

URL: <http://asset.jmir.pub/assets/8e3a0bae262ca28d0e92e31d05837216.docx>

Statements and results of the mHealth Usability Questionnaire (MAUQ) are presented.

URL: <http://asset.jmir.pub/assets/2786b97a5df4872cf9e956c688ee065e.docx>

Quotes from interviews and focus groups.

URL: <http://asset.jmir.pub/assets/08956ce913764a8ac11c6321293b4160.docx>

