Addressing and evaluating health literacy in mHealth: a scoping review

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Background: Recent surveys have revealed many adults have basic or below basic health literacy, which is linked to medical errors, increased illness, and compromised public health. Health literacy as a concept is multi-faceted extending beyond the individual to include social structures and the context in which health information is being accessed. Delivering health information via mobile devices (mHealth) expands the amount of information available while presenting challenges to ensuring these materials are suitable for a variety of literacy needs. The aims of this study are to discover how health literacy is addressed and evaluated in mHealth app development.

Methods: A scoping review of 5 peer-reviewed databases was conducted. Eligible articles were written in English, addressed general literacy or mHealth/digital/eHealth literacy, and collected literacy information in order to incorporate literacy into the design and/or modification of an app or collected literacy information to describe the population being studied. The "Health Literacy Online" (HLO) United States (U.S.) government guide was used as a framework.

Results: Thirty-two articles were reviewed. Articles included health literacy recommendations for all HLO categories and some recommendations not aligned with these categories. Most articles addressed health literacy using specific HLO categories though none incorporated every HLO category. The most common categories addressed engagement and testing of mHealth content. Though several studies addressed health literacy through a formal assessment tool, most did not. Evaluation of health literacy in mHealth was end-user focused and did not extensively evaluate content for fit to a variety of individuals with limited health literacy.

Conclusions: The recommendations seen consistently in our results in conjunction with formal HLO categories can act as beginning steps towards development of a health literacy evaluation tool for mHealth apps themselves. It is clear efforts are being made to reduce barriers to using mHealth for those with literacy deficits, however, it was also clear that this space has room to be more pragmatic in evaluation of mHealth tools for literacy. End user engagement in design and testing is necessary in future mHealth literacy tool development.

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Introduction

The United States (U.S.) Department of Education's most recent survey revealed 36% of adults have basic or below basic health literacy and only 12% have proficient health literacy (1). The annual U.S. associated costs for low health literacy are estimated to be up to 238 billion dollars. Deficiencies in health literacy are linked to medical errors, illness and disability as well as compromised public health (2,3). A more recent report on health literacy conducted in eight European Union member states found 47% of participants had problematic or inadequate health literacy (4). Among low to middle income countries, the proportion of individuals with inadequate levels of health literacy ranges from 32% in Ghana (5) to 52% for both Afghanistan (6) and Philippines (7). Health literacy as a concept emerged in the 1980s after major public health campaigns failed to affect positive health changes in populations with limited education or economic instability (8). However, as demonstrated by the dearth of current national data, substantial efforts to improve health literacy are still needed (9). As such, Healthy People 2030 identified health literacy as a priority area of focus for improvement of public health (10).

Early definitions of heath literacy focused on reading ability, but a much broader understanding of health literacy has evolved over the years (11). For example, Healthy People 2030 defines health literacy as complex, extending beyond the individual to include families, corporations, systems, and communities (10). Healthy People 2030 also posits that health literacy is comprised of abilities which go beyond reading and understanding material but encompasses one's ability to analyze information, accurately interpret symbols, charts, and diagrams, factor in risks and benefits and then assimilate this information to make informed decisions (10). This expansive health literacy definition captures the multi-faceted nature of this concept, reflecting the importance of the context in which health information is being accessed.

It is of no surprise that with the advent of the Internet in the 1990s, health-related websites in the 2000s, and mobile health apps in the 2010s, innovative modes of accessing information have created new challenges in addressing health literacy. The delivery of health information no longer occurs in a siloed clinic environment. Information is accessible in a variety of formats. For instance, information delivered over the Internet and via related technologies is commonly referred to as eHealth (12) whereas mHealth has been defined as mobile devices (such as mobile phones, tablets, monitoring devices and other wireless technology) being used to support both individual and public health (13). Regardless of specific delivery modality, the amount of health information available to the public and the means with which one can access health information has increased substantially. However, this increase has made addressing health literacy a more difficult pursuit.

In an effort to synthesize the evidence for this relatively new area of research of mHealth related to health literacy, a scoping review was planned. At the time of this scoping review, many review studies related to health literacy for mHealth or eHealth had been published with significant variation in topics such as the examination of health literacy levels of specific apps (14,15); the effects of mHealth-based interventions on health literacy (16,17); and discussions on health literacy of mobile apps for cancer (18,19), diabetes (20), heart disease (21,22), chronic pain management (23), and mental health (24,25). While previous reviews have explored health literacy in the context of mHealth or mHealth interventions, to our knowledge, none of the published reviews used a theoretical framework specific to health literacy to systematically examine comprehensive aspects of health literacy within mHealth.

Our original intention with this scoping review was to identify a health literacy evaluation tool that could be used to evaluate mobile app content. However, we were unable to identify such a tool. It became clear that it was necessary to first understand how health literacy needs have been addressed (e.g., design or accommodations) in mHealth thus far to inform the development of such a tool. Therefore, the purpose of this scoping review was to answer the following questions: (I) How is health literacy addressed in mHealth app development? and (II) How is evaluation of health literacy addressed in mHealth apps?

The first question pertains to mHealth development or design aspects that may be noted in the literature to account for literacy variability in the mHealth app whereas the second question pertains to how the mHealth was evaluated to speak to health literacy in relation to mHealth. Based on our previous expertise in this area there are a variety of ways in which literacy variability can be discussed when it pertains to mHealth. mHealth apps may consider the use of techniques or design strategies to accommodate for literacy needs. However, others may have factored in literacy suitability by evaluating health literacy directly and deriving a relationship about the literacy as it pertains to mHealth. The research team felt that two questions were necessary to be answered in this scoping review to extrapolate these various means that have been noted to understand the relationship of health literacy in mHealth.

Objectives of the study

A scoping review of the literature was conducted to identify the existing tools and criteria for evaluating mobile health apps from a health literacy perspective. Given the broad nature of the subject matter, conducting a scoping review would allow researchers to examine how health literacy is addressed in mHealth research, particularly as it pertains to mobile app development and design.

Methods

Guidelines

We followed the Joanna Briggs Institute (JBI) Scoping Review guidelines to conduct this review study (26). The JBI guidelines are a comprehensive set of guidelines which are updated periodically.

Protocol and registration

A search of the literature was performed following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Scoping Review guidelines (27) (available at https://mhealth.amegroups.com/article/view/10.21037/mhealth-22-11/rc). The reporting required for the PRISMA-ScR is consistent with other guidance for scoping reviews provided by the JBI. Please see the following link for complete search details: https://digitalcommons.unmc.edu/search/11/.

Eligibility criteria

Articles were eligible for inclusion if they were English language articles and addressed general health literacy or mHealth/digital/eHealth literacy. Articles also needed to meet one of the following inclusion criteria: (I) collected literacy information in order to incorporate literacy into the design and/or modification of an app or (II) collected literacy information to describe the population being studied. Because we were interested in the articles which dealt with the design and evaluation of mHealth tools, we excluded grey literature, book chapters, and commentaries with an expectation that articles of interest are most likely to be found in peer-reviewed journals. Conference abstracts were excluded due to an anticipated difficulty obtaining the complete information about the study. Articles on literacy regarding specific health conditions (e.g., mental health literacy) were excluded because our primary interest was on health literacy not specific to given health conditions.

Information sources and search strategy

Embase, Scopus, PubMed, CINAHL, and PsycINFO databases were searched on March 17, 2021. The following words and their permutations were used for the search: health literacy, mobile health application, and tool or model. Searches were performed for articles published for all years. Two reviewers independently reviewed the reference lists to identify potentially eligible articles. The team then made a decision whether to include the article. All articles pulled from the search strategies were compiled and deduplicated using RefWorks and Zotero.

Selection of sources of evidence

Figure 1 presents the PRISMA-ScR scoping review process. Initially, there were 1,010 abstracts identified and 294 of them were removed due to duplication, resulting in 716 unique abstracts. All abstracts were independently reviewed by two individuals to determine the article's eligibility. If the article was found to be ineligible, the reviewer noted the reason(s) using the eligibility criteria. In cases of disagreements on the eligibility, the pair met to discuss and resolve conflicts. In any instance, the pair was unable to resolve conflicts, the larger group evaluated and came to a consensus. A master sheet was created and data on all fulltext articles were documented (e.g., author, year, article

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Figure 1 Scoping review flow chart. *, some articles had multiple exclusion reasons.

type, study objectives, sample description, study design, if literacy information was collected, type of literacy collected/ addressed, literacy tool name, results related to literacy, and if literacy was incorporated into app design/modification). During the full-article review, 100 additional articles were identified from the reference lists of articles reviewed. In order to identify eligible articles, we used the same process of reviewing the abstracts and the full articles by two reviewers. A total of 57 articles were identified for inclusion in the scoping review.

After examining the 57 identified articles, a qualitative review of articles identified two distinct categories of articles. The first category of articles focused on creating and/or modifying an app with accommodations for health literacy concerns. The second category of articles focused on estimating health literacy levels or examining the association between literacy and outcomes such as intention to use a health app. Because it was thought that the first category of articles would be most important in understanding how apps have been designed or evaluated for those with limited health literacy, the decision was made to focus on this category of articles (n=32) in this scoping review. To address the second category of articles (n=25)identified in this scoping review a second manuscript using the same process will be written.

Data charting and synthesis of results

Data were summarized and analyzed using a data extraction table. The data extraction table included the following categories: (I) authors; (II) year of study; (III) study objective; (IV) sample description; (V) methods; (VI) results related to health literacy level; and (VII) health literacy integration recommendations. Sample descriptions

included location of the study, sample size, age, sex, race/ ethnicity, and education levels. Methods included the type of study (app development, app testing, review of apps, review of app studies), data collection methods, the type of literacy (e.g., general, technology), and the literacy tool(s) used. Pairs of reviewers reviewed the full-text articles independently and met to resolve conflicting results. Further differences identified in the initial charting were resolved among all the reviewers. To summarize the data, we first extracted information that addressed each data element (e.g., sample description). We then standardized the description of the data—for example, for the location information, we reported the state information for the U.S. studies and for the sex information, we reported the percentage of females.

Health literacy framework

The framework for this scoping review needed to capture two critical concepts: health literacy, and app/mobile platform design from a low literacy user perspective. Previous studies have concluded that there is a lack of a common definition and common methods of operationalizing health literacy as applied to digital platforms (28).

In trying to address this gap, Monkman & Kushniruk (in 2013), developed a set of heuristics for evaluating mobile health applications (29). These heuristics were based on the U.S. Department of Health & Human Services, Office of Disease Prevention and Health Promotion publication entitled "Health Literacy Online" (HLO) (in 2010) (30). The original (in 2010) and updated (in 2015) HLO documents serve as our framework for examining how health literacy is addressed in mHealth app development (30). The major advantage of the HLO documents is that they provide clear, actionable content which is usable by those designing apps for health consumers (31).

Six broad categories of strategies are identified in the HLO document: (I) what we know about users with limited health literacy skills; (II) write actionable content; (III) display content clearly on the page; (IV) organize content and simplify navigation; (V) engage users; and (VI) test your site with users with limited literacy skills. The first strategy is the only one which displays significant changes from its original 2010 version to the current 2015 version. The strategies identified in the articles reviewed in this paper were mapped to the strategies identified in the HLO to highlight those which appear to be most salient. For details

about each of the HLO strategies, please visit https://health.gov/healthliteracyonline/.

Results

Selection of sources of evidence

There were 1,010 records identified through database searching and an additional 100 identified from using references lists. After the abstract and full-text review, 32 articles were included in our final list for analysis (*Figure 1*).

Characteristics of evidence sources

Table 1 summarizes the sample characteristics, methods and results, and Table 2 summarizes the HLO recommendations. Of the 32 articles reviewed, two were reviews of mobile app studies (32,33), two were reviews of publicly available mobile apps (34,35), nine were articles which described development and evaluation of an app (36-44), five were articles which described development of an app (45-49), one article described the heuristics evaluation of a mobile health app (29) and the remaining 13 were evaluations of an app. The majority of mobile app development/evaluation studies were conducted in the U.S. The study populations included in the app development/evaluation studies ranged from the general population to primary care clinic patients and providers to patients with specific health conditions (e.g., dual antiplatelet therapy, chronic kidney disease).

Results of individual sources of evidence

To answer the first research question "How is health literacy addressed in mHealth app development?" We described the characteristics of the study sample, methods and results in *Table 1*. Also, in *Table 2* we included recommendations authors made to address health literacy. To answer the second research question "How is evaluation of health literacy addressed in mHealth apps?" We included the health literacy tool used in the study and presented the recommendation authors made to evaluate health literacy in *Table 2*.

Synthesis of results

Evaluation of health literacy

Neither of the two reviews of app studies, nor the five studies which described the development of an app used a health literacy tool (32,33,45-49); of the two reviews of

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Table 1 Summary of reviewed articles

Primary author [year]	Objective(s)	Sample description	Methods	Results re. health literacy level	Health literacy integration into design	HLO 2016 strategies (2010 strategy*)
Abujarad [2018]	To describe how an mHealth tool was	Connecticut, USA	Development and evaluation of app	Not reported	Desired reading level was at 8th grade level	2.6: Write in plain language
n A A	designed, developed, and evaluated for advancing the informed consent process	N=14 Patients and researchers from an asthma clinic and a university institutional review board member Age: 21–74 years	User-centered design methodology Focus groups, pilot of app General literacy Literacy tool: not used		Text-to speech translation is a key feature of VIC and is achieved by online and automated text-to-speech translation	3.11: Make your site accessible to people with disabilities
		55.7% female 66.7% white 77.8% Bachelor+			Text-to-speech interfaces addresses literacy issues and makes the IC process an option for inexperienced computer users	5.1: Share information through multimedia
Bahadori [2020]	To assess the readability of the	Location: UK	Systematic review of apps	Only one app reached "easy to	Consider specific needs of target population	1.2*: Understand their motivations
	information provided within total hip replacement and total knee	N=15 apps	General literacy GFI, FKGL, FRES	read" criteria across all three indices	Target a GFI and FKGL of 6 and FRES of 70	2.6: Write in plain language
	replacement apps to understand more				Decrease number/length of sentences	3.1: Limit paragraph size. Use bullets & short lists
	about the impact this could have on patients				Involve patients in app development and user acceptance testing	6.1: Recruit users w. limited literacy/health literacy skills
					Monitor patient experience to see if readability needs to be improved	6.4: Test whether your content is understandable and actionable
Ben-Zeev [2013]	To describe the development of a smartphone illness self-management	Illinois, USA N=8 a. Practitioners from a psychiatric rehabilitation agency Age: not reported Sex: not reported Race/ethnicity: not reported Education: not reported	Development of app Survey, focus group General literacy Literacy tool: not used	Not reported	Apps and technological systems must be usable by people with low literacy levels and cognitive impairments	1.1: Reading & cognitive processing challenges
system for people v	system for people with schizophrenia.				Deploying existing mHealth resources intended for the general population may prove problematic	1.4: Mobile considerations6.1: Recruit users w. limited literacy/health literacy skills6.4: Test whether your content is understandable & actionable
Bender [2016]	To describe promoters' and health care providers' current practices and experiences disseminating health education and perceptions regarding visuals promoting physical activity and limiting sedentary behavior for a visually enhanced low-text mHealth app	Location: California, USA N=21 Eligibility: bilingual healthcare providers in low-income Latino communities Age: mean 41.2 years 86% female Race/ethnicity: not reported Education: not reported	Evaluation of app Focus groups, qualitative interviews Health literacy Literacy tool: not used	Not formally assessed in clinics, but difficulty frequently observed in ad-hoc assessments Limited health educational materials with visual aids exist	Use visuals with simple text and culturally tailored themes and imaging	3.8: Use images that help people learn
						Make sure the meaning of your image s clear to all users
					Formalize health literacy measurements	NA
Boyd [2015]	To describe the design, methodology, limitations, and results of the MyIDEA tablet app	Illinois, USA N=5 Advisers of drug-eluting stent patients	Development of app App development Health literacy Literacy tool: not used	Identified by 5 patient advisors as a key attribute of the patient population	Write text at a sixth-grade reading level and provide narration as an additional method for individuals with low literacy to understand text-based information	2.6: Write in plain language
		Age: not reported Sex: not reported Race/ethnicity: not reported Education: not reported			Include audio and images as supplemental information for people below a sixth-grade reading level	3.8: Use images that help people learn
Casey [2014]	To explore patients' views and experiences of using smartphones to promote physical activity in primary care	UK N=12 Smartphone owners Age: 17–62 (mean 42) years 75% female Race/ethnicity: not reported Education: not reported	Evaluation of app Interviews Smartphone literacy Literacy tool: not used	83% had emailed on phone, 33% had downloaded apps previously	Reduction, or simplifying a task to influence behavior, was evident by the reports that the app was easy to use, required basic numerical literacy, and was highly visible on the home screen	4.1: Create a simple & engaging homepage4.2: Label & organize content with your users in mind4.3: Create linear information paths4.7: Provide easy access to home & menu pages

Table 1 (continued)

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Primary author [year] Objective(s)		Sample description	Methods	Results re. health literacy level	Health literacy integration into design	HLO 2016 strategies (2010 strategy*)
Ceasar [2019]	To utilize focus groups for gathering qualitative data to inform the development of an app that promotes physical activity among African	Washington DC and Maryland, USA N=16 African American women in low-income areas of Washington DC	Development of app Focus group Technology literacy Literacy tool: not used	Technology literacy identified as a perceived barrier towards using apps to promote physical activity	Use focus groups as a collaborative tool to inform app development	2.1: Identify user motivations and goals.6.1: Recruit users with limited literacy skills6.4: Test whether your content is understandable and actionable
	American women in Washington, DC	Age: 51–74 (mean 62.1) years Bachelor± 63%			Increase relatability with local information	5.3: Provide tailored information
					Check-ins or IT support to address technical difficulties	6.4: Test whether your content is understandable and actionable6.8: Test on mobile
Chaudry [2013]	To (1) determine whether the interface design can help a low literacy population accurately estimate portion sizes of various liquids; and (2) to confirm the successful results of our previous study when the interface is high fidelity	Indiana, USA African American patients with chronic kidney disease Study 1 (n=10): mean age 58 years, 40% female Study 2 (n=18): mean age 53 years, 72% female Education: not reported	Development and evaluation of app Health literacy REALM	Literacy only assessed in study 1 because participants were embarrassed to complete the test in front of peers 6/10 patients read below a 9 th grade level People with varying literacy skills were able to comprehend and navigate the design of the interface to search and select specific portion sizes	Recommend using literacy tests other than REALM to reduce discomfort when speaking aloud	1.1: Reading and cognitive processing challenges6.2: Identify and eliminate logistical barriers to participation
Connelly [2016]	To provide a case study of design of an ecological momentary assessment mobile app for a low-literacy population.	New York, USA N=41 Farming population of Mexican American women, primarily Spanish speaker, none completed college Ages: 18–45 years for Phases 1–3, mean age 28.8 years for Phase 3	Development and evaluation of app Focus groups Health literacy SAHL-S&E, NVS	Phase 1: Mean SAHL 16.1, 3/8 women scored as low literacy, all women struggled to complete tasks Phase 2: Literacy not assessed Phase 3: Mean SAHL 14.2, 4/11 women scored as low literacy. Mean NVS score of 1 Phase 4: 5 of 7 participants had low literacy skills	Differences in health literacy better identified with NVS than SAHL with usability best tested in situ Interface has larger pictures with short labels and could be read aloud Mobile app focus groups to explore app design Provide a case study of design of an ecological momentary assessment mobile app for a low-literacy population Iterative, user-centered design process with focus groups was essential for designing the app rather than merely replacing words with icons and/or audio	 1.1: Reading and cognitive processing challenges 6.3: Create plain language testing materials 3.8: Use images that help people learn 6.1: Recruit users with limited literacy skills 6.4: Test whether your content is understandable and actionable 6.4: Test whether your content is understandable and actionable
Coughlin [2017]	To develop an app to provide women with information about how they can reduce their risk of breast cancer through healthy behaviors.	Washington and Georgia, USA N=5 Women interested in breast cancer risk reduction Age: not reported Race/ethnicity: not reported Education: not reported	Development of app eHealth literacy Literacy tool: not used	Not reported	Varying levels of eHealth literacy will be addressed by using simple navigation features and providing straightforward instructions about how to use the app and connect it to commercially available products It will be possible for women to use the app without interfacing with commercial Internet sites	1.2: Understanding navigation2.5: Provide specific action stepsNA
Dev [2019]	To present feedback on a family planning app.	Kenya N=42 Postpartum women (n=25) and family planning providers (n=17) from maternal and child health clinic Age: 14–21 years for patients (n=15) and 18–58 years for providers Education: not reported	Development and evaluation of app Interviews General literacy and technology literacy Literacy tool: not used	General and technological literacy were seen as potential barriers	Increasing graphics, audio, and video were recommended to overcome literacy barriers	5.1: Share information through multimedia.5.2: Design intuitive interactive graphics and tools

Table 1 (continued)

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Primary author [year]	Objective(s)	Sample description	Methods	Results re. health literacy level	Health literacy integration into design	HLO 2016 strategies (2010 strategy*)
Dunn-Lopez [2020]	To determine: readability, types of functions, and linkage to authoritative sources of evidence for self-care focused mHealth apps targeting heart failure available in the Apple and Google Play Stores	N=10 apps Inclusion: mHealth apps targeting patients with heart failure in the Apple and Google Play app stores	Review of apps General literacy FKGL	Average reading grade level 9.35 Only 1 app had a reading grade level of <6th grade	Essential elements in providing health literate content at a 6th grade reading level include plain language, short sentences, brief paragraphs, bulleted or numbered lists, and actionable content	2.5: Provide specific action steps2.6: Write in plain language3.1: Limit paragraph size. Use bullets and short lists
Fontil [2016]	To (I) adapt the literacy level and cultural relevance of online program content for low-income, underserved	California, USA Sample size not reported Low-income prediabetes patients at a large safety net	Development and evaluation of app Focus groups Technology literacy	Not reported	In addition to simplifying overall language, we simplified explanations of scientific concepts, preserving core concepts while improving understandability	2.3: Describe the health behavior – just the basics
populations; and (II) test and acceptability of the program	and acceptability of the modified program	Age: not reported Sex: not reported Race/ethnicity: not reported Education: not reported	Literacy tool: not used		To address concerns about the complexity of the curriculum, we adapted the readability level of each lesson (originally 9th grade or higher) to mostly a 5th- grade level or below	2.6: Write in plain language
					Creating technical assistance tools for various stages of the program to address lower technology literacy	6.5: Use moderators who have experience with users with limited literacy skills
Gibbons [2014]	To explain health information technology (HIT) universal design	Review study	Reviews of app studies Health literacy, IT literacy Literacy tool: not used	Not reported	Use disparities-oriented use cases when designing an app	NA
	principles derived from the human factors engineering literature that can help to overcome potential usability and/or patient safety issues that are associated with unrecognized, embedded assumptions about cultural groups when designing HIT systems				Use symbols that have been found to be common across culture	3.8: Use images that help people learn
					Include a target population with low health literacy during usability evaluation	6.1: Recruit users with limited literacy skills—and limited health literacy skills
Giunti [2018]	To examine how mHealth can facilitate physical activity among those with multiple sclerosis (MS) and understand the motivational aspects behind adoption of mHealth solutions for MS.	Switzerland Patients with MS and healthcare professionals N=12 patients, 12 professionals Age: 35–62 years for patients, 26–64 years for professionals 50% female Race/ethnicity not reported Bachelors+: 33%	Evaluation of app Mixed methods: focus group, interview, survey eHealth literacy eHEALS	Patient eHealth literacy median score 17.75 (IQR 11–28.5)	Personas were created to represent persons with MS at different eHealth and health literacy levels	3.8: Use images that help people learn
Huang [2015]	To enhance foreign visitors' capabilities in communication during exchange information with local foreign doctors by developing an effective patient- physician communication mobile system	Austria and Taiwan Sample size not reported Foreign students seeking medical care and physicians Age: not reported Sex: not reported Race/ethnicity: not reported Education: not reported	Evaluation of app Case studies and interviews Health literacy Literacy tool: used but the name of the tool not reported	Foreign patients scored significantly higher after exposure to eHealth system compared to before the exposure	The voice-to-text bilingual function will be used to assist the patients with low health literacy	5.1: Share information through multimedia
Lord [2016]	To explore provider and staff perceptions of implementation of the A-CHESS mobile recovery support app with clients in 4 addiction service settings	United States N=12 Clinicians and administrators from 4 agencies that serve people with substance use disorders Age: 25–53 years 50% female 91% white Education: not reported	Evaluation of app Qualitative interviews, deductive analysis guided by CFIR model General literacy and technology literacy Literacy tool: not used	Not reported	Use speech-to-text functionality to help individuals with low literacy	5.1: Share information through multimedia

Table 1 (continued)

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Primary author [year]	Objective(s)	Sample description	Methods	Results re. health literacy level	Health literacy integration into design	HLO 2016 strategies (2010 strategy*)
Mackert [2017]	To explore the perceived role of men in prenatal health, use of an e-health application, and participant suggested ways of improving the application	Texas, USA N=23 General population of adult males Age: mean 26.0 years 52% white 100% some postsecondary ed	Evaluation of app Semi-structured interview Health literacy NVS	Average NVS score 5.3, suggesting the sample had adequate levels of health literacy Can balance between being broad applicability and individualization, regardless of level of health literacy users have	Need app design to be engaging and interactive, from adding videos and games inside the application, to personalizing the experience, to changing font size and color Encouraged dynamic personalization allowing users to input personal data	5.1: Share information through multimedia5.2: Design intuitive interactive graphics and tools5.3: Provide tailored information
Miller [2017]	To determine whether patients from vulnerable populations could successfully navigate and complete an mHealth patient decision aid	North Carolina, USA Patients due for colorectal cancer screening N=450 Age: 50–74 years 53.8% female	Evaluation of app Secondary usability analysis Health literacy Literacy tool: validated item, "How confident are you filling out medical	36.9% with limited health literacy	Design apps for those with low health literacy and low computer literacy: use a simple interface displaying only one question per screen with large response buttons, similar to what would be found at an automated teller machine or self-checkout kiosk	1.4: Mobile considerations5.4: Create user-friendly forms and quizzes
		Education: not reported	iomis by yoursell?		Use simple language and include audio narration to assist those with literacy barriers	2.6: Write in plain language 5.1: Share info through multimedia
Monkman [2013]	To (I) adapt a set of existing guidelines for the design of consumer health Web sites into evidence-based heuristics; and (II) apply the heuristics to evaluate a mobile app	NA	Evaluation of app using heuristics Health literacy Literacy tool: not used	As the heuristic evaluation yielded valuable recommendations for improving the app, this approach (based on modifying evidence-based design guidelines) to developing heuristics for investigating usability and health literacy appeared to be successful	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices	 1.4: Mobile considerations 2.2: Put the most important information first 2.4: Stay positive. Include the benefits of taking action. 2.5: Provide specific action steps 2.6: Write in plain language 2.7: Check content for accuracy Category 3: display: 3.1–3.11 Category 4: organize: 4.1–4.10 5.1: Share information through multimedia 5.3: Provide tailed information 5.5: Consider social media sharing options
Mueller [2020]	To develop, pilot, and assess a serious game for mobile devices that teaches geohazard, maternal, and neonatal health messages	Nepal N=71 Age: mean 40 years Education: informal to bachelor's degree	Development and evaluation of app Observation and focus groups Development and field evaluation of a game designed for individuals with low literacy General literacy Literacy tool: not used	Not reported	Co-design of images with intended population Pictogram sets can be switched out for newly designed pictograms that are contextualized and localized to other study areas, countries, or topics	1.1*: ID your users. Who are they?3.8: Use images that help people learn (choose realistic images)
Muscat [2020]	To develop an intervention that addressed health literacy for Australian adults with kidney failure requiring dialysis to promote active patient participation in CKD management and decision-making	Location: Australia No participants other than the research team	Development of app Health literacy Literacy tool: not used	Not reported	Calculate readability statistics	5.4: Create user-friendly forms & quizzes6.4: Test whether your content is understandable & actionable
					Apply the Patient Education Materials Assessment Tool	6.4: Test whether your content is understandable & actionable
	U U				Supplement written content with audiovisual formats	5.1: Share information through multimedia
					Incorporate micro-learning and interactive quizzes	5.4: Create user-friendly forms & quizzes
					Improve literacy skills with question prompt lists, volitional help sheets, and skills training	NA

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Table 1 (continued)

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Primary author [year]	Objective(s)	Sample description	Methods	Results re. health literacy level	Health literacy integration into design
Ownby [2012]	To evaluate the extent to which an electronic intervention targeting health literacy and organized by the elements of the Information-Motivation- Behavioral Skills model could improve patients' health literacy and medication adherence.	Location: Florida, USA N=124 Persons with HIV Age: 20–67 (mean 47.1) years 29% female 63.4% African American, 36.6% white 10.5% college graduates	Evaluation of app Health literacy TOHFLA	Mean TOFHLA: numeracy 46.02, reading 42.46, total: 88.48 6 participants with inadequate health literacy, 10 marginal, 108 adequate Intervention led to greater increases in adherence among those with lower numeracy and lower baseline adherence	Present numeric dosing data in a graphic calen
Poduval [2018]	To determine whether there was evidence of a digital divide when a Web-based self-management program for type II diabetes mellitus was integrated into routine care	London, UK N=330 Adults with type 2 diabetes Age: mean 58.4 years 44.5% female 45.5% white 48.8% bachelors or more	Evaluation of app Retrospective analysis General and digital health literacy Literacy tool: not used	Not reported	Consideration of literacy levels and audio/visua for usability Text written for people with a reading age of 12 essential information was provided in video as text format Personal stories included
Povey [2020]	To use a participatory design research approach to understand adaptations which might improve the engagement, reach and acceptability of this resource from the perspective of Aboriginal and Torres Strait Islander youth	Torres Strait N=120 Co-design group: Islander youth (n=45) aged 10– 18 years, 47% female, 93% in secondary school Survey: Islander people (n=75), 51% under 18, 60% female	Evaluation of app Mixed methods, participatory design General literacy and mental health literacy Literacy tool: not used	Not reported	Engagement via humor, music, vibrant colors, r images, and stories about positive change Audio and intuitive visuals encouraged for lowe Sustain use with customization, interactive acti challenges/records of progress over time and c
Povey [2016]	To explore Aboriginal and Torres Strait Islander community members' experiences of using two culturally responsive e-mental health apps and identify factors which influence the acceptability of these approaches	Torres Strait N=9 People identifying as Aboriginal/Torres Strait Islanders who spoke English and did not have a severe level of mental illness. Age: 18–60 years 66.7% female Education: not reported	Development and evaluation of app Qualitative focus group General literacy Literacy tool: not used	Not reported	sharing Graphics and animation perceived as supportin motivation Culturally relevant graphics, voices, animation, optional short video clips may assist in engage content and overcome literacy issues.
Schnall [2015]	To understand the perceived ease of use, usefulness, risk and trust that contribute to behavioral intention to use a mobile app for meeting the healthcare needs of persons living with HIV (PLWH)	Location: New York, USA N=80 PLWH and clinicians/case managers PLWH (n=50): ages 18–59 years, 26% female, 52% Black, 50% Hispanic Clinicians/case managers (n=30): ages 23–62 years, 83.3% female, 56.7% white, 20% Hispanic Education: not reported	Evaluation of app Qualitative participatory design via focus groups, app evaluation General and technology literacy Literacy tool: not used	Not measured	App should not rely on internet connectivity Present information with simplicity

Table 1 (continued)

HLO 2016 strategies (2010 strategy*)

ndar format 5.2: Design intuitive interactive graphics and tools

al media	2.6: Write in plain language 5.1: Share information through multimedia
2, all s well as	2.6: Write in plain language5.1: Share information through multimedia
	5.3: Provide tailored information
relatable	2.4: Stay positive. Include benefits of taking action5.1: Share info through multimedia
er literacy	3.8: Use images that help people learn (choose realistic images – photos of "real" people)5.1: Share information through multimedia
tivities, and options for	5.3: Provide tailored information
ing	2.4: Stay positive. include benefits of taking action (give users motivation to make a change)
, and ement with	3.8: Use images that help people learn (choose realistic images)

NA

2.2: Put the most important information first
2.3: Describe the health behavior – just the basics
2.6: Write in plain language

Table 1 (continued)

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Primary author [year]	Objective(s)	Sample description	Methods	Results re. health literacy level	Health literacy integration into design	HLO 2016 strategies (2010 strategy*)
Siedner [2015]	To identify predictors of uptake of an mHealth application for a low-literacy population of people living with HIV	Location: SW Uganda N=385 PLWH undergoing CD4 testing and can access a	Evaluation of app Secondary data analysis from randomized clinical trial General literacy Ability to read a complete sentence	Confirmed literacy at the time of enrollment was a robust predictor of SMS text message receipt, identification, and appropriate response for PLWH in rural Uganda	Coded messages, which obviate the need for literacy, were as effective as direct messages and might augment privacy	1.1: Reading & cognitive processing challenges
(PLWH) in rural Uganda a the efficacy of various sh service (SMS) text messa to optimize the balance b confidentiality and acces	(PLWH) in rural Uganda and; evaluate the efficacy of various short message service (SMS) text message formats to optimize the balance between confidentiality and accessibility	Mobile phone Age: median 32 years 65.2% female 10.6% post-secondary			In person confirmation of mobile phone competency was highly predictive and should be considered for future similar interventions where possible End-user characteristics, particularly literacy and technology experience are important predictors of an mHealth intervention for PLWH in rural Uganda	1.1*: ID your users. Who are they?
					Thorough assessments of end-user written literacy and technology experience should be made before and during implementation design	6.1: Recruit users with limited literacy skills – and limited health literacy skills
					Coded messages can have similar efficacy as text messages, while maintaining confidentiality	6.4: Test whether your content is understandable and actionable
Sox [2010]	To create an interface for parents of children with ADHD to enter disease- specific information to facilitate data entry with minimal task burden	Massachusetts, USA N=17 English or Spanish speaking parents who are primary caretakers of a school-aged child with ADHD Age: not reported Sex: not reported Race/ethnicity: not reported Education: not reported	Development and evaluation of app Needs analysis, usability testing, and performance testing Health literacy TOFHLA	2/10 participants with lower health literacy (<81)	Alternative text explanations and audio files to support lower health literacy	5.1: Share information through multimedia
					Acknowledge tension between expectations of a highly-educated parent and a parent with limited health knowledge	NA
Srinivas [2019]	To report a case study involving the design and evaluation of a mobile ecological momentary assessment (EMA) tool that supports context- sensitive EMA-reporting of location and social situations accompanying eating and sedentary behavior	Midwest, USA N=59 Obese women a referred to HealthyMe program Age: 35–64 years 83% Black, 17% White 61% college	Development and evaluation of app Focus groups, semi-structured interviews, prototype testing, 2 field trials Health literacy NVS	59.3% low health literacy	Specific to reducing burden while capturing a user response, we suggest designing a system that uses simple-worded, direct questions with fewer words that are easier to read and quicker for the participant to understand and has simple response options that are easier to read, quicker for the participant to understand and select from	3.1: Limit paragraph size. Use bullets & short lists5.2: Design intuitive interactive graphics & tools5.4: Create user-friendly forms & quizzes
Wildenbos [2018]	To synthesize literature on aging barriers to digital (health) computer use, and explain, map and visualize these barriers in relation to the usability of mHealth by means of a framework	NA	Review of app studies Scoping review Computer literacy Literacy tool: not used	Cognitive barriers impact satisfaction via diminishing age dependent abilities (numeracy & representational fluency) Motivational barriers impact learnability via diminishing age- dependent computer literacy	Encourage designers, programmers and developers should be to create mHealth interventions with inclusive design, or flexible enough to be usable by people with no limitations as well as by people with functional limitations related to disabilities or old age	3.11: Make your site accessible to people with disabilities
					The MOLD-US framework can aid mHealth designers in inclusive design efforts. The visual overview of MOLD-US enables a quick assessment of aging barriers and medical conditions that involve deteriorating capacity	3.11: Make your site accessible to people with disabilities

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Table 1 (continued)

Primary author [year]	Objective(s)	Sample description	Methods	Results re. health literacy level	Health literacy integration into design	HLO 2016 strategies (2010 strategy*)
Wildenbos [2019]	To assess usability problems older patients, encounter in two mHealth apps, aiming show the value of MOLD-	Netherlands N=23 Age >50 years, can read Dutch	Evaluation of app Case-study Computer literacy	28 high severe usability issues of the mHealth apps were identified	Cognitive load should be minimized, i.e., by a clear navigational structure and aligning an interface with expectations of older adults mind	4.2: Label and organize content with your users in mind
	US, a recent aging barriers framework, as a classification tool to identify the intrinsic cause of these problems.	Sex: not reported Education: not reported	Think Aloud method	Core natures were related to motivational and cognitive barriers of older adults Participants had difficulties understanding app navigation structure, missing important text, buttons and icon elements	Advise to put more emphasis on addressing motivational barriers of older adults within user interface design and guidelines	1.2*: Understanding their motivations. Why are they here?2.1: Identify user motivations & goals. Why are they here?
					User-interface design elements such as font size and buttons should be adjusted to the older adult user population.	3.3: Use a readable font that's at least 16 pixels
					Advise to involve older populations as co-creators in the requirements analysis and design phases when developing mHealth	6.1: Recruit users with limited literacy skills – and limited health literacy skills
					Usability evaluation approaches may need adjustments to prevent reporter bias and become better suited for testing mHealth services with the older adult and chronically ill patient populations	6.2: ID & eliminate logistical barriers to participation
					Colored information visuals explaining navigation and consequences of decision could be used as a decision aid tool since these types of visuals have a positive effect on the accuracy of the decisions made by older adults in eHealth tools	NA
					Using feedback messages in interfaces should not only inform users on (the result of) their actions but should also offer the user options to recover from wrong actions and return to previously retrieved information or actions	1.2: Understanding Navigation
						A clear (video) instruction on how to use an app should be given when older users register for an app, including an aid to return to this instruction during any point in an app's usage"

*, Recommendation from 2010 guidelines. CKD, chronic kidney disease; HIV, human immunodeficiency virus; ADHD, attention-deficit hyperactivity disorder; eHEALS, eHealth Literacy Scale; CFIR, Consolidated Framework for Implementation Research; VIC, Patient Centered Virtual Multimedia Interactive Informed Consent tool; IQR, Interquartile range; GFI, Gunning Fog Index; FKGL, Flesch-Kincaid Grade Level; FRES, Flesch Reading Ease Score; NVS, Newest Vital Sign; REALM, Rapid Estimate of Adult Literacy in Medicine; SAHL-S&E, Short Assessment of Health Literacy-Spanish and English; TOFHLA, Test of Functional Health Literacy in Adults; HLO, Health Literacy Online; NA, not applicable.

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Table 2 HL	C	strategies and	corresponding	author	recommendations
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HLO strategy	Author/year	Recommendation
Section 1 [2015]: What we know	about users with lin	nited literacy skills
1.1 Reading & cognitive processing challenges	Ben-Zeev [2013]	Apps and technological systems must be usable by people with low literacy levels and cognitive impairments
	Chaudry [2013]	Recommend using literacy tests other than REALM to reduce discomfort when speaking aloud
	Connelly [2016]	Differences in health literacy better identified with Newest Vital Sign than Short Assessment of Health Literacy with usability best tested <i>in situ</i>
	Siedner [2015]	Coded messages, which obviate the need for literacy, were as effective as direct messages and might augment privacy
1.2 Understanding navigation	Coughlin [2017]	Varying levels of eHealth literacy will be addressed by using simple navigation features and providing straightforward instructions about how to use the app and connect it to commercially available products
	Wildenbos [2019]	Using feedback messages in interfaces should not only inform users on (the result of) their actions but should also offer the user options to recover from wrong actions and return to previously retrieved information or actions
1.3 Using search	N/A	NA
1.4 Mobile considerations	Ben-Zeev [2013]	Deploying existing mHealth resources intended for the general population may prove problematic
	Miller [2017]	Design apps for those with low health literacy and low computer literacy: use a simple interface displaying only one question per screen with large response buttons, similar to what would be found at an automated teller machine or self-checkout kiosk
	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
Section 1 [2010]: Learn about yo	our users & their goa	ls
1.1 ID your users. Who are	Mueller [2020]	Co-design of images with intended population
they?	Siedner [2015]	In person confirmation of mobile phone competency was highly predictive and should be considered for future similar interventions
		End-user characteristics, particularly literacy and technology experience are important predictors of an mHealth intervention for PLWH in rural Uganda.
1.2 Understanding their	Bahadori [2020]	Consider specific needs of target population
motivations. Why are they here?	Wildenbos [2019]	Advise to put more emphasis on addressing motivational barriers of older adults within user interface design and guidelines
1.3 Understanding their goals. What are they trying to do?	N/A	NA
Section 2: Write actionable cont	ent	
2.1 Identify user motivations &	Ceasar [2019]	Use focus groups as a collaborative tool to inform app development
goals. Why are they here?	Wildenbos [2019]	Advise to put more emphasis on addressing motivational barriers of older adults within user interface design and guidelines
2.2 Put the most important information first	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
	Schnall [2015]	Present information with simplicity
2.3 Describe the health behavior – just the basics	Fontil [2016]	In addition to simplifying overall language, we simplified explanations of scientific concepts, preserving core concepts while improving understandability
	Schnall [2015]	Present information with simplicity

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Table 2 (continued)

Table 2 (continued)		
HLO strategy	Author/year	Recommendation
2.4 Stay positive. Include the benefits of taking action	Povey [2020]	Engagement via humor, music, vibrant colors, relatable images, and stories about positive change
	Povey [2016]	Graphics and animation perceived as supporting motivation
	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
2.5 Provide specific action steps	Dunn-Lopez [2020]	Essential elements in providing health literate content at a 6th grade reading level include plain language, short sentences, brief paragraphs, bulleted or numbered lists, and actionable content
	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
	Coughlin [2017]	Varying levels of eHealth literacy will be addressed by using simple navigation features and providing straightforward instructions about how to use the app and connect it to commercially available products
2.6 Write in plain language	Abujarad [2018]	Desired reading level was at 8th grade level
	Bahadori [2020]	Target a Gunning Fog Index and Flesch Kincaid Grade Leve of 6 and Flesch Reading Ease Score of 70
	Boyd [2015]	Write text at a sixth-grade reading level and provide narration as an additional method for individuals with low literacy to understand text-based information
	Dunn-Lopez [2020]	Essential elements in providing health literate content at a 6th grade reading level include plain language, short sentences, brief paragraphs, bulleted or numbered lists, and actionable content
	Fontil [2016]	To address concerns about the complexity of the curriculum, we adapted the readability level of each lesson (originally 9th grade or higher) to mostly a 5th-grade level or below
	Miller [2017]	Use simple language and include audio narration to assist those with literacy barriers
	Poduval [2018]	Consideration of literacy levels and audio/visual media for usability
		Text written for people with a reading age of 12, all essential information was provided in video as well as text format
	Schnall [2015]	Present information with simplicity
	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
2.7 Check content for accuracy	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
Section 3: Display content clear	ly on the page	
3.1 Limit paragraph size. Use	Bahadori [2020]	Decrease number/length of sentences
bullets & short lists	Dunn-Lopez [2020]	Essential elements in providing health literate content at a 6th grade reading level include plain language, short sentences, brief paragraphs, bulleted or numbered lists, and actionable content
	Srinivas [2019]	Specific to reducing burden while capturing a user response, we suggest designing a system that uses simple-worded, direct questions with fewer words that are easier to read and quicker for the participant to understand and has simple response options that are easier to read, quicker for the participant to understand and select from
3.2 Use meaningful headings	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices

 Table 2 (continued)

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HLO strategy	Author/year	Recommendation
3.3 Use a readable font that's at least 16 pixels	Wildenbos [2019]	User-interface design elements such as font size and buttons should be adjusted to the older adult user population
	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
3.4 Use white space & avoid clutter	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
3.5 Keep the most important information above the fold – even on mobile	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
3.6 Use links effectively	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
3.7 Use color or underline to ID links	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
3.8 Use images that help	Bender [2016]	Use visuals with simple text and culturally tailored themes and imaging
people learn	Boyd [2015]	Include audio and images as supplemental information for people below a sixth- grade reading level
	Connelly [2016]	Interface has larger pictures with short labels and could be read aloud
	Gibbons [2014]	Use symbols that have been found to be common across culture
	Giunti [2018]	Personas were created to represent persons with MS at different eHealth and health literacy levels
	Mueller [2020]	Pictogram sets can be switched out for newly designed pictograms that are contextualized and localized to other study areas, countries or topics
	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
	Povey [2020]	Audio and intuitive visuals encouraged for lower literacy
	Povey [2016]	Culturally relevant graphics, voices, animation, and optional short video clips may assist in engagement with content and overcome literacy issues
3.9 Use appropriate contrast	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
3.10 Make web content printer friendly	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
3.11 Make your site accessible to people with disabilities	Abujarad [2018]	Text-to speech translation is a key feature of VIC and is achieved by online and automated text-to-speech translation
	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
	Wildenbos [2018]	Encourage designers, programmers and developers should be to create mHealth interventions with inclusive design, or flexible flexible enough to be usable by people with no limitations as well as by people with functional limitations related to disabilities or old age
		The MOLD-US framework can aid mHealth designers in inclusive design efforts. The visual overview of MOLD-US enables a quick assessment of aging barriers and medical conditions that involve deteriorating capacity
3.12 Make websites responsive	NA	NA

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 Table 2 (continued)

HLO strategy	Author/year	Recommendation
3.13 Design mobile content to meet mobile user's needs	NA	NA
Section 4: Organize content & sin	mplify navigation	
4.1 Create simple & engaging homepage	Casey [2014]	Reduction, or simplifying a task to influence behavior, was evident by the reports that the app was easy to use, required basic numerical literacy, and was highly visible on the home screen
	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
4.2 Label & organize content with your users in mind	Casey [2014]	Reduction, or simplifying a task to influence behavior, was evident by the reports that the app was easy to use, required basic numerical literacy, and was highly visible on the home screen
	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
	Wildenbos [2019]	Cognitive load should be minimized, i.e., by a clear navigational structure and aligning an interface with expectations of older adults
4.3 Create linear information paths	Casey [2014]	Reduction, or simplifying a task to influence behavior, was evident by the reports that the app was easy to use, required basic numerical literacy, and was highly visible on the home screen
	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
4.4 Give buttons meaningful labels	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
4.5 Make clickable elements recognizable	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
4.6 make sure the browser "Back" button works.	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
4.7 Provide easy access to home & menu pages	Casey [2014]	Reduction, or simplifying a task to influence behavior, was evident by the reports that the app was easy to use, required basic numerical literacy, and was highly visible on the home screen
	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
4.8 Give users options to browse	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
4.9 Include a simple search	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
4.10 Display search results clearly	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
Section 5: Engage Users		
5.1 Share information through multimedia	Abujarad [2018]	Text-to-speech interfaces addresses literacy issues and makes the IC process an option for inexperienced computer users
	Dev [2019]	Increasing graphics, audio, and video were recommended to overcome literacy barriers
	Huang [2015]	The voice-to-text bilingual function will be used to assist the patients with low health literacy
	Lord [2016]	Use speech-to-text functionality to help individuals with low literacy

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Table 2 (continued)

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HLO strategy	Author/year	Kecommendation
	Mackert [2017]	Need app design to be engaging and interactive, from adding videos and games inside the application, to personalizing the experience to changing font size and color
	Miller [2017]	Use simple language and include audio narration to assist those with literacy barriers
	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
	Muscat [2020]	Supplement written content with audiovisual formats
	Poduval [2018]	Consideration of literacy levels and audio/visual media for usability
		Text written for people with a reading age of 12, all essential information was provided in video as well as text format
	Povey [2020]	Engagement via humor, music, vibrant colors, relatable images, and stories about positive change
		Audio and intuitive visuals encouraged for lower literacy
	Sox [2010]	Alternative text explanations and audio files to support lower health literacy
5.2 Design intuitive interactive graphics & tools	Dev [2019]	Increasing graphics, audio, and video were recommended to overcome literacy barriers
	Mackert [2017]	Need app design to be engaging and interactive, from adding videos and games inside the application, to personalizing the experience to changing font size and color
	Ownby [2012]	Present numeric dosing data in a graphic calendar format
	Srinivas [2019]	Specific to reducing burden while capturing a user response, we suggest designing a system that uses simple-worded, direct questions with fewer words that are easier to read and quicker for the participant to understand and has simple response options that are easier to read, quicker for the participant to understand and select from
5.3 Provide tailored	Ceasar [2019]	Increase relatability with local information
information	Mackert [2017]	Encouraged dynamic personalization allowing users to input personal data
	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices
	Poduval [2018]	Personal stories included
	Povey [2020]	Sustain use with customization, interactive activities, and challenges/records of progress over time and options for sharing.
5.4 Create user-friendly forms & quizzes	Miller [2017]	Design apps for those with low health literacy and low computer literacy: use a simple interface displaying only one question per screen with large response buttons, similar to what would be found at an automated teller machine or self-checkout kiosk
	Muscat [2020]	Calculate readability statistics
		Incorporate micro-learning and interactive quizzes
	Srinivas [2019]	Specific to reducing burden while capturing a user response, we suggest designing a system that uses simple-worded, direct questions with fewer words that are easier to read and quicker for the participant to understand and has simple response options that are easier to read, quicker for the participant to understand and select from
5.5 Consider social media sharing options	Monkman [2013]	Although the majority of the recommendations from the HLO guide for Web sites were applicable for assessing mobile usability, the heuristics generated in this study may benefit from being complemented with other evidence-based heuristics specific to mobile devices

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Table 2 (continued)

HLO strategy	Author/year	Recommendation
Section 6: Test your site with use	ers with limited litera	cy skills
6.1 Recruit users with limited literacy skills – and limited health literacy skills	Bahadori [2020]	Involve patients in app development and user acceptance testing
	Ben-Zeev [2013]	Deploying existing mHealth resources intended for the general population may prove problematic
	Ceasar [2019]	Use focus groups as a collaborative tool to inform app development
	Connelly [2016]	Mobile app focus groups to explore app design
	Gibbons [2014]	Include a target population with low health literacy during usability evaluation
	Siedner [2015]	Thorough assessments of end-user written literacy and technology experience should be made before and during implementation design
	Wildenbos [2019]	Advise to involve older populations as co-creators in the requirements analysis and design phases when developing mHealth
6.2 ID & eliminate logistical barriers to participation	Chaudry [2013]	Recommend using literacy tests other than REALM to reduce discomfort when speaking aloud
	Wildenbos [2019]	Usability evaluation approaches may need adjustments to prevent reporter bias and become better suited for testing mHealth services with the older adult and chronically ill patient populations
6.3 Create plain language testing materials	Connelly [2016]	Differences in health literacy better identified with Newest Vital Sign than Short Assessment of Health Literacy with usability best tested <i>in situ</i>
6.4 Test whether your content	Bahadori [2020]	Monitor patient experience to see if readability needs to be improved
is understandable and actionable	Ben-Zeev [2013]	Deploying existing mHealth resources intended for the general population may prove problematic
	Ceasar [2019]	Use focus groups as a collaborative tool to inform app development
		Check-ins or IT support to address technical difficulties
	Connelly [2016]	Iterative, user-centered design process with focus groups was essential for designing the app rather than merely replacing words with icons and/or audio
		Provide a case study of design of an ecological momentary assessment mobile app for a low-literacy population
	Muscat [2020]	Calculate readability statistics
		Apply the Patient Education Materials Assessment Tool
	Siedner [2015]	Coded messages can have similar efficacy as text messages, while maintaining confidentiality
6.5 Use moderators who have experience with users with limited literacy skills	Fontil [2016]	Creating technical assistance tools for various stages of the program to address lower technology literacy
6.6 Pretest your moderator's guide	NA	NA
6.7 Use multiple strategies to make sure participants understand what you want them to do	NA	NA

HLO, Health Literacy Online; REALM, Rapid Estimate of Adult Literacy in Medicine; NA, not applicable; PLWH, persons living with HIV; IC, informed consent; IT, information technology.

Check-ins or IT support to address technical difficulties

Ceasar [2019]

mHealth, 2022

6.8 Test on mobile

publicly available apps, one used the Gunning Fog Index (GFI) (34) and the other one used the Flesch-Kincaid Grade Level (FKGL) (35). Of the nine studies which described the development and evaluation of an app, five did not use any health literacy tools (36,39-42) whereas the four other studies used at least one health literacy tool such as the Rapid Estimate of Adult Literacy in Medicine (REALM) (37), Test of Functional Health Literacy in Adults (TOFHLA) (43), Short Assessment of Health Literacy-Spanish and English (SAHL-S&E) (38), or Newest Vital Sign (NVS) (38,44). Of the 13 studies that described the evaluation of an app and the one study that described the heuristics evaluation of an app, seven did not use any health literacy tool (29,50-55) and three used an existing tool including XXXX (eHEALS) (56), NVS (57), or TOFHLA. The remaining evaluation studies had participants read a complete sentence (58), used the "Think Aloud" method (59) implemented a validated question developed in another study (60), or used a tool but did not include the name of the tool in the article (61).

HLO categories and recommendations

At least one of HLO categories (I) what we know; (II) write; (III) display; (IV) organize; (V) engage; and (VI) test, was addressed in all of 32 articles reviewed in this study. Examples of recommendations from each of the categories are given below. Details are presented in Table 2.

Category 1 What we know

This category included thirteen recommendations addressed by ten articles (29,34,37-39,41,45,58-60); 5 HLO strategies were incorporated into the 10 articles with Monkman and Kushniruk (in 2013) speaking to one (29). Ben-Zeev et al. (in 2013), who conducted a survey and a focus group with psychiatric rehabilitation agency patients and practitioners indicated that "deploying existing mHealth resources identified for the general population may prove problematic" (45). They commented that a user-friendly mobile app needs to be developed for people with schizophrenia. This app should avoid distracting and superfluous elements; use minimal steps to access content; utilize simple screen arrangements, sentence composition, and concrete wording; include memory aids (e.g., "continue" button on the bottom of the screen); and use an interface organized using a simple geometry. Bahadori et al. (in 2020), who reviewed 15 apps for patients undergoing hip and knee replacement, recommended identifying and taking into consideration the specific needs of a target population when designing the app (34). They recommended involving patients in app development and acceptability assessments. Further, they suggested conducting ongoing monitoring of patient experience to determine if readability of the content needs to be addressed.

Category 2 Write

This category included 18 recommendations addressed by 14 articles (29,34-36,39,40,42,46,47,53-55,59,60); six HLO strategies were incorporated into the 14 articles with Monkman and Kushniruk (in 2013) speaking to five HLO strategies. Fontil et al. (in 2016) who conducted focus groups with low-income prediabetes patients at a large safety net clinic recommended simplifying overall language as well as simplifying explanations of scientific concepts (40). They also recommended adapting the readability level to mostly a 5th grade level or below (62). Poduval et al. (in 2018) conducted a study among 330 adults with diabetes and recommended using text written for a reading age of 12 (53). Finally, Miller et al. (in 2017) suggested using a simple interface displaying only one question on each screen and using simple language (60).

Category 3 Display

This category included 15 recommendations addressed by 15 articles (29,32-36,38,41,42,44,46,50,54,56,59); four HLO strategies were incorporated into the 15 articles with Monkman and Kushniruk (in 2013) speaking to 11 HLO strategies. In order to improve the display, the following suggestions were made: decrease the number or length of sentences (34); use simple-worded, direct questions with fewer words (44); use an interface with larger pictures and short labels (38); include visuals with simple text with culturally tailored themes and images (50); and incorporate culturally relevant graphics, voices, animation and videos (54).

Category 4 Organize

This category included five recommendations addressed by three articles (29,51,59); 4 HLO strategies were incorporated into the 3 articles and Monkman and Kushniruk (in 2013) speaking to 10 HLO strategies. Wildenbos et al. (in 2019), who conducted a study with adults 50 years and older, recommended adjusting userinterface elements such as buttons for the older adult population and minimizing cognitive overload for this population group (59). The users in their study found navigation hierarchy confusing and did not know how to return to previously shown information in the app. Wildenbos et al. (in 2019), commented that cognitive overload can be addressed by using a clear navigation structure and an interface that aligns with expectation of older adults (59). Casey *et al.* (in 2014) conducted an interview of smartphone owners. Participants in their study found that the app they examined was easy to use because it reduced and simplified tasks to influence behavior (51). Siedner *et al.* (in 2015), who conducted a study in rural Uganda, found that "ease of use plays a dominant role in technology uptake "(58).

Category 5 Engage

This category included 24 recommendations addressed by 13 articles (36,42-44,47-49,52,53,57,60-62); four HLO strategies were incorporated into the four articles and Monkman and Kushniruk (in 2013) speaking to three HLO strategies. Two studies recommended a text-to-speech and voice-to-text bilingual function (36,61). Mackert *et al.* (in 2017) stated that in order to increase engagement and interaction, the app designer could add videos and games inside the app and allow users to change font size and color (57). In their study with people with multiple sclerosis (MS), Giunti *et al.* (in 2018) created personas to represent persons with MS for an app to promote physical activity (56). They created four different types of personas taking into consideration age, level of physical activity and motivation level.

Category 6 Test

This category included 21 recommendations addressed by ten articles (32,34,37,38,40,45,47,49,58,59); four HLO strategies were used by the ten articles. Bahadori *et al.* (in 2020) recommended involving patients in app development and user acceptance testing and monitoring patient experience to assess if readability needs should be improved (34). Two articles recommended using "focus groups as a collaborative tool to inform app development" and "mobile app focus groups to explore app design" (38,47). Also, Fontil *et al.* (in 2016) suggested to "create technical assistance tools for various stages of the program to address lower technology literacy" (40).

Recommendations not aligned with HLO guidelines

Not all recommendations fell under one of the HLO categories. For example, Coughlin *et al.* (in 2017) suggested that users should be able to use the app without interfacing with commercial internet (39). Muscat *et al.* (in 2021) stated that it is possible to improve literacy skills with "question prompt lists, volitional help sheets, and skills training (49). Sox *et al.* (in 2010) who conducted a study with parents with children with attention deficit hyperactivity disorder found "tension between expectations of a highly-educated parent and a parent with limited health knowledge" (43). Connelly *et al.* (in 2016) tested a mobile app with Mexican women

aged 18–45 (38). They found that differences in health literacy and numeracy were better identified with the NVS compared with the SAHL. SAHL could assess whether the participant can read health vocabulary and recognize word meaning; however, it does not test more complex comprehension skills. Povey *et al.* (in 2020) who conducted a mixed methods study with Torres Strait islander youth suggested engaging with users through stories about positive health behavior changes (42).

Discussion

Our results undoubtedly suggest that there are a variety of ways in which health literacy is being considered within mHealth. Much of what is being done in this space centers around what we have learned from written material combined with the broader evolving definition of health literacy. Recognizing that when we refer to health literacy within mHealth we are going beyond the written words and expanding to how the content is placed on a small screen, or how easily one can navigate the material without challenges. Our results suggest incorporating common strategies noted among the articles within this scoping review can serve as a foundational starting point for the development of a brief screening tool which addresses the expansive nature of health literacy in mHealth.

How has health literacy been addressed in mHealth app development?

The HLO guidelines serve as a framework to understand different aspects of the health literacy of mHealth tools. By using the HLO guidelines, we were able to systematically review the articles to understand the potential gaps. Our results demonstrate that no single article addressed all of the components of the HLO guidelines except for the article by Monkman and Kushniruk (in 2013); however, the top two categories used addressed Engagement or Testing of the mHealth content.

Within the Engage category, by far the most often recommended action for app developers was to engage users via multi-media: audio, video, and interactive graphics. While text-to-speech is addressed in the HLO as a means of addressing those with disabilities, multi-media recommendations including text-to-speech are intended for individuals with low (health) literacy. The thought behind recommending multi-media is to increase engagement with the end users. For example, studies that examined

the role of multi-media in general showed the positive effect of multi-media on patient engagement levels among individuals with diabetes and inflammatory bowel disease (63,64). However, it is not clear how the increased level of end-user engagement relates to health literacy and the exact role of multi-media in achieving intended outcomes. Thus, more research is needed to better understand the relationship between multi-media, engagement and health literacy.

In the Test category a majority of the recommendations were related to ensuring the usability and acceptability of the app by the target population. This occurred through the use of focus groups (38,47), readability assessments (34,49), and usability testing with end users (32). Interestingly, many of the authors engaged individuals from their app's target population in the development stage rather than the testing stage (just the opposite of what the HLO discusses). Regardless of when the testing took place, ensuring that the material was vetted by intended end users is critical. Co-designing mHealth apps can facilitate the app design alignment of the app to account for end user behaviors and how they use the information. This may, in turn, promote adoption of mHealth and reduce barriers for mHealth use (65). Additionally, recommendations in the Test category also spoke to understanding the end user literacy and technology characteristics (58), as well as incorporating information technology (IT) check-ins or technical assistance (40).

Recommendations pertaining to Writing and Display categories of the HLO were the next most cited by the authors, followed by What We Know and then Organize. Writing comes as no surprise—recommendations about simplifying writing to accommodate those with poor literacy skills have been made for decades (66-68) and a subcategory "write in plain language" is by far the most-often recommended within this category. This recommendation is congruent with guides previously published on creating easy to understand written materials by avoiding technical jargon, lengthy sentences, lengthy paragraphs and/or with words that contain 3 or more syllables (69).

Within the display category, the most-often recommended actions regarded imagery and accessibility. Images are powerful tools and often authors' recommendations around imagery were to provide visuals that the target audience could relate to: images of individuals who looked like the end users, images of real people, and culturally appropriate images. Culturally appropriate images may be especially important as data demonstrates that those with low literacy are often individuals from areas with the greatest socioeconomic challenges, and these areas are predominantly African American and Latinx communities (70). Recommendations around accessibility largely centered on the inclusion of screen readers/textto-speech capabilities. While the original intent of this recommendation was no doubt to address those with physical disabilities, those with poor literacy skills would also benefit from being able to listen to rather than having to read the content of an app. Incorporating accessibility features with attention to inclusive design considerations can promote usability of mHealth to for consumers with and without noted disabilities expanding reach to a much larger audience (71).

Despite the Organize and What We Know categories being updated to include newer research regarding cognitive processing and navigation patterns in those with limited literacy skills, these were the least addressed categories among the articles being reviewed. The What We Know category discusses in depth the most recent research on how those with poor literacy skills engage with digital media sources including mobile devices, yet this category was notably absent among recommendations made in reviewed articles. This may be due to some of recommendations in this category being moved to other categories with the HLO updates. Overall, despite some categories appearing to a lesser degree than others, our findings support the use of the HLO as a guide for app development given that every category was discussed by at least one author.

Notably, there was one article, Monkman and Kushniruk (in 2013) that provided recommendations for all the HLO categories except the Test category. This article was uniquely different than the other 31 articles in that it was focused on applying a heuristics evaluation derived from the HLO guide to mobile apps. The most-frequently incorporated recommendations in the heuristics are from the Display and Organize categories, followed by the Write, Engage, and What We Know categories. The heuristics come as close to an evaluation tool as the authors were able to find in this scoping review. Yet the heuristics do not lend themselves to serve as an easily applied evaluation tool for clinicians in real world settings. Further, the heuristics appear to be intended for use in the development stage of an app versus a brief health literacy mHealth app evaluation tool.

How is the evaluation of health literacy addressed in mHealth apps?

Several of the studies addressed health literacy through the

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use of a formal health literacy assessment tool such as NVS or TOFHLA or through the use of a tool such as Flesch Reading Ease Score (FRES) which provided an indication of reading level. The majority of the studies, however, did not use a formal assessment but rather discussed how health literacy needs could be addressed based on input from their study participants. Importantly our results indicate the evaluation of health literacy in mHealth primarily was end-user focused and did not appear to extensively evaluate the mHealth content itself for literacy fit to a variety of individuals with limited health literacy.

Notably, engaging an end user in the design and testing of mHealth technologies seemed to be quite informative for adapting the mHealth application to meet the intended needs of a given population (65,72). Further, ensuring that the many of the same strategies used to account for variability in literacy levels for written materials are also pertinent in the delivery of content in mobile forms as well.

Developing a tool enabling clinicians to quickly evaluate apps for use within their patient populations should stem from the HLO categories which were commonly employed in the studies reviewed. For instance, ensuring that the tool is quickly and effectively able to determine the reading level of the mHealth app content would be important (73). Additionally, recognizing that literacy aspects in mHealth go beyond strictly written material but also encompasses how the material is displayed and featured to promote user engagement. Less certain is how to incorporate (I) HLO strategies that were used infrequently; (II) recommendations that did not fit into any HLO category; or (III) the use of a formal literacy assessment. Gaps remain in understanding what is the bare minimum criteria needed to screen an app and if there are categories which lend themselves to promote app suitability from a provider perspective versus a patient perspective.

Strengths and limitations

This study systematically reviewed the available evidence using the HLO framework, which made it possible to discuss concrete ideas to address different aspects of health literacy. The findings of this study could provide research and program insights to design and evaluate mHealth among individuals with a wide range of health literacy. This scoping review has some limitations. This review excluded certain types of articles including the grey literature and conference abstracts and was limited to English language articles only, which may have led to some degree of evidence omission and publication bias. As mentioned earlier, Monkman and Kushniruk (in 2013) heuristics begin to bring us closer to having a tool which could be employed to evaluate apps themselves (29). But we remain without an adequate framework for evaluating mHealth apps themselves from a health literacy perspective beyond the broader strokes of the HLO. Although content added to the 2nd edition of the HLO addresses mobile considerations, the material focuses on how the information is being delivered and accessed (e.g., small viewing device) versus providing direction on how to evaluate the content being delivered within the app itself.

Conclusions

As healthcare and public health professionals continue to leverage and increase the use of mobile apps to aid in educating patients and promoting self-care management, we need to ensure communication provided in mobile apps is suitable to the target patient populations (74). The development of a brief tool which can be easily and effectively used to evaluate content being delivered via mHealth which screens for acceptability for low health literacy populations is warranted. Future work should focus on which of the HLO recommendations are most crucial to incorporate into such a tool and which are less valuable in sifting through mHealth content. Additionally, piloting such a tool with providers working in environments where there are higher rates of low literacy populations to determine acceptability and feasibility of incorporating this into clinical practice is needed.

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