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Graduate thesis in Medicine

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Abstract

Background: Neonatal jaundice is usually harmless but may, if it is not timely detected, lead to permanent neurological deficits and in the worst cases death. The disease burden is greatest in low- and middle-income countries, partly due to low availability and high cost of medical devices used to detect the condition. Picterus JP (Picterus Jaundice Pro) is a low-cost smartphone-based mHealth solution intended for use by parents/caregivers and health care workers for the detection of neonatal jaundice. No previous studies have investigated the user experience of Picterus JP among parents in a low-income setting.

Research aims: The main aim of this project was to explore and compare parents' user experience with the mHealth smartphone app Picterus JP in an urban and a rural low-income setting in Mexico. The secondary aim of this project was to explore and compare the self-reported level of knowledge of jaundice among the same parents.

Research methods: Data collection was performed in the state of Oaxaca, Mexico, from August to September 2022. The user experience of Picterus JP and the level of knowledge about jaundice among the participants were assessed through a paper-based questionnaire. Parents of newborns and pregnant women were invited to participate in the study at an urban clinic and a rural hospital. After the data collection period, we analysed the distribution of responses using quantitative methods. Mann-Whitney U test was applied to explore whether there was a statistically significant difference between the two study sites.

Results: A total of n=96 questionnaires were used for data analysis. Among these, n=47 were collected from an urban clinic, and the remaining n=49 from a rural hospital. According to our results, the study participants were on average satisfied with the usability and utility of Picterus JP. The participants from the urban clinic were overall more positive towards the app compared to the ones from the rural hospital. In regard to knowledge about jaundice, 52,1 % (n=50) of the participants had never heard about the condition. Furthermore, our data analysis revealed that the level of knowledge was systematically lower at the rural hospital.

Conclusion: Our study revealed that the participants generally had a good user experience with Picterus JP, although this finding must be understood in the context of this study's limitations. Therefore, we think that the app has great potential to be used in a low-income setting like Oaxaca, but that it needs improvements to serve people with limited experience with mobile technology.

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List of abbreviations

BIE Bilirubin induced encephalopathy

eHealth Electronic health

G6PD Glucose-6-phosphate dehydrogenase

GDPR General Data Protection Regulation

GPS Global Positioning System

HAQ Healthcare Access and Quality

IMSS Mexican Institute of Social Security

INSABI Institute of Health for Wellbeing

ISSSTE Institute for Social Security and Services for State Employees

LMIC Low- and middle-income country

MAUQ mHealth App Usability Questionnaire

mHealth Mobile health

neoSCB Neonatal scleralconjunctival bilirubinometer

NSD Norwegian Centre for Research data

NTNU Norwegian University of Science and Technology

OECD Organisation for Economic Co-operation and Development

Picterus JP Picterus Jaundice Pro

RBC Red blood cell

TcB Transcutaneous bilirubinometer

TSB Total serum bilirubin

UGT Uridine diphosphate-glucuronosyltransferase

WHO World Health Organization

WiFi Wireless Fidelity

1. Introduction

Neonatal jaundice – also known as icterus or hyperbilirubinemia – affects the majority of newborns during their first week of life. The condition is predominantly self-limiting and harmless but may lead to permanent neurological deficits and death if not timely detected (1). Globally, approximately 114 000 infants die each year due to delayed diagnosis and treatment of severe cases of neonatal jaundice. The burden is greatest in low- and middle-income countries (LMICs), partly due to low availability and high cost of medical devices used to detect the condition (2).

A multidisciplinary group of researchers in the Norwegian company Picterus AS has developed a smartphone app for detecting neonatal jaundice called Picterus JP (Picterus Jaundice Pro) (3). The app is intended for use by parents/care givers and health care workers in LMICs. Picterus JP has proven to be a sensitive and accurate screening device for neonatal jaundice, and a recent study revealed a want from health care workers in Nigeria to implement the app in their daily workflow (4). However, no research has been done on the user experience of the app among parents in LMICs.

Our thesis assessed the user experience of parents with Picterus JP in a low-income setting in Mexico, and their knowledge of jaundice. Participants were recruited from an urban and a rural study site in the state of Oaxaca, Mexico, and their responses have been compared.

This study was part of the PhD project JAUND-EASE (Health service innovation of neonatal jaundice detection by mHealth technology in a low-income setting: user-centred implementation project in Mexico), led by PhD candidate Dr Gabriela Jiménez Díaz. The main objective of JAUND-EASE is to innovate the health service for neonatal jaundice detection by contextually implementing the novel mHealth technology Picterus JP and assess its usability and user experience compared to standard care for neonatal jaundice detection in low-resource settings in Mexico.

2. Background

2.1 Neonatal jaundice

Neonatal jaundice is one of the most frequent reasons for readmission to hospital after birth (5, 6). As much as 80 % of preterm and 60 % of term neonates develop jaundice within the first week of life (1). The term neonatal jaundice does not refer to a singular disease but rather the physical finding of yellow discolouration of the neonate's skin, sclera, mucous membrane and other tissues caused by elevated levels of bilirubin (1).

Neonatal jaundice can be harmless or harmful depending on its aetiology and the degree of bilirubin increase (7). The condition is usually a benign and transient event due to various characteristics of neonatal physiology. However, for various physiologic and pathologic reasons, some newborns develop severe hyperbilirubinemia, which puts them at risk for developing bilirubin induced encephalopathy (BIE). BIE ranges from slight behavioural changes to severe and lifelong neurological impairment and death (8, 9). Hence, early detection and warranted preventative therapy of severe hyperbilirubinemia is crucial, particularly in underdeveloped countries where the occurrence of BIE is greatest (9).

2.1.1 Metabolism of bilirubin

Approximately 80 % of bilirubin is derived from the breakdown of red blood cells (RBCs), while the remaining 20 % comes from non-erythroid heme-containing proteins found in various tissues (10). Macrophages of the reticuloendothelial system are responsible for the breakdown of senescent RBCs and heme production through haemoglobin catabolism (10, 11). Heme is then converted to biliverdin, which in turn is reduced to unconjugated bilirubin. Unconjugated bilirubin is insoluble in water and binds tightly to albumin for transportation to the liver. Once in the liver, unconjugated bilirubin becomes water soluble through conjugation by the enzyme uridine diphosphate-glucuronosyltransferase (UGT). This alteration enables the excretion of bilirubin into the duodenum as part of bile (10, 12).

In the colon, bilirubin is deconjugated by bacteria into urobilinogen. The majority of urobilinogen is further converted into stercobilin and eliminated through faeces. The remaining either become part of so-called enterohepatic circulation - where urobilinogen is

transported back to the liver and recycled for bile production - or excreted as urobilin in the urine (12).

2.1.2 Physiologic neonatal jaundice

The physiological type of neonatal jaundice accounts for 75 % of the cases. It starts after 24 hours of age and typically peaks around 48-96 hours before resolving within 2-3 weeks in full-term infants (1). Physiological jaundice is due to several characteristics of the neonates, where their immature physiology makes them more vulnerable to developing elevated levels of unconjugated bilirubin (unconjugated hyperbilirubinemia). Even in healthy neonates, the bilirubin level is higher than in adults (1).

There are three main reasons why the level of unconjugated bilirubin is increased as a physiological condition in neonates: shortened lifespan of RBCs, decreased bilirubin conjugation and reduced bilirubin elimination through faeces (7).

In healthy adults, the average lifespan of RBCs is about 120 days, unlike in neonates, where they have a reduced circulating half-life with an average lifespan of 70-90 days. The reduced lifespan of the RBCs leads to an increase in the production of unconjugated bilirubin (13). This is the first main reason why jaundice often develops in various degrees in the neonate (1, 14).

Secondly, UGT in the full-term newborn has an activity of only about 1 % of the adult level (14). As mentioned earlier, conjugation of bilirubin by UGT found in hepatocytes is a prerequisite for eliminating bilirubin through bile. As the immature liver struggles to conjugate the excessive amounts of bilirubin produced by the reticuloendothelial system, the level of unconjugated bilirubin increases, and the neonate develops jaundice (14).

The third reason that contributes to physiological jaundice in newborns is their decreased amount of bacteria which can convert conjugated bilirubin to stercobilin in the intestinal tract. Instead, the enzyme beta-glucuronidase transforms bilirubin to its unconjugated form, which is then reabsorbed through enterohepatic circulation and results in increased concentration of bilirubin in blood (7).

2.1.3 Pathological neonatal jaundice

A variety of pathologic conditions in the neonate may also lead to unconjugated hyperbilirubinemia and neonatal jaundice. Pathological neonatal jaundice usually appears within the first 24 hours after birth (7). Among the most common reasons are blood group incompatibility between the mother and the baby, Gilbert syndrome and GD6P deficiency (1). Conjugated hyperbilirubinemia in newborns – sometimes referred to as neonatal cholestasis – is a rare cause of neonatal jaundice. The condition is almost always pathologic and due to various causes, including biliary atresia and viral infections. Regardless of aetiology and severity, it requires rapid and targeted treatment (1).

2.1.4 Severe hyperbilirubinemia and its treatment

The bilirubin level is measured as total serum bilirubin (TSB), which is based on the combined concentration of unconjugated and conjugated bilirubin. Severe hyperbilirubinemia can be defined as TSB > 428 $\mu\text{mol/L}$ (25 mg/dL) in term and late preterm newborns (8). It can develop from both physiological and pathological conditions.

As mentioned above, unconjugated bilirubin binds reversibly to albumin with high affinity. However, it may be found in its free form when the concentration exceeds the carrier-capacity of albumin (7). Free unconjugated bilirubin is neurotoxic, can cross the blood-brain barrier, bind to brain cells, and cause damage to specific regions in the brain, including the basal ganglia, globus pallidus and cerebellum (9). Early diagnosis and treatment of severe hyperbilirubinemia is essential to avoid the development of extreme hyperbilirubinemia, defined as TSB > 513 $\mu\text{mol/L}$ (30 mg/dL), which can result in BIE (8).

Treatment of severe hyperbilirubinemia is ideally based on aetiology and TSB. The threshold for treatment also depends on factors like gestational age and weight of the newborn (1, 15). A systematic review of global clinical practice guidelines for neonatal jaundice was conducted in 2021. All the investigated guidelines included phototherapy and exchange transfusion as treatment options (16). Phototherapy transforms unconjugated bilirubin into water-soluble isomers that can be excreted without conjugation in the liver (17). This is a simple but effective treatment with very few adverse side effects and therefore the first-line treatment of neonatal hyperbilirubinemia (1). If the phototherapy is not effective enough or if

the bilirubin levels rise too rapidly, exchange transfusion should be considered. Exchange transfusion involves the replacement of the newborn's blood with compatible donor blood (18). This is the fastest way to reduce bilirubin levels, but it can, in certain instances, cause serious side effects like internal bleeding (1, 19).

More targeted treatment can also be done depending on the specific aetiology of jaundice. An example is intravenous immunoglobulin (IVIG) if the jaundice is caused by immune-mediated haemolysis (1).

In LMICs, however, national guidelines for the effective treatment of severe hyperbilirubinemia are rare (20). Another general problem is that even though guidelines exist, adherence to them could still be poor. A study in a selection of American hospitals found a marked interhospital variation regarding adherence to existing guidelines at the point. (21). This highlights the problem with severe neonatal jaundice and its solutions across health care systems.

2.1.5 Methods for detecting neonatal jaundice

When diagnosing neonatal jaundice, the gold standard is to measure TSB through a blood test (4,5). While this gives the most accurate result, the method is invasive and can lead to pain, stress, and risk of infection for the neonate being assessed (22). The use of a transcutaneous bilirubinometer (TcB) is a useful and well-established alternative for screening. Obtaining a TcB measurement is fast, non-invasive and agrees well with laboratory findings obtained by a blood test (23-25).

In most LMICs, diagnosing neonatal jaundice is done by visual assessment, as measurements with blood tests and TcB devices are expensive and are not widely available (26). The most common form of visual assessment is the Kramer score. This method is based on the advancement of jaundice from the head to the hands and feet of the neonate. However, studies have shown that Kramer score cannot be used to identify newborns needing treatment for neonatal jaundice (26-28).

The use of visual assessment alone as a screening method is unfortunate, as it can entail neonates not getting the appropriate care, which can lead to permanent consequences for the

child (28-30). In 2015, a group of researchers gathered from different regions of the world and concluded that inexpensive and simple-to-use devices for measuring bilirubin were essential and should be a target to reach for in the future (30).

Over the last decade, at least three smartphone apps for detecting neonatal jaundice have been developed: Picterus JP, BiliCam and neoSCB (Neonatal scleralconjunctival bilirubinometer). Currently, only Picterus JP got CE approval (3, 31).

The benefit of a mHealth (mobile health) tool for jaundice screening is documented in a recent randomised controlled study in Hainan, China. The study demonstrated that a smartphone-based solution for screening of neonatal jaundice decreased the neonatal readmission rate within 30 days from the first discharge (32).

2.2 mHealth

According to previous UN Secretary General Advisor Jeffrey Sachs, “Mobile phones and wireless internet end isolation, and will therefore prove to be the most transformative technology of economic development of our time “ (33, 34). Mobile technology is spreading faster than any other technology globally (35). Today’s smartphones offer mobility, are flexible, easy to use, allow immediate communication across geographical barriers, enable access to vast amounts of valuable information regarding everything from job and investment opportunities, weather forecasts, preventative measures for health, and have shown to be a helpful tool for education (36). From a health care perspective, low-cost mobile technology’s potential to improve health services and their delivery in developing countries is increasingly recognised (37). According to the German-founded market research company Statista Research & Analysis, the health industry will play a significant role in the upcoming advance of mobile technology (38).

With the increasing availability of mobile technology, a new subtype of eHealth (electronic health), called mHealth (mobile health), has emerged. While eHealth refers to the use of information and communication technology in health care, for example the use of digital health records, the latter is defined by WHO as “medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices” (39, 40).

2.2.1 Types of mHealth

The majority of mHealth solutions are based on functionalities of conventional mobile phones and complex smartphones (41). The most common types of mHealth are smartphone applications and short message service (SMS) (42). Through basic functions like voice message communication, health line services are only a phone call away, and health care professionals can get hold of information in order to assess a patient's need for an in-person consultation. SMS has been used to spread awareness, mass educate populations and remind patients about appointments (42).

Today's smartphones offer Bluetooth, Global Positioning System (GPS) and the possibility to access the internet through WiFi or broadband cellular network technology (3G or 4G) (39). With help from Bluetooth technology, smartphones can collect information from glucose sensors, blood pressure monitors and other medical devices. While GPS is helpful in order for patients to locate health institutions, extensive amounts of information regarding diseases and preventative measures are available through internet access. Internet access also enables remote patient monitoring, aids doctors' decision-making, and makes video calls between health care professionals and patients possible. mHealth apps have become economically profitable for tech developers, and as of 2021, over 350 000 mHealth apps were available for smartphone owners through app stores (43). The Canadian-Indian market research company Precedence research valued the global mHealth market to be 54,3 billion US dollars in 2021. According to their predictions, this market will reach over 243,6 billion US dollars by 2030 (44).

2.2.2 Implementation of mHealth in developing countries

Simultaneously as the field of mHealth continues to evolve, health care systems in developing countries face serious economic struggles, a lack of health care workers and a shortage of medical devices (42). A group of researchers from the University College of London hypothesised that using mHealth solutions in LMICs can improve the quality and effectiveness of the health care delivered while also reducing costs (37). An increasing

number of mHealth solutions are specifically developed for use in low-resource settings, but the majority fail to scale up from pilot studies or experimental projects (45, 46). Sociocultural differences, technological challenges and illiteracy are among the factors that complicate the process of mHealth implementation in developing countries (47).

Wallis et al claimed that “A system that is difficult to operate for the user is most likely to fail, and it is paramount to have the end-user in mind when developing mHealth systems. If a system or device is not usable, then the intervention will not be able to make it out of the pilot phase” (45).

In other words, feedback from the intended users of a mHealth solution needs to be taken into consideration for it to be taken into widespread use.

2.3 Picterus JP

2.3.1 The technology behind Picterus JP

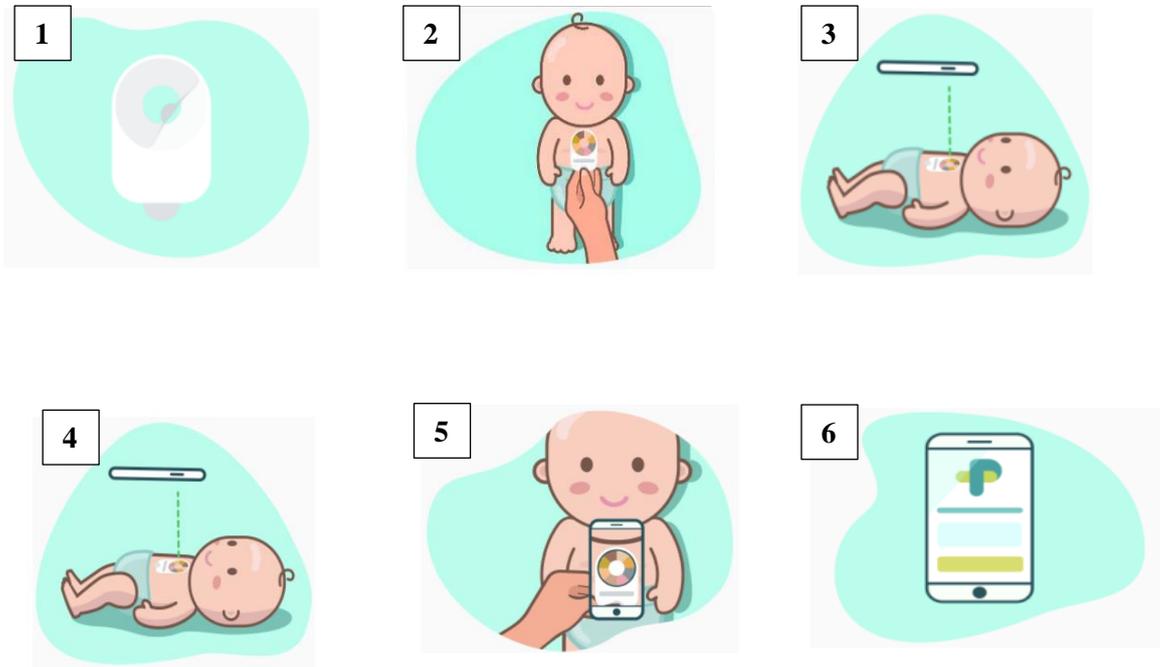
Picterus JP is an easy-to-use smartphone app which offers an affordable, instant, and accessible solution to estimate bilirubin levels using novel and patented skin colour-based screening technology (48).

The technology behind Picterus JP is based on how factors like skin thickness, bilirubin, haemoglobin and melanin levels affect skin reflectance. A colour calibration card must be used to correct for variations in illumination. A mathematical model was used to create a library of simulated reflectance spectra of the skin in neonates and later adapted for use with a smartphone camera (48). A mathematical model was used to create a library of simulated reflectance spectra of the skin in neonates and later adapted for use with a smartphone camera.

In order to estimate the bilirubin level using Picterus JP, the examiner must first remove the glue-protection on the calibration card and then attach the card to the newborn’s chest.

Subsequently, the examiner uses the Picterus app on a smartphone to take pictures of the skin on the baby’s chest along with the calibration card. When holding the smartphone at the right angle and distance from the newborn, six pictures are obtained automatically, three with and three without flash. See figure 1.

Figure 1: Picterus JP – instructions for use (49)



2.3.2 Previous studies and gaps in the field regarding mHealth solutions for detecting neonatal jaundice

Regarding validating the specificity and sensitivity of detecting jaundice, Picterus JP has been tested in studies in Norway, Mexico, and the Philippines (48, 50, 51). These studies showed that the app could be an accurate and affordable screening tool to improve neonatal detection, with the estimates from the app being moderate to strongly correlated with TSB levels. The diagnostic accuracy of Picterus JP is comparable to other smartphone-based apps for detecting neonatal jaundice (52, 53).

Two studies in LMICs have been conducted regarding the health care workers' attitudes towards Picterus JP. A master thesis study in Nigeria investigated health care workers' attitudes towards Picterus JP. The study revealed that most health care workers found the app intriguing and would want to implement the solution into their daily practice. The authors recommended that parents' perspectives should be addressed in future research (4). A pilot

study in Mexico (manuscript in preparation) also revealed a clear want and need from health care workers for an accurate and available tool for detecting neonatal jaundice in low-income settings where other alternatives are unavailable.

In the validation study of the sclera-based neoSCB app, feedback from mothers on the procedure used was documented. However, the findings regarding this point do not appear clear (53). No other studies focusing on parents' user experience using a neonatal jaundice detecting tool (in low-income settings) were found and there is limited knowledge. As previously mentioned, users' experience must be considered for a mHealth solution to be widely used (45, 47). In other words, if Picterus JP is to be implemented by parents and health care workers in low-income settings, the app's developers should make necessary adjustments based on feedback from the intended target group.

2.4 The Mexican context

2.4.1 Socioeconomic challenges in Mexico

With over 131 million inhabitants, Mexico is the 10th most populous country in the world (54). Based on the gross domestic product (GDP) in 2021, the country had the second largest economy in Latin America and placed among the top fifteen economies from a global perspective (55). However, despite the status as an upper-middle-income country and the economic growth seen in the last decades, financial and social disparities between urban and rural parts of Mexico remain a major issue, as well as the population's unequal access to health care (56-59). According to DataMéxico, 44,5 % of the Mexican population was reported to live in moderate or extreme poverty as late as 2020. In the same year, deprivation of social security, health services and food access were the main social challenges seen in the country (60).

Mexico is considered one of the most unequal countries in the world. While 57,4 % of the country's total income goes to the top 10 % of wage earners, the bottom half of workers receive as little as 9,2 % (56). One out of five Mexicans lives in rural communities, where the economic situation is considerably worse than the national average, with a poverty rate of 58 % (57, 61).

The Healthcare Access and Quality (HAQ) Index from 2018 is based on the Global Burden of Diseases, Injuries and Risk Factors Study 2016. By surveying the frequency of 32 causes of death in 195 countries and territories and subnational locations in selected countries, a population's access to quality health care was presented as a number between 0 (worst performance) to 100 (best performance). Among the OECD countries, Mexico had the lowest HAQ of 66,3, and from a global perspective, the country was ranked number 91 (62).

The economic struggle is most significant in the less industrialised southern states of Chiapas, Guerrero and Oaxaca, where the average poverty rate is close to 70 % (63). These three also have a higher proportion of indigenous people and a low degree of urbanisation compared to many of the other Mexican states (61, 64).

The availability of health services also varies greatly from state to state. The population of the wealthiest state – Nuevo León – was reported to have the highest access to quality health care (HAQ=72,8). In contrast, the lowest HAQ obtained were from Chiapas (HAQ=55,8) and Oaxaca (HAQ=59,5) (65).

2.4.2 The Mexican health care system

The Mexican health care system comprises a wide range of private and public providers. Workers in the formal sector can obtain social security and health care through large institutions like IMSS (Mexican Institute of Social Security) or ISSSTE (Institute for Social Security and Services for State Employees). Institute of Health for Wellbeing (INSABI) are for people with informal employment or those out of work. According to WHO's review of the Mexican health care system, these institutions covered 37,5 %, 5,7 % and 26,1 % of Mexicans in 2020, respectively (66). In 2018 approximately 8 % of the population had private insurance (alone or in addition to public insurance), and almost 14 % were reported to be uninsured. The report also revealed that only 3,3 % of the 4341 Mexican hospitals were localised in rural areas. Furthermore, 30 % of the hospitals were public. Among these, 61 % provided health care for the uninsured population (57).

2.4.3 IMSS and IMSS-Bienestar

This study took place in collaboration with IMSS, which is the largest social welfare institution in Latin America (57). The organisation has a legal mandate derived from Article 123 of the Mexican Political Constitution and is an integral part of the country's health care system. According to IMSS' website, their mission is to be the "basic instrument of social security, established as a national public service, for all workers and their families" (67).

In 1973 the Mexican Social Security Law was modified to empower IMSS to extend its action to population centres without taxpaying capacity due to poverty. In the wake of this, the first antecedent of IMSS-Bienestar was created (68).

The IMSS-Bienestar program offers free health care to those in need within family medicine, obstetrics-gynaecology, general surgery, internal medicine and paediatrics, among others. Another aim of the program is to enhance the knowledge of health and preventative measures among the indigenous, rural and urban communities belonging to the areas and regions of responsibility(68).

IMSS-Bienestar is represented in 19 of the 32 Mexican States, with a registered population of 11,6 million. It serves more than 20 000 localities (68). Oaxaca state has the highest number of municipalities where the program is present (69). Out of the 4,1 million inhabitants in the state, there are over 1,2 million beneficiaries of the program (70).

2.4.4 Neonatal jaundice in Mexico

The incidence of severe neonatal jaundice in high-income countries varies between 2 and 42 per 100 000 live-born infants (71). Such estimates using population-based data are lacking in most LMICs and Mexico. However, the incidence of neonatal jaundice in LMICs is projected to be higher because of a variety of aetiological factors like low birth weight, prematurity and sepsis, which is more common in many low-income settings (20).

IMSS have guidelines for diagnostics, treatment and follow-up for neonatal jaundice. For neonates at home, it is recommended that parents should carry out a visual examination to look for jaundice (72). The knowledge that visual inspection is unreliable, even for trained

professionals, underscores the potential for an easy-to-use app that could be highly beneficial in Mexico (26-28).

3. Research aims

- 1) The main aim of this project was to explore and compare parents' user experience with the mHealth smartphone app Picterus JP in an urban and a rural low-income setting in Mexico.
- 2) The secondary aim of this project was to explore and compare the self-reported knowledge of jaundice among the same parents.

4. Research methods

This study was a quantitative, paper-based survey. Data collection was performed between August and September 2022.

4.1 Research questions

- 1) How are the parents' user experience of Picterus JP in an urban and a rural low-income setting in Mexico concerning the:
 - a) Overall user experience of the app?
 - b) Usability of the app?
 - c) Utility of the app?
- 2) What is the knowledge level about jaundice in an urban and a rural low-income setting in Mexico?

Within this thesis, "Overall user experience" refers to how the participants on average responded to the questionnaire regarding their experience with Picterus JP.

"Usability" is defined as "the extent to which a product can be used by specified users to achieve specific goals with effectiveness, efficiency, and satisfaction in a specified context of use". "Utility" is defined as the "ability to satisfy a particular need; usefulness" (73, 74).

4.2 Preparations

4.2.1 The questionnaire, information sheet and consent form

The questionnaire (appendix 1), information sheet (appendix 2) and consent form (appendix 3) were prepared in Trondheim, Norway, ahead of the data collection period. While the questionnaire was designed in English and translated into Spanish, the remaining two forms were created in Spanish by Dr Jiménez Díaz.

The first part of the questionnaire explored the participants' self-reported level of knowledge jaundice. The respondents were asked to choose one of the following: "I have never heard about jaundice", "I have heard about jaundice, but I am not sure what it is", "I have heard about jaundice and understand what it is" or "I am very familiar with jaundice".

The second part of the questionnaire included ten statements about the user experience of Picterus JP. The participants replied to each statement through a 7-point Likert scale, with responses ranging from "Totally disagree" to "Strongly agree". The survey was heavily inspired by the validated "mHealth App Usability Questionnaire (MAUQ) for Standalone mHealth App Used by Patients" but adjusted with regard to the language barrier and purpose of this study (75). Lack of experience with mHealth or questionnaires among the participants were also taken into consideration during the preparation phase.

The information sheet included a brief presentation of ourselves, the aim of our study, a short explanation of the technology behind the app, why detection of neonatal jaundice is important, and what participation would include, was created. A consent form with name, signature, and date of the day was added to the information sheet.

4.2.2 The study sites in Oaxaca, Mexico

Parents of newborns and pregnant women were recruited to participate in this study at two different IMSS health care facilities in the state of Oaxaca, Mexico. As previously mentioned,

Oaxaca has a high poverty rate, and the access to quality health care in the state is poor (65, 76). For these reasons, parents who want to screen their infant for jaundice may find access to a low-cost, quick, and non-invasive screening tool like Picterus JP useful. If the app accommodates the needs and wants of the parents in the area, it might become widespread in use and thereby increase the detection rate of neonatal jaundice. Furthermore, Dr Jiménez Díaz's large network and numerous contacts in the state greatly simplified the data collection process.

The first part of fieldwork occurred between 23rd August 2022 and 9th September 2022 at IMSS Clinic for Family Medicine No. 65 in the urban municipality Santa Lucía del Camino, adjacent to the state capital Oaxaca de Juárez. The second part of the fieldwork occurred between 13th September and 28th September, thirty kilometres away, at IMSS-Bienestar Hospital for Rural Solidarity in the rural municipality of Tlacolula de Matamoros.

At the time of data collection, IMSS Clinic 65 (from now on referred to as the “urban clinic”) provided first-level care to their right-holders, that is to say, those with insurance through formal employment in the private sector – and their families. The hospital in Tlacolula de Matamoros (the “rural hospital”) was part of the IMSS-Bienestar program and offered free health care within family medicine, obstetrics-gynaecology, general surgery, internal medicine and paediatrics. In the same way the urban clinic accepted patients from outside Santa Lucía del Camino, the rural hospital also welcomed those who resided in municipalities other than Tlacolula de Matamoros.

As presented in Table 1, there were several socio-economical differences between the inhabitants of Santa Lucía del Camino and Tlacolula de Matamoros in 2020. The poverty rate was found to be higher, and the education level lower, in Tlacolula de Matamoros. More than 90 % of the inhabitants in both municipalities resided in a household with cell phone access. However, as for access to the internet, this applied to a considerably higher proportion of the ones living in Santa Lucía del Camino (77, 78).

Table 1: Socioeconomic characteristics of Santa Lucía del Camino and Tlacolula de Matamoros in Oaxaca, Mexico (77, 78).

	Santa Lucía del Camino (Location of the urban clinic)	Tlacolula de Matamoros (Location of the rural hospital)
Percentage of the population living in moderate or extreme poverty	27,2	40,7
Percentage of the population who speaks at least one indigenous language	13,2	19,1
Percentage of the population who are illiterate	2,4	6,5
Percentage of households with access to cell phone	93,6	91,2
Percentage of households with access to the internet	71,0	39,1
Distribution of the population by education level	<ol style="list-style-type: none"> 1. Bachelor’s degree (31,5 %) 2. High school or General Baccalaureate (23,2 %) 3. Middle School (21,4 %) 	<ol style="list-style-type: none"> 1. Primary School (29,6 %) 2. Middle school (26,8%) 3. High School or General Baccalaureate (20,0 %)

4.3 Inclusion criteria

The following people were eligible to partake in the study:

People seeking health for themselves or their baby and hospitalised mothers with one of the following characteristics:

- Pregnant women in the third trimester (28 weeks or more of pregnancy).
- Parents of babies born less than 31 days ago.

Collaboration between both parents of a newborn while trying the app and filling out a single questionnaire was accepted.

4.4 Exclusion criteria

Exclusion criteria in the study were:

- Those who had previously participated in the project.
- Those whose partners had previously participated in the project.
- Those not able to understand oral English nor oral Spanish.

4.5 Recruitment and procedure

At both clinics, we introduced ourselves to assistants, nurses, doctors, and social workers at the relevant departures. We oriented them about the project and asked them to recruit potential participants by informing them about our project. All in all, the procedure for each patient consisted of three steps. The first step was to receive information and give consent. The second step was trying the app, as described under “background”, on a doll, which we will refer to as the “exercise” in this section. The last step was filling out the questionnaire. Below we will describe how these steps were carried out in the two clinics.

- 1) In the urban clinic, we set up a stand with information and the needed equipment in the hallway close to the waiting room to be able to see most of the patients on the way to their appointments. We approached the potential participants from our stand, or we approached them in the waiting area. In the rural hospital, we set up a stand in a classroom, and most participants went through the whole process in this setting. Most of the participants were recruited by health care workers, mainly nurses, after their appointment. We also recruited some from the waiting area and brought them to the classroom, where they got the written information and were allowed to ask questions. With the help of health care workers, we also approached parents in the maternity ward.

A short presentation about ourselves and the project was given orally in Spanish, and those interested were handed the written information sheet with the consent form attached. We underscored that they would perform the exercise on a doll, not their baby, and that the project was completely voluntary. Participants got the opportunity to ask questions about the project, and if we did not understand the questions, we would call in one of the native Spanish speakers in the clinic. All participants had to read through the information sheet and sign the consent form before trying the application.

- 2) The second part was trying out the app. When the participants had agreed to perform the “exercise”, we explained that they had everything they needed to complete the exercise and that the instruction about how to use the app was found in the app. We also told them that we could not help them with how to use the app and that if they were stuck, they could either reread the instructions and try as many times as they

wanted or finish the exercise and fill out the questionnaire regardless. We then let them read the instructions and try the app until they either got a result or did not want to try anymore.

Most participants tried out the app from our stand, but a minority tried the app in the waiting room on a chair/table or in the doctor's office. At the rural hospital, in the maternal ward, some mothers performed the exercise in their beds since they were not allowed to leave their beds.

Samsung Galaxy S7 smartphones, a doll and calibration cards were provided by Picterus AS. Thus, the patients did not have to install software on their smartphones or try the app on their babies. Consequently, participating in the project did not affect their or their baby's health care.

- 3) After finishing the exercise, we presented the questionnaire to the participants. We instructed them on how to fill it out correctly and explained that the questionnaire was anonymous and that they could be completely honest. While they filled out the questionnaire, we walked away so the participants would feel that we observed what they answered. After they finished the questionnaire, they were asked to fold the paper before putting it in a folder. As a general rule, the parents or pregnant women filled out the questionnaire on their own or with their partner without us interacting.

4.6 Data analysis

Statements 1-6 and 9 explored the usability of Picterus JP. The remaining statements – 7, 8 and 10 – covered the app's level of utility.

Answers on the 7-point Likert scale were converted to numbers from 1-7, where 1 corresponded to "Totally disagree", and 7 corresponded to "Strongly agree". A high level of agreement with the statements indicated that the experience with Picterus JP was positive. To aid the interpretation of the data, results from the 7-point Likert scale were categorised into Disagree ("Totally disagree", "Disagree" and "Somewhat agree"), Neutral ("Neither agree nor disagree") and Agree ("Somewhat agree", "Agree" and "Strongly agree").

Frequencies, means and standard deviation were calculated.

Mann-Whitney U test was applied to explore whether there was a significant difference between the two study sites regarding their user experience with Picterus JP (in the categories “Overall user experience”, “Usability” and “Utility”) and knowledge about jaundice. A p-value of <0.05 was used as our cut-off for statistical significance.

Analysis was done using IBM SPSS Statistics version 27. Tables and graphs were made using Microsoft Excel 2016 and Microsoft Word 2016.

4.7 Ethical approval and personal data storage

Standard informed consent protocols were applied, and data privacy was ensured for all individuals participating in the study by following the EU’s General Data Protection Regulation (GDPR) guidelines. The project was reported to NSD, the Norwegian centre for research data (reference number: 599238), as a part of the PhD project JAUND-EASE at the Department of Public Health and Nursing, NTNU (Norwegian University of Science and Technology).

Since no health-sensitive data was collected, there was no need for ethical approval for the current project. The project was approved locally in the state of Oaxaca, Mexico, according to their own procedures by the directors of both facilities through the contacts of Dr Jiménez Díaz.

The responses from the questionnaires were collected anonymously. As the participants did not consent to the acquisition of personal data, the consent form was shredded after the data collection period. Questionnaires will be kept until the thesis is delivered and approved by NTNU, and then shredded.

5. Results

A total of n=54 questionnaires were filled out and handed in by parents and pregnant women visiting the urban clinic during the data collection period. Out of these, n=7 questionnaires were invalid and therefore not used in the data analysis. Therefore, a total of n=47 questionnaires were analysed from the urban clinic.

A total of n=60 questionnaires were collected from the rural hospital. Among these, n=11 did not qualify to be included in the data analysis. The remaining n=49 questionnaires from the rural hospital were analysed.

The questionnaires were regarded as invalid when the respondents had not answered one or more questions or when they had checked more than one alternative in one or more questions. These questionnaires were not included in the analysis.

5.1 The user experience of Picterus JP

5.1.1 The user experience among all the participants

Table 2: Distribution of responses and mean ratings for the ten statements regarding the user experience (all participants, n=96)

Statements	Distribution of responses			Mean rating (μ) (SD)
	<i>Disagree</i>	<i>Neutral</i>	<i>Agree</i>	
1. The app was easy to use	11,4 % (n=11)	1,0 % (n=1)	87,5 % (n=84)	5,8 (1,6)
2. It was easy for me to learn how to use the app	9,3 % (n=9)	4,2 % (n=4)	86,5 % (n=83)	5,9 (1,5)
3. I like the design of the app	3,1 % (n=3)	4,2 % (n=4)	92,7 % (n=89)	6,0 (1,1)
4. I like what is shown on the app screen	2,1 % (n=2)	4,2 % (n=4)	93,8 % (n=90)	6,0 (1,0)
5. The information in the app was well-organised, which made it easy for me to find the information I needed	6,2 % (n=6)	5,2 % (n=5)	88,5 % (n=85)	6,1 (1,3)
6. The amount of time required to use the app has been adequate for me	7,3 % (n=7)	3,1 % (n=3)	89,6 % (n=86)	6,0 (1,4)
7. The app would be useful to assess the health and well-being of my baby	4,1 % (n=4)	-	95,9 % (n=92)	6,3 (1,1)
8. The app can help me decide when to contact the doctor	6,2 % (n=6)	2,1 % (n=2)	91,7 % (n=88)	6,0 (1,3)
9. In general, I am satisfied with the app	4,1 % (n=4)	8,3 % (n=8)	87,5 % (n=84)	5,9 (1,3)
10. I would feel comfortable using the app on my baby	3,1 % (n=3)	4,2 % (n=4)	92,7 % (n=89)	6,1 (1,2)

As seen in table 2, all responses were skewed towards agreeing with the proposed statements, meaning the participants, on average, had a favourable experience with Picterus JP. For all the statements, the number of participants who agreed clearly outnumbered the ones who disagreed.

The participants' responses to the statements "The app would be useful to assess the health and well-being of my baby" (statement 7) obtained the highest mean rating ($\mu=6,3$). As many as 95,9 % (n=92) agreed to this statement.

“The app was easy to use” (statement 1) obtained the lowest mean rating of all ($\mu=5,8$) and the highest number of negative replies (11,4 % (n=11)). The responders were also less satisfied with how easy it was to learn how to use the app (statement 2) ($\mu=5,9$). Furthermore, when asked, “In general, I am satisfied with the app” (statement 9), twelve participants (12,4 %) chose the alternatives “Totally disagree”, “Disagree”, “Somewhat disagree”, or “Neither agree nor disagree” ($\mu=5,9$).

Table 3: Distribution of responses and mean ratings for statements in the categories overall user experience, usability and utility (all participants, n=96)

Categories	Distribution of responses			Mean rating (μ) (SD)
	<i>Disagree</i>	<i>Neutral</i>	<i>Agree</i>	
Overall user experience	5,7 %	3,7 %	90,6 %	6,0 (1,0)
Usability	6,2 %	4,3 %	89,4 %	6,0 (1,1)
Utility	4,5 %	2,1 %	93,4 %	6,1 (1,1)

According to the results found in table 3, the participants were slightly more positive towards the utility (statements 7, 8 and 10) of Picterus JP compared to the app’s usability (statements 1-6 and 9). The overall user experience’s mean rating (statements 1-10) was $\mu=6,0$ – which corresponds to “Agree” on the Likert scale used for this survey.

5.1.2 Comparison of the user experience among the participants at the urban and the rural study sites

Table 4: Distribution of responses for statements in the categories overall user experience, usability and utility among the participants at the urban (n=47) and the rural (n=49) study sites

Categories	Distribution of responses					
	<i>Disagree</i>		<i>Neutral</i>		<i>Agree</i>	
	Urban	Rural	Urban	Rural	Urban	Rural
Overall user experience	3,5 %	7,9 %	0,8 %	6,3 %	95,8 %	85,7 %
Usability	3,0 %	9,3 %	1,2 %	7,3 %	95,8 %	83,5 %
Utility	4,3 %	4,7 %	-	4,1 %	95,7 %	91,2 %

Table 4 presents how the participants at the two study sites differed on average in the categories “Overall user experience” (statements 1-10), “Usability” (statements 1-6 and 9), and “Utility” (statements 7, 8 and 10).

Overall user experience

For the category “Overall user experience”, on average 95,8 % in the urban and 85,7 % in the rural area agreed to the statements. Consequently, a greater proportion of the people in the rural area were more negative and were either neutral (6,3 %) or disagreed (7.9 %) than in the urban area (0.8 % and 3,5 % respectively).

The Mann-Whitney U test revealed that the difference regarding the overall user experience between the two populations was statistically significant ($p=0.001$).

When looking at the individual statements, the biggest differences were found on the three statements: “It was easy for me to learn how to use the app” (statement 2), “The amount of time required to use this app has been adequate for me” (statement 6) and “In general, I am satisfied with the app” (statement 9) (see appendix 4). For these three statements, the average percentages of participants in the urban population who agreed was 95,8 % , 97,8 % and 93,7 % respectively. Looking at the corresponding numbers for the rural population, the percentages were 77,6 % , 81,6 % and 81,6 % . This means that even though both study groups in general were satisfied, a greater proportion of the participants in the rural setting were neutral or negative to these statements.

The statements where the participants from the urban and the rural area were most in agreement with each other were the three regarding the app’s utility (statements 7, 8 and 10). In both groups, more than 90 % agreed on some level on all three statements in this category, indicating that on average they found the app very useful.

Usability

When assessing the responses to app’s usability (statements 1-6 and 9), on average 95,8 % agreed to these statements in the urban clinic. The corresponding percentage was only 83,5 % at the rural hospital (table 4). Furthermore, mean rating for the urban population regarding usability was $\mu=6.4$. This puts them between “Agree” and “Strongly agree”. The mean rating for the rural participants was $\mu=5.6$. This puts them between “Somewhat agree” and “Agree”, indicating that they were less satisfied than the urban population.

The Mann-Whitney U test on the usability statements confirmed that the difference between the urban and rural participants was statistically significant ($p < 0.001$).

Utility

Table 4 shows that regarding the questions about the utility (statements 7, 8 and 10) of the Picterus JP app, on average in both groups, more than 90 % agreed on some level to these questions, indicating that they found the app useful. More people (8,8 %) in the rural hospital were either neutral or negative to the utility of Picterus JP than in the urban clinic (4,3 %). As described earlier, these were the questions where the responses from the two groups were most in accordance with each other.

The mean score in the urban population on these statements was $\mu = 6.2$, while it was $\mu = 6.0$ in the rural population. This puts both groups closest to “Agree”, with the urban group slightly more positive than the rural group.

A Mann-Whitney U test was performed and found that there was no statistically significant difference in how the two groups scored the utility of Picterus JP ($p = 0.143$).

5.2 The level of knowledge about jaundice

5.2.1 The level of knowledge about jaundice among all the participants

Table 5: Level of knowledge about jaundice among all the participants (n=96)

	Distribution of responses
Statements	
I have never heard about jaundice	52,1 % (n=50)
I have heard about jaundice, but I am not sure what it is	25,0 % (n=24)
I have heard about jaundice and understand what it is	21,9 % (n=21)
I am very familiar with jaundice	1,0 % (n=1)

The participants (n=96) were asked which statements best described their level of knowledge about jaundice (table 5). Slightly more than half (52,1 % (n=50)) had never heard about jaundice. A quarter (n = 24) reported: “I have heard about jaundice, but I am not sure what it is”. Of the remaining responders, n=21 (21,9 %) had heard about the condition and understood what it is. Only one person (1,0 %) stated to be very familiar with jaundice.

5.2.2 Comparison of the level of knowledge about jaundice among the participants at the urban and the rural study sites

Table 6: Comparison of the level of knowledge about jaundice among the participants at the urban (n=47) and the rural (n=49) study sites

	Distribution of responses	
	Urban (n=47)	Rural (n=49)
Statements		
I have never heard about jaundice	31,9 % (n=15)	71,4 % (n=35)
I have heard about jaundice, but I am not sure what it is	34,0 % (n=16)	16,3 % (n=8)
I have heard about jaundice and understand what it is	34,0 % (n=16)	10,2 % (n=5)
I am very familiar with jaundice	-	2,0 % (n=1)

There is a notable difference between the participants of the urban and the rural study sites in their self-reported level of knowledge about jaundice (see table 6).

In the urban clinic, the answers from the participants are almost equally distributed between the three first alternatives. None of the participants reported being “very familiar with jaundice”. While two-thirds of the urban sample had at least heard about jaundice, one-third had never heard about the condition before.

On the contrary, a more significant proportion (71,4 % (n=35)) of the participants in the rural hospital reported that they had never heard about jaundice. Only 16,3 % (n=8) reported that they had heard about jaundice but were unsure what it is, and one person (2 %) chose the alternative “I have heard about jaundice and understand what it is”.

The Mann-Whitney U test indicated that the difference between the two study sites was statistically significant ($p < 0.00$). This implies that the sample from the urban clinic systematically reported a higher knowledge about jaundice than the participants from the rural hospital.

6. Discussion

6.1 Main findings

6.1.1 The user experience

Our results showed that the group's overall experience of Picterus JP was favourable. Our data analysis also revealed that the whole group of participants on average rated the app's level of utility slightly better compared to its usability. When studying the responses towards each of the statements, one could see how the study group tended to be more supportive towards the app's potential to assess their baby's health and were less satisfied with how easy it was to use the app.

The data analysis revealed that even though the majority (52,1 % (n=50)) had never heard about jaundice, as much as 95,9 % (n=92) agreed on some level that Picterus JP would be useful for them to assess the health and well-being of their baby.

Another interesting finding was the high number of participants (95,9 % (n=92)) who reported that the app could help them decide when to contact the doctor, even though the version of Picterus JP used in the project did not provide any information on the significance of the result obtained, or whether the parents should contact health professionals or not based on this result. This general tendency people of reporting very positive answers could be a result of an acquiescence bias where the participants try to please the researchers. This, and other hypotheses trying to explain the results, will be further discussed under "Strengths and limitations".

Part of the main aim was to distinguish similarities and differences in the responses from the urban and rural cohorts. Concerning overall perception, Mann-Whitney U-test revealed that the participants from the urban clinic systematically gave the app a higher rating. However, the difference was only significant regarding the app's usability and not utility. This can be explained because the category "Usability" consists of seven individual statements and is, therefore, more heavily weighted when analysing the data than the category "Utility", which only consists of three individual statements.

6.1.2 The level of knowledge about jaundice

The exploration of the participants' self-reported level of knowledge revealed that 77,1 % (n=74) had either never heard about jaundice or were unsure of what it is. Our data also suggests that participants recruited from the urban clinic reported a higher level of knowledge than those from the rural hospital. The results from the Mann-Whitney U-test confirm that the difference is statistically significant.

Some recent studies have assessed the knowledge about jaundice of mothers and expectant mothers. Two studies in Ghana found that respectively 85,4 % of mothers and 77,1 % of expectant mothers had heard about neonatal jaundice (79, 80). Another study from 2021 showed that among mothers with healthy infants only 46,4 % had good knowledge about neonatal jaundice (81). Further, in a study among Egyptian mothers published in 2016, Moawad et al. discovered that those residing in urban areas were significantly more knowledgeable than those residing in rural areas (82). To our best knowledge, there are no studies in Mexico about knowledge about jaundice in any part of the population.

When comparing our results to the previous studies in LMIC, the level of knowledge was lower than what was found in these (79, 80). However, when we distinguished between the two study sites, the level of knowledge from the urban clinic was more consistent with what was found in these studies. On the other hand, the level of knowledge among the participants from the rural hospital was surprisingly low compared to both the urban study site and the previous studies. As described in the background section (table 1), the education level is generally higher in the urban area. Both the study of Moawad et al. and Huang et al. looking at mothers' knowledge about neonatal jaundice revealed that higher education was associated with a higher level of knowledge about Jaundice (81, 82). Therefore, this might be a possible explanation, but we cannot say this for sure because we did not collect information about this. The significant difference between the two study sites was in line with results from Moawad et al., who also demonstrated a significant difference between participants residing in an urban and a rural area (82). It is worth noting that our study also allowed fathers to participate in both study sites, while other studies were conducted on either mothers or pregnant women.

6.2 Strengths and limitations

6.2.1 The study population

As described earlier, the data collection period aimed to recruit participants in a low-income setting in Mexico. This was accomplished by collecting data from the state of Oaxaca, where as many as 63,9 % of the population lives in moderate or extreme poverty (76).

A strength of the study was that the inclusion and exclusion criteria for participation in the project were identical for both study sites. At the same time, one should keep in mind that only formal workers and their families had access to the health service provided at the urban clinic. In contrast, the rural hospital provided free health care regardless of insurance status. The differences observed in the responses between the two study groups may have something to do with socioeconomic status differences.

The narrow inclusion criteria ensured that only the project only conducted opinions of those who, at the time, had a newborn to take care of and those who would soon have one (pregnant women in the third trimester). In other words, intended users of Picterus JP.

At the same time, the number of participants could have been considerably higher if, for instance, pregnant women in the second trimester, partners of pregnant women, and parents of babies older than a month were also invited. However, in the absence of other such studies in Mexico, this study still provides solid initial findings on user experience of Picterus JP.

Those whose partner had previously participated in the project were not invited. This was a strength of the study, as it reduced the likelihood of responses being influenced by someone else's experience with the app.

Participation in the project was completely voluntary. A consequence of this may have been that the project recruited the ones who for a start felt the most comfortable with or had a more positive attitude towards mobile technology and questionnaires in general.

In addition, it was observed that a larger proportion of the parents and pregnant women at the rural hospital than those at the urban clinic declined the invitation to participate in the project. Some expressed that their lack of reading skills or experience with mobile technology was why they did not want to participate. It is possible that this impacted how the study group reviewed the app's usability at the rural hospital.

Further on, it was observed that trouble with interpreting the instructions, or unfamiliarity with using smartphones, resulted in increased time use, which in turn demotivated participants from further attempts. Those who did not use the app correctly did not make it to the result page, which may have influenced their perception of how they reviewed the app's usability and utility.

6.2.2. The recruitment process and procedure

The information sheet and consent form were written by Dr Jiménez Díaz, who is a native Mexican and is well-familiar with the culture and language of our study sites. This strengthened the recruitment process, as the information was conducted in a language suitable for the recruited parents. Furthermore, assistance from health care workers at the study sites eased the communication with the parents. This makes it more likely that they decided whether to take part in the project or not on the same grounds.

It should be mentioned that a larger proportion of the participants at the rural hospital than at the urban clinic were recruited with help from nurses, doctors and assistants. Those approached by health care personnel might have felt more pressured to participate, which may have influenced their attitude towards the project, experience with the app or response to the survey. At the same time, the assistance from the employees in the recruitment process likely resulted in a higher number of collected questionnaires.

In the rural hospital, n=2 of the participants could not read Spanish, and they received help from a nurse or one of the researchers to read the instructions to the app, consent form and the information sheet. To avoid bias, we made sure only to read the instructions found in the app and not to rephrase or instruct in a way that would give them an advantage compared to those who read the instructions themselves. These two participants also received help reading the

statements and the possible responses on the questionnaire. They would then tell us what response they felt was most fitting for their user experience and knowledge about jaundice and we would fill out the questionnaire for them in this manner. Even though this goes against our main rule of not helping with the questionnaire to not bias the replies, we chose to deviate from the rule to be able to get feedback from a wider selection of the population as we found no better practical way of getting their written feedback. An additional n=2 participants in the rural hospital preferred to have the consent form and information paper read out loud by one of the researchers but read the instructions by themselves and filled out the questionnaire independently. In the urban clinic all participants read all the information without help from the researchers or staff from the hospital.

Some days at the rural hospital, the internet connection was unstable. Therefore, n=10 participants did not get a bilirubin estimation from the app even though they did it correctly, and the application gave an error message instead. We then explained or demonstrated with a screenshot on another phone what we would get if there were an internet connection.

Regardless they were allowed to fill out the questionnaire. In the urban clinic, trouble with the internet connection never occurred. This might have affected the feedback from the rural hospital in a negative way and could explain why there is more negative feedback from the rural hospital.

6.2.3 The questionnaire

The questionnaire was based on the MAUQ, which has shown to have good reliability and validity when it comes to assessing usability for mHealth applications (75) . Using only close-ended questions in the survey was appropriate for the project as it made it easier to collect data from the participants since the questionnaire was rather easy and quick to fill out. As described in the method section, Dr Jiménez Díaz assisted in the preparation of the questionnaire. There is therefore reason to believe that the modifications and translation of the statements fitted to the project. This is a strength of the study, and it gives our results credibility and makes the results easier to compare with previous and future studies about users' experience of Picterus JP.

Two reasons should be mentioned why the reliability and validity might not be the same in our study as described in the original MAUQ paper where these factors were assessed. The

first is that the MAUQ was validated on a sample vastly different from ours. In the original study by Zhou et al., only people that had completed high school or higher education and that had at least a few years of experience using smart devices were allowed to participate (75). The prior knowledge about technology in our group and in the original was therefore markedly different, as several of the participants we spoke to, especially at the rural hospital, had little to no prior experience with smartphones. The second point has to do with translation and customisation. Modifying a questionnaire can be flexible and convenient, but it does not guarantee that the properties of the questionnaire are intact. Even though our survey was translated with the help of a medical doctor from Mexico, yet the reliability and validity could still be affected by cultural bias or interpretation issues. Even though customisation may have affected the validity of the questionnaire, this was necessary to make it more comprehensive and to measure the unique features of Picterus JP, especially since the app is meant for their baby and not themselves.

Based on our personal observations, the participants had greater trouble with using the app than what was reported on the questionnaires. Examples of mistakes we observed were that the participants had an incorrect angle or distance between the smartphone and the doll with the calibration card. For some of the participants, the feedback from the app (red/yellow colour indicating that it was incorrect) did not seem to help them get the phone in the correct position, and they therefore could not obtain the pictures necessary for getting a result.

The impression of a discrepancy we are left with between our observed performance and what the data suggests could be explained by an acquiescence bias where the responses are artificially positive. This could be to satisfy the researchers or be unintentional, even though we tried to avoid this by letting the participants fill out the survey in private and telling them it was completely anonymous. The statements of the questionnaire could have been more neutral instead of them all being worded in a positive manner like it was in the questionnaire (e.g., “easy”, “well organised”, “adequate” and “comfortable”). Another potential factor is that those who could not get a result on the app might also have difficulties filling out the questionnaire correctly. As previously mentioned, incomplete questionnaires were excluded from data analysis. In other words, the opinions of the participants who struggled the most with Picterus JP might not have been included.

Something that could explain the skewness of the responses toward "Strongly agree", however not the discrepancy, is a selection bias towards individuals with more knowledge and experience with technology than what we expect the population to have. This would lead to more people in our sample having experience with technology than what would be representative for the actual population. On the other hand, this is also the target population for the app and the results can still be of great value for the developers of the Picterus JP app and for other mHealth developers.

Another limitation of this exploration is that responders might have under- or overestimated their level of knowledge about jaundice. Participants who filled out the form in the sight of their partner, with help from health care personnel or ourselves, might have felt reluctant to admit to having never heard about the condition.

7. Contribution to science and further recommendations

This project emphasised the viewpoint about Picterus JP of parents and pregnant women in the state of Oaxaca, Mexico. Similar studies about the user experience of this group have not been conducted, not for Picterus JP nor other smartphone apps intended for detecting neonatal jaundice. The thesis also assessed this group's knowledge about neonatal jaundice. No other studies have investigated the knowledge level among any demographic group Mexico. Our study therefore adds valuable information to the field and can be used by developers of mHealth applications to gain a deeper understanding of the users' attitudes toward their app. Our study also provides the first ever information about parents' knowledge about neonatal jaundice.

To further explore the user experience of parents with the use of a mHealth application for detecting neonatal jaundice, whether that is Picterus JP or another app, we recommend a qualitative research method where the parents can elaborate on their challenges with the app. Because of the very positive responses from our study, despite the observed difficulties we observed, we further recommend a more objective approach to investigating the user experience (time to result, error rate etc.).

We also recommend assessing the knowledge with specific questions about neonatal jaundice, instead of only self-reported knowledge. In this way one could get a more comprehensive picture of the kind of knowledge gaps that exists in the population.

8. Recommendations for developers of Picterus JP

From our point of view, modifications to Picterus JP's design and instructions should be made to increase the app's level of usability, especially among those with limited experience with mobile technology, lack of reading skills and knowledge about jaundice.

First and foremost, the instructions on the how-to-use page should be more straightforward regarding the calibration card's utilisation and positioning of the phone. There is a possibility that instructions would be better displayed through a real-life video. In addition, we suggest a more intuitive way to guide the user on how he or she should alter the angle or distance during a measurement session.

The app's developers should consider that the potential users of the app might have limited or no knowledge of jaundice. We propose that the result page of the app provide the user information on whether the result obtained is within the normal range or not. If the latter is the case, Picterus JP should guide the user to contact health services for further evaluation.

9. Conclusion

This study explored the user experience of the mHealth tool Picterus JP and the knowledge about neonatal jaundice among parents in a low-income setting in Oaxaca, Mexico in an urban health clinic and a rural hospital. We further compared the results from the urban and rural study sites. A quantitative method based on a questionnaire with close-ended questions was used to investigate this. Our study revealed that the participants generally had a good user experience with Picterus JP, regarding both the usability and utility of the app. Regardless of the question there was little difference in the user experience when looking at the population as a whole. However, a greater difference was found between the responses from the urban clinic and the rural hospital. The participants in the urban clinic generally had a better user

experience than the participants from the rural hospital. Moreover, we observed that the participants had greater trouble using the app what was reflected in the results from the questionnaires. Therefore, we think that the app has a great potential to be used in a low-income setting like Oaxaca, but that it needs improvements to serve people with limited experience with mobile technology. To achieve this, further research should therefore have a qualitative focus to address the specific changes that can be made to the app.

Our results also revealed that the level of knowledge about jaundice in our sample was low, and about half (52,1 %) of the population had never heard about jaundice before. Our data also suggested that the rural population's knowledge level about jaundice is lower. These findings are interesting as it showed that even though the knowledge about jaundice was low, people still found Picterus JP to have high utility.

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Appendices to “Assessment of the user experience by parents of the novel mHealth technology Picterus to detect neonatal jaundice in a low-income setting in Mexico”

Appendix 1: The questionnaire



Picterus - Usability questionnaire

Which statement is the most correct?

1. I have never heard about jaundice
2. I have heard about jaundice, but I am not sure what it is
3. I have heard about jaundice and understand what it is
4. I am very familiar with jaundice

Statements	Totally disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Agree	Strongly agree
1. The app was easy to use							
2. It was easy for me to learn how to use the app							
3. I like the design of the app							
4. I like what is shown on the app screen							
5. The information in the app was well-organised, which made it easy for me to find the information I needed							
6. The amount of time required to use the app has been adequate for me							
7. The app would be useful to assess the health and well-being of my baby							
8. The app can help me decide when to contact the doctor							
9. In general, I am satisfied with the app							
10. I would feel comfortable using the app on my baby							

Appendix 2: The information sheet

EXPERIENCIA DE LOS PADRES DE RECIÉN NACIDOS SOBRE EL USO DE UNA APLICACIÓN (APP) PARA TELEFONO CELULAR PARA LA DETECCIÓN DE ICTERICIA DEL RECIÉN NACIDO

¿Les gustaría participar en este proyecto? A continuación encontrarán más información del mismo.

¿De que se trata?

Somos estudiantes de medicina de la Universidad Noruega de Ciencia y Tecnología (NTNU) y estamos aquí para hacer nuestra tesis de maestría, la cual se trata de conocer la experiencia de los padres de recién nacidos al usar una aplicación ó app, para teléfono celular que se llama Picterus. Esta app se desarrolló en Noruega y sirve para detectar la ictericia en los bebés recién nacidos, es decir, cuando se ponen amarillos. Hasta ahora la app solo se ha usado en hospitales pero la idea es que en el futuro pueda ser usada por los padres en casa. Por tal razón en nuestro proyecto queremos conocer cuál es su opinión después de haber usado la app.

¿Qué es la ictericia del recién nacido y porqué es importante detectarla a tiempo?

La ictericia de los recién nacidos es muy frecuente y es secundaria al aumento de la bilirrubina en la sangre. Por lo general no tiene complicaciones pero en algunos casos, si la bilirrubina aumenta demasiado, puede ser peligrosa si no se detecta a tiempo provocando daño permanente en el cerebro. Normalmente los doctores o enfermeras detectan la ictericia observando la piel y los ojos del bebé. La intención de esta app es apoyar al personal de salud para mejorar la detección de esta condición y por lo tanto ofrecer el tratamiento adecuado a los bebés afectados.

Si ustedes tienen alguna duda o pregunta sobre la ictericia del recién nacido, puede preguntarle a su doctor o enfermera sobre el tema.

¿Quien es responsable de este estudio?

La Universidad Noruega de Ciencia y Tecnología (NTNU) es responsable de este estudio

¿Porque los estamos invitando a ustedes a participar?

Dado que en este proyecto queremos conocer la opinión sobre el uso de la app de padres o futuros padres de recién nacidos, ustedes tienen las características de los participantes que necesitamos para este estudio.

Los estamos invitando a participar porque su bebé o usted son pacientes de la UMF 65 o del Hospital Rural 36 Tlacolula, que son los sitios incluidos en nuestro proyecto.

¿Cómo funciona la app Picterus?

La app funciona usando la cámara del teléfono celular y una tarjeta de papel que se coloca en el pecho del bebé. Luego se toman fotos de la piel y se analiza el color para calcular la cantidad de bilirrubina.

¿Qué tendrían ustedes que hacer como parte de este proyecto?

Para nuestro estudio lo que queremos es que ustedes prueben esta app en una muñeca y contesten un cuestionario que durará no mas de 10 minutos, para conocer su opinión y experiencia al usarla.

Esto es voluntario y si decide no participar, no habrá ninguna consecuencia en la atención médica o el tratamiento para su bebé o usted.

¿Cómo tratamos los datos que recopilamos?

El cuestionario que le vamos a hacer no tiene preguntas sobre información personal confidencial. Se usará para mejorar el uso de la app y así poder ayudar a más bebés en el futuro

¿ Como pueden ustedes encontrar mas información si tienen preguntas?

Pueden contactarnos por correo electrónico: Åsa Lerum, aasale@stud.ntnu.no

Pueden también contactar la directora de proyecto Dra. Gabriela Jiménez Díaz en el correo electrónico gabriela@picterus.com

Si usted desea participar, por favor llene y firme el formulario en la siguiente página.

Appendix 3: The consent form

Formulario de consentimiento

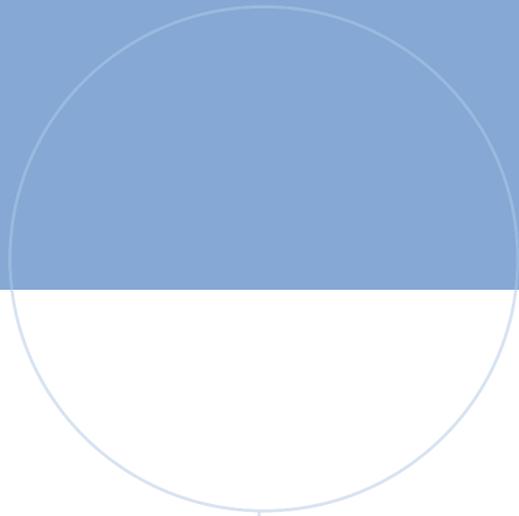
He recibido y entendido la información sobre el proyecto "EXPERIENCIA DE LOS PADRES DE RECIÉN NACIDOS SOBRE EL USO DE UNA APLICACIÓN (APP) PARA TELEFONO CELULAR PARA LA DETECCIÓN DE ICTERICIA DEL RECIÉN NACIDO". Se me ha dado la oportunidad de preguntar sobre el proyecto y sobre el uso de las respuestas que proporcionaré.

Acepto participar en el proyecto probando la app en una muñeca y contestando el cuestionario.

(Nombre, firma y fecha)

Appendix 4: Distribution of responses regarding the user experience among the participants at the urban and the rural study sites

Statement	Distribution of responses					
	Urban total n=47 Rural total n=49					
	<i>Disagree</i>		<i>Neutral</i>		<i>Agree</i>	
	Urban	Rural	Urban	Rural	Urban	Rural
1. The app was easy to use	6,4% (n=3)	16.3% (n=8)		2,0% (n=1)	93,6% (n=44)	81.6% (n=40)
2. It was easy for me to learn how to use the app	4,2% (n=2)	14.3% (n=7)		8.2% (n=4)	95,8% (n=45)	77.6% (n=38)
3. I like the design of the app	-	6.1% (n=3)	2,1% (n=1)	6.1% (n=3)	97,9% (n=46)	87.7% (n=43)
4. I like what is shown on the app screen	-	4.1% (n=2)	2,1% (n=1)	6.1% (n=3)	97,9% (n=46)	89.7% (n=44)
5. The information in the app was well-organised, which made it easy for me to find the information I needed	4,2% (n=2)	8.1% (n=4)	2,1% (n=1)	8.2% (n=4)	93,7% (n=44)	83.7% (n=41)
6. The amount of time required to use the app has been adequate for me	2,1% (n=1)	12.2% (n=6)	-	6.1% (n=3)	97,9% (n=46)	81.6% (n=40)
7. The app would be useful to assess the health and well-being of my baby	2,1% (n=1)	6.1% (n=3)	-	-	97,9% (n=46)	93.9% (n=46)
8. The app can help me decide when to contact the doctor	6,4% (n=3)	6.1% (n=3)	-	4.1% (n=2)	93,6% (n=44)	89.8% (n=44)
9. In general, I am satisfied with the app	4,2% (n=2)	4,0% (n=2)	2,1% (n=1)	14.3% (n=7)	93,7% (n=44)	81.6% (n=40)
10. I would feel comfortable using the app on my baby	4,3% (n=2)	2,0% (n=1)	-	8.2% (n=4)	95,7% (n=45)	89.8% (n=44)



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