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Digital innovation and global public health: Pathways for sustainable entry of digital innovations into LMIC health systems

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Digital innovation and global public health: Pathways for sustainable entry of digital innovations into LMIC health systems

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Table of contents

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A geospatial platform to support visualization, analysis, and prediction of tuberculosis notification in space and time

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Background: Tuberculosis has caused significant public health and economic burdens in Vietnam over the years. The Vietnam National Tuberculosis Program is facing considerable challenges in its goal to eliminate tuberculosis by 2030, with the COVID-19 pandemic having negatively impacted routine tuberculosis services at all administrative levels. While the turnaround time of tuberculosis infection may delay disease detection, high transportation frequency could potentially mislead epidemiological studies. This study was conducted to develop an online geospatial platform to support healthcare workers in performing data visualization and promoting the active case surveillance in community as well as predicting the TB incidence in space and time.

Method: This geospatial platform was developed using tuberculosis notification data managed by The Vietnam National Tuberculosis Program. The platform allows case distribution to be visualized by administrative level and time. Users can retrieve epidemiological measurements from the platform, which are calculated and visualized both temporally and spatially. The prediction model was developed to predict the TB incidence in space and time.

Results: An online geospatial platform was developed, which presented the prediction model providing estimates of case detection. There were 400,370 TB cases with bacterial evidence to be included in the study. We estimated that the prevalence of TB in Vietnam was at 414.67 cases per 100.000 population. Ha Noi, Da Nang, and Ho Chi Minh City were predicted as three likely epidemiological hotspots in the near future.

Conclusion: Our findings indicate that increased efforts should be undertaken to control tuberculosis transmission in these hotspots.

KEYWORDS

tuberculosis, geospatial, visualization, prediction model, artificial intelligence

Introduction

Spatial science has developed markedly in recent years due to innovations in surveying and analysis. Geospatial data comprise a highly diverse range of features, including geographical locations, environment features, human data such as postal codes, and satellite-based information, with data coverage ranging from an individual-level to population-level. This wealth of information types creates a data network that scientists can use to analyze and simulate realistic phenomena based on geospatial imagery and information (1, 2). Disease can be caused not only by individual-based risk factors but also by environment-based factors. Exposure to risk factors in terms of environment, living habitats, and mobility trends may significantly contribute to the possibility of a particular disease spreading in a community (3). To address problems of this type, geospatial artificial intelligence (GeoAI) has been developed; this approach has considerable applications for epidemiological studies. In a disease context, GeoAI involves the use of machine learning algorithms, which are supported by geospatial datasets, to explore the impacts of social components, such as population density and migration trends, on community-based disease incidence rates. Such technologies are also beneficial for epidemiologists, as geospatial insights can dramatically strengthen study hypotheses. Maike et al. applied geospatial modeling to identify the association between environmental factors and gestational diabetes mellitus (2). Their study collected postal information, with a sample size comprising nearly 9,000 pregnant women in United States (2). Another study by Lawrence et al. investigated the correlation between environmental pollution and acute asthma events using a dataset including population features, land-use data, distance and topography reports, traffic, and road systems (4). Their study identified a positive correlation between the concentration of chemical gases and the risk of acute asthma events (4).

Tuberculosis (TB) is an airborne disease that can transmit from human to human and causes severe damage to different organs. TB has been a leading health and economic burden worldwide, especially in low–middle-income countries, with a global incidence rate of 127 cases per 100,000 population recorded in 2020 (5). Vietnam remains among the 30 countries with the highest prevalence rates of TB, despite efforts by the Vietnam National TB Program (NTP) to decrease the disease burden over the past decade (5, 6). Given the effects of the COVID-19 pandemic, TB case notification was halted in 2021, which could lead to a potential setback of 8 years on the pathway to the program's goal to end TB by 2030 (7). To promote active case identification, several studies conducted geospatial analyses to determine the distribution of TB cases (8, 9). While TB was frequently detected in low-income areas and those with poor sanitation, the disease prevalence was higher in these areas among subjects who did not have consistent residency status, such as refugees, asylum seekers, and regular immigrants (10). A person who is diagnosed with pulmonary TB and has a high frequency of transportation can cause numerous human-to-human infections and seed new disease clusters (11, 12). The turnaround time of TB infection might also be lengthened, thereby biasing retrospective epidemiology investigations. This issue thus highlights the need for an improved GeoAI application to support healthcare workers in analyzing the spatial characteristics of TB and predicting this disease's epidemiological trends. Thus, the current study was conducted to develop an online GeoAI platform to temporally and geospatially visualize, analyze, and promote TB case notification as well as to predict the TB incidence in community. This GeoAI platform could provide more real-time data relating to demographic information and case distribution, allowing physicians to identify whether a subject is likely to belong to a high-risk group for TB infection.

Materials and methods

Study subjects

The participants in our study were bacteriologically confirmed TB patients managed by the Vietnam NTP.

Study design

This is a cross-sectional study, conducted from the 1st of January 2020 to the 30th of April 2022.

Study location

The study location comprises all of the facilities that provided TB services at any administrative level and that were managed by the Vietnam NTP.

Study content

The factors that were deemed to contribute to an increased risk of TB infection are as follows:

- Transmission factor: the number and distribution of TB cases from both temporal and spatial perspectives.
- Individual factor: comorbidities and living habits that increase the risk of TB transmission.
- Mobility factor: internal or external migration of residents. Migration and contact events increase the likelihood of pathogenic human-to-human transmission.

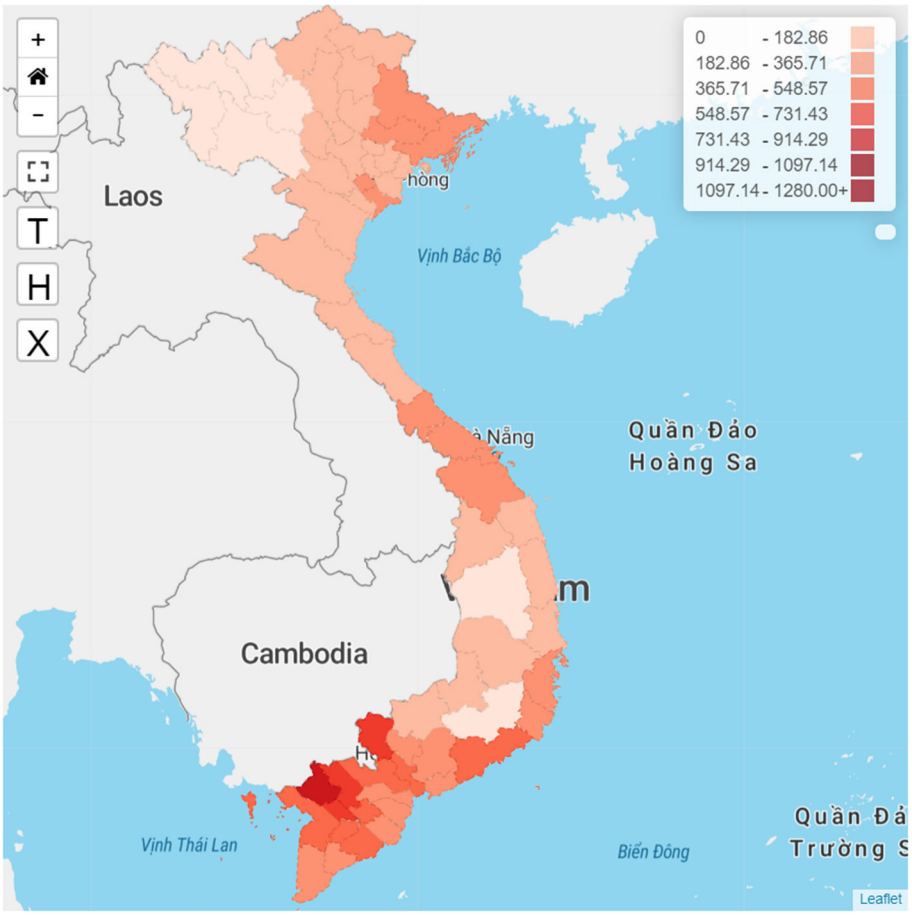

FIGURE 1
Home screen of the GeoAI platform.

- Climate factor: factors including temperature, humidity, evaporation, radiation, sunshine h, rain, and wind regimen; these depend on the season and, therefore, promote or reduce the likelihood of TB infection.
- Spreading factor: facility-based factors around TB patients that directly affect disease progression, such as high-risk areas (hospitals, industrial clusters, schools, restaurants, tourist areas, crowded areas), population density (typically urban, rural, or mountainous areas), and sensitive areas (boundary areas).
- Socio-economic factor: affects the capacity of TB patients to pay for consultation and treatment. Factors included in the modeling were Gross Domestic Product per person and the rate of poor households in the simulated area.
- Policy factor: administrative solutions by governmental agencies to control the risk of outbreak spread. Intervention policies, such as zoning of epidemic areas and supporting treatment will directly affect the progression of infections.

Data collection

We collected data from the Vietnam NTP program from the 1st of January 2016 to the 31st of July 2020. Data including the name, age, gender, ethnicity, and physical address of the TB patients were collected for modeling.

Algorithm features

The cause of TB infection is the transmission of *Mycobacterium tuberculosis* from TB patients to others in the community, which can be reflected by mobility and contact. The transmission magnitude can be considered a function of environmental factors, the infectiousness of TB patients, and the medical status of contacts, including their comorbidities, age, smoking and drinking status, etc. The mobility in the prediction model is indicated by the number of people moving across regions in real time. TB patients would encounter people

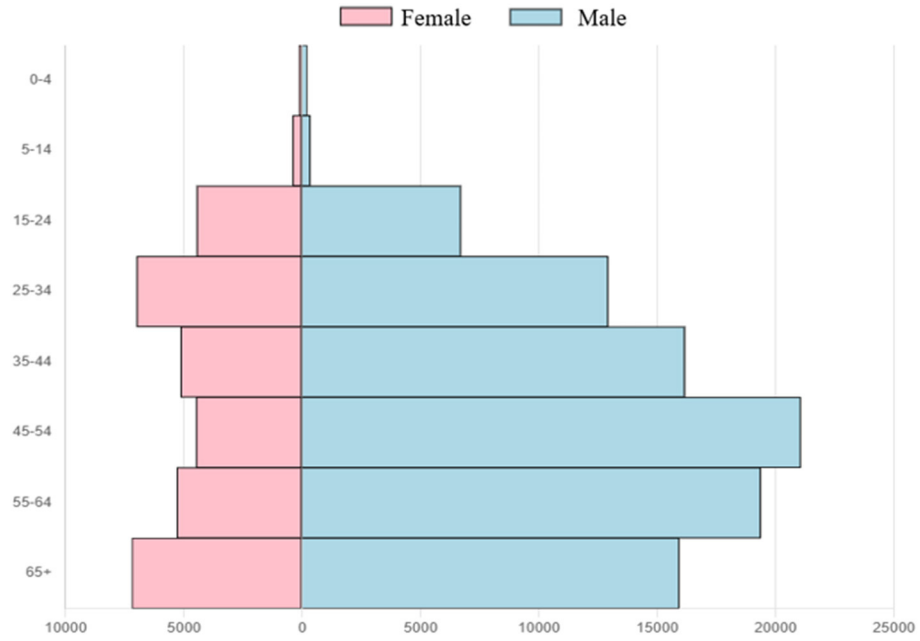

FIGURE 2
Distribution of TB notifications by sex and age group in Vietnam in 2020.

in an area and their movement to other regions is randomly simulated at all levels of prediction.

Factors relating to population (population density, gender, age), social–economy, climate status, and individual history (i.e., comorbidities and living habits) were included in the predictions to enhance the AI-based simulation, in addition to information from the collected database. Multiple variables were modeled as weighting parameters for users to modify in real time. One such variable is the policy factor, which can indirectly affect the infection magnitude through other factors. To predict TB notification, the GeoAI model includes all the factors described above contributing to TB transmission. The accuracy of the simulation is determined by the quality of the input data; the more detailed the input data is, the more accurate the prediction that can be achieved.

The input parameters which were included during the modelling comprised transmission factor; individual factor; mobility factor; climate factor; socio-economic factor and policy factor. These input parameters were divided into different classes of the Deep-LSTM (Long Short Term Memory) network. The model development was conducted based on the following steps: (1) the above-mentioned parameters were assigned as initial values, a cost function was then developed, (3) the gained values were modified across different steps of looping in order to optimize the developed cost function, and (4) the model were continuously processed until the converged value was achieved. Subsequently, the values which were the inputs of the prediction model was retrieved after the Deep-LSTM model development had been completed. Finally, upscaling methodology was applied to cover all of administrative levels, from district- to nation-level.

We developed an online geospatial platform to support efforts for visualization, analysis, and prediction of TB cases nationwide. The GeoAI platform is managed *via* a uniform resource locator (WebGIS), which requires log-in credentials to access the user interface. The users who registered and provided credentials can log in and review the distribution of TB notifications in space and time. The platform can be viewed in Vietnamese for the convenience of local users in medical practices. Users can access the platform at the following web address: https://geotb.herokuapp.com/.

Statistical analysis

The distribution of TB cases was visualized while the model's prediction outcomes were both plotted and visualized.

Ethical approval

All procedures used in this study followed the ethical standards of the Ethical Review Board of the National Lung Hospital (IRB approval No. 48/20/CN-HDDD; approved on 31st December 2020).

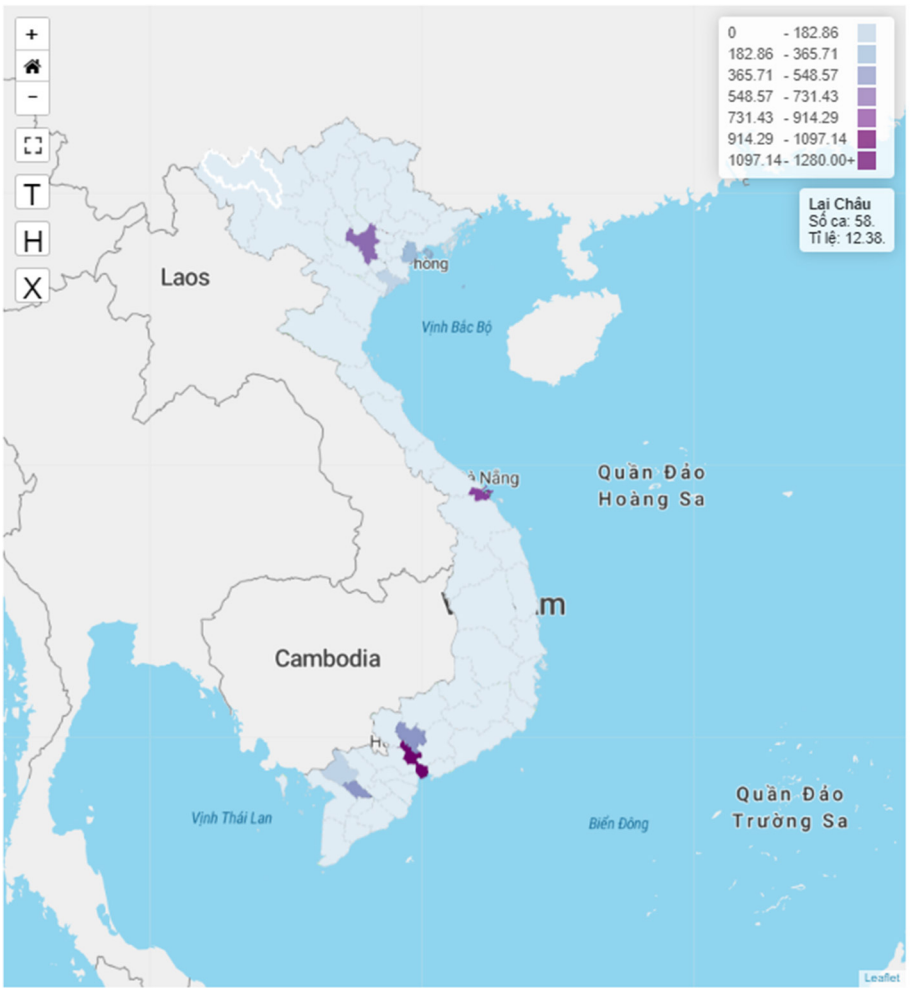

FIGURE 3
Prediction of TB hotspots in Vietnam.

Results

We achieved a sample size of 400,370 TB cases with bacterial evidence. To account for the effects of the COVID-19 pandemic in 2020, we excluded the data from 2020 from the prediction modeling. The data for 2020 were included for epidemiological visualization purposes alone. Based on the study's data, the prevalence of TB in Vietnam was calculated at 414.67 cases per 100,000 population.

Figure 1 shows the home screen of the GeoAI platform, including interactive elements. The left part of the screen visualizes the distribution of TB notifications using a color spectrum, with darker colors representing more TB cases. Users can enter a full-screen view by clicking on the ⛶ button. To view the map at a province level, users can click on the "T" button while the "H" button and the "X" button represent district and commune levels, respectively. Users can also click on the "+/−" buttons to zoom the map view in and out.

The right part of the screen visualizes TB epidemiological parameters by either population or region, the number and rate of TB cases by time, the distribution of drug-resistant TB cases by age, the distribution of TB cases by treatment outcomes, and the distribution of HIV status in Vietnam. We also designed a filter bar located at the top of the platform that allows users to adjust the data visualization based on either time or administrative levels.

The spatial distribution of TB notification rates in Vietnam at a province level from 2016 to 2020 is illustrated in Figure 1. The TB notifications were relatively higher in the southern part of the country than in the central and northern regions. The TB notifications were notably high in the An Giang, Tay Ninh, Can Tho, Dong Thap, and Soc Trang areas.

Figure 2 shows the TB notification rates in Vietnam by sex and age in 2020. TB notifications tended to increase with age, with different TB notification rates recorded between men and women. Adult men had a higher TB notification rate than women of the equivalent age groups, with the lowest male-to-female case ratio of 1.5:1 in the 15–24 age group and the highest ratio of 4.7:1 in the 45–54 age group.

Figure 3 illustrates the spatial predictions of TB notification in Vietnam based on our model. With all the transmission factors included in the model, three were three cities which were predicted as major TB hotspots, namely Ha Noi, Da Nang, and Ho Chi Minh City.

Discussion

Our findings indicate that TB notifications in Vietnam show spatial heterogeneity, as demonstrated by the spatial clustering of notifications and predicted hotspots in certain provinces and cities. TB notification rates tend to increase with age and men have higher TB notification rates than women in all age groups.

The high TB rate notification clusters are concentrated in the south of the study area, especially in the southwestern part of the country. This result is consistent with the findings of the second TB prevalence survey in Vietnam, in which TB prevalence was found to be higher in the south compared to the central and northern areas of Vietnam (13). The predicted TB hotspots in the model are Vietnam's three main cities, which are Ha Noi, Da Nang, and Ho Chi Minh City. With the rapid pace of migration and urbanization in Vietnam during the past decade, almost half of the migration in the country was from rural areas to cities (14). Our predictions suggest that TB patients could move to major cities, thus transmitting the infection and creating TB hotspots in these areas. These results are in line with other studies from Zimbabwe (15, 16), where TB hotspots and clusters can be found in urban areas with large populations.

Spatial analysis of TB notification distribution shows that TB is heterogeneous in both time and space, meaning that TB control strategies should be individualized for each area; thus, provinces or regions with high TB rates require increased control efforts compared to those with low TB rates. Areas that are hotspots or clusters of TB cases should be subjects for active TB case identification and innovative interventions. Healthcare policymakers should thus focus on strengthening TB prevention and control measures in these hotspots to mitigate the transmission of this disease.

In addition to the above findings, our study also has certain limitations. Firstly, our main input data source is the TB notification data in Vietnam; due to the effects of the COVID-19 pandemic, the notification data do not accurately represent the TB caseload in Vietnam during the pandemic period, thus greatly affecting the accuracy of our predictions. Secondly, we used aggregated notification data from provincial-level TB hospitals. With the high migration rates in Vietnam, TB patients may have visited more than one provincial TB hospital, thus resulting in duplicate entries. Thirdly, the TB notification system does not include data from TB cases whose treatment was initiated in the private sector. Lastly, the current modeling sample excluded data from 2020 and thus does not fully reflect the most up-to-date epidemiological situation. These problems might cause bias and subsequently affect the prediction of TB hotspots in our model.

Conclusion

Our GeoAI platform predicted the distribution of TB hotspots, which are located in the major cities of Vietnam. Our findings provide new insights into the spatial patterns of TB, which is essential for targeted regional TB control interventions. This approach is highly important in lower–middle-income countries such as Vietnam, where available resources for TB control are limited and need to be carefully allocated to areas with higher TB caseloads.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Author contributions

TD, HB, and XH conceived of the study. TD, HB, XH, and HaN collected and cleaned data, performed the official statistical analyses, interpreted the results, and wrote the manuscript. DoN, NH, TP, DuN, HoN, ND, CD, and NN provided the critical revision of the manuscript for important intellectual content. All authors contributed to the article and approved the submitted version.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Using wearable devices to generate real-world, individual-level data in rural, low-resource contexts in Burkina Faso, Africa: A case study

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Background: Wearable devices may generate valuable data for global health research for low- and middle-income countries (LMICs). However, wearable studies in LMICs are scarce. This study aims to investigate the use of consumer-grade wearables to generate individual-level data in vulnerable populations in LMICs, focusing on the acceptability (quality of the devices being accepted or even liked) and feasibility (the state of being workable, realizable, and practical, including aspects of data completeness and plausibility).

Methods: We utilized a mixed-methods approach within the health and demographic surveillance system (HDSS) to conduct a case study in Nouna, Burkina Faso (BF). All HDSS residents older than 6 years were eligible. $N = 150$ participants were randomly selected from the HDSS database to wear a wristband tracker (Withings Pulse HR) and $n = 69$ also a thermometer patch (Tucky thermometer) for 3 weeks. Every 4 days, a trained field worker conducted an acceptability questionnaire with participants, which included questions for the field workers as well. Descriptive and qualitative thematic analyses were used to analyze the responses of study participants and field workers.

Results: In total, $n = 148$ participants were included (and n = 9 field workers). Participant's acceptability ranged from 94 to 100% throughout the questionnaire. In 95% of the cases ($n = 140$), participants reported no challenges with the wearable. Most participants were not affected by the wearable in their daily activities ($n = 122$, 83%) and even enjoyed wearing them

($n = 30$, 20%). Some were concerned about damage to the wearables ($n = 7$, 5%). Total data coverage (i.e., the proportion of the whole 3-week study duration covered by data) was 43% for accelerometer (activity), 3% for heart rate, and 4% for body shell temperature. Field workers reported technical issues like faulty synchronization ($n = 6$, 1%). On average, participants slept 7 h (SD 3.2 h) and walked 8,000 steps per day (SD 5573.6 steps). Acceptability and data completeness were comparable across sex, age, and study arms.

Conclusion: Wearable devices were well-accepted and were able to produce continuous measurements, highlighting the potential for wearables to generate large datasets in LMICs. Challenges constituted data missingness mainly of technical nature. To our knowledge, this is the first study to use consumer-focused wearables to generate objective datasets in rural BF.

KEYWORDS

wearables, consumer-based wearables, digital technologies, health research, real world data, SSA, sub-Saharan Africa, global health

Introduction

Wearables for health research in low- and middle-income countries

Wearable devices increasingly find their way into health care and health research (1). For example, advantages of consumer-based wearables compared to research-grade devices and questionnaires are low costs, user-friendliness, and unobtrusiveness, as well as the ability to collect data in the natural environment of study participants (2). Also, the accuracy and reliability of these devices have improved, even leading to clinically approved certifications [like the US Food and Drug Approval or the European CE approval (2, 3)].

Wearable data thus may generate valuable data for global health research even on an individual level (4), as wearables allow for remote measurements of continuous physiological data in the wearers natural environment (so-called ecological momentary assessment) (2).

Wearables are already used to forecast infectious disease outbreaks (5, 6) and gain population-based insights using big data (2, 7) or conduct healthcare research in low-resource contexts (8).

For example, Radin et al. (5) used wearable data to forecast rates of influenza-like illness. Using de-identified Fitbit data on heart rate, sleep, and weekly estimates of influenza-like illness (ILI) rates at the state level (reported by a US authority), they could significantly improve predictions. Authors thus emphasized the potential of wearable data for fast outbreak response. Based on this work, the Robert Koch Institute, the German research institute for disease control and prevention, launched the so-called "Datenspende" study (6). With de-identified wearable data donated by German citizens ("Datenspende"), they were able to predict regional probabilities of COVID-19 outbreaks. Incorporated were data on pulse, physical activity (PA), and sleep, as well as weather data. The development of predictive models from wearable data, such as body shell temperature, could aid in the control of the rising burden of communicable and non-communicable diseases in high-exposure countries, such as sub-Saharan Africa (5). Wearable devices might also effectively identify patients at risk and enable better patient monitoring and health care in rural settings (8).

Heart rate (measured with standard, non-wearable devices) has previously been able to predict all-cause mortality of vulnerable populations in sub-Saharan Africa (9, 10). These punctual/point measurements were only conducted in clinic. Wearable devices might not only generate long-term data automatically but are low cost generated in the natural environment of patients (2). They might also effectively identify patients at risk and enable better patient monitoring and health care in rural settings (8). Overall, insights into activity, morbidity, and vital patterns could be starting points for tailoring and targeting of public health and behavior change interventions (11, 12). A few projects are already underway in this regard; like the International Physical Activity and the Environment Network (IPEN) project (13), which may be the largest study to date using wearable devices to track movement in different countries and continents, has been used to design activity-friendly built environments (14).

Abbreviations: MC, multiple choice (questions); MEMS, micro-electromechanical system; Tucky, Tucky axillary thermometer patch; Wearable, consumer-grade Wearable device; WPHR or Withings, Withings Pulse HR fitness tracker wristband.

Despite the fact that the potential and usefulness of wearables in rural and low-resource contexts have been widely identified (1, 2, 8), most research has been undertaken in high-income contexts (1). Wearable devices are used in a variety of ways in high-income research contexts, including testing novel technologies, producing population-based insights, employing wearables in treatments and monitoring, etc. (1). There are limited insights on individual and cultural acceptability and (technical) feasibility of wearables in LMICs settings. Few studies have been conducted to date, most of them mainly qualitative (not including wearable device data) or using high-end, non-consumer-based wearables. For example, Larnyo et al. conducted a qualitative study on the general preparedness of Ghanaian family caregivers of dementia patients to employ wearables. They found that caregivers were willing to recommend the usage of healthcare wearable devices for dementia patients (15). Davies et al. evaluated a wearable device and home-based sensor for monitoring epilepsy in children in South Africa and found their proof-of-concept study provided beneficial outcomes for remote patient monitoring (15, 16). However, they reported issues with wearable management and internet connectivity in the field (16). Wearable photoplethysmography measurements may be impeded by variations in ambient conditions (e.g., heat exposure), everyday activities (e.g., farming), and signal crossover (17–20). More research is needed to understand the effect of skin pigmentation and its interference with measurements; some studies found no evidence (17, 20), while others did (21). Furthermore, wearables must be accepted or even desired by users in order to generate meaningful measurements (22). Thus, insights into the feasibility of wider applications of wearables, acceptability, and technological reliability in rural settings are still limited.

HDSS is ideal for population health surveillance and as a launching point for introducing wearables as a routine measurement to capture individual-level health effects

In rural, low-income regions, health and demographic surveillance systems (HDSSs) are an ideal starting point for evaluating wearable devices. Each HDSS represents a dynamic population cohort that varies over time frequently based on entry (birth, in-migration) and exit (death, out-migration) events. Through routine data collection, longitudinal databases of individuals and social units are collected in areas where vital events registration and health information systems are weak or non-existent. The HDSS provides a well-structured platform to collect valid and reliable population-based data, particularly in areas where vital events registration and health information systems are weak or non-existent. In rural, low-resource contexts, HDSS provides an infrastructure for conducting individual studies (23, 24) and implementing consumer-based wearable devices for population research.

This case study seeks to understand if consumer-based wearables could be used to generate longitudinal, high-quality individual-level health data in vulnerable populations in LMICs using two wearables: (i) Withings Pulse HR fitness tracker wristband (WPHR) and (ii) the Tucky axillary thermometer patch (thermometer patch). Specifically, we aimed to (i) evaluate the feasibility of using wearables in rural communities in the Nouna HDSS in Burkina Faso (25) with regard to data quality (plausibility of output values) and quantity (data completeness) and (ii) understand acceptance among the study population.

Our specific objectives were to:

(i) understand study participant and field worker acceptability of wearable devices with respect to hindering and enabling factors, and
(ii) evaluate data quantity (i.e., data completeness and its potentially influencing factors) and quality (i.e., the plausibility of output values) of wearables within the context of the Nouna HDSS to understand individual sleep, activity, and heart rate characteristics within vulnerable populations.

Methods

This case study used a mixed-methods approach with a convergent explanatory design (26, 27) in which qualitative data complemented quantitative data. Our results are reported in line with the Consolidated Standards of Reporting Trials (CONSORT) extension for randomized pilot and feasibility trials (28) (Supplementary material S1). This study is further detailed in the protocol paper; for details, see (4).

Study location: The Nouna HDSS in Burkina Faso

As part of the INDEPTH network, the HDSS in Nouna, Burkina Faso, managed by the Centre de Recherche en Santé de Nouna (CRSN), gives access to retrospective health and population data encompassing about 115,000 individuals over 20 years (25, 29). Since 1992, the Nouna HDSS has been managed by the CRSN, a Ministry of Health-affiliated research institute. Burkina Faso is located in sub-Saharan Africa and has one of the highest burdens of climate-sensitive diseases. The surveillance area of the Nouna HDSS is characterized by a tropical climate with one rainy season lasting from May to September (mean annual rainfall of 800 mm) and year-round high temperatures. Malnutrition and malaria are common in the Nouna HDSS (25).

Sampling and study population

We calculated a sample of $n = 150$ participants, based on a rounded population size of $n = 100{,}000$ (total HDSS population excluding children under the age of 6 years), a confidence level of 95%, and a margin of error of 8%. This sample size was deemed adequate and consistent with the available literature (30) for estimating acceptability in this population and evaluating feasibility. Eligible were all HDSS inhabitants older than 6 years, willing to participate and wear the wearables. Participants were randomly assigned to two study arms.

Seven villages within a closer range (walking distance below 30 min) to a health facility were randomly selected from the HDSS database. Field workers were assigned villages in close proximity to each other to optimize data collection. We conducted purposive block randomization with the existing HDSS population and randomly drew $n = 170$ individuals through the database (n = 150 study population, oversampling of $n = 20$). Refer to the protocol paper for exact details on randomization and sampling (4).

Study procedures

The case study was conducted at the Nouna HDSS from January 2021 to March 2021, enclosing three study cycles with each n = 50 study participants (1st cycle: 18/01/2021–07/02/2021; 2nd cycle: 08/02/2021–28/02/2021, and 3rd cycle 1/03/2021–21/03/2021).

In each study cycle, $n = 27$ out of 50 participants (study arm 1) were instructed to wear the WPHR all day, while $n = 23$ study participants (study arm 2) also wore the thermometer patch at night (to determine if wearing multiple devices affects acceptability and data completeness). Every 4 days, study participants met with a field worker to complete an acceptability questionnaire, synchronize data, and charge the WPHR battery (study arm 1). Study participants who wore a thermometer patch received a smartphone and a portable solar panel to charge their devices during the study period. Participants' vital parameters were remotely monitored *via* the wearable platforms, so participants with abnormal measurements could be referred to a health facility.

The project was designed in close collaboration with the CRSN team and community leaders, like village chiefs and household heads, to ensure their awareness and acceptance. The field team contacted study participants, as well as family members and community leaders, to inform them about the study and obtain informed consent *via* fingerprint [for details, see protocol paper (4)]. Study participants could withdraw their participation at any time. Consistent with other HDSS-related studies, participants received the US $6 for their participation.

Wearables

Table 1 outlines the details of the two employed wearables. Reasons for selecting these devices include the low cost to facilitate population health surveillance, user-friendliness, functionality, and validity [for details, see (4)].

While the participant conducted the questionnaire with the field worker, the wearables automatically synchronized with the tablet of the fieldworker which then uploaded the data to the respective wearable platforms. Data obtained from the Withings platform (31) included heart rate, physical activity [e.g., measures of steps, distance, calories burnt, activity categories (automatically classified by the WPHR)], and sleep measures (duration, awakenings, and sleep quality; WPHR output, exact preprocessing undisclosed). Body shell temperature data were downloaded from the Tucky platform (32). For both wearables, the specifics of data preprocessing were unavailable and we had no access to raw data. Furthermore, we collected data on sex, date of birth, weight, height, and blood pressure.

Questionnaire

We developed a 5-item Likert-scale questionnaire with multiple-choice (MC) and open-ended questions regarding: (a) participant demographics, (b) ease of use of wearable as reported by field worker, (c) study participants' acceptance of wearables, and (d) daily self-reported activity of study participants (Supplementary material S2). The questionnaire is based on established, applied questionnaires such as (33) and (34) and was adapted to the study setting. The survey was conducted using Survey Solutions (35), a freely available survey software that was run on our local project server. The field staff asked questions to the participants who collected responses on their tablets (except for three multiple-choice (MC) and one open-ended question answered by the field staff). Therefore, unless otherwise stated, questionnaire results refer to participants responses. Fieldworkers visited participants every 4 days at times and locations that were convenient for each participant; thus, each participant completed five questionnaires during the course of one study cycle. Furthermore, after receiving consent, the first author (SH) conducted informal feedback meetings with study managers.

Data analysis

Objective 1: Acceptability—Hindering and enabling factors

We analyzed qualitative data (open-ended questions and informal feedback sessions with stakeholders and field workers) convergent with quantitative data (Likert-scaled and MC questionnaire responses, wearable data), to facilitate a better understanding of quantitative data and findings. Responses to Likert-scale and MC question items were analyzed descriptively,

TABLE 1 Details on Withings Pulse HR fitness tracker (WPHR) and the Tucky thermometer patch [adopted from the protocol (4)].

	Withings pulse HR	Tucky thermometer
Consumer-grade wearables part of the feasibility study		
Measures	- **Steps (distance and kilocalories):** • Measured continuously with accelerometery (impact of the foot on the ground, exact algorithm undisclosed) - **Activity:** • Activities like walking, running, swimming, cycling, and different sports (soccer, fitness, boxing, basketball, squash, etc.) are detected with accelerometery, algorithm undisclosed - **Heart rate:** • Routinely measured every 10 min with photoplethysmography (exact algorithm undisclosed) • Measurement every 1 s if workout detected - **Sleep** • Based on accelerometer (i.e., sleep is calculated based on the absence or decrease of movements, exact algorithm, and thresholds for awake/sleep undisclosed; the sleep quality algorithm considers the following factors: sleep duration, sleep depth (calculated with movement intensity), regularity (uniformity of bedtime and rising time), interruptions (waking phases as identified by the wearable)	- **Body temperature (shell temperature)** • Measured continuously with contact sensor
Wear location	Wrist	Under right armpit
Wear frequency	During the whole study cycle	During night
Data synchronization	5 days of local data storage between synchronizations (within 10 m of tablet)	Requires regular synchronization (within 10 m of tablet)
Connectivity	Bluetooth low energy	Bluetooth low energy

while open-ended questions were coded thematically (36–38). We followed the steps "compiling, disassembling, reassembling, interpreting, and concluding" (39). Data were cleaned in Excel. After repeatedly reading responses (familiarization), themes were inductively identified from questionnaire responses.

Objective 2: Quantity and quality of wearable data to understand individual sleep, activity, and heart rate characteristics within vulnerable populations

R was used for analysis and visualizations (40). Demographic, wearable, and survey data were descriptively summarized as mean (standard deviation) or median (first quartile, third quartile). Categorical variables were counted and provided as numbers (percentage). We used quantiles to split age groups (i.e., minimum, 25th, 50th, 75th, maximum).

We refer to data coverage as the proportion of the study for which wearable data were collected (with an acceptable data rate for the respective data output rate). Literature (41–44) and sampling rates of wearables used in our study (Table 1) guided our analysis, so a single data point covered the following epochs (i.e., the following time spans were tolerated between two measurements and seen as time covered by data):

- accelerometer data (activity): 60 min [During the continuous activity, output data are sampled every second; however, the wearable does not distinguish between inactivity and non-wear, both of which result in data output gaps. As similar issues exist with research-grade accelerometers, we use the commonly utilized interval of 60 min (41, 42) as maximal inactive time without measured

movement still designated as sedentary/inactive time; everything over 60 min without movement is therefore regarded as time not covered by data, i.e., missing data. Thus, a single output value may cover 60 min; everything above 60 min between two values is considered missing for time, or missing data.].

- body shell temperature: 5 min (output data frequency: every minute when attached for sleep, the rest of the time is tolerance, i.e., anything more than 5 min between two output data values is considered missing data).
- heart rate: 15 min (output data frequency: every 10 min, rest is tolerance; i.e., anything more than 15 min between two output data values is regarded as missing data).

For data coverage of each participant and each day, we calculated the difference between two measurements, deducted

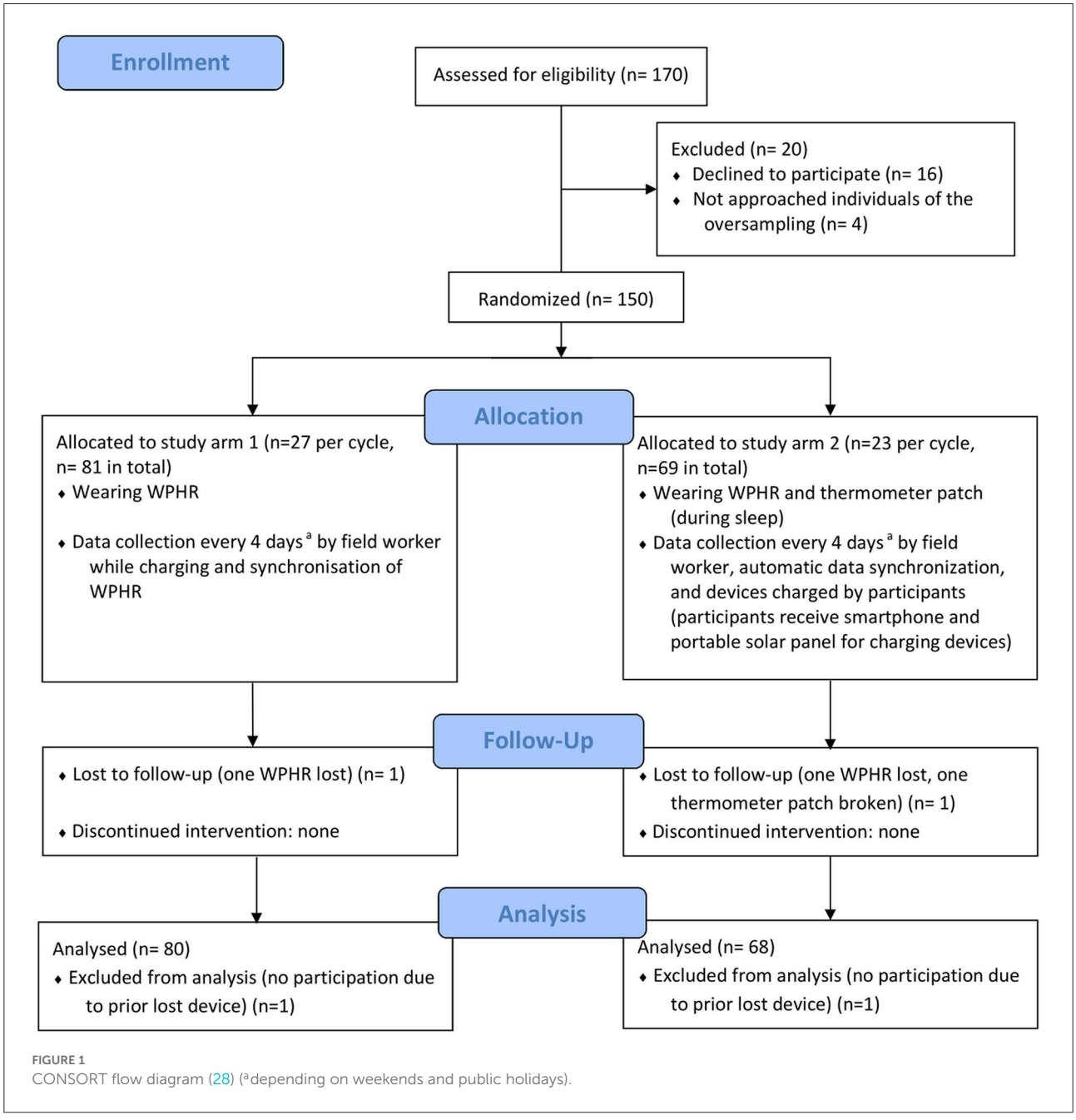

FIGURE 1
CONSORT flow diagram (28) ([a]depending on weekends and public holidays).

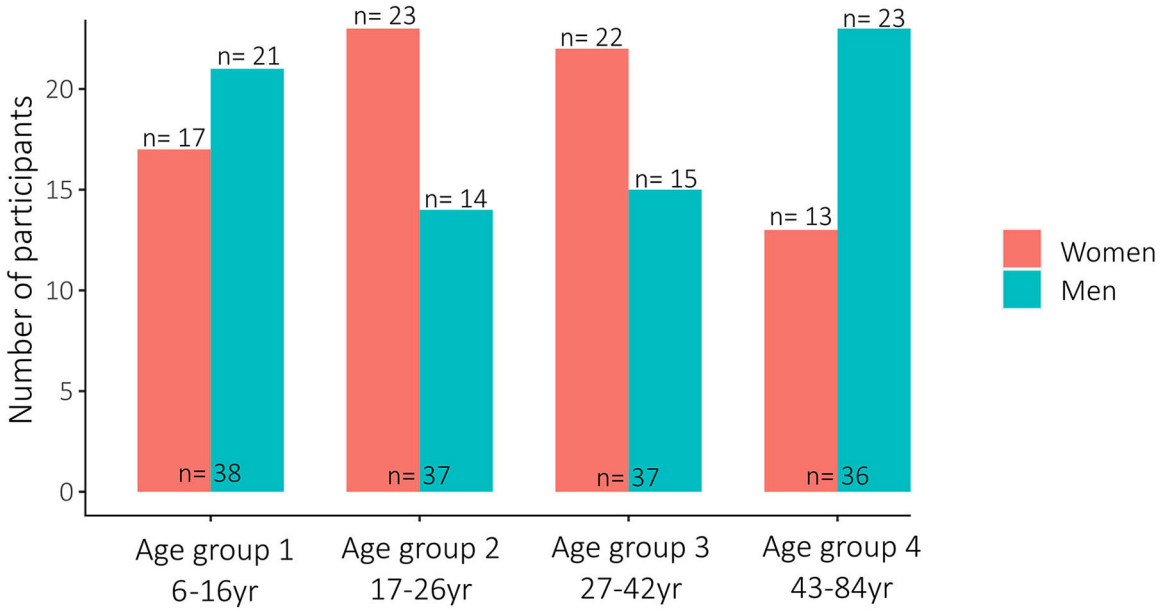

FIGURE 2
Overview of all study participants per age groups and sex.

the tolerances (i.e., 60/5/15 min for accelerometer/body shell temperature/heart rate data; see above), and added all values >0 (i.e., the excess of study time, not covered by a data point and the tolerance interval).

The thermometer patch was only worn during sleep, and its duration of use varied among study participants; a daily average of 8 h of sleep was used to calculate data coverage (45). Thus, the calculated time not covered by data was subtracted not from the total duration of the study (24 h × 3 weeks) but from a duration that had been adjusted for data coverage (8 h × 3 weeks). We did not use the WPHR sleep data as a reference because the data completeness of the WPHR is being investigated in this study, and the data may be inaccurate and inconsistent across individuals (e.g., one might only want to wear one wearable). Despite the fact that the 8-h reference may be inaccurate due to individual sleep variations, the data coverage of the thermometer patches was also consistent when using references for sleep duration other than 8 h (Supplementary material S3A).

Results

The study involved $n = 148$ participants (see Figure 1). A total of $n = 73$ (49%) women and $n = 75$ (51%) men were included (see Figure 2), with a median age of 26 years (range 6–84 years); $n = 80$ (55%) only wore the WPHR, and $n = 67$ (45%) additionally wore the thermometer patch. A total of $n = 16$ individuals (women $n = 9$, men $n = 7$) refused to consent; oversampled study participants were approached (see Figure 1). In the second study cycle, two WPHRs (4%) were lost and one thermometer patch (4%) was damaged. Therefore, the third cycle comprised $n = 48$ study participants, i.e., one participant less per study arm (see Figure 1). Three further patches (13%) were damaged at the end of the last cycle.

Objective 1: Acceptability—Hindering and enabling factors

A total of 841 questionnaires containing responses from study participants and field workers were collected. Likert-type items were grouped into three categories: (i) acceptance toward wearable, (ii) acceptance toward wearing two wearables, and (iii) technical feasibility (answered by field workers).

Fourteen out of 17 question items had 90% or higher positive agreement ("Agree" and "Strongly agree" responses) (see Figure 3). The majority of study participants agreed on acceptability, with agreement ranging from 94 to 100% (mean: 97%).

Agreement on questionnaire items was comparable across subgroups of sex, age, study arms, and study cycles (Supplementary material S3B).

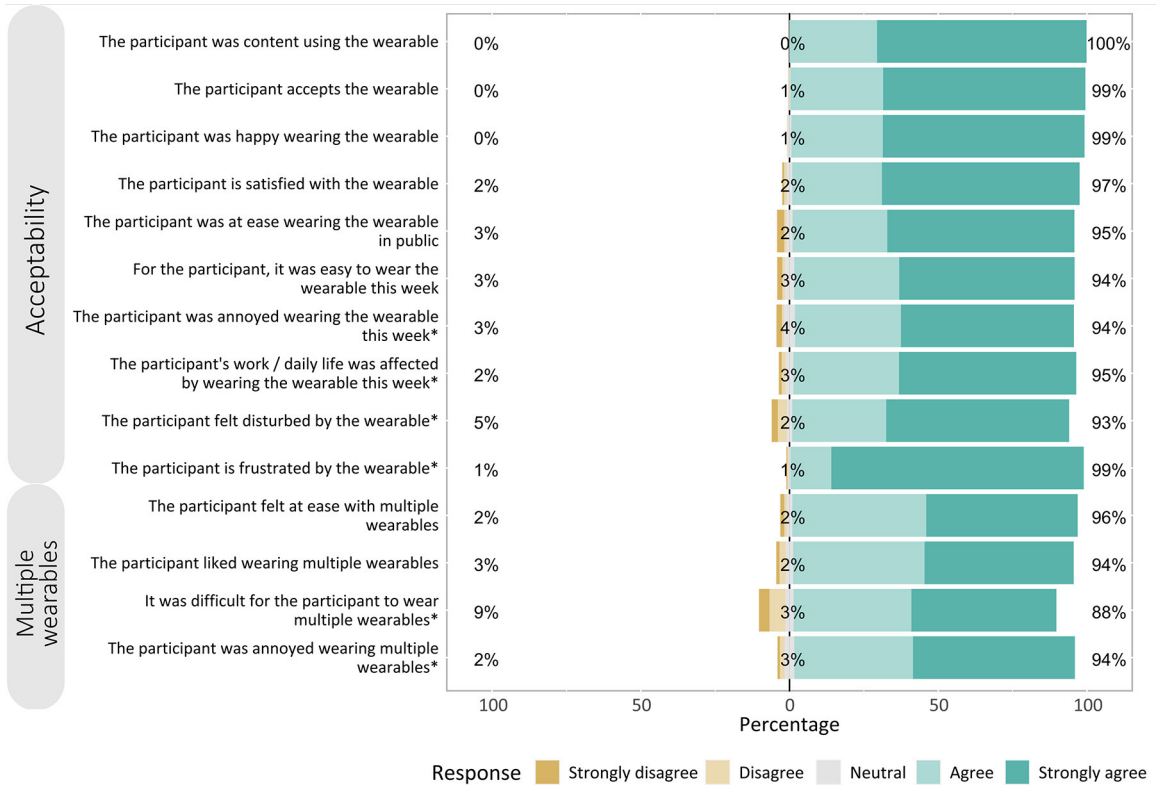

FIGURE 3
Responses to Likert-type questions. Likert-type responses and their percentages according to the three categories: (1) acceptability of wearing a wearable, (2) wearing multiple wearables at once, and (3) technical feasibility of implementation and maintenance. Items with negative statements (marked with *) have reversed scales for readability and comparability.

Field worker's feedback

Field workers reported informally that they frequently observed participants enjoying the wearables, e.g., considering them as "cool." On the other hand, field workers reported concrete technical issues such as internet connection issues, data synchronization issues between wearable and tablet, and the patch falling off. Two of nine field workers (22%) minimally once responded "Disagree" or "Strongly disagree" when asked if using a tablet to manage data was difficult. Nevertheless, for many field workers, handling data was straightforward (synchronization) ($n = 8$, 89%), as was using the tablet-based wearable application ($n = 9$, 100%).

Quality-impeding questionnaire items

MC and open-ended questions led to varied responses (see Tables 2–4). The majority of study participants ($n = 122$, 83%) were not irritated by wearable devices, and they were often overlooked ($n = 51$, 35%). Ten participants ($n = 10$) found the thermometer patch difficult to wear, and seven (5%) needed extra time to handle the wearables. A few participants ($n = 3$, 2%) felt limited in their movement by the wearables or removed them ($n = 1$, 1%); one (1%) experienced increased transpiration. One female participant (1%) of age group 3 (27–42 years) had palpitations while wearing the WPHR (she was referred to a health facility without diagnosis).

Most participants ($n = 136$, 93%) reported that the wearable had no effect on their sleep. Some ($n = 4$, 3%) noted that the thermometer patch came off during the night. Others ($n = 4$, 3%) woke up during the night, while one (1%) had trouble sleeping.

The study participants perceived the look and wear of the wearables as positive (see Table 3), including weight ($n = 89$, 60%), wear comfort ($n = 83$, 56%), appealing device appearance ($n = 76$, 51%), size ($n = 73$, 49%), or practical wear ($n = 52$, 41%). Study participants ($n = 16$, 19%) also enjoyed the wearable in general and the information it provided ($n = 2$, 1%). Some ($n = 7$, 5%) reported difficulties wearing the device, particularly the thermometer patch not adhering well to the skin, as well as the wearables being too big ($n = 1$, 1%) or being frequently asked about it by friends ($n = 1$, 1%).

TABLE 2 Overview of key responses to multiple-choice and open-ended questions about participants' general experiences with wearables and effect on sleep.

	Answers	*n*	*n*%	Quotes
Experiences	**What did you experience and feel when wearing the wearable?**			
	I was not disturbed	122	83%	"It's like a watch [Withings], not disturbing"
	I forgot that I wear it	51	35%	"Wearing the wearable had no effect on me," "I forgot it"
	Sometimes difficult	10	7%	"The Tucky is difficult to wear"
	It needed time/attention	7	5%	"I paid extra attention not to damage it"
	The wearable limited my movements	3	2%	
	Removing wearable	1	1%	"I just wanted to remove it," "I had to take it off for some days because it was itchy"
	Transpiration	1	1%	"It adhered to my skin [Withings]"
	Other	1	1%	"I had heart problems [palpitations while wearing the Withings]"
Sleep	**Did wearing the wearables have an effect on your sleep?**			
	Yes	7	5%	
	No	136	93%	
	What effect occurred because of the wearable device during your sleep?			
	The wearable fell off during the night	4	3%	"The adhesive of my Tucky did not adhere well"
	I woke up sometimes	4	3%	
	I woke up often	2	1%	"I woke up often to drink to calm my palpitations," "The Tucky disturbs my sleep"
	I could not sleep at all	1	1%	"I [felt like I] could not turn"

Analyzed were n = 841 valid questionnaires of n = 148 participants.

The peer perceptions of wearables varied. Family and friends of some study participants ($n = 41$, 25%) were curious and asked about the wearables. Common questions were about the device's purpose and why they wear it ($n = 19$, 13%), as well as possible medical applications like monitoring or healing COVID-19 ($n = 14$, 9%). Few people enquired about details about wearing the wearable and wanted to touch it and try it on ($n = 14$, 9%). People also asked what the wearable is ($n = 11$, 7%), how it was acquired ($n = 5$, 3%), and about any side effects, also in relation to magic (superstition) ($n = 3$, 2%). Some recognized the wearable from another study participant they had met and were curious about the study and how they could participate ($n = 3$, 2%).

In 95% of the cases ($n = 140$), study participants reported no challenges with the wearable (see Table 4). Challenges were mostly of technical nature such as broken devices or synchronization problems ($n = 5$, 3%), as well as perceived limitation of movement ($n = 1$, 1%). Two participants (1%) experienced itching.

Almost all study participants ($n = 141$, 96%) reported wearing the wearables continuously during the current study week. When asked if they could imagine wearing the wearable for a longer period (i.e., a year), a third ($n = 53$, 35% 281/841) answered there would be no problem at all, while a third ($n = 48$, 32%) said that 1 year would be too long, and the participation, i.e., the weekly questionnaires, would take too much time ($n = 46$, 31%). Furthermore, some ($n = 13$, 9%) perceived familial and social acceptance as uncertain. Negative effects for daily life ($n = 5$, 4%) included paying greater attention when wearing the wearable for fear of damaging it. Some participants ($n = 4$) desired more health information, i.e., a screen on the thermometer patch. Others feared adverse effects ($n = 4$, 3%).

Objective 2: Quantity and quality of wearable data to understand individual sleep, activity, and heart rate characteristics within vulnerable populations

Regarding the results of the questionnaires and the feedback from field workers, data missingness was largely attributable to two factors: (i) incorrect or non-wearing of the wearable by study participants and (ii) technical difficulties like synchronization issues and measurement failures.

We found a wide range of missingness, ranging from 0 to 100 % data coverage. Accelerometer data were most complete, with higher missingness for heart rate and body shell temperature data (see Table 5, and for more details, see Supplementary material S3C). Mean data completeness for accelerometry was 43%, heart rate 3%, and body shell temperature data 4%. Among all 148 participants, $n = 20$ participants (14%) had <1% data completeness for accelerometry and $n = 96$ (65%) for heart rate data. Of $n = 68$

TABLE 3 Overview of key responses to multiple-choice and open-ended questions about perceptions on wearables (of participants and social circle).

	Answers	*n*	*n*%	Quotes
Participant's perceptions	**What did you like about the wearables?**			
	Good weight	89	60%	
	Easy/comfortable wearing	83	56%	"I like the wear of the wearable"
	Looks nice	76	51%	"That is a nice watch"
	Good seize	73	49%	"I like the shape"
	Practical/handy to wear	52	35%	"It's just like a watch you can wear everyday"
	Just liking the wearable	30	19%	"I enjoy the wearable," "It's amusing," "I like the wearable"
	Informative	2	1%	"The wearable enables me to see and follow my daily activity and energy expenditure," "It helps me control my health"
	What did you not like?			
	Difficult to wear	7	5%	"The Tucky is difficult to wear [and keeping adhered]"
	Too big	1	1%	
	Other	1	1%	"My friends disturbed me a lot as they also wanted to wear and see the it [Withings]"
Peer perceptions	**Did people ask you about the wearable?**			
	Yes	41	25%	
	No	107	73%	
	About what wearable did the people ask?			
	Withings	38	25%	
	Tucky	10	6%	
	What questions did they ask?			
	Aim of wear, functionality	25	17%	"Why do you wear that," "That is a nice watch, […] what is it for?," "What is the aim of wearing this watch?," "What is it doing?," "Is it a toy?," "Its purpose [?]"
	Medical/health beliefs	19	13%	"Is it because of HIV that they gave you this," "People asked if that is how they control COVID with," "If it's a medicament," "Is it for [your] health?"
	What is it?/curiosity and desire to touch	14	9%	"What is it, … let me try," "They were curious and wanted to touch," "What kind of watch is it?," "They asked what I am wearing"
	Where from?/acquiring	11	7%	"Do you sell it? Do you have it in stock?," "How can someone acquire such a watch?," "Did you buy it?," "You have a nice watch, who gave it to you?," "Is it from the market?"
	Side effects on health	5	3%	"If it's a magical watch?," "Is it dangerous to wear?," "They asked if it makes me ill," "If it has side effects"
	People recognizing the study participation through the wearable	3	2%	"You also got 'their' watch?," "Children also wear that [study] watch? Who gave it to you?," "So you also have one of these watches, no?"
	Details on wearing	3	2%	"They asked if it's disturbing," "[Some asked] if I constantly wear it even while taking a shower?," "If I feel at ease when wearing the wearable"

Analyzed were n = 841 valid questionnaires.

participants (68/148, 46%) who wore the thermometer patch, *n* = 51 participants (75%) had <1% data completeness (Table 5).

Data completeness between sex and age groups, as well as study arms and acceptability levels, was similar (see Figures 4–6, Supplementary material S3C).

The mean data completeness decreased from 53% in the first cycle to 31% in the last cycle regarding accelerometer data (see Figure 7 and Supplementary material S3C). The second week in cycles had the highest data completeness (Figure 8).

Wearable data quality: Individual sleep, activity, and heart rate

Overall, activity, heart rate, sleep, and body shell temperature values were widely spread (see Table 6,

TABLE 4 Overview of key responses to multiple-choice and open-ended questions about experienced challenges with the wearables, and hindering factors for a possible long-term study with wearables.

	Answers	*n*	*n*%	Quotes
Challenges	**Did you experience challenges with the wearable/s this week?**			
	Yes	4	3%	
	No	140	95%	
	What challenges did you experience with the wearable/s?			
	Technical	5	3%	"[My] Tucky is not working anymore," "The display of the Withings does not light up anymore," "Problems with synchronization, we had to take the Tucky to Nouna to synchronize it with another device"
	Limiting movements	1	1%	"Sometimes hindering"
	Pain caused by wearable	1	1%	"I had heart problems [palpitations]"
	Did you remove the wearable/s this week?			
	Yes	7	3%	
	No	141	96%	
	Why did you remove it?			
	Device broke/technical issue	5	3%	"The bracelet of the Withings broke," "The Tucky does not work anymore," "When the Tucky fell off, I did not wear it anymore," "The participant just reset the tablet "[field worker]," "We had to take the device to Nouna because it was not synching [field worker]"
	Only temporary removed due to daily life/routine	4	3%	"I removed it when having morning sickness [due to pregnancy]," "I removed the wearable for taking a shower because I feared to spoil it," "For charging"
	Itching	2	1%	"I had to remove it due to itching"
Hindering factors for long-term wear	**What would be obstacles for you to wear the wearable for a longer study period (i.e., a year)?**			
	No problem at all	53	35%	"I am available no matter the study duration!!," "I am always available if you need me [for the study]," "I am absolutely okay with a longer period as I feel at ease wearing the wearable," "There are no obstacles as I feel at ease wearing the wearable"
	Study period was too long	48	32%	"[I] can't wear it for a very long time," "Impossible," "Yes I would have a hard time wearing for such a long period"
	Participation/questionnaires consume too much time	46	31%	
	Familial, social acceptance	13	9%	"My husband would be the problem," "If I have the permission of my husband," "If my father gives his permission," "It depends on the decision of my parents," "If my husband gives his permission again"
	Affecting daily life and activity (negatively)	5	4%	"When washing, I paid extra attention not to spoil it," "It hinders me doing everything"
	Not informative enough concerning health	4	3%	"I am discouraged by the fact that the Tucky does not give any information [on a screen]"
	Possible side effects	4	3%	"[I] fear side-effects or long-term consequences"

Analyzed were n = 841 valid questionnaires.

Supplementary Figures 9, 10, Supplementary material S3D). On daily average, study participants burnt about 1,300 kilocalories (kcal), walked over 8,000 steps, covered a distance of 5, 6 km and slept 7 h (Table 6). Heart rate averaged 73 beats per minute (bpm). On average, the participants' activity levels decreased in the afternoon (Figure 9). Participants woke around 7:00 and went to sleep between 22:00 and 23:00 (Supplementary material S3D). Most body shell

TABLE 5 Data completeness of the variables: accelerometry, heart rate, and body shell temperature for all study participants for the complete 9-week study period.

	Mean data completeness	Max data completeness	*n* (%) participants with data completeness <1%
Accelerometry data	43%	100%	20 (34%)
Heart rate data	3%	43%	96 (65%)
Tucky temperature data	4%	59%	51 (75%)

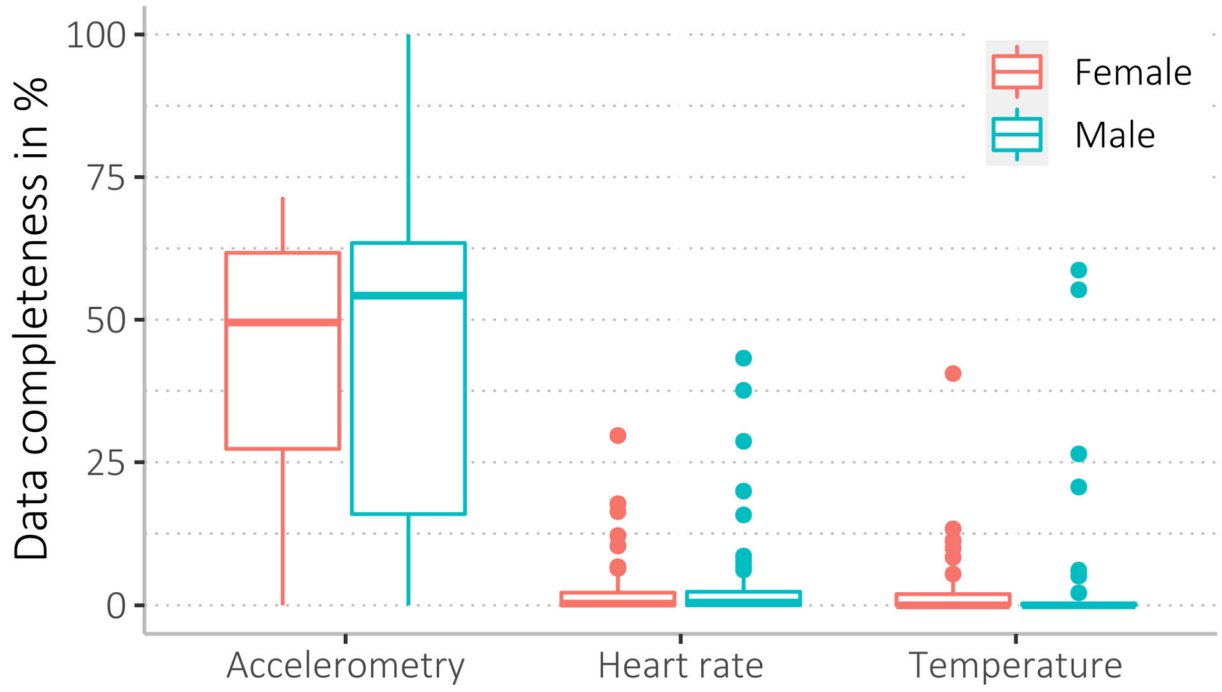

FIGURE 4
Data completeness of female and male participants regarding the three data sources (accelerometry, heart rate, and temperature).

temperatures ranged between 34 and 37°C, with some outliers (Supplementary material S3D).

Discussion

Overall, acceptance of wearables was high in rural Burkina Faso and seemed to be independent of individual factors like age, sex, and study arm. Accelerometry data were generated most reliably, while photoplethysmography and thermometer measurements proved more difficult with higher data missingness. Data quantity and quality did not appear to be affected by acceptability. Rather, open communication and regular follow-ups of study participants are needed to avoid distress and improper use of the wearables.

Objective 1: Acceptability—Hindering and enabling factors

Overall, the wearable devices were highly accepted among study participants and field workers. Field workers reported that study participants were enthusiastic, with some describing the wearable as a fashionable item well-taken care of. Resultantly, some wanted to extend their participation in the study. In line with other research in sub-Saharan Africa (15, 16, 46), study participants were interested in their personal health data and showed an overall openness to this new technology. If study participants had better access to their wearable health data, for example, with training showing them how to access this data, this interest may even be increased. Also, study participants in our study were quite young, with a median age of 26 years, which may explain why there was such a high level of acceptance for new technology since younger people are typically more

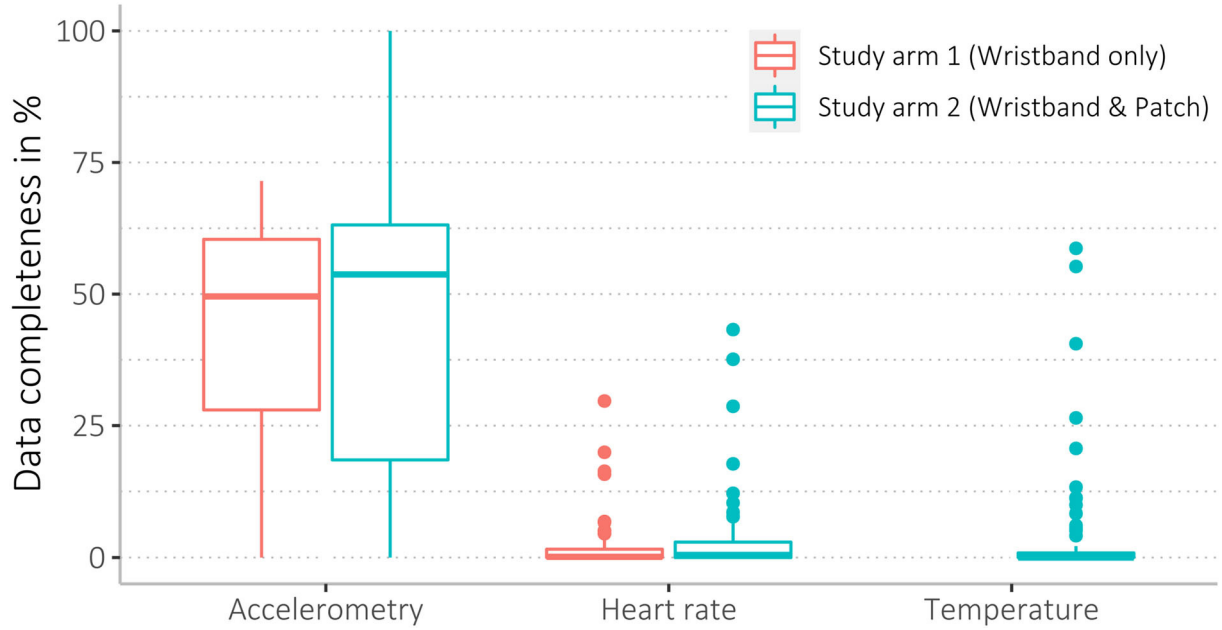

FIGURE 5
Data completeness of study arms. As the participants from study arm 1 only wore the WPHR, there is no temperature data for this group.

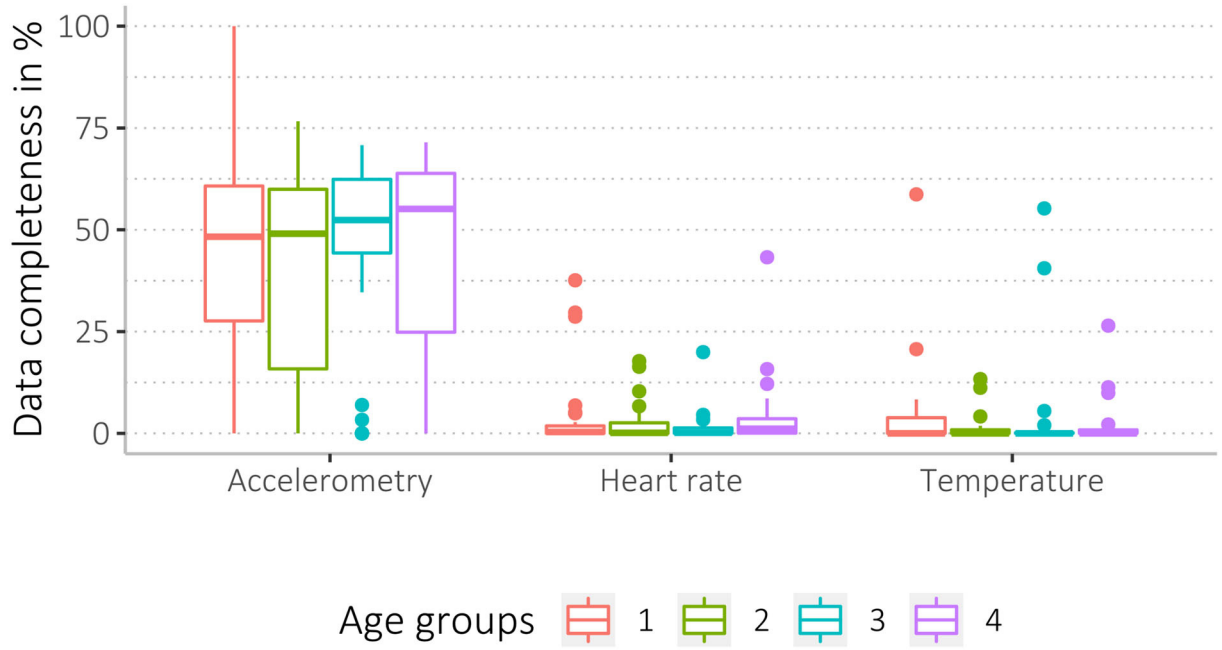

FIGURE 6
Data completeness of the four age groups (6–16 yrs, 17–26 yrs, 27–42 yrs, and 43–84 yrs) regarding the three data sources (accelerometry, HR, and temperature).

responsive and adaptable to new technologies. This may also highlight the potential for future global health research to use wearables, as nearly half of Burkina Faso's population is under 14 years (45%) (47). Another aspect that may have contributed to high acceptance may be social desirability. About 44% of Burkinabés live on <$1.90 per day (47). The compensation of US

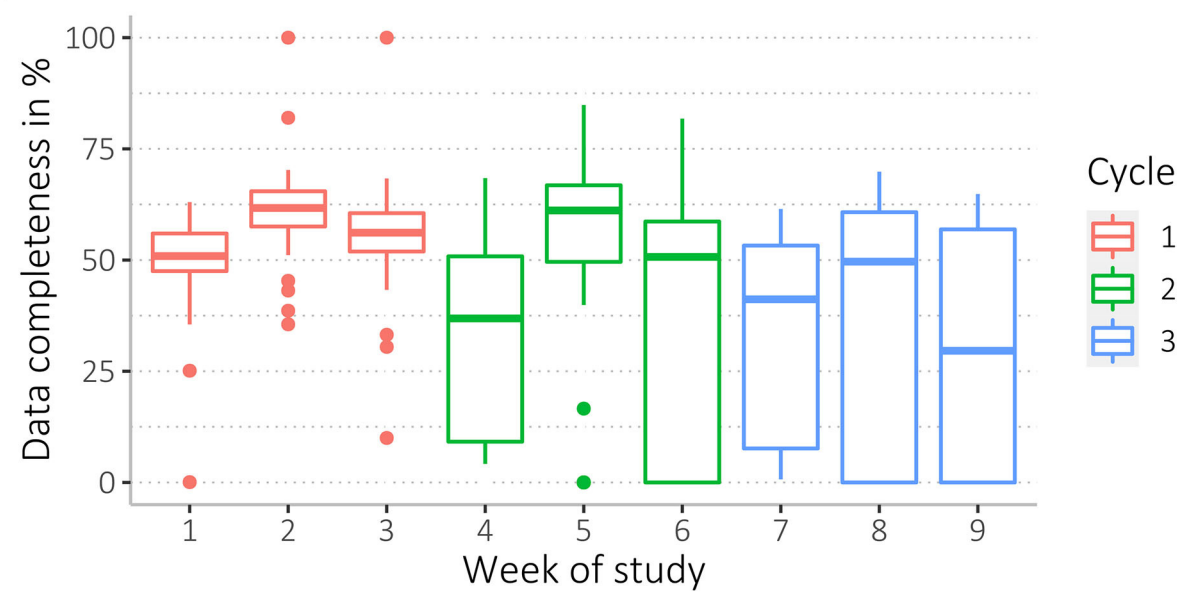

FIGURE 7
Completeness of accelerometry data collected during the complete study (duration of 9 weeks).

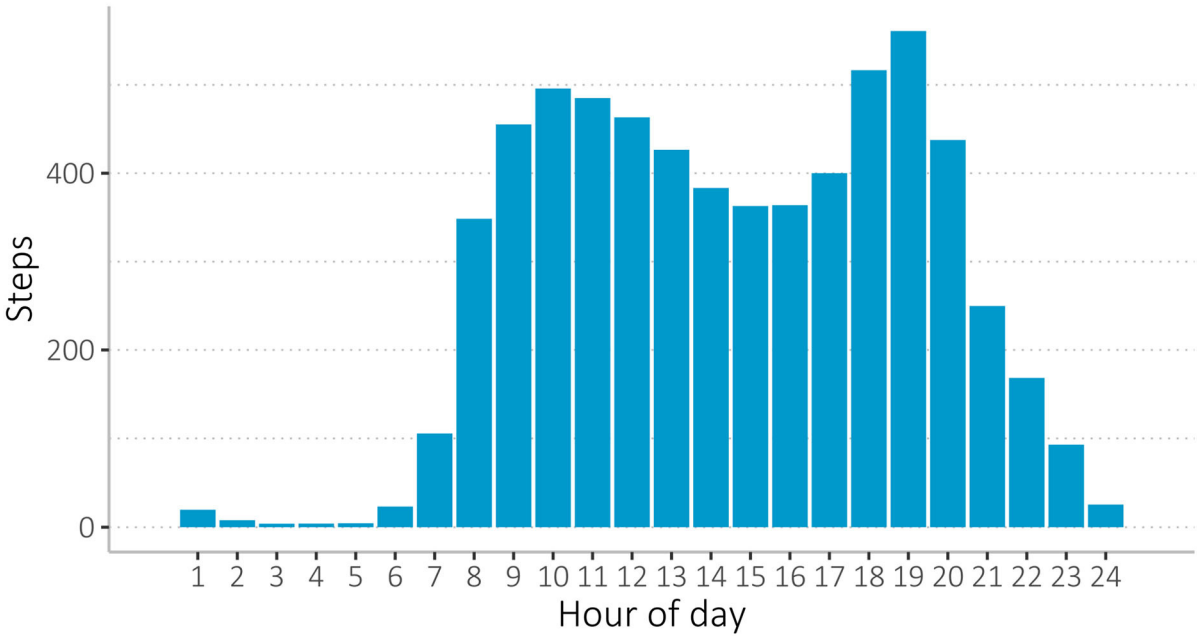

FIGURE 8
Overview of average steps taken during the day per study participant (average of all study participants over the full 9-week study period), measured with the WPHR wearable. During the hottest part of the day, there is a drop in activity between 12 pm and 6 pm.

$6, which reflects a typical participation rate in the Nouna HDSS, may have been considerable for some and boosted acceptance. Participants may not have provided negative responses for fear of losing their study compensation or being excluded from future study participations. This bias in a such low-resource setting is well-documented (48, 49).

TABLE 6 Summary of wearable measurements, including heart rate, energy expenditure, steps, and distance (in meter) covered per day measured with the fitness tracker and body shell temperature (in °C) measured with the thermometer patch.

	Min.	1st Qu.	Median	Mean	3rd Qu.	Max.
Heart rate (bpm)	32	54	70	73	89	211
Energy expenditure per day (kcal)	778	1,121	1,293	1,296	1,476	2,576
Steps per day	11	3,982	7,373	8,054	11,530	34,052
Distance covered per day (m)	8	2,747	5 035	5,627	7,933	26,610
Sleep time per day (h)	4	7	8	8	9	18
Temperature (°C)	24	34	35	34	36	44

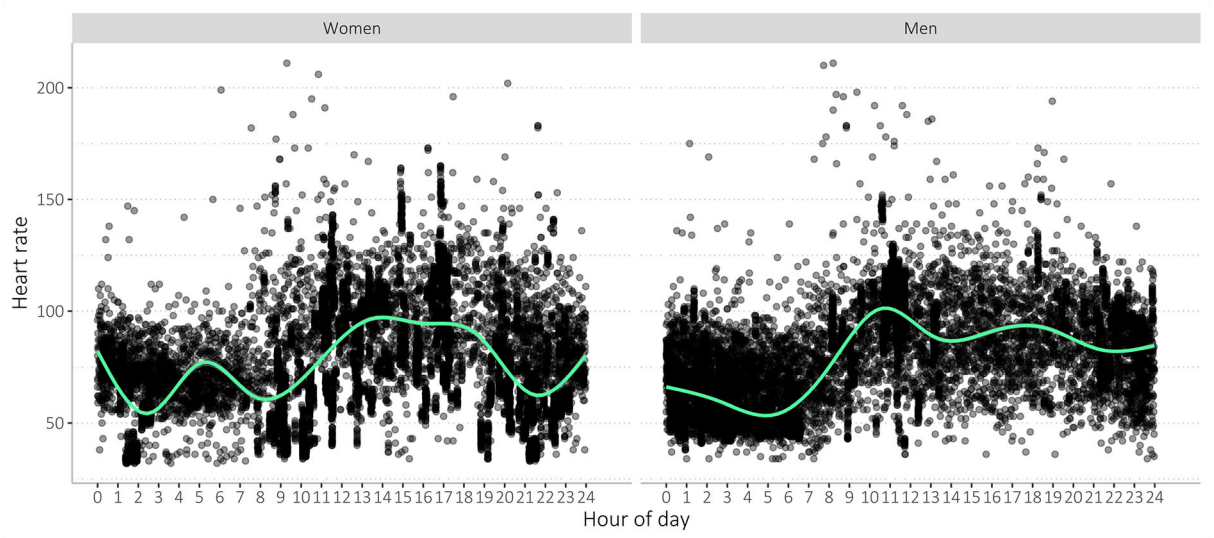

FIGURE 9
Overview of participant's heart rate measurements. As measured by the WPHR wearable device, all study participants over the full 9-week study period were displayed per gender. Measurements were widely variable, and the values were lower during the night.

Few participants considered possible adverse health effects of wearables. Some peers mistook the wearables for monitoring devices for HIV- or COVID-19-positive status, raising concerns about stigmatization. Field workers shared with us that study participants felt worried about who could access their data. The presence of terrorism in Burkina Faso is likely to have sensitized the population to such matters. Other studies using wearables in sub-Saharan Africa also reported similar concerns about adverse health effects, stigmatization, and data security (15, 16). Our study's wearables did not capture GPS data or any other personally identifiable information. Data protection for participants must be a top priority.

Reasons that may have impeded wearing the wearable may be derived from cultural factors, as some questionnaire responses suggested that familial acceptance, especially of the household head, may have an impact on young or female study participants' compliance and study participation. In Burkina Faso, most households are led by male household heads, like husbands, fathers, or other male family members (50). Considering that decision-making and risk assessment are more of a familial than an individual issue (50), the participation of female study participants and/or children may have been hindered as a result. The social environment outside the family may also have a substantial impact on study involvement and adherence, especially in rural areas of Africa, where community bonds are especially strong (51). Thus, it appears that not only the acceptability of the study participants, but also that of their family and community members, is crucial for the effective implementation of wearables as a routine monitoring instrument in such settings. Therefore, previous involvement with the community by study managers and/or field workers who introduce the study, the device, and its necessity and advantages for the community appears to be a prerequisite for introducing such novel devices.

We also discovered that members of the family or community associated wearables with magic, HIV- or COVID-19-positive status (surveillance), and adverse health effects, which may also hinder study participation. In our experience, such aspects may be mitigated through regular and transparent communication, explaining the study and wearable devices to study participants, household heads, and community leaders from the beginning (community engagement). Support and question-and-answer sessions for study participants on a regular basis may boost their involvement and compliance.

Participants rarely reported itching, excessive sweating, or perceiving the wearable as generally disturbing. Participants were advised to tighten the wearable wristband, which may have been perceived as too tight by some participants who may have loosened the wristband resulting in heart rate measurement failures. We trained field staff to regularly check the correct position of the wearable and tightness of the wristband, which eventually translated into an increase in data coverage. The number of valid measurements has increased as a result of providing participants with clear instructions on how to wear the device and conducting regular follow-ups on the correct usage.

Objective 2: Quantity and quality of wearable data to understand individual sleep, activity, and heart rate characteristics within vulnerable populations

During the study, six devices were damaged, which was in the scope of our expectations. Other studies have reported on damaged or lost wearables, corroborating our findings (52) (two WPHR, 4%; four thermometer patches, 17%). Heat and dust exposures in the study environment may have contributed to the deterioration of wearables, leading to inaccurate or missing measurements. Given that 69% of Burkina Faso's population live in rural areas and are mostly engaged in subsistence agriculture (47), wearables are exposed to dust, heat and persistent, long-term physical stress as people engage in farming (intensive manual work combined with soil contact).

Overall, the amount of data acquired for each participant ranged from no data to nearly a complete dataset containing all three variables of physical activity (steps), sleep, and heart rate. In comparison to other studies, it appears as though we were able to obtain a higher amount of data than reported elsewhere (16).

Wearable data quality: Individual sleep, activity, and heart rate

As we summarized the data (see Table 6, Supplementary material S3D), we found that some measurements were clearly outliers (i.e., heart rate of 32 bpm). However, it was not entirely clear to us, as even more extreme levels of activity, such as the physical activity of 34,000 steps/day, may reflect the high physical activity level of rural Burkinabé and may not be considered an anomaly in this context, although it would be in other contexts, like urban ones or high-income contexts. Other studies undertaken in sub-Saharan Africa have revealed high levels of physical activity among young rural populations and relatively low levels among urban populations (11, 53, 54). Therefore, it has to be considered that regional and age factors likely contribute to physical activity variances (55). We observed a high number of body shell temperature measurements outside of a normal range of 34–37°C (see Supplementary material S3D) (56). Likely, the patch recorded ambient room temperature when participants did not wear the device. For future analysis, we may only use values within the normal body temperature range and included possibly feverish readings up to 41°C.

Interestingly, we found that the participants' activity levels decreased in the afternoon (Figure 8), possibly as a result of heat stress, which generally peaks during these hours. Thus, wearable data may reveal the direct effect of heat on an individual level in vulnerable populations, which may allow for future studies focusing on climate change-induced weather extremes and health that help to understand individual exposures. As climate change is expected to have a significant impact on sub-Saharan African countries, particularly in the form of increased heat exposures with adverse health and nutritional security impacts, there is a pressing need for adaptation strategies (57, 58). However, there is a dearth of data to inform research and decision-making, and technological innovations such as wearables can make a substantial contribution, as we have established in this study that wearables can create relevant data in low-resource contexts. In that way, interventions could be better targeted and tailored for public health and prevention interventions in Burkina Faso, and likely in similar countries in the Southern African region. Long-term, we anticipate that this type of data collection will support improved prevention and public health approaches that are more appealing to those who directly benefit, as the data can be collected more efficiently and cost-effectively, while also providing individual-level data that can help us to understand distinct subpopulations in terms of climate change and health exposures, but also in terms of the larger picture of communicable and non-communicable diseases. Our study is one of the first to investigate wearables in low-resource, rural communities; therefore, additional research is required to better understand barriers, facilitators, best practices, and how to increase benefits for research and decision-making (59).

Data coverage and influencing factors

Generally, data completeness was rather low; however, other studies using wearables even experienced higher levels

of missing data (16, 60–63) as we encountered in our study. In a number of villages in the study area, intermittent internet connection prevented data synchronization on-site, necessitating the return of wearables to the Nouna HDSS center (CRSN). This procedure also contributed to missing data, as wearables were not worn by study participants for a couple of days. In addition, data completeness is contingent upon its underlying definition. Other studies, for instance, handled missing data differently and allowed longer periods before declaring data as missing (16, 60–63). For example, another study in SSA using accelerometry sensors to assess epilepsy reported a median of 30% data coverage, whereby a day was reported as 100% data coverage when more than 4 h of data per day were available (16). Currently, there is no standard for reporting the completeness of wearable data making comparison difficult. Furthermore, Kruizinga et al. (61) emphasized that even with some data missing, wearable-generated datasets are substantially larger than non-wearable studies, which may outweigh the disadvantages of missing data, and the pursuit of achieving 100% data completeness. Although most study participants reported to have worn the wearables continuously, several have been cautious fearing breaking the wearables and having to pay for them. Other studies observed similar concerns (16). As a precaution, participants may have taken off the wearables, resulting in missing data. It may be advisable to encourage study participants to take good care of the wearable and emphasize that any accidental damage will not be charged to them.

Age, sex, acceptability, or even dislike of wearables had little effect on data coverage. Mainly, technical issues caused low data coverage, rather than non-compliance of participants, although individual factors may still have an influence. Data coverage of activity data declined over time, possibly due to data synchronization issues. Even when a mobile data connection was established, data were not always sent to the cloud. Furthermore, neither of the two wearable device suppliers offered platforms for manual data download or raw data access. For this study, we used the consumer-focused platforms for data synchronization and study participant management, which may not have been fit to host a larger number of wearable users, as it was the case in our study.

Regarding the thermometer data, participants and field staff reported that the r patch did not adhere to the skin for longer periods and did not connect *via* Bluetooth or synchronized with tablets used by field workers to collect data. To resolve this issue, we had to update all Android-based smartphones to the latest version. Other studies also reported on connectivity issues (16, 46, 63). During the study, we have sensitized field workers to monitor data synchronization closely and fixated the thermometer patch with an adhesive tape to keep it from falling off.

Regarding data of the wristband wearable, both, activity (steps) and heart rate data, were collected by the same device, but with two different sensors (accelerometer and photoplethysmography), yet there were large differences in data coverage. Other research (61), as well as user forums and articles (64–67), reported on discrepancies between the two measurements, and a high level of missing heart rate data seems not uncommon for such devices. Heart rate measurements may be particularly vulnerable and affected by high transpiration (due to the climate with rather extreme heat periods), dark skin (photoplethysmography may not have penetrated the skin sufficiently), improper sensor positioning (as some consumer-grade devices have a single, small photoplethysmography sensor), loose wristbands, and intense movement (17, 18, 68). The quality of heart rate data is rarely studied despite the abundance of validation and accuracy research (3, 69, 70). More research is needed to understand how diverse factors effect heart rate measurements in different populations, such as in rural, low-resource settings.

Limitations

We acknowledge that reported acceptability was high and may have been influenced by social desirability. Also, data completeness was low, thus decreasing our confidence in drawing conclusions. Furthermore, possible effects of acceptability, sex, or age might not have been identified. Additionally, wearable measurements may be inaccurate and invalid to some extent. Data provided by wearables are not standardized but differ from wearable brand's algorithms and internal data processing. Furthermore, the amount of missing data may have influenced our characterizations of sleep, activity, heart rate, and body shell temperature. However, as this is a case study which primarily focused on understanding general acceptability, reliability, and feasibility of wearable devices, the primary outcome was not statistical validation but technical and human factors, as well as identifying barriers and the feasibility of collecting data with wearables and their acceptability (7).

As the output data of both wearables are preprocessed by the manufacturer (details on data preprocessing are undisclosed), single output values may thus be aggregated values. We did not calculate data coverage for WPHR sleep data since the aforementioned approach (defining 8 h as sleep length) has some imprecision and sleep diaries would be inadequate in our context. Because the WPHR uses accelerometry to track sleep, the data coverage of the activity data served as an estimate.

It has to be noted that there is no standardized, established method to analyze missing data of consumer-grade wearables. Utilizing tolerance limits (60/5/15 min) for data coverage, we have established a method that we deemed appropriate for our study based on exchanges with experts and comprehensive

literature analysis. These tolerance limits might influence insights on data coverage. However, we explored different limits to understand the impact on outcomes of data coverage and found no relevant differences in tolerance limits (see Supplementary material S3A).

Conclusion

Overall, both wearable devices—wrist-worn wearable and thermometer patch—were highly accepted by study participants in the Nouna HDSS in Burkina Faso. Study participants showed interest and desire for both wearables, and few expressed concerns or reported adverse health effects. Data completeness was higher than previously reported, but we still encountered data missingness, particularly in heart rate and temperature measurements which warrants further research. Nevertheless, with both wearables, we were able to generate continuous datasets incorporating individual-level activity and vital data. We found several major criteria for data missingness to be mostly technical in nature, including damaged wearable devices—also likely caused by prolonged exposures to dust and heat—intermittent data synchronization, and Bluetooth connectivity.

As the epidemiological transition progresses throughout sub-Saharan Africa, life lived with diseases is an increasingly important part of a population's burden of disease, particularly for climate change vulnerable, low-resource countries such as Burkina Faso.

In rural, low-resource contexts, wearables may for the first time provide objective insights into the activity and vital patterns of the individuals. Our study underlines that wearables can generate large and longitudinal datasets on activity (steps), sleep duration and quality, and heart rate, which can be added to existing population health routine measurements such as in the HDSSs. This could be crucial for designing and targeting public health and behavior change interventions in LMICs. To our knowledge, this is the first study to use consumer-focused wearables to generate individual data in the rural setting of Burkina Faso. Future research may aim to explore factors hindering heart rate measurements, especially in non-laboratory settings, as well as barriers and facilitators for using wearables for population health surveillance in LMICs.

Data availability statement

The data sets generated during the study are not publicly available due to the small sample size and concerns regarding participant confidentiality and anonymity but may be made available in a deidentified version from the corresponding author upon request.

Ethics statement

Ethical approval for this study was provided by the Ethics Committee of the Medical Faculty, Heidelberg University, in 21/05/2019 (S-294/2019), and the Comité d'ethique pour la recherche en santé in Burkina Faso (approval date: 13th March, 2020; 2020-3-041). Written informed consent to participate in this study was provided by the participants' legal guardian/next of kin. Written informed consent was obtained from the individual(s), and minor(s)' legal guardian/next of kin, for the publication of any potentially identifiable images or data included in this article.

Author contributions

SB, TB, and AS conceived and designed the project. AS, VB, and WAO managed the study in Burkina Faso with remote guidance of SB, SH, AB, MAM, and H-CG. SH monitored the data during the study, analyzed the data, and drafted the manuscript in close collaboration with SB. All authors contributed to the critical revision of the draft and approved the final version of the manuscript.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2022.972177/full#supplementary-material

SUPPLEMENTARY MATERIAL S1
Consolidated Standards of Reporting Trials (CONSORT) extension for randomized pilot and feasibility trials checklist.

SUPPLEMENTARY MATERIAL S2
Original questionnaire.

SUPPLEMENTARY MATERIAL S3
Supplementary tables and figures concerning A: analysis of data completeness calculation, B: acceptability, C: data completeness, and D: wearable measurements.

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The effectiveness of web-based interventions on non-alcoholic fatty liver disease (NAFLD) in obese children: A study protocol for a randomized controlled trial

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Aim: Non-alcoholic fatty liver disease (NAFLD) is currently the most prevalent liver disease in the world, increasing the risk of cirrhosis and hepatocellular carcinoma, and contributing to the development of type 2 diabetes, cardiovascular disease, and chronic kidney disease. This study aims to carry out a web-based continuum of a care intervention model to provide comprehensive care interventions for obese children with NAFLD, to improve the effectiveness of treatment of children with NAFLD.

Design: A 1-year single-blinded randomized clinical trial in hospital in Zhejiang Province.

Methods: Eighty subjects will implement the program in a randomized order. The interventions for the control group mainly consisted of the routine distribution of health education materials and health education by holding health-themed lectures, and the preliminary proposed interventions including establishing management teams, regularly delivering related health knowledge, daily uploading of health intervention records, regular supervision and mutual encouragement, home visiting and psychological guidance. The primary outcomes are serum biomarkers such as alanine aminotransferase (ALT) and gamma-glutamyl transferase (GGT), aspartate aminotransferase, and imaging (liver ultrasound and magnetic resonance imaging). Second outcomes are: BMI, waist-to-hip ratio and quality of life. In addition, socio-demographic characteristics such as age, gender and ethnicity will be recorded. Children aged 7–18 years old and diagnosed with NAFLD will be included, patients will be not eligible if they do not agree to participate or are participating in other health intervention programs. This study was registered on ClinicalTrials.gov (NCT05527938).

Results: Over the past 30 years, NAFLD has been recognized as one of the most common liver diseases in adults and children. The current studies have focused on promoting lifestyle changes in children with NASH by providing some education and advice to children and their families to improve the histological features of NASH and lose weight. Because of the convenience

and efficiency of the internet can provide some new strategies and ways for lifestyle interventions for children with NAFLD. In addition, we have designed a high-quality RCT based on the SPIRIT guidelines, which also provides strong evidence in this area.

KEYWORDS

NAFLD, obese children, education, protocol, web

Introduction

With the development of economy and the improvement of material life, diet and living habits continue to change (excessive food intake, lack of exercise, etc.), over the past 30 years, the prevalence of overweightness and obesity among children and adolescents worldwide has increased at an alarming rate (1, 2). Nearly 1 out of every 6 children or adolescents in the U.S. has a body mass index (BMI) for age and sex above the 95th percentile and is considered obese (3).

Studies have found that the occurrence of fatty liver is directly related to the degree of obesity (4), and in recent years, non-alcoholic fatty liver disease (NAFLD) in children has surpassed hepatitis B as the most common liver disease in China (5). In children, the overall prevalence of NAFLD is 3–10%, rising to 40–70% in obese children (6). The prevalence of NAFLD in Asian and Chinese children is 6.3 and 3.4%, respectively (7). NAFLD is a clinicopathological syndrome of chronic hepatic steatosis involving more than 5% of hepatocytes in children and adolescents under the age of 18 years, excluding alcohol consumption and other definite causative factors leading to chronic fat deposition in the liver, and is a metabolic stress closely related to insulin resistance and genetic susceptibility The spectrum of disease includes non-alcoholic hepatic fat deposition. The disease spectrum includes non-alcoholic fatty liver (NAFL), non-alcoholic steatohepatitis (NASH) and its associated liver fibrosis and cirrhosis. Although fatty liver is a benign lesion and generally has little effect on children, it is often closely related to hyperlipidemia. It may develop into NASH and end-stage liver disease if not adequately diagnosed and treated, which may pose a potential threat to health and even life after adulthood, such as coronary heart disease, hypertension, and diabetes. It is a very important and urgent problem to reduce the incidence of childhood obesity and NAFLD.

Obesity is an independent risk factor for NAFLD, and the detection rate of fatty liver in obese children in China is 23.33% (5). Investigation shows that overnutrition and lack of moderate exercise are the main causes of obesity and fatty liver formation in children. Adjusting the diet and changing the lifestyle are the main interventions to control and prevent childhood obesity (8, 9), children have poor self-control and often fail to adhere to the planned measures, requiring the cooperation of parents, teachers, and doctors to supervise the implementation. Traditional interventions, in the process of implementation, are difficult to achieve the desired results due to time and frequency constraints, parental coddling, and lack of long-term effective and high-frequency participation and guidance from professionals, low compliance of the affected children.

Information technology has been increasingly used in the medical industry, from medical information records query to remote consultation and treatment, information technology has made a huge change in the traditional medical industry. The web-based continuity of care model based on new Internet technology can break traditional follow-up services' time and space limitations, expand service supply, improve service efficiency, and precisely match the diversified and multi-level health needs of nursing service recipients (10, 11). In this study, we followed the pace of the times. We tried for the first time the web-based continuity of care intervention model to provide comprehensive nursing interventions for obese children with NAFLD, always tracking their performance status, enabling them to grasp the knowledge of healthy weight loss, develop good lifestyle habits, and reduce their weight, thus reducing the incidence of NAFLD in children.

Methods

Reporting method

Following the Standard Protocol Items: Recommendations for Interventional Trails (SPIRIT 2013) checklist (12).

Study design and setting

We will conduct a 1-year single-blinded randomized clinical trial. To recruit more study subjects, the study will conduct at a large hospital in Zhejiang Province (Figure 1).

Eligibility criteria for patients

In order to be eligible to participate in this study, patients should be: Children aged 7–18 years old and diagnosed

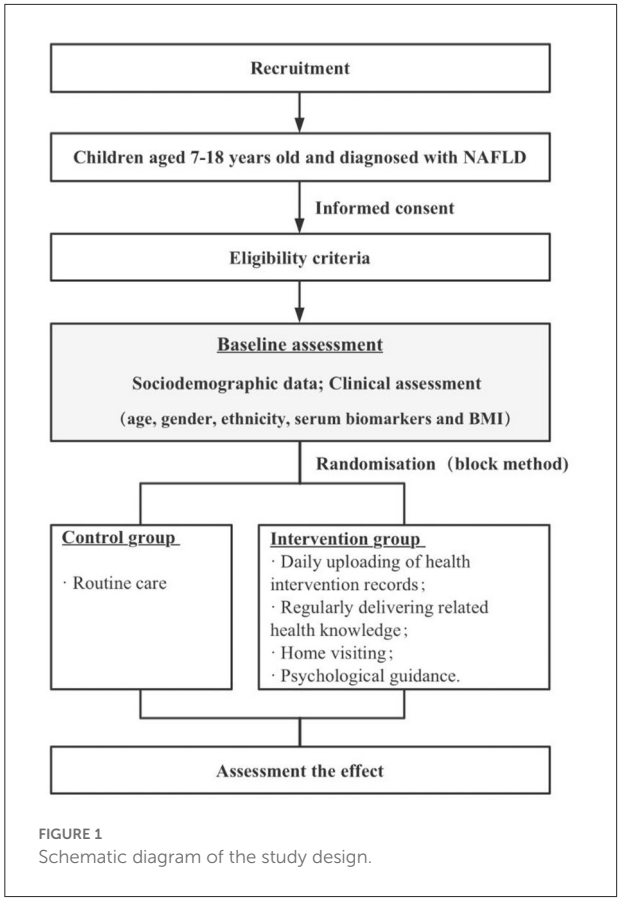

FIGURE 1
Schematic diagram of the study design.

with NAFLD: Referring to the Expert Consensus on the Diagnosis and Treatment of Non-Alcoholic Fatty Liver Disease in Children (13), the clinical diagnostic criteria need to meet 1–4 of the following, and any 1 of (5) or (6): (1) except for other pathological obesity; (2) in addition to the clinical manifestations of the primary disease, some patients may have non-specific symptoms and signs such as weakness, dyspepsia, vague pain in the liver area, hepatosplenomegaly, etc.; (3) overweight, obesity (centripetal obesity), elevated fasting glucose, lipid metabolism disorders, hypertension, and other metabolic syndromes; (4) alanine aminotransferase (ALT) is elevated more than 1.5 times the upper limit of normal value (60 U/L) and persists for more than 3 months; (5) liver imaging technique to diagnose hepatic steatosis; (6) histological changes in liver biopsy meet the pathological diagnostic criteria of fatty liver disease. Patients will not be eligible if they do not agree to participate or participate in other health intervention programs.

Intervention

The interventions for the control group mainly consist of the routine distribution of health education materials and health education by holding health-themed lectures, and the preliminary proposed interventions are shown in Table 1.

TABLE 1 Control group.

Intervention	Intervention content and frequency
Routine care	At each visit to the hospital, in this time, the child and his parents are given health education on diet and exercise booklets, and the parents supervise the child's daily life. The team members will review the child's condition every month for feedback.

To the above, the following four intervention components will be added, which shown in Table 2.

Outcome

The primary outcome are serum biomarkers such as alanine aminotransferase (ALT) and gamma-glutamyl transferase (GGT). Second outcomes are: aspartate aminotransferase, and liver imaging (liver ultrasound and magnetic resonance imaging), BMI, waist-to-hip ratio and quality of life. In addition, socio-demographic characteristics such as age, gender, and ethnicity will be recorded. All outcomes were measured at baseline, week 4, week 16, week 24, week 36, and week 48 to determine the trajectory of change in outcome variables over intervention process.

Participant timeline

Baseline characteristics of the patient (e.g., age, gender, ethnicity, serum biomarkers, and BMI) will be collected.

Sample size

Sample size estimation will be performed using Professional Association for SQL Server (PASS) 2014 software for grasp degree analysis (Power Analysis). The mean effect size of the lifestyle intervention on the improvement of ALT indicators (Effect size) was estimated to be −1.35 according to the Meta-analysis of the clinical study conducted by Utz-Melere et al. (14, 15). The sample size required will be 32 study subjects per group by power analysis in reaching 80% effectiveness, using a two-tailed test with a test level of 0.05. Based on a 20% failure rate, this part of the study required 80 subjects, 40 in each group.

TABLE 2 Intervention group.

Intervention	Intervention content and frequency
1. Establishing management teams	In addition to the subject leader, seven research team members will be each responsible for several participants (children with NAFLD) in need of intervention and formed a WeChat group for their parents.
2. Establishment of a nursing intervention team.	Composed of the Director of Nursing, a pediatric endocrinologist, a senior health lecturer and a nutritionist, three nurse leaders and a charge nurse with a master's degree. The director of the nursing department is the team leader. All members received half-month training from the team leader, including data collection, the purpose, model and implementation methods of the extended care intervention, and communication skills with the children and their parents. The training will be mainly in the form of intensive classes, and a theoretical examination will be conducted at the end of the training, requiring each member to pass.
3. Daily uploading of health intervention records	The nutritionist on the team develops personalized diet menu for each child based on age, height, weight, previous medical history, and any allergies, and at the same time, and an exercise therapist develops the tailored exercise plan for each NAFLD children (Appendix). The children and their parents upload the amount of exercise, and diet in the WeChat group every day, all parents can monitor and encourage each other in the group. Questionnaires are regularly posted in the group to judge the intervention effect and to adjust the implementation plan according to the individual intervention effect, with the aim of optimizing the plan and thus personalizing the intervention, and for subsequent studies we will consider using apps or WeChat applets for the intervention.
4. Regularly delivering related health knowledge.	Management team members Forming a WeChat group of children with NAFLD family members. Regularly through the WeChat platform, research team send relevant promotional materials such as nutrition knowledge and exercise knowledge to the children and parents 5 times per week, and we can also distribute some PPTs and videos of the professional nursing staff's promotional knowledge.
5. Home visiting	Members of the group made regular home visits, usually once every 2 weeks. The purpose of the visit is to grasp the development of the child's condition and to provide health education and dietary guidance to the child based on the visit results. If there is no one at home, it will be accessed by phone.
6. Psychological guidance.	The health teachers in the team should closely understand the psychological trends of the patients during the telephone follow-up and home visits and verbally communicate more with the children to stimulate them to develop good living habits and increase their confidence in healing.

Recruitment

In this study, participants will be recruited through two pathways. First, through the assistance of nurse managers of relevant departments in hospitals has been established to recruit, post or place leaflets, posters in departments of hospitals, and have researchers promote the project after the daily treatment of patients to attract interested patients. Secondly, through network: Release and diffuse recruitment information through WeChat friend circle, WeChat group, Weibo and other network platforms.

Assignment of intervention

Before randomization grouping, the children's medical records will be read carefully to obtain information about their demographics and diseases. Patients will be numbered according to the enrollment order and assigned to the experimental and control groups according to the random number table method. Statistical analyses will be performed to compare the balance of the two groups in terms of age, sex, ALT, BMI, and quality of life scores. The child's parents are entered into the same group as the child.

Blinding

Study personnel involved in the data assessment of the study are blinded to the patients' treatment assignment. The clinical doctors that deliver the study treatment are not blinded and are therefore uninvolved in the patients' data assessments related to this study. Data analysts are blinded to group allocation.

Data collection and management

First, members of the research team explained the purpose and significance of the study to the participants and obtained consent and support. Then, subjects who met the inclusion criteria were selected and the purpose, content, and significance of the survey were explained to them, explaining that the study

results would be used only for scientific research and that medical confidentiality would be strictly observed. After that, the investigator personally distributed the questionnaire, and the patients filled it out under a uniform instructional language. For patients with no reading ability or writing difficulty but could understand and answer the questions correctly, the researcher will repeat the questions and options in a neutral tone, and the patients themselves chose. The researcher assisted in filling out the questionnaire, which will be distributed and collected on the spot. The questionnaires took about 25–30 min to fill out; finally, the researcher carefully check the collected questionnaires and promptly eliminated invalid ones. In addition, anthropometric measurements [length, weight, waist circumference (waist circumference) and blood pressure], blood sampling [serum alanine aminotransferase (ALT), insulin, glucose and lipids] and 1H-MRS were taken to determine hepatic steatosis. Use the collected height and weight data to calculate age-adjusted BMI-z scores (16).

Statistical analyses

First, after eliminating the questionnaires that did not meet the requirements, all data will be organized and quantified and then entered the statistical software in pairs for analysis. Then statistical description of the data will be done, including descriptive statistical analysis of patients' general information, the mean and standard deviation will be used to describe the measurement data that conformed to normal distribution. Finally, statistical inferences will be made and *t*-test, ANOVA. The effect of the intervention on NAFLD w analyzed using McNemar's test for paired categorical data and χ^2 or Fisher's exact test for independent categorical data, as appropriate. Changes in continuous variables will be analyzed using paired Student *t*-test. Statistical significance will be set at $P < 0.05$. Using analysis of covariance we evaluated whether baseline variables predicted changes in liver fat content and ALT during 6 months of treatment.

Ethics approval and consent to participate

This study protocol will be conducted at the study site only after obtaining review permission from the hospital administration where the study participants will be enrolled. The investigator must obtain informed consent from the participant and minimize the participant's exposure to other risks. Before the start of the study, the investigator introduced himself or herself and fully informed participants of the content and purpose of the study so that they were aware of the behaviors they might be asked to cooperate with and the amount of time they would spend in the study. The investigator informed participants that the study would not provide them with any realistic benefits, but also no disadvantages or risks; participants were informed that all recorded material would be used for research purposes only. Participants participated in the study anonymously in a WeChat group, where each person was required to change their name (replaced by a serial number) after joining the group. Participation was voluntary and participants could opt out of this study at any time. Verbal informed consent will be obtained from the participant before the start of the formal interview. The real names of the participants will be not used in the data and study reports; instead, numbers will be used to identify the participants. This study was registered on ClinicalTrials.gov (NCT05527938).

Discussion

NAFLD is currently the most prevalent liver disease in the world, increasing the risk of cirrhosis and hepatocellular carcinoma, and contributing to the development of type 2 diabetes, cardiovascular disease, and chronic kidney disease (17, 18). BMI remains an important risk factor for NAFLD in children and young adults, and adipose tissue dysfunction contributes to the pathogenesis of NAFLD (19). General healthy eating advice and physical activity are recommended to promote weight loss in pediatric NAFLD. However, lifestyle interventions, be it general caloric restriction diets or low-fat or low-carbohydrate diets with or without increased physical activity, are frequently afflicted with low compliance and high drop-out and relapse rates in children and adults (20–22). In this study, we will implement the web-based intervention to provide more social and peer support to the affected child and family to improve their compliance with the intervention.

This current study has several strong features. Firstly, lifestyle interventions are the first step in managing children with NAFLD (14). The current studies have focused on promoting lifestyle changes in children with NASH by providing some education and advice to children and their families to improve the histological features of NASH and lose weight. As a previous systematic review mentioned, there is significant heterogeneity in study design quality, sample size, duration, outcome measures, and treatment interventions in RCTs for children with NAFLD. There is also a lack of effective and well-established lifestyle intervention programs to explore improvement in NAFLD. In addition, to our knowledge, web-based studies are currently being applied in adult NAFLD, providing web-based online training for those unable to attend face-to-face or group education (23). However, compared to adults, the child population is less sensitive to the Internet and adherent. Then, interventions for the entire population of children with NAFLD were not appropriately

graded according to the severity of the disease, much less individualized for the different levels of intervention. Therefore, we used an adaptive strategy through Internet technology to implement individualized interventions according to each child's disease severity.

There are also some limitations that need to be addressed. Firstly, we estimate that there will be an attrition rate of ∼10% of children who enroll in the study, mostly due to financial issues or time constraints. To minimize the effect of the biases, we will conduct the analysis on an intention-to-treat basis. It is important to consider that although this study will be conducted in the hepatobiliary ward of a specialist women's and children's hospital in Shaoxing, Zhejiang Province, this may lead to limitations in the findings. However, we are conducting a formative evaluation throughout the implementation of the project to explore which interventions or environmental factors may hinder or contribute to the effectiveness of this project at different stages of implementation to facilitate global replication.

Author contributions

CT, XT, and GW: systematic concept and designed. CT, XT, and LY: analysis the data. CT and XT: drifting the manuscript. All authors: revised the manuscript. All authors have read and approved the submission of this manuscript.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2022.930901/full#supplementary-material

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Perceptions of the use of mobile phones to access reproductive health care services in Tamale, Ghana

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Introduction: Africa has one of the world's highest populations of young people. In addition, Africa has one of the highest proportions of young people facing the worst health challenges. Although previous scholars have reported that young people were using mobile phones to fill in the gaps in accessing reproductive health services, among other health services, there was little comprehensive research on the perception of young people in Tamale, Ghana, on the use of mobile phones to access reproductive health services. This study analyzed the perceptions on mobile phone use to access reproductive health services among young people in Tamale, Ghana.

Methods: The research used a quantitative method design from a target population of 72,706 young people from selected peri-urban, low-income, middle income and high-income residential areas in Tamale Metropolis, Ghana. The sample size used was 397 young people. Participants were selected using a stratified multistage sampling strategy. Descriptive statistics were used to analyse the data.

Results: A total of 86% of the respondents agree that the use of mobile phones helps to overcome cultural challenges that young people in Tamale encounter in accessing reproductive health care. Also, 84.6% of the respondents agree that the use of mobile phones helps them to overcome inadequate access to reproductive health information and services. The use of mobile phones helps to overcome the negative attitude of health providers toward young people in need of reproductive health services was agreed by most of the respondents [strongly agree (35.4%) and agree (49.4%)].

Conclusion: This study informed highly positive perceptions and attitudes toward the use of mobile phones to access Reproductive Health Services in Tamale, Ghana. There is, therefore the need for the health sector to reform its mode of prescriptions of medication, consultation, and service delivery to leverage on the advantages that mHealth presents.

KEYWORDS

mHealth (mobile health), low- and middle-income countries (LMICs), digital technologies, young people, reproductive health care service

Introduction

Ghana's population is a youthful population and they can greatly contribute to the socio economic development of Ghana. However, despite the progress in health care delivery, young people are still exposed to health risks which result in premature deaths (1). Young people face various socio-cultural and technological changes that expose them to many health challenges. These challenges limit their choices and can lead to emotional stress, conflict and risk-taking behavior.

In Ghana, social stigma still persists regarding young people's reproductive health issues and health-seeking behaviors (2). Reproductive health is particularly a sensitive issue among young people in Ghana, that many health care providers targeting young people still struggle to address, consequently hindering accessibility to health care services by young people. The health and lives of many young people are jeopardized due to a lack of access to reproductive and sexual health information, services, and supplies, despite the fact that young people play an essential part in fostering the expansion and development of the country. In 2020 alone, the Northern Region of Ghana, of which Tamale, the study area is the capital, recorded 9,249 pregnancies among young girls aged 10–24 (3).

There is a general lack of information regarding sexual and reproductive health (SRH) and this is prevalent among young people (4, 5). There is also a low reported knowledge of reproductive among young people who are in and out of school (6). Young people do not seek health care when they need it because of several barriers, including the difficulty of scheduling appointments, lack of youth-friendly health services, high costs of accessing services, no or limited privacy, confidentiality and the negative and judgemental attitudes of healthcare providers (7).

The use of mobile and wireless technologies (mHealth) can change the way health services are provided around the world and help LMICs reach the UN's Sustainable Development Goals (SDGs) (8). The implementation of the mobile healthcare system in Ghana is slow, and many health services do not deliver the best results (9). Not all young people use mobile phones to access healthcare, and only a small percentage of young people in Ghana use these services after having adopted these services (10). The low patronage of mobile healthcare services raises important questions about why young people fail to seek mHealth care and the factors that influence these decisions, and these studies fill this missing gap.

Sexual activity occurs during one's teenage years. However, young people rarely utilize sexual and reproductive health services and therefore fail to obtain quality treatment. mHealth provides an opportunity for young people to get knowledge on reproductive health. Factors impacting the acceptance of mHealth include users' perception of mHealth platform's ability to resolve healthcare-related issues. Some people believe that mHealth will improve the quality of treatment, enhance connectivity, provide timely information, minimize costs, etc. The perceived benefits of phone-based interventions in improving young people's sexual and reproductive health is high.

Perception influences the use or rejection of new technology. mHealth helps people to increase their self-confidence in the choice of their contraceptive method. Apart from this, mHealth services are noted to give a clearer appreciation of family planning methods or contraceptives (11). Feroz et al. (12) assessed the access to mobile phones between teenage girls and young women in six Nigerian States. They explored the obstacles and limitations to using their phones to seek sexual and reproductive health (SRH) -related information and services. Results of their study showed high access to cell phones but restricted use of mobile phones to access sexual and reproductive health information and services. The perceived obstacles were the shyness in the young women and the justification that young girls are inherently more reserved. This fact is not surprising as the Nigerian community frowns on any attempts made by women to discuss sexual reproductive health issues. As a result, many teenagers in Nigeria are more likely to either be misinformed or poorly informed about SRH issues. The study established a number of barriers, including anonymity, confidentiality, and lack of confidence in service.

Contrary to the above study, which found that mobile phone access was not associated with access to SRH information, studies by Jadhav and Weis (13) found that owning a mobile phone is associated with the overall contraceptive use among people in Uganda, Tanzania, and Haiti. This data was obtained from the Demographic and Health Surveys for six countries by using data collected from 2016 through 2017 for women 15 through 49. The reviewed papers thus reveal that phone access does not completely explain the relationship between SHR uptake and phone access. This depends significantly on how individuals and the various stakeholders understand the role of mobile phones in providing access to reproductive health services. Positive perceptions are likely to influence adoption and vice-versa. Lim et al. (14) show that the low acceptance of using cell phones to seek health information confirms this claim. Study findings found that perceived utility and self-efficacy positively predicted the intention to use a mobile phone for health information. Education is necessary to enable women and men to use mobile phones to access SRHR information and services. The studies by both Jadhav and Weis (13) and Lim et al. (14) focused on respondents outside the UN definition of young people, hence the need for research to address this gap. According to a study by Nuwamanya et al. (15), mobile phone applications in Uganda have the potential to control access to reproductive health information, products, and services. Outcomes of the study were that there was a substantial change in the awareness of SRH, increased contraceptive usage, increased HIV testing, increased STI testing and treatment, and increased condom use.

Similarly, in a study by Gonsalves et al. (16), through the adolescent/youth reproductive mobile access and distribution initiative for love and life (ARMADILLO), young people in Peru and Kenya were better able to dispel contraceptive myths and stereotypes than those who did not have access to ARMADILLO. Based on the findings of the two studies, young people tend to be enthusiastic adopters of digital technology, as evidenced by their ease of using and interaction over multiple platforms on features and smartphones. Additionally, the essence of cell phone technology guarantees a degree of discretion and privacy not available with other contact modes, such as face-to-face communication. However, there is a dearth of evidence about the accessibility of digital health interventions among the rural poor, which leaves a considerable gap in the knowledge.

In Ghana, young people cannot get reproductive health services because of the lack of privacy and poor youth-friendly health services. In response, the Ghana Health Service, which is in charge of the health of the Ghanaian populace, introduced the You Must Know (YMK) mobile application to give young people the privacy and confidentiality they need when accessing reproductive health services and to also attempt to solve the challenge of service availability for young people. From user feedback, it is reported that users thought that the mobile application was easy to find and that it took less time to get to their reproductive health services. They also noted that the YMK app was a simple, flexible, and well-organized system that kept private information private and offered the needed safe space for young people. This perceived ease of use is likely to improve the use of SRH services among YMK users compared to non-YMK users (17). However, no study has explored individuals' perceptions of using mobile phones to access SRH services in the northern region. This study, conducted in Tamale in the Northern Region of Ghana, fills this gap in the literature.

Materials and methods

The research used a quantitative method design from a target population of young people from selected peri-urban, low-income, middle income and high-income residential areas in Tamale Metropolis in Ghana. Tamale is the regional capital of the Northern region of Ghana. It is one of the 26 districts in the Northern Region of Ghana and is reported to be the third largest city in Ghana, after Accra and Kumasi. According to the 2014–2017 Medium Term Development Plan of the Tamale Metropolitan Assembly, there are a total of 116 communities, 41 of which are considered to be urban communities, 17 of which are considered to be peri-urban, and 58 of which are considered to be rural in nature. Tamale has been selected for this research because, according to the statistical service, Tamale is the fastest growing metropolitan area after Greater Kumasi (18). According to the 2021 Population and Housing Census, the city is the fourth largest city in Ghana, with an estimated population of 374,744, with 185,051 males and 189,693 females (19). Tamale is one of the five predominant areas with urban population living in slums (20). Tamale is listed among the fastest growing cities in West Africa, with the majority of the residents being Muslims, and they practice the polygamous marriage system with large family sizes (21). The city's population is young, with almost 36.4% of the population under the age of 15 (22). Tamale has attracted immigrants from poor rural areas in northern Ghana and has been growing at an average of 4% per year for the past ten years.

The sample size of 397 was determined based on the Krejcie and Morgan's (23), sample size calculation and determination based in the population of 72,706. Young people aged 10–24 years located within six (6) selected communities (Vittin-Target, Tutigli, Kalariga, Tishigu, Warizehi and Lamashegu) in Tamale, Ghana were interviewed. Participants were selected using stratified multistage sampling strategy. A three-stage sampling procedure was used to select the study respondents. A sample of primary units was chosen, a secondary unit sample was picked from each of the selected primary units, and a tertiary unit sample was selected from the secondary units.

The study used a standardized questionnaire that provided quantitative information. To measure the perception of young people, regarding the use of the mobile phone to access reproductive health services, thirteen (13) test items assessing different aspects including how mobile phones can be used to manage reproductive health, capability to increase reproductive health management, overcoming cultural challenges using mobile phones, bridging the inadequacy of reproductive health information using mobile phone among other aspects of individual perceptions. Three of the test items were on a 3-point scale (*Agree, Neutral and Disagree*) while 10 test items were on a 2-point scale (Agree, Disagree). Descriptive statistics were used to analyse the data on perceptions of young people about the use of mobile phones to access reproductive health services.

To ensure proposer data management, as soon as the data collected from respondents were entered into SPSS, the paper forms were stored in a locked cabinet at the private residence of the Principal investigator, and this was accessible only to the Principal Investigator. Upon the completion of the research project, all paper forms were destroyed through shredding.

Results

This section presents the results on the perceptions of young people on using mobile phones to access reproductive health services in Tamale. The findings of this research revealed that more than half (52.9%) of the respondents agreed that the use of mobile phones to access reproductive health services, helps them to manage their daily reproductive healthcare needs more quickly. Only a few, (21%) of the respondents disagreed that using the mobile phone to access reproductive health services

helped them in managing their daily reproductive healthcare needs more quickly. Slightly more than those who disagreed (26.1%) indicated that they were neutral on whether using a mobile phone to access reproductive health services helps them manage their daily reproductive healthcare needs more quickly.

From the survey findings, a majority (61%) of the participants who took part in the study agreed that using the mobile phone to access reproductive health services increases their capability to manage their reproductive health. A small number of the respondents (13.7%) disagreed that using the mobile phone to access reproductive health services increases their capability to manage their reproductive health. There was a reasonable number of 25.3% of the respondents who opted to be neutral on whether the use of mobile phones to access reproductive health increases their capacity to manage their reproductive health or not.

This study further found that a majority (69%) of the survey respondents agreed that using a mobile device to search for reproductive health information was beneficial to them. A significant number of the survey respondents (24.1%) were neutral on whether using a mobile device to search for reproductive health information was beneficial to them or not. A very small percentage of respondents (6.9%) of the survey respondents disagreed with the assertion that using a mobile device to search for reproductive health information was beneficial to them.

Using mobile phones to access reproductive health services helps young people to overcome cultural challenges that young people in Tamale encounter. This was agreed upon by almost all respondents (85.8%) of the survey. Only a small number of the survey respondents (14.2%) disagreed with the assertion that the use of mobile phones helps them to overcome cultural challenges that young people in Tamale encounter in accessing reproductive health care.

A majority of the study respondents (84.6%) agreed that the use of mobile phones helps to overcome the lack of access to reproductive health information and services in the Tamale metropolis. Only a small number (15.4%) were not in agreement that the use of mobile phones helps to overcome inadequate access to reproductive health information and services. Also, 84.8% of the survey respondents reported that the use of mobile phones helps to overcome the negative attitude of health providers toward young people in need of reproductive health services. Only 15.2% of the respondents disagreed that mobile phones helped them overcome the negative attitude of health providers toward young people who needed reproductive health services.

This research found that a majority (82.5%) of the study respondents agreed that the use of mobile phones to seek reproductive health services helps them to overcome the lack of information on reproductive health service points. Only 17.5% of respondents were not in agreement that the use of mobile phones helped them overcome the lack of information on reproductive health service points.

The research further sought to find out from the survey respondents whether the use of mobile phones to access reproductive health services helps them to overcome the impact of religious teachings on the access to reproductive health services by young people in Tamale. More than half (79.5%) of the study respondents agreed that using mobile phones helps overcome the impact of religious teachings on the access to reproductive health services by young people in Tamale. Even though the majority of survey respondents were in agreement that the use of mobile phones helps to overcome the impact of religious teachings against the access to reproductive health services by young people in Tamale, 20.5% of the survey respondents disagreed that the use of mobile phones helps them to overcome the impact of religious teachings against the access to reproductive health services by young people in Tamale.

The study found that 81.3% of the study respondents, representing a majority of the sampled young people, agreed that using mobile phones to access reproductive health care information and services is an effective way to overcome the limited reproductive health care information and service delivery outlets. Among the respondents, 18.7% disagreed with the majority's opinion that, the use of mobile phones can help overcome the limited reproductive health care information and service delivery outlets.

This study further revealed that a majority of the study respondents (86.3%) agreed that using mobile phones makes it easier for young people to access reproductive health information and services for much less money. Only 13.7% of the respondents disagreed that using mobile phones helped them to overcome the challenge of the high cost of assessing reproductive health information and services. Similarly, 86.1% of the study respondents agreed that the use of mobile phones to access reproductive health services, helps in overcoming the challenge associated with distance to health facilities. However, 13.9% of the study participants disagreed that using their mobile phones to access reproductive health services helped them to overcome the challenge associated with distance to health facilities.

A majority (84.3%) of the study respondents concurred that using mobile phones helped them overcome the challenge of not knowing the accuracy of the information young people receive from their friends. Only 15.7% of the study participants disagreed with this.

Finally, a majority (89.1%) of the study respondents agreed that using mobile phones helps them overcome the fear of being judged and stigmatized as a result of assessing in-person reproductive health services. Only a small percentage of 10.9, disagreed that using mobile phones helps them overcome the fear of being judged and stigmatized as a result of assessing reproductive health services, as shown in Table 1 of this report.

TABLE 1 Perceptions about the use of mHealth.

Variable	Category	%
Using the mobile phone to access reproductive health services helps me in managing my daily reproductive healthcare needs more quickly	Disagree	21.0%
	Neutral	26.1%
	Agree	52.9%
Using the mobile phone to access reproductive health services increases my capability to manage my reproductive health	Disagree	13.7%
	Neutral	25.3%
	Agree	61.0%
Using my mobile device to search for reproductive health information is beneficial to me.	Disagree	6.9%
	Neutral	24.1%
	Agree	69.0%
Level of agreement/disagreement to the following statements		
The use of mobile phones helps to overcome cultural challenges that young people in Tamale encounter in accessing reproductive health care	Agree	85.8%
	Disagree	14.2%
The use of mobile phones helps to overcome inadequate access to reproductive health information and services	Agree	84.6%
	Disagree	15.4%
The use of mobile phones helps to overcome negative attitude of health providers toward young people in need of reproductive health services	Agree	84.8%
	Disagree	15.2%
The use of mobile phones helps to overcome the lack of information on reproductive health service points	Agree	82.5%
	Disagree	17.5%
use of mobile phones helps to overcome the impact of religious teachings against the access of reproductive health services by young people in Tamale	Agree	79.5%
	Disagree	20.5%
The use of mobile phones helps to overcome the limited reproductive health care information and service delivery outlets	Agree	81.3%
	Disagree	18.7%
The use of mobile phones helps to overcome the challenge of high cost of assessing reproductive health information and services	Agree	86.3%
	Disagree	13.7%
The use of mobile phones helps to overcome the challenge associated with distance to health facilities	Agree	86.1%
	Disagree	13.9%
use of mobile phones helps to overcome the challenge of Not knowing the accuracy of the information young people receive from their friends	Agree	84.3%
	Disagree	15.7%
The use of mobile phones helps to overcome the fear of being judged and stigmatized as a result of assessing reproductive health services	Agree	89.1%
	Disagree	10.9%

Discussions

Perception influences the use or rejection of new technology. mHealth helps people to increase their self-confidence in the choice of their contraceptive method and is noted to give a clearer appreciation of family planning methods or contraceptives (11). This study found a high perception of mHealth use. The findings of this research, which showed that more than half (52.9%) of the respondents agreed that the use of mobile phones to access reproductive health services helped them to manage their daily reproductive healthcare needs more quickly, indicating a higher level of agreement than the findings of Macharia et al., (24), who reported that 21.6% (29/134) of their respondents reported improved decision-making as a result of using mHealth services. Hill et al., (25), report that mHealth services are used to change behavior and to increase the uptake of reproductive health services. Other research evidence suggests that mHealth interventions are an effective way to increase respondents' autonomy to make the needed decisions on their preferred contraceptive methods because, through their mobile phones, they have unlimited access to readily available, complete, and validated information (11).

A person's ability to make sound reproductive health decisions has been known to be strongly impacted by the person's level of knowledge and awareness. Dev et al. (26), found that people who understood family planning were more inclined to use it. People's ability to make decisions and empower themselves has also been given a boost through the use of mobile interventions. People's knowledge, attitudes, and practices regarding modern contraception may be influenced by the availability and use of mobile health solutions, which helps them better understand family planning alternatives. Smith et al. (27), reported that their study participants had difficulties retaining information on their family planning methods. However, they reported that mHealth services helped them to retain useful information about family planning contraception, which was difficult before the mHealth intervention.

This study found that a majority (69%) of the survey respondents agreed that using a mobile device to search for reproductive health information was beneficial to them. This suggests a high positive perception of respondents for the use of mHealth. Although the findings suggest that more than half of the respondents have a positive perception of the use of mHealth, significant numbers show neutrality in their responses. A probable explanation for this could be that they may not have had any encounter yet with an mHealth service and thus, are not able to explicitly state a position on the use of mHealth. Using mobile phones to access reproductive health services can increase decision-making and empower users of mHealth services (26). mHealth is more advantageous than face-to-face contact with health care providers (28). The advantages of mHealth can be viewed from privacy, where the person accessing the information does not necessarily need to have a face-to-face encounter with anyone, stress-free because one can sit in the comfort of one home or anywhere and get the needed information. From the economic perspective, because the message is by SMS or the fact that one does not need to travel to a health center, it saves money and time, which are invaluable.

Using mobile phones to access reproductive health services helps young people to overcome cultural challenges that young people in Tamale encounter. This was agreed upon by almost all respondents (85.8%) of this research. The Ghanaian culture considers discussions about sexuality as a sacred topic with young people, and thus, discussions about sexuality are perceived generally as introducing young people to early sexual intercourse. Among some ethnic groups in Ghana, it is considered an abomination to talk about sexual issues with a child because the belief is that the child could be 'spoilt'. This further goes to the point where even if the child needed to find out certain things about sexuality, the child was told he or she was not of age to know about such issues (29). The socio-cultural factors such as stigma, myths and misconceptions are reported to have negatively affected the provision of reproductive health services and have hindered the delivery and utilization of sexual reproductive health services for young people (30). These findings, therefore, suggest that young people can leverage on mHealth services to access all of their reproductive health needs without the fear of being subjected to the cultural barriers that they would ordinarily have faced.

A majority of the study respondents (84.6%) agreed that the use of mobile phones helps them to overcome the lack of access to reproductive health information and services in the Tamale metropolis. This suggests that young people have a strong positive perception about the use of mobile phones to access reproductive services and bridges the barrier of poor health worker attitude toward them. This finding supports the earlier finding of Feroz et al. (28), in their study to understand how the use of mobile phones can improve the uptake of antenatal and post-natal services in Pakistan. Feroz et al. (28), reported that a large number of their respondents were willing to use mHealth because they considered it to be more beneficial than the face-to-face communication that they had previously experienced with health care workers.

mHealth solves many of the problems that young people face when they are looking for reproductive health information and services. When young people try to get reproductive health information and services, they often say that health care workers make them feel bad about themselves or treat them badly. Young people can access any sexual and reproductive health information and service if youth-friendly services are provided. Research has demonstrated that young people place high importance on maintaining their privacy while obtaining sexual and reproductive health information and services, and these same young people are more likely to seek sexual and reproductive health treatment and interventions when their confidentiality is ensured (31). Additionally, young people, both married and unmarried, are usually disregarded, and there is a general lack of youth-friendly services. The attitude of providers is frequently cited as one of the most significant obstacles to accessing health care in a variety of LMIC settings. Many health workers discourage young people from using services because of a lack of confidentiality, attitudes of judgement, disdain, or a failure to take seriously, the sexual and reproductive health needs of adolescents. (32). The cost and getting to medical facilities can also be a problem. Young people find it hard to get good, comprehensive information about sexual and reproductive health because they feel embarrassed and think adults do not care about their privacy and confidentiality (33).

Consistent with earlier research, this research found that a majority (82.5%) of the study respondents agreed that the use of mobile phones to seek reproductive health services helps them to overcome the lack of information on reproductive health service points. This suggest that mHealth fills in the gap of the lack of information on youth-friendly service points. This is consistent with the works of Abrejo et al. (11), who reported that mHealth fills in the gap in information around family planning methods. Sexual and reproductive health information sent through mobile phones have the potential to raise awareness

rapidly and to spread to a larger audience than was originally intended. It has been observed that the use of mobile phones, in particular smartphones, might satisfy the curiosity of young people regarding the changes that are taking place in their bodies as well as the desire that young people have to gain knowledge of new things. Through the use of mobile phones, young people would have access to helpful information and be able to clear up any misunderstandings (8).

The research sought to find out from the survey respondents whether the use of mobile phones to access reproductive health services helps them to overcome the impact of religious teachings on the access to reproductive health services by young people in Tamale. More than half (79.5%) of the study respondents agreed that using mobile phones helps overcome the impact of religious teachings against the access to reproductive health services by young people in Tamale. This suggests that young people have a positive perception of the use of mHealth as they believe that it helps them to overcome the impact of religious teachings against access to reproductive health services.

81.3% of the study respondents are in agreement that using mobile phones to access reproductive health care information and services is an effective way to overcome the limited reproductive health care information and service delivery outlets. This suggests that, for communities that have few health facilities as well as few service delivery outlets, mHealth can bridge these gaps. The finding of this research is consistent with earlier research by Ochieng et al. (8), who concluded that mobile phones could help adolescents learn and access helpful information about sexually transmitted infections (STIs) and how to avoid them. The study further found that 86.3% of the respondents agree that using mobile phones makes it easier for people to access reproductive health information and services for much less money. This is consistent with the study by Abrejo et al. (11), who found that respondents believed that mobile phones would save them the cost of transportation they would usually have had to incur if they wanted to get information about their reproductive health or receive services related to it at a health facility.

The accuracy of information is a crucial factor in determining young people's choice in the use of mHealth services, especially today, where information seems to abound. A majority of the study respondents concurred that using mobile phones helps them overcome the challenge of not knowing the accuracy of the information young people receive from their friends. The findings from this research suggest that with mHealth, young people trust that they will have access to up-to-date and accurate information, regarding their sexual and reproductive health, as this will assist them in making more informed decisions that will be beneficial to their overall health.

The response from the high proportion of respondents (89.1%) who agree that the use of mobile phones helps to overcome the fear of being judged and stigmatized as a result of assessing reproductive health services is consistent with similar studies from Alhassan et al. (34), who found in their studies that the use of mobile phones provides young people with the anonymity as well as confidentiality, and privacy that they need, and this helps to reduce the discrimination, stigma, and the shyness that is associated with young people's access to STIs services at various health facilities.

Conclusion and recommendations

The findings of this study on the perceptions of young people on the use of mHealth show that young people have a positive perception of using mobile phones to access reproductive health services. These findings are consistent with those of Obasola and Mabawonku (35), who reported that women had positive perception of sexual and reproductive health interventions that are ICT-based. They analyzed that mobile health interventions were appealing to young people. Young people positively perceive health-related apps because they are convenient and safe and offer the utmost privacy. The results show that using mobile phones for reproductive health services provides quick access to information and services.

The high positive perception rates recorded confirm that there is value in using mobile phones to access reproductive health services as it addresses a number of critical barriers that young people face in assessing reproductive health services. Mobile phones have been proven to be a safe, cost-effective, and reliable method of delivering acceptable, secure, and accurate information and services on sexual and reproductive health (36). Using mobile phones for reproductive health care can improve health awareness and is generally well-received by young people (37). There are several hurdles that young people encounter in their quest to access reproductive health and information and services. These, which include privacy and secrecy in accessing sensitive materials and information, were reported to be resolved by the advent of mHealth and the use of mobile phones (30, 38). This current study provides evidence that using mobile phones helps young people overcome the fear of being judged and stigmatized as a result of assessing reproductive health services. Young people place a high premium on maintaining complete secrecy whenever they access sexual reproductive health services. (24). When young people seek information and services related to their sexual and reproductive health, they want to be assured that their confidentiality will be respected and safeguarded.

Health care providers and policymakers must strive to implement multi-faceted patient engagement strategies to provide young people with the resources to manage their reproductive health needs on their own, as innovations such as mHealth continue to permeate the industry.

Service providers and policymakers should explore incorporating technology in addressing the challenges faced

in accessing health care in Ghana. The use of mobile phon33e technology can also be applied to medical consultations that are traditionally done in consulting rooms in health facilities. The health facilities can institute the mHealth applications to help remove some barriers young people face in accessing reproductive health services.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving human participants were reviewed and approved by Navrongo Health Research Center Institutional Review Board (NHRCIRB), Ghana. Written informed consent to participate in this study was provided by the participants' legal guardian/next of kin.

Author contributions

JA led in the conduct of the research by collecting data, analyzing the data, and writing the draft manuscript. DN and SM provided overall supervision of the research by supervising the data collection and data analysis and edited the manuscript. All authors read, contributed to the research design, and approved the final manuscript.

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Conflict of interest

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The strength of weak bonds: Using a novel ecosystem approach to promote public sector scaling of innovations in resource limited settings

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Introduction

Recent years have seen unprecedented growth in the scale and scope of tech innovations across sub-Saharan Africa and other low- and middle-income countries (LMICs) (1, 2). This was further accelerated by the COVID-19 pandemic, which disrupted the traditional forms of health service delivery, forcing providers to adopt "non-physical" ways of providing care (3). The general view is that we are unlikely to revert to the pre-pandemic state and that new technologies will continue to emerge across different facets of healthcare. We have seen a wide variety of tech innovations, ranging from tools for communicating to communities, electronic health records and telemedicine to more advanced applications for creating intelligent systems such as machine learning and artificial intelligence (2).

At present, most innovations scale through the market, rarely penetrating public healthcare systems. This contributes to inequity by locking out vulnerable groups that seek care from public facilities (4). This is unusual on the one hand because government systems offer a "ready-made" pathway to scale that may help them reach millions of people quickly while having to devote less time and effort to generating demand in a highly competitive environment. However, widespread perceptions of government as less innovative and the notion of public health systems being slow and resistant to change have discouraged many innovators from considering the public sector as a feasible or attractive scaling pathway. Other reasons for low public sector scaling (PSS) of potentially useful innovations include a lack of awareness within government around innovations that exist, mistrust between public and private sectors hindering their collaboration for scale-up, inadequate inclusion of innovators and other non-state actors in planning and low emphasis on sustainability, partly caused by overreliance on aid. The gradual transition away from aid dependency is therefore a watershed moment, presenting LMIC governments with the opportunity to pursue alternative priority setting and investment mechanisms that make better use of local ecosystem actors, including innovators.

While there is growing evidence showing that scaling up digital health innovation within the public sector could accelerate progress toward universal health coverage (2), there is still very little research and analysis that has specifically

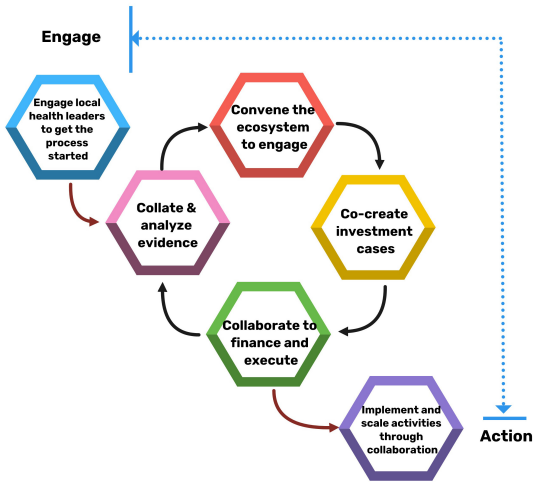

FIGURE 1
The Open Phences "Engage to Action" model.

set out to explore how PSS scaling could be achieved, more so, using the ecosystem approach. That said, a recent analysis linked the use of the co-creation approach to improved adoption of digital health innovations (5).

In this commentary, we look at how an ecosystem approach could be used to create value propositions that support the shift toward PSS. We present the Open Phences "Engage to Action" model (Figure 1) that entails facilitating ecosystem actors to identify genuine need and express demand for the right innovations. Our title borrows heavily from Nick Granovetter's "Strength of Weak Ties," theory, which posits that "weak ties" (meaning individuals that are loosely connected to a person) are more likely to provide new/more useful information when the person is in need, compared to the "strong ties," who are likely to be individuals with similar information and characteristics as the person in question. We build on this line of thought, arguing that public sector scaling of private innovations could massively strengthen health services through injecting new ideas and interventions, despite the "weak bonds" that typically link the public and private health sectors across many SSA countries.

The ecosystem building, planning, and investment approach

Open Phences is a "Think and Do Hub" that works to democratize public private collaborations in health. The Hub's "Engage to Action" model (Figure 1) proposes a unique approach to ecosystem building, joint priority-setting and planning, and investing based on shared goals. The aim is to create a shift from the push-model (where innovators compete to sell innovations to a usually disinterested ecosystem) to the "pull-model" (where a cohesive and informed ecosystem defines priorities and demands the right innovations).

Starting December 2021 with seed funding from the UK Foreign, Commonwealth and Development Office (FCDO), Open Phences is piloting the Model's potential to improve RMNCAH services in four Kenyan counties of Homa Bay, Kisumu, Kiambu and Trans Nzoia (RMNCAH stands for reproductive, maternal, neonatal, child and adolescent health). For every county, four key steps are being followed namely, (i) understanding the RMNCAH situation and mapping existing innovators and innovations, (ii) supporting county-led RMNCAH ecosystem building and cohesion activities, (iii) facilitating co-creation workshops to identify priority challenges and develop suitable investment cases, and (iv) identifying public and private investors and funders to fill the funding gaps in the investment cases and get a suitable return (e.g., social impact, equity, or a fair commercial return). Central to all these is the inclusion of the most suitable tech innovations in the county plans, which increases the probability of scaling them through the public health sector and with funding from Treasury and the counties.

The first step entails understanding the RMNCAH situation (the need/demand) and existing innovations (the supply), which provides the information needed for ecosystem actors to engage in meaningful discussion downstream. The assessment considers tech and non-tech solutions that are contributing directly and indirectly toward improving RMNCAH. The first step ends with each county having a RMNCAH and innovations situation report.

The second step involves mapping ecosystem actors and helping to organize them into associations with elected representatives for subsequent engagement with government. Here, we borrowed from the World Bank Toolkit for mapping stakeholder for public private dialogue, which details crucial steps, including ways of identifying less visible actors and understanding motivations (6). The ecosystem actors are brought together to discuss the RMNCAH report, share experiences, and agree on priority challenges affecting their communities. It is at this stage that the role of innovations is discussed in detail. The second step ends with each county having a RMNCAH priority investment areas report that highlights the most pressing challenges and potential solutions. Ecosystem actors involved include public and private sector representatives for different areas, including medical service providers, pharmacy, diagnostics, nutrition services, childhood education and agriculture among others. Also included are health financing institutions and community representatives selected to ensure gender, equity and social inclusion.

In the third stage, we support the ecosystem actors to refine the priority investment areas and develop costed RMNCAH investment cases, with funding gaps highlighted. Here, we borrow from the widely tested and validated Global

Financing Facility (GFF) approach to developing investment cases for maternal and child health across resource constrained settings (7).

The final step involves two sets of activities: embedding the investment cases into the county planning processes to benefit from Treasury allocation in future funding cycles; and connecting county leadership to other potential funders to help fill the funding gaps. Partners may include blended financing or impact investors, traditional debt and equity investors, as well as other untapped sources like local high net worth individuals who may be persuaded to lend support against well-defined investment cases.

Discussion—What opportunities does the novel approach present?

While we are still testing the model across the four counties (now entering step 3 above), we have already made some notable observations.

First, we note that the approach allows elaboration of priority challenges and RMNCAH gaps that represent genuine inadequacies. For instance, in cases where county managers would have asked for funds to establish an operating theater for obstetric emergencies, they are now asking for a much lower investment—e.g., by contracting theater space from idle private facilities within the county, a solution unearthed through the engagements across the ecosystem. We are seeing new opportunities emerge, including the potential to scale innovative tele-radiology and tele-pharmacy services through public channels. We are also beginning to see stronger emphasis on community services, with proposals to incorporate tech innovations to expand the service offering, all proposed by the actors during co-creation. The value of creating systems that encourage prioritization of digital solutions is something that has been emphasized in previous discussions (8).

Second, we are seeing a more democratic, level playing field for innovators in terms of how they are engaged and assessed by government actors. The Model is helping to create a fair platform for innovators to present their products, and for providers to share experiences with the use of the innovations in the local environment. Prior to that, the innovators' market was highly fragmented, with low visibility for decisionmakers and little opportunity for innovators to showcase their work in comparison to others. This results in low public sector uptake, and whenever innovations find their way to public systems, it is usually because those behind them have some leverage with decision makers. The risk here is that the products taken up are not selected on the basis of the evidence and may be neither the most innovative nor impactful, in the process creating an inequitable procurement environment that stifles innovation and healthy competition. Our proposed approach may also contribute to higher scrutiny and use of proper methods to evaluate digital health innovations, crowding out poorly designed ones and building trust among users (9). What we are seeing is the ecosystem approach building trust among actors and allowing a more open discussion on the most appropriate choices to make. This injects transparency in the process, reducing risk to all concerned and making it easier to justify adopting and scaling the innovation. Credibility and legitimacy have been shown to be important contributors to successful scaling of innovations (10).

Finally, we are starting to see the approach creating clearer pathways to scale through their inclusion in county plans. In so doing, counties can competitively award contracts to innovators with the most suitable solutions, and have the costs covered through their core budgets. This is crucial, considering the government is the largest single payer and provider of healthcare services in most LMICs. Our hope is that these currently fragmented instances of public sector scaling become the new norm, part of a strong and sustainable market in which demand and supply are matched efficiently and appropriately through a sustainable and credible vehicle. We believe that this is the most sustainable pathway for generating impact at scale through tech innovations in health. At the same time, establishment of such pathways will trigger more innovation, as entrepreneurs aim to satisfy the expressed demand. One lesson we got from the height of the COVID-19 pandemic, was the fact that whenever need is expressed at scale, traditional barriers to uptake of innovations can be suspended, including regulatory hoops and low motivation to change/adopt technology (5).

To share the learning from our model and further support the adoption of public sector scaling approaches, Open Phences are now proudly working with others across East Africa as part of a new Public Sector Scaling Action Lab facilitated by Results for Development with support from Grand Challenges Canada. The Lab comprises of a group of healthcare champions who are researching, designing and testing new partnership approaches that have the potential to improve public sector sourcing and scaling of the most suitable innovations for public good.

A key strength of our opinion piece stems from the fact that we are drawing lessons from a real-life project in a low-resource setting. In addition, we believe that the approach proposed is sector agnostic, and could strengthen other areas like education, water and environment, and social services. However, the fact that the project is still ongoing and hasn't been evaluated presents the main point of weakness in our view. It is possible that new insights may emerge that change how we have presented our thoughts. Further, our approach feels suited to a decentralized country context, where crucial decisions that touch on priority-setting and resource allocation can be made through local ecosystem building effort. Strongly centralized economies may have higher diversity in ecosystem formation and interests, possibly needing a modified approach. That said, there is value in sharing these kinds of experiences early, especially in the context of a growing pipeline of innovations that are not thinking about public sector scaling as an option for growth, equity, and sustainability.

Conclusion

The public private sector discourse has been excessively dichotomized, creating a schism, a black and white situation. Yet, we believe that there is a lot of gray in between—not least the opportunity to generate faster and greater impact through the scale-up of innovation within the public sector. This can be achieved sustainably through ecosystem-wide participation in planning, resource allocation and investment, but this requires a strategic approach such as the one presented here. To paraphrase Henry Ford, nothing is particularly hard if you divide it into small tasks. There is value in taking a stepwise approach that includes building the ecosystem, creating mutual trust, identifying common and high priority challenges, co-creating solutions and investment cases, and finally, working together to identify gaps in resources and bring on board investors and partners. This is a faster and more pragmatic alternative to structuring complex longwinded public private partnership contracts.

Open Phences

Members of Open Phences are Lyndon Marani, Irene Khayoni, Noelle Orata, Brenda Bunyasi, Annette Murunga, Elizabeth Gitau, Eric Tama, Cornelius Kiptoo, Paul Waswa, Muriithi Njogu, and Peter Nguhiu.

Author contributions

FW conceived and wrote the first draft of the opinion piece. TF contributed to the conception and drafting. The Open Phences team members are implementing the project on which the opinions shared are partially based. All authors contributed to the article and approved the submitted version.

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Conflict of interest

Author FW is a member of the Open Phences, the team that is piloting the model that has been presented and discussed in this paper.

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Internet of Things, Machine Learning, and Blockchain Technology: Emerging technologies revolutionizing Universal Health Coverage

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Introduction

In 2015, all member states at the United Nations General Assembly renewed their commitments toward achieving the Universal Health Coverage by 2030. UHC formed the bedrock of Sustainable Development Goal 3. The goal of the UHC is mainly to provide access to quality health care to everyone without incurring any financial risk. According to the World Health Organization, about 100 million people are pushed to extreme poverty yearly due to out-of-pocket healthcare payments, while about 50% of the world's population lack access to quality health care (1). While some countries of the world like Japan, France, Brazil, and Turkey have successfully achieved this goal, some (Ghana, Indonesia, and Vietnam) are clearly on the course of achieving it by 2030 as planned, but some developing countries like Nigeria, Bangladesh, and Ethiopia are still far from achieving this feat by then (2).

COVID-19's shockwaves have predicted new healthcare concerns worldwide, including severe problems and difficulties in areas like patient consultations, remote monitoring, medical resources, and healthcare staff (3). However, it promoted the development and use of new technologies and innovations in healthcare. These innovations include artificial intelligence, blockchain technology, the Internet of Things, and Big Data and Analytics. These technologies are promising in reducing health expenditure and improving quality and access to healthcare in high, middle, and low-income countries.

In this paper, we discussed our perspective on how the Internet of Things (IoT), Machine Learning (ML), and Blockchain Technology contribute to UHC, especially in developing countries. Internet of Things is a technology that allows the embedding of objects, animals, or people with sensors, software, and other technologies to collect or exchange data on the internet. Machine learning is a subfield of artificial intelligence where computers learn to discover associations and patterns in data using statistical models and apply such associations to predict future results. While blockchain technology allows for the secure management of a shared ledger where transactions are verified and stored on a decentralized network (4).

Emerging technologies and UHC

Internet of Things

The Internet of Things (IoT) has recently made significant advancements in healthcare through smart wearables and personal monitoring making it suitable for all age groups and across healthcare specialties (5). The integration of IoT and medical equipment enables healthcare service quality and the tracking of patient progress for individuals who require continuous and real-time medical monitoring and preventative actions. IoT enables the early identification of illnesses and aids in the diagnostic and treatment process in fitness programs, chronic diseases, and elderly patient care. Its usefulness and potential in remote management has been reported during the COVID-19 pandemic (6).

The prevention and management of chronic diseases can be made more affordable with the help of a variety of new technologies. Among them are devices that capture real-time health data when a patient self-administers a therapy. These devices automatically administer treatments or devices that continuously monitor health indicators such as wearable devices, glucose monitors, ECG, amongst other examples (7). A review by Giannakopoulou et al. (8) highlighted latest algorithms that support the cost-effective management of Parkinson's disease using data generated from IoT enabled devices to make accurate predictions through Artificial Intelligence. Many people now utilize mobile applications to manage their different health requirements due to the increasing availability of high-speed Internet and cellphones. The Internet of Medical Things (IoMT) rapidly integrates these devices and smartphone apps with telemedicine and telehealth. Remote monitoring of type-2 diabetes mellitus with intelligent IoMT has been found to be effective in improving medical outcome and lowering burden on both patient and doctor (9). Aside its use in e-Health and health monitoring, IoT is also beneficial in pharmaceutical industry for drug safety, storage and supply chain monitoring (10). There is a growing application and adoption of IoT in healthcare both in high income and low income countries (11).

With all of its benefits, the Internet of Things (IoT) application comes with the possibility of new security possible threats in healthcare systems. Concerns of availability, integrity, and confidentiality are rising (12).

Newer and stronger security standards should be implemented utilizing a resilient method. Moreover, future research on this topic is promising because IoT-based solutions will make it possible to serve the AI algorithms for the prognosis or diagnosis of the disease. They will support innovative healthcare services in general (13). Current and future health IoT solutions should pioneer the way by considering healthcare needs, including usability, interoperability, and security, to have a high impact and success in the healthcare industry shortly. These Industry 4.0 technologies might provide a slew of new ideas and approaches to dealing with medical emergencies locally and globally.

Machine Learning

The ability of Machine Learning algorithms to see and learn from patterns that are obscure to humans afford them the utilization in mass disease screening, with little or no input from qualified clinical personnel. The use of ML models to support diagnosis have evolved in the last three decades favoring deep learning and clustering facilitated by the adoption of electronic medical records (14). A study carried out in 2020 was able to predict the incidence of Alzheimer's disease in older people by training Machine Learning algorithms on MRI tests using the algorithm called "Support Vector Machines." The ML algorithm could diagnose the disease with an accuracy, sensitivity, and specificity of 96.12, 94.94, and 98.23%, respectively (15). Catboost is another ML algorithm that screens for anxiety and depression among seafarers, with accuracy and precision of 82.6 and 84.1%, respectively (16). Its use in pediatrics have also been reported mostly in neonatal medicine, psychiatry and neurology mainly due to shortage of experts in these subspecialties (14).

The accurate predictive capability of ML algorithms could potentially reduce the strain and tremendous workload on health workers, with their attention needed only in complicated cases or just for final verification of the algorithm's prediction especially in low-resource settings. However, lack of reliable health data is a major barrier for developing efficient ML models in low and middle income countries.

Aside predictive diagnosis, ML could be used in healthcare insurance system. A study in Rwanda had shown that ML models could predict future out-of-pocket expenditures of households through the sociodemographic variables (17). With households knowing their predicted out-of-pocket expenditure, they can therefore opt for the most appropriate insurance plan to match such spending. This would also allow policymakers

to create and implement a range of proper insurance plans to meet these predicted needs, thus optimizing the health insurance system and making the achievement of Universal Health Coverage much more feasible.

Chatbots technology also follows the machine learning can make quality health care delivery independent of a physical hospital building or a compulsory attending clinician. This could help increase access to health care and manage the ever-increasing demand for health services without needing a physical doctor or a visit to a hospital (18). This is achieved by algorithms that provide instant responses to health inquiries, look for generic patterns in specific diseases and diagnose from that place, retrieve and analyze previous health data and set health-related reminders (19).

However, despite the potential of ML, its use in clinical practice is still questioned as it requires more improvement and research (20).

Blockchain Technology

Blockchain Technology proffers sustainable solutions, mainly to health financing, a significant component of UHC. The emergence of Bitcoin and other cryptocurrencies eliminates third-party financial institutions in global health financing, allowing philanthropists to make donations directly to support the healthcare system quickly and with minimal transaction risks.

Because the blockchain uses the decentralized system, it is open and does not require any permission whatsoever and making it a perfect way forward for healthcare. Blockchain Technology has been used in COVID-19 response such as surveillance, contact tracing, and vaccine monitoring (21). Besides, blockchain technology has also been employed in electronic medical record, IoT devices and supply chain monitoring to secure data effectively (21).

However, there has been a massive demand for blockchain development, and a study conducted by Deloitte revealed that the local industry is searching for an avenue to use blockchain to solve its pressing needs (22).

Immutability, cybersecurity, and interoperability are three peculiar features of blockchain technology that can facilitate adequate data privacy, storage, and management at minimal cost and risk (22). A framework was used to diagnose and treat cancer tumors for some patients remotely using a blockchain model of telemonitoring healthcare and also monitoring of dermatological issues (23). However, it was recommended that guidelines should be put in place for the utilization of contracts, including blockchains which can be used in the validation of data generated at health facilities as well as individual residents.

Blockchain Technology has also been used in geriatrics, management of chronic diseases, biomedical and pharmaceutical industries for research and clinical practice (24).

TABLE 1 SWOT analysis of blockchain technology.

Strengths	Weaknesses
• Cost efficiency • Speedy access to medical data • Autonomous • Tamper-proof information sharing	• Less number of software and system vendors • Not much scalable • Lack of storage capacity for a large amount of data
Opportunities	**Threats**
• Lower fraud risk in the chain of medical supply • Beneficiaries get more control over the data • Potential for start-ups and forged partnerships in healthcare • The anonymity of data will help in medical research	• Non-standardization • Interoperability issues • Hesitant social adoption of technology • Cultural and trust concerns to adopt blockchain for sensitive data

A survey by Statista 2015 observed an increase in blockchain investment globally, hence, providing opportunities for healthcare financing (25). Despite the significant potential contribution of this technology to health institutions, its usage is still very minimal (Table 1).

Challenges and recommendations

While these emerging technologies look promising in the revolution of UHC, imperfections should also be considered. Some services and resource availability may be disrupted due to the usage of alternative data transmission channels, such as satellite communication in the use of IoT. As a result, an independent and dependable data transmission route is essential to ensure the continuous availability of resources and services (26). Hence, rather than distributing several small IoT networks as timely attachments to global IoT platforms to use their resources and services, provisions should be made for an independent and reliable data transmission channel required for the continuous availability of resources and services (26).

The integration of Blockchain in healthcare to ensure secured automatization of transaction and exchange of information among individuals might be a severely restrictive instrument in which deleting the third-party entity eliminates the only entity capable of preserving human rights (27). Consequently, a decentralization technology might be repurposed into a way of retaining centralized control (27).

Energy usage is rapidly growing due to internet-enabled services and cutting-edge equipment (26). As these technologies

largely depend on energy sources for efficient operations, there is the need to create more devices that use less energy and pose almost zero threat to the environment. One of the issues associated with environmental effects is energy consumption by IoT devices (26). Therefore, green technology should produce a more environmentally friendly IoT device with less energy consumption.

The algorithm's capacity of machine learning to generalize new datasets may be hampered since it may leverage potentially untrustworthy unknown cofounders in place of the actual signal (28). In a study by Finlayson et al. (29) it was shown that machine learning algorithms were subject to manipulation by inputs that are purposefully meant to trick them, therefore, posing incapacity outside the domains where they are trained. There is a need for independent datasets that denote future target populations and compare different algorithms while being cautious of signs of potential bias. More work to improve algorithm interpretability and understand human–algorithm interactions will be required for their future adoption and safety, supported by the development of meticulously planned regulatory frameworks.

Conclusion

Achieving the UHC by 2030 will require an innovative and holistic approach. Emerging technologies in healthcare discussed in this paper have potential in increasing access and reducing cost of healthcare delivery. The shortcomings, and recommendations to leverage the potentials of these technologies for the attainment of the UHC, especially in middle and low-income countries, have been highlighted in this paper.

Author contributions

AOB and TOT conceptualized and designed the study. TOT, OA, MFS, ATR, AAA, and BJD wrote the first draft of the manuscript. AOB and ATA revised the manuscript. All authors reviewed the final manuscript and agreed to the submission of the manuscript.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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Use of provider-to-provider telemedicine in Kenya during the COVID-19 pandemic

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Introduction: According to the World Health Organization (WHO), about 90 percent of countries continue to report COVID-related disruptions to their health systems. The use of telemedicine has been especially common among high-income countries to safely deliver and access health services where enabling infrastructure like broadband connectivity is more widely available than low- and middle-income countries (LMICs). The Addis Clinic implements a provider-to-provider (P2P) asynchronous telemedicine model in Kenya. We sought to examine the use of the P2P telemedicine platform during the second year of COVID-19.

Methods: To assess sustainability, we compared the data for two 12-month calendar periods (period A = year 2020, and period B = year 2021). To examine performance, we compared the data for two different 12-month periods (period C = pandemic period of February 2021 to January 2022, and period D = baseline period of February 2019 to January 2020).

Results: Sustainability of the P2P telemedicine platform was maintained during the pandemic with increased activity levels from 2,604 cases in 2020 to 3,525 cases in 2021. There was an average of 82 specialists and 5.9 coordinators during 2020, and an average of 81 specialists and 6.0 coordinators during 2021. During 2020, there were 444 cases per coordinator, and 587 cases per coordinator in 2021($P = 0.078$). During 2020, there were 32 cases per specialist, and 43 cases per specialist in 2021($P = 0.068$). Performance decreased with 99 percent of cases flagged as "answered" during the baseline period (period D), and 75 percent of cases flagged as "answered" during the pandemic period (period C).

Conclusion: Results suggest that despite a decline in certain sustainability and performance indicators, The Addis Clinic was able to sustain a very high level of activity during the second year of the pandemic, as shown by the continued use of the system. Furthermore, despite some of the infrastructure challenges present in LMICs, the P2P telemedicine platform was a viable option for receiving clinical recommendations from medical experts located remotely. As health systems in LMICs grapple with the effects of the pandemic, it is worthwhile to consider the use of telemedicine to deliver essential health services.

KEYWORDS

digital health, telemedicine, coronavirus, COVID-19 pandemic, frontline health workers, LMICs, health systems

Introduction

According to the World Health Organization (WHO), about 90 percent of countries continue to report COVID-related disruptions to their health systems, with 66 percent citing health workforce-related issues as the most common causes (1). Reasons such as essential health workers needing to stay at home to care for sick family members, employees requiring quarantine because of COVID exposure, and health professionals leaving the workforce have put extreme pressure on health systems. Moreover, the pandemic has diverted many of the resources for health away from other areas. A recent report by The Global Fund suggests that the spillover effects of COVID-19 have eroded decades of progress in fighting diseases such as human immunodeficiency virus (HIV), tuberculosis (TB), and malaria (2). COVID-related disruptions have been particularly harmful for low- and middle-income countries (LMICs) due to the unpredictable nature of the disruptions coupled with the evolving pandemic. Furthermore, public health measures like social distancing and patients' fear of contracting COVID-19 have further exacerbated the decline in access to health services.

Adoption of digitally-enabled solutions like telemedicine has increased substantially since the start of the pandemic (3). Being able to digitally deliver healthcare *via* telemedicine has allowed providers and patients to safely deliver and access essential health services. Survey results from the WHO suggest that 48 percent of countries employed telemedicine to replace in-person consultations during the pandemic (1). The use of telemedicine to mitigate COVID-related disruptions has been especially common among high-income countries where enabling infrastructure like broadband connectivity is more widely available than in LMICs (4). Studies suggest, however, that there is a willingness to adopt telemedicine in low resource settings with several examples of telemedicine use during the COVID-19 pandemic (5, 6).

Kenya confirmed its first case of COVID-19 in March 2020. Since then, the country has experienced several waves of infection, with 333,000 confirmed cases up to June 2022.[1] To curb the rate of transmission, Kenya enforced strict public health measures such as social distancing, travel restrictions, and curfews. The restricted mobility along with COVID-related fears and stigma, reduced patients' willingness to seek essential health services, and limited their access to health facilities. One study found that there was a decrease in expectant mothers choosing to deliver in health facilities because of fears of getting infected, which in turn led to an increase in home deliveries (7).

The Addis Clinic, a non-profit organization based in the United States, implements a provider-to-provider (P2P) telemedicine program in Kenya. Since 2011, The Addis Clinic has been providing access to specialized medical experts for frontline health workers (FHWs) treating patients in low resource settings. The organization connects 430 FHWs in Kenya with a network of 117 physician specialists (specialists) located remotely, providing a mechanism for the communication of diagnostic and management recommendations *via* asynchronous technology (8). The teleconsultation process begins with FHWs submitting cases to the telemedicine platform using a mobile phone app. Cases are then triaged to the appropriate specialist by in-country case coordinators (coordinators), at which point an asynchronous communication is established between the parties.

Evidence suggests that telemedicine has the potential to mitigate the spread of infectious diseases and improve access to health services in LMICs (9). Yet, most of the telemedicine reported has required enabling infrastructure, which is often a barrier in limited resource settings (9). A previous study of The Addis Clinic telemedicine work in Kenya showed that teleconsultations increased substantially during the first year of the pandemic, probably because the network had expanded its referral base by increasing the number of FHWs in Kenya (10). However, it was unclear whether the high caseloads being managed by coordinators and specialists, would be sustainable in the longer term. This is especially relevant as COVID-related disruptions exacerbated many of the systems-related issues that LMICs were already struggling with prior to the pandemic.

In the present study, we examined The Addis Clinic telemedicine work in Kenya during the second year of the pandemic to assess the sustainability of its operations. We also reviewed the performance and quality of service delivered both before and during the pandemic.

Methods

Sustainability was measured in terms of the performance of The Addis Clinic telemedicine network. Measurement of performance is a fundamental aspect of network evaluation, and we have previously suggested a general framework for this purpose (11). The framework entails assessment of various metrics including network activity and efficiency.

Network activity and efficiency

Network activity was measured as the number of cases submitted to the network each day, excluding any test cases.

Network efficiency can be defined as the ratio of Output to Input, where Output is a measure of what has been produced by the network, and Input is a measure of the resources that were consumed to produce that output. The output produced

1 https://covid19.who.int/region/afro/country/ke

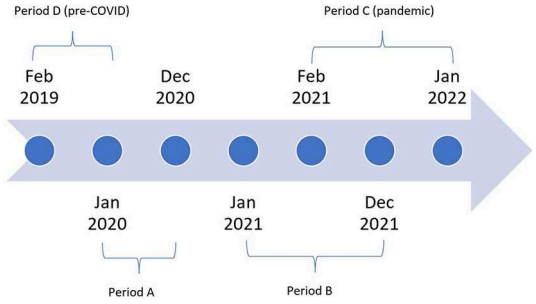

FIGURE 1
Study timeline: Period A (calendar year 2020), Period B (calendar year 2021), Period C (pandemic period = February 2021 to January 2022), and Period D (pre-COVID = February 2019 to January 2020).

by a network is related to the number of cases dealt with during the period of interest, i.e., cases answered. It is also related to their complexity and to the speed of the responses provided. A crude estimate of the output can be obtained from the referral rate (10).

The input to a network is related to the resources consumed during the period of interest, an important part of which is the number of people who were needed to run the network and the time they spent doing it. We therefore considered the numbers of coordinators and the specialists who were involved in the cases that were handled during the period of interest. For these two types of users, a measure is required of the time spent in dealing with the cases. Such data is not normally available in any telemedicine network, so we estimated it from the number of coordinators and specialists who were known to be active during the period of interest.

Network performance and service quality

Network performance was based on four simple performance statistics that are of interest to the users and the operators of a network:

- Referral rate—The number of referrals received in unit time;
- Allocation delay—The interval between the arrival of the case and the first time it is allocated for reply;
- Query delay—The time between a case being assigned to a specific specialist and that specialist responding; and
- Answer delay—The delay after a case has been submitted before the first reply is received from a specialist.

Service quality was based on the speed of the telemedicine responses provided by the network and their quality. Speed of response can be measured as the answer delay. The quality of the responses is more difficult to measure, but can be inferred from the user feedback (12): in the telemedicine system used by The Addis Clinic, requests are sent automatically to FHWs to complete a user feedback questionnaire 21 days after each teleconsultation has been submitted. FHWs can respond by completing a questionnaire containing 12 questions. The present work considered the following questions relating to service quality:

Q1 "Was the case sent to an appropriate expert?"
Q2 "Was the answer provided sufficiently quickly?"
Q3 "Was the answer well-adapted for your local environment?"
Q6 "Did you find the advice helpful?"
Q7b "Did it [the advice] assist with your management of the patient?"
Q8 "Do you think the eventual outcome for the patient will be beneficial?"
Q9 "Was there any educational benefit to you in the reply?"

Answers could be chosen from multiple choice responses (yes/no/don't know).

Analysis

We conducted a retrospective analysis of the telemedicine cases referred to The Addis Clinic from Kenya. To assess sustainability, we compared the data for two 12-month periods (period A = calendar year 2020 and period B = calendar year 2021). To assess performance, we compared the data for two 12-month periods. Period C includes the pandemic period of February 2021 to January 2022, while period D (pre-COVID) consists of the baseline period of February 2019 to January 2020, see Figure 1.

In comparing data from different study periods, differences in proportions were examined using the chi-squared test. Differences in numbers of observations were examined using the *t*-test or Mann-Whitney test, according to whether the distributions were normal or not.

Information relating to all cases was extracted from the database of the telemedicine system. Formal research ethics permission was not required, because patient consent to access the data had been obtained and the work was a retrospective chart review conducted by the organization's staff in accordance with its research policies.

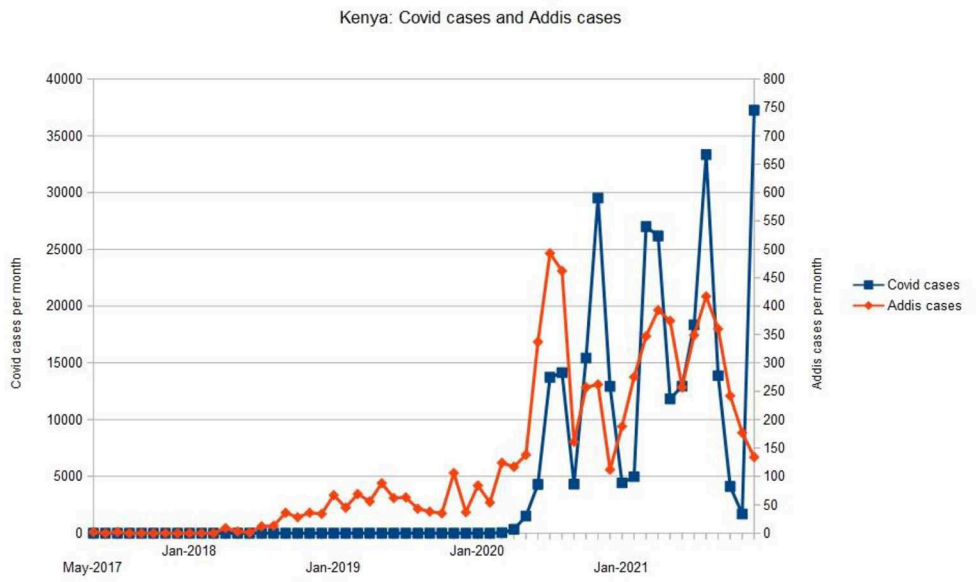

FIGURE 2
Relationship between the number of telemedicine cases referred to The Addis Clinic and the number of confirmed COVID-cases nationally.

Results

Sustainability

A comparison of data for periods A and B was used to assess sustainability.

Activity

During 2020, 2,604 cases were received; the mean submission rate was 217 cases/month (SD 147). During 2021, 3,525 cases were received; the mean submission rate was 294 cases/month (SD 94). The increase in mean submission rate was not significant ($t = 1.52$, $P = 0.14$). Changes in the number of cases referred to The Addis Clinic were associated with changes in the number of confirmed COVID-cases nationally, see Figure 2.

Efficiency

There was an average of 82 specialists and 5.9 coordinators during 2020. There was an average of 81 specialists and 6.0 coordinators during 2021.

During 2020, there were 444 cases per coordinator, and during 2021 there were 587 cases per coordinator. The increase was not significant ($P = 0.078$). During 2020, there were 32 cases per specialist, and during 2021 there were 43 cases per specialist. The increase was not significant ($P = 0.068$).

Performance

A comparison of data for periods C and D was used to assess performance.

During the baseline period, 726 cases were received; during the pandemic period, 3,548 cases were received. Cases were flagged automatically as "answered" when a response was received from one or more specialists. During the baseline period, 99 percent of cases were flagged as "answered;" during the pandemic period, 75 percent of cases were flagged as "answered."

A random sample of cases ($n = 20$) which had not been flagged as "answered" were examined. This showed that in 25 percent of these cases, the coordinator had provided advice or guidance directly to the FHW, i.e., the case had in fact been answered from the FHW's perspective. In 35 percent of cases, further information had been requested from the FHW, but not received. The remainder reflected miscellaneous other reasons for a non-answer, such as miscommunication between FHW and coordinator. The analysis which follows was conducted on the cases that had been flagged automatically as "answered."

Patient characteristics

The median age of the patients was 30 years ($n = 715$) during the baseline period and 28 years ($n = 2,636$) during the pandemic period. The proportions of child and adult patients were almost identical during the two study periods: 28 percent

of cases were children. The median bodyweights were 60 kg (n = 698) and 61 kg (n = 1,963) during the baseline and pandemic period, respectively. The sex ratio (M:F) was 0.42 (n = 708) during the baseline period and 0.41 (n = 2,623) during the pandemic period, see Table 1.

TABLE 1 Patient characteristics.

	Baseline			Pandemic		
	n	**%**		***n***	**%**	
Female	411	57.1		1,536	58.1	
Male	297	41.3		1,087	41.1	
Not recorded	12	1.7		21	0.8	
Adults (18 years and older)	511	71.0		1,884	71.3	
Children (under 18 years)	204	28.3		752	28.4	
Age not recorded	5	0.7		8	0.3	
	Median	**IQR**	***n***	**Median**	**IQR**	**n**
Age (years)	30.0	16.0–43.0	715	28.0	15.0–40.0	2,636
Bodyweight (kg)	60.0	42.3–70.0	698	61.0	36.0–70.0	1,963

Reason for referral

The two most common reasons given for referral were "*What other diagnoses should be considered?*" and "*Could you provide more information about the disease/condition?*". During the baseline period, these accounted for 70 percent of cases, and during the pandemic period, they accounted for 72 percent of cases, see Figure 3.

The most common reason for referral during both study periods was "*What other diagnoses should be considered?*". During the baseline period, this was given as the reason for referral in 40 percent of cases, while during the pandemic period, it was given as the reason in 54 percent of cases: the difference was significant (chi^2 = 40.8, P<0.0001).

Speed of response

Following the submission of a case, the median time to send it to an appropriate specialist (the allocation delay) was 1.8 h during the baseline period (n = 720) and 4.0 h during the pandemic (n = 2,444). The median time before a specialist responded (the answer delay) was 13.1 h during the baseline period (n = 719) and 18.9 h during the pandemic (n = 2,440). Seventy-eight percent of cases were answered within 48 h of submission during the baseline period (n = 564) and 70 percent during the pandemic (n = 1,838), see Table 2.

Type of expertise

The most common types of specialist consulted during the study were from Internal Medicine: 37 percent of cases during the baseline period (n = 288) and 35 percent during the pandemic (n = 1,036). There were minor differences between the two periods: fewer pediatricians were consulted during the pandemic period, and more radiologists, see Figure 4.

Complexity of cases

The mean number of queries (i.e., requests to specialists) per case was 1.3 during the baseline period (n = 909) and 1.2 during the pandemic (n = 3,079). The mean number of messages about each case was 6.0 during the baseline period (n = 4,304) and 4.9 during the pandemic (n = 12,911). The median length of time between the first message about a case and the last message (the dialogue time) was 34 h during the baseline period (n = 719) and 24 h during the pandemic (n = 2,512), see Table 3. The differences were significant, see Table 3.

Follow-up reports

A total of 190 follow-up reports were provided by the FHWs during the baseline period, and a total of 158 reports during the pandemic. The responses to the seven questions about the value of the service were mainly positive, both at baseline and during the pandemic. For each question, the proportion of positive responses was lower during the pandemic period, and this difference was significant, see Table 4.

Discussion

The present study shows that The Addis Clinic telemedicine platform was heavily used during both the first and second year of COVID-19. While many of the network performance indicators decreased somewhat during the pandemic period, the high volume of cases indicates that the FHWs continued to find the telemedicine service useful to them. This also suggests that despite some of the infrastructure challenges present in LMICs, the P2P telemedicine platform was a viable option for receiving clinical recommendations from medical experts located remotely. Moreover, it is notable that changes in the number of cases referred to The Addis Clinic were associated

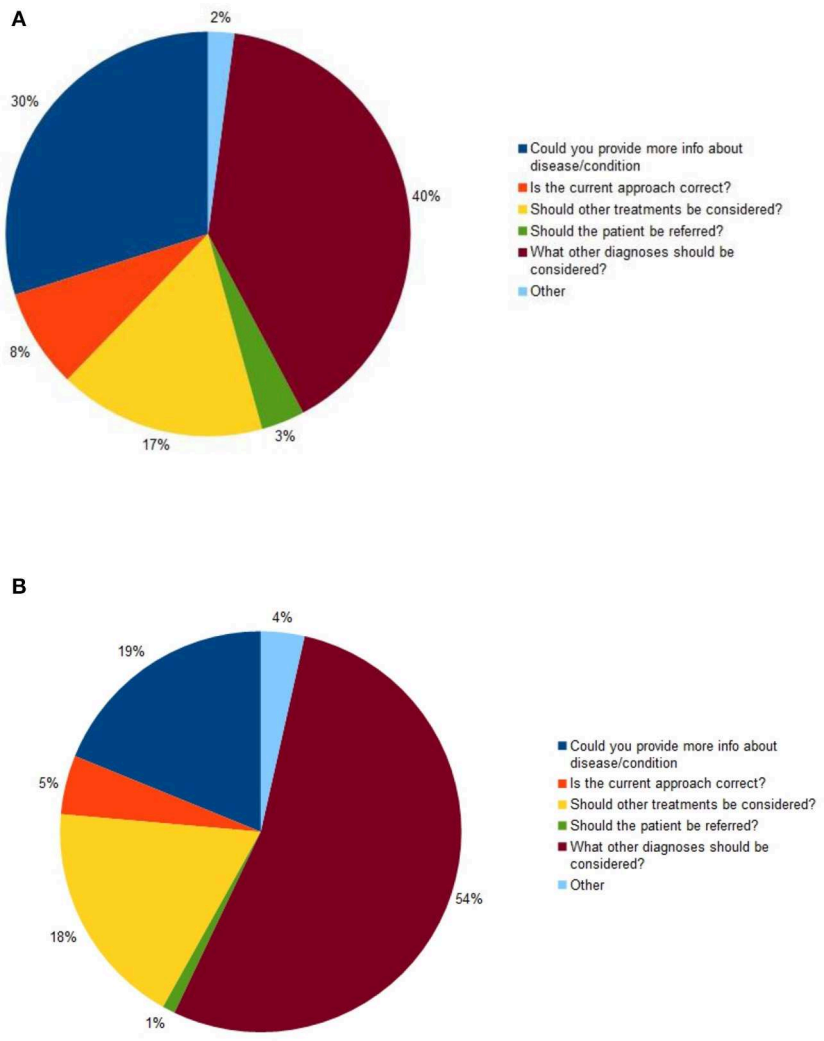

FIGURE 3
Primary reason for referral: **(A)** during the baseline period ($n = 720$); **(B)** during the pandemic period ($n = 2{,}644$).

with changes in the number of confirmed COVID-cases nationally, see Figure 2. Whether patients were being redirected from overstretched public health facilities or redirected for other COVID-related reasons, the increase in the number of teleconsultations may have been a consequence of the COVID-related disruptions to the health system. It is worth mentioning that prior to COVID-19, The Addis Clinic expanded its telemedicine operation in Kenya by hiring healthcare recruiters to provide peer-to-peer training and support in the use of the telemedicine platform, as well as recruiting new FHWs to participate in the program. Additionally, the organization transitioned the responsibilities for triaging cases from U.S.-based coordinators to in-country staff to reduce logistical barriers such as time zone differences. How far these operational changes or the COVID-related disruptions to the health system contributed to the increase in teleconsultations is not known. However, our findings demonstrate that The Addis Clinic network was able to sustain a high level of activity and utilization throughout 2020 and 2021. This also suggests that if additional resources had been available, the observed falls in some quality indicators (e.g., response time) might have been avoidable.

Network activity and efficiency

The results indicate that The Addis Clinic was operating at a high level of activity during the pandemic, with a five-fold increase in the number of teleconsultations during the pandemic compared to pre-pandemic. There were also increases in network efficiency, as judged by the numbers of cases managed by coordinators and specialists (although the increases were not significant). However, the allocation process and

TABLE 2 Speed of response.

	Baseline			Pandemic			
	Median	IQR	*n*	Median	IQR	n	*z*
Allocation delay (h)*	1.8	0.5–4.4	720	4.0	1.4–11.4	2,444	14.2
Answer delay (h)*	13.1	5.7–39.5	719	18.9	7.4–46.7	2,440	5.2
	n	%		*n*	%		chi^2
Cases answered within 48h*	564	78.3		1,838	69.5		21.5

*The statistics exclude ∼200 cases that the case coordinators answered without needing to involve a physician specialist.

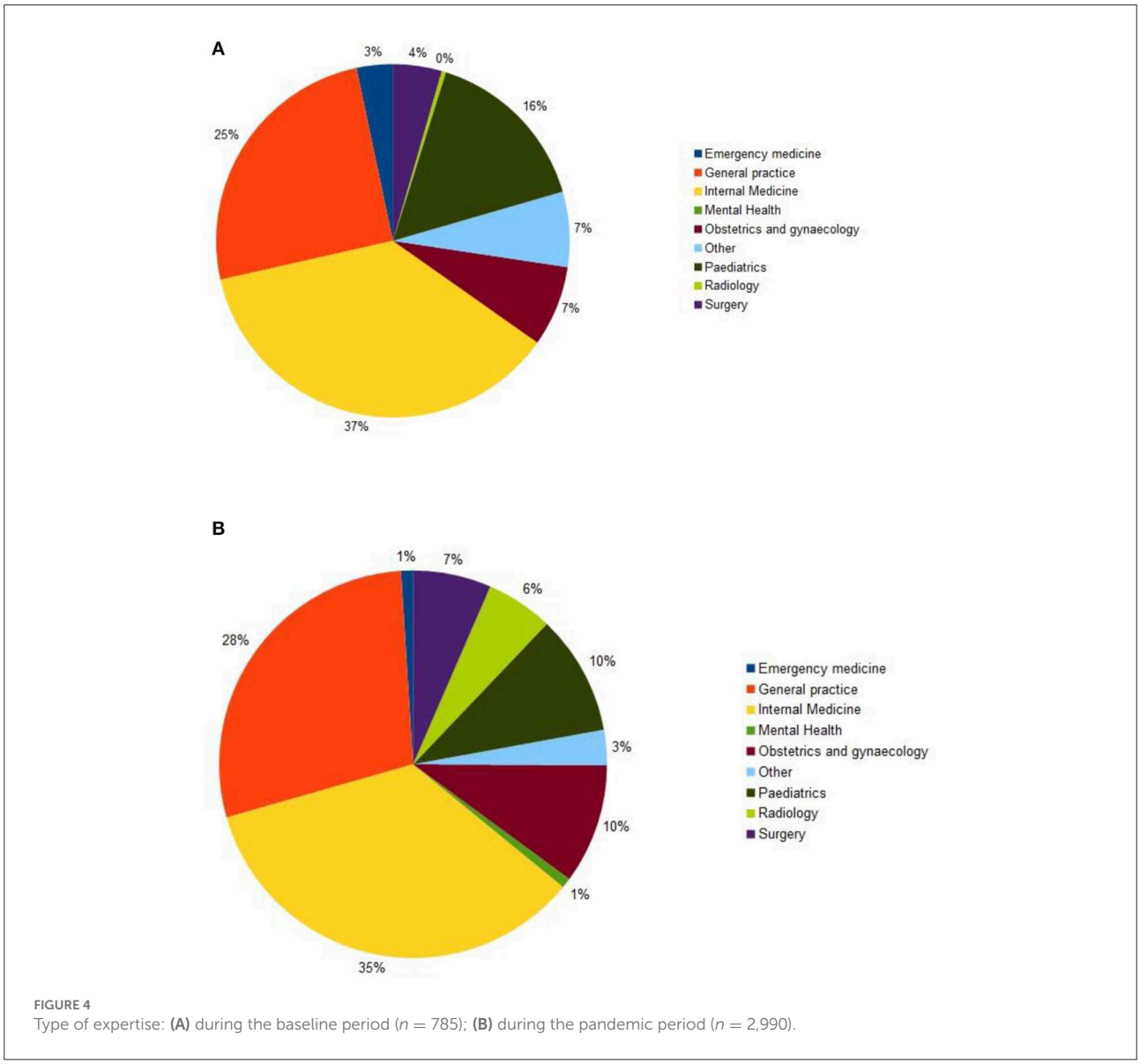

FIGURE 4
Type of expertise: **(A)** during the baseline period ($n = 785$); **(B)** during the pandemic period ($n = 2,990$).

speed of response from specialists was slower during COVID-19 compared to the baseline. Although the number of FHWs increased during the pandemic, the number of coordinators and specialists remained the same. Nonetheless, a similar proportion of cases were answered within 48 h of submission, with 70 percent during COVID-19 compared to 78 percent

TABLE 3 Complexity of cases.

	Baseline			Pandemic			
	Mean	**SD**	***n***	**Mean**	**SD**	***n***	***z***
Queries per case	1.3	0.49	909	1.2	1.3	3,078	14.0
Messages per case	6.0	2.1	4,304	4.9	2.1	12,911	17.7
	Median	**IQR**	***n***	**Median**	**IQR**	***n***	***z***
Dialogue time (h)	34.0	12.8–87.9	719	23.9	9.2–63.5	2,512	4.9

TABLE 4 Follow-up reports.

	Baseline		Pandemic		
	No of responses	**Yes %**	**No of responses**	**Yes %**	**chi^2**
Q1 "Was the case sent to an appropriate expert?"	190	99.5	158	82.9	31.9
Q2 "Was the answer provided sufficiently quickly?"	190	98.4	158	81.0	30.4
Q3 "Was the answer well-adapted for your local environment?"	190	99.5	158	81.0	36.1
Q6 "Did you find the advice helpful?"	190	100	158	84.8	30.9
Q7b "Did it [the advice] assist with your management of the patient ?"	190	96.8	158	75.3	35.8
Q8 "Do you think the eventual outcome for the patient will be beneficial?"	190	94.7	158	76.0	25.5
Q9 "Was there any educational benefit to you in the reply?"	190	99.5	158	80.4	37.5

during the baseline period. This suggests that The Addis Clinic network was able to manage and maintain acceptable operational standards, as it did before the pandemic. Given the environmental factors (e.g., COVID-19) during 2020 and 2021, it is fair to assume that COVID-related disruptions affecting health workers also adversely affected specialists' abilities to respond to teleconsultations, similar to reports from other health systems during the pandemic (13). It is also reasonable to infer that elements of The Addis Clinic telemedicine model (e.g., teleconsultation process, asynchronous technology), may have contributed to its resiliency during COVID-19. Operational changes such as expanding its presence in country may have allowed The Addis Clinic to absorb the increase in the level of activity from its FHWs, as evidenced by the non-significant increase in the number of cases per coordinator and the number of cases per specialist from 2020 to 2021. As future telemedicine programs are developed and deployed in LMICs, decision-makers should therefore consider establishing a strong in-country presence to ensure not only sustainability, but also resiliency during times of increased stress.

Network performance and service quality

During the pandemic, there was a decrease in certain service quality and efficiency-related indicators (i.e., speed of response). However, The Addis Clinic was able to satisfy the needs of FHWs, as shown by the increase in activity during 2021. Moreover, the reasons for the referrals were commonly related to understanding whether other diagnoses should be considered. This suggests that the types of patients presenting to The Addis Clinic network may have had symptoms that overlapped with several other diseases, like COVID-19 and other respiratory conditions (i.e., malaria). It is also worth noting that the mean number of queries per case and the mean number of messages about each case both significantly decreased from baseline to the pandemic period. This may have been the result of FHWs improving their clinical knowledge using the telemedicine platform, resulting in less dialogue between FHW and specialist.

Limitations

The study results are based on a single organization, which has the potential to incur bias and limit generalizability. Furthermore, it is difficult to know whether COVID-related disruptions to the health system had a spillover effect on The Addis Clinic network. Similarly, it is unclear whether operational changes made prior to the pandemic contributed to the rise in teleconsultations in 2020 and 2021. Future studies of the referral activity post-pandemic would be useful to better understand the drivers for submitting cases to the telemedicine system.

Conclusion

Although certain service quality indicators declined during COVID-19, the present study shows that The Addis Clinic was able to sustain a very high level of activity and efficiency during the second year of the pandemic. By examining the level of activity and operational aspects of the organization delivering P2P telemedicine services, our results reveal key elements (i.e., in-country presence, asynchronous technology) needed to successfully implement such programs in LMICs. As health systems in LMICs grapple with the effects of the pandemic, it may be worth considering the use of telemedicine to deliver essential health services.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Author contributions

EK contributed to the study design, data interpretation, and wrote the first draft of the paper. RW contributed to the study design, conducted the data analysis, data interpretation, and edited the manuscript after the first draft. MM, AK, and SC reviewed the final version and provided content input. All authors have read and agreed to the published version of the manuscript.

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We are grateful to all concerned with the operation of The Addis Clinic telemedicine system, both in Kenya and beyond.

Conflict of interest

Author EK served as an independent consultant, while authors MM and AK were employed by The Addis Clinic Inc. Author RW was a member of Collegium Telemedicus. Author SC has served as a consultant for Acceleron Pharma and United Therapeutics, held research grants from Actelion, Bayer, and Pfizer, was a director, officer, and shareholder of Synhale Therapeutics, and filed patents regarding metabolic dysregulation in pulmonary hypertension.

Publisher's note

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Perceptions on a mobile health intervention to improve maternal child health for Syrian refugees in Turkey: Opportunities and challenges for end-user acceptability

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Background: Mobile health (mhealth) technology presents an opportunity to address many unique challenges refugee populations face when accessing healthcare. A robust body of evidence supports the use of mobile phone-based reminder platforms to increase timely and comprehensive access to health services. Yet, there is a dearth of research in their development for displaced populations, as well as refugee perspectives in design processes to improve effective adoptions of mhealth interventions.

Objective: This study aimed to explore healthcare barriers faced by Syrian refugee women in Turkey, and their perceptions of a maternal-child health mobile application designed to provide antenatal care and vaccine services. These findings guided development of a framework for enhancing acceptability of mobile health applications specific to refugee end-users.

Methods: Syrian refugee women who were pregnant or had at least one child under the age of 2 years old at the time of recruitment ($n = 14$) participated in semi-structured in-depth interviews. Participants had the opportunity to directly interact with an operational maternal-child health mobile application during the interview. Using a grounded theory approach, we identified critical factors and qualities mhealth developers should consider when developing user-friendly applications for refugees.

Results: It was observed that a refugee's perception of the mobile health application's usability was heavily influenced by past healthcare experiences and the contextual challenges they face while accessing healthcare. The in-depth interviews with refugee end-users identified that data security, offline capability, clear-user directions, and data retrievability were critical qualities to build into mobile health applications. Among the features included in the maternal-child health application, participants most valued the childhood vaccination reminder and health information features. Furthermore, the application's multi-lingual modes (Arabic, Turkish, and English) strengthened the application's usability among Syrian refugee populations living in Turkey.

Conclusions: The inclusion of refugee perceptions in mhealth applications offers unique developer insights for building more inclusive and effective tools for vulnerable populations. Basic upfront discussions of the mobile application's health goals and its personal value to the user may improve their long-term use. Further prospective research is needed on retention and use of mobile health applications for refugee women and other displaced populations.

KEYWORDS

mobile health (mHealth), refugees, digital health, maternal child health (MCH), user experience (UX)

Introduction

Since the start of the Syrian Civil War in 2011, 12 million Syrians have been forcibly displaced from their homes. Turkey hosts nearly four million of these refugees, which constitutes the largest population of refugees in the world (1). Healthcare services are free in Turkey for the Syrian refugee population through national insurance. However, despite these services, there has been an increase in morbidity and mortality among Syrian refugees, particularly women and children (2). Outbreaks of vaccine-preventable diseases among Syrian refugee children in Turkey are increasing despite numerous immunization campaigns (3). Similarly, pregnant Syrian women appear particularly susceptible to the ill effects of missing preventive prenatal and antenatal care. Peer-reviewed studies in Turkish hospitals indicate that refugee women are more likely to die during and after labor (2) and fewer than 50% of pregnant Syrians attend at least four prenatal care visits (4).

A robust body of research evidence supports the use of mobile phone-based reminder platforms to increase timely and complete access to health services, such as childhood immunizations and prenatal care (5–7). A systematic review found that the majority of text message reminder interventions improved health outcomes (8). Additionally, a multinational review of Syrian refugees and other vulnerable Arab populations indicated that these populations have widespread access to mobile phones and cellular networks (9). While specific Syrian refugee data in Turkey is difficult to obtain beyond market surveys, in a recent study with over 1,000 participants, 95.5% of Palestinian refugees in Jordan reported having a mobile phone (10). Additional qualitative studies demonstrate that mobile health interventions may be acceptable and feasible for refugee populations (9, 11, 12).

With numerous studies showing access to technology for refugee populations, efforts to develop useful maternal-child health applications are currently underway. For example, UNRWA, the United Nations Relief and Works Agency created for Palestinian refugees, has deployed a mobile health application that shares maternal-child health educational materials with refugees registered with UNRWA's independent health system and holds their health records (10). Yet, there is a relative dearth of evidence about the effectiveness of mobile phone-based medical reminder platforms in refugee populations. Refugees face unique barriers to care: much of the Syrian population lives outside of formal refugee camps, in the slums of urban centers in search of economic opportunities (13). It is therefore hard to track refugee populations, maintain their health records, and ensure their awareness of the available services. The demand side of the problem is further aggravated by competing priorities (e.g., finding a job, schooling for children, etc.) for survival as a recent refugee. Despite these factors and the increasing usage of mobile phone- based reminders in low and middle-income countries (LMICs), few studies have examined refugee end-user attitudes toward these programs.

HERA, or Health Recording App, is a mobile health (mHealth) medical reminder intervention designed for the Syrian refugee population. It aims to leverage the high levels of smartphone usage in the community by providing specific and integrable solutions. HERA can be used for novel data collection, health information dissemination, and targeted health behavior changes for refugee populations. Furthermore, the HERA application enables users to receive healthcare appointment reminders, receive health information, centralize medical records, contact emergency services, and navigate the Turkish healthcare system in multiple languages.

A prior proof-of-concept study of this mHealth innovation was conducted in Turkey under the approval of an ethics review board in 2018, which informed the prototype of the mobile application and its initial features (14). This study aims to: (1) define the needs of Syrian refugee end-users, including specific barriers to healthcare access, (2) understand their perceptions on utility of a mobile health application for improving their healthcare-seeking behavior for antenatal care and vaccinations, and (3) enhance the user experience of the HERA mobile application by including end-users in the ideate mode of the application's design.

Methods

Context

The study site was located in Istanbul, Turkey, where almost one million Syrian refugees live. Study participants included 14 Syrian women who either had at least one child under the age of 2 years old or was pregnant at the time of recruitment. Participants primarily included individuals who had not attended a previous training session from the application developers on using the mobile application. The data collection period was conducted from July to November of 2019.

Study design

The study used a grounded theory method with purposive sampling. The researchers conducted semi-structured and in-depth interviews of the participants using an exploratory approach to capture the individual experiences of using the application on the mobile device. The framework of the refugee interviews began by inquiring into their demographic background and the type of features they thought would be useful in an application for seeking preventive care, specifically prenatal care and vaccination services. This was followed with a direct observational component where the interviewer observed the interviewee navigate through the application to complete a given task. The interviewee was asked to narrate their thought process as they completed the task. Following the completion of the task, the participants shared their reflections on the mobile application.

A purposive sampling method was used to recruit at least nine participants that met the study criteria, at which, code definitions reach saturation or are typically found to stabilize (15–17). To increase generalizability, multiple regions in Istanbul where Syrians are known to reside in high numbers were targeted. To enroll participants, the research team contacted non-profit organizations that work with the Syrian population and clinics for Syrian patients. These organizations referred participants based on the refugee's availability and interest in participating. All those asked to be interviewed participated in the study. As refugees may be displaced or migrate, the interview was conducted in a single session. Participants were asked to download the application from an online application store (e.g., Google Play Store) during the interview if they had not already installed it prior to the training session.

The research protocol was developed by Turkish and American researchers who received graduate-level research training. The gender of the researchers was balanced and the field staff included a local female Turkish qualitative researcher and female Arabic interpreters of Turkish and Syrian origin. All field staff participated in a qualitative training process before piloting. The interview guide was first piloted with the help of the Arabic interpreters and was adjusted based on their feedback. Two pilot interviews were done to evaluate the external validity as well as translations of the questions, and the research team's efficiency in interviews.

Interviews were conducted by a research assistant and a translator, fluent in Arabic and Turkish, in either a meeting space provided by a non-profit organization or at the participant's house. Each interview was 1-h long. All interviews were conducted in privacy, with only the participant, the female interpreter, and interviewer. All interviews were audio recorded, following informed written and verbal consent. Audio recordings were directly transcribed verbatim in either Turkish or Arabic and subsequently translated to English by a native speaker. Interviews conducted with the assistance of an Arabic translator were also transcribed in Arabic and Turkish prior to English translation.

Open-ended individual interview guides were administered to pregnant and non-pregnant participants. The interview guide for non-pregnant participants focused on the child vaccination features and experiences, while the pregnant participants' guide focused on exploring their perspectives on prenatal health experiences and the mobile application features.

Thematic coding and analysis

Three investigators (CM, AS, NN) reviewed the translated interview transcripts and wrote memos to capture prominent ideas. Key issues, concepts, and themes that emerged from the data were examined using constant comparison: each item was checked or compared with the rest of the data to identify and index analytical categories, or codes (17). All the developed codes were documented in a codebook. Summary reports of each code were created with examples of supporting text and reference to aid in the process of synthesizing data into key themes. Microsoft Excel 16.45 was used to manage the data (18). NVivo 12 was used to facilitate inductive data analysis and create diagrams (19).

Ethical considerations

Institutional review board approval was obtained from Acibadem Mehmet Ali Aydinlar University Medical Research Ethical Board with decree number 2019-14/45 on 09/12/2019. An informed consent form in Turkish, English, and Arabic was prepared. The consent form participants were asked to sign was read and explained in Arabic by the interviewer. All but one participant agreed to be audio-recorded and everyone consented to participate.

Results

Participant demographics

A total of 14 participants were interviewed. Five were pregnant at the time of the interview, while the rest were not pregnant but had children. The median age of participants was 24 years (min = 19, max = 37). A majority of the participants had completed their lower secondary education (median years of education = 9). Other than two of the pregnant participants, all had at least one child at the time of the interview. Half of the participants had no fewer than two children (median = 2), and all but one did not have employment. The household had a median of 5 people (min = 3, max = 12) and a residing period of 4 years in Turkey. While one participant had arrived in Turkey only 3 months prior to the interview, the longest time spent in Turkey was 8 years. Additionally, three subjects had previously miscarried. A summary of individual participant demographics is presented in Table 1.

Emergent themes

Five overall emergent themes were identified: (1) Healthcare experiences in Turkey, (2) Knowledge of Turkey's healthcare system, (3) Challenges and facilitators of healthcare access, (4) Use of technology, and (5) Experience with the mHealth application. A coding tree diagram of the themes and sub-themes that emerged from the participant's responses is depicted in Figure 1.

Healthcare experiences in Turkey

All participants reported prior experience with the healthcare system and hospital-level facilities in Turkey, either for themselves or their children. The choice of facility varied between private hospitals, public hospitals, and Syrian-run clinics. Emergency services were not frequently used as only two participants had previously utilized these services. One participant used the emergency services at a public hospital during her pregnancy because she had difficulties scheduling appointments at the public hospital and could not afford a private hospital (Aaliyah, 26).

Pregnant participants were asked about their healthcare experiences. Although Turkey offers free routine pregnancy services universally, none of the pregnant participants met the minimum clinically recommended number ($n = 4$) and frequency of prenatal clinic visits (20). Additionally, none of the participants had prepared a plan for their pregnancy due date, including selecting a health facility for delivery. While some of the participants had given birth in Syria or in other countries, none reported any difference in healthcare services they received during that time when compared with Turkey.

No participant reported any issues with their current pregnancy at the time of the interview. However, the subjects mentioned that the private hospitals in Turkey were generally more expensive and thus difficult to access.

> *"I was going to a private hospital, but it was kind of expensive and my situation is difficult." (Aaliyah, 26)*

The public polyclinics were reported to infrequently have specialized obstetrics and gynecological departments which led to referrals to more expensive private hospitals or physicians for services such as ultrasounds. The long wait time for public facilities also incentivized participants to seek care from private facilities. Wait times were also exacerbated if health records were not readily accessible for either the patient or the care provider at the point-of-care site.

> *"At my last appointment, I had a problem. I forgot my health records at home, but I went there, and I was waiting for a couple of hours...they sent me back home to get the paper and come back. The time I spent in line went to waste and I had to come back again." (Gul, 24)*

At least half of the participants said that they had received healthcare services from a non-Turkish provider. When study participants visited Syrian polyclinics, they typically used vaccination services and were referred to either private hospitals or Turkish physicians for gynecological services and other specialty care. The private hospitals could have Turkish doctors or doctors with different nationalities. One participant noted that additional healthcare services for Arabic speaking patients has been set up, which employs Arabic-speaking physicians (e.g., Syrian, Iraqi, and Palestinian trained-physicians). This service now has the capacity to provide prescriptions whereas previous Syrian polyclinics could not provide pharmaceutical services.

The children of participants generally received vaccinations, which could be administered at polyclinics. Only one participant indicated hesitancy toward the vaccination schedule, wanting to wait until her child was slightly older. Very few women reported already utilizing emergency services for severe diseases, accidents (e.g., drowning) or injuries for their children during their time in Turkey ($n = 2$). The personal health issues that some subjects experienced included perinatal infections with fever, chronic illness such as asthma, and mental health deterioration, including postpartum depression. Three subjects had experienced miscarriages, but this occurred prior to their arrival in Turkey. Health services that some subjects listed as important included more advanced prenatal care technology and mental healthcare resources as the Syrian female refugee population was often isolated during the pregnancy process.

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TABLE 1 Demographic characteristics of participants.

Participant pseudonym	Age	Number of children	Highest level of education attained	Employment experience	Currently pregnant	Pregnancy month	Household size	Time in Turkey (years)
Aaliyah	26	2	Primary education	Hairdresser	Yes	6	4	6
Amara	29	4	Lower secondary education	No	Yes	7	5	1
Amina	25	1	Lower secondary education	No	Yes	9	3	8
Aisha	19	0	Lower secondary education	No	Yes	2	4	4
Amal	24	0	Upper secondary education	No	Yes	8	4	4
Calla	24	2	Upper secondary education	No	No	-	4	6
Cyra	27	2	Lower secondary education	No	No	-	4	4
Celina	39	5	Lower secondary education	No	No	-	7	4
Dani	23	3	Lower secondary education	No	No	-	5	5
Ezra	24	3	Lower secondary education	No	No	-	5	4
*Farrah**	24	1	Lower secondary education	No	No	-	2	0.25 (3 months)
*Fatima**	30	2	Primary education	No	No	-	3	4
Gul	24	2	Lower secondary education	No	No	-	12	3
Hyat	36	6	Post- secondary vocational education	No	No	-	8	2

*Indicates the participant previously attended a HERA mobile application training session.

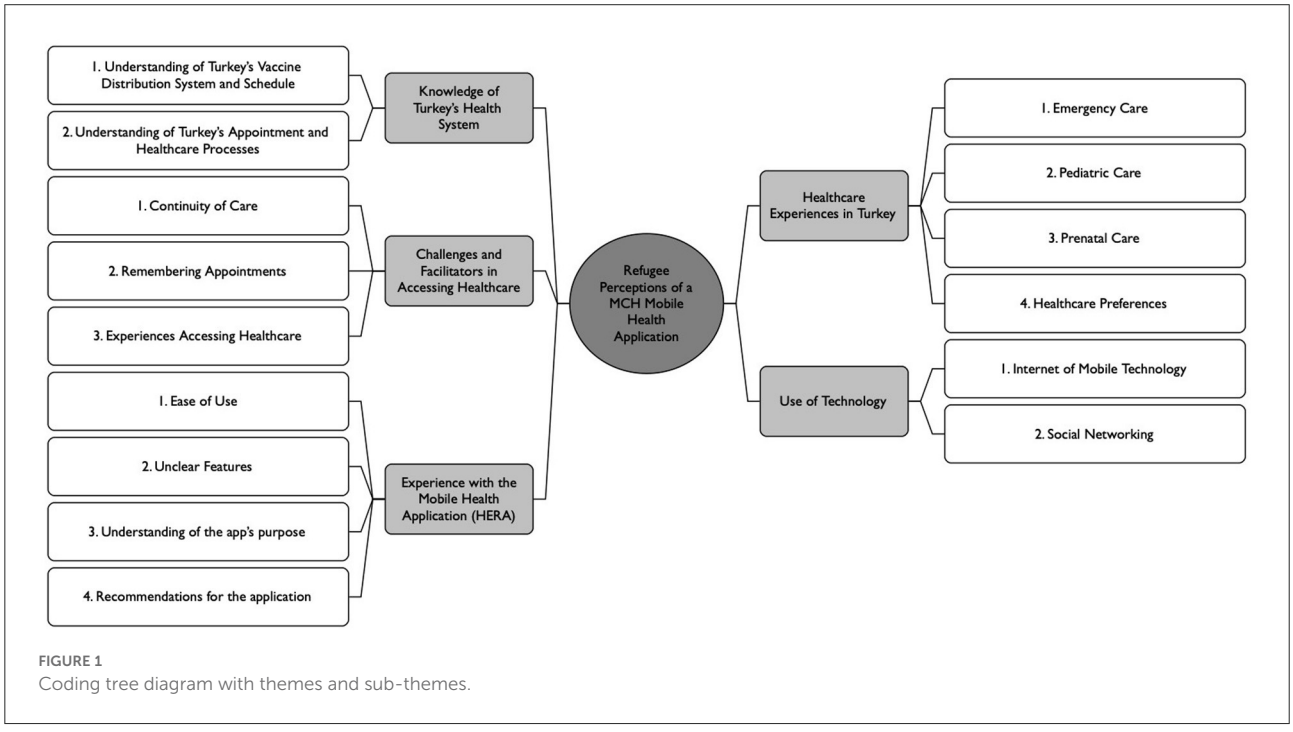

FIGURE 1
Coding tree diagram with themes and sub-themes.

> *"...Most Syrian women are suffering from depression because they usually give birth alone, they do not have their mothers with them, they do not have their sisters with them. They feel alone, they feel tired of their children and their husbands. I felt very depressed after I gave birth." (Hyat, 36)*

Knowledge of Turkey's health system

Participants were asked about their knowledge of Turkey's health system and the process for accessing care. While participants were aware of the ambulance system, most did not know the contact number, or that it was free-of-charge for

everyone in the country, including refugees and immigrants. It was also unclear to the participants what healthcare services were provided (7). None of the participants could comment on if Syria and Turkey had the same vaccination schedule.

Additionally, there was no standard procedure that the refugees followed to make healthcare appointments in Turkey. Some sought help from Turkish nationals to help them schedule appointments and navigate the healthcare system; while the others used the Central Physician Appointment System (Merkezi Hekim Randevu Sistemi, MHRS), a national unified call center to make appointments at second and third-tiered hospitals having translation services to assist non-Turkish people. Some participants also made appointments with private providers who had translators. One subject reported that she had attempted to download the MHRS mobile application but eventually used the MHRS call center because she did not have the government identification number necessary to use the application. Another subject scheduled the appointment through the local municipal government offices.

Challenges and facilitators in accessing healthcare

Challenges

In terms of the participants' continuity of care, routine vaccinations were reported to be more regularly obtained compared to prenatal care. Migrant clinics (rather than hospitals) in Istanbul were the primary providers of pediatric care and vaccine services for the study subjects' vaccine-eligible children. Of the vaccine subjects ($n = 8$), only one subject reported that one of her children was unvaccinated because of the Syrian Civil War. However, the same subject's youngest child received all their vaccinations in Turkey (Fatima, 30). While some participants reported regularly getting prenatal care during their pregnancy, those who were not pregnant at the time of the interview reported receiving routine care less frequently.

Participants discussed several challenges when they accessed health services, including language, wait times at public facilities, expenses at private facilities, and uncertainty about the additional cost-free health services available to them as refugees, especially among those without Turkish identification documents. According to the participants, disparities in access to timely care was due to the Turkish bias toward Syrian refugees. Furthermore, as highlighted by a participant, the lack of transportation and childcare support exacerbated their difficulties with healthcare access.

Language was described as a considerable challenge by the study participants. Many indicated that their Turkish neighbors helped them set up appointments, or they preferred going to Syrian-run clinics.

> *"I understand Turkish, but not much. Then, the Syrian doctors understand Turkish, but not much. I mean, for example, what does the doctor say? If I didn't understand something... then the Syrian doctor is better for me then" (Amal, 24)*

Wait times were often mentioned as an ongoing challenge in accessing healthcare from public healthcare facilities. For example, while one subject did not have a preference of where she wanted to give birth, another favored private over public facilities.

> *"No thank God. I go to private hospitals–I don't go to public hospitals." (Calla, 24)*

> *"Only private hospitals, you never went to a public hospital?" (Interviewer)*

> *"I went once and saw that it was really crowded so I only went to private hospitals." (Calla, 24)*

The participants also faced long wait times at clinics for walk-in vaccination appointments.

> *"One time [the doctor] told me to come back at nine and I went at ten, so I had to wait a while...about an hour and a half." (Hyat, 36)*

According to the participants, their Syrian identity prevented them from accessing timely healthcare. A pregnant subject noted she had difficulties vaccinating her oldest child because one of the clinics she visited appeared not open to Syrians. Another participant felt that the long wait time at the public facility was a direct form of discrimination against Syrians.

> *"Yes, I went there [a public hospital] but they made me wait so long [that] my child got so much worse, so I had to take her to a private hospital...I paid 300 liras and all of it was because we are Syrian." (Cyra, 27)*

Besides the challenges mentioned above, the refugee participants had little to no knowledge of the healthcare benefits available to them. For example, one participant wanted to know if she needed an identification document for vaccinations (Farrah, 24). Another participant changed facilities because of unclear hospital requirements, such as whether government hospitals were allowed to charge money for prenatal services (Amina, 25).

Cost was an additional barrier. When asked about whether she received regular access to healthcare during current and past

pregnancies, one participant who was 6 months into her current pregnancy, responded:

> *"With my first son, yes, I used to go regularly but now I am not going because I do not have the money to go to a private doctor and I cannot make an appointment at a public hospital." (Aaliyah, 26)*

The process of scheduling appointments was also difficult for the participants, especially during the season of Ramadan. As per the account of a study subject, appointments for routine prenatal care may also be scarce due to her difficulty in setting prenatal care appointments.

> *"There is no [physical] line [at the public hospital]...Every time that I call them they postpone me to the next month then I come back again the next month and they tell me to come back the month after that so it has been six months like that...I went once to a private doctor on the European side and I called again but they told me there was no appointment" (Aaliyah, 26)*

Overall, participants did not find it difficult to remember scheduled medical appointments. The subjects discussed a variety of methods for remembering their medical appointments; some of the subjects who had to remember follow-up vaccine appointments referred to vaccination cards provided by the vaccinating facility with a designated follow-up date. One subject stated that the facility would call her if she missed her appointment, and another participant was reminded by her Turkish neighbor. Alternatively, study participants relied solely on their memory of the provider's verbal instruction to return for a follow-up appointment. According to another subject, the MHRS (the Ministry of Health's Central Appointment System) mobile application was also not easily accessible. In the case of setting and remembering vaccination appointments, most study subjects indicated placing their faith in physicians to provide the date that a child should make vaccination appointments. Physicians typically recorded this information on vaccination cards that the parents could refer to. However, one subject in the current investigation was not given a follow-up date.

Facilitators

Among the study participants, accessing healthcare was facilitated by more inclusive health systems and community support. For example, one subject noted that Syrian physicians staffing newly opened immigrant health centers made her feel more comfortable.

> *"When they opened the health centers for immigrants, we relaxed because of the Syrian doctors." (Aaliyah, 26)*

Moreover, as many of the subjects did not speak Turkish, Arabic translators in healthcare settings were commonly cited by participants as helpful during their healthcare experiences. Syrian physicians who speak Arabic fluently were preferred. Outside of the health system, two participants stated that their Turkish neighbors helped them navigate the healthcare system by making appointments on their behalf.

Use of technology

All the participants were actively using their mobile phones. Social media applications and communication applications (e.g., WhatsApp) were the most common reason for using the phone other than contacting their family globally. While not a standard approach for scheduling appointments, such communication apps may also facilitate appointment scheduling with private facilities. However, one refugee participant did not have regular access to wireless internet and did not utilize communication applications because she was restricted to using her phone credit. In addition, some participants knew they could arrange their health appointments through the MHRS phone number; however, none of the participants successfully utilized the MHRS application. Among other routine uses of social media, one participant used her network to find customers for her informal hairdresser job where she provided services at her home.

Experience with the mobile health application (HERA App)

Overall, the subjects said they found the mobile application easy to use and clear with regards to design. One participant had previously attended a training session with the HERA team. However, despite attendance at the training, the subject did not use the application for its designated purpose (e.g., she did not enter her children's information to calculate the vaccination date reminders). Some other individuals said they thought the application was useful but noted that they did not understand how to use it and would need more time to learn about it.

> *"Do you find it difficult to open the application?" (Interviewer)*
>
> *"I can learn little by little." (Hyat, 36)*

One major feature that the participants liked about the application was that everything was accessible in Arabic, which is seldom the case for most of the online information. Another application feature, namely, the location finder for the nearest healthcare facility, was found to be particularly useful, especially when taking children to the hospital. One participant said that she can directly show it to the taxi driver, eliminating the need for giving directions and improving communication.

The location feature of the HERA application was the most-favored by multiple participants. Upon opening the mobile application, the photo-taking feature was not as obvious to users. However, once the purpose of the feature was clarified (e.g., storing medical records digitally), the participants seemed more interested in the feature. While the participants mostly understood the features, the mHealth application's relevance and feature navigation was unclear to some.

All the subjects said they would recommend the application to their pregnant friends or those with children. Participants had differing opinions on which feature they found most useful, with the most common answers being the vaccination reminders and the health information resources. Some participants also reported feeling less stressed about missing the vaccination appointments as the application could send them reminders.

Some participants felt reading about pregnancy, healthy nutrition, and other topics helped with their anxiety and worry about their pregnancy, especially for first-time pregnant women.

> *"I liked that you can read a lot of information about pregnancy especially because I do not take care of myself and during pregnancy I feel very depressed, I sometimes feel suicidal." (Aaliyah, 26)*

Responses on the mobile application's user experience design generally focused on content recommendations. Pregnant study subjects recommended including information on symptoms associated with pregnancy, as well as health and wellbeing advice for infants and mothers during the postpartum period. For example, more details on nutrition for infants, newborn health indicators (e.g., recommended height and weight based on age), and potential health complications for mothers (e.g., thyroid issues, postpartum depression) were requested.

One of the major concerns was data security and whether the application shared personal data and sensitive information with anyone. For example, a participant highlighted that some refugees do not have formal refugee status or identification and that some potential application users may be married at the age of 16, which is legal in Syria but not in Turkey.

Another issue that came up was the lack of phone memory. Participants were afraid that their added information to the application would deplete their phone's storage capacity. Participants were also concerned whether their data (e.g., digitally stored health records) would be retrievable if something happened to the mobile health application.

> *"Did you download the application on your phone after the [mHealth app] training?"*
>
> *(Interviewer)*
>
> *"I did but my phone memory card is very bad, everything got deleted even the photos." (Farrah, 24)*

> *"The app is very nice, but what if it was deleted? I have a little girl and she likes to play with my phone so if I downloaded it again, will I have to reenter all the personal information?" (Calla, 24)*

Another critique of the mobile application's functionality highlighted that it was disconnected from Turkey's larger hospital health system.

> *"It would be better if this application was for a hospital, and we went regularly to that hospital and we would use it there. It would be nice because we would go regularly to that hospital." (Calla, 24)*

While a majority of subjects did not specify any changes in the design of the application (n = 8), scheduling medical appointments was desired by a participant. Although this could indicate an overall appreciation for the current mobile application's design and usability, alternative reasons for the limited responses may be: (1) the subjects had limited time to use the mobile application, and (2) social desirability bias in which social norms discourage the subjects from directly critiquing the mobile application in front of interviewers associated with the mobile application's developers.

Discussion

The current research investigation aimed to provide insight into the most significant mHealth features which should be considered when designing mobile health applications for refugee populations. Overall feedback from this limited sample of users was positive; refugee women found the mobile application for preventive maternal-child healthcare extremely useful and were willing to recommend it to their peers. Important insights about the refugee healthcare experience for Syrian women living under temporary protection in Turkey were also explored in the study, including prior healthcare experiences, knowledge of the system, challenges to accessing care, use of technology, and specific application-related features.

Moreover, there appeared to be a high usage of mobile phones with internet capability among the study participants. Although the young median age (24 years) of study participants might have contributed to higher levels of mobile device use, in general, the Syrian population that has taken refuge in Turkey is very young; 50% are under the age of 18. Given the rapid growth of the immigrant population, with more than 400,000 Syrian refugee children born in Turkey since 2011 (21), high smartphone penetration may be viably leveraged for future refugee-directed interventions. There further appeared to be desire for understanding vaccine and antenatal care importance,

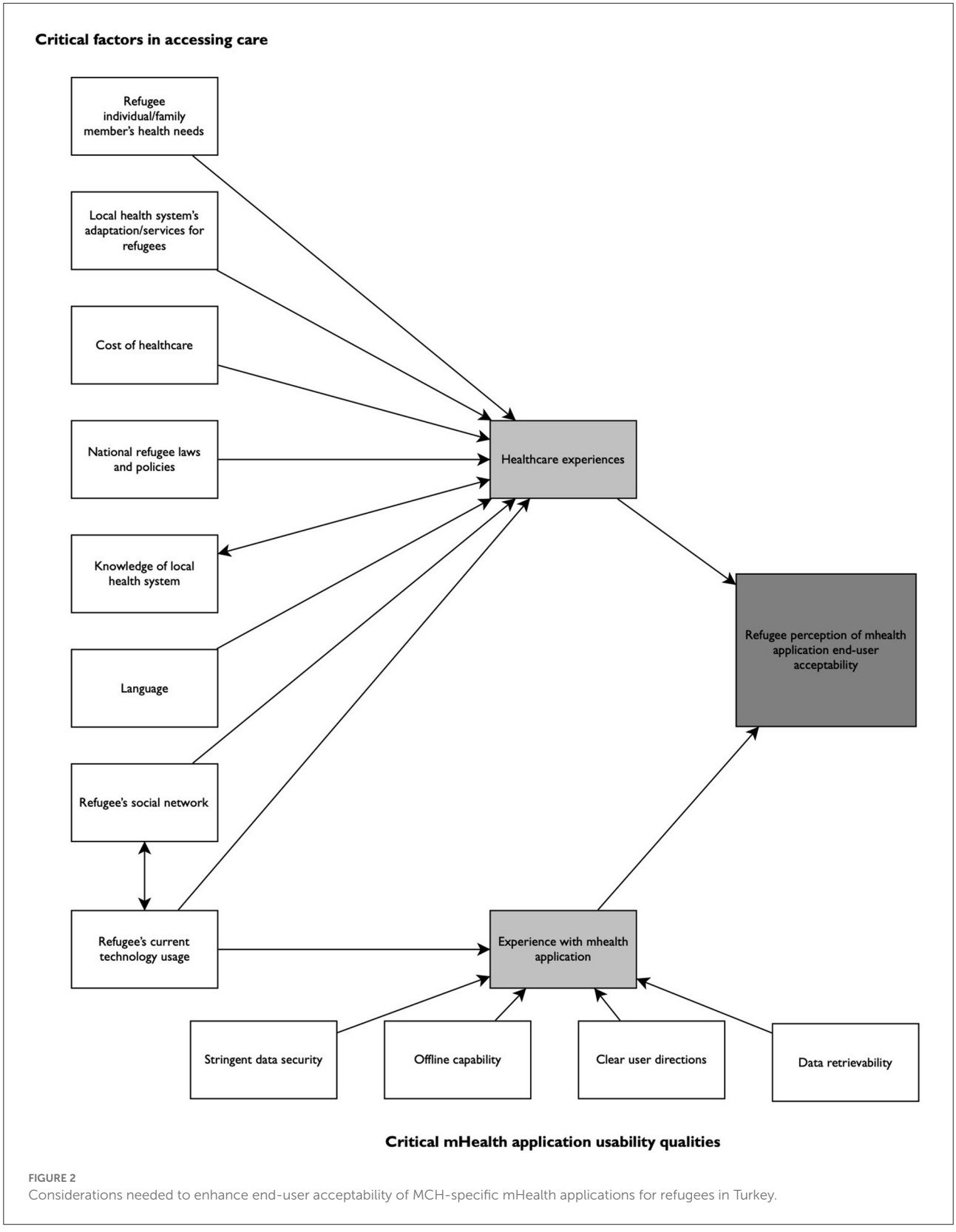

FIGURE 2
Considerations needed to enhance end-user acceptability of MCH-specific mHealth applications for refugees in Turkey.

with only one participant indicating hesitancy toward the vaccination schedule.

A few specific themes offer opportunities for further study. First, participants valued the vaccination reminder and the health information features the most. This is consistent with prior systematic reviews and a recent meta-analysis demonstrating improved vaccination uptake with health education and mobile phone appointment reminders as a pre-recorded message, particularly a combination of voice and text message, in low- and middle-income countries (LMIC) (22–24). Unfortunately, although the potential for mhealth interventions to improve vaccination coverage appears clear, existing studies in LMICs and vulnerable populations are reported as low to moderate quality (25). The dearth of rigorous studies in countries or populations facing the greatest barriers to immunization impedes evidence-based practice implementation in these settings.

Second, the use of emergency services was an important theme highlighted in this study. The participants had limited knowledge of available emergency services and the type of services provided. Although the participants did not appear to frequently use emergency services, it is possible that there was a lack of awareness that these services exist. For example, the emergency calling feature within the application recurrently received positive feedback, as the concept of a centralized ambulance system or services was not available in pre-war Syria. Participants who had been in Turkey for less time did not know what to do in emergency situations, representing future areas for targeted education and intervention.

Third, the impact of language barriers on the ability of refugee women to access healthcare was another consistently referenced opportunity. Although Turkey and Syria are neighboring countries, they do not share the same language or alphabet. Even prior to interfacing directly with the healthcare system, participants indicated the need for network assistance from Turkish neighbors to set up appointments, with a preference for Syrian-run clinics. The need for translation services often creates an informal market for interpreters within proximity to hospitals, to approach Arabic-speaking patients and provide assistance for a fee. Current interpreter services in hospitals are limited through a Turkish Ministry of Health employee. There is no reliable formal access to in-person translators, which may create additional utility for mobile-based services and refugee-specific interventions. Additionally, the participants viewed the application's Arabic language setting as one of the most favorable features.

The challenges that the refugee participants faced when seeking healthcare were critical in informing how to enhance the usability of a MCH mobile application for refugees in the Turkish context. The subjects often discussed how their healthcare decision-making process was deeply influenced by the trade-offs between the use of public and private facilities. Refugee patients discussed uncertainty about their ability to access specific services or facilities based on their identities as Syrian refugees or their official refugee status. While the Turkish health system has created a formal legal infrastructure for refugees to theoretically access care, discrimination continues to exist as the practice of administering such care is left to the discretion of individual providers. Systemic discrimination against Syrian refugees may also arise from the design of the health system. For example, provider payment incentives based on performance indicators (e.g., patient retention during routine prenatal follow-up appointments) can discourage providers from accepting migratory patient populations, including refugees, who may not as reliably follow up for care.

An additional challenge participants met was scheduling medical appointments. While some participants who were more familiar with the local resources were able to schedule appointments through Turkey's Central Physician Appointment System (MHRS), others would wait for an appointment at the facility. Some leveraged their extended social network by asking their Turkish neighbors to make appointments on their behalf. Since scheduling appointments can reduce appointment wait times and potentially increase the utilization of antenatal care (24), expanding appointment scheduling features or resources in the application may be beneficial for improving maternal-child healthcare.

The participants' recommendations for improving the mobile health application focused on expanding the available health information content, especially including resources on treating postpartum depression and mental health during perinatal care. The aspects of the mobile application the participants were most hesitant about centered around privacy concerns and data security, with regards to whether data was retrievable if a mobile device is replaced. Providing a clear explanation about the application's security protocols to ensure the privacy of their data, as well as providing secure cloud storage may improve refugee users' trust in the application's performance.

Previous research has cited "price value" as the cognitive trade-off between the monetary cost needed to use the application and the perceived quality or benefits from the application as a critical feature to increase the acceptance and use of mHealth technology (26). Although the HERA mhealth application is free for refugee users, access to affordable wireless internet and phone data may have implications on the application's perceived price value. The continued development of offline use could help mitigate this factor.

Through an exploratory examination of the end-user perceptions of a novel mobile maternal-child healthcare application developed for Syrian refugee women, we were able to identify valuable considerations that refugee mobile health application developers should take to increase an application's acceptability. As depicted in Figure 2, a refugee's perception of a mobile health application is likely informed by their own

healthcare experiences and the usability of the application. While there are many factors that influence an individual's healthcare experience, directly identified factors from Syrian refugee participants are critical for the ongoing content development of focused mHealth applications. Additionally, further exploration of the challenges and concerns the participants described with application use, can enhance uptake among this vulnerable patient population. The participants' concerns and questions about the described application inform critical mHealth usability qualities for current and future refugee mHealth applications.

Strengths and limitations

Strengths of this study include a targeted focus on a doubly vulnerable population: Syrian refugee women is a study population often marginalized from standard data. The unique focus on the Turkish health system, which has been adapted to include refugees, provides a setting where financial access to healthcare does not introduce an additional barrier to care. Finally, local staff conducting this study using a grounded theory approach enabled the necessary rapport to allow for an exploratory understanding of users' actions in a local context, and with data depth and richness (27, 28).

The present study has several limitations. The research investigation relied on the participant's self-reported perceptions of the application, which, while important in exploratory studies, is susceptible to response and social desirability biases. The generalizability of the study is further limited by selection bias as the participants were recruited at local refugee organizations and the sample size is small. These participants may better reflect the experiences and interests of those with increased support as compared to more marginalized refugees at the periphery. Finally, sharing the application under facilitated supervision may have unintentionally provided application guidance for this subset of users, which may affect the generalizability of findings for future users in the community.

Conclusion and future implications

This study explored perceptions, barriers, and facilitators to enhance the acceptability of a mobile application in refugee populations. User experiences have been categorized at the intersection of critical factors in accessing care and critical mHealth application qualities, to describe refugee healthcare experiences and their perceptions of a novel mHealth application. Based on the end-users' direct experience of the HERA mHealth application, several practical adaptations can be further explored. More basic and upfront education of the specific goals of the mHealth application and its personal significance to the user should be provided, prior to education about specific application features, in order to optimize buy-in and sustainability of use.

Finally, expanded integration within the health system for more bi-directional interface with hospitals and clinics may increase application utility if healthcare providers can also view and add specific visit-related information. The mobile application intervention's theory of change premise is to facilitate the user's understanding and navigation of the health system to regularly access care. As such, enhancing the application's inter-operability with the subjects' health system could be beneficial for attaining the desired user experience and the application's purpose. However, data security and privacy for a politically vulnerable population would remain an important challenge in the implementation of these adaptations.

Exploring the acceptability of similar types of mHealth solutions will require further research on the readiness of (1) local infrastructure to accommodate the integration of mHealth, and (2) national level stakeholder collaboration to ensure health systems integration. While this study provides promise into initial user perceptions, further prospective research is needed on long-term retention and use of mHealth applications for refugee women and other displaced populations.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by Acibadem Mehmet Ali Aydinlar University Medical Research Ethical Board. The patients/participants provided their written informed consent to participate in this study.

Author contributions

CM and AS designed and implemented the intervention and coordinated all aspects of the study. CM performed data collection, data analysis, and drafted the initial manuscript results. AS and NN assisted with qualitative analysis and coding. AS drafted initial methods. NN drafted the discussion as well as provided critical manuscript revisions and advisory support. CH drafted the introduction and provided critical revisions of the entire manuscript. All authors agree on the final submitted version of the manuscript.

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Conflict of interest

Authors AS and NN are founders of HERA Digital Health, a non-profit that created HERA App, the described open source mhealth intervention. Neither receive funding or compensation for this role.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2022.1025675/full#supplementary-material

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Environmental scan of mobile apps for promoting sexual and reproductive health of adolescents in low- and middle-income countries

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Background: Adolescence is a period of emotional, mental, and physical change. To increase health seeking behaviors, reduce risky sexual behavior, and improve sexual and reproductive health (SRH) knowledge, adolescents require support and access to SRH services. Providing evidence-informed SRH knowledge to adolescents in low- and middle-income countries (LMICs) can be a challenge as they face unique barriers such as lack of confidentiality, fear of refusal, and stigma from cultural norms. Increasing availability of mobile apps necessitates a comprehensive evaluation of the quality and classification of these SRH mobile applications so that accurate and evidence-based information is reaching its users. Failure to provide SRH services can have damaging effects throughout their development.

Objective: Provide an overview of current adolescent SRH (ASRH) mobile applications targeting adolescents in LMICs by evaluating their quality and classifying their characteristics.

Methods: 21 search terms related to ASRH mobile apps was developed. These terms were searched in the Apple IOS store and Google Play stores. Inclusion and exclusion criteria were used to screen these apps. Resulting apps were assessed using the Mobile App Rating Scale (MARS) tool. Data extracted was used to rank order each app and identify any gaps in quality.

Results: Search strategy yielded 2,165 mobile apps. Of these, only 8 were assessed using the MARS tool. Functionality subdomain scored highest at 4.6, while Information scored lowest at 2.5. None of the assessed apps contained information on the MARS items: Evidence base and Goals. Too Shy to Ask had the highest individual app mean score of 4.1, while e-SRHR scored lowest at 2.3.

Conclusions: The goal of this study is to classify and rate the quality of mobile apps designed to promote ASRH behaviors and knowledge in LMICs. Numerous apps were reviewed and all of them failed to provide evidence-based and goal oriented SRH information. Strengths include

ease of use, navigation, and gestural designs. Weaknesses include evidence base, goals, willingness to pay, customization, and interactivity. These findings can be potentially used to guide future app development and educate decision makers responsible for policy changes.

KEYWORDS

sex education, adolescents, sexual and reproductive health education, mobile applications, mHealth

Introduction

Adolescence is a dynamic process where an individual goes through many physical and psychosocial changes. In this phase, individuals are transitioning from childhood to adulthood by going through rapid changes in sexual, emotional, social, and mental health (1). The World Health Organization (WHO) defines adolescents as persons between the ages of 10–19 (2). This is a vulnerable time as they must learn to navigate a variety of obstacles ranging from sexual experimentation, developing sexual identities, sexual relations, and lack of self-esteem that may impact their physical, mental, and emotional health. Furthermore, insufficient knowledge of sexual and reproductive health (SRH) in adolescents can contribute to unintended pregnancies, unsafe abortions, and sexually transmitted infections (STIs) (3). Globally, over seven million adolescent females unintentionally become pregnant as a result of poor SRH education (4). While many developed and higher-income countries have legalized abortion, many developing and lower-income countries still contain repressive laws on abortion (5). In fact, of the estimated 20 million global unsafe abortions, 95% of them occur in developing countries (5). A large gap exists in SRH between higher income and lower-and middle-income countries (LMICs). For instance, maternal morbidity in Sub-Saharan Africa is 1 in 13 while in the United States it is 1 in 2000 (6). This substantial difference in higher-income countries compared to LMICs necessitates greater support for adolescents in these regions regarding increasing health-seeking behavior, and accessibility to SRH services and information such as birth control, STI prevention, and LGBTQ+ information. However, adolescents in LMIC seeking SRH services and information often find that their needs are unmet and experience unique barriers to accessing SRH information and services (7). Some of these include misconceptions regarding SRH information due to familial influences such as low parental education and low family socioeconomic status (8), accessing SRH services and information is considered a stigma and taboo for young unmarried people, hesitations surrounding healthcare provider confidentiality (7) and fear of refusal also exists among many adolescents as being sexually active at a young, unmarried age goes against many societal and cultural norms in LMICs (9). For example, menstruation is greatly neglected in LMICs as many girls have misconceptions regarding menstruation resulting in feelings of unpreparedness, fear, and anxiety (10). Although adolescents have physically developed bodies, their growing cognitive and emotional faculties necessitate further educational support on SRH. Knowledge and safe practices gained by adolescents from SRH services will support and guide their health and developmental milestones before they transition into adulthood. Failing to provide confidential, accessible, and stigma-free SRH information and services to adolescents irrespective of country income status can be detrimental to their current and future relationships, sexual health, and overall well-being (11).

Increasing production of mobile phones and the availability of affordable data plans in LMICs are steadily transitioning these countries more into the digital world (12). This can be attributed to the increased enthusiasm adolescents display about new technologies (13). For instance, 70% of South African adolescents own mobile phones and 6% use Internet services daily (14). As a result of increasing mobile ownership, digital tools for promoting adolescent SRH have achieved many positive results such as increased use of condoms and awareness of the negative consequences that arise from risky sexual behaviors (15). Using mobile apps to promote SRH education and services can be highly effective in overcoming the barriers that prevent adolescents in LMICs from accessing health services free from stigma and lack of privacy. Another appeal of mobile technology as a health promotion tool is that it can provide accurate, cost-effective, confidential, and tailored health promotion information to adolescents (9). A study in Ghana found that mobile health (mHealth) programs for adolescent girls were effective in increasing SRH knowledge and parental support despite the cultural barriers present in the target population (16). Interactive components of mobile technologies report improved adherence, involvement, and motivation among adolescents learning safe sex practices (17). Previous interventions regarding mobile technologies illustrate that mobile phone applications particularly have great potential to provide safe, accurate, and high-quality SRH information and support to adolescents in LMICs (9). Mhealth interventions contain a broad range of technologies, such as websites, web applications, and mobile applications to name a few. Unlike other alternative digital sources, mobile applications allow users to interact offline and provide a greater sense of security as apps must first be approved by the app stores before use (18).

On the other hand, web applications require an active internet connection to function (19). Mobile application use is thus more valuable in LMICs as resource constraints often struggle to provide quality, high-speed internet (20). For these reasons, only mobile applications were investigated in this study.

With the increase in cell phone accessibility and usage in LMICs, access to SRH knowledge is easier for adolescents (21). However, little information is available about the quality and characteristics of these mobile apps. A systematic approach is needed to evaluate the quality of adolescents' SRH mobile apps to ensure that adolescents are receiving the most accurate information in an accessible manner. Mobile apps that are culturally conscious and inclusive are more effective in improving sexual health practices and outcomes (22). Adolescents need to receive proper evidence-based SRH information to make informed decisions. Therefore, evaluating the quality and characteristics of mobile apps developed for adolescents living in LMICs is imperative to improve ASRH outcomes.

In this study, a systemic evaluation of the existing SRH mobile apps developed specifically for the adolescent population in LMICs will be achieved through an environmental scan approach. While previous studies have been done to evaluate the quality of ASRH mobile apps, few have been focused on LMICs. For instance, a content analysis on comprehensive sexual education apps focused on teenagers and young adults in the United States concluded that current apps mostly contain education on STI and pregnancy prevention rather than a holistic and comprehensive based education (23). Content such as anatomy and physiology, pregnancy and reproduction, personal safety, healthy relationships, identity, sexual pleasure, STIs and HIV, and communication and interpersonal skills were analyzed (23). Despite these categories, app quality and characteristics such as the presence of evidence-based information, ease of use, and appropriateness for the target group was not evaluated. Furthermore, this study also highlights the need for comprehensive SRH for adolescents in LMICs where reproductive outcomes and socioeconomic statuses tend to be poorer (23). Another example of a lack of ASRH in LMICs can be seen in a mobile app named GirlTalk which was developed by researchers to educate adolescent girls regarding sexual and reproductive health in the United States or more specifically Rhode Island (24). Although this study concluded that Girl Talk is a reliable and accessible educational tool for adolescent girls to use, there is a need for such studies to expand to adolescents of all genders in LMICs (24).

As opposed to previous research, this study will systematically classify and rate the quality of SRH mobile apps for adolescents residing in LMICs. The findings from the environmental scan will offer information on [1] the quality and characteristics of mobile apps available to promote adolescent SRH in LMICs and, [2] areas of improvement for the development of future apps, thereby potentially improving access to SRH information to adolescents in LMICs.

Methods

Study designs

An environmental scan (ES) is used to identify current SRH mobile applications (hereinafter referred to as "apps") available in the IOS App store and Android Play store. Furthermore, the Mobile Application Rating Scale (MARS) screening assessment tool is used to perform app quality assessments. Although environmental scans are commonly used in the business sector, they are not as well-established in the healthcare services context (25). A working definition developed by researchers of an ES scoping review defined environmental scans as a form of inquiry that collects and synthesizes existing information from internal or external environments to examine current landscapes, practices, policies, etc. so that future policies, models, and structures can be built to improve patient safety, programs, and overall quality (26). An ES is particularly advantageous as it allows for information to be gathered from an environment where evidence-based information surrounding a specified topic has not been developed yet (27). In comparison to rapid reviews and other forms of literature reviews, collecting information for an ES is not restricted to databases containing peer-reviewed and or grey literature. For this reason, an ES was the preferred method of research due to the lack of peer-reviewed and grey literature publications present that assessed the quality and characteristics of mobile apps currently available. An ES is also beneficial in that it allows us to systematically assess internal factors that may be impacting the quality and characteristics of ASRH mobile apps in LMICs (28). Internal factors are application quality and its characteristics. Through assessment of internal derived factors, all data trends that impact the quality of mobile apps can be used as evidence to educate decision-makers and guide app developers on improvements needed for ASRH in LMICs (29). After mobile apps are scanned from the app stores, the Mobile Application Rating Scale (MARS) screening assessment tool is used to perform app quality assessment.

Search strategy

Since our research objective is to assess SRH apps for adolescents in LMICs, we searched for apps available in the largest stores in the world: Apple IOS store and Google Play store. According to the website Statista, the Google Play store contains the largest number of available apps in the market at around 3.5 million smartphone applications (30). Apple store is the second largest app store in the world and contains roughly

2.2 million apps available to the public (30). As there were limited to no studies investigating mobile apps for ASRH in LMICs in peer-reviewed and grey literature, information on these apps could not be collected from these sources. For this reason, mobile apps were scanned from the App store and Play store. To discern whether the mobile apps collected focused on ASRH in LMICs, a set of inclusion and exclusion criteria were created to screen the mobile apps. Before searching for the apps, 21 key search terms were created and run through the custom software individually. This custom python 3-based software was built using an iTunes App store Scraper and a Play store Scraper, in which a CSV file of non-personalized search results was generated. This was used to create an index of applications and their characteristics. The databases of apps searched were the Google Play Store and Apple App Store, from both the US and Canada. The custom software returned the first 50 search results for each search term, for each of the 4 stores searched, before removing duplicate results and creating two final lists of apps: one from the CA and US Play Store, and one from the CA and US App Store. Apps from these stores were then collected and categorised based on app title, publisher, description, primary category, and price. 21 key search terms that were developed and then searched for in our custom electronic software:

1. Adolescents
2. Teenagers
3. Youth
4. Sex
5. Sexuality
6. Sexual health
7. Reproductive health
8. Sexual and reproductive health education
9. Sexual and reproductive health services
10. Pregnancy
11. Contraceptives
12. Safe Sex Practices
13. Sexually transmitted diseases (STDs)
14. Sexually transmitted infections (STIs)
15. Abortion
16. Low- and Middle-Income Countries
17. Developing Countries
18. Mobile Applications
19. E-Health Literacy
20. Mobile Health (mHealth)
21. Pre-marital sex

Application screening

Our search strategy yielded a total of 1107 results for the App store and 1060 for the Play store. These results were organized into a Microsoft Excel 2019 spreadsheet in tabular format and were screened based on our inclusion and exclusion criteria. Microsoft Excel was used given the ability of this software to permit a systematic screening process in an organized manner. For an app to be considered, it must meet all inclusion criteria and exclusion criteria. To assess whether an app met the criteria, reviewers examined the app name, description, pictures, and developer name. For example, when discerning if an app targeted LMIC adolescents, reviewers examined the "About this App" section for any indications of the name of any LMICs or words such as "teenager," "adolescents, and "youth." One reviewer screened apps against our a-priori inclusion and exclusion criteria, which was verified for accuracy and completeness by a second independent reviewer. Any differences in app screening were discussed between reviewers until a consensus was reached.

Five inclusion criteria and four exclusion criteria were:

Inclusion criteria:

1. Contains content related to sexual health education
2. App's intended audience is adolescents (age 10-19 years)
3. App still exists in the Play/App store when being assessed.
4. Target to adolescents living in LMICs as defined by World Bank
5. Compatible for phones available to LMICs

Exclusion criteria:

1. Did not address any component of sexual health/sexuality
2. Not in English
3. Paid
4. Developed for a specific event such as a conference

Before apps can move onto the assessment phase, we ensured that apps must target the population of interest and contain any component of sexual health education. Specifically, they target adolescents living in LMICs so that the desired demographic can be investigated. In addition to demographic, apps must still exist in the stores when being assessed so that reviewers can evaluate them. Lastly, the app must be compatible with phones available in LMICs so that it can still be used by people in those regions and reviewers can provide an accurate overview of current apps available in the market. If an app did not address any component of sexual and reproductive health, it was excluded from the study to maintain objectivity. Apps that did not contain content available in English did not proceed into the assessment phase since the research team's primary language is English and thus cannot conduct assessments unless the content is readable. In addition to language, paid apps were also excluded, This was done to accommodate lower- and middle-income status of users and to also search for accessible and cost-effective resources. Lastly, apps that were developed for a specific event or conference were also excluded as they are found to be non-functioning outside of event purposes and thus unusable by the adolescent population.

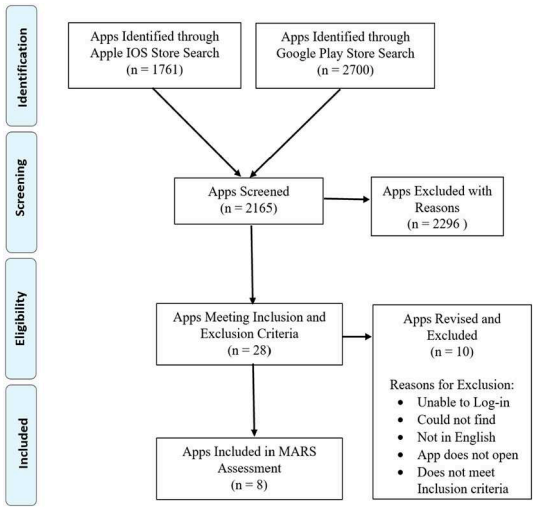

FIGURE 1
Cumulative scores for each app's MARS subdomain.

After screening, the included apps are analyzed using the MARS. Data extracted from the MARS was then converted to a graph (Figures 1, 2). Lastly, we evaluated for app quality and any areas of improvement by comparing item mean scores to each SRH app specific to adolescents in LMICs.

MARS quality assessment

The MARS is a validated tool used to evaluate the quality of mobile health applications (31). It is a simple and reliable tool that not only classifies and assesses the quality of mobile health apps but also can be used to provide evidence to app developers on creating new higher quality apps (31). Furthermore, a 2020 study found that the MARS tool has good to excellent reliability and objectivity (32). The MARS has a high level of interrater reliability that is ensured by using multiple raters who have been either trained or developed a shared understanding of the target group of apps (31). In this study, two reviewers were trained on how to use the MARS and assess apps. When ambiguity arose, both reviewers clarified the meaning of MARS items and reviewed until a consensus was reached. This approach was done rather than averaging the scores of both reviewers to maintain a high level of interrater reliability. Objectivity was ensured by excluding the subjective quality subscale from the overall mean app quality score (31). Due to its high interrater reliability and objectivity along with its simple and multidimensional uses, the MARS tool was used to assess the quality of mobile apps in this study.

The MARS tool consists of five subscales: engagement, functionality, aesthetics, information, and subjective quality. Within each subscale are three to seven items. For instance, the functionality subscale contains three items: layout, graphics, and visual appearance. Layout item examines whether the app's arrangement and size of buttons, icons, and content are appropriate and zoomable if needed. The second item, graphics, asks how high the quality or resolution of the buttons, icons, and content are. Lastly, visual appearance examines the quality of appearance of the app, and how memorable or poorly designed the smartphone application is. Each item consists of a scale of one to five. Reviewers will assign each item a score from this scale and then later assign a consensus score. These scores are then averaged so that each app can be ranked and compared in terms of app quality (31).

Data extraction

To analyze apps using the MARS scores, data must first be extracted. We used the MARS scale, a scale-based expert assessment tool, to characterize smartphone applications. Using Excel, we categorized our included apps in a tabular format and two reviewers (AP, SK) independently scored each app to collect our data. To assess each app using the MARS tool, two reviewers (AP, SK) installed each approved Apple IOS app and Android Play store app onto their respective devices. Once installed, reviewers created an account for the apps so that content could be accessed. Then, reviewers spent 10 mins interacting with each app before using the MARS scale to calculate item scores. Reviewers first filled in descriptive and technical information about the app. They then proceeded to app quality rating. Reviewers start with the engagement subscale, for each item – entertainment, interest, customization, interactivity, and target group – and assigned a score out of five. The same was done for the rest of the subscales (functionality, aesthetic, information, and subjective quality) and items. When reviewers began rating the information subscale, published literature was searched to examine whether apps had been trialed or tested. Apps that had not been tested at all were assigned a score of zero rather than N/A so that results could be quantified and converted to a graph. Data were extracted using this method for each of the 8 included apps. In the end, a consensus score was agreed upon by the two reviewers (AP, SK) and a final item score was assigned to maintain the MARS level of high interrater reliability.

Analysis

After extracting the data, we used descriptive statistics to analyze our data. We calculated the scores for each subscale item and then averaged the items to achieve a mean subscale score. These scores were then converted to a score out of five using a 5-point Likert-type scale, thus creating a total or overall app quality score out of 5 A score out of 5 is established so that it can

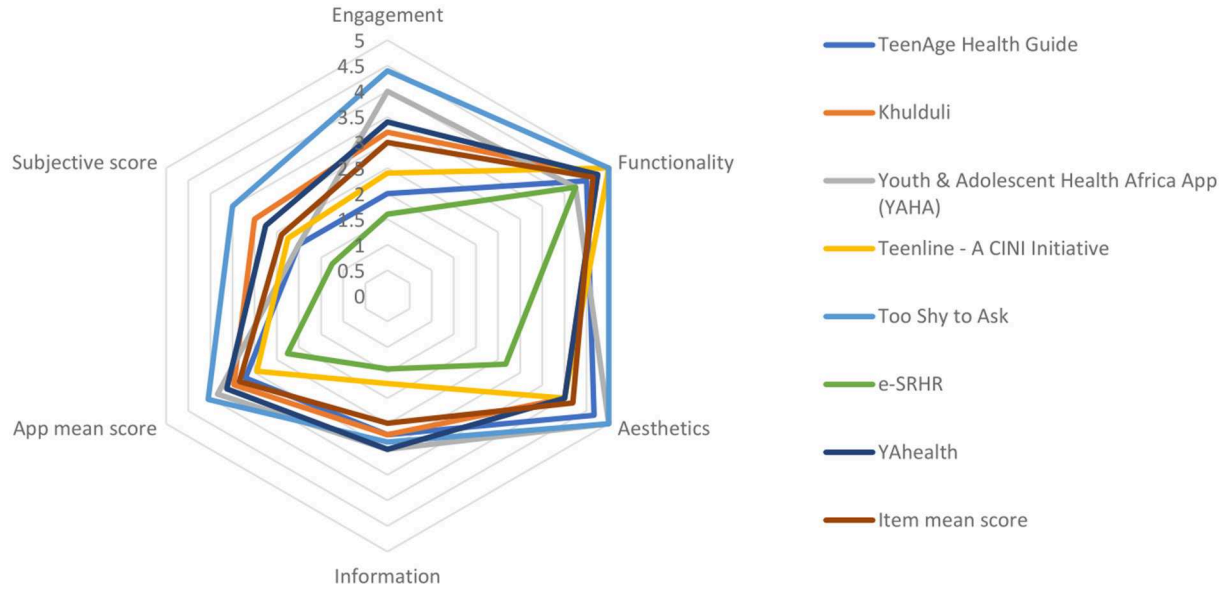

FIGURE 2
MARS mean item scores for each app.

be easily interpreted like the overall star ratings found in app descriptions. This was done because there is a high correlation between the MARS quality total score and its overall star rating therefore indicating that the overall MARS quality scores can capture the perceived overall quality described by the star rating (31). Another reason this process was done is because the MARS score and its subscale scores consist of high interrater reliability and internal consistency (31). To ensure objectivity, we excluded the subjective quality score from the total MARS mean scores. This is because the subjective nature of the app can decrease the objectivity of the MARS total score (31).

Using the MARS mean total scores, subscale scores, and item scores, we were able to rank order each app. MARS mean scores describe the overall quality of the app while the subscale and item scores describe the app's specific strengths and weaknesses (31). Therefore, these scores were used to identify any gaps in app quality and any areas of improvement.

Results

Screening findings

Our search strategy retrieved a total of 1,059 mobile applications for the Apple IOS store and 1,106 mobile applications for the Google play store. From the Apple store, 702 applications were duplicated and removed. While 1,594 applications from the Play store searches were duplicates and removed. Out of the remaining applications, 28 total applications were reviewed against the a-priori inclusion criteria, 20 applications were revised and excluded on this initial screening and 8 moved forward to the MARS assessment. Of the 28 mobile apps, all 6 mobile apps found in the Apple store were revised and excluded from the MARS assessment while only 14 of the 22 Play store apps were revised and excluded. The final 8 apps assessed using the MARS were all from the Google Play store.

Common reasons for the exclusion of 20 apps during the screening include reviewers unable to log in to the app, the app no longer available on the App store or play store, app content did not contain English, and the app no longer met inclusion criteria. For example, Too Shy to Ask, was available on both the Apple and Google platforms. However, it is important to note that this app could not be found in the Apple IOS store when searching for it in the search bar. One of the apps did not target adolescents living in LMICs and another required payment to access SRH content and resources.

After screening, apps that were included in the MARS assessment are: Digital Platform for Adolescent Health, TeenAge Health Guide, Khulduli, Youth and Adolescent Health Africa App (YAHA), Teenline - A CINI Initiative, Too Shy to Ask, e-SRHR, and YAhealth. These apps were then classified based on platform, focus, theoretical background, affiliations, age group, technical aspects, and region of development. All these eight apps functioned on the Android platform only. Content found in the apps mainly focused on topics such as alcohol/substance use, anxiety/stress, depression, and physical health. There were two apps, e-SRHR and YA health which

incorporated information on relationship issues. Whereas, another two, Digital Platform for Adolescents and Too Shy to Ask, included content on behavior changes. The MARS also asks reviewers to classify apps based on theoretical background or strategies developers incorporated in the apps. All eight apps provided some form of advice/tips/strategies or skills training to adolescents. They also offered forms of ASRH information or education in their apps. Some apps, Digital Platform for Adolescents, Too Shy to Ask, and Khulduli provided feedback. For instance, both apps contained SRH content quizzes in which the user can receive feedback on if they answered correctly or incorrectly. Lastly, two apps, Khulduli and YAhealth, allowed monitoring and tracking. More specifically, both apps allowed users to track their menstruation cycle. In addition to background, apps were also classified based on affiliation. Digital Platform for Adolescents, Khulduli, and YAhealth were affiliated with government programs. Teenline – A CINI Initiative and Too Shy to Ask were developed in collaboration with the NGOs. Lastly, TeenAge Health guide was developed by a university, Lady Hardinge Medical College. Of the eight apps, TeenAge Health Guide targeted both adolescents and the general population. While, Too Shy to Ask targeted adolescents, young adults, and adults as well. The rest of the six apps only focused on adolescent and young adult populations. With regards to technical aspects, two out of eight of the apps, TeenAge Health Guide and e-SRHR, could not be assessed as either contained features found in the 6 categories described in the MARS. Three out of the eight apps, Digital Platform for Adolescents, Youth & Adolescent Health Africa app, and Too Shy to Ask, featured an app community in which adolescents can ask and respond to others' questions or comments. Two of the apps, Youth & Adolescent Health Africa App and Khulduli, required web access required to access additional functions of the apps. One app, Too Shy to Ask, provided password protection upon entering the app and also required login feature to access app contents. In terms of region of development, Youth & Adolescent Health Africa App (YAHA) and e-SRHR were developed in Uganda. Furthermore, TeenAge Health Guide and Teenline - A CINI Initiative was developed in India. In addition to Uganda and India, the app Khulduli was developed in Nepal. An LMIC that developed the Digital Platform for Adolescents is Bangladesh. Lastly, it is unknown what country is responsible for developing apps Too Shy to Ask and YA health.

Study findings

Results of MARS subdomains and items, and app-related strengths and weaknesses

The 8 included mobile applications have an overall mean app quality score of 3.3/5. These apps scored highest in the functionality subdomain with a mean score of 4.6. Whereas, information scored lowest as part of the overall mean app quality, at 2.5. Overall subjective quality score rated low at 2.4. The rest of the subdomain mean scores are summarized below in Table 1.

MARS subdomains

As seen in Figure 3, the individual app means scores range from 2.26/5 to 4.05/5. From highest to lowest the apps score: Too Shy to Ask (4.1/ 5), Youth and Adolescent Health Africa App (YAHA) (3.8 /5), YAhealth (3.6 /5), Khulduli (3.0 /5), TeenAge Health Guide (3.2/ 5), Teenline - A CINI Initiative (2.9/ 5), e-SRHR (2.3/ 5). Too Shy to Ask scored highest in the Functionality and Aesthetics at 5/5, and Engagement, at 4.4/ 5, subdomains. However, for the Information subdomain, YAhealth and Youth & Adolescent Health Africa App (YAHA) score highest at a tied score of 3/ 5.

Apps strengths

The eight mobile apps assessed using the MARS tool highlighted that the apps scored highest for ease of use, navigation, and gestural design (Figure 1). Ease of use describes, "How easy is it to learn how to use the app; how clear are the menu labels/icons and instructions?" While, navigation inquires, "Is moving between screens logical/accurate/appropriate/ uninterrupted; are all necessary screen links present?" Gestural design, "Are interactions (taps/ swipes/ pinches/ scrolls) consistent and intuitive across all components/screens?" scored high. Following gestural design, performance scored next. These results suggest that mobile developers and researchers have ensured adequate functionality of the apps and should continue to include them in future app development.

Other mean items that scored adequately are layout, graphics, and visual appeal of the aesthetics subdomain. Layout asks reviewers if the "arrangement and size of buttons/icons/menus/content on the screen is appropriate or zoomable if needed?" The mean item score of graphics is slightly lower than the layout and it investigates the quality of graphics and visual design used within the app. Visual appeal scored slightly lower than graphics. This MARS item describes the level of attractiveness and appeal of the app through graphics and colour to enhance app features. These findings highlight that aesthetics, second priority to functionality, was satisfactorily developed by researchers when designing apps targeted to adolescents.

Lastly, the MARS item, accuracy, of the information subdomain scored adequately as well. This item examines whether the app description matches what is displayed within the app. This data implies that developers were somewhat transparent with their users as many of the apps contained all or most of the functions/components described in the app store description.

TABLE 1 MARS subdomain scores and overall app quality scores.

App name	Engagement mean score	Functionality mean score	Aesthetics mean score	Information mean score	Subjective quality mean score	App quality score
Digital platform for adolescents	4	4.5	2.67	2.57	3.25	3.40
Teen age health guide	2	4.5	4.67	2.71	2	3.21
Khulduli	3.2	4.75	4	2.71	3	3.47
Youth & adolescent health Africa (YAHA)	4	4.25	5	3	2	3.84
Teenline – A CINI initiative	2.4	5	4	1.71	2.25	2.95
Too shy to ask	4.4	5	5	2.85	3.5	4.05
e-SRHR	1.6	4.25	2.67	1.43	1.25	2.26
YAhealth	3.4	4.75	4	3	2.75	3.63

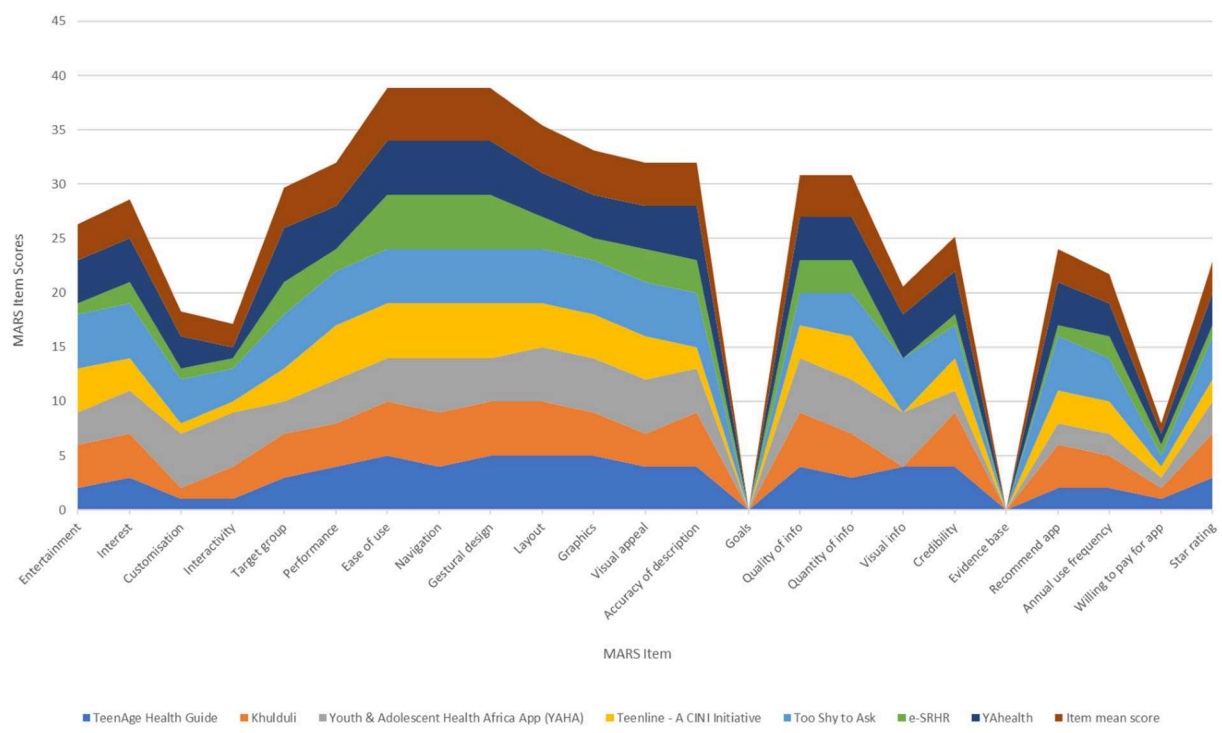

FIGURE 3
PRISMA diagram of the app screening process.

Apps weaknesses

Our study identified two major gaps in the MARS item scores (Figure 1). The first gap was the goal item score. This item asked the question, "Does the app have specific, measurable, and achievable goals (specified in the app store description or within the app itself)?" For all eight apps, the score for goals was zero. The second gap was the evidence base. This MARS item score was also zero for all apps. Evidence base asks whether or not the app has been tested and contains verifiable evidence published in scientific literature. Before rating the information subdomain,

reviewers carried out a literature search in which no results appeared. Hence, a score of zero was assigned to all apps. These gaps highlight the need for researchers to incorporate goals and a strong evidence base for the future development of SRH mobile apps to meet the needs of its users better.

In addition to goals and evidence base, there was a significant decrease in scores for the following items: willingness to pay, interactivity, and customization. Willingness to pay scored the least among the three, and it entails whether the user would pay for this app or not. Interactivity, "Does it allow user input, provide feedback, contain prompts (reminders, sharing options, notifications, etc.)? Note: these functions need to be customizable and not overwhelming in order to be perfect," scored slightly above willingness to pay. Customization scores slightly above interactivity and it asks, "Does it provide/retain all necessary settings/preferences for app features (e.g., sound, content, notifications, etc.)?" These results suggest that following evidence base and goals, researchers should then consider willingness to pay and focus on strengthening customization and interactivity so that their target audience can be more engaged.

Discussion

This environmental scan synthesized all existing SRH mobile apps targeted to adolescents in LMICs and evaluated their quality and characteristics using the MARS tool. Despite the growing development of mobile apps, little research has been done on evaluating SRH apps targeted to adolescents in LMICs. This environmental scan aims to fill that gap and provide a comprehensive overview and assess the characteristics and quality of these ASRH apps for those living in LMICs. The findings from our environmental scan add to the issue of whether mhealth interventions can provide accessible and evidence-based knowledge to adolescents living in LMICs. The increasing availability of mobile phones presents exciting opportunities in overcoming barriers faced by adolescents in developing countries (9). These obstacles include confidentiality, access to cost-free services, accessibility to stigma-free education, and restrictive SRH laws to name a few (7, 9).

Despite the eight apps included in this review, there remain few apps developed specifically for SRH needs of adolescents in LMICs. The lack of effective ASRH apps necessitates further app development since many common avenues of providing comprehensive SRH education have been ineffective against the barriers found in LMICs (33). Political and social factors can also heavily influence prioritization of ASRH services in LMICs, despite the economic and scientific evidence provided (34). In terms of social elements, school-based programs were found to be the most common approach for SRH education in Sub-Saharan Africa, however, their effectiveness is yet to be evaluated (35). Furthermore, community-based programs focused on HIV prevention rather than providing comprehensive SRH education to adolescents due to ideological and financial restrictions in developing countries (33). Another avenue for receiving ASRH education in LMICs is through parents (33). However, researchers noted that many parents were not taught SRH education themselves or felt discomfort thereby impeding their ability to guide their children (33). Furthermore, many LMICs have differing cultures, social attitudes, and policies regarding ASRH. For example, community members in rural Kenya perceive adolescents carrying condoms as deviant and should be subjected to punishments such as beatings (36). In fact, Western Kenya contains education policies that sanctions adolescents found to be carrying condoms in school (36). In terms of politics, the majority of restrictive abortion laws are found in LMICs (37). Moreover, many LMICs that still contain a low legal age of marriage for girls which can potentially lead to increased adolescent pregnancies and maternal death (38). To deal with these barriers, government commitments and mobile phone technologies can potentially lead to positive results (34, 39). In a report describing political commitments that can improve ASRH, researchers report that a government's commitment to integrating adolescent-friendly services into public health policy, such as HIV/AIDs prevention programs, has had positive outcomes on progressing ASRH and making it a national concern (34). Mobile phone technologies, such as apps, can be particularly valuable for adolescents in LMICs as information regarding contraception can be provided discretely and conveniently (39). These studies highlight the need for comprehensive ASRH education that is not only free from consequences but is also tailored to the needs of adolescents in these specific social and cultural contexts. Even in the eight apps that have been developed for these purposes and within the LMICs context, our review highlights that more work is needed in the development of apps that are useful and usable for this population.

Our study identified eight SRH mobile apps developed for adolescents in LMICs that were scored using the MARS scale. Although the MARS scale does not test for cultural context suitability, reviewers noted that some apps did include specific information relating to the app's origin of development. For instance, Too Shy to Ask was developed by the WE foundation and India's Metropolis Health solutions and contained information on the legal rights of Indian women and case studies examining Indian adolescents. Furthermore, this information was available not only in English but also in Hindi, the language of the origin of development.

The MARS tool showed us that all apps had the highest scores in the Functionality subscale (4.6) and lowest scores in the Information (2.5) and Subjective Quality (2.4) subscales. A higher rating for functionality demonstrates that app developers prioritized performance, ease of use, navigation, and gestural design over other items such as those found in the information and subjective quality subdomains. Despite a high scoring

of items found within the functionality subscale, there exist two major items from the information domain in need of development: evidence base and goals.

Although mHealth interventions can provide low-cost services, they often lack delivering evidence-based information (40). This was evident in our study, where there is a sharp drop to zero for evidence base (see Figure 1). This finding is consistent with other studies since many users have expressed scepticism and are reluctant to rely on mHealth tools because of their lack of credibility and validity (40). Adolescents specifically have expressed concern over the accuracy of health-related content found online and are reported to be drawn to information from reliable sources such as healthcare professionals or experts (41). These findings suggest that researchers should highly consider prioritizing evidence-based information when developing mobile apps for adolescents.

In addition to evidence, goals were also significantly absent across all apps. Literature reveals that setting specific and attainable goals can improve adolescent cognitive and social development (42). The process of goal setting itself builds self-regulation as it requires individuals to identify a goal, take necessary steps, monitor their performance, and evaluate and adjust their strategies (43). Researchers of previous studies have reported that participants found goal setting and goal attainment features as necessary motivational factors that should be included in mobile apps (44). Furthermore, they described goal setting as an important contributor to maintaining self-discipline, gradually changing their behaviors, and allowing them to monitor their progress and receive real-time feedback (45). By empowering adolescents to set goals via mobile apps, developers can create higher quality apps.

Researchers should also focus their attention on interactivity and customization when developing apps for ASRH purposes in LMICs. The MARS tool has shown that interactivity and customization items are significantly lacking in mobile apps (Figure 1). Interactivity is an essential component of app development as they not only increase user commitment and learning but also brings about a sense of belonging to the users (46). Previous research on mobile apps for adolescents reported that interactive components of an app improved adherence, involvement, and motivation (17). Another weakness found in many apps is customization. This component allows users to feel autonomous and thus more engaged with their health (47). In many LMICs, adolescents face numerous barriers in accessing SRH information and may potentially feel a lack of control over their health. A study on perceptions of ASRH and rights reported that adolescents lack the autonomy to access SRH information and services due to the taboo and stigma associated with this subject (48). By strengthening customization and interactivity features within mobile apps, researchers can design more effective apps for adolescents in LMICs.

A probable reason for a low willingness to pay score is because of low ratings found in other items across the MARS scale. An improvement in customization, interactivity, evidence base information and goal-setting features can positively influence user willingness to pay for these ASRH apps. Based on our findings, we suggest program developers and researchers strive to implement evidence base and goal-setting components and strengthen customization and interactivity components when developing future mobile app interventions for ASRH purposes.

Limitations and future research

Although the MARS tool has high interrater reliability, reviewer differences in education and culture can impact the scores given. This is because differences in opinions and how different cultures might teach ASRH education can influence the reviewer's subjective quality scores. Therefore, the findings should be interpreted considering several limitations.

Before rating mobile apps using the MARS, reviewers spent 10 min engaging with each app. This short duration gives rise to potential errors in interpreting app information or unintentionally excluding content necessary for rating apps. Moreover, having two reviewers assess the same apps regardless of needing a consensus score, can also lead to potential exclusions and mistakes.

Since app analysis is done from a Canadian adult perspective, the research team's positionality vs. the culture of the populations that these apps are meant to serve can potentially result in a higher score. In particular, all members of the research team have multiple post-secondary degrees and are residents of a higher-income country, Canada. This can influence the subjective quality subscale as researchers are living in an environment with greater resources, and thus may expect higher standards. For example, the ease-of-use MARS item asks reviewers how easy it is to learn to use the app. When exposed to more resources in higher-income countries, researchers may have a greater technology literacy and competency that may result in higher-than-normal scores rated. For a more accurate evaluation of ASRH apps for LMICs, consultation with researchers residing in these areas should be undertaken.

A unique feature found in many ASRH mobile apps was the clinic or nearby services' locative information. App reviewers were unable to evaluate this feature as it was unavailable in their region. If this app were evaluated in the region the app is meant to serve, a higher score may be awarded.

Furthermore, we did not include apps in languages other than English in our study due to feasibility reasons. This may have limited the number of apps included in this review given that many LMICs have a primary language other than English. In addition to languages, paid apps were excluded from our paper. As our target population is adolescents from countries of lower- and middle-income, many may be unwilling or unable to spend

money on apps. For this reason, we chose to exclude paid apps. A potential limitation of excluding paid apps is the exclusion of higher quality apps that target adolescents in LMICs from this study.

Additionally, we cannot assess connectivity and internet quality in the regions where these apps are being accessed. We hope that most of the apps' content can be accessed without the need for a high-speed or quality internet connection. However, we did not include this in our inclusion-exclusion criteria as this was difficult to screen for. This issue can potentially impact whether app information and services reach the end user.

Lastly, as this study is providing an overview of the quality and characteristics of SRH mobile apps designed for adolescents in LMICs, it is important to consider whether cultural context suitability is included within the apps. However, the MARS tool is not designed to assess whether apps contain culturally acceptable information. Moreover, the closest information relating to culture the MARS collects is information on who the app developer is and whether the quality of information is accurate, clearly communicated, and relevant to the topic of the app (31). Further assessment is necessary to evaluate accurate and culturally acceptable information on the effectiveness and usability of mobile apps.

As digital health tools are rapidly updating, further investigation is needed to analyse the efficacy and usability of these apps. Ultimately, additional research is necessary to understand the differences in the teaching of ASRH among different cultures to appropriately evaluate these mobile apps for LMICs.

Conclusion

Mobile health interventions in the form of apps have immense potential in providing accessible, confidential, and stigma-free SRH services and information to adolescents in LMICs. Despite many apps available claiming to provide these services, very few contain evidence-based and goal-setting ASRH information. This environmental scan thoroughly classifies and rates the quality of current SRH mobile applications targeted toward adolescents in LMICs, their strengths and weaknesses, and suggestions for future app development.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

Author contributions

Initial conception and design: SM. App screening, data analysis, literature search, and manuscript writing: AP. Data extraction: AP, SK, and SL-P. Manuscript revisions: SL-P and SM. Manuscript feedback: ZL. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Discernment on assistive technology for the care and support requirements of older adults and differently-abled individuals

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Assistive technology for the differently abled and older adults has made remarkable achievements in providing rehabilitative, adaptive, and assistive devices. It provides huge assistance for people with physical impairments to lead a better self-reliant daily life, in terms of mobility, education, rehabilitation, etc. This technology ranges from simple hand-held devices to complex robotic accessories which promote the individual's independence. This study aimed at identifying the assistance required by differently-abled individuals, and the solutions proposed by different researchers, and reviewed their merits and demerits. It provides a detailed discussion on the state of art assistive technologies, their applications, challenges, types, and their usage for rehabilitation. The study also identifies different unexplored research areas related to assistive technology that can improve the daily life of individuals and advance the field. Despite their high usage, assistive technologies have some limitations which have been briefly described in the study. This review, therefore, can help understand the utilization, and pros and cons of assistive devices in rehabilitation engineering and assistive technologies.

KEYWORDS

assistive technologies, intellectual disabilities, machine learning, telecare, autism

1. Introduction

Assistive technologies are used by individuals with special needs which help them in performing their daily routine or accessing computers for self-care activities. Globally, billions of people need assistive products but they don't have access to them. Wheelchairs, spectacles, prostheses, tablet organizers, memory aids, etc., are examples of assistive products. Advancements in assistive products help persons who need them to come out of their isolation, reducing their dependence on others for their health and care,

and building confidence in them. People with non-communicable diseases like stroke or diabetes, persons with mental health conditions like autism or dementia, individuals with slow health deterioration, and older adults need assistive technologies for their positive wellbeing and health.

Affordable assistive technologies are needed for people across low-income countries. Wheelchair access is required by nearly 75 million people, but only 10% of them have it. Of the 460 million people with hearing challenges, only 10% have hearing aids. Most persons with poor vision cannot access assistive devices to correct their vision. The development of affordable, easily available, non-invasive assistive devices will help those in need to lead a fully functional life (1).

Assistive technology has wide applications in multiple fields of individual care and is not limited to mental health. Its use is evident in dementia (assistive technology for memory support), autism, knee/spinal cord injury, quadriplegia, tetraplegia, exoskeleton, diabetes (therapeutic footwear), stroke, mobility, cognitive, visual, eating, hearing impairments, personal emergency response systems, accessibility software in education, computer accessibility, home automation, walkers, elderly care, IT accessibility, etc. Figure 1 offers some examples of application fields where assistive technology is used.

Assistive devices can also be used for individuals with gradual functional decline, orthotics, vehicle modifications, recreational aids, environmental controls, communication, assistance dogs, and learning. Diagnosing the impairments and assisting in the proper use of assistive technology can be made possible using artificial intelligence and machine learning techniques for more accurate diagnosis (2). The related apps and smartphones have made the process of applying assistive technologies easier, making it more user-friendly for the common man. This paper reviews assistive technology for individual care and the related work in literature.

1.1. Review outline

The following contributions are made through this review study:

(i) A detailed discussion on the available assistive devices for differently-abled individuals and older adults reviews their merits and demerits and provides key insights regarding their usage. This review includes rehabilitation research, which previous studies have overlooked.

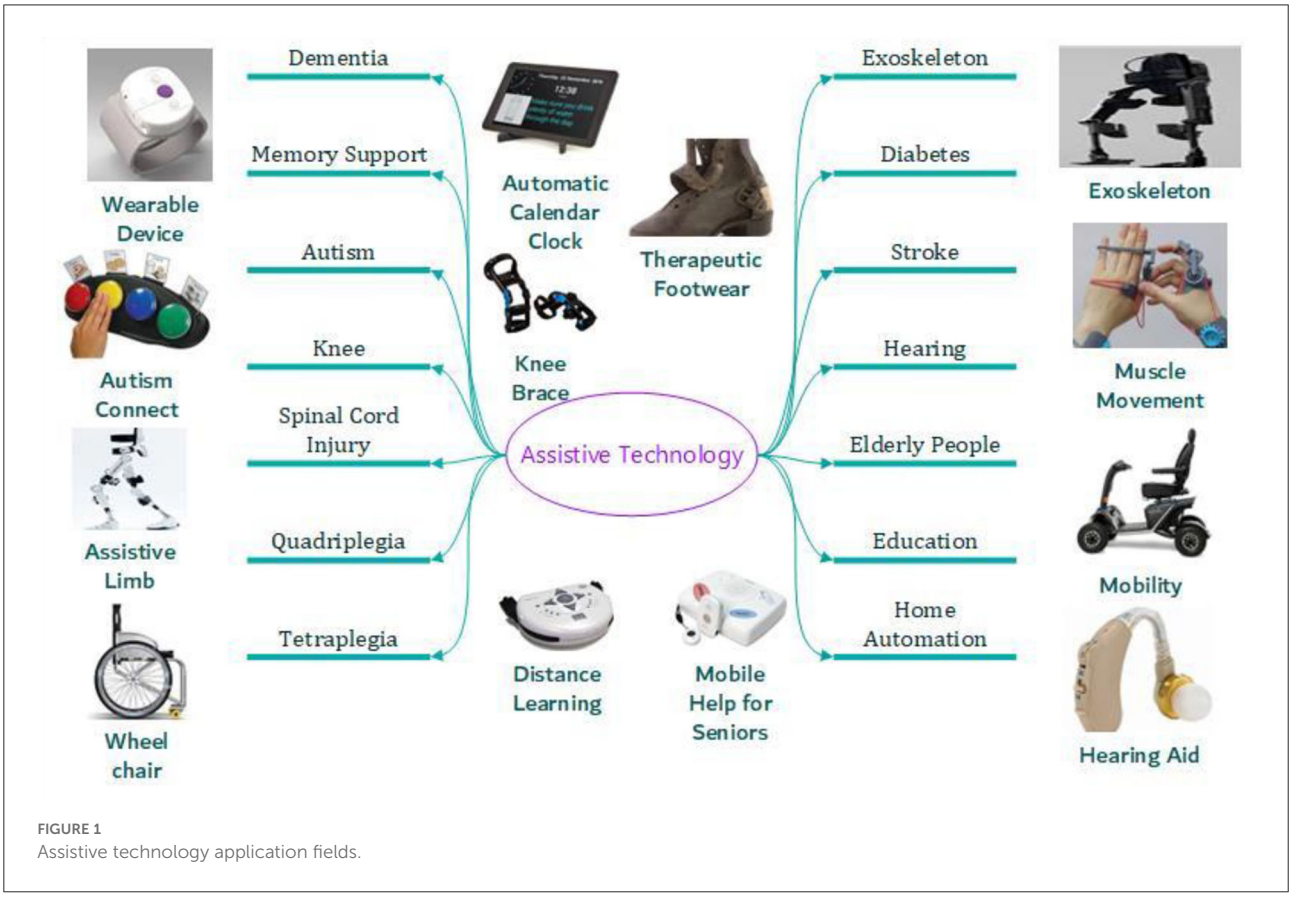

FIGURE 1
Assistive technology application fields.

(ii) A systematic review of assistive devices and their usage in various application fields of assistive technology is undertaken.
(iii) A comprehensive discussion reviews the challenges in using these devices for the differently-abled and offers suggestions on how they can be overcome.
(iv) Future research pathways relating to individual care using assistive devices for learning and computer accessibility are analyzed.
(v) This review emphasizes how most of the research on assistive devices can help advance research on other diseases.

2. Application fields of assistive technology

Robots-assisted surgery and AI-powered medical devices prove the emergence of machine learning (ML) and AI techniques in assistive technology, with doctors and entrepreneurs paving the path for an AI-based future. Regardless of an individual's ability, effective implementation of assistive technology improves the person's accessibility and quality of life. The application fields where assistive technology is used and applied are discussed below.

2.1. Mental health—Dementia

Dementia is caused by many diseases, which mainly affect the thinking, memory, and social abilities of the individual. Disorientation, confusion, poor motor functions, planning, organizing special needs, complex task handling, problem-solving, reasoning, communication issues, and memory loss are the cognitive changes caused because of dementia. Damage or loss of nerve cells and their brain connection is the cause of dementia. The different types of progressive dementia include vascular, frontotemporal, Lewy body, Alzheimer's, and mixed dementia. The individual may lack social behavior, language, memory, and attention. Table 1 provides an overview of recent research in dementia care.

Shuai et al. proposed a predictive model for use of assistive technology by individuals with dementia. A video streaming system using a mobile phone was developed with data mining approaches for classification. The streaming system provided reminders for everyday tasks, which is helpful for the individual and the caregivers. The extracted data included details such as gender, mini-mental state examination, age of the individual, patient's equipment skill, previous profession details, mobile reception, broadband, existing preparation, caregiver involvement, physical health, and extra support. A greedy algorithm step-wise regression was applied to select the best features. CART decision tree, KNN, adaptive boosting, support vector machine, decision tree, Naive Bayes, and neural network algorithms were applied for classification. K nearest neighbor (KNN) with seven features provided an accuracy of 0.84 ± 0.0242 (3). Additional data and more work on caregivers are required for improving the prediction model.

Suijkerbuijk et al. proposed a suitable private assessment model (designed in the form of a game) to appraise assistive technology for dementia-recovered individuals for their daily assistance. Twelve households having persons with dementia supported by a caregiver participated in the study to provide a first-person perspective for the research. The developed personal evaluation game included an ecologically valid tool that was explorative and qualitative. Options to take pictures, speak, and write were included in the game since the person's preferences were unknown. More options were included to facilitate longitudinal and flexible data collection to provide providing complete insights into the use of assistive technology for the person. The proposed game, "Aangenaam," collected data on experiences related to day-to-day happenings, personal events and targets, and physical and social context through flexible choice-based question cards. The question cards had intelligent, simple, personal, environment, and daily activities interactive questions.

A likely drawback of the proposed game is that the caregivers' involvement may potentially provide biased and less valid answers (4).

In another study, Sonja et al. (5) developed a usage-prediction tool and technology adoption for assistive technology for persons with dementia. Forty participants were included in the study and the parameters considered were MMSE, age, gender, previous profession, physical health impairments, broadband connection information, technology knowledge, caretaker participation, mobile phone usage, extra support by friends and family members, adoption level, alleged utility and caregiver's gender, and age. A binary logistic regression model was used for classification after factor analysis and assenting classification assessment. In their study, Juan et al. (6) provided a hands-on experience for persons with intellectual ailments using assistive technology and discussed its challenges and opportunities.

Bruce et al. proposed a modified "whack-a-mole" game for individuals with moderate dementia to identify intellectual capacity variations. Twelve adults with dementia were studied for 1 year using a mobile app game (7). Session score levels were measured and it proved on day progression.

2.2. Mental health—Autism

Autism is a neurodevelopmental disorder characterized by repetitive behavior and challenges in social communication. Affected persons find it difficult to express themselves and

TABLE 1 Summary of previous research on dementia care.

Reference	Model	Performance	Dataset	Influencing factors
Shuai et al. (3)	7 features were selected for predictive model. kNN proved efficient	Accuracy: 0.84 ± 0.0242	Data collected from 40 participants	The person living alone or not is also considered for study
Suijkerbuijk et al. (4)	Personal evaluation game—to evaluate the sleeping pattern of individual	First-hand experience data obtained	Data collected from 3 dementia patients. 26 photos, 3 s audio were gathered	425 answers received. Tablets, laptops, paper versions used
Sonja et al. (5)	Binary logistic regression model	82.5% accuracy; 0.89 sensitivity and 0.64 specificity	40 individuals data were collected from patient visit logs and databases	Four fold validation was performed. Adopters and non-adopters were identified
Juan et al. (6)	Mobile app for daily tasks micro-prompting, outdoor, indoor way finding,	Quantitative study results after hands on experience	NA	Studies carried out in ambient intelligence lab were discussed
Bruce et al. (7)	Game to identify cognitive ability changes—regression to measure related features	Session score level gave 1 false positive and 1 false negative for eleven participants	12 participants from adult day program joined the study	Minimental state exam score was considered based on their demographics

are unable to understand other people's thoughts and feelings. While they lag in some skills, they can develop skills like problem-solving and analysis. The types of disorder manifest in autism are Asperger's syndrome, pervasive developmental, childhood disintegrative, and autistic disorder. Autism levels are determined by support requirements at various levels and development assessments and constant evaluations can help in the early diagnosis of autism in children. The different levels of autism are as follows.

1. Asperger's Syndrome or level 1 spectrum is where the individual possesses good verbal skills and intelligence but faces problems in social communication.
2. Rett Syndrome affects the child's life, but family support can help them.
3. Childhood Disintegrative Disorder, which causes delayed development in social, language, and motor skills.
4. Kanner's Syndrome is a classic autistic disorder. The individual is alert, attentive, and intelligent but possesses issues in interaction, holding things, etc.
5. Pervasive Developmental Disorder—Not Otherwise Specified (PDD-NOS), where the individual exhibits mild autistic behavior.

Based on the level of autism, diet and behavioral modifications can help the individual. Technology helps children with autism to improve in multitasking. But digital technology makes the individual focus in one task at a time. There are app-based assistive devices that are currently available for autistic individuals. They are necessary for their development. But it is additional work for the caregivers/parents to minimize their usage and ensure that their wards do not become too dependent on assistive devices.

For people with autism, assistive technology can be used to improve behavior, academic skills, cognitive development, social skills, and communication. Some examples of assistive technology aids include social stories, social rule cards, social scripts, audio, videotaping, schedules, forewarning, directions, digitized speech, pencil augmentations, pencil replacements, and computer-based and tablet-based devices.

Noreen et al. examined the use of robots to improve learning and cognitive abilities in children with autism. LEGO Mindstorms EV3 robot was used for eight children and provided positive improvement in learning among them. It created a happy learning environment, engagement, interest, focus, attention, communication, and interactions (8) by adopting non-formal therapy and learning, supporting autism in early years, reinforcement cycle, action, and integrated activities with motor manipulation. However, not every school or person can afford to buy the robot, which is a limitation. One session with limited period access was given to each child which was not sufficient for the study. In addition, the study population was too small.

Along similar lines, Katrin et al. (9) reviewed robot-based intervention for persons with autism. The study participants were categorized based on age, gender, and wordings for participants. The robots were used for skill development like emotion, expression control, recognition, social convention, interaction and responding. The recommendations of the review were based on longitudinal studies, course of intervention sessions, study design, participants' experience with the robots, participants' characteristics, a measure of engagement, robot types, and supporting members assignation while in the study. However, further research is required, particularly in robot-based interactions for autism affected children with a greater number of samples.

Michal et al. proposed a stress-observing device for persons with autism. A wristband comprising autonomic wearable components with mechanical, electronic parts, and

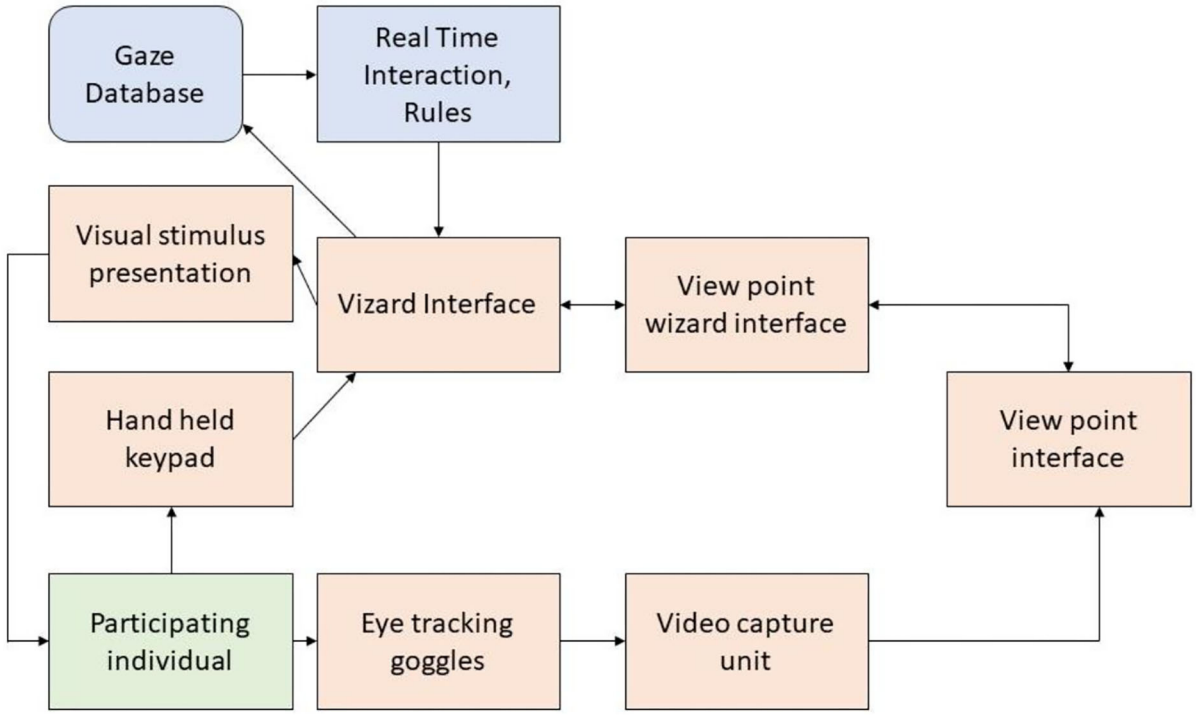

FIGURE 2
Data acquisition and control mechanism of the VR-based eye-gaze monitoring system.

software measured movement, temperature, heart rate, and skin resistance using sensors (10). Stress results in neuro-hormonal modifications in a flight-or-fight state. Therefore, the stress data of the individual was recorded over time on a device that was easy to use, flexible, and wearable. The device was helpful for therapists and educational institutions having individuals with autism. Similarly, Uttama et al. (11) designed an adaptive gaze-sensitive response technology for children with autism using virtual reality (VR). The real-time observing patterns helped quantify a person's engagement level and improve the children's social communication behavior. The device, composed of a VR-based task presentation module and a bi-directional conversation module design, included an adaptive response unit with performance-sensitive and engagement-sensitive components. The limitation of the wearable device is that it used a bidirectional conversational module and wearable eye tracker which is not suitable for less-functioning individuals with autism.

Uttama et al. (12) also designed a gaze-aware virtual social interactive system for children with autism. People follow different viewing patterns while communicating, so analyzing the eye gaze can offer a few indications. In this interactive system, a story is created in virtual reality (VR) using visual objects called avatars, with neutral, angry, and happy facial expressions. While interacting with the VR avatar, the individual's eye gaze is monitored. The data acquisition and control mechanism followed is given in Figure 2. The work-related event identifiers are stored in the gaze database. The eye tracker records the user's eye movement using a video recorder with Viewpoint software. The features extracted from the database are the mean blink rate, pupil diameter, average fixation period, and total fixation counts. Real-time feedback is provided to the user based on the acquired data and analysis.

In their study, Fabio et al. explored applied behavior analysis for treating autism by reviewing 86 articles and offering their insights. Persons with autism may be categorized as severe, moderate, or mild. The study analyzed the behavioral studies that were done in past but found no data to ascertain whether the observed behaviors were socially significant. In addition, the targeted behavior studies were incomplete because of limited data availability. The studies presented more user test results but their acceptance and validations were not included. Robots helped in motivating persons with autism to undertake repetitive and specific tasks (13). Web systems based on robots, image processing, gamification was developed for autism affected children. Cognitive ability of the autism individuals was different from those with other mental disabilities.

The features extracted from the system are the sum of fixation counts, the average rate of blinking, the rate of fixation, the average fixation from each segment of the monitored signal, and the average pupil diameter. The unit was tested with six adolescents for engagement measurement.

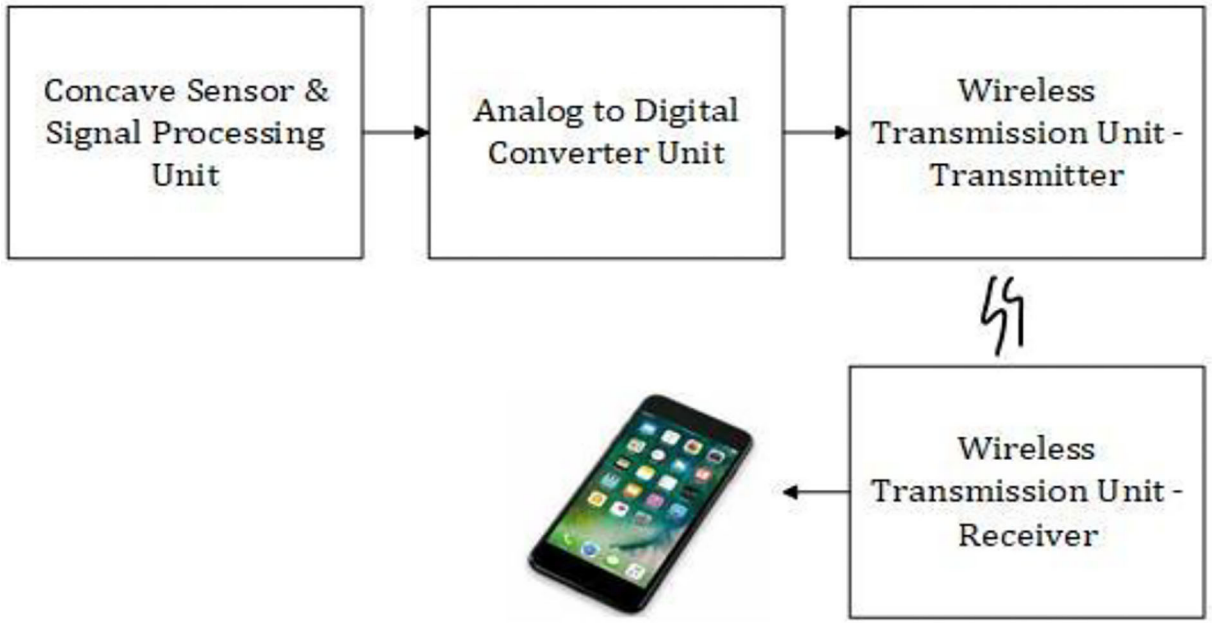

FIGURE 3
System design of the wearable pulse oximeter device.

2.3. Knee replacement

Knee arthroplasty or knee replacement surgery is required when the knee joint is damaged reducing mobility and causing extreme pain in patients. It can be caused by hemophilia, osteoarthritis, unusual bone growth resulting from disorders, injury in the knee, loss of cartilage resulting in knee deformity, blood supply issues causing the death of bone in the knee joint, or gout. The amputation rate caused by an infection resulting from a knee replacement is 0.1–10%. Knee replacement surgeries may be total or partial replacement procedures and some of the available assistive devices for knee replacement are folding shower chairs, quad, clip and pulling dressing aids, walkers, abduction pillows, and raised toilet seats (14).

Li Zhang et al. (15) reviewed assistive devices for the human knee joint based on mechanical system design components such as actuation, joint alignment, human attachment, and power transmission design. The control systems and sensing design were based on human device interaction signals, control system-based device signals, and control systems dependent on human manual signals. However, the actuator devices were bulky, stiff, consumed more energy, and heavy. Wearing comfort and good human device interaction with soft and passive actuators are suitable assistive devices.

For gait rehabilitation, Hao et al. proposed a user-dependent aid made of assistive knee braces. The brace was designed by configuring the appropriate stages of various assistive functions using a fuzzy expert system for gait analysis and reviewing the patient's physical condition (16). A reference key trajectory was generated based on the individual's gait and the force was measured using a cross-impedance controller. The objectives of the assistive functions were torque assistance and trajectory control (17).

In their study, Siyu et al. suggested a wearable knee assistive device for construction workers' kneeling tasks. The integrated inertial measurement units estimated lower limb pose and gait (18). These data can control the assistive torque of the knee joint with quasi-direct drive propulsion. The knee exoskeleton included a waist belt, shank support frame, loadcell, actuator, thigh support frame, elastic straps, hinge, linkage, and control electronics. The beginning and finishing of the kneeling gait were identified by a threshold-dependent kneeling gait recognition process (19). Comfort and fit on wearing the device had to be taken care of. A half-rigid assistive device for the knee exomuscle was developed by Zhang et al. (20) which used the advantages of soft and rigid structures. A route was developed for the tendon and the system removed the misalignment between the center of rotation of the knee joint and the device. Deterministic load compensation was achieved with 38 Nm assistive torque to the knee joint.

A wrist pulse-oximeter was developed by Grantham et al. (21) to find pulse rate and oxygen saturation level in an individual's blood which is of neo-reflective type. The data was wirelessly transmitted to a mobile phone for analysis. The system design is given in Figure 3.

Signal processing was done by low pass filters to acquire DC components, band pass filter, and amplifier to obtain the amplified AC component from the concave sensor module. The AD converter converted the signal to a digital component so that it can be easily sent to wireless modules and processed. The wristband and the smartphone are connected wirelessly with a transmitter and receiver.

Massimo et al. (22) modeled the human knee for assistive technologies using motion capture technology and an EMG-based musculoskeletal knee model. They proposed a muscle model based on infinitely stiff tendons which could speed up the muscle force computation and joint movement calculation accurately and 3D musculo tendon kinematics were derived from the model. The process included gathering human motion information by movement capture method, modeling and simulation of the logged human motion, and setting and implementing the EMG-driven model.

Using assistive control models, Mohammad et al. (23) proposed a motion estimation for the lower limb using ultrasound imaging. The rectus femoris muscle's ultrasound features were analyzed while on a non-weight-bearing extension trial. A random sample consensus (RANSAC) algorithm was applied for the segmentation of the muscle and fascicle after a multi-scale ridge filtering to excerpt the structures. The model parameters were estimated, though outliers and noise were presented by the RANSAC, in a two-phase hypothesis generation and evaluation technique. MSAC (m-estimator sample consensus), a modified version of RANSAC, could detect accurately even in the presence of other objects. Weights for cost function evolved from the grayscale intensities (24), and the angular velocity and the knee joint angle were found with an average root mean square error of 0.262 rad/s and 7.45°. However, deformation may lead to modifications in muscle morphology, resulting in a blurry image and reducing the accuracy of segmentation.

2.4. Spinal cord injury

Disks, ligaments, and vertebrate damage lead to spinal cord injury causing dislocation, spine fracture, and compressing or crushing of vertebrates. The related complications are bowel, bladder, and circulatory control, pressure injuries, breathing difficulties, bone density issues, depression, pain, sexual health, wellness, fitness, and muscle tone problems. Minimized functional movements and activity limitations at different levels suggest the need for assistive devices for individuals with spinal cord injuries. These assistive devices include wheelchairs, hand bikes, canes, crutches, adapted shoes, walking frames, full and semi-electric or manual beds, transfer boards, positioning devices, ventilators, etc.

Replacing a missing body part to perform the part's tasks is called a prosthesis. Neuroprosthetic devices can substitute for impairments in sensory, motor, or cognitive functions caused because of nervous disorders. These types of prosthetics could be transradial, transtibial, transhumeral, or transfemoral. Based on the specific needs of the person, full or partial prosthetic hands or feet can be replaced. Artificial fingers, noses, and eyes are also available.

Rudiger et al. (25) proposed a non-invasive hybrid neuroprosthesis to be used after spinal cord injury of paralyzed upper extremity functional rehabilitation. A hybrid system comprising orthoses and functional electrical stimulation can restore a fully lost arm tasking. Interfacing the brain and computer depending on motor images is an excellent alternative instead of a neuroprosthetic regulator. Lateral grasp helps in lifting flat things between flexed thumb and fingers, and palmar grasp positions the thumb in opposition to the index finger allowing easy handling of larger objects generated by grasp neuroprosthesis. The hybrid system was evaluated with performance metrics reliability, stability, delay, degrees of freedom, selectivity, and the number of discrete levels of activation.

For individuals with spinal cord injuries and muscle interfacing implantation, an intramuscular EMG- based musco-skeletal device was proposed by Jung et al. (26). Joint torques are estimated to control assistive devices with entrenched EMG sensors. There exists a non-linear relation between muscle activation and neural activation given by:

$$m\,(t) = \frac{e^{Su(t)} - 1}{e^{S} - 1} \tag{1}$$

where $m(t)$ is muscle activation and S is a non-linear shape factor, inside the range $(-3, 0)$. The best fit normalization is body weight times height joint torque normalization, which assists in analyzing the effect of weight and height on peak joint torque values.

Patients with cervical spinal cord lesions followed by coughing require assistance and in their study, Lior et al. (27) propose a sniff controller to self-help stomach functional electrical stimulus. Through changes in nasal airflow, the sniff controller can trigger peripheral devices. Slight changes in the nasal airflow are converted into electrical signals that can control exterior devices. It can control assistive devices for communication to mobility. The Functional Electric Stimulation (FES) is self-triggered by the sniff controller. The activated device could increase peak exploratory flow ±25–27%. The device setup had the following components as shown in Figure 4. The endoscopic video camera, microphone, nasal airflow measuring device, and signal amplifier are synchronized.

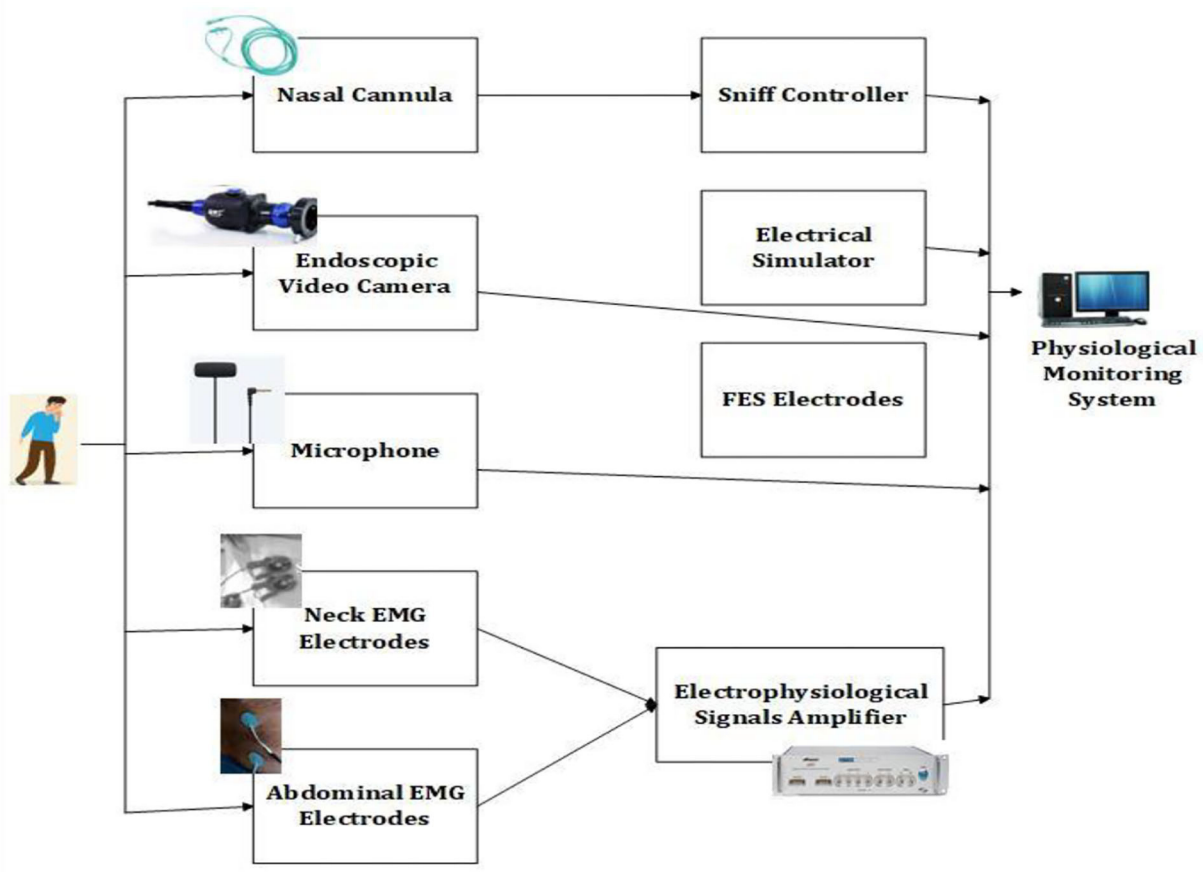

FIGURE 4
Experimental setup for cough stimulation.

Eight electrodes are connected with two sets of output poles for acquiring the data.

A mini wireless nasal sensor instead of a nasal cannula can be an optimal sniff-controlled system. The nasal cannula is a device through which supplemental oxygen therapy is delivered for individuals with lower oxygen levels, and can be used for low or high flow. It is used until the patient recovers from the illness and is replaced every 3 weeks of use.

Dae et al. (28) undertook a pilot study to identify the use of wheelchair-mounted robotic arms for spinal cord-injured patients. Two control modes were set, and performance was measured for baseline characteristics, psychometrics, and quantitative performance measures. Learning improvement by minimizing command count and mean task completion time was seen in the manual mode and variability minimization was seen in the auto mode. The study was conducted over 3 weeks and the steps involved pre-evaluation, initial training, top-shelf, bottom-shelf, and final training followed by post-evaluation. This assistive device could improve the pick and place tasks of the patients involving two shelf levels and six objects.

2.5. Exoskeleton

The biological capacities of humans can be enhanced to a greater extent by wearing an external frame support called an exoskeleton. It also helps to overcome injuries caused. A lower limb exoskeleton helps individuals when they are not able to perform their daily actions. They aid walking and work using electric motors. The upper limb exoskeleton is a wearable device joined to the arm. Signals to control the device are given by the user (29). Active exoskeletons are those with motors and passive ones are those without motors. The risk of musculoskeletal injuries can be reduced while lifting heavy objects using a powered or active exoskeleton. Passive exoskeletons are used to hold objects, provide ergonomic support, and prevent injuries. Quasi-passive exoskeletons are used to carry loads while walking and include a knee variable damper, and hip and ankle springs.

The exoskeleton gloves include actuators and sensors to mimic human muscles and nerves. Sarac et al. (30) surveyed hand exoskeletons for assistive, haptic applications, and rehabilitation. The treatment process and motor learning were significantly improved by using assistive technology during

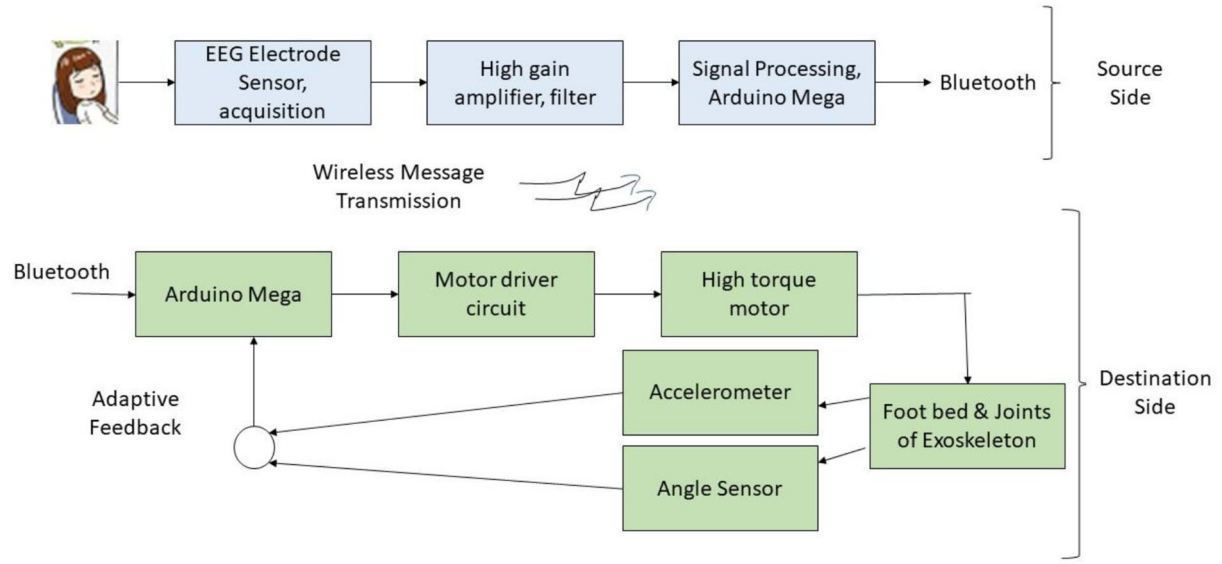

FIGURE 5
Experimental setup of the brain-activated multi-dimensional exoskeleton.

physical therapy sessions. A wearable hand exoskeleton gives accurate kinesthetic feedback through active force transmission using mechanical components. The features required from the device are safety, hand anatomy, affordability, comfort, and effective force transmission. Assistive exoskeletons help differently-abled persons to grasp and hold objects. For wider usage, the exoskeletons should be easily affordable, natural, wearable, lightweight, and portable.

Akim et al. (31) explored the application of assistive-powered upper limb exoskeletons, especially for older adults for performing their daily tasks. Beginning from the first prototype for upper limbs where the hand was attached to a string and modifying the string length exerted arm movement and the motor and control parts were located on the backside of the wheelchair, the authors review various prototypes. In the latest exoskeleton under research (AXO-SUIT) the user-robot interaction is carried out through the force sensors dispersed in the upper limbs. The limb movement at the joints is assisted by the actuators. Electric actuators providing the highest precision for position control, easy programming, silent operation, smooth functioning, and high repeatability were used with trade-offs in cost, size, and weight. Sensors that could analyze limb motions improved the interaction feedback between the exoskeleton and the user.

Wujing et al. (32) designed and tested a hip assistance soft exoskeleton with hip flexion, hip extension, and flexion assistance modes. A feedforward model controlled the assistive force with a proportional derivative reiterative learning controller. The proposed exoskeleton was analyzed during the walking motions. Based on metabolic reduction, the hip extension model recorded improved performance compared to hip flexion for single hip movement assistance.

Rehabilitation of post-stroke paralyzed patients through a brain-assisted adaptive lower limb exoskeleton is discussed by Vinoj et al. (33). The false rate of the device was minimized through adaptive sensory feedback. Impairment-based flexibility, emergency data transmission to caregivers, and a microprocessor-based brain computer interfacing system for signal transmission are some of the features of the exoskeleton which achieved a classification accuracy of 80%. A threshold for tilt is inbuilt to identify the fall of the patient and the caregivers are called for emergency rescue. Figure 5 illustrates the experimental architecture of the proposed brain-actuated exoskeleton, which had separate source and destination sides, and the human controls the exoskeleton. The electroencephalograph (EEG) signals are obtained by non-invasive method from the person. A set of fourteen electrodes calculate the measurement, including two reference electrodes. The signals are amplified and filtered for analysis (34). After windowing, the data is converted to digital and given as input to the microcontroller. The controller learns the data after extracting their features, for the commands right and left turn, sit, stand, and forward motion. Machine-learning-based training and testing were performed. Connection to the exoskeleton is through Bluetooth and the controller converts the results and motor action. Regular feedback is obtained for further modifications.

Walsh Hadamard transform extracts the user motion features to be sent to the lower limb and brain through Bluetooth. The extracted features and Hadamard coefficients are

then used for actual brain signal reconstruction (35). However, the inconvenience of wearing a headset and the high cost of the device are trade-offs of the device.

Patane et al. proposed a compliant lower limb multi-joint exoskeleton for pediatric patients with neural problems with their locomotion and ankle-knee motion. The wearable device with a position control worked in coordination with the individual's musculoskeletal system. 5.6 Nm/rad torque and 8.8% hysteresis were achieved (36). Walking assistance testing was performed, and the device assisted in the right foot landing in the gait cycle start. Heel strike, swing, mid and fore strike features were used for the device operation.

2.6. Diabetes—Therapeutic footwear

Insulin pens, syringes, pumps, sugar testing devices, strips, diabetes medical alert bracelets, etc. are the devices necessary for individuals with diabetes. Peak plantar pressure is found in older adults with diabetic neuropathy and therapeutic footwear is more efficient in making them walk comfortably. Lesions are not felt because of sensory damage, resulting in ulcers (37). The peak plantar value of 599.9 g/cm^2 on barefoot decreased by 4.3% using normal footwear; wearing diabetic footwear recorded a reduction of 22%. The use of therapeutic footwear has been reviewed by Gustav et al. (38) in their study.

2.7. Stroke

Stroke may lead to paralysis of the body on one side or weakness, alterations in understanding, learning, and speaking capabilities. Assistive technology for stroke-affected people includes live scribe echo smartpen, shower chair, Velcro fastenings, pocket talker, foot socker, echo dot, etc. Zih et al. (39) developed a 3-dimensional printed multi-functional hand device for assisting persons affected by stroke to grasp objects. They found that the hand clutch strength improved by 36% and adjacent weak energy by 54.1%. Biomechanical evaluations were performed in terms of hand function, strength, and statistical analysis. The device also improved the training frequency, rate of recovery, and level of stroke patients. Lateral pinch and grip force improvements were clearly visible.

Huang et al. (40) proposed a similar device for coordinated functional opposition for advanced prehensile motion and manual dexterity. Following informed consent, a baseline assessment was undertaken, and randomization was performed for a study population of ten. Measurement, manufacturing, and task-oriented training of the device were executed. Post-term and follow-up assessments were done to analyze the device's operation. A portable assistive glove for hand-impaired stroke patients was proposed by Heidi al. (41). Passive cyclical stretching with active assisted task-dependent training improved doing tasks and upper limit motor control. The components included a control box, linear actuator for extension forces as per tension sensor recordings, tension sensor, cable guides, and quick disconnect connector. High gain and clinical performance were achieved by persons affected by stroke using assistive gloves.

To help persons affected by stroke to recover their ability to walk, an assistive control method limb exoskeleton was proposed by Spencer et al. (42). The device worked without modifications with spatiotemporal characteristics of the joint motion. Even after a single session, improvements were visible in patients who used the device with modifications to the gait. Aaron et al. (43) designed a hand extension robot orthosis glove to assist hand-impaired stroke survivors. To extend and flex the fingers, along with the actuator, the gloves included tendons. Inertial measurement device signal thresholds automated the grasp assistance and the robot's finger extension. The glove comprised of a linear actuator, cable tie pawl, battery, microcontroller, selection buttons for manual and automated mode, cable tie tendons, battling glove, open palm, and finger thimbles. The robot orthosis glove provided promising results in terms of spasticity, tone range of motion, pinch, grip, block, box test, hand activity inventory, and Chedoke arm test.

Wing et al. (44) proposed a brain-computer interface to help stroke-affected people with motor ailments. Electrode manufacturing time was minimized with improved reliability and accuracy of 90%. Support vector machine (SVM) recursive feature elimination and fisher's criterion were used for the evaluation of the approach (45). Fisher's approach identified the relationship between the class label and features. Support vectors of the two classes were identified by SVM. For fewer channels, the performance index reduced exponentially. Muscular hypertonus and spasticity were seen in stroke-affected patients affecting their functional characteristics (46). Davide et al. studied the effects of visual feedback and training on arm stiffness while in assisted motion after a stroke attack. The objectives of the study were to get reliable values for the mechanical characteristics of the upper limb while in robotic therapy, acquire visual feedback on viscosity, and identification of arm stiffness effects to examine if the stiffness, training, and visual feedback depended on the level of assistance, speed, and position.

2.8. Mobility impairments—Wheelchair, prosthesis

Impaired body structures minimize mobility tasks in individuals which may be due to cerebral vascular accidents, limb or spinal cord injuries, multiple sclerosis, or other effects. Assistive technology for the improvement of their movement may be through devices like prosthetic limb control, peripheral nervous system boundary, computer vision improved control,

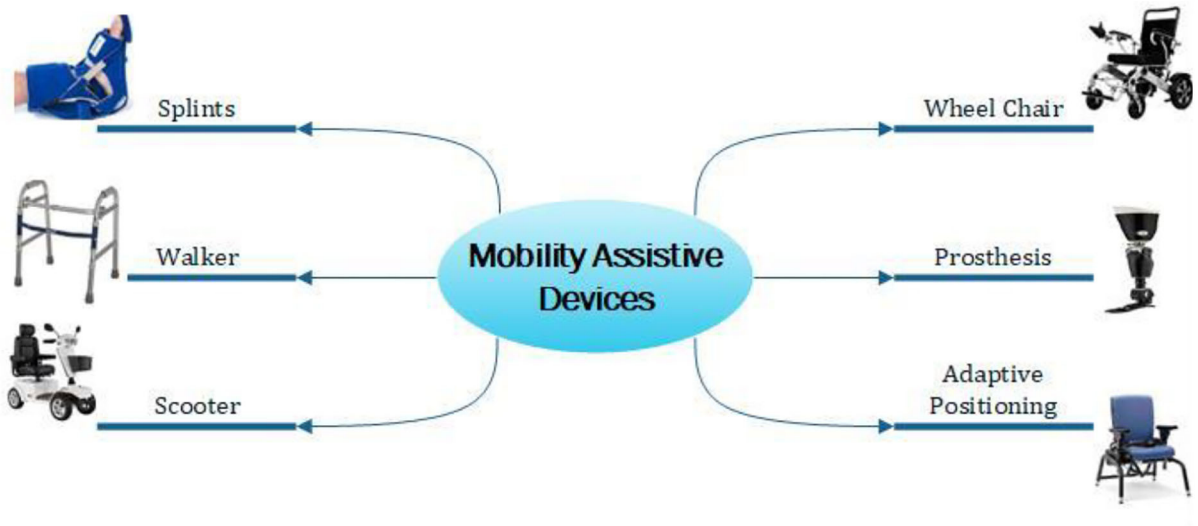

FIGURE 6
Mobility assistive devices.

kinematic, dynamic control, and mechanical exoskeletons. Figure 6 shows the mobility-related assistive devices.

Due to motor and cognitive impairments, powering a wheelchair is a tough task for motion-impaired individuals. Mobility assistive devices help individuals to move as per their wish. Automatic wheelchairs with wireless control facilities, intelligent robotics integrated electric wheelchairs, hand rim ergonomics, sit and stand wheelchairs, and illuminated and self-driving wheelchairs are some of the modern wheelchairs that have been developed. Richard et al. (47) proposed an automatic adaptation in the NavChair assistive wheelchair with a control system. Depending on the wheelchair's location and state, the suitable operating mode is chosen and operates through that. However, additional information needs to be provided to the Bayesian network for its improved tasking. Wearable vibrotactile haptics was used for powering the wheelchair in a study by Louise et al. (48). The navigation data was provided by four uniformly spaced vibrotactile armbands. The adaptive arm band reduced collision by 49%.

Emily et al. (49) designed an electromyographically controlled ankle-foot prosthesis to help with rock climbing. Subtalar joints and motorized ankle helped in free space motion. A robotic and traditional prosthesis measured the hip, ankle, and foot joint angles. Subtalar positions and ankle range were improved significantly, reducing maximum knee flexion and hip flexion angles by the proposed approach. The design specifications were 250 mm build height, 1,292 g mass, ±0.008 rad accuracy, 2.18 rad/s velocity, 0.55 Nm free space torque, and 100+ Kg max payload.

A tongue-controlled robotic arm prosthesis was proposed by Johansen et al. (50). The system proved to be efficient by 1.15 s compared to the standard EMG type, with an added feature of computer and environment control. Li et al. (51) proposed a gait evaluation and simulation device for hip disarticulation prosthesis testing. The human motion trajectory was adapted by the robot which had prosthetic thigh simulation. By training an adaptive neural network, the walking pattern was made possible. The neural network solved the big trajectory tracking mistakes and unstable movement. The tested prosthesis kinetic and kinematic data were collected for analysis.

The gait prosthesis device architecture can be seen in Figure 7. The Gaussian smoother used the data from the collected trajectory data. The data is mapped into a Prosthetic Thigh Simulation Robot (PTSR). The sensors are connected to the Hip Disarticulation Prostheses (HDP) and PTSR. The smoothed trajectory is mapped to the PTSR's initial position. The ground reaction forces are measured with a pressure-monitoring treadmill. The stability is controlled by an Adaptive Neural Network using the joints database.

2.9. Visual impairments

The assistive devices which may be applied for visually challenged individuals are tactile huge print keyboards, braille embossers, displays with braille, magnifiers, optical character recognition system, navigation assistance, wearable technologies, canes, screen readers, etc. These devices help individuals live independently by performing their day-to-day tasks. Figure 8 lists some of the assistive devices for the visually challenged.

A haptic telepresence system with depth, color camera, telepresence robot, and haptic interface was designed for visually challenged users to explore rich observation centers by Chung

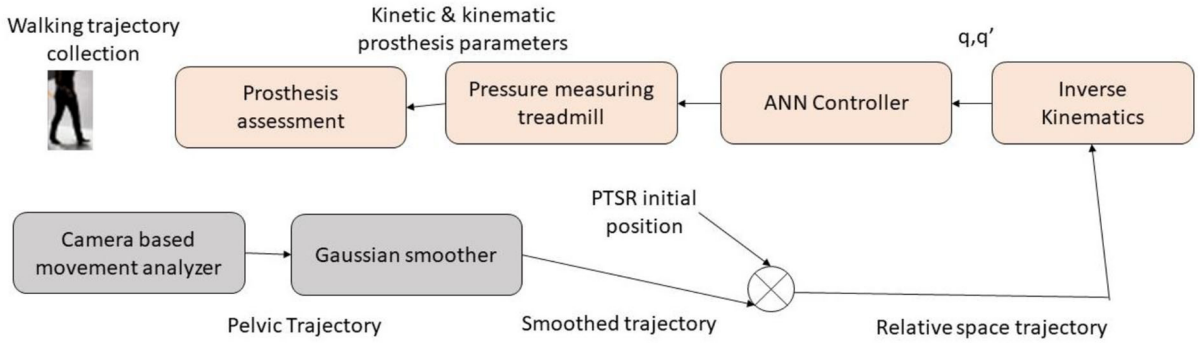

FIGURE 7
Gait simulation and evaluation device.

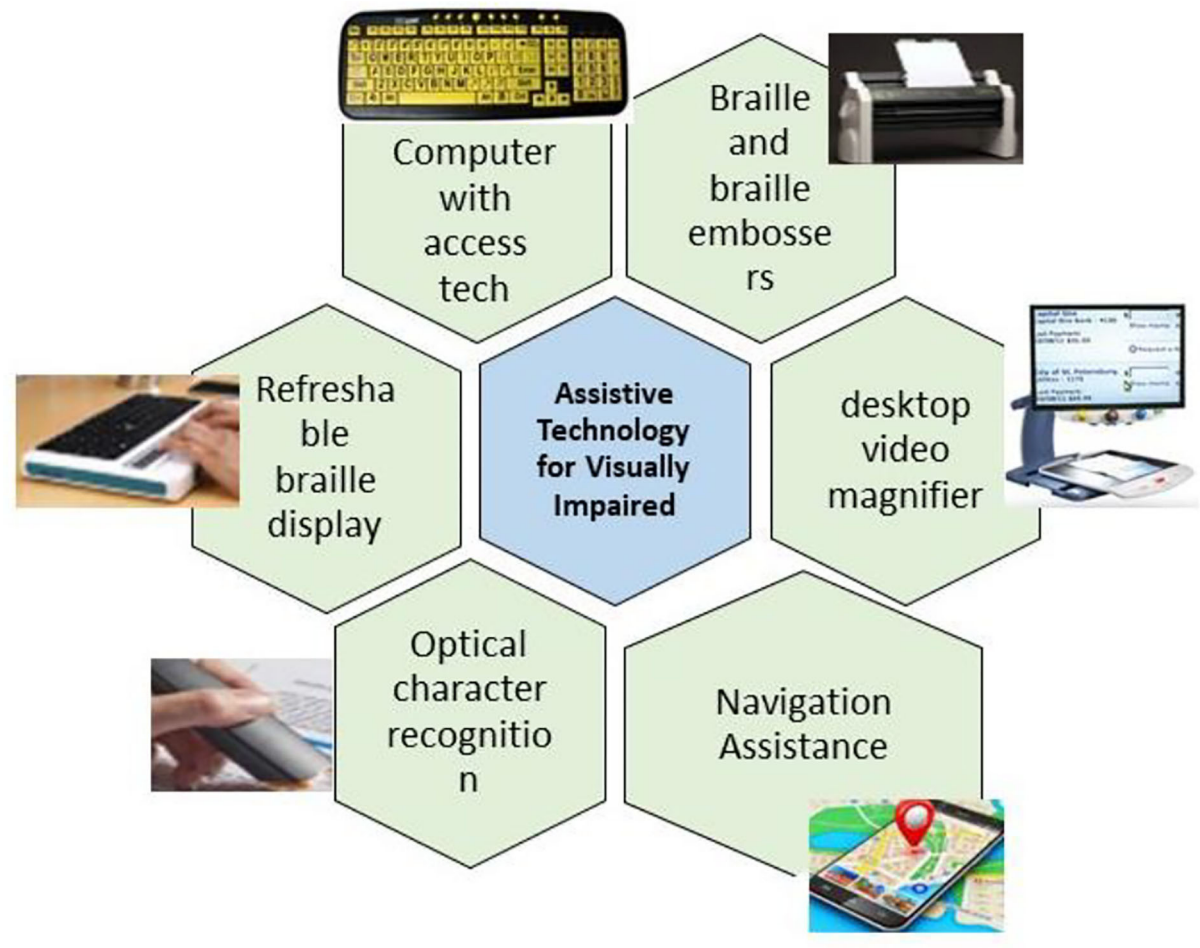

FIGURE 8
Assistive devices for visually challenged individuals.

et al. (52). Three-dimensional real-time spatial data access was achieved in the form of point clouds. Through the haptic interface and rendering, the individual can feel the 3D space and control the remotely available robot. By calculating the nearest surface distance and volume interpreting force, the visual proxy force feedback is obtained with a 3D map. Content adaptive

multimedia handling and a better sophisticated haptic sensation would improve the system's efficiency.

In the study by Barros et al. (53), educational robotics—CardBot 2.0 is proposed for programming teaching aids. On a table or board, the geometric cards are organized by the individual programming the robot. The teacher can include new languages or tasks for the student. Luis et al. (54) proposed a time-of-flight sensor for a book reader system integrated with a high-resolution CCD camera. The page curvature was corrected by integrating a high-resolution image and the low-resolution time of the flight sensor. The images in the book were flattened and the accuracy of reading was improved by a mathematical framework. 95% reading accuracy was achieved on reading 200 pages. The design setup included a heatsink, bracer, Argos3D-P100 sensor, a book holder platform, and a Canon G6 camera. The acquired images were matched, registered, corrected, optical character recognized, and forwarded to the text-to-speech unit.

2.10. Personal emergency response systems

The general personal emergency response system consists of a telephone line connected to a console, a radio transmitter, and an emergency response center. The device is compact and wearable. Voice dialers, touch-and-talk voice pendants, fall detectors, mobile emergency alert systems, and panic button help dialers are some examples of personal emergency response systems. Dahl et al. (55) studied a sensor-based therapeutic observant device that acts as an individual's alternative device with a caregiver view. Fall detection and user-initiated alerts were initiated by the device. The parameters checked were sensor trust, accuracy, ergonomics, form factor, user control, and system feedback.

2.11. Augmentative and alternative communication (AAC)

AAC is a communication means used instead of speech or writing for language and speech-challenged individuals. The AAC forms include aided (external support), unaided (facial expressions, gestures), low-tech, and high-tech AAC. its users include intellectually-challenged individuals, persons with autism, cerebral palsy, aphasia, traumatic brain injury, developmental verbal dyspraxia, locked-in syndrome, Parkinson's disease, amyotrophic lateral sclerosis, dementia, and multiple sclerosis.

Gemma et al. (56) presented an AAC device using communication boards and an electronic communicator's speech. The blocks communicate wirelessly. Based on the user's vocabulary and availability of symbols, the communication sheets were designed to be simple, cost-efficient, and with the added advantage of scalability. The sounds were played and recorded by the active sheets in the digital system. Tablets, computers, or smartphones can replace the digital system, providing improved efficiency. The communication sheets are A4 paper classifiers. The grouped messages belong to bigger boxes. Communication devices and electronic controls are powered by a battery source. The sheets provide data to the player through wireless means to get audio output.

Murat et al. (57) provided a brain-computer interface for AAC in clinical and technical domains. The input modalities to the interface include auditory, and visual event-related tasks, volitional cortical tasks, and steady-state evoked tasks. The factors that affect the speller's performance are inter-symbol interval, oddball effect, various matrices, flash organizations, gaze-based, error-related tasks, feature attention, and context information. The physiological input modality used was non-invasive EEG signals. A device with input as voice and outcome as a voice was developed by Mark et al. (58) for AAC to produce synthetic speech from distorted speech. The main device requirements were formulated from the developmental user-centered design. With less available training data, speaker-based automatic speech recognizers with mini vocabularies were built. Even perpetual data provided 96% accuracy performance. The trade-offs were in message production speed and data outcomes range. Geoffrey et al. (59) developed a silent speech recognition system AAC using the surface electromyographic motion of speech musculature from the face and neck and generated speech or speech-to-text forms. The silent speech was also predictable using this approach. A 10.3%-word error rate was achieved.

2.12. Older adults

The assistive devices for older adults include medication reminders, telehealth systems, pill dispensers, personal alarms, GPS trackers, communication aids, etc. All these devices are user-dependent and based on their knowledge to handle and their minor requirements. The devices focus primarily on mobility, self-care, safety, and communication (Figure 9).

The study by Ester et al. (60) discusses assistive technology used by older adults such as robot assistants and physical and cognitive rehabilitation for older adults. Physical rehabilitation, speech therapy, social assistants, healthcare companion robots, and many similar such assistive technologies have been discussed by the authors. In their study, Juan et al. (61) propose a socially assistive robot-human interaction to encourage older adults to exercise regularly. High user preference was seen in using this product. Workout, imitation, and memory games were accessible in the system. Feng et al. (62) discuss using an ambient intelligent device for older adults using home appliances. The device consisted of activity identification, sensor

FIGURE 9
Assistive devices for older adults.

synthesizing, and case-dependent reasoning. Depending on the sensors available in the smart home, rough set theory was used. Improvement in context consciousness was visible. Context identification included layer recognition, context middleware layer, sensing, and perception layer. Followed by context modeling, case comprehension included assisting, controlling, and acting layers leading to assistance action.

2.13. Hearing impairments

Hearing loss influences access to spoken language, involving cognition and evolution, and negatively impacts social wellbeing. Auditory impairment can affect the quality of life and spoken communication, inhibiting the evolution of a child's spoken language, and presenting the risk of dementia and cognitive deterioration in older ages (63).

Chung et al. used a sound-sensitive adaptive directional microphone responding to one direction alone. The sound location was found with high volume and improvements in SNR (64). Best et al. used pinna effect simulation—a multi-channel adaptive directional microphone designed to revive the impact of pinna for behind-the-ear type aids. Filtering was not performed, and the hearing aid received the input audio (65).

Keidser et al. (66) studied the effects of directional microphones, minimizing noise in hearing aids. The authors reviewed available data separately from the front, back, left, and right dimensions and concluded that the performance during horizontal localization was the most changed out of all the signal-related parameters. The front and back errors were minimized and right and left errors increased on applying various microphones. The localization sense may be upgraded for hearing aid-using individuals.

2.14. Cognitive impairments—Educational software

The use of educational tools for the literacy process of differently-abled individuals has received great attention from the Special Education field from the point of view of inclusive education. This field has encouraged methods and technology created to promote learning through assistive technologies. However, most of the software and hardware which can embed programming for the differently-abled was not much successful.

Lucas et al. designed a digital game for learning-deprived children. The system consisted of education methods based on Paulo Freire's techniques. The games were developed and implemented for differently-abled children. These games include continuous monitoring and analysis of the understanding and practice levels addressed in the games. The successful adoption of the proposed technology showed acceptable results (67).

Chaita et al. implemented LIBRAS educational software in Portuguese for hearing-challenged students in their schools. The creative and exciting software included digital games that enable students to understand more recent and adequate means of communication (68).

Acuna et al. investigated the construction of the torso of a humanoid robot built by an additive manufacturing process with an interactive graphical user interface developed for students to self-learn the language. The humanoid was assessed with students using traditional teaching and a humanoid robot. With the humanoid robot, the students could recite the self-learning process many times and learning times were decreased by 25%. Analogized to the traditional method, it operated as a trainer and served as an interactive means of contact between the hearing-challenged community and listeners (69).

In another study, Aranyanak et al. proposed a device that tracked the reader's finger movements in real time based on an Android tablet.

It was equipped with:

- Online visual knowledge on finger movement practices.
- Total reading duration.
- Average reading pace.

This permitted investigators to analyze braille reading in better profundity to enhance the readers' braille reading dexterities (70).

3. Inferences

Based on the discussions in the previous sections, the following findings and inferences are being made:

(i) Differently-abled individuals who need assistive devices prefer to perform their daily tasks on their own despite the availability of devices that perform the same task. Artificial intelligence-based technology can help customize the devices to meet the specific needs of individuals.

(ii) The study population in most of the studies is very less, which makes it difficult to project device usability on a larger scale.

(iii) Assistive devices have drastically reduced the burden on the caregiver and formal health and support services. More research in this field will help individuals improve their social interaction, opportunities, and functioning.

(iv) Economic and cost-benefit analyses of available devices are not discussed by the researchers, which is an essential factor in the usage of rehabilitation devices.

(v) Caregiver injury and the individual user's injury in the absence of a caregiver have not been studied. A detailed study of the pros and cons of the assistive device is essential for its usage and further development.

An overview of the year of publication of recent research on assistive technology reviewed in this paper is listed in Table 2.

Most of the reviewed research on assistive devices is marked by the rapid development of the field, yet, at the same time, there are gaps and scope for further research.

4. Discussion

This section discusses additional challenges and future scope in the usage of assistive and rehabilitative devices.

4.1. Challenges

A comprehensive review of current literature on the subject has flagged multiple challenges.

(i) The limited study population and the support provided to the individual and the caregiver are important factors in analyzing the usefulness of the technology. The sample population is very less in most studies although the requirement for the devices is significantly huge.

(ii) Economic assessments of the effectiveness of assistive technology are not reported in the studies relating to impairment assistive device evaluation.

(iii) Identification and awareness of the appropriate device, its quality, and its use, along with the assistive device's access, availability, and adaptability are the present challenges in its wider and regular use.

(iv) Standardized protocols are required for different assistive technology designs and those that need them with a common lexicon.

(v) Device effectiveness is mostly dependent on surveys, which may be biased because of users' enthusiasm and unstructured feedback.

(vi) It is imperative to develop multidisciplinary devices that are flexible and based on user requirements.

(vii) The involvement of the caregiver and family makes a difference in device usage.

(viii) Lack of training, skills, and knowledge of device usage may lead to improper usage causing inconvenience to the user.

(ix) User attitude toward assistive devices and self-training are the drawbacks of assistive device usage.

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TABLE 2 Year of publication of recent state of art research papers on different assistive technology fields.

Dementia	Autism	Knee replacement	Spinal chord injury	Exoskeleton	Diabetes-therapeutic footwear	Stroke	Mobility impairments—wheel chair, prosthesis	Visual impairments	Personal emergency response system	Augmentative and alternative communication (AAC)	Elderly	Hearing impairments	Cognitive impairments—educational software
2022	2020	2021	2021	2022	2017	2022	2021	2022	2021	2022	2022	2022	2019
2021	2019	2020	2016	2021	2016	2020	2017	2021	2017	2021	2021	2021	2015
2020	2016	2018	2015	2020	2015	2019	2016	2020	2016	2020	2020	2020	2014

4.2. Future scope

In this review, efforts have been taken to highlight new technologies and devices that address the needs of differently-abled individuals and older adults. A few potential avenues for further research which can extend the field of assistive technology have been mentioned below.

(i) Current research in the field of assistive technology uses exploratory designs strategy based on current knowledge levels. Exploratory research based on hypothesis will help in getting optimum caregiver response.
(ii) Qualitative methods are necessary to analyze the assistive devices.
(iii) A study of other unseen factors that may impact using a device will improve assistive device adaptability for individuals.
(iv) Artificial intelligence and machine learning-based assistive devices can be developed to improve the usability and flexibility of the devices.

The future for potential research in assistive technology development is unlimited. Hardware and software development are required to bring affordable assistive devices to a wider population that needs them.

5. Conclusion

A comprehensive discussion on various assistive technology applications and devices has been undertaken in this study. Assistive technology is a multi-disciplinary research field with huge research gaps and immense potential. The choice of specific assistive technology depends on the task to be performed, social influence, the type of technology, and the individual's choice. This paper reviewed the research in assistive technology which may be adopted for the improvement of the individual's day-to-day tasks. From this study, it is evident that there is a need for further research and development in the field of assistive technology which is likely to expand tremendously in the future. Better integrated devices reduce the human burden and enable differently-abled individuals to lead self-sufficient lives. Intelligent and accurate computer-based devices are the need of the hour to address the needs of differently-abled individuals and older adults.

Author contributions

PM performed conceptualization, methodology, design, data collection, data visualization, formal analysis, reviewing, and editing. YT carried out conceptualization, methodology, design, investigation, data collection, data analysis, and writing original draft preparation. SL done

conceptualization, methodology, data collection, data visualization, formal analysis, reviewing, and editing. SD involved in data curation, critical analysis, writing, reviewing, and editing. KL contributed in formal analysis, reviewing, and editing. XW involved in reviewing and editing. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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The influence of price value on purchase intention among patients with chronic diseases in medical e-commerce during the COVID-19 pandemic in China

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Background: During the COVID-19 pandemic, medical e-commerce (MEC) has provided a way for patients with chronic diseases to purchase drugs online to maintain social distancing, decrease the risk of infection and community transmission, and relieve the burden on medical resources. Therefore, research which seeks to elucidate the drivers of purchase intention (PI) among patients with chronic diseases in MEC is vital. This study extended the theory of planned behavior (TPB) by integrating the price value (PV) variable into the original TPB framework and explored the effect of PV on patients' PI in MEC during the coronavirus pandemic.

Methods: Empirical data was gathered from 414 Chinese participants. Structural equation modeling was applied to explore the mechanism of chronic patients' PI in MEC. In addition, this study also estimated the moderating effect of gender, income, and region and the mediating role of attitude (ATT), subjective norm (SN), and perceived behavioral control (PBC) between PV and PI.

Results: Patients' PI in MEC is significantly affected by ATT, SN, and PBC. PV delivers significant influence on ATT, SN, PBC, and PI, with PV having the strongest effect on ATT. Gender, income, and region can significantly moderate the relationship between PV and ATT.

Conclusion: These findings can contribute to design targeted interventions to increase the adoption of MEC for patients with chronic diseases, decrease infection rates, and alleviate the strain on medical resources in the COVID-19 era.

KEYWORDS

purchase intention, medical e-commerce, theory of planned behavior, price value, patients with chronic diseases, COVID-19 pandemic

1. Introduction

COVID-19 (coronavirus disease), a highly contagious pneumonia, has become a pandemic (1). Several studies have suggested that the transmission of the 2019 novel coronavirus infection occurs primarily through contact transmission and respiratory droplets (2, 3). In China, people were requested to stay at home and practice social distancing during the COVID-19 outbreak to overcome its rapid spread (4). During this time, many patients, especially people with chronic diseases, had difficulty accessing medical aid, as valuable resources in hospitals were allocated toward mitigating COVID-19 (5). In addition, gathering in hospitals increases the risk of nosocomial infection for patients who already have various diseases or have low immunity; it also significantly increases the risk of community transmission (6). E-commerce platforms, especially medical e-commerce (MEC) platforms, naturally have such characteristics to avoid

close social contact (7, 8). Therefore, from the perspective of decreasing the risk of face-to-face contact in hospitals, purchasing drugs from MEC platforms, which makes the online search for drugs more accessible to patients than on-site, is helpful for people with medical demands during the COVID-19 pandemic (9). Most MEC platforms provide excellent customer service, quality assurance, and rapid delivery, making purchasing drugs online stress-free and convenient (10). After several years of development in China, the industrial structure of MEC, which ensures medication safety through strict laws and regulations, has developed rapidly. Take JD Health, a renowned MEC platform, as an example, many patients with chronic diseases purchased drugs online during the outbreak of COVID-19 in 2020. As of December 31, 2021, JD Health's annual active user number reached 123 million, representing a net increase of 33.56 million active users compared to 2020. During the reporting period in 2021, JD Health's total revenue was 30.68 billion RMB, up 58.3% year-on-year. The total trading volume of MEC was ∼195 billion RMB in 2018, which reached 255.4 billion RMB in 2019, representing a growth rate of 31%, thereby indicating a strong growth trend of the MEC industry, with substantial room for development (11).

The Report of Nutrition and Chronic Diseases on Chinese Residents published by the National Health Commission in 2020 shows that more than 300 million people accounted for 86.6% of all deaths owing to chronic diseases, and patients with chronic disease accounted for 70% of the overall disease burden in the country. In 2020, the mortality rate of patients with comorbidities was 1.4%. It is significantly higher than that without comorbidities (12). In this context, strengthening the protection of patients with chronic diseases can significantly reduce mortality. Along with the policy released by China National Health Commission issued during the coronavirus pandemic, the government encouraged designated medical institutions to provide "do not meet" drug purchase services and realized online medical insurance settlement for qualified online medical services (13). Consequently, MEC platforms would improve the effectiveness of doctors' work, which would significantly optimize medical resource allocation efficiency.

However, research on patients' purchase intention (PI) among patients with chronic diseases in MEC is minimal. Existing studies have explored digital healthcare retail (10, 14–17). For example, Yang et al. (10) revealed that patients' experience was exclusive to internet pharmacy services, and patient compliance can be enhanced by their experience and network social support. Liu et al. (14) proposed an algorithm and used users' purchase data to develop users' diseases to provide product recommendations for pharmaceutical e-commerce platforms. Sreejesh et al. (15) examined how the technology-enabled service co-creation affected patients' service purchase behavior in medical and health services retail. Zehnder et al. (16) studied the growth of Swiss community pharmacies on the internet over the period 2000–2003, which showed that pharmacy-group portals were promoters of internet pharmacies. Ma (17) investigated the factors underlying non-adopters' intention to purchase drugs online *via* the technology acceptance model. Few studies have considered the factors that stimulate patients, especially patients with chronic diseases, to form PI on MEC platforms.

Previous researchers have used the theory of planned behavior (TPB) from multiple disciplines to predict various behaviors [e.g., (18–21)]. The TPB model is also adopted to explore people's health behavioral intentions (22, 23). Although the TPB model provides a conceptual framework for human social behavior research, Ajzen (24) suggested that researchers could extend the TPB model to explain or predict complicated psychological mechanisms. Many previous studies have added factors to extend the TPB model and improve its effectiveness and applicability. Price value (PV) is an important factor that could influence patients' PI in MEC (25–28). For example, Crawford (25) stated that easy for price comparisons were an important advantage of online pharmacies. Brown et al. (26) administered a cross-sectional anonymous survey and found that the population of online pharmacies was highly associated with the costs of prescription drugs while searching for opportunities for cost savings increased consumers' online PI. Fittler et al. (27) found that patients may care about discounts, bonuses, and gifts from online pharmacies, which also affected patients' attitudes toward purchasing drugs online. Liu et al. (28) analyzed consumers' online pharmacy purchasing comments and found that price (including affordable and expensive) was an important attribute, which affected patients' satisfaction. Chronic patients need to purchase drugs continuously and are more sensitive to prices (29). Accordingly, we add PV to help explain and predict the PI in MEC among patients with chronic diseases during the coronavirus pandemic.

Therefore, this paper aimed to (a) investigate the mechanism of PV on chronic patients' PI in MEC during the coronavirus pandemic using an extended TPB model, and (b) examine the moderating effects of the relationships within the model, subgroups classified by gender, income, and region. The findings of this study can provide new insights for governments, business practitioners, and researchers to promote the adoption of online drug purchasing by patients with chronic diseases, decrease infection rates, and improve the utilization efficiency of medical resources during the COVID-19 pandemic.

2. Theoretical background and hypotheses

2.1. Theoretical background

The present study used the TPB as a framework to employ the psychological mechanism of chronic patients' PI in MEC during the coronavirus pandemic. The TPB model has four primary constructs, including behavioral intention (BI), attitude (ATT), subjective norm (SN), and perceived behavioral control (PBC). Notably, ATT, SN, and PBC are independent determinants of BI (30). The more favorable of the ATT, SN and PBC, the stronger the people's BI (31). Moreover, TPB is a validated model that has been used in many public health-related behavior explanations such as the intention to get coronavirus vaccines (32) and use traditional Chinese medicine (TCM) (33). Chang et al. (29) explored the factors that affect chronic patients' PI in offline pharmacies based on the TPB model. In the TPB model, the main assumption is that people are rational in their decision-making, such that the actual behavior can be predicted *via* cognitive approaches (24). In this study, the patients' PI in MEC depends on several predictors, including ATT toward purchasing drugs online, SN for purchasing drugs from MEC platforms, and PBC over MEC platforms.

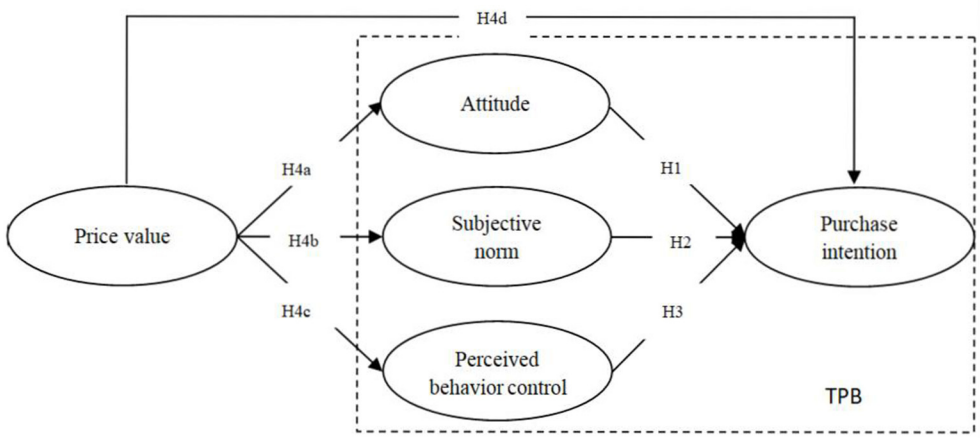

FIGURE 1
Conceptual model and hypotheses.

2.2. Research hypotheses

2.2.1. Attitude

Notably, ATT is defined as an individual's positive or negative evaluation of a particular behavior (24). According to the TPB concept, PI can be affected by one's ATT toward the behavior. When appraising the medical behaviors during the COVID-19 epidemic, people are likely to evaluate various aspects of medical requests, such as the ATT toward the level of risk they are willing to take (34). In the present study, ATT means patients' overall estimation of MEC participation during the COVID-19 pandemic. When patients' ATT in MEC is positive, their PI in MEC is more likely to be positive. As such, this study proposes the following hypothesis:

H1: Attitude has a positive and direct influence on PI in MEC during the COVID-19 pandemic.

2.2.2. Subjective norm

Moreover, SN is defined as individuals' perception that most people who have significant influence on them believe that they shall or shall not execute the behavior in question (24). Individuals may evaluate their beliefs and changes their consumption patterns, as induced by people have an important influence on them (35). Chang et al. (29) found that SN has a weak overall impact on offline pharmacy PI, as patients with chronic diseases have a relatively rich experience in drug use and purchase. However, the intention of patients with chronic diseases to purchase drugs on MEC platforms may be more susceptible to others because of the need to maintain social distancing during the coronavirus pandemic. If patients consider that people who can influence their behavior believe purchasing drugs from MEC platforms is a good choice during the COVID-19 pandemic, their PI in MEC will be enhanced. Hence, we propose the following hypothesis:

H2: Subjective norm has a positive and direct influence on PI in MEC during the COVID-19 pandemic.

2.2.3. Perceived behavioral control

Furthermore, PBC refers to individuals' perceived ease or difficulty in performing a behavior (24). Some scholars state that PBC refers to people's perceived ability to control behavior (36). In the present study, PBC means patients have the resources, knowledge, and capacity to purchase drugs from the MEC platform during the COVID-19 pandemic. Strong PBC may induce positive PI. Based on the above-mentioned, this study proposes the following hypothesis:

H3: Perceived behavioral control has a positive and direct influence on PI in MEC during the COVID-19 pandemic.

2.2.4. Price value

Finally, PV presents an overall evaluation of a product's utility and benefits, such as convenience, price, and time cost (37). A product or service's PV is generally determined by its monetary cost or price in conjunction with the quality of the offering (38). When the benefits are perceived to be larger than the price, PV will positively affect PI (39). Therefore, it is necessary to analyze PV's impact on chronic patients' intention to purchase drugs online. This study defines PV as the cognitive tradeoff patients make between the perceived benefits and monetary costs in the transaction online. Thus, we hypotheses discussed below:

H4a: PV has a positive and direct influence on ATT in MEC during the COVID-19 pandemic.
H4b: PV has a positive and direct influence on SN in MEC during the COVID-19 pandemic.
H4c: PV has a positive and direct influence on PBC in MEC during the COVID-19 pandemic.
H4d: PV has a positive and direct influence on PI in MEC during the COVID-19 pandemic.

In summary, Figure 1 shows the framework of this research, and depicts the relationships between PV, ATT, SN, PBC, and PI in MEC during the COVID-19 pandemic.

TABLE 1 Measurement instruments.

Construct	Measurement items	References
Attitude (ATT)	Please fill out the below questions about your attitude in MEC during the coronavirus pandemic.	Taylor et al. (40)
	ATT1. Purchasing drugs from MEC platforms is a good idea.	
	ATT2. Purchasing drugs from MEC platforms is a wise idea.	
	ATT3. I like the idea of purchasing drugs from MEC platforms.	
	ATT4. Purchasing drugs from MEC platforms is a pleasant experience.	
Subjective norm (SN)	Please fill out the below questions about subjective norm in MEC during the coronavirus pandemic.	Venkatesh et al. (41) Mathieson (42)
	SN1. People who influence my behavior would think that I should purchase drugs from MEC platforms.	
	SN2. People who are important to me think that I should purchase drugs from MEC platforms.	
	SN3. People whose opinions I value prefer me to purchase drugs from MEC platforms.	
Perceived behavior control (PBC)	Please fill out the below questions about perceived behavior control in MEC during the coronavirus pandemic.	Taylor et al. (40)
	PBC1. I am able to purchase drugs from MEC platforms.	
	PBC2. Purchasing drugs from MEC platforms is entirely within my control.	
	PBC3. I have the resources, knowledge, and ability to purchase drugs from MEC platforms.	
Price value (PV)	Please fill out the below questions about price value in MEC during the coronavirus pandemic.	Venkatesh et al. (37)
	PV1. Drugs in MEC platforms are reasonably priced.	
	PV2. Drugs in MEC platforms are good value for money.	
	PV3. At the current price, MEC platforms provide a good value.	
Purchase intention (PI)	Please fill out the below questions about purchase intention in MEC during the coronavirus pandemic.	Venkatesh et al. (43) Kucukusta et al. (44)
	PI1. I intend to purchase drugs online.	
	PI2. I predict I would purchase drugs from MEC platforms.	
	PI3. I plan to purchase drugs from MEC platforms.	
	PI4. I will strongly recommend others purchase drugs from MEC platforms.	

3. Methodology

3.1. Survey design and measurement items

We performed an anonymous, cross-sectional survey in China. The questionnaire included three parts. The first part explained the objective of the survey and the definition of MEC platforms. The second part of the questionnaire contained the participants' demographic data. The third part contained 17 items (Table 1) measuring five constructs: ATT, SN, PBC, PV, and PI.

All the items were adapted from earlier research but tailored to meet the context of this study. The variables were measured using the following sources: ATT from Taylor and Todd (40); SN from Venkatesh and Davis (41) and Mathieson (42); PBC from Taylor and Todd (40); PV from Venkatesh et al. (37); PI from Venkatesh et al. (43) and Kucukusta et al. (44). The scale ranged from 1 (strongly disagree) to 7 (strongly agree) on a seven point Likert scale. Prior to data collection, the survey was pre-tested and piloted among a selection of participants to gauge their comprehension of the problems it raised and to enhance the caliber of the research findings. Based on responses from the participants, the questionnaire was modified for further data collection.

TABLE 2 Demographic of respondents.

Items	Category	Frequency	Percentage (%)
Gender	Male	184	44.4
	Female	230	55.6
Monthly income (yuan) (1 yuan = 0.105 USD*)	Less than 5,001	196	47.3
	5,001–8,000	100	24.2
	8,001–15,000	94	22.7
	15,001–20,000	16	3.9
	20,001 above	8	1.9
Region	East	192	46.4
	Midwest	222	53.6

*As of October 5, 2022.

3.2. Data collection

We conducted an online anonymous cross-sectional survey in July 2022 in China. The reason for choosing China as our survey location is because the prosperity of e-commerce offers enormous potential for MEC (17). The questionnaire was designed

TABLE 3 Reliability and validity analysis.

Construct	Item	Average variance extracted (AVE)	Composite reliability (CR)	Cronbach's alpha	Loadings
ATT	ATT1	0.608	0.861	0.856	0.831
	ATT2				0.781
	ATT3				0.785
	ATT4				0.717
SN	SN1	0.508	0.755	0.751	0.672
	SN2				0.790
	SN3				0.670
PBC	PBC1	0.527	0.769	0.766	0.792
	PBC2				0.668
	PBC3				0.713
PI	PI1	0.631	0.872	0.869	0.783
	PI2				0.753
	PI3				0.867
	PI4				0.770
PV	PV1	0.582	0.806	0.805	0.692
	PV2				0.773
	PV3				0.818

Model fit indices: $\frac{\chi^2}{df} = 2.13$, GFI = 0.94, AGFI = 0.91, RMSEA = 0.05, PNFI = 0.74, PGFI = 0.67, CFI = 0.96, NFI = 0.93, IFI = 0.96.

TABLE 4 Distinguishing validity test of model.

Items	ATT	SN	PBC	BI	PV
ATT	**0.780**				
SN	0.271	**0.713**			
PBC	0.356	0.340	**0.726**		
PI	0.668	0.501	0.523	**0.794**	
PV	0.355	0.218	0.274	0.502	**0.763**

Diagonal values are square root of the AVE value (bold values).

through Credamo, a data consulting company providing large-scale research, data collection, and business application solutions for research institutions and enterprises. The questionnaire was written in Chinese to ensure that each question item was fully understood. The data were gathered through Credamo. A sample of 489 responses was obtained. We excluded invalid surveys such as those with incorrectly answered screening questions or those where the respondents had never used MEC platforms before. Eventually, 414 valid surveys were used for the final sample.

3.3. Demographic statistics

Table 2 shows the demographics of the respondents. The percentages of male and female respondents are 44.4 and 55.6%. The most common monthly income in our sample is under 5,001 RMB (47.3%). A total of 192 (46.4%) participants come from East China, and 222 (53.6%) participants come from Midwest China.

4. Results

4.1. Measurement model assessment

To examine the variables' reliability, Cronbach's alpha coefficient of each construct is recommended to be above 0.7 (45). The results showed that Cronbach's alpha coefficient of each construct above 0.7 (Table 3).

Confirmatory factor analysis was carried out to inspect the model fit, validity and composite reliability (CR) using AMOS 24.0. The fitness indices ($\frac{\chi^2}{df} < 3$, GFI > 0.9, AGFI > 0.8, RMSEA < 0.08, PNFI > 0.5, PGFI > 0.5, CFI > 0.9, NFI > 0.9, IFI > 0.9) were introduced to inspect the model fit (46). Table 3 shows that all fit indices exceeded the recommended value.

Furthermore, CR, factor loading, and average variance extracted (AVE) were adopted to test the measurement model's validity. The results showed that the CR values of all latent variables above 0.7, ranging from 0.755 to 0.872 (47). The standardized factor loadings for all items were larger than 0.5 (47). Table 3 shows that the AVE values range from 0.508 to 0.631 and exceed the recommended value (47). Furthermore, the square root of the AVE was compared against the inter-correlations among constructs. Table 4 shows that the diagonal arithmetic square root of AVE is larger than its correlations with the other constructs (45), suggesting that the model has good discrimination validity.

4.2. Structural model assessment

Structural equation modeling (SEM) was used to test the hypotheses in AMOS. Table 5 shows the results and Figure 2 presents the result of SEM graphically depicted. The model fit indices of the

TABLE 5 Summary of hypotheses test.

Hypotheses	Path	Ustd.	S.E.	*T*-value	*P*	β	Supported
H1	ATT → PI	0.468	0.058	8.094	***	0.439	Yes
H2	SN → PI	0.263	0.051	5.162	***	0.258	Yes
H3	PBC → PI	0.183	0.043	4.252	***	0.215	Yes
H4a	PV → ATT	0.295	0.052	5.685	***	0.355	Yes
H4b	PV → SN	0.190	0.056	3.387	***	0.218	Yes
H4c	PV → PBC	0.287	0.066	4.360	***	0.274	Yes
H4d	PV → PI	0.205	0.044	4.667	***	0.231	Yes

***p < 0.001.

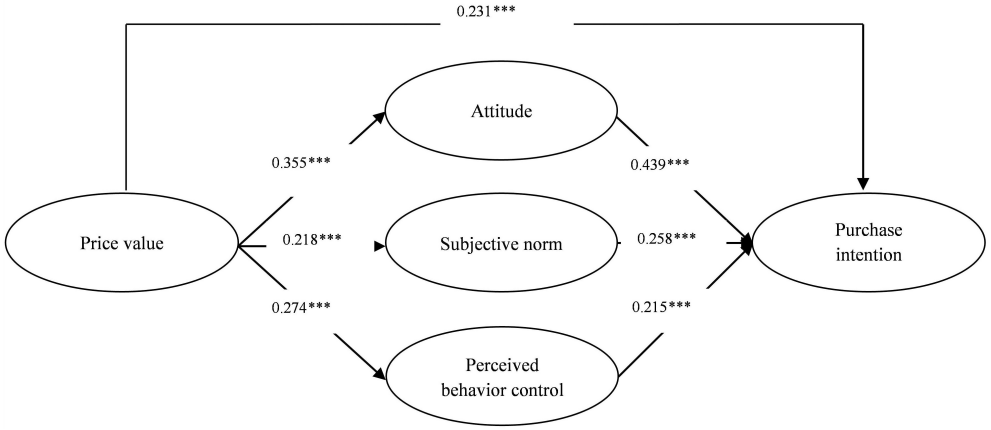

FIGURE 2
Analysis results of structural model. ***$p < 0.001$; Model fit indices: $\chi^2/df = 2.13$, GFI = 0.94, AGFI = 0.91, RMSEA = 0.05; PNFI = 0.75, PGFI = 0.67, CFI = 0.96, NFI = 0.93, IFI = 0.96; R^2 for attitude = 0.14, R^2 for subjective norm = 0.07, R^2 for perceived behavior control = 0.10, R^2 for purchase intention = 0.62.

structural model ($\frac{\chi^2}{df} = 2.13$, GFI = 0.94, AGFI = 0.91, RMSEA = 0.05, PNFI = 0.75, PGFI = 0.67, CFI = 0.96, NFI = 0.93, IFI = 0.96) all passed the minimum cutoff points (46). ATT ($\beta = 0.439$, $p < 0.001$), SN ($\beta = 0.258$, $p < 0.001$) and PBC ($\beta = 0.215$, $p < 0.001$) were significant predictors of the PI of MEC use during COVID-19. Hence, H1, H2, and H3 are accepted. Moreover, PV significantly affected ATT ($\beta = 0.355$, $p < 0.001$), SN ($\beta = 0.218$, $p < 0.001$) and PBC ($\beta = 0.274$, $p < 0.001$). Accordingly, H4a, H4b, and H4c are accepted. In addition, PV positively affected PI ($\beta = 0.231$, $p < 0.001$). Therefore, H4d is accepted.

4.3. Moderating effects

We conducted a multi-group analysis (MGA) to test the moderating effects of gender (i.e., male and female), income (i.e., high income and low income), and region (i.e., East and Midwest). Differences between gender, income, and regional groups were determined by pairwise comparisons of each relationship between the unconstrained model and constrained model. Here, we impose an equal constraint on each path in the constrained model. A moderating effect exists if the change of chi-square values in the two models is significant (48).

For the gender group comparison (Table 6), gender significantly moderated the relationship between PV and ATT ($\chi^2 = 8.920$, $p < 0.05$), the moderating effect of PV on PBC was also significant ($\chi^2 = 5.273$, $p < 0.05$). Compared by males ($\beta = 0.267$, $p < 0.01$), ATT of females ($\beta = 0.434$, $p < 0.001$) was more likely be influenced by PV. Furthermore, PV had a significant impact on PBC among females ($\beta = 0.404$, $p < 0.001$), but the effect of PV on PBC for male group was not significant ($\beta = 0.160$, n.s.). Overall, the model explained 58.3% of the variance in PI in the male group and 64.6% variance in the female group.

Table 7 shows the income group comparison. The effect of PV on ATT was significantly different between high- and low-income patients ($\chi^2 = 6.043$, $p < 0.05$). PV had a stronger effect on ATT for low-income patients ($\beta = 0.420$, $p < 0.001$) than for high-income patients ($\beta = 0.268$, $p < 0.05$). Overall, the model explained 61.5% of the variance in PI for the high-income group and 62.2% for the low-income.

Table 8 presents the region group comparison. It was found that PV had a stronger effect on the ATT for patients from Midwest China ($\beta = 0.463$, $p < 0.001$) than East China ($\beta = 0.193$, $p < 0.05$), and the moderating effects was significant ($\chi^2 = 7.564$, $p < 0.001$). The region also significantly moderated the relationship between PBC and

TABLE 6 Path coefficients comparison of MGA by gender.

Hypothesis	Path	Gender				Path difference
		Male ($n = 184$)		Female ($n = 230$)		
		β	t-statistic	β	t-statistic	$\Delta\chi^2$ ($df = 1$)
sH1	ATT → PI	0.418	4.547***	0.503	6.826***	0.245
H2	SN → PI	0.210	2.519*	0.343	5.241***	1.581
H3	PBC → PI	0.342	4.085***	0.215	3.200**	0.439
H4a	PV → ATT	0.267	2.723**	0.434	4.991***	8.920**
H4b	PV → SN	0.189	1.916	0.273	3.131**	1.202
H4c	PV → PBC	0.160	1.719	0.404	4.530***	5.273*
H4d	PV → PI	0.309	4.000***	0.143	1.918	0.737
Explained variance in the overall model		58.3%		64.6%		

*p < 0.05; **p < 0.01; ***p < 0.001.

TABLE 7 Path coefficients comparison of MGA by income.

Hypothesis	Path	Income				Path difference
		High (≥5,001) ($n = 218$)		Low (<5,001) ($n = 196$)		
		β	t-statistic	β	t-statistic	$\Delta\chi^2$ ($df = 1$)
H1	ATT → PI	0.514	5.594***	0.432	5.721***	1.361
H2	SN → PI	0.301	3.145**	0.300	4.416***	0.03
H3	PBC → PI	0.176	2.059*	0.294	3.982***	1.566
H4a	PV → ATT	0.268	3.009*	0.420	4.578***	6.043*
H4b	PV → SN	0.318	3.387***	0.179	1.947	0.252
H4c	PV → PBC	0.220	2.558*	0.329	3.491***	2.027
H4d	PV → PI	0.191	2.583*	0.211	2.689**	0.71
Explained variance in the overall model		61.5%		62.2%		

*p < 0.05; **p < 0.01; ***p < 0.001.

PI ($\chi^2 = 13.866$, $p < 0.001$). PBC significantly affected the PI for patients from Midwest China ($\beta = 0.411$, $p < 0.001$), but the effect was not significant in patients from East China ($\beta = 0.078$, n.s.). The moderating effect of PV on PBC was significant between patients from East and Midwest China ($\chi^2 = 3.953$, $p < 0.05$). PV was a significant determinant of PBC for patients from Midwest China ($\beta = 0.404$, $p < 0.001$), but not for patients from East China ($\beta = 0.149$, n.s.). Overall, the model explained 69.5% of the variance in PI of the East China group and 63.0% of the Midwest China group.

5. Discussion

This research aims to search for the mechanism of chronic patients' PI in MEC during the COVID-19 pandemic. PV is added to the model based on the TPB framework to explore the mechanism of chronic patients' PI in MEC. The multi-group analysis is conducted by gender, income, and region. The results verify the importance of ATT, SN, PBC, and PV on chronic patients' PI in MEC. The results supported all seven hypotheses and revealed the gender, income, and region differences in the structural relationships among the variables.

First, ATT delivers the most positive effect on PI in MEC, consistent with earlier research on online shopping consumer behavior (49–51). The COVID-19 pandemic has sparked a sharp growth in retail digitalization. Wang et al. (52) found that shoppers' ATT was the strongest contributor to their online PI during the coronavirus pandemic. Patients' PI is often affected by their ATT. On the one hand, purchasing drugs online provides patients with utilities such as instant feedback and fast and reliable home delivery services (17). On the other hand, e-commerce industry has stepped to the maturity stage in China. Purchasing drugs from MEC platforms is also acceptable when patients can get the same quality and service as offline pharmacies. The more patients know about the dominance of MEC, the stronger their ATT to purchasing drugs online; as a result, the PI in MEC will become stronger. Moreover, SN has a relatively weak effect on patients' PI in MEC, which is consistent with the earlier research on exploring online shopping consumer behavior using the TPB model (53, 54). With the perceptions of online shopping, consumers' online PI can also be affected by SN during the COVID-19 pandemic (54). Therefore, patients' PI in MEC is recognized, encouraged, and implemented by SN. Notably, PBC in MEC has a positive but less significant effect than ATT and SN on PI, meaning that patients have sufficient knowledge of different aspects of purchasing drugs online, thus prompting them to adopt MEC platforms. This finding is coherent with former research on consumers' online purchase behavior (55, 56). The reason for such

TABLE 8 Path coefficients comparison of MGA by region.

Hypothesis	Path	Region				Path difference
		East ($n = 192$)		Midwest ($n = 222$)		
		β	t-statistic	β	t-statistic	$\Delta\chi^2$ ($df = 1$)
H1	ATT → PI	0.561	6.372***	0.420	5.618***	2.203
H2	SN → PI	0.338	4.27***	0.266	4.031***	0.006
H3	PBC → PI	0.078	1.176	0.411	5.289***	13.866***
H4a	PV → ATT	0.193	2.119*	0.463	5.292***	7.564***
H4b	PV → SN	0.353	3.656***	0.199	2.308*	1.555
H4c	PV → PBC	0.149	1.676	0.404	4.457***	3.953*
H4d	PV → PI	0.296	3.881***	0.118	1.552	1.719
Explained variance in the overall model		69.5%		63%		

*p < 0.05; ***p < 0.001.

a relationship may be due to the simple and legible online shopping procedure of the MEC platforms (57). Almost all mainstream Chinese MEC platforms provide buyers with a simple and legible shopping process. Therefore, patients' PBC has little influence on PI in MEC.

Second, PV has significant influence on ATT, SN, PBC and PI; PV has the strongest positive effect on ATT, which is consistent with the earlier research. Cheah et al. (58) found that fair-priced and good-value products positively affected consumers' ATT when they used electronic deals. Value perception has a significant correlation with consumers' PI (59). When the benefits overweight the costs, customers perceived the valuation of the product or service (60). The more the expected reduction in long-term costs, the greater the PV perceived (61). Furthermore, PV positively affects patients' ATT in MEC. When patients understand that they can benefit from online drugs purchasing, they will show positive ATT toward purchasing drugs online during the COVID-19 pandemic. Additionally, PV can affect PI through the mediating effect of ATT. The empirical results also demonstrate that PV can influence PI *via* the mediating of SN and PBC. PV plays a vital role in guiding patients' PI in MEC. In China, MEC platforms provide a wide variety of medicines and health products with rapid delivery and excellent services. Owing to enhanced ties among parties related to the industry and digital tools, online sales of prescription drugs have commenced and launched nationwide under the Chinese government administration. In some areas of China, patients can purchase drugs online using medical insurance, which significantly influences of chronic patients' PI.

Finally, this study used MGA to explore the moderating effects of gender, income, and region. Gender is a significant moderating variable from PV to ATT. Compared to males, females' ATT in MEC can be stronger affected by PV. This finding is coherent with former research. Hou et al. (62) identified that females were more likely than males to be bargain hunters in online auctions. Females had significantly higher price consciousness than males (63). As a result, PV seems to exert a greater influence on female patients than on male patients. Regarding income, the effect of PV on ATT is stronger for low-income patients than for high-income patients. It means that if PV is beyond willingness-to-pay levels, the intention to purchase drugs online of low-income patients is more affected by PV than high-income patients in the COVID-19 era. The result is coherent with former research on customer online behavior during the COVID-19 pandemic (64). It is also consistent with the consumption theory. During the COVID-19 pandemic, people with lesser incomes could have tighter budgets and more pressing financial needs, thereby necessitating government relief plans. Furthermore, the region was also a significant moderating variable from PV to ATT. The ATT in MEC of patients from Midwest China may be more affected by PV than that of patients from East China because of the regional development distinction.

6. Conclusions

The results of this study make several theoretical contributions. First, this study explores the influencing mechanism of chronic patients' PI in MEC during the COVID-19 pandemic in China which was not discussed by previous research. Thus the results are supposed to contribute to promoting the adoption of MEC among patients with chronic diseases. Second, this study extended the TPB model by integrating the PV variable into the original TPB framework to complement the understanding of patients' PI in MEC. Finally, while examining the adoption of MEC, subgroups categorized by demographic of respondents exhibit different patterns, which may shed light on how to impulse patients' PI in MEC based on the characteristics of different consumer subgroups. The findings of this study are as follows: (i) ATT, SN, and PBC had a significant influence on patients' PI in MEC, and ATT had the strongest effect on the PI. (ii) PV had a significant effect on ATT, SN, PBC, and PI, with PV having the strongest effect on ATT. (iii) In the aspect of mediating effect, PV had a significant indirect influence on PI in MEC through ATT, SN, and PBC. (iv) Gender, income, and region can significantly moderate the relationship between PV and ATT.

Based on the above-mentioned findings, the practical contributions of this study are several: First, as ATT is an important driving factor of MEC adoption, it is important for online drug retailers, MEC platforms, and the government to improve patients' ATT in MEC. With the permission of the government, MEC platforms can launch the "medicine + doctor" model, and provide clinical service and medication guidance to establish and enhance positive ATT in MEC among patients with chronic diseases. Furthermore, MEC platforms can adopt the online-to-offline model to provide services to patients. Patients can order drugs online and

pick up drugs in offline pharmacies where additional medication guidance can provide for them. Second, according to our findings, PV has a significant effect on ATT, SN, PBC, and PI. Therefore, it is necessary to strengthen the perception of PV in connection to MEC during the pandemic prevention and control period. For instance, as medical insurance in China is regulated by areas, policymakers should put posit integrate medical insurance and ensure that patients can pay for online drugs purchasing by medical insurance, which may greatly improve patients' ATT and PI in MEC. In the case where medical insurance has not been fully launched, MEC platforms and medical enterprises can conduct chronic care plans, and medical enterprises can provide subsidies to reduce the burden of medication for patients with chronic diseases. Third, since patients' traits, such as gender, income, and region can moderate the impact of some antecedents, targeted strategies can be developed to improve the PI of different chronic patients groups. For instance, patients from Midwest China should receive extra attention, as their ATTs in MEC tend to be more affected by PV than patients from East China. Marketers should also provide corresponding marketing strategies for male and female subgroups, or high- and low-income patients, as the effect of PV on these subgroups' ATTs in MEC are significantly different.

This is the first study to investigate the purchase intention among patients with chronic diseases in MEC during the COVID-19 pandemic. For patients, MEC can provide a way for them to purchase drugs online and reduce the risk of infection. For the government, MEC can relieve the burden on medical resources and decrease community transmission. For MEC platforms, online drug retailers, and medical enterprises, MEC makes it possible for them to sell drugs online under strict laws and regulations, and excellent services will make them even more competitive. The results of the study explored the factors that affect patients' purchase intention in MEC. For the government, forwarding the integration of medical insurance and making sure patients can use medical insurance to purchase drugs online will significantly influence their purchase intention in MEC. For MEC platforms, online drug retailers, and medical enterprises, providing convenience, excellent and personalization service for patients can greatly improve their ATT in MEC. Under the joint efforts of government and enterprises, MEC will develop healthily and serve public health.

The limitations of our study should be acknowledged. First, the questionnaire survey was geographically limited. Future studies should explore how social and cultural differences affect patients' online PI. Second, this study extended the TPB model by introducing just a single variable, PV. Future research could add additional variables within the same context to increase the explained variance.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

Ethical review and approval was not required for the study on human participants in accordance with the local legislation and institutional requirements. Written informed consent from the participants was not required to participate in this study in accordance with the national legislation and the institutional requirements.

Author contributions

LH and XH participated in designing their study, data analysis, and the manuscript, involved in the investigation, and the supervision. All authors contributed to this work and approved the manuscript.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Online HIV prophylaxis delivery: Protocol for the ePrEP Kenya pilot study

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Background: Online pharmacies in Kenya provide sexual and reproductive health products (e.g., HIV self-testing, contraception) and could be leveraged to increase the reach of HIV pre-exposure and post-exposure prophylaxis (PrEP/PEP) to populations who do not frequently attend health facilities. To date, evidence is limited for operationalizing online PrEP/PEP delivery and the type of populations reached with this differential service delivery model.

Methods: The ePrEP Kenya Pilot will deliver daily oral PrEP and PEP *via* MYDAWA, a private online pharmacy retailer, to clients in Nairobi for 18 months. Potential clients will obtain information about PrEP/PEP on MYDAWA's sexual wellness page and self-screen for HIV risk. Individuals ≥18 years, identified as at HIV risk, and willing to pay for a blood-based HIV self-test and PrEP/PEP delivery will be eligible for enrollment. To continue with online PrEP/PEP initiation, eligible clients will purchase a blood-based HIV self-test for 250 KES (∼USD 2) [delivered to their setting of choice for 99 KES (∼USD 1)], upload an image of their self-test result, and attend a telemedicine visit with a MYDAWA provider. During the telemedicine visit, providers will screen clients for PrEP/PEP eligibility, including clinical concerns (e.g., kidney disease), discuss self-test results, and complete counseling on PrEP/PEP use and safety. Providers will refer clients who self-test HIV positive or report any existing medical conditions to the appropriate services at healthcare facilities that meet their preferences. Eligible clients will be prescribed PrEP (30-day PrEP supply at initiation; 90-day PrEP supply at follow-up visits) or PEP (28-day supply) for free and have it delivered for 99 KES (∼USD 1). We will measure PrEP and PEP initiation among eligible clients, PEP-to-PrEP transition, PrEP continuation, and implementation outcomes (e.g., feasibility, acceptability, and costs).

Discussion: Establishing pathways to increase PrEP and PEP access is crucial to help curb new HIV infections in settings with high HIV prevalence. The findings

from this study will provide evidence on the implementation of online pharmacy PrEP and PEP service delivery that can help inform guidelines in Kenya and similar settings.

KEYWORDS

PrEP, PEP, HIV prevention, telehealth, differentiated service delivery, implementation science, Kenya

Introduction

While online pharmacies were initially available only in high-income countries, they have been increasing in many low- and middle-income countries (1). The scope of online pharmacies may include direct-to-client distribution of health products through online and mobile channels, digital health information, and remote consultations with health providers. In Kenya and other sub-Saharan African countries, HIV pre-exposure and post-exposure prophylaxis (i.e., PrEP and PEP, respectively) services are mainly delivered through HIV comprehensive care clinics at public sector health facilities. Often PrEP initiation and continuation at these facilities is poor, which can be attributed to client-level barriers, such as a lack of privacy, HIV-related stigma, and time spent traveling to and waiting at the clinics (2, 3), as well as provider-level barriers, such as competing treatment priorities, overcrowding, and a lack of PrEP and PEP knowledge (4, 5). Despite the availability of PrEP, new and diverse HIV prophylaxis delivery models are needed to overcome these barriers and enable individuals to select a delivery model that fits their preferences and facilitates continuation during their periods of HIV risk.

Online HIV prophylaxis delivery, defined as the ability to initiate PrEP or PEP using telemedicine visits with remote clinicians, at-home HIV testing, and PrEP/PEP medication delivery, has not been tested in Africa. However, during the COVID-19 pandemic, some core components of this model, such as telemedicine visits (6–10), at-home HIV testing (6, 9–12), and at-home medication delivery (9, 10), were implemented successfully in low and middle-income countries to maintain access to HIV prevention and treatment services when travel restrictions were in place. While these models helped maintain service delivery among clients already engaged in care at public facilities during the pandemic, they also have the potential to reach new clients at HIV risk not currently receiving or interested in HIV prevention services at public facilities. New technologies, like HIV self-testing (HIVST) and growing access to mobile devices and networks among individuals across income brackets in Africa (13, 14), further support the feasibility of an online HIV prophylaxis delivery model in the region.

Kenya is well-positioned to lead efforts to develop, test and implement an online model for HIV prophylaxis service delivery, which could potentially serve as a model for other countries. As of 2022, an estimated 300,000 people in Kenya initiated PrEP services, one of the largest initiation rates in the east and southern African region (15). Kenya also continues to cater to the treatment needs of over 1.4 million people living with HIV (16, 17). Finally, Kenya boasts strong tech development talent and a large middle class population (18, 19) that provides further potential support for developing such an innovative delivery model. This pilot study aims to design and test the first online PrEP/PEP delivery model in Africa. We hypothesize that an online PrEP and PEP delivery model will be feasible, acceptable, and safe and can be delivered at a reasonable cost in Kenya.

Materials and methods

Study setting

Nairobi, the capital of Kenya, is a dense urban city with a population of 4.3 million (20) and a population-level HIV prevalence of ∼5% (21). For the pilot, we will collaborate with MYDAWA, Kenya's first licensed online pharmacy (https://mydawa.com). MYDAWA has developed technical and operational capabilities to tackle and overcome traditional supply chain challenges (e.g., inconsistent pricing of health care products, stock-outs, substandard products) and provide affordable access to a wide range of quality prescription and over-the-counter medicines and products delivered directly to the consumer quickly, confidentially, and conveniently. Additionally, MYDAWA's platform often attracts clients seeking sexual and reproductive health products, such as emergency contraceptive products and HIVST kits, who might also be interested in the online delivery of HIV prevention services.

Design of the online HIV prophylaxis delivery care pathway

To design a care pathway for online PrEP/PEP service delivery, we adapted an existing one for the delivery of PrEP and PEP services at brick-and-mortar pharmacies in Kenya (22), then refined this with input from key stakeholders and findings from a discrete choice experiment (DCE). Specifically, at meetings with Kenyan PrEP implementation experts, researchers, and Ministry of Health officials, we presented the adapted care pathway, elicited stakeholder feedback, and refined the model as needed. We ultimately landed on a care pathway that utilizes a prescribing checklist—similar to that used in the brick-and-mortar pharmacy PrEP/PEP service delivery model (22)—to identify clients eligible for online PrEP/PEP services (i.e., at HIV risk with no medical conditions that might contraindicate PrEP/PEP safety), and refer clients that do not meet the checklist criteria to clinic-based PrEP services. We also conducted a DCE with ∼800 potential online PrEP/PEP clients to elicit their preferences for different

core components of the intervention (described below) (23). The analysis of the DCE findings is ongoing; once completed, we plan to meet again with key stakeholders to share our findings and further refine the care pathway for online PrEP/PEP service delivery.

Pilot design and population

We will conduct a prospective, single-arm pilot study to test this novel online PrEP and PEP delivery model. MYDAWA clients will be eligible to participate in the study if they are ≥18 years old, self-identify as at risk for HIV, and meet the criteria for online PrEP/PEP delivery on the prescribing checklist (e.g., self-tested HIV-negative, no contraindications to PrEP). Clients who self-report having a history of liver disease, kidney disease, diabetes, or hypertension will not be medically eligible to receive PrEP through the study. In addition, clients reporting symptoms that might reflect acute HIV infection, including sore throat, headache, or fever after having sex without a condom in the last 30 days, will not be eligible to receive PrEP through this study. Pregnant or breastfeeding women will remain eligible for online PrEP and PEP services.

As MYDAWA's business is conducted solely through their English-language website and mobile phone application, clients need to have access to a smartphone or computer during the pilot duration and be able to read and understand English. Although MYDAWA currently offers delivery across all of Kenya, clients must provide a delivery address within Nairobi County for efficient delivery to be eligible for this study. Additionally, eligible MYDAWA clients must be willing to pay for blood-based HIVST and PrEP/PEP delivery. We have not limited the number of clients who can enroll in this research and access online PrEP and PEP services, as this is an implementation study, and these are two of our primary outcomes.

Pilot procedures and data collection

The care pathway for online HIV prophylaxis delivery consists of the following core components: (1) demand generation, (2) screening for HIV risk, (3) HIV testing, (4) medical eligibility assessment (*via* a telemedicine visit), (5) HIV prophylaxis delivery, and (6) PrEP or PEP support (see Figure 1). We describe each of these phases and associated procedures below.

Demand generation

We will advertise the online PrEP and PEP delivery model to potentially new and existing MYDAWA clients through multiple marketing channels, including social media campaigns (e.g., on Facebook and Instagram), search engine optimization for online searches of sexual and reproductive health products, and cross-promotion (i.e., targeting customers of other products and services sold by MYDAWA).

Screening for HIV risk

All MYDAWA clients interested in PrEP or PEP delivery must first complete an online self-screening of HIV risk or recent HIV exposure. Clients can access this online screening by following links on MYDAWA's sexual health and wellness page. We based this self-screening on Kenya's PrEP Rapid Assessment Screening Tool (RAST)—an eight-item questionnaire routinely used at Kenyan public clinics to determine HIV risk and PrEP eligibility (24). This tool includes questions on clients' HIV status and that of their partner(s), as well as their sexual history in the past 6 months, including history of sexually transmitted infections, needle sharing, sexual assault, and PEP usage. We then modified this tool for this pilot to ask an additional four questions about clients' exposure to HIV in the past 72 h and anticipated risk behaviors in the coming month. If a client answers yes to any of the screening questions, they will be potentially eligible for online HIV prophylaxis.

HIV testing

Clients identified as eligible for online HIV prophylaxis *via* the online self-screening tool will be directed to purchase a blood-based HIVST kit *via* MYDAWA to confirm their HIV-negative status prior to any prophylaxis initiation. Clients may choose between two different blood-based HIVST kits. The HIVST kits will be subsidized, and clients will be charged 349 Kenyan Shillings (KES) (∼$3.50 US Dollars [USD]) for online delivery of an HIVST kit: 250 KES (∼USD 2.50) for the kit and 99 KES (∼USD 1.00) for the delivery fee. A MYDAWA pharmaceutical technologist will deliver this HIVST kit to clients at their desired location and provide pre-test counseling and instructions on the self-test use and interpretation of results at the point of delivery if requested.

To continue with the online PrEP/PEP delivery process, clients will need to upload an image of their self-test result and self-interpretation of this result *via* the MYDAWA platform (instructions on these steps will be delivered with the HIVST kit). Further instructions will be available on the MYDAWA platform. The user-friendly instructions and HIVST upload platform were developed by Audere (www.auderenow.org), a digital health nonprofit. Audere developed custom artificial intelligence algorithms which leverage computer vision and machine learning to ensure the uploaded image contains an HIV self-test result and is of high quality. For example, if the image is blurred or does not meet orientation and proximity expectations, the user interface will suggest that clients take a new image of the HIVST result to re-upload *via* the online platform.

Medical eligibility assessment

After HIV risk screening, clients can book a telemedicine consultation with a MYDAWA clinician using their unique user account ID *via* the online platform. This secured and deidentified ID links clients to their MYDAWA visits, allowing the researchers to track clients' PrEP follow-up visits over time. During the telemedicine visit, MYDAWA clinicians will review the HIV risk self-screening assessment completed by clients and the image of the client's uploaded HIVST result. Then, based on the client's exposure to HIV in the past 72 h, the clinician will determine if the client is best suited for PEP or PrEP. Clients who are eligible for PrEP/PEP but have not uploaded their HIVST results will be asked to upload their test results and book another telemedicine appointment once they have done so.

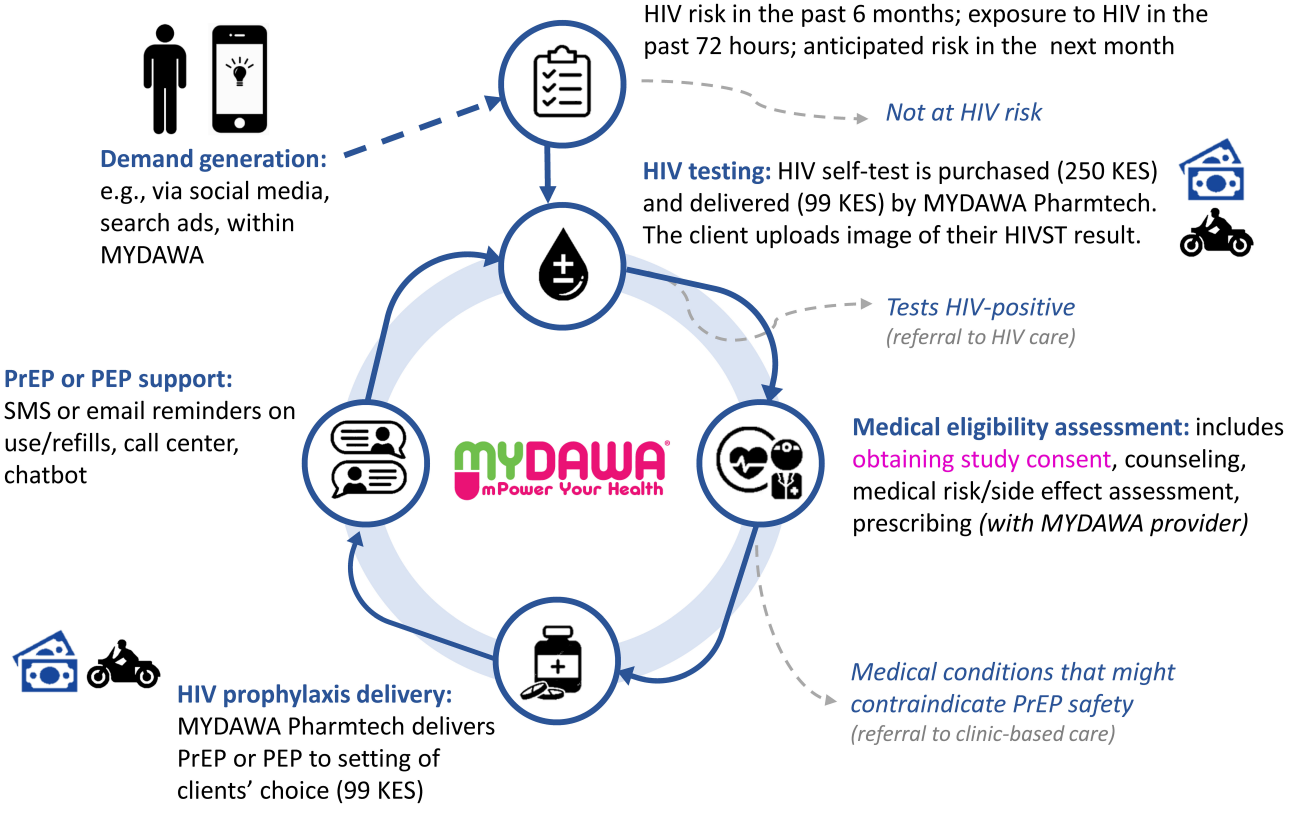

FIGURE 1
The proposed care pathway for online pharmacy PrEP or PEP service delivery *via* MYDAWA.

MYDAWA clinicians will have access to a decision support package to facilitate their interpretation of the clients' HIVST results and inform PrEP/PEP prescribing. The support package will include an image of the test captured by the client, the client's interpretation of the self-test, and three artifacts provided by Audere's algorithms: (1) an indication if a control or test line is present on the HIVST, (2) a cropped image of the HIVST result window, and (3) an enhanced view of the HIVST result window which attempts to highlight faint test lines. Clients whom MYDAWA clinicians determine self-tested HIV positive will be referred to treatment services at public or private healthcare facilities that meet their preferences.

Clients whom MYDAWA clinicians determine self-tested HIV negative will answer questions about medical conditions that might contraindicate PrEP safety (i.e., kidney or liver disease, diabetes, hypertension, or signs of acute HIV infection). Thus, MYDAWA clinicians will verify online HIV prophylaxis eligibility. Clients who report any medical conditions that might contraindicate PrEP safety will be referred to public or private clinics (client's choice) for in-person PrEP care by a clinical provider.

Clients who are confirmed HIV negative, at HIV risk, and medically eligible for PrEP or PEP by a MYDAWA clinical provider will be sent a link for an electronic consent form by the provider. This link will be sent to the client's phone or computer *via* short message service (SMS) or email. Once informed consent has been signed by the client, MYDAWA clinicians will prescribe PrEP or PEP and add the appropriate drug supply (30-days at PrEP initiation, 90-days at PrEP continuation, 28-days at PEP initiation) to the client's MYDAWA e-shopping cart.

HIV prophylaxis delivery

Clients determined eligible for online PrEP/PEP by the MYDAWA clinician may choose to order PrEP or PEP drugs *via* MYDAWA in the quantity associated with initiation or continuation visits. For this pilot study, the Kenya Ministry of Health is providing all PrEP and PEP drugs for free, and clients will only be charged a flat-rate 99 KES fee (~USD 1.00) for drug delivery services. Thus, this drug delivery fee will remain the same even as the volume of PrEP drugs may vary from initiation to refill visits. In addition, we will use pharmaceutical technologists to deliver PrEP and PEP drugs at the clients' preferred location and provide additional counseling on drug use and side effects at the point of delivery, as needed.

PrEP online refill

At the end of the telemedicine consultation, the clinician will inform clients that they will receive a PrEP refill reminder two days before their anticipated refill date *via* a secure email and encrypted

text message. Clients must log in to the MYDAWA platform using their unique user account ID and repeat the HIVST process and medical safety assessment (via a telemedicine consultation) to complete the PrEP refill process.

PEP completion

All clients prescribed PEP will also be reminded to repeat HIVST at 1 month and 3 months post PEP prescription per Kenya Ministry of Health guidelines (25). At the one-month post-PEP prescription, the MYDAWA clinician will encourage those clients who are negative for HIV and at high risk for HIV acquisition to transition to PrEP if medically eligible.

PrEP or PEP support

Support options will include a call center and a MYDAWA chatbot feature to discuss PrEP or PEP concerns and potential side effects. Additionally, clients can request a telemedicine consultation with a clinical officer.

Pilot data collection

The study team will obtain de-identified client-level data from MYDAWA *via* a secure data-sharing platform. This will include clients' age, sex, behaviors associated with HIV risk (i.e., responses to the modified 12-question RAST), HIV status (self-reported and confirmed *via* HIVST), and medical history (i.e., responses to questions asked by the MYDAWA clinician during the telemedical consultation). MYDAWA will also share de-identified data about all enrolled clients' purchases and deliveries related to sexual and reproductive health and online HIV prophylaxis delivery (e.g., HIVST, PrEP, and PEP dispensing). Additionally, de-identified data on clients' use of PrEP and PEP support tools (e.g., chatbot use and frequency and duration of calls to the MYDAWA call center) will be shared by MYDAWA with the study team.

Pilot outcomes

Utilization and process outcomes

Our primary pilot outcomes will be PrEP and PEP initiation at 1 month among MYDAWA clients screened and determined at HIV risk and medically eligible for online HIV prophylaxis service delivery and PrEP continuation at 1 month among clients that initiated online PrEP (see Table 1 for details). Secondary outcomes will include PEP-to-PrEP transition and additional PrEP continuation outcomes (e.g., any continuation over the study period, $\geq$2 refills among those eligible). We will also measure PrEP stopping and restarting, defined as having a lapse in PrEP use for >14 days (26). Additionally, we will measure several process outcomes, including the percentage of clients who have HIVST delivered, uploaded the result of their self-test *via* the MYDAWA platform, correctly interpreted their self-test result, received reminders for PrEP refills, and used different MYDAWA support options (e.g., call center, telemedicine consultation, and chatbot) throughout their online HIV prophylaxis service delivery journey. Finally, throughout the pilot, we will carefully screen for and measure any social harms (e.g., gender-based violence) related to online PrEP and PEP delivery.

Client characteristics

We will measure the demographic characteristics (e.g., age. sex, marital status) and behaviors (e.g., sexual behaviors, health-seeking behaviors) of clients using online PrEP and PEP to understand if this novel delivery model expands the reach of HIV prophylaxis services beyond clients already being reached at public healthcare facilities.

Pilot data analysis

We will use descriptive statistics to summarize online HIV prophylaxis delivery utilization outcomes (e.g., PrEP initiation and continuation), process outcomes (e.g., HIVST uptake), and the characteristics of clients who initiate and do not initiate these online services. We will summarize these outcomes among all enrolled participants and key sub-groups of interest, such as sex groups, age groups, and groups that did and did not achieve different process outcomes (e.g., received email and SMS reminders and utilized support tools). Additionally, we will use bivariate and multivariate regression models to identify client characteristics associated with PrEP initiation, PEP initiation, PEP-to-PrEP transition, and any PrEP continuation.

In a secondary analysis, we will also summarize the characteristics of the "early adopters" (those who engage in online PrEP services closer to launch, i.e., within the first 6 months) vs. the "late adopters" (those who engage in online PrEP services later in the pilot, i.e., after the first 6 months) to help MYDAWA establish more targeted marketing strategies for potential clients who fall later in the adoption continuum. All quantitative analysis will be completed in SAS, R, or STATA.

Assessment of implementation outcomes

Acceptability and feasibility

We will assess the acceptability and feasibility (27) of an online HIV prophylaxis delivery model among clients and providers using behavioral questionnaires, in-depth interviews (IDIs), and routine implementation data (e.g., notes from meetings with the implementation team).

We will complete behavioral questionnaires with up to 500 clients enrolled in the study to understand their experiences with and perceptions of the intervention. This sample size is similar to other PrEP implementation studies that have measured like outcomes (28–30). A trained research assistant will call clients that have completed informed consent and invite them to complete a questionnaire that takes ~60 min. We will invite eligible clients to participate in these questionnaires right after enrollment

TABLE 1 The utilization outcomes, process outcomes, and client characteristics measured in the pilot study.

Category	Outcome	Definition	Measurement	Timing
Utilization outcomes	PrEP initiation[a] (primary)	% of clients screened and determined at HIV risk and PrEP eligible *via* the online platform (MYDAWA) that initiated PrEP.	MYDAWA data; client surveys	Month 2
	PEP initiation (primary)	% of clients screened and determined at HIV risk and PEP eligible *via* the online platform (MYDAWA) that initiated PEP.	MYDAWA data; client surveys	Month 1.5
	PrEP continuation within 45 days of inititaion[b] (primary)	% of clients who refilled PrEP *via* the online platform (MYDAWA) within 45 days of initiation among those who initiated PrEP.	MYDAWA data; client surveys	Month 2
	PEP to PrEP transition	% of clients screened and determined at HIV risk and PrEP eligible *via* the virtual platform (MYDAWA) that initiated PrEP after PEP completion.	MYDAWA data; client surveys	Month 1.5
	PrEP continuation with at least one refill[b]	% of clients who refilled PrEP *via* the online platform (MYDAWA) among those who initiated PrEP.	MYDAWA data; client surveys	Months 2 & 6
	PrEP continuation with at least 2 refills[b]	% of clients who refilled PrEP at least twice *via* the online platform (MYDAWA) among those who initiated PrEP.	MYDAWA data; client surveys	Months 2 & 6
	PrEP stopping and restarting	% of clients who refilled PrEP *via* the online platform (MYDAWA) with a gap of >14 days in pill coverage among those who initiated PrEP.	MYDAWA data; client surveys	Months 2 & 6
Process outcomes[c]	HIVST utilization	% of clients screened and determined at HIV risk and PrEP eligible *via* the online platform (MYDAWA) that ordered an HIVST.	MYDAWA data	N/A
	HIVST image upload	% of clients who uploaded the image of the self-test result on the online platform (MYDAWA) among those that ordered an HIVST.	MYDAWA data	N/A
	HIVST interpretation	% of clients who correctly identified the presence of test and control lines on their self-test result on the online platform (MYDAWA) among those that ordered an HIVST.	MYDAWA data	N/A
	MYDAWA clinical officer utilization	% of PrEP clients that consulted with the MYDAWA clinical officer (including and excluding during the prescribing process); summary of consultation topics discussed	MYDAWA data	N/A
	Selection of PrEP support tools	% of clients that used chatbot and call center to ask PEP/PrEP-related questions	MYDAWA data	N/A
Client characteristics[c]	Demographics	Client demographics including age, sex, income, occupation, and other demographics	MYDAWA data; client surveys	Month 0
	Behaviors associated with HIV risk	% of clients reporting different demographics (e.g., marriage, SES) and sexual behaviors (according to Kenya's RAST tool)	MYDAWA data; client surveys	Months 0, 2, & 6
	History of PrEP use	% of clients that are: (1) first time PrEP users, (2) past PrEP users, or (3) current PrEP users.	MYDAWA data; client surveys	Month 0
	Contraceptive use	% of clients reporting contraception use/type; frequency of EC	Client surveys	Month 0

[a]For all enrolled clients, we will call them 2 months following enrollment to measure self-reported outcomes.
[b]To remind clients to refill PrEP via the online platform, we will use SMS/email reminders.
[c]The pilot process outcomes and clinical characteristics include but are not limited to those listed in this table.

and again at 2 and 6 months (PrEP clients) or 1.5 months (PEP clients) following enrollment (see Figure 2). Questionnaires will be conducted in-person or remotely, depending on the client's preference. Topics covered in the questionnaire include more detailed client demographics, assessment of clients' sexual behaviors, screening for the prevalence of depression, HIV prophylaxis use history, stigma associated with PrEP use, HIVST use history, adherence to HIV prophylaxis, potential side effects experienced, online HIV prophylaxis acceptability, willingness to pay for online HIV prophylaxis and social harms experienced during the study period (see Table 2 for details). Additionally, we will include quantitative assessments for online HIV prophylaxis acceptability.

Study staff will purposively identify (based on gender and age), contact, and invite clients and providers engaged in online HIV prophylaxis services to participate in IDIs that focus on the intervention-, client-, provider- and system-level factors influencing the implementation of the intervention (see Table 3 for

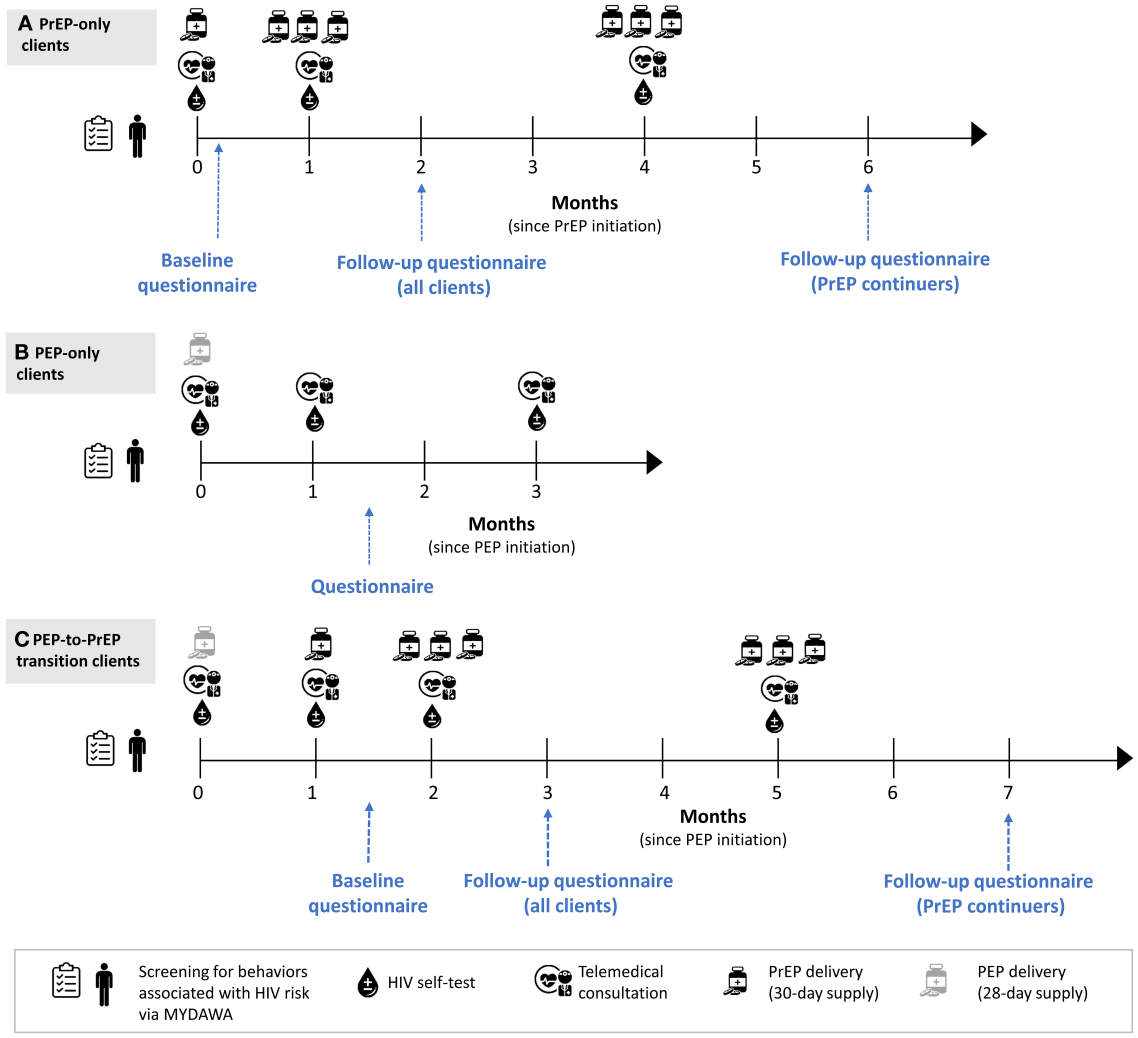

FIGURE 2
Overview of quantitative data collection at the client level. **(A)** PrEP only clients. **(B)** PEP-only clients. **(C)** Clients who transitioned from PEP to PrEP.

details). We will conduct up to 100 IDIs, 80 IDIs with clients, and 20 IDIs with providers. All IDIs will be conducted in English or Swahili (the local language), either in-person or virtually, depending on the interviewee's preferences. The IDIs will last ~60 min and will be guided by the Theoretical Framework of Acceptability (31) to help us better define the multi-dimensional construct of acceptability, as well as the Structured Assessment of Feasibility (32) and the Health Belief Model (33), to help us identify potential barriers and facilitators of feasibility and behavior change. With permission, the IDIs will be audio-recorded. In addition, once a month, we will hold meetings with MYDAWA staff to discuss their primary responsibilities for this delivery model, challenges faced, and opportunities to improve PEP/PrEP delivery *via* this platform using structured guides. With permission, the discussion will be audio-recorded.

We will use descriptive analysis to summarize the proportion of MYDAWA clients who reported that the online HIV prophylaxis delivery was acceptable, according to the assessments included in our questionnaires. Then we will use inductive and deductive qualitative analysis approaches and data from the IDIs to identify key themes related to the determinants of the intervention's acceptability and feasibility as well as any barriers and facilitators to implementing the online HIV prophylaxis delivery model. We will summarize key themes and relevant codes in a spreadsheet matrix guided by the socio-ecological framework (i.e., with client-, provider-, and system-levels) (34) and explore how these themes vary across these different levels. Additionally, to document any modifications that may occur to the online PrEP and PEP delivery model during implementation, we will use the Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS) (25). Finally, we will use Dedoose (https://www.dedoose.com/) to support the review and coding of all IDI transcripts and MYDAWA staff meeting minutes.

Costs

We will conduct micro-costing, staff interviews, and time-and-motion observation to estimate the financial and economic costs of

TABLE 2 Behavioral data collection activities at enrollment (Baseline) and follow-up visits.

Survey section	Description	Timing	
		Baseline	Follow up[a]
Demographics	Gender, age, education, monthly income, relationship status, marital satisfaction	X	
Sexual behaviors	Number of sexual partners, partners' HIV status, contraception use, if the client trying to conceive	X	X
Depression	Patient Health Questionnaire-2 (PHQ-2) tool	X	X
PrEP/PEP knowledge and use history	When and how the client learned of PrEP/PEP and online PrEP/PEP, prior PrEP/PEP use, source, reasons for stopping use, preference for where to obtain PrEP/PEP	X	
PrEP stigma	Client perceptions about PrEP stigma	X	
HIV testing history	prior HIV testing history, prior HIVST use history	X	
PrEP/PEP adherence	Number of PrEP/PEP pills missed in the past month, self-reported adherence quality, strategies used to remember taking pills	X	X
Potential drug side effects	Diarrhea, nausea, fatigue, aches	X	X
Online PrEP/PEP acceptability	Theoretical Framework of Acceptability (e.g., affective attitude, burden, perceived effectiveness)	X	X
Willingness to pay	HIVST, telemedicine, PrEP/PEP supply	X	X
Social harms	Gender-based violence and harms related to online PrEP/PEP service delivery	X	X

[a]Only PEP clients that transition to PrEP complete follow-up questionnaires.

implementing online PrEP and PEP delivery. Costs will be collected from the payer perspective. A trained research assistant will utilize standardized Excel cost menus to collect intervention costs: including start-up, software development, training, space, human resources, and supplies/equipment. Capital and start-up costs will be annualized, assuming a useful life of 5 years and a discount rate of 3%. The research assistant will interview staff and providers to assess the daily responsibilities of implementing online PrEP and PEP delivery. Time-and-motion observation of intervention activities from user/provider interactions (telemedicine visits with MYDAWA clinicians, delivery of HIVST by pharmaceutical technologists) will be used to measure staff time costs. Research time (e.g., administering informed consent) and other research costs will be removed from programmatic costs.

We will estimate the total annual cost and cost per client-initiated on PrEP using uptake data from the pilot and compare this to other models of PrEP delivery, including the standard-of-care at public clinics and the newly developed model of pharmacy-based PrEP delivery (22). Cost per client will be calculated as the total annual cost divided by the number of clients initiated on PrEP. We will estimate the costs of different operational components of online PrEP delivery, including demand generation approaches and HIV testing modalities. We will conduct scenarios and sensitivity analyses to assess the impact of various assumptions (e.g., client volume and scale, HIV testing strategies, demand generation approaches, and cost-sharing models among providers, payers, and clients).

Discussion

This study will evaluate the initiation and continuation of PrEP and PEP, the feasibility and acceptability of an online PrEP and PEP delivery model, describe the characteristics of clients obtaining PrEP and PEP online, and evaluate the costs and implementation factors associated with online HIV prophylaxis delivery in Kenya. The evidence from this study will help us better understand who might be reached with an online model of PrEP and PEP service delivery, what their engagement in care might look like over time, and how much this new service delivery model might cost; information that can inform guidelines on online HIV prophylaxis delivery in Kenya and similar settings.

This study has several limitations. First, our study population is limited to individuals with computer or phone access who have sufficient technology and English language literacy to navigate an online pharmacy platform. Similarly, our study population is limited to individuals with the financial resources to pay for HIVST kits and PrEP or PEP medication delivery. Therefore, our findings may not be generalizable to individuals who do not have the technological literacy to use a platform like MYDAWA or do not have the financial resources to pay for the convenience of online service delivery. Third, due to the short follow-up period, we will not measure longer-term implementation outcomes (27). Despite these limitations, we anticipate that we will still be able to identify individuals who are not currently engaged with PrEP or PEP services, have unmet needs for these medications, and may use the online platform to access them.

Policy changes would need to occur for this model to be scalable and sustainable beyond this research study and frameworks for public-private partnerships would need to be established. For example, in Kenya and many other settings, HIVST is only recommended as a screening test, not to inform prescribing and dispensing of antiretrovirals (25, 35). In addition, while there has been progressive growth of telemedicine in Kenya, especially since the start of the COVID-19 pandemic, national guidelines

TABLE 3 Description of implementation outcome measures in the pilot study.

Outcomes	Definition[a]	Measurement approach	Level of analysis
		Sample questions	
Acceptability	The perception among stakeholders that online PrEP/PEP delivery is agreeable, palatable, or satisfactory.	Quantitative questions for clients based on the Theoretical Acceptability Framework (5-point Likert scale): *"I like getting PrEP/PEP through MYDAWA"* *"I would like to continue getting PrEP/PEP through MYDAWA"* Qualitative questions for clients: *What did you **like** about getting PrEP/PEP from MYDAWA?* *What did you **dislike** about getting PrEP/PEP from MYDAWA?* Qualitative questions for providers: *What are your thoughts on how this program might be effective in providing HIV services for customers not reached by traditional methods?*	Client-, provider- and systems-level
Feasibility	The extent to which online PrEP/PEP delivery can be successfully implemented at scale in Kenya.	Qualitative questions for providers: *Do you think it is possible to implement online pharmacy services in Kenya to deliver PrEP/PrEP? Tell me more about that.*	Provider- and systems-level
Costs	The incremental cost of implementing online PrEP/PEP delivery in Kenya.	*Micro-costing, staff interviews, and time and motion observation to estimate the financial and economic costs of implementing online PrEP/PEP delivery.* Willingness to pay question for clients: *Approximately how much would you be willing to pay for a remote/online clinical encounter to start PrEP/PEP services? (in Kenyan Shillings)*	Client-, provider- and systems-level

[a]Definitions derived from Proctor's framework of seven implementation outcomes (27).

for HIV services are premised on in-person care. Uploading a photo of an HIV test result to inform remote prescribing of antiretrovirals is new and some regulations around this process may need to be established. In this study, public-sector goods (e.g., PrEP and PEP drugs) were also provided for free to a private-sector company (e.g., MYDAWA) to help keep the price of online PrEP and PEP service delivery affordable to interested clients. For these public-private partnerships to be sustained, frameworks are needed to guide this collaboration and inform the amount private companies can charge for public goods. Additionally, record systems will need to be established to track the delivery of public commodities in private settings, among other things.

As access to telecommunications and new technologies continue to rise in sub-Saharan Africa (36), technology-based interventions, such as online HIV prophylaxis delivery, have great potential to expand the access of existing services to new populations and relieve overcrowded public healthcare facilities. This novel model of online PrEP and PEP delivery integrates telemedicine, at-home HIVST, and courier delivery to support at-home PrEP/PEP initiation and PrEP continuation, the first of its kind in Africa. This research will inform and potentially expand the list of HIV prophylaxis delivery models to help maximize the impact of these interventions and end the AIDS epidemic (37).

Ethics statement

This research protocol has been reviewed and approved by the Scientific and Ethics Review Unit at the Kenya Medical Research Institute (Nairobi, Kenya) and the Institutional Review Board at the University of Washington (Seattle, USA). All research participants will provide electronic documents of written informed consent to participate in this study.

Author contributions

KFO, KN, MLM, MS, and AS conceptualized this study. CK, PN, JCD, RCM, and MR were responsible for project administration. CK, PN, KFO, JCD, MLM, and AS completed writing. KFO, KN, and MLM provided supervision and acquired funding. All authors edited and revised the paper. All authors contributed to the article and approved the submitted version.

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Mobile health can be patient-centered and help solve inequality issues in Brazil's Unified Health System

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KEYWORDS

mHealth, digital health, public health care systems, patient—centered care, SUS—Brazilian national health system

Introduction

The use of mobile health (mHealth) is on the rise in many fields (1). The Global Observatory for eHealth of the World Health Organization defines mHealth as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices (2)." The desire to overcome obstacles imposed by the pandemic made mHealth more popular than ever in the past years (3). Ethical issues, however, stimulate discussions about the theme (1, 4).

MHealth could help the biggest governmental health care system in the world

In Brazil, one of the most challenging public health problems is attending to the universality principle of the country's Unified Health System or, in Portuguese, Sistema Único de Saúde (SUS). SUS is the world's largest health care system run by a government. The challenge is not only due to the almost 200 million users of the system, but also due to the continental dimensions of the country. Therefore, although SUS is offered to the everyone in the country, including foreigners, some areas have better access to health service than others. But, in face of that problem, some mHealth initiatives have started to help solve this inequality issue (5).

With an estimated 6 billion users in 2022, "mobile phones have become nearly ubiquitous both at the margins and the centers of capitalism (6)." That means mobile phones can serve as instruments to help solve the problem of inequality in public healthcare access worldwide, since many studies have proven mHealth can be an efficient way to deliver health services at lower costs (1, 2, 4, 5). In fact, The Universal Declaration on Bioethics and Human Rights presented by the United Nations Educational, Scientific, and Cultural Organization (UNESCO) has stated the necessity to rapidly share new therapeutic modalities or products stemming from research with countries in the developing world (7).

Mhealth can be personalized and patient-centered too

In spite of its potential, mHealth assistance carries disadvantages over in-person care. It is no secret that mHealth deprives patients and healthcare professionals (HCP) of

essential elements of interpersonal communication (e.g., full body language) (4). But it also has advantages. Having the chance to communicate with the HCP and access other health services using a mobile phone in the comfort of home has proven to be cost-effective and to have, in many cases, satisfactory outcomes in patient self-efficacy, quality of relationship between HCP and patient and overall health outcomes (1, 4, 6, 7). While mobile health industry may inadvertently convey the idea that HCP can be replaced by artificial intelligence, nothing is equivalent to or better than the bond between HCP and patients. Unless a mobile application is facilitating that relationship, it is probably not as good as it could be if it created a space for that rapport to flourish.

Many studies have demonstrated patient-centered care has positive outcomes in satisfaction and self-management (8). The vulnerability of a human being in need of help is not better covered by artificial intelligence than by another human being's sensitivity. Studies have shown technology works at best when it facilitates and strengthens the relationship between the parts involved in healthcare. A meaningful relationship in the context is not only important for patients, but for HCP as well, being recently rated as the most significant source of professional satisfaction among physicians (4). Since mHealth can serve as a channel of relationship *via* synchronized and unsynchronized communication, it can serve as an environment for humanized patient-centered healthcare. Adjusting to users' preferences and enabling a meaningful experience for both sides can help in the context. Instead of rapidness and depersonalization, which characteristics associated to mobile applications, mHealth can provide unhurried, deep healthcare experiences.

Discussion

The field of mHealth may offer promising tools against health inequalities in Brazil and other parts of the developing world. They may have quality problems, as in person healthcare does. But what determines whether healthcare is patient-centered is the focus on the patient and his or her needs and not the environment where it occurs. Different environments, including those mediated by technology, can serve as scenarios where human dignity is promoted. In fact, many solutions in mHealth have good outcomes, equivalent to those in-person (1, 2, 4–6). Therefore, due to its vast capillarity, mHealth may help attenuate the problem of inequality in healthcare assistance in public health in Brazil and other parts of the developing world and should be the target of substantial investment and research.

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The author confirms being the sole contributor of this work and has approved it for publication.

Conflict of interest

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Uptake and effectiveness of a mobile application for real-time reporting and quality assurance of decentralized SARS-CoV-2 testing in Uganda

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Background: Effective management of the COVID-19 pandemic required rapid expansion of diagnosis. The introduction of antigen tests presented an opportunity to decentralize testing, but raised challenges with ensuring accurate and timely reporting of testing data, which is essential to guide the response. Digital solutions can help address this challenge and provide more efficient means of monitoring and quality assurance.

Methods: Uganda's existing laboratory investigation form was digitized in the form of an Android-based application, eLIF, which was developed by the Central Public Health Laboratory and implemented in 11 high-volume facilities between December 2021 and May 2022. The app enabled healthcare workers to report testing data via mobile phone or tablet. Uptake of the tool was monitored through a dashboard that enabled real-time visibility into data being transmitted from sites, as well as qualitative insights from site visits and online questionnaires.

Results and discussion: A total of 15,351 tests were conducted at the 11 health facilities during the study period. Of these, 65% were reported through eLIF, while 12% were reported through preexisting Excel-based tools. However, 23% of tests were only captured in paper registers and not transmitted to the national database, illustrating the need for increased uptake of digital tools to ensure real-time data reporting. While data captured through eLIF were transmitted to the national database within 0–3days (min, max), data transmitted through Excel were transmitted in within 0–37days (min, max), and data for paper-based reporting took up to 3months. The majority of healthcare workers interviewed in an endpoint questionnaire responded that eLIF improved timeliness of patient management, and reduced reporting time. However, some functions of the app were not successfully implemented, such as providing random selections of samples for external quality assurance and enabling seamless linkage of these data. Challenges arose from broader operational complexities, such as staff workload, frequent task-shifting and unexpected changes to facility workflows, which limited adherence to the envisioned study procedures. Ongoing improvements are needed to adjust to these realities, to strengthen the technology and support to healthcare workers using it, to optimize the impact of this digital intervention.

KEYWORDS

COVID-19, decentralized diagnosis, digital, data, surveillance, quality assurance

Introduction

Since the first reported case of SARS-CoV-2 in Uganda in March 2022, over 169,000 infections and 3,620 deaths have been registered, as of August 2022 (1, 2). The pandemic has manifested through multiple waves of infections, each associated with the emergence of variant strains that may increase transmission rates (3, 4). To ensure timely and agile responses to this rapidly evolving virus, expansion of diagnostic coverage—along with rapid access to reliable data on testing outcomes—is essential (5).

Polymerase chain reaction (PCR) targeting various SARS-CoV-2 conserved gene regions is the gold standard for diagnosis, due to its high sensitivity and specificity (6). However, the method is expensive, has a long turnaround time to results, and requires specialized laboratory facilities and personnel skills (7). In the first year of the pandemic response, this caused delays in detection and missed opportunities for timely interventions (7). The introduction of rapid antigen diagnostic tests (Ag-RDTs)—which are less costly and have fewer requirements in terms of infrastructure, biosafety and skill—presented exciting opportunities to increase access to testing and strengthen surveillance, particularly at the peripheral level of health systems in low-and middle-income countries (LMICs) (8).

In September 2020, following field evaluation, Uganda adopted SARS-CoV-2 Ag-RDTs for use in health facilities and community testing. However, uptake has been relatively low, accounting for 6% of the 3.98 million tests COVID-19 tests conducted in Uganda by December 2022 (9). Data management has been one of the challenges associated with expansion of decentralized rapid diagnostic testing and implementation of electronic health interventions is constrained by the complexity of Uganda's health system design (10).

Timely reporting of SARS-CoV-2 infections is a critical pillar of the pandemic response (5). Daily reporting is more feasible with centralized PCR testing in laboratories that typically have elaborate laboratory information management systems. It is difficult to realize timely and accurate reporting on Ag-RDT testing at numerous lower-level health facilities that lack electronic information systems. In settings where paper-based data management is used, long lags in the transmission of Ag-RDT testing data have been noted. For example, in South Africa, it was estimated that the median time between testing and reporting for Ag-RDTs was 29.7 days in the public sector (11).

In LMIC settings, digital solutions have provided a means to ensure that data could be reliably collected from decentralized testing sites (12, 13). While digital solutions have often served a similar function in other disease responses in Uganda in the past (12, 13), the national e-Health and data management strategy highlights that these tools have often been fragmented, with limited scale-up outside of individual projects (14).

Mobile networks cover almost all of Uganda, including rural and remote areas since 2012 and 60.53 per 100 people in the country were mobile phone subscribers by 2020 (14, 15). As such, digital tools have considerable potential to transform the timeliness and efficiency with which health data is reported and used to inform decisions. For optimal scalability of such tools especially in remote areas, they would need to be accessible via mobile phone, so as to minimize infrastructure requirements, and integrated with national health data systems for seamless transfer of patient information.

In the context of the COVID-19 response, there was also an opportunity to use digital tools to support external quality assurance of Ag-RDT testing, as at the time of their introduction, the field performance of these tests was not routinely monitored in Uganda. Establishment of end-to-end patient records that linked outcomes of both rapid and confirmatory PCR tests could enable such post-market surveillance to be routinely conducted. Inclusion of symptom data in these patient records also offered the possibility of deeper insights into the relationship between clinical factors and SARS-CoV-2 outcomes.

In the first year of the pandemic response, COVID-19 testing data were largely captured by facilities in a paper-or Excel-based Laboratory Information Form (LIF), from which data was subsequently uploaded to the national results dispatch system (RDS). This required multiple steps of capturing, transcribing and transmitting data—and for Excel-based reporting, access to a computer in the facility. This study aimed to evaluate the uptake and effectiveness of a digitized form accessed through an Android-based app, eLIF (electronic LIF), that could be used by healthcare workers on mobile devices and integrated with RDS to enable real-time reporting and monitoring of testing.

Sustainable entry of digital tools into public health systems requires identifying and working with enablers and constraints of successful adoption, which vary between and within countries. A recent review of lessons from the implementation of digital solutions for community and primary healthcare workers in different African countries highlighted wide variation in the effectiveness of these interventions, with the most common issues being infrastructure (connectivity and uninterrupted power supply) and digital literacy in the health workforce (16). However, with these and other considerations being highly context-specific, there is a need to design localized evaluations of the adoption of digital technologies, in order to understand key success factors as well as opportunities for improvement.

Methods

Study design

This was a cross-sectional multi-site study conducted in 11 health facilities, selected on the basis of having high COVID-19 testing volumes with limited access to PCR testing and long result turnaround time.

The study included all suspected SARS-CoV-2 cases presenting to participating facilities who were eligible for COVID-19 testing according to the national testing guidelines. Patients received the standard of care with the study interventions focusing on data capture and selection for external quality assurance (EQA).

A mixed-methods analysis was used to evaluate feasibility, uptake and acceptability of the app. This comprised analysis of quantitative data on utilization, site visits for direct observation of implementation, and structured questionnaires administered to healthcare workers.

Overview of digital system

eLIF presented a sustainable option for digitizing rapid testing data as it was fully developed and hosted by Uganda's Central Public Health Laboratory (CPHL), allowing for easier customization and alignment with broader digital systems than if the technology was owned by a third party.

The main components of the eLIF system are the users, access devices, mobile application, database server and web services. Information such as user's details and patient information are stored in the databases. Web services are used to transfer information between the mobile application and the web applications (RDS and COVID-19 Dashboard). The mobile application provides different interfaces for users based on the activities they need to perform. Figure 1 describes the high-level architecture of the mobile application for eLIF system.

The eLIF mobile application uses JavaScript Object Notation (JSON) format for data transmission from the web server to the mobile application for log-in. JSON is used because it is supported by most major programming languages and is used commonly as a preferred information exchange format between web clients and servers (Figure 1).

Development process

The development of eLIF was led by Uganda's CPHL ICT team, with technical inputs from Foundation for Innovative New Diagnostics (FIND), the global alliance for diagnostics. The development was done in line with principles of digital development (17). The seven phases of the software development lifecycle were as follows: planning, definition of user requirements (Laboratory Investigation Form), design and prototyping, software development, testing, deployment, operations and maintenance. The study focused on the last two phases of this lifecycle.

Mobile app design

Once a health worker logged in, eLIF presented the "*Enter investigation data*" tab to capture patient information. This included patient identifiers (only accessible to facility or CPHL personnel, to protect confidentiality), demographic and clinical information, and sample type.

Once this was completed and a sample taken for the rapid test, the patient's information was available in a "*pending results*" tab. Healthcare workers could capture investigation data for additional patients while waiting for the test to complete (approximately 15 min), then return to the "pending results" tab to enter the test result and date. eLIF was also designed to randomly select and flag every tenth negative sample for referral to EQA, which included confirmatory PCR testing as well as genomic sequencing to determine which variant of SARS-CoV-2 caused the infection. All positive samples were also referred for EQA. The overall target for EQA (4000) was determined based on feasibility. These estimates also informed the frequency of random selection of negative Ag-RDTs (1 in 10) to ensure sufficient volume was reached. After the tester assigned a result, the app would flag a request for EQA by PCR for selected samples, with a provision to scan the barcode attached to the Ag-RDT sample for ease of linking records between the rapid testing site and the PCR lab.

Once results had been entered, an "*Edit Recently Entered Results*" allowed healthcare workers to correct any errors within 5 min of the result entry. Thereafter, it was not possible to make changes to the test result, which is a standard measure used by CPHL to ensure data integrity. It was assumed any errors would be detected within this time frame, after which the client may have departed and the test cleared away. The application also included a verification quality control step, displaying the test result and identifiers before the submission of the final result. A "*view submitted results*" tab enabled healthcare workers to search any records that had been captured in eLIF using patient identifiers. eLIF was linked to RDS for automated transmission of all data into the national COVID-19 data repository. Through the "*Go to Results Dispatch System*" tab, healthcare workers could print official test reports for patients where required.

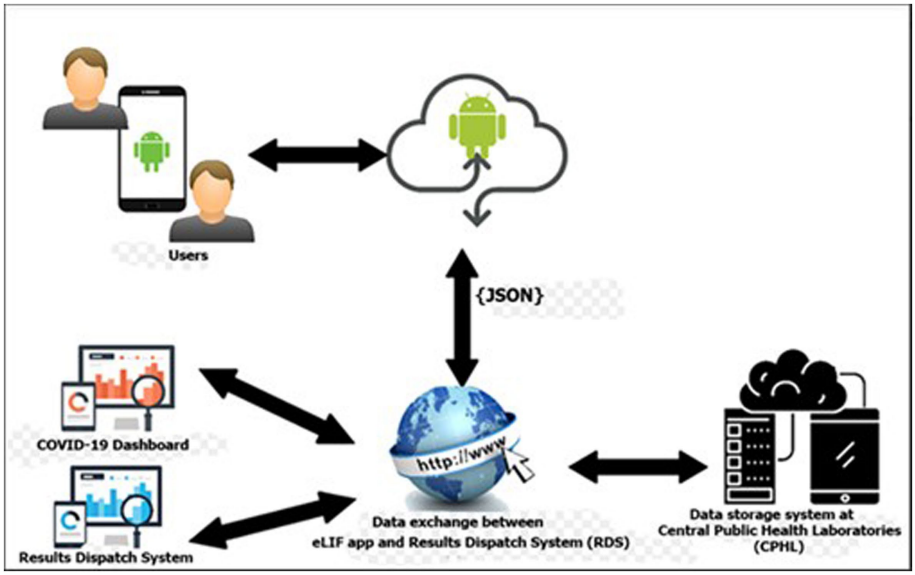

FIGURE 1
eLIF architecture. CPHL, Central Public Health Laboratory; eLIF, electronic Laboratory Information Form; JSON, JavaScript Object Notation; RDS, national results dispatch system.

In addition to capturing patient data, eLIF also included functions to support implementation monitoring. Through the "*Enter Logistics Data*" tab, healthcare workers could report on stock status of the supplies used for testing, such as Ag-RDTs and swabs. The "*COVID-19 Dashboard*" tab also gave them access to the study dashboard, which was used to monitor disease trends and performance indicators.

COVID-19 dashboard design

The study dashboard, developed as an open-source web application, was hosted within the CPHL server and allocated a public IP address to enable access to offsite users. The dashboard is responsive and accessible across mobile devices with various display dimensions. Facility users and approved study personnel with log-in credentials could access a study-specific section of the national dashboard,[1] where more detailed data and analytics from the participating facilities were hosted. This study data could be viewed via download of an Excel dataset with raw, disaggregated and de-identified records for all patients whose data had been entered into eLIF.

The dashboard also included performance monitoring tabs that provided aggregated epidemiological and operational indicators from the facilities, with automated alerts to flag if any indicators went outside a pre-defined "acceptable" range and thus prompt further investigation by CPHL. A log of queries submitted by study facilities, with notes on the status and how these had been addressed, were also visible on the dashboard.

User requirements

eLIF was available in the Google Play Store ("eLIF-UGANDA") for use by healthcare workers in participating study facilities. To access eLIF, healthcare workers needed a mobile device that used an Android operating system and had available memory of 110 MB. Once installed, they were required to log in using the individual username and password assigned by the CPHL team to protect access to data and ensure that data could be linked to a specific health worker and facility. While internet connectivity was required for transmission of data to RDS, data capture and other app functions did not require an active connection, to enable use at health facilities with poor internet connection.

Privacy and confidentiality

To ensure confidentiality of information, each user was given restricted access and sharing of accounts was discouraged. A second level of authentication within eLIF was highly recommended. During login, a code was sent to the mobile device via text message, which was mandatory to input in order to access the system.

Training and roll-out

A training of trainers was conducted at CPHL, following which trainers were dispatched to facilities to train laboratory and clinical healthcare workers from participating facilities on the use of the app and the study workflow. Each facility was provided with two mobile devices and internet bundles to support data capture, with healthcare workers also encouraged to install and use the app on their personal devices where needed, and provided with internet data bundles to facilitate this.

Monitoring implementation

Monitoring was conducted through analysis of data accessed through the dashboard, together with site visits and qualitative interviews. This informed targeted actions by CPHL, where needed, for continuous quality improvement (Figure 2).

Data analysis

Both quantitative and qualitative data were collected from the 11 health facilities. Qualitative data were collected using semi-structured questionnaires during site visits midway the study implementation period, and endpoint assessment was done using online Google forms. The quantitative dataset was downloaded from a central database in Microsoft Excel format. The dataset was cleaned and exported to STATA 14.2 for analysis.

Comparators were largely not available as most facilities do not conduct routine monitoring of the study indicators being investigated, which formed part of the rationale for introducing this digital intervention. However, if participating facilities used multiple reporting methods, comparison between different reporting methods was conducted where possible.

Ethical approval

All study procedures were approved by the Uganda National Health Laboratory Services (UNHLS) Research Ethics Committee and the Uganda National Council for Science and Technology (UNCST), research registration number (HS1723ES), protocol amendments, or deviations during the course of implementation, were also submitted for approval.

Results

Uptake

Uptake of eLIF in testing sites

eLIF was rolled out in all 11 health facilities, ranging from health centers to referral hospitals. At the time the study was designed, COVID-19 testing was typically centralized within facilities, but as the pandemic response shifted from an emergency response to routine management, testing was increasingly disseminated across facilities. During the mid-point site visits (March 2022) it was noted that on

1 http://covid19.cphluganda.org/

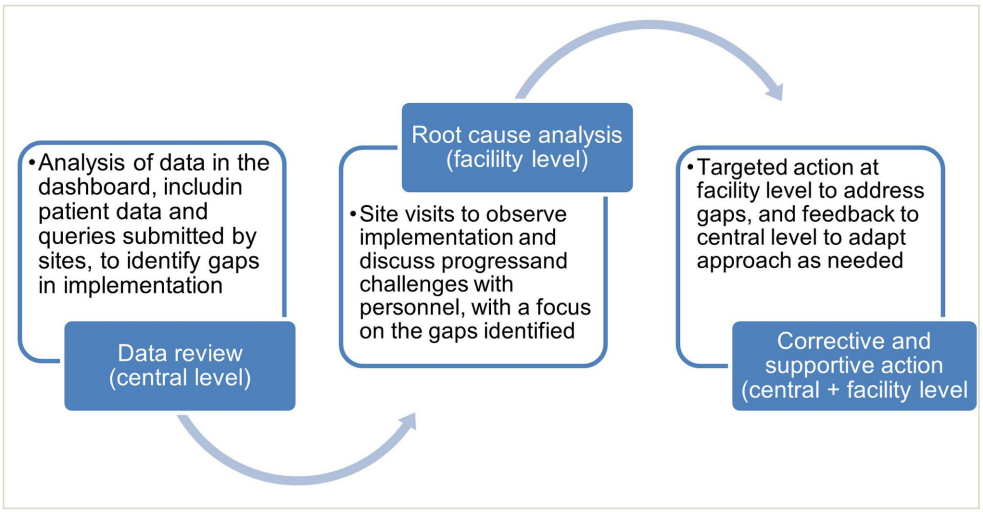

FIGURE 2
Feedback cycle informed by data from eLIF and site visits.

TABLE 1 Proportion of COVID-19 Ag RDT test records captured through different reporting methods.

Health facility	n	Count (%) of real-time data	Count (%) of .csv data	Count (%) of paper registers
Butabika RRH	880	850 (96.59)	30 (3.41)	0
Entebbe RRH	1,438	793 (55.15)	26 (1.81)	619 (43.05)
Jinja RRH	2097	338 (16.12)	1,514 (72.20)	245 (11.68)
Kawempe NRH	954	540 (56.60)	1 (0.10)	413 (43.29)
Kiruddu NRH	1,010	59 (5.84)	1 (0.10)	950 (94.06)
Mbale RRH	315	144 (45.71)	1 (0.32)	170 (53.97)
Mulago NRH	4,956	4,955 (99.98)	1 (0.02)	0
Moroto RRH	168	143 (85.12)	9 (5.36)	16 (9.52)
Soroti RRH	1897	1858 (97.94)	39 (2.06)	0
St. Mary's Hospital, Lacor	805	144 (17.89)	159 (19.75)	502 (62.36)
Wakiso HC IV	831	150 (18.05)	7 (0.84)	674 (81.11)
Total	15,351	9,974 (64.97)	1788 (11.65)	3,589 (23.38)

(A) Real-time data were captured by health facility personnel using eLIF app within 0–3 days (min, max) with a median time of 24 h. (B) Data in .csv format were captured by health facility personnel using the Microsoft Excel spreadsheet and uploaded into RDS within 0–37 days (min, max) with a median time of 24 h. (C) Missed data were captured from COVID-19 paper registers by CPHL staff using the eLIF app during project mid-assessment as an intervention to ensure completeness of data collected at health facilities.

average each health facility had two testing points, while at least two facilities were providing COVID-19 testing across all wards. Reporting practices varied both between these testing points, and across facilities. The degree of uptake of eLIF in testing sites was determined by looking at the route through which data was transmitted to RDS.

Where eLIF was not used, some healthcare workers continued to use alternative digital reporting channels such as Microsoft Excel uploads to RDS, while in some cases data were captured on COVID-19 paper registers and not transcribed to any electronic tools. The latter proportion was determined through a view of facility files during the site visits, and these data were then manually added to electronic databases. Table 1 shows the proportion of records captured through each of these methods, by facility. Overall, 64.97% of patient records were submitted via eLIF and 11.65% through alternative digital channels, while 23.38% were only recorded on paper registers and had to be manually transmitted to the national repository by study personnel during site visits (Table 2).

Utilization

The original methodology for measuring utilization assumed a largely static staff complement, with utilization to be calculated based on the proportion that regularly submitted data via eLIF. In practice, however, staff movement was more complex. Some study staff left facilities during the implementation period, while others were on occasion reassigned to other units of the facility to meet demand for other services, especially when COVID-19 testing demand decreased. This unpredictability in staff movement required an adjusted approach during the study.

TABLE 2 eLIF app user activity from December 2021 to May 2022.

Summary	
Total number of users accounts issued overstudy duration	40
Total number of user-months (# of users x # of months with existing acct)	195
Proportion of all user-months that were active	50.3%
Proportion of all study-trained users still active at end of study	12.5%
Proportion of users trained at beginning ("original users") still active at end of study	23.8%
Proportion of users deactivating during study	22.5%
Proportion of non-deactivated users still active at end of study	16.1%
Proportion of all-time users that were onboarded during study ("new users")	0.0%
Proportion of users with inactive status at any point	92.5%
Proportion of users active for at least 70% of their user-months	22.5%

To account for changes in staff workflow throughout the study, utilization was therefore determined in monthly units—calculating the number of months that all users registered in the system were active, as a proportion of the total potential months that they could have been active. Months during which users left health facilities were excluded from the denominator, with these users considered to have "deactivated" their accounts, while those who were still in the facility but not uploading data via eLIF were marked as "inactive."

The final utilization, per user and facility, are presented in Table 2. A total of 40 user accounts were issued across the facilities during the study period. User accounts were assigned to specific COVID-19 focal persons with the responsibility of performing tests and data capture at the health facilities. Although sharing of accounts was disallowed under the study procedures, anecdotal evidence suggests that other healthcare workers may have used the focal person's account, due to frequent and often unforeseen task-shifting to other support staff in the COVID-19 testing centers. As a result, the actual number of end-users was larger than the number of documented user accounts.

A total of 22.5% of accounts were deactivated during the study period. Overall, 50% of total potential user-months were active, with over 90% of healthcare workers being inactive at some point during the study, during which COVID-19 positivity rates declined from an initial peak during the Omicron wave of December 2021. Due to the difficulties of monitoring shifting workflows within facilities, it is possible that inactivity may have corresponded with periods during which the staff assigned to that account remained within the facility but were not conducting testing.

In the final month of the study, by which a wider drop in both positivity rates and demand for testing had taken place, only 16% of user accounts were actively submitting data.

Effectiveness

Data timeliness

The main objective of eLIF was to decrease the time between testing and central results reporting. Throughout the study, the time between test being conducted and data reporting into RDS varied by collection method. Data that were captured in paper registers (23.38% of patient records) were not transcribed into any electronic reporting system, and had to be entered by CPHL staff during mid-term assessments, which were conducted 3 months after study initiation. The delay between testing date and date of entry into the register by CPHL staff varied from 0 to 130 days with a median of 24 h. Records entered via eLIF were reported within 0–3 days, with a median time of 24 h. In facilities where pre-existing reporting systems were uploaded to RDS using Microsoft Excel, a median reporting time of 24 h was also reported with a range of 0 to 37 days (min, max). In the post-study questionnaire with representatives of all facilities involved, 75% of them agreed that eLIF decreased time to results reporting, with half of these reporting strong agreement. However, 19% of respondents disagreed that the digital tool decreased reporting time, while 6% were neutral.

Data completeness

While eLIF strengthened results reporting, some data fields were still missing in patient records, particularly reporting of symptoms. Overall, 84% of all records submitted lacked symptom data. Among patients with positive rapid tests, across all reporting methods only 23% had complete symptom data. All symptom data came from records captured on eLIF, as other forms of reporting did not include fields for this; however, even when using eLIF healthcare workers did not always complete this step.

EQA

According to the study protocol, all positive samples were supposed to be referred for PCR testing as part of routine EQA, while 10% of negative samples were to be randomly selected for EQA via an automated prompt built into the app. Adherence to this procedure varied widely across facilities. Overall, only 27% of positive samples were referred for EQA, with two facilities not referring any and another three referring less than 5% of positive samples. Only two facilities (Mulago and Butabika) referred over half their positive samples for EQA.

Based on total volumes, the study met the target of testing 10% of negative samples. However, two facilities (Mulago and Kawempe) accounted for a disproportionate share of EQA volumes: contributing 42% of all negative samples, but 85% of the corresponding EQA tests on negative samples. The majority of facilities referred less than 50% of their negative tests for EQA, with site visits confirming that these referrals were not randomly selected, indicating that the eLIF selection algorithm for EQA was not effective in this study (Table 3).

Overall, 836 out of 3,124 (27%) eligible Ag-RDT positive samples were referred for EQA testing. All eligible Ag-RDT negative samples

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TABLE 3 Eligible and referred volumes for EQA.

Health facility	Eligible Ag-RDT positive	Total Ag RDT-negative	Eligible Ag-RDT negative (10% of total)	Positive PCR tested	Negative PCR tested	% Positive PCR tested	% Negative PCR tested
Wakiso HC IV	283	548	55	0	31	0%	57%
Soroti RRH	586	1,311	131	227	35	39%	27%
Mulago NRH	725	4,232	423	392	753	54%	178%
Jinja RRH	293	1804	180	90	147	31%	81%
Entebbe RRH	424	1,013	101	15	33	4%	33%
Butabika RRH	144	736	74	83	34	58%	46%
Kiruddu NRH	232	778	78	2	28	1%	36%
Kawempe NRH	69	885	89	12	135	17%	153%
St. Mary's Hospital, Lacor	279	526	53	11	16	4%	30%
Mbale RRH	68	247	25	0	6	0%	24%
Moroto RRH	21	147	15	4	2	19%	14%
Total	3,124	12,227	1,223	836	1,220	27%	100%

Ag-RDT, antigen rapid diagnostic test; EQA, external quality assurance; HC IV, health center 4; NRH, National Referral Hospital; PCR, polymerase chain reaction; RRH, Regional Referral Hospital. EQA tests performed from eligible and referred samples across 11 health facilities.

were referred for EQA testing. Referral for positive EQA Ag-RDTs was low with no samples sent from Wakiso Health Centre IV and Mbale Regional Referral Hospital.

EQA concordance

The concordance of PCR and Ag-RDT results is shown in Table 4. A statistically significant difference was found between true positive and false negative results (value of $p = <0.0001$) as well as true negative and false positive results between health facilities. Samples with PCR cycle threshold values less than 29.99 were also significantly more likely to have false negative results. The discordance of test results was highest at day 3 since onset of symptoms.

Improvement in services

The majority of healthcare workers interviewed in the endpoint assessment agreed that the use of eLIF improved their adherence to diagnostic algorithms (94%). While 75% of respondents agreed that eLIF decreased the amount of time patients had to wait between presentation and appropriate management by the facility, 6% disagreed and 19% were neutral (Figure 3).

The effect of eLIF on staff workload was also assessed in the endpoint questionnaire, with healthcare workers asked whether there was a decrease in the time they spent on administrative tasks related to reporting. Three quarters of the facility representatives interviewed agreed that the efficiencies created by eLIF reduced the time spent on administrative tasks, with 31% reporting strong agreement. However, 19% disagreed with this statement and 6% were neutral.

Feasibility and acceptability

In the endpoint questionnaire, healthcare workers were asked whether the facility was sufficiently equipped, in terms of infrastructure and personnel, to implement eLIF. Overall, 75% of respondents agreed that their facilities had sufficient infrastructure, with 44% strongly agreeing. The perception of personnel capacity to implement eLIF was lower: only 19% strongly agreed, while 25% disagreed, that their facilities have sufficient personnel to implement eLIF.

Healthcare workers were also asked to grade their satisfaction as low, moderate or high. Half of the healthcare workers were moderately satisfied with the use of eLIF app for data collection and fitness for purpose and 31% were highly satisfied with the app. However, 19% reported low satisfaction with the eLIF app. The key challenge highlighted was instability (freezing and malfunctioning): this was flagged as the main area of improvement by half of the respondents.

Discussion

eLIF enabled healthcare workers to capture and transmit testing data to the national reporting system more rapidly and efficiently than paper-based registers but at comparable speeds to Excel-based uploads. However, the app did not achieve the objective of creating a seamless process for collection and analysis of EQA data.

There was extensive heterogeneity in the implementation of eLIF both across facilities, and between multiple testing points in the same facilities, highlighting the complexity of rolling out new digital tools in public health systems. Compared with the original workflow described in the methods section (Figure 4) the actual workflow implemented in the study had several points of divergence (Figure 5).

Site visits to understand the reasons behind implementation successes and challenges as observed in the data, identified several factors that determined how consistently the envisioned workflow could be implemented. These included study-related factors such as training and re-training, challenges related to the tool and availability of technical capacity to promptly resolve software challenges, and broader health systems factors such as staff turnover, personnel bandwidth for data capture, resistance to system use by service

TABLE 4 EQA concordance between PCR and Ag-RDT testing.

	True positive (TP)	False negative (FN)	*p*-value	True negative (TN)	False positive (FP)	*p*-value
Gender						
Female	382	76		489	48	
Male	318	60	0.7787	628	55	0.5806
Age (years)						
0–12	61	8		154	21	
13–18	56	7		133	6	
19–25	105	16		131	15	
26–35	216	47		234	23	
36–45	124	26		179	18	
46–55	65	18		133	11	
Above 56	72	14	0.4737	151	8	0.1555
Health facility						
Butabika Hospital	82	1		29	5	
Entebbe RRH	13	2		27	6	
Jinja RRH	57	33		137	10	
Kawempe NRH	5	7		114	21	
Kiruddu RRH	1	1		26	2	
Lacor Hospital	7	4		9	7	
Moroto RRH	4	0		2	0	
Mulago NRH	318	74		720	33	
Soroti RRH	213	14		29	6	
Mbale RRH	–	–		5	1	
Wakiso H/C IV	–	–	<0.0001***	19	12	<0.0001***
Symptoms duration (days)						
0	13	5		9	0	
1	20	9		7	0	
2	31	5		10	1	
3	41	10		9	3	
5	14	8		18	4	
6–14	24	5	0.0589	4	4	0.1068
PCR cycle threshold (CT) value						
Less than 29.99	519	98		n/a	n/a	
Above 30.00	121	37	0.0259*	n/a	n/a	

*Means the *p*-value has statistical significance, ***statistical significance representing <0.0001.

providers and availability of logistical requirements needed for adherence to the study protocol.

Uptake

This study demonstrated that it is possible to implement real-time data capture at all levels of the health system, with participating facilities ranging from a level IV health center to a referral hospital. However, evaluation of the intervention was complicated by having multiple and frequently-shifting testing points within facilities, which changed at different stages of the study period depending on demand for testing and availability of human resources.

Using eLIF, it was not possible to detect the exact location within each facility associated with each patient record, so findings were aggregated at facility level, preventing an understanding of variations in diagnostic and reporting practices based on where testing was conducted (e.g., in the laboratory compared with the emergency room). The nature of services being provided likely influenced use of the tool—for example one facility which treats psychiatric patients, Butabika, noted that challenges around getting patients to cooperate with testing made it difficult to simultaneously do real-time data capture.

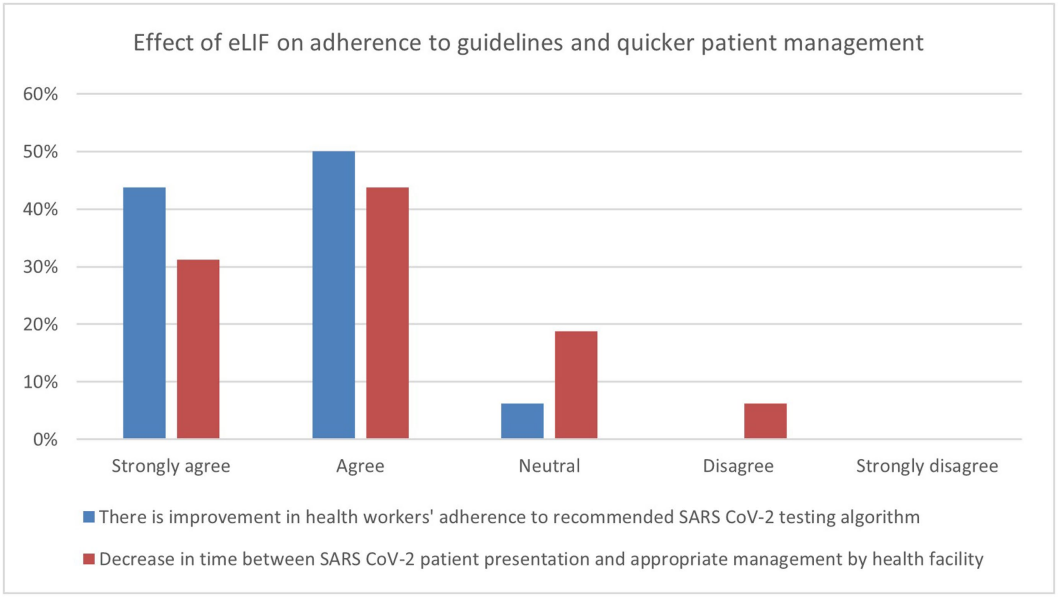

FIGURE 3
Endpoint assessment of health worker perspectives on improvement in services due to eLIF. Findings of the endpoint assessment of healthcare workers' (*n*=16) perspectives using eLIF in percentages. Blue=percentage responses on improvement in healthcare workers' adherence to recommended SARS-CoV-2 testing algorithm, Red=percentage responses on decrease in time between SARS-CoV-2 patient presentation and appropriate management by health facility. SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

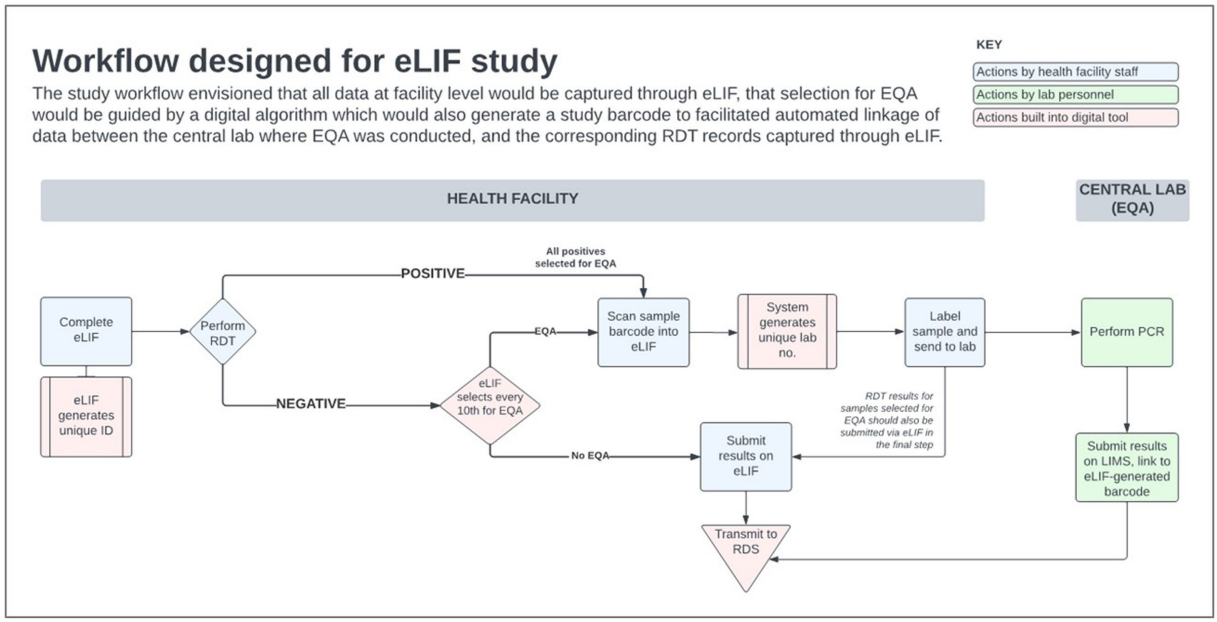

FIGURE 4
eLIF workflow. eLIF; electronic Laboratory Information Form; EQA, external quality assurance; RDS, national results dispatch system; PCR, polymerase chain reaction; Ag-RDT, antigen rapid diagnostic test.

However, the most common reason given for not entering data in real-time via eLIF was workload, with traditional methods of data capture perceived to be quicker as these were systems with which personnel were familiar. Overall, around 65% of records were captured in real time via eLIF, while 12% were captured via Excel upload. Some sites reported that their reporting method varied from day to day depending on the length of the patient queue. During site visits conducted mid-way the study, it was also observed that some healthcare workers documented patient data on paper forms or Excel, and later transcribed it to eLIF. This resulted in increased workload for reporting at health facility level—and for duplicate records that were entered in both eLIF and Excel, necessitated retrospective data

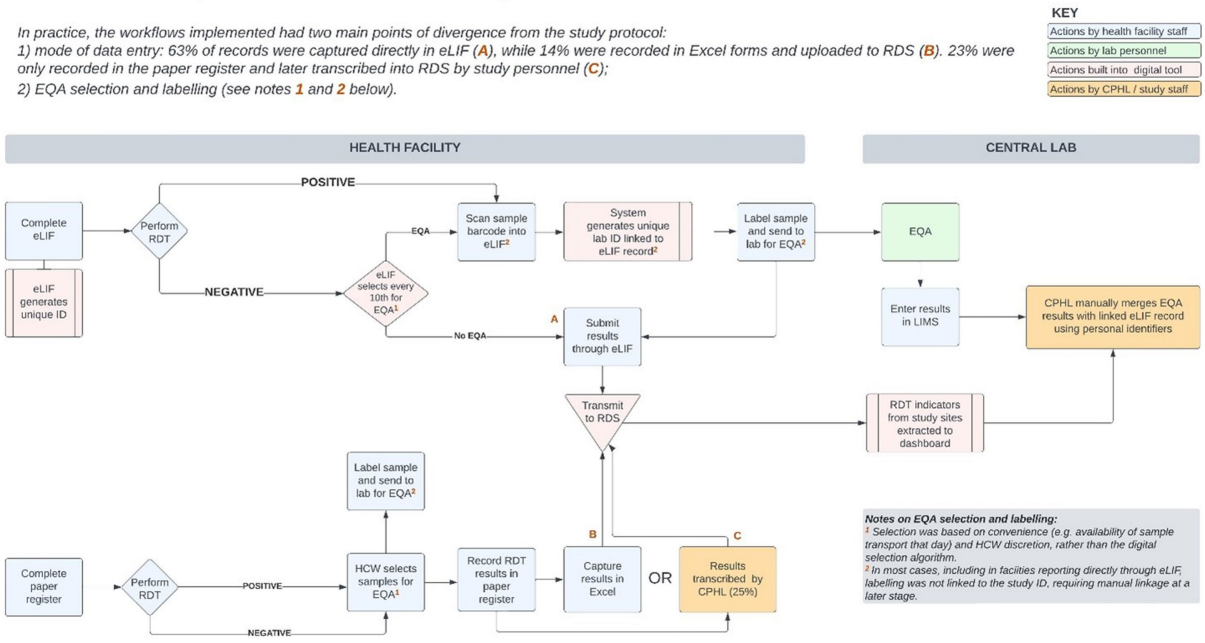

FIGURE 5
Workflows implemented in the eLIF study. CPHL, Central Public Health Laboratory; eLIF, electronic Laboratory Information Form; EQA, external quality assurance; RDS, national results dispatch system; PCR, polymerase chain reaction; RDT, antigen rapid diagnostic test.

cleaning by CPHL. Additional implications of using different tools included lack of alignment in the data fields and formats captured, and lack of adherence to the automated process that had been built into the app for EQA sample selection and labeling.

A review of facility files found that 23% of tests that had been captured on paper registers were not transcribed into any digital tool and thus transmitted to the national repository. These "missing cases," accounting for nearly 1 in 4 of all tests conducted, point to the importance of digital tools for providing a complete picture of diagnostic efforts and disease burden. This applied to 8 out of 10 facilities, which accounted for nearly half of all testing records (49.6%). In these sites, 47% of testing records were still captured on paper only, with eLIF and.csv accounting for 30.3 and 22.6%, respectively. In the remaining three facilities (Mulago, Soroti, and Butabika) where paper was not used, 99.1% of tests were reported through eLIF with.csv accounting for the remainder. During the facility feedback session with healthcare workers, some indicated that they experienced challenges with data entered into eLIF going "missing." Underlying reasons for these challenges include that healthcare workers captured data offline due to limited data connectivity and users occasionally experienced limited local data storage while using personal phones. Other reasons included non-compliance with the work flow during data capture such as failing to scan the unique identifier (ID) bar codes for the EQA samples and a lack of standardized allocation of unique IDs by health facilities, whereby similar unique IDs were repeated each new day. Tablets and routers were provided to healthcare workers as a solution to these issues. In the future, it would be key to set minimum device requirements for the implementation of the eLIF application. An additional exception-handling mechanism should also be introduced in the app to prevent data loss by ensuring storage is not used up and to ensure healthcare workers can only use eLIF after offline data have been synced with the server. In addition, health facilities should also develop and generate standardized unique identification for patients. Finally, periodic communication and training on new eLIF versions should be provided to the end users. The digital system, particularly the dashboard, supported uptake by informing targeted interventions to be taken by CPHL based on analysis of performance indicators in the dashboard—including retraining of staff where needed and addressing technology challenges such as the app freezing, which discouraged personnel from using eLIF. However, some of the factors related to broader health system challenges, such as workload, were broader than the scope of the study interventions. To optimize the impact of digital tools, user-centered change management strategies are required which take into account facility and personnel workflows, as well as the operating environment.

Forty eLIF user accounts were issued over the study duration from December 2021 to May 2022, although the number of individual end-users in facilities was higher due to sharing of accounts. This was due to frequent task-shifting within facilities, with patterns that were not easy to predict or monitor. The practice of account-sharing presented a challenge for monitoring as it was difficult to measure the exact number of healthcare workers who interacted with eLIF, and where performance indicators were sub-optimal, there was a lack of accountability of data transmitted from the health facility if the specific personnel corresponding with the record could not be traced.

Only half of the total user months were active, which is notably low due to work schedule rotations and high staff turnover. This point is illustrated by the intern laboratory technologists in St. Marys' Lacor who were trained on eLIF but all reassigned during the course of the study. Halfway into the study, at least four facilities reported that staff who had been trained were no longer conducting testing.

There was insufficient transfer of knowledge as staff shifted roles, leading to difficulties with using the tool or following study procedures. With few human resources permanently assigned to perform COVID-19 Ag-RDT testing, only 23.8% of users trained at the beginning of the study were still active at end of study, highlighting the role of periodic support supervisions and mentorship during the implementation of digital tools at health facilities.

Effectiveness

Data timeliness

A key concern with decentralization of Ag-RDT testing has been the ability to access data if diagnosis is delivered outside of laboratories that have well-established reporting systems, as illustrated by the long reporting lags in other settings (11, 18). This study demonstrated the value of digital tools in enabling real-time or near real-time monitoring of decentralized testing, provided the necessary measures are put in place to facilitate implementation by healthcare workers and performance of the digital technology.

While eLIF was designed for real-time data collection and transmission, it was necessary to allow for interruptions to internet connectivity, through offline capability that allowed for data to be captured and transmitted to RDS when connectivity was restored. Due to intermittent connectivity, many records captured in eLIF were not transmitted instantaneously, and the median time between testing and reporting was therefore the same for eLIF compared with reporting via .csv (24 h).

However, records entered via CSV were delayed by up to 37 days in some cases, compared with the maximum lag between testing and reporting for eLIF, which was 3 days. By contrast, the testing records captured on paper were delayed by up to 130 days, reducing their value for COVID-19 surveillance which requires timely data.

Additionally, the majority of healthcare workers interviewed at the end of the study (75%) reported that eLIF reduced the time required to manage patients, and in facilities that had access to both reporting methods eLIF was used for the majority of tests. In sites that had multiple electronic reporting options, 65.4% of records were transmitted through eLIF while only 4.5% were transmitted through .csv and the remainder by paper, suggesting preference for use of eLIF over other reporting methods. However, in one site (Jinja), over 80% of tests were reported by entering data directly into a laboratory information system (LIS) that could readily be downloaded as a .csv file and uploaded into RDS, allowing for ease of transmission.

Data completeness

The study aimed to capture symptom data that could be used to analyze correlations between clinical factors and testing outcomes to strengthen testing guidelines—for example, on more targeted selection for confirmatory PCR testing. However, symptom data were not captured for the 84% of records. This was in part due to the use of alternative reporting methods that did not have fields for data entry on symptoms, but the majority of records entered through eLIF also skipped this step. Adjustments to the tool to encourage adherence to symptom data collection could enhance data completeness and hence the insights that can be gained from this tool, for example by making it mandatory for staff to confirm that the patient does not have any symptoms in order to proceed to the next step (Figure 6).

EQA

The EQA selection algorithm was largely not followed, with only 1,050 referrals for PCR—51% of the expected EQA number based on the programmed procedure within eLIF. Even for these tests, selection was largely based on convenience and determined by the personnel on duty that day, rather than on the app. There were several reasons for this, summarized below.

Technological factors

In some testing sites, use of other modes of reporting data/results apart from eLIF meant that healthcare workers were not exposed to the selection algorithm, while intermittent malfunctioning of eLIF also contributed to lack of adherence to this procedure. It was also recommended that the selection step be made more prominent in the app—for example, by including pop-out notices for eligible EQA samples in the form of a message on screen, alert sound or change of text color.

Improper labeling also resulted in difficulty tracking samples that were referred for EQA. Unique bar codes in triplicates were allocated to each of the study facilities, which were supposed to be scanned into eLIF for every sample selected for EQA with another barcode placed on the EQA sample, for ease of linkage. Inconsistent implementation of this procedure, or facilities running out of barcodes, resulted in some EQA results not being traceable to the corresponding patient records captured through eLIF. To resolve this, manual linkage using patient names was used.

While this enabled the study team to retrieve the missing data, it required significant time compared with the automated process that had been envisioned through use of linked barcodes. Improved use of barcodes is highly recommended, as it reduces transcription errors, and enables easier linkage of records through electronic tracking systems. The intervals should be readable, water resistant, and distribution to health facilities should be monitored alongside testing demand to ensure uninterrupted supply.

HR-related factors

High staff turnover, and lack of sufficient training for new and remaining staff on EQA sample selection affected adherence to study procedures across all areas. High workload, due to limited number of staff available to manage large volumes of patients, also resulted in healthcare workers skipping this step. High volumes of samples selected for EQA can discourage compliance with selection procedures, as this is perceived as added work that may cause delays in the routine Ag-RDT testing. To prevent overloading healthcare workers, it may be necessary to adjust the selection algorithm to account for increased volumes or input daily maximum number of eligible EQA samples for each facility.

Logistics factors

Storage space and infrastructure in the facility, as well as the sample transportation schedule and availability, affected whether or not staff retained remnant samples for EQA. Availability of freezers to support cold chain temporary storage, in line with the required temperature and retention time to preserve the integrity of the remnant test, is necessary to ensure adherence to EQA algorithms for decentralized testing. There is also a need for enhanced training and supportive supervision on remnant sample management and cold chain for personnel at all testing points.

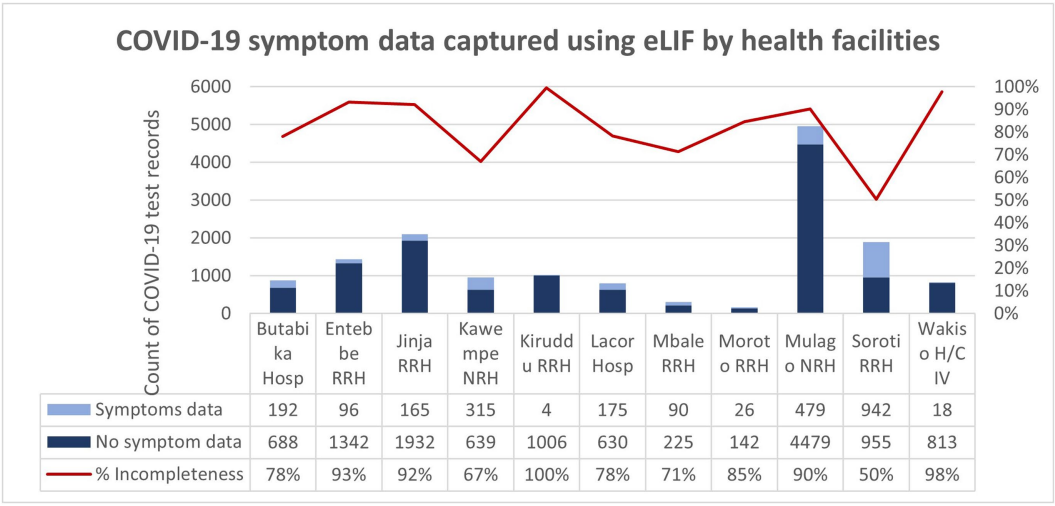

FIGURE 6
COVID-19 symptom data captured using eLIF app by health facilities. The proportion of records with incomplete symptom data (100%) was highest in Kiruddu RRH and was lowest (50%) in Soroti RRH. Overall, 84% of the COVID-19 test records transmitted using the eLIF app had incomplete COVID-19 symptom data.

Improvement in services

The variations in health worker practices and health facility context were reflected in the endline feedback on how eLIF affected patient services. The strongest effect was on adherence to diagnostic algorithms, with all but one facility respondent reporting an improvement in this area. This could be due to a combination of specific guidance built into the app, and targeted supervision by CPHL based on performance gaps identified through the dashboard. It was not possible to validate healthcare worker perceptions against baseline measurements of adherence, as previous reporting methods did not allow for monitoring of this, illustrating the value of digital tools that are tailored to the insights required to inform continuous quality improvement.

Feedback on the effect of eLIF on time required for patient management and reporting was less unanimous. Overall, 75% of respondents agreed that eLIF decreased total time required for patient management, as well as time spent on administrative tasks related to reporting. However, one in five healthcare workers disagreed with the latter, experiencing increased time spent on reporting. The variation in reporting methods, particularly double data entry in some cases, may explain the increased workload experienced by some staff due to eLIF. Other contributors to increased workload could include the EQA process as explained above, training and retraining, and transitioning to a new technology that experienced some glitches during implementation.

Feasibility and acceptability

While no healthcare workers disagreed that the facility had sufficient infrastructure to implement eLIF (although 25% registered a neutral response), 19% responded that their facilities did not have sufficient personnel to implement the app, which may be related to the workload challenges outlined previously. Only 31% of healthcare workers reported a high degree of satisfaction with the app, while 19% reported low satisfaction and the rest, moderate satisfaction.

The main challenge reported by facility respondents was sporadic freezing of the eLIF. The technical team identified that this was due to large volumes of data being entered without assigned results. In response to this, users were advised to assign results to batches of at most 20 entries. Poor internet connectivity issues at some sites such as St. Mary's Lacor and Moroto Regional Referral Hospital were also reported, and affected ability to transmit data with the frequency required.

While most facility respondents (88%) agreed that CPHL provided technical and troubleshooting support, this study highlighted that dedicated support at both central and facility level is important when introducing a new digital system, as existing personnel are required to support multiple tools at different levels, which would limit their capacity to provide timely support during the teething phase.

This study also highlighted the challenges of rolling out a new digital tool as part of an emergency response, which requires a more rapid development and deployment phase than would typically be expected. To optimize the design and implementation of digital interventions, a sufficient time frame is necessary to go through multiple steps of product development, including outlining detailed requirements and process evaluation for the system; conducting software development and configuration; performing robust multi-site testing and software verification processes; and finally rolling it out to staff with a go-live plan and dedicated support. Multiple factors during the pandemic made it difficult to follow this process, including increased urgency of the need for new tools, limited availability of personnel due to demands of the COVID-19 response, and mobility restrictions.

As the app was accessed via Play Store and thus subject to Google policies, this also created some additional challenges. At the start of the COVID-19 pandemic, there was an increase in demand for the development and use of Android/mobile-based applications for health services. Google developed new policies with a purpose to validate the information transmitted through the mobile applications, to mitigate

the risk of false information and protect users of the applications. New policies are reviewed and shared by Google periodically, and each mobile application is obliged to adjust its settings to align with the revised policies.

The eLIF app was affected by these policy changes as it is a data capture tool for COVID-19. One of Google's revised policies included restrictions on access to camera settings by the user, implemented by Google to ensure privacy and confidentiality. However, the eLIF app required a procedural step to scan barcodes for sample and data identification, which led to the app being rejected, and inaccessible to users via the Play Store in January 2022. During this time, the CPHL team provided app updates to facilities via an Android Package Kit and support to install these updates on users' phones. Within a month, Google approved the use of camera settings after CPHL provided justification of the necessity of bar code scanning.

Implementation cost and timeline for eLIF development

While the study design did not include a detailed cost analysis, key drivers are described below to illustrate the economic considerations that would go into setting up such a system. The main cost drivers for eLIF implementation were software development (as a software developer was hired to develop, test and continually update features), hardware (internet routers and Android tablets were distributed to healthcare workers to support data capture), maintenance costs for the data center (which hosts the RDS, stores all data and avails it to users), training and mentorship supervision, and data bundles. It is difficult to compute overall work done on eLIF but tool implementation and troubleshooting took a significant amount of time. There were several eLIF implementation steps including initial supervision visits to health facilities to improve adherence to the study protocol, streamline workflow and improve real-time data capture. Thereafter, four separate virtual calls were conducted to provide feedback from monitoring visits. eLIF then underwent several modifications along with the dashboard based on Ministry of Health and Foundation for Innovative New Diagnostics (FIND) reviews. After which, a virtual stakeholder sensitization meeting was held on eLIF deployment over 1 day. An end user manual was also developed and deployed and health workers were issued with end usernames and passwords to restrict access. The dashboard was further modified to enable viewing of eLIF inputs. A customer feedback desk was established to receive end user complaints/feedback and troubleshoot any issues pertaining to eLIF. Finally, healthcare workers were trained centrally in 1 day and onsite within 5 weeks across all study facilities (between 21 October and 2 December 2021) before eLIF roll out.

During implementation, several gaps including incorrect EQA selection process and incomplete logistics data were identified through a review of study data in the dashboard, and subsequent engagement through onsite mentorship supervision with health facilities focal persons. This necessitated a mid-assessment intervention to ensure completeness of data collected at the health facilities, which entailed site visits and healthcare worker interviews using pre-structured questionnaire over a period of 4 days. Additional site visits over 4 days were conducted by Foundation for Innovative New Diagnostics (FIND) to assess compliance with study protocols and plans the assessments utilized a questionnaire focused on understanding current facility practices around COVID-19 testing and reporting. A refresher training was also provided for the main gaps identified in the first few months. Overall, this study took 9 months longer than expected due to implementation and technology issues as well as staff down time due to the pandemic.

Key findings

The challenges of deploying a new digital tool during a pandemic response point to the need for consistent investments in countries' digital health architecture, as a critical component of pandemic readiness and health systems resilience. This should include deployment of interoperable, rapidly customizable tools at the point of care.

Timely and accurate reporting of information as enabled by eLIF, has advantages for Uganda's CPHL. The data are valuable to several relevant stakeholders and are key in determining the distribution of infection rates (especially among high-risk populations, e.g., truck drivers, local, and international travelers) and transmission patterns. The data from eLIF are also important in informing COVID-19 vaccination campaigns and useful for surveillance of infection rates in schools.

Although the eLIF app was initially developed for COVID-19 data capture, it has since been adopted for use in other disease such as human African trypanosomiasis, waste-water based surveillance for COVID-19 surveillance of water bodies and at the mobile Ebola testing laboratory in Uganda. Moving forward, the eLIF app should be optimized to capture real-time and quality data for outbreak and notifiable diseases in Uganda, regionally and globally. The learnings from this intervention can be used to guide future applications of eLIF, including modifications to bridge the gaps noted in this initial roll-out. Firstly, there is a need to reduce the number of mandatory data fields to minimize the time taken to complete application workflow. As eLIF was initially derived from the paper-based Laboratory Investigation Form, it originally included data fields such as recent travel, which were relevant at the start of the pandemic but unnecessary later on. This highlights the importance of continually adapting digital data solutions to evolving realities. At a systems level, this requires mechanisms for regular alignment of data needs between policy and implementation levels, including validation exercises upon tool customization with sufficient input from health personnel at all levels of the facility to ensure the digital solution is sufficiently tailored to current realities.

Secondly, it is important to implement a bidirectional feedback function within the eLIF app that can support troubleshooting when malfunctions occur. Furthermore, it is important to ensure that there is interoperability between eLIF and the existing LIS, so that the app can be implemented smoothly. Future implementations of eLIF could also investigate the value of capturing GPS coordinates to map geographical data of where the app is used to allow insights into where testing is happening, including visualization of disease data by location and time, hotspots and disease patterns. This functionality could be a powerful real-time data source for public health responses. Development of an iOS version of the eLIF app would also increase access for international users who may use iOS devices.

In conclusion, despite some challenges with the roll-out and implementation of eLIF, the tool added value to CPHL's efforts to monitor the decentralization of Ag-RDT testing in Uganda—most notably by improving timeliness of data in facilities that adopted eLIF which previously used paper-based reporting and providing granular visibility into implementation of diagnosis in facilities. This visibility enabled CPHL to identify and address challenges through targeted interventions. eLIF also enabled efficiency gains, particularly around staff time spent on reporting. Improvements to the tool to address the challenges experienced would enhance implementation of this tool, particularly in terms of supporting greater adherence to guidelines,

preventing freezing when dealing with large volumes of data, and ongoing monitoring and calibration in response to evolving facility workflows. EQA procedures should also be designed to account for logistical and operational constraints in facilities which may prevent personnel from adhering to guidelines. More dedicated technological support is essential in the early stages of deploying an app for speedy resolution of challenges, to avoid discouraging staff from continued use of the technology.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving human participants were reviewed and approved by the Uganda National Health Laboratory Systems Research Ethics Committee and the Uganda National Council for Science and Technology (UNCST). Written informed consent from the patients/participants was not required to participate in this study in accordance with the national legislation and the institutional requirements.

Author contributions

HN, IS, PA, RK, and OA participated in conception and design of the research work. HN and IS participated in implementation and overall study management. PN participated in the conception and review of digital health tools. JW participated in development of the eLIF mobile application. NL participated in the development of the COVID-19 dashboard. IS and OA provided technical guidance in the development of the digital health tools. HN, IS, PA, and OA participated in study monitoring and interim analysis. HN participated in quantitative data analysis. PA and KS participated in qualitative data analysis. PA wrote the manuscript. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Building management and innovation capabilities for global health: a senior executive program

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Accurately approaching the major challenges associated with global health management has become a mandatory key point in the training of medical leaders around the world. The Senior Executive Program in Global Health Innovation Management (SEPGHIM) seeks to provide an answer to the need for innovation and managerial capacity building in Global Health and to address the current detachment between Public Health Organizations and Business Schools. In 2019, SEPGHIM's first edition was led by five prestigious academic institutions on three continents. The first cohort included a total of 27 high-level health professionals and executives from 16 countries with 7–10 years of working experience who participated during the 11 months of the course. The program sought to fill an often-found knowledge gap among health professionals in terms of health innovation, leadership, and management. SEPGHIM relied on multiple pedagogical methods conveyed through a robust theoretical and applied syllabus that included case studies, simulations, guest speakers, debates, site visits, and an executive challenge. The program achieved various results. First, it recruited high-level health professionals that ensured diversity of backgrounds, allowing an exchange of experiences and different ways of addressing global health challenges. Second, it created a network of health professionals for possible future collaborations that can anticipate new trends and opportunities in global health and work together with stakeholders from other sectors. This networking was one of the most highly rated benefits by the students. Finally, the participants expressed great eagerness to recommend the program (4.9 out of 5) to other decision-makers and leaders in the global health field. These results provide positive insights regarding the value of such a training program for senior health professionals.

KEYWORDS

global health, management, innovation, training, entrepreneurship, executive, Global South

1. Introduction

In a context where economic pressure is increasing healthcare costs (1, 2) while financial resources remain limited, ensuring high-quality healthcare seems challenging (3). Moreover, the still ongoing COVID-19 pandemic and the constant risk of new outbreaks of diseases—as well as the risks that large migrations bring—evidenced the importance of innovation,

creativity, and new solutions in global health, hence the need for skilled health professionals to drive innovations (4, 5).

Trained leaders and executives can respond to the increasing global health needs and create the right environment for high-quality care (6). Due to the complex nature of leadership development, the challenge lies in integrating these skills effectively into the national health services' staff training and empowering leadership at a local level (7).

Multiple scholars have acknowledged that management training is needed for improving health systems (3, 7, 8). Nevertheless, business schools are underrepresented in many interprofessional health training plans, creating disparities in the medical curricula, especially for professionals in developing countries, where institutional voids and insufficiency of resources are the norm (3).

When framing global health difficulties in the context of the rich North and poor South proposed by the Brandt Line (an imaginary division), the scope of the problem becomes even wider, as many of the poor nations are forced to face these challenges in a quotidian manner (9). By bringing together professionals from both geographies within the same cohort, there is not only an opportunity to enrich and provide them with a full-picture vision but also to generate shared value and networking (10).

To better understand the needs of senior-level professionals and executives working on Global Health, the Barcelona Institute for Global Health (ISGlobal), a Senior Executive Program in Global Health Innovation Management (SEPGHIM) partner, performed an online survey in 2018, gathering insights from 126 health professionals from 44 countries interested in expanding their knowledge and skills in leading innovation.

Most respondents (63.5%) were eager to participate in education training combining Global Health, Innovation, and Management. Preferred formats were mostly short courses (45%) or executive programs (25%), with very low interest for MBAs, master's, and Executive MBAs (<8%). Blended programs, including both online and face-to-face sessions, were largely selected (70%) against full-online programs (20%). Finally, 82% of respondents preferred a part-time format against full-time (11%), and 84% expressed a strong interest in working on an executive challenge.

The above needs assessment survey results do not match the current market educational offer, since out of the 52 active educational programs identified worldwide on Global Health Innovation and/or Management, only four provide blended content, and the rest include long-term programs (e.g., master's and MBAs), limited content, unique format, and location.

These data were complemented with a set of semi-structured interviews with innovators and executives responsible for innovation or human resource departments from leading industries. Interviewees were partners within the European Institute of Innovation and Technology (EIT) Health Network, an alliance of leading academic institutions and industries in health innovation financed by the European Union. Insights were refined in a Design Thinking workshop held at IESE Business School with a wide range of actors and stakeholders in 2018. The results were updated by IESE in a second survey in 2020.

Among the gaps exposed by the survey and the interviews was how, in the fast-changing Global Health context, the need for managerial and innovation capacity building is more critical than ever, highlighting the key role of a better approach to executive education. However, the traditional educational offer is directed to limited targets (e.g., master's), has geographical limits (low number of programs including cross-continent partnerships between Latin America, Africa, and Asia), a unique condition focus (e.g., malaria), and its content usually does not cover all aspects of global health, innovation, and entrepreneurship.

With these insights, SEPGHIM aims to bridge the persistent gap between higher education and innovation (SIA2021-27[1]) by bringing together five world-class academic institutions—supported by EIT Health—to launch SEPGHIM, a fellowship program with a curriculum tailored to provide solutions to the challenges identified. The program aimed to have global outreach through a broad network that would connect future fellows and current global health leaders with institutions. The support of EIT Health was vital to the development of the program, which realized the importance of connecting with Global Health partners in the Global South to achieve its goal of fostering business, research, and education to bring innovative and real-world health solutions to markets.

2. Context

From the perspective of business, SEPGHIM was led by IESE Business School in Barcelona, INCAE Business School in Costa Rica, and Strathmore Business School in Kenya. Jointly, these institutions supported the initiative by building a solid program to address management, leadership, and innovation. These institutions also have a trajectory related to managing healthcare programs. IESE runs the Center for Research in Healthcare Innovation Management (CRHIM), INCAE leads the Central American Healthcare Initiative (CAHI), and Strathmore Business School offers the Managing Healthcare Businesses (MHB) program (11).

On the Global Health side, SEPGHIM was led by ISGlobal, the Barcelona Institute for Global Health associated with the University of Barcelona and the University Pompeu Fabra in Spain, and the Heidelberg Institute of Global Health (HIGH) associated with the University of Heidelberg in Germany. Both institutions are leading partners of TropEd, the network for education in international health.[2] These two institutions collaborated with the business schools mentioned above to design and deliver SEPGHIM.

Regarding the target audience of the program, it is intended to be broader than just clinician leaders. SEPGHIM targets **senior executives in the field of Global Health with 7–15 years of working experience**, such as decision-makers, executives, and leaders in global health-related fields, such as health providers and authorities, initiatives by international health organizations, the industry (pharma, med/biotech, and IT), the healthcare system, ministries of health, and leading non-governmental organization activities.

1 The SIA 2021-2017 statement regarding the "innovators and business creators lack the needed entrepreneurial and innovations skills" is confirmed by the educational offer gap identified through the Market Research conducted in 2018 and updated in July 2020.

2 tropEd - https://troped.org/.

TABLE 1 SEPGHIM fellows' demographics and affiliations.

	Fellowship 2019	
	Fellows	%
Total	27	100
Region		
Europe	9	33
Central America	6	22
Africa	5	19
North America	3	11
Asia	2	7
South America	2	7
Gender		
Male	10	37
Female	17	63
Affiliations		
Academia/Research institution	7	26
Non-governmental organization	7	26
Healthcare providers	5	19
Pharma/Medtech	3	11
Start-up/Biotechnology	3	11
Policymakers	2	7

Since the program aims to develop a multidisciplinary approach to solving health problems in various geographical settings, a special effort has been made to **recruit participants with various cultural, geographical, gender, institutional, and professional backgrounds**.

The initial recruitment for SEPGHIM's first generation was through a social media campaign among the different official sites and alumni communities of the academic institutions involved. Registration was formalized on SEPGHIM's official website, and subsequently, an Evaluation Committee, composed of at least one representative of each partner, remotely assessed and scored the applicant's adequacy to the program according to pre-established criteria regarding the level of education, working experience, and level of expertise, measured on years of experience in global health, innovation, and/or management. We also looked at their likely impact, including their motivation and the type of project they would be working on throughout the program, as well as their background and geographical location (see Table 1).

Once completed, SEPGHIM 2019 retained high-level health professionals and executives from 16 countries with a working experience of 7–10 years. The cohort had a total of 27 participants out of 53 applicants from diverse settings: public, private, and non-governmental organizations (NGOs).

The limited number of participants could be considered a limitation of the SEPGHIM program; rather, this constitutes an opportunity to guarantee a high level of selection and therefore ensure rich exchanges among participants, especially for the executive challenge, including peer feedback sessions in small groups and individual mentoring with high-level experts.

The group's composition provided perspectives from nations such as Brazil, the Netherlands, Sri Lanka, and Uganda. It also managed to have significantly more female than male participation. This statistic addresses the importance of women leaders, as stated again by the WHO in 2019: healthcare is delivered by women but led by men (12). Thus, SEPGHIM trains a multidisciplinary group of high-profile professionals and decision-makers—many of them women—equipping them to address global health challenges.

3. Sepghim program

3.1. Modules and learning objectives

The SEPGHIM program is based on a learning journey where the blended methodology (face-to-face sessions and online sessions) aims to (1) foster **innovation and entrepreneurial capacity** for global health executives, (2) increase the ability of learners to use new **digital technologies** to support the development of new solutions to global health challenges, and (3) strengthen a **sustainable global health network** across three continents.

Each module hosts a half-day open co-creation Workshop, bringing together citizens, local experts, and SEPGHIM participants to create concrete solutions to address global health challenges. In addition, the different modules revolve around hands-on experiences (onsite visits to the local innovation ecosystem), working group exercises, simulation, interaction with the main stakeholders of the sector (panels and inspirational talks), and networking events, including local experts and SEPGHIM alumni.

These modules are complemented with online pre- and post-module activities and an executive challenge running throughout the program to address key competencies such as digital and data literacy, health system awareness, management and leadership, entrepreneurship and multidisciplinary skills, innovation, critical thinking and decision-making, citizen-oriented skills, and communications abilities.

The **first** module delivered by the Heidelberg Institute of Global Health (HIGH) in Germany focused on *Understanding the Health Challenges in the Global Context*. The module's objectives were to strengthen the ability of each participant to lead change in global health across policies, sectors, and disciplines while addressing current and potential future global health challenges. Participants acquired tools to help them determine the innovation potential of global health ecosystems and create feasible strategies in the broader context of political and economic factors.

This initial module addressed topics of global health in the context of the Sustainable Development Goals: innovation, integration of health prevention and promotion, digital health strategy for health system strengthening, and opportunities for intersectoral collaboration. In line with the program, site visits were organized to provide participants with the opportunity to experience the local innovation ecosystem. Students visited BASF, a chemical company that combines business and social perspectives to create shared value. The focus of the BASF executive

presentation was on food fortification and strategies to tackle nutrition deficiencies.

The second module took place in Costa Rica and was hosted by INCAE Business School. This module, called *Leading Innovation and Change*, explored how entrepreneurship—and other business models—can contribute to global health and the challenges it faces in the context of middle- and low-income countries. Students discussed how to use ethnographic methods and develop business models to serve communities at the base of the pyramid.

The specific objectives of this module are to (1) explore how an entrepreneurial mindset can drive global health innovation, (2) acquire management tools and skills to integrate stakeholders' needs and resources to support the success of their projects, and (3) analyze innovative business models to serve the base of the pyramid.

Some of the topics in this module were discussed with a case study methodology, potentiating the students' critical thinking. Other sessions included conferences on challenges for entrepreneurship in the Latin American context and on the Costa Rican healthcare system, which is internationally recognized for its universal coverage and the strength of its primary level of attention. Intrapreneurship was covered through a simulation where students had to lead a change initiative within an organization.

Students also visited one of Costa Rica's primary care clinics (EBAIS) and attended a panel discussion with prestigious non-governmental organizations working with vulnerable populations and their health challenges. Finally, a local scientist and entrepreneur shared the opportunities and challenges of doing first-class clinical research—finding the cure for pancreatic cancer—in a middle-income country like Costa Rica.

The third module was held in Nairobi, Kenya, led by Strathmore Business School, and was oriented on *Developing New Services and Products in Global Health*. This module developed effective strategies to fully leverage the potential of digital transformation in Global Health, expanding understanding of operational challenges facing global health organizations to achieve breakthrough services, and leveraging opportunities in innovative financing mechanisms.

The specific learning objectives for this module are to (1) develop effective strategies to fully leverage the digital transformation in global health, (2) expand the understanding of the operational challenges facing global health organizations to achieve breakthrough service, and (3) leverage opportunities in Innovative Financing Mechanisms.

Under this framework, fellows learned about the digital startup and innovation ecosystem in Kenya, universal access to healthcare, virtual training for health professionals, and the role of impact investment in global health innovation. The former encouraged the participants to place themselves in the shoes of entrepreneurs and medical leaders to fully understand how diverse challenges developed in different contexts on the African continent. Examples of live cases were *Access Afya*, a primary healthcare social enterprise building affordable, convenient, and effective access to healthcare for Kenyan communities, and *m-Tiba*, a mobile phone platform that connects people, payers, and providers in the healthcare sector 24/7, among many others.

A visit to SHOFCO, an organization that catalyzes large-scale transformation in urban slums with critical services for people in Kibera and Mathare, provided participants with a real-life experience of challenges in a complex context. "*Professionally interesting and personally touching. A great opportunity to know the reality of living conditions for many people in urban areas of low-middle income.*"

The fourth module engaged "*Getting things done: the art of implementation*," led by the IESE Business School with the collaboration of ISGlobal in Barcelona, focusing on leadership and managing change and implementation, and communication tools. The module was developed under three specific learning objectives based on (1) reflecting on your leadership style and acquiring tools to enhance communication with your management team; (2) developing new negotiation skills and deploying them in collaborative and competitive situations; and (3) strengthening project management skills for strategic implementation.

Through highly interactive cases around global economic contexts, participants took active roles in presentations and small group work. Field visits included the Innovation Unit of Hospital Sant Joan de Déu, one of the most innovative pediatric hospitals in Europe. A final panel brought together experts from the Agency for Healthcare Quality and Assessment of Catalonia (AQuAS), ISGlobal, the Spanish Parliament, and Medicos Sin Fronteras (MSF Spain), discussing challenges and opportunities at different levels of governance, reviewing relevant stakeholders in the global health context, their roles, and how to strengthen their alignment and cooperation.

All modules were delivered with 1 month of self-learning in between to allow participants to internalize the new knowledge and skills and apply them to their own personal projects.

3.2. The executive challenge

The executive challenge aims to provide participants with the opportunity to address relevant real-time strategic, operational, or personal business challenges and discuss them in teams of eight participants with complementary expertise and backgrounds, enabling interesting and productive discussion. The executive challenge included sessions of mentoring and individual coaching with the SEPGHIM faculty and additional relevant experts (see Figure 1).

It included a variety of initiatives in different sectors for instance, an African executive sought to strengthen the Nigerian primary healthcare services by improving data management systems and enhancing logistics and supply chain management systems. Other challenges had to do with private enterprises. For example, a proposal presented by a Lithuanian entrepreneur sought to launch a new medical device to monitor vitamin D levels and stimulate its synthesis while protecting from harmful radiation and erythema. Another challenge was developed by an NGO leader from Spain, aiming to address the upgrading and expansion of an artificial intelligence platform to improve the diagnosis of infectious diseases in low-income areas with difficult access to health facilities.

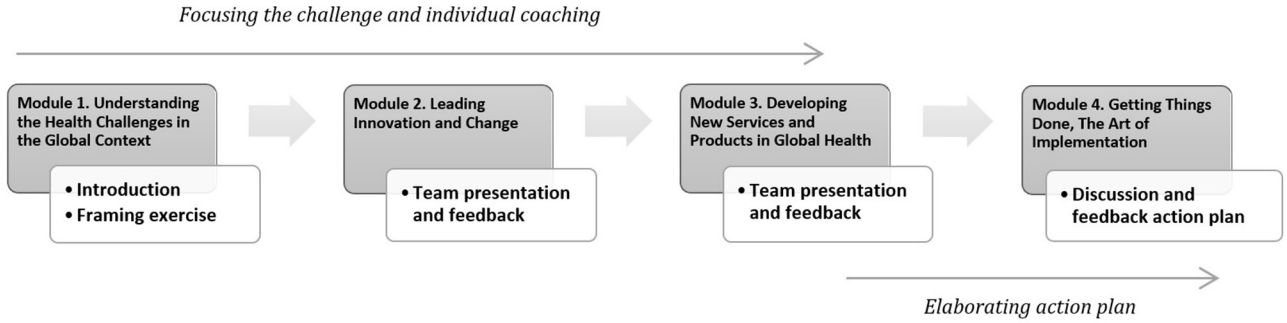

FIGURE 1
Progression steps of the executive challenge during and in-between modules.

4. Results

The assessment of SEPGHIM was performed at different stages of the implementation of the program using quantitative (satisfaction module-specific online and program surveys) and qualitative methodology (interviews with learners and faculty). To measure the impact of the program (on the economic, educational, and societal levels), evaluate the SEPGHIM program, and monitor the learners' involvement, a multi-level evaluation was conducted based on the Kirkpatrick model.

Regarding levels 1 and 2 of reaction and learning of the Kirkpatrick model, learners answer an online survey before and after the program to assess the change in their knowledge, skills, and attitudes in global health, innovation, and entrepreneurship (GHIE). The software Evolute Tricuspoid 2.0 was used to analyze entrepreneurship skills and attitudes, measuring the evolution of learners' creative tension, meaning the difference between their current perceived level of competence and the level they would like to achieve. Learners should show less creative tension after the course than at the beginning.

A post-course satisfaction survey assesses various aspects: overall satisfaction (>80% highly satisfied), achievement of learning objectives and content (80%), creative tension of entrepreneur competencies and skills (30% decrease), likelihood of recommending the course (80%), intention to pursue another innovative project or continue with the challenge (60%), satisfaction with the executive challenge plan (80%), knowledge increase (35%), skills and attitude enhancement (20%), and learners benefiting from mentoring (80%).

Qualitative feedback through interviews with students and faculty during the ongoing modules was a tool to enable potential adjustment between modules. Meanwhile, levels 3 and 4 of the Kirkpatrick model regarding behavior and results were measured through online follow-up surveys to assess the impact and individual progress. The overall rating for this first edition of the program was 4.5 out of 5.

The exit survey also asked students about their perceived benefits. Like in other innovation and entrepreneurship programs (10), accessing a network of health professionals was particularly valued by participants. The second most important benefit perceived was learning about new trends and opportunities in global health, as this knowledge supports their innovation skills and allows them to be at the industry's forefront. Finally, participants valued the opportunity to work together with different stakeholders, confirming the importance of a diverse cohort (see Table 2).

Overall, participants agreed that SEPGHIM was groundbreaking for their personal growth and added great value to their professional careers, increasing their ability to innovate in a complex and fast-changing environment. They also expressed great willingness to recommend this program (4.9 out of 5) to decision-makers and leaders in global health, denoting their perception that the program would be useful for their peers.

A year after concluding the program, IESE performed follow-up evaluations among SEPGHIM alumni. The results show that 60% increased responsibility and salary, and 80% implemented their executive challenge. Respondents gave an evaluation of 4.6 out of five on the usefulness of the knowledge and skills learned in the program.

5. Discussion

Effectively addressing global health challenges will require managing limited resources and innovating health products and services, as well as business models. Academic programs that seek to train professionals working in global health must complement health-related education with management capabilities—including the ability to innovate. As university departments often work in silos, many executive programs focus on a single academic discipline. A program such as SEPGHIM combines the expertise and knowledge of both Health and Business schools, enlarging the set of capabilities that participants can acquire to tackle global health challenges.

In addition, executive programs for professionals working on global health will likely benefit from more geographically diverse cohorts. Even though middle- and low-income countries might share similar health challenges, their institutional environments and solutions could vary significantly. Programs such as the CAHI at INCAE (3) or the MHS at Strathmore (11) are more regional than global in terms of participants' origin. Instead, SEPGHIM recruits from a geographically diverse pool of candidates through its different academic partners located on three continents. A geographically diverse cohort provides the opportunity for

TABLE 2 Perceived benefits by SEPGHIM participants.

	Score over five points
Criteria	
Connect to a network of health leaders and innovators	4.5
Anticipate new trends and opportunities in global health	4.3
Work together with stakeholders from other sectors	4.2
Advance your professional career	4.1
Implement and manage an innovation project in global health	4.1
Motivate and manage a team	4.1
Consider alternative business models to deliver global health solutions	4.1
Address global health challenges with broader approaches	4.0
Testimonials of the participants	
"The best part of Module 1 is the lecture on personnel management and the introduction to the Executive Challenge"	Participant of module 1
"I discover new topics such as ethnographic research very valuable. Also, the boot camp visiting health providers in Costa Rica, and the entrepreneurship testimonies. I also love the class of literature and leadership"	Participant of module 2
"The best was the practical examples given by the entrepreneurs. I have learned a lot discussing the challenges and trying to connect that with the challenges that I'm facing right now founding my own company"	Participant of module 3
"The best of the module were the sessions on soft skills, e.g., communication, power dynamics, and agile project management"	Participant of module 4

exchanging knowledge and broadening perspectives, supporting the development of innovations that can improve health outcomes.

The Global Health field is not led by governments alone. The private sector, civil society, and multilateral organizations are all engaged in efforts toward improving health in low- and middle-income countries. Intersectoral partnerships become essential for these efforts to succeed, as, among other things, they help accelerate the development and deployment of new medical technologies and treatments (13). Collaborative work could represent the best way to increase affordable access to high-quality healthcare and, ideally, universal health coverage (14, 15). As shown by SEPGHIM, executive programs that provide the opportunity for representatives of multiple sectors to connect and network are highly valued by participants.

Countries around the world are seeking to increase their preparedness to respond to health emergencies and pandemics by building stronger health systems that are better equipped to handle these crises (8, 16). In addition, problems related to finances and inequality (North-South), fragmented systems, access to knowledge, and trained human resources need to also be addressed to set the pace for an optimum health system (17). Through programs such as SEPGHIM, academia could contribute to building the capabilities of health professionals and business executives to achieve a more equitable, resilient, and innovative-oriented health system.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, only under request.

Ethics statement

Ethical review and approval was not required for this study in accordance with the local legislation and institutional requirements. Written informed consent from the program evaluation focus group participants was not required to participate in this study in accordance with the national legislation and the institutional requirements.

Author contributions

All authors listed have made a substantial, direct, and intellectual contribution to the work and approved it for publication.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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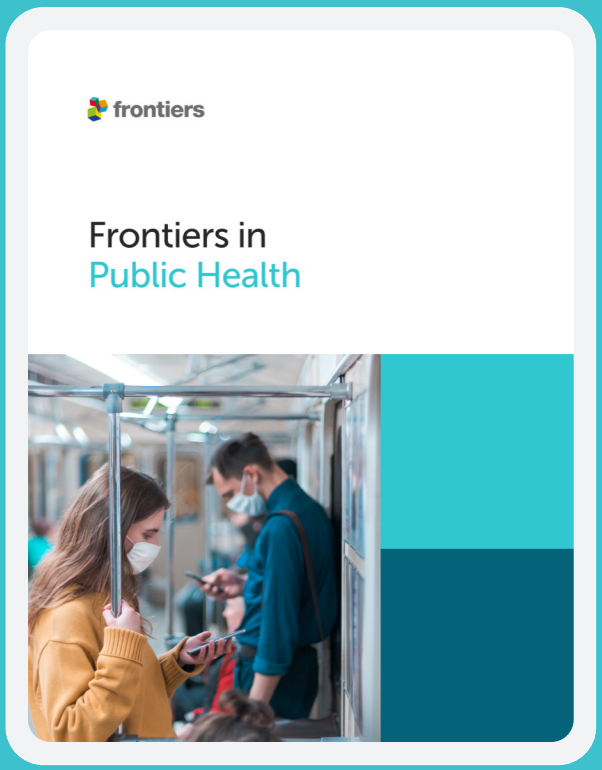

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