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Assessment frameworks for digital public health interventions in low-resourced settings: A Scoping Review

DigiHealth

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Abstract

Background: Increasing digital solutions in the healthcare sector has progressed further, not only recently due to the COVID-19 pandemic. The field of application and research of digital public health (DPH) thus increasingly came to the fore. However, digital solutions are also becoming increasingly important for public health outside of the pandemic. It is unclear whether these innovations enhance health prevention or health promotion. Leading evaluation methods such as the Health Technology Assessment (HTA) are reaching their limits and prevent evidence-based proof. In addition, public health interventions (PHI) require a broader view that increasingly incorporates social, cultural, and country-specific contexts. It is particularly problematic for underinvested and low-resource settings (LRSs). Otherwise, digital public health interventions (DPHIs) could exacerbate health inequality and more unintended effects. This master thesis aims to shed light on existing frameworks for the assessment of DPHIs and how these should be adapted in the context of LRSs.

Method: A scoping review was carried out within three databases in accordance with the guidelines of the Joanna Briggs Institute (JBI). Two research objectives were pursued:

(1) Identification of assessment frameworks which could be applied to DPHIs.

(2) Recommendations for the assessment of DPHIs in LRSs were identified.

Results: One hit was recorded specifically for the first objective. Consequently, holistic frameworks for evaluating digital health interventions (DHI) were also included in the scoping review, leading to four additional results. The second objective found that the areas of user and stakeholder participation to enable human-centered design (HCD), infrastructure and technical functionality, government-provider collaboration, and sustainable resources and financing were among the most important areas for DPHI evaluation in LRSs.

Conclusion: There is a gap in the assessment of DPHIs in LRSs as the existing frameworks are either not yet sufficiently validated for their usefulness or the assessment criteria used are inadequate. Further research is needed to provide HTA similar recommendations for public health decision-makers in LRSs.

Key words: Digital Public Health, Health Technology Assessment, Low-resourced settings

Abstract in German

Hintergrund: Die Verbreitung digitaler Lösungen im Gesundheitswesen ist nicht erst seit der COVID-19-Pandemie weiter vorangeschritten. Der Anwendungs- und Forschungsbereich der digitalen öffentlichen Gesundheit (Digital Public Health, DPH) rückte damit zunehmend in den Vordergrund. Aber auch außerhalb der Pandemie werden digitale Lösungen für die öffentliche Gesundheit immer wichtiger. Es ist unklar, ob diese Innovationen die Gesundheitsprävention oder die Gesundheitsförderung verbessern. Führende Bewertungsmethoden wie das Health Technology Assessment (HTA) stoßen an ihre Grenzen und verhindern einen evidenzbasierten Nachweis. Darüber hinaus erfordern Interventionen im Bereich der öffentlichen Gesundheit (Public Health Interventions, PHI) eine umfassendere Sichtweise, die zunehmend soziale, kulturelle und länderspezifische Kontexte einbezieht. Besonders problematisch ist dies für unterinvestierte und ressourcenarme Gebiete (LRS). Andernfalls könnten digitale Public-Health-Interventionen (DPHI) die gesundheitliche Ungleichheit verschärfen und weitere unbeabsichtigte Auswirkungen haben. Ziel dieser Masterarbeit ist es, bestehende Rahmenwerke für die Bewertung von DPHIs zu beleuchten und herauszufinden, wie diese an den Kontext von LRS angepasst werden sollten.

Methodik: Es wurde ein Scoping Review in drei Datenbanken gemäß den Richtlinien des Joanna Briggs Institute (JBI) durchgeführt. Es wurden zwei Forschungsziele verfolgt:

(1) Identifizierung von Bewertungsrahmen, die auf DPHI angewendet werden könnten.

(2) Es wurden Empfehlungen für die Bewertung von DPHI in LRS identifiziert.

Ergebnisse: Ein Treffer wurde speziell für das erste Ziel verzeichnet. Folglich wurden auch ganzheitliche Rahmen für die Bewertung von Maßnahmen im Bereich der digitalen Gesundheit (DHI) in das Scoping Review einbezogen, was zu vier zusätzlichen Ergebnissen führte. Die zweite Zielsetzung ergab, dass die Bereiche Beteiligung von Nutzern und Interessenvertretern zur Ermöglichung einer menschenzentrierten Gestaltung (HCD), Infrastruktur und technische Funktionalität, Zusammenarbeit zwischen Regierung und Anbietern sowie nachhaltige Ressourcen und Finanzierung zu den wichtigsten Bereichen für die Bewertung von DPHIs in LRS gehören.

Schlussfolgerung: Es besteht eine Lücke bei der Bewertung von DPHIs in LRS, da die bestehenden Rahmenwerke entweder noch nicht ausreichend auf ihre Nützlichkeit hin validiert sind oder die verwendeten Bewertungskriterien unzureichend sind. Weitere Forschungsarbeiten sind erforderlich, um HTA ähnliche Empfehlungen für Entscheidungsträger des öffentlichen Gesundheitswesens in LRSs bereitzustellen.

List of abbreviations

AI	Artificial Intelligence
DGG	Digital Global Goods
DHI	Digital Health Intervention
DHT	Digital Health Technology
DHTEfHO	Digital Health Technology Evaluation for Health Organizations
DPG	Digital Public Good
DPH	Digital Public Health
DPHI	Digital Public Health Intervention
DT	Digital Technology
DTAC	Digital Technology Assessment Criteria
EHR	Electronic Health Record
ESF	Evidence Standards Framework
FinCCHTA	Finnish Coordinating Center for Health Technology Assessment
HCD	Human Centered Design
HIC	High-Income Countries
HIS	Health Information Systems
HTA	Health Technology Assessment
ICT	Information and Communication Technologies
IT	Information Technology
IVD	In Vitro Diagnostic
JBI	Joanna Briggs Institute
LMIC	Low- and Middle-Income Countries
LRS	Low-Resourced Setting
MARS	Mobile App Rating Scale
mHealth	Mobile Health
NCD	Non-communicable Disease
NHS	National Health Service

NICE	National Institute for Health and Care Excellence
PHI	Public Health Intervention
RCT	Randomized Control Trial
R&D	Research and Development
SDG	Sustainable Development Goal
UHC	Universal Health Coverage
UK	United Kingdom
WFPHA	World Federation of Public Health Associations
WHO	World Health Organization

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1 Introduction

The background to this master thesis is explained. The objectives and their scientific relevance are part of this chapter, as are the scope and limitations of this master thesis.

1.1 Background

With the emergence of DHT, there are seemingly endless opportunities for new approaches to public health improvement, particularly in health promotion, prevention, and reducing health disparities through easier access to healthcare. The COVID-19 pandemic has accelerated this transformation, necessitating swift adjustments to national healthcare systems due to its rapid spread [1]. At the same time the field of public health emerged and changed the area of healthcare with digital transformation [2], [3], [4]. DPHIs offer significant advantages in various public health domains such as health prevention, health communication, and health promotion using mobile Health (mHealth), Big Data, and wearables and sensors. These technologies enable personalized and precise health solutions, improve prediction and data analytics, and contribute to a shift from cure to prevention, care closer to people, and safer, faster, and more efficient services [5].

In addition to the pandemic as a catalyst for digitalization in the healthcare sector, the shortage of skilled workers, the ageing population and the increasing cost pressure on the healthcare system are just some of the other reasons for the increased use of DHIs to relieve the burden on the healthcare system [6]. Nevertheless, the healthcare sector is at least 10 years behind other sectors when it comes to implementing information technology (IT) solutions. The increasing number of technologies raises the question as to which of these should be usefully incorporated into healthcare practice [6]. This requires suitable measures to identify the value of the technologies for the healthcare system [7].

Digital transformation in public health, increasingly referenced as "digital public health," has fundamentally changed the approach to population-based disease prevention, control, and health promotion [3]. Technological innovations, such as apps and health behavior tracking, have become integral to public health research and practice, offering the promise of reaching vast audiences at minimal expense while generating extensive data for assessing and refining public health initiatives [3], [8]. For instance, in 2022, 63% of the smartphone users utilize (or plan to use) health apps, where as in 2020 it were 36% to do so [4].

However, the development of DHIs has largely been driven by technological advancements and business opportunities by the private sector rather than the needs of users and public health challenges [1], [9]. The development of assessment methods for DPHIs has not kept up with the high speed of technological development, as demonstrated by the lack of associated evaluation studies [3]. For instance, numerous technological advancements made in reaction to the COVID-19 epidemic have not yet received official assessments [10]. This has led to a lack of consideration for public health perspectives in the planning and assessment of digital health initiatives, risking the continued use of subpar tools that are ineffective and potentially harmful [11]. With regard to the gold standard framework of health technology assessment (HTA) for medical devices and pharmaceuticals, there are currently no published studies that list the methodological frameworks used for digital HTA [12]. Therefore new critical assessment frameworks must ensure the effectiveness and sustainability of DHIs while mitigating risks to the health of the population [13], [14].

The master thesis aims to shed light on which evaluation frameworks for DHI can be used or already exist in the field of public health. Another focus is the use of technologies in LRSs [5]. In which for example the lack of funds for technical infrastructure and knowledge presents particular challenges for public health authorities, which involves challenges in deciding how to allocate funds as well as in creating, conducting, and completing implementation and validation studies [15] to carefully consider what intervention they actually need [16]. Failure to rigorously assess the suitability, feasibility, security, acceptability, and effectiveness of complex DPHI could result in ineffective interventions, wasted resources, potential harm to patients and communities, and a loss of trust in DHIs [17], [18]. Over time, this could result in a widening gap between technological advancements and genuine health benefits, exacerbating health inequities, spreading the digital divide and undermining the overall objectives of PHI [19]. While assessment frameworks for DHIs are absent from LRSs, they have been incorporated into clinical pathways and even pricing and reimbursement legislation in European countries [7], [20]. The World Federation of Public Health Associations (WFPHA) [21] expressed worries regarding the scarcity of available research concerning evaluations of the effects of DT on public health and equitable healthcare access. Despite the widespread launch of numerous DHI globally, there seemed to be a notable absence of data regarding their impacts on both health outcomes and equitable access to healthcare. In addition the assessments prior to the introduction of DT to respond to public health issues remain important as an ongoing practice after the pandemic [22]. As in the future, technology use may improve engagement, collaboration, empowerment,

and justice in settings, but it may also exacerbate exclusion and injustice in the absence of appropriate framework conditions [23]. Therefore, a scientifically proven concept in LRSs for the assessment of DPHIs is of great importance to ensure an effective and sustainable impact of these technologies.

1.2 Objectives and significance of the study

The goal of this master thesis is to identify existing assessment frameworks that can be used for DPHIs, as DPH is an emerging field of research, which still has a vacuum of evidence [24], [25]. The scientific methodology consists of a scoping review, to obtain a comprehensive view on the topic. Moreover because of the immersive lack of assessment methods in LRSs (e.g. in HTA) [26], it was the goal to find recommendations for the assessment of DPHIs in LRSs, as assessment tools should genuinely align with the nuanced dynamics and challenges inherent in LRSs. This is because public health functions differ between different health systems and their validity is limited to the universal context [27]. Therefore, this master thesis is intended to provide information on which assessment approaches for DPHIs in LRSs are expedient. The scoping review of available assessment frameworks of DPHIs in LRSs had two-fold objectives:

The *first question* concerns the topic of which assessment frameworks already exist for evaluating DPHIs:

Which assessment frameworks for DPHIs exist?

The *second question* relates to how these assessment approaches can be transferred in a context with low resources:

How can the identified existing assessment frameworks for DPHIs be applied or transferred in the context of LRSs?

The scientific relevance on the one hand is to provide an overview of existing frameworks for the assessment of DPHIs and to make suggestions on how to adapt them to the specific context of limited resources, because inhere is an increasing demand for integrated, interdisciplinary approaches and tactics for managing, assessing, and utilizing DHIs, especially when it comes to public health [1]. A standardized assessment framework could provide use and collection of health information to reduce the evidence gap of these interventions and would perhaps enable public health professionals and policymakers to think about how to guarantee a unified strategy for DPH that goes beyond the present divisions in public health [13], [25]. Another value of a DPHI assessment frameworks for LRSs would be that it would have a preventive effect on the neglected discussion about the social and health consequences [11]. Socioeconomically disadvantaged communities could receive better global healthcare delivery when using an LRS method that benefits both Low- and middle-income countries (LMIC) and high-

income countries (HIC). This approach may also encourage knowledge sharing across digital public health initiatives [15].

An assessment methodology could be used to establish new market requirements and conditions for innovative software products that guarantee effective, safe, and sustainable interventions [28]. It could identify priority areas in which the use of DPHIs is significant in gaining social, health and economic benefits [9]. Alternatively, initiatives such as the HealthTech Hub Africa [29], a pan-African health technology accelerator that works with governments and innovators to improve healthcare systems through data and technology-enabled solutions, can be end users. Thus, the focus of the master thesis is to elaborate the fundamental approach and necessary adoptions of current frameworks for the development of an assessment framework for DPHIs in LRSs, which output should serve as decision support for developers and decision-makers before implementation (delivering similar information as an HTA report).

1.3 Scope and limitations

The master thesis is conducted in cooperation with the DigiHealth Institute from the University for applied Science Neu-Ulm. It is part of the “DigiAfya” project which aims to develop and validate a context-specific assessment tool that ensures digital health initiatives align with core public health functions, leading to fortified health systems in vulnerable regions. The DigiAfya project initiated a cross-country collaboration between Tanzania, Rwanda, South Africa, and Germany and interdisciplinary collaboration across medical informatics, nursing, mental health, and information systems.

The distinction between the term´s of DHT and DHI is that the term “technology”. include various applications, platforms, devices, and systems that aim to support healthcare, prevention, diagnosis, treatment, monitoring, and management (e.g. mobile phone apps, electronic health records (EHRs), AI) Although these have an impact on healthcare, they do not usually serve a specific goal, which is the case with interventions. The assessment frameworks are therefore centered around DHIs that have a clear public health objective. A clear classification is therefore made in chapter 2.1.3.

In the scoping review, assessment frameworks used at the time of development and design, or subsequent evaluation are considered, frameworks with the focus on implementation and diffusion were not considered and therefore do not constitute results for the first research question. The results of the second research question are to be understood as a recommendation for the assessment approach of DPHIs in LRSs, which will be taken up in the discussion. In the discussion section, the features and structure of the identified frameworks are reviewed for their suitability first for the DPH context and second for the LRSs context.

2 Theoretical framework

The theoretical basis for the master thesis is based on the findings on the digital transformation of public health. It uses the literature that delineates and defines the scientific field of DPH and classifies DHIs for public health. The general risks and potentials of the field and the technologies are identified on the one hand from the findings of the COVID-19 pandemic and on the other hand supplemented with further research results. The use of DPHIs in LRSs are then listed. To conclude the theoretical part, a comparison between HTA and digital HTA is done. The current methods and challenges to assess DPHIs are presented and the usage of HTA in LRSs are highlighted.

2.1 Digital public health

In the following, the definition of DPH is first differentiated from "digital health" and "eHealth" as well as other technology-related terms such as “mHealth”. The digital transformation in the field of public health is then described. Finally, the current theories on the classification of DPHIs are presented and their potentials and risks are described.

2.1.1 Definition and differentiation from related research areas

Currently, DPH is not a mainstream topic in research, teaching, and implementation. Yet DT is rapidly changing the way public health is practiced. Therefore, a need for researchers and stakeholders in the field of public health to face up to this development, to take on a formative and leading role in this highly dynamic development rather than a passive one. However, there is already disagreement on the terminology term for DPH [3]. The World Health Organization (WHO) proposes ten key functions [30] that encompass critical functions to promote and protect the health of the population. The emergence of DT has created new opportunities to effectively implement these functions to ensure the health and well-being of the population. These operations serve as the backbone of public health efforts worldwide, addressing a range of issues from disease surveillance to health promotion and policymaking. Each operation plays a unique yet interconnected role in ensuring the well-being of communities. DT can be located and used in all these areas, but their potential and risks for public health must also be

investigated [3]. In relation to the digital transformation of public health, terms like “eHealth” and “mobile health” (mHealth), as well as “digital health”, are commonly employed. From 2019 onwards, there has been a growing mention of the term “Digital Public Health” in some scholarly publications [27]. One of the first established umbrella terms for digitalization in the healthcare sector is the term "e-health" [31]. There has been disagreement and lacking about a clear and selective definition of e-health since the beginning [32], with a review from 2005 [33] listing 51 different definitions. A more recent overview uniformly describes e-health as the provision of user-centered health services through information and communication technologies (ICT) with a focus on the Internet [31]. E-health is therefore a connecting element between the use of ICTs and health and disease [11]. In 2020 there were already more than 90 different definitions for term “digital health” which includes eHealth, mHealth, self-tracking, wearable devices, artificial intelligence (AI), and information systems in health care, and where dominated by mHealth and its functions [34]. Figure 1 shows that the difference between the terms lies in their application at the individual or population level. Furthermore, mHealth usually focuses on prevention and health promotion, while eHealth and digital health is an umbrella term that also encompasses far-reaching and cross-system technologies.

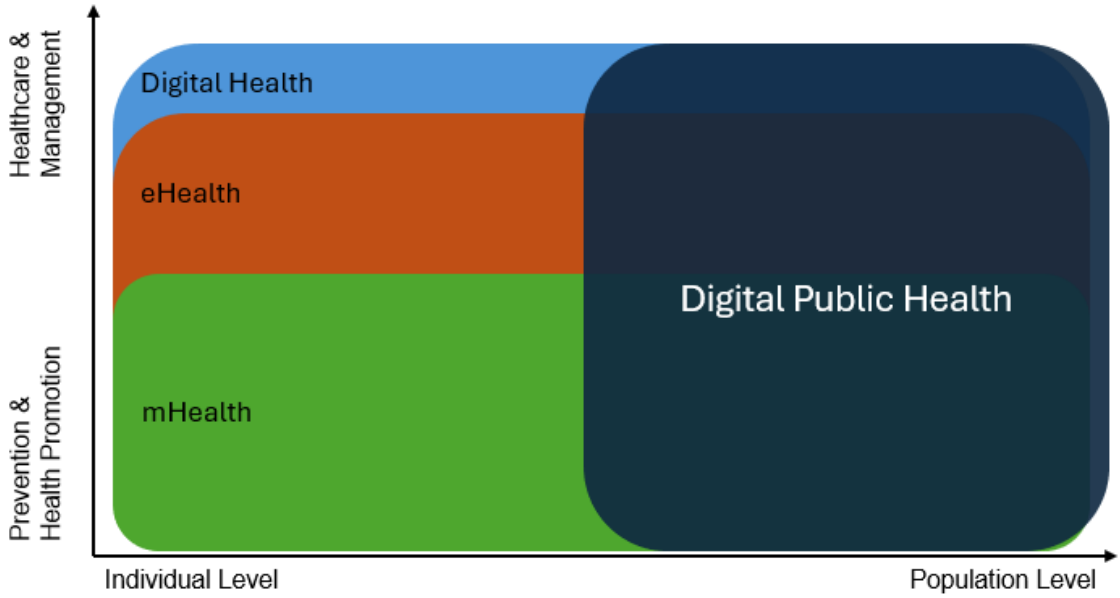

Figure 1: Core Field of Action and Target Group Level of mHealth, eHealth, Digital Health and Digital Public Health
Source: Based on [27, p. 24]

The term “digital health” hardly differs from the terms "E-health" or "Health 2.0", both of which focus on the application of ICT to individual health [3]. Health promotion and disease prevention has significantly transformed global health outcomes. It encompasses telemedicine, mHealth, wearable devices, health analytics, telemedicine platforms and electronic health records [35], [36], [37], [38]. The WHO [39] has expanded

its definition of digital health to include digital consumer devices, the Internet of things, AI, big data, and robotics. A broader definition describes the diversity of the use of digital health. This states that digital health encompasses a wide spectrum, ranging from technological innovations to user experiences, services, products, processes, and even forms an independent ecological system within the broader framework of health services. Expanding this term to include public health, i.e. "the art and science of preventing disease, prolonging life, and promoting health through the organized efforts of society" [40, p. 63], means that the term public health is not limited to the medical and health field, but is also understood as a field of study and practical application in the general life. This is the juncture where digital health and DPH diverge, as DPH endeavors to enhance health and wellness at a population scale [27]. However, for a more nuanced understanding, it is essential to analyze the similarities and differences in DT and the associated challenges in areas such as prevention and health promotion [41]. A clear definition of DPH an emerging field of research since, has thus far remained obscured within the research domain, that so far there is no uniform consensus on the definition among practitioners and researchers [42]. According to Iyamu et al. [42] public health researchers and practitioners should enhance the advancement of the discipline by achieving greater clarity and agreement regarding the definition of DPH. This can be accomplished by articulating the purpose of their work and offering a well-defined roadmap for continual progress. Clarity helps define goals and operational strategies to integrate digital interventions into public health and ensure successful implementation and evaluation [42].

At this point DPH is overshadowed by strong terms such as "Digital Health" or "eHealth," and is unlikely to establish itself due to the dynamic environment and diversity of terminologies. Sub-types of eHealth such as mHealth are clearly focused on a specific technology (smartphones and sensors) [43]. On the one hand, unlike mHealth and other terms, DPH provides a clear classification of its application domain [3]. The central aim of DPH is to enhance the population´s health status through the utilization of novel digital technologies at the individual, community, and global levels [44]. The technologies used to achieve the goal of DPH, on the other hand, is strongly oriented towards the use of ICTs [27], [44], [45]. The problem with focusing the definition on technology (e.g. internet connection as the digital component or ICTs) is that it is not possible to assign it to public health [3]. Since DPH concentrates on developmental, applicational, and epistemological interests in public health, thus focusing on prevention, health promotion, and related foundational sciences such as epidemiology [27]. The specific care context for the

individual patient, such as in telemedicine (exchange between physician and patient) where concrete treatment needs are met, is not the primary focus.

The definition of DPH is a contested concept, with two main interpretations. One view sees it as the integration of digital technologies to achieve existing public health goals, while the other sees it as a transformation of public health services and goals using DT [42]. A review of existing DPH definitions shows that there are only two out of eleven definitions in which "digital public health" is explicitly defined. In England's digital strategy for public health [46], DPH is depicted as an opportunity to reconceptualize the public health sector by integrating new DT with public health knowledge. The aim is to enhance the flexibility and resilience of public health systems through their utilization. This definition underscores the importance of ensuring internet access for the population to avoid excluding anyone from utilizing digital technologies [46]. In the second definition by Odone et. al [5], DPH is not an independent field, but an asset that the public health community can leverage to achieve its goals and mission. The digitalization process does not change the health system goals pursued by public health professionals in terms of quality, accessibility, efficiency, and equity. The other nine definitions are clarifying digitization, digitalization, and digital transformation in relation to public health (view 2.1.2). According to Zeeb et al. [3] the definition and categorization of DPH have limitations. While these methods are effective in delineating various technologies and providing an overview of the field, they do not fully address the needs of public health nor facilitate the development and evaluation of measures aimed at achieving public health objectives.

2.1.2 Digital transformation in public health

The COVID-19 crisis served as the pivotal moment that hastened the conceptualization, execution, and expansion of public health initiatives [2]. Modern public health has swiftly evolved to address current challenges and openings. One notable transformation is seen in the digitization of the healthcare realm, resulting in the emergence of “digital health”. This plays a crucial role in fortifying health systems, promoting fairness in accessing healthcare services on a global level [47].

Digital health has the potential to significantly contribute to the realization of the Sustainable Development Goals (SDGs) by playing a pivotal role in human development [21], [39]. Since the Millennium Development Goals in 2000, the widespread adoption of ICT has transformed individuals´ behaviors and many changes have been introduced into people´s daily lives, from the way they communicate and receive data and information, to the way they consume and purchase content, to the way they travel and

work, and many other routines, leading to a paradigm shift in the approach towards SDGs, with all SDGs having a digital component included. ICTs have ushered in novel methodologies for engaging with and managing health across the lifespan, including enhanced communication with healthcare professionals and diversified access to healthcare services [48]. The Pan American Health Organization [49] suggests eight principles for the digital transformation of the public health sector (Figure 2).

1. Achieve universal connectivity in the health sector by 2030
2. Co-create digital public health goods for a more equitable world
3. Accelerate progress toward inclusive digital health, with emphasis on the most vulnerable populations
4. Implement open, sustainable, interoperable digital information and health systems
5. Mainstream human rights across all areas of digital transformation in health
6. Participate in global cooperation on artificial intelligence and any emerging technology
7. Establish mechanisms for the confidentiality and security of information in the digital public health setting
8. Design a renewed public health architecture for the age of digital interdependence

Figure 2 Eight principles for the digital transformation of the health sector
Source: Based on [49, p. 10]

In the realm of DPH, three key concepts play pivotal roles: digitization, digitalization, and digital transformation. Digitization constitutes the initial step, involving the conversion of analog information into digital formats [42]. In DPH, this manifests in the transition from paper-based records to EHRs, facilitating easier access, storage, and transfer of health-related data [50]. Digitalization builds upon the foundation laid by digitization, encompassing the integration of DT in the production of services and utilization of DT to streamline processes in a new way, this includes among others the implementation of telemedicine platforms for remote patient consultations [51] or leveraging mHealth applications for patient monitoring [52]. Digitalization is not an end, but a means to an end. The overall goal for which it is used is generally “individual well-being”, but the specific aim of health policy and medicine is “patient well-being” [53, p. 1] Involvement of institutions to safeguard the technology, e.g. in Germany the Federal Institute for Drugs and Medical Devices (BfArM) which assess´ digital mHealth apps on its eligibility for reimbursement for the statutory health insurance as well [28].

Digital transformation is the most comprehensive of the three concepts, entails a strategic reimagining and restructuring of healthcare systems e.g. in form of new professional fields and market requirements and conditions for innovative software products as well as the consideration and use of data and practices. Leading to the pervasive adoption of digital technologies beyond the health care sector [28]. Given its dual nature, which is both specific to health and influenced by broader societal shifts, the

digitalization of public health is propelled by various factors. These include the widespread accessibility of smartphones, heightened consciousness regarding health and lifestyle data monitoring, and the management of extensive and diverse datasets. While these datasets may not be directly linked to health, they play a crucial role in comprehending health trends and outcomes within populations [42]. In DPH, this involves leveraging emerging technologies such as AI as an ideal way of tackling global health challenges [48] or individualized-integrated care pathways which could represent the main structural change to revolutionize various aspects of PHI [28]. However, a digital transformation also goes with new needs and goals. The scalability of digital innovations (through minimal costs per user) means that most of the population can be reached, but there is the paradox that the privileged health groups already benefit from these services, whereas vulnerable groups do not benefit from them, because for example the access cannot be made possible, meaning that health inequalities within the population can even be increased. This shows one aspect of the complexity for digital transformation in the public health sector [14], [54], [55].

It is an ongoing change, transition or disruptive process that requires a concerted effort to meaningfully integrate technology into the healthcare system. Though there were differences in opinion, the consensus in the literature reviewed was that these three themes represent an increasing level of complexity, inclusiveness, and strategic thinking in the integration of DT into public health approaches. Notably, the most complex and fundamental integration of DT across the industry was seen in digital transformation [42]. This is because there are many different players with different roles and opinions, which have wide range of demands on the digital transformation in the healthcare sector (Figure 3).

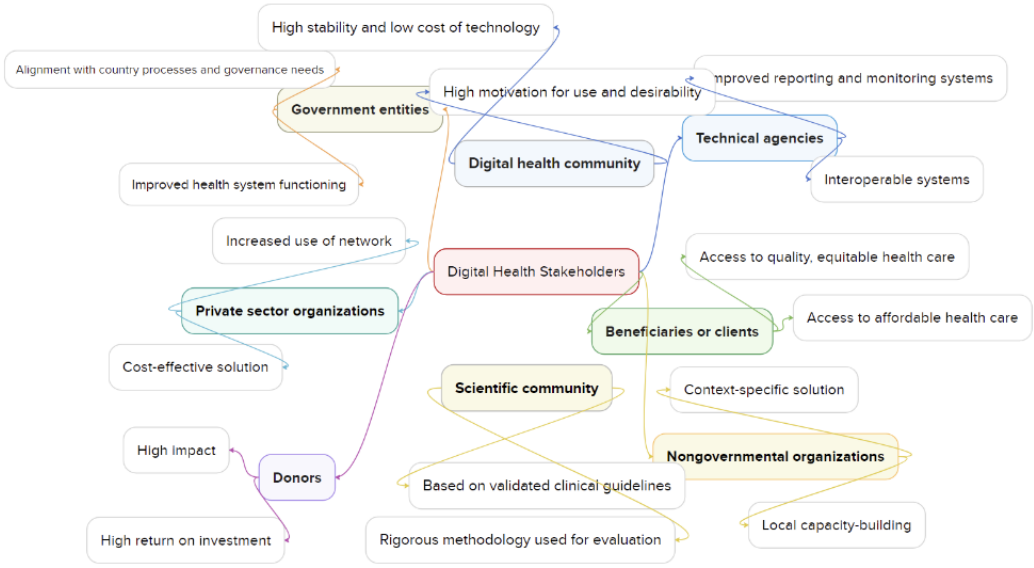

Figure 3 Illustrative categories of digital health stakeholders and claims
Source: Based on [56, p. 20]

DT aim to improve health and contribute to equitable access to healthcare by serving clinicians, clients, and health systems based on patient and community needs [57]. As the these digital transformations have given rise to the concept of DPH, governments must incorporate digital (public) health strategies into their national health policy and healthcare in order to coordinate and administer the digital transformation [9]. These could be, for example, nationwide internet access or standardized data protection regulations [23]. The healthcare system's conceptualization is evolving from acute care to disease prevention and management within a population-based framework, highlighting the emergence of DPH as a nascent field [48].

2.1.3 Classification of DPHIs

The classification of DPHI is a complex and evolving field, with a lack of consensus on its definition [42]. It encompasses a range of DT, including social media, mobile applications, and websites, which are used by public health operators and health care workers to improve communication and health literacy [58].The field is characterized by conceptual and terminological challenges, a lack of high-quality evidence, and a need for a discussion on unintended consequences and side effects [55]. Therefore, the presentation of models for the classification of DPHI seems to make sense. The WHO categorizes DHI user-depended [59]:

- Interventions for clients: Use of health services and health promotion activities.
- Interventions for health providers: Members of the health workforce who deliver health services.

- Interventions for the health system: Are involved in the management and monitoring of the public health system, which includes interventions for data services, consisting of cross-cutting functions to support a wide range of activities related to the collection, management, use and exchange of data.

A common approach to DPH lays in the sense of digital health as “Health in All Policies” therefore Dockweiler [24] divides the technologies into different areas. These are mobile content (e.g. social media), mobile economy (e.g. online pharmacies), mobile networking (e.g. e-health card), mobile health (e.g. exercise or nutrition monitoring) and mobile care (e.g. telemedicine: Doc2Patient). The technical infrastructure (e.g. internet, AI, robotics) then forms a fundamental level. The basic technologies are to be distinguished from the other categories and are not considered DHI in the following but take on the role of assistance systems that serve as a basis for the implementation of the intervention and do not pursue a clear public health goal. According to the WHO [59, p. 5], a “DHI represents a discrete functionality of the digital technology to achieve health sector objectives.” The definition of the boarders of DPH is important because upcoming definitions of DPHI are evolving over the time [27]. Beside the focus on technical aspects DPHI should be categorized by their targeting goal [3]. This could be in related to the ten essential health public health operations (Figure 4) suggested by the WHO.

1. Surveillance of health and well-being of the population,
2. Surveillance of health threats and health emergencies and countermeasures,
3. Health protection measures (including environmental, occupational and food safety measures),
4. Health promotion, including measures related to social determinants and health interventions,
5. Disease prevention, including early detection,
6. Ensuring policymaking and governance for better health and well-being,
7. Ensuring sufficient numbers of skilled public health workers,
8. Ensuring sustainable organizational structures and funding,
9. Persuasion, communication, and social mobilization for health,
10. Promote public health research for application in policy and practice.

Figure 4 Ten essential public health operations
Source: Based on [30, p. 2]

Wienert et. al [27] suggested to look at the DPHI from three different perspectives two of them are directly focusing on a more precise classification of DPHI as one reaches further to the development process of DPHI where the participant of the user perspective is a decisive criterion. The first one is based on the ten essential public health operations which serve as overview for mapping and identifying of DPHI and their goals. It is important as it offers insight into the types of actions aimed at enhancing and preserving the health of populations, which fall within the realm of public health as a field. Consequently, it defines what constitutes a public health intervention [27]. It suggests

that the technologies should not be categorized based on their specific platforms or software, but rather by their functions they serve in accomplishing health-related goals [55]. The second viewpoint concentrates on an intervention´s digital component. The Evidence Standards Framework (ESF) [60] for Digital Health Technologies, created by the National Institute for Health and Care Excellence (NICE) in England, provides a suitable framework for this purpose. It fits the functions of DPH in terms of user proximity and depth of interaction while also assigning different requirements for evidence quality to these functions. As a result, it can be used as the foundation for a summary of the products and services available in the DPH market.[3]. It should be noted that public health functions may differ in different health systems (such as LRSs), which may limit the universal applicability of one categorization framework. Therefore, a DPHI should focus on the use of DHIs to fulfill basic public health functions adapted to the context [27].

A proposed but not yet finalized classification by Maaß et al. [61] (Figure 5) shows the categorization of DHI according to the type of prevention (primary, secondary or tertiary), as well as the purpose for public health research. To avoid any misunderstandings, it should be clearly explained at this point that technology such as smartphone apps, wearables, telemedicine and EHR is not a DPHI, but only becomes one when it is assigned a goal, in this case the stages of prevention or research. Clear applications and their potentials and risks are therefore listed in the following chapter.

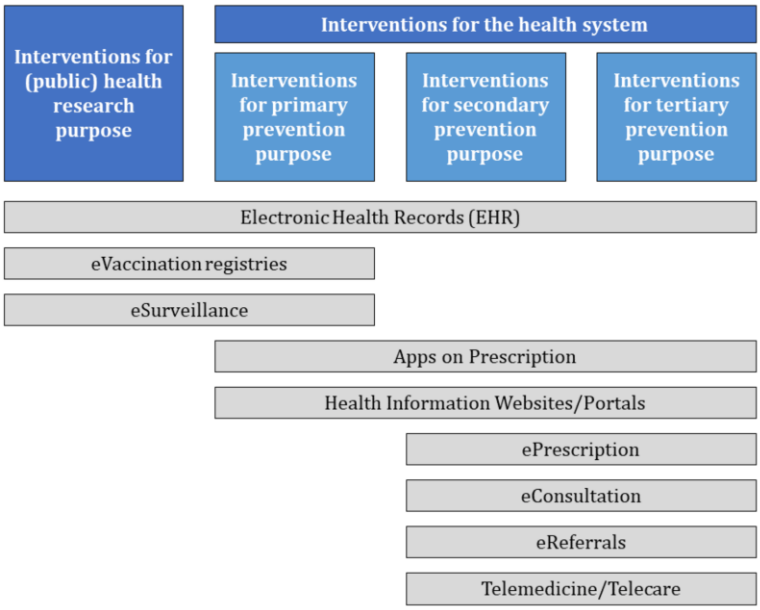

Figure 5 The proposed landscape of digital public health intervention classification
Source: Original from [61, p. 3]

2.1.4 Potentials and risks of DPHIs

Internet-based technologies have become more important for public health since the early 1990s. Several applications provide entertainment-focused, peer-to-peer educational content for particular health promotion and prevention [62]. ICTs in general play a dominant role for DPH. These are not only changing healthcare itself, but also the lives of individuals, as evidenced by new forms of communication, e.g. via the internet or mobile devices, and new methods of handling data and information [48]. The European Public Health Association has established a DPH section to capture the diverse interactions between modern ICT and public health. The section focuses on the areas of AI, EHR and data for public health surveillance and aims to help European public health be an integral part of DHIs, ensuring “Digital Health for All” [63]. The technological advantages from DPHIs are illustrated by the example of the past COVID-19 pandemic, which started the upswing through global investment in DPH. Four main public-health needs for DHI have emerged in response to the COVID-19 pandemic. These included public communication, quick case identification, stopping community transmission and digital epidemiological surveillance. These were key public health functions which were addressed by digital innovations implemented in response to the COVID-19 pandemic [10], [64]. In contrast a review of the implementation of DT in response to COVID-19 examined range of barriers (e.g. investment, data availability and quality, human resource, infrastructure) apart from the technology themselves [10, p. 13]. The largest obstacle might be proving the effectiveness of DHI implementation and directly linking its use to improvements in population health and health inequalities [3], [65]. Many reports e.g. on AI and big data analytics innovations have shown weaknesses in study design, limiting their generalizability and transferability. This highlights the need for more pragmatic studies and evaluation designs in the field, to identify risks and undesirable side effects [66].

DPHI in the COVID-19 response had a multitude of options for patients, but it also has the potential to introduce new issues or exacerbate pre-existing ones. The issue of DHI should be clarified by the interdisciplinary public health perspective, which serves as a mediator between technical, individual medical, and population-related perspectives and objectives. At the same time, the application-related perspective of digital health and eHealth should serve to enrich the public health perspective on public health measures and interventions [11]. The WHO sees the following questions as one of the biggest challenges for use of digital technologies in the healthcare system [67]:

- How can we ensure that people without access to or knowledge of digital devices are not left behind?

- How can we ensure that sensitive health data is properly secured so that citizens feel safe using the services?
- Can digital health solutions ensure that people receive high-quality care?

Beyond the clinical quality of the interventions, insofar as this can be directly proven at all (e.g. in the case of mHealth interventions for health promotion or prevention), the population-based application of DPHI raises further questions that fall more into ethical issues, but which may also influence the health of the population in the long term.

One of main issues in the public health evolution is the treat of a potentially widening "digital divide" between and among nations´ populations which opens up questions of ethical justice [68]. On the one hand DPHI could lead to more participation and empowerment by providing understandable access to health interventions and information adapted to each population group, but on the other hand it could reinforce the exclusion of minority populations and injustice if there are no suitable general conditions, but demonstrating the impact of DHI on population health and health inequalities is difficult [21], [23]. Wong et al. [1] further stress the necessity to mitigate inequalities in access and competence across demographic segments, underscoring the paradox where those who could benefit most from digital innovations face the highest barriers. A population survey from Germany supports this opinion, showing that the use of DHIs in HIC also leads to inequal usage. There, it is mainly privileged people with higher incomes who use digital health services. A higher level of digital health literacy is also found in this social group together with younger people and people who are otherwise also more educated [14]. As for example health promotion initiatives, as highlighted by encounter hurdles in developing applications tailored to specific target groups´ needs and preferences, digital health literacy (the ability to absorb and process knowledge using digital health technologies) emerges as a pivotal issue, impacting both access and comprehension of technologies, highlighting the importance of educational efforts [3]. The unequal availability of DPHI leads to inequalities ranging from limited access due to infrastructural constraints (e.g. when financial investment is required for the individual) to insufficient representation of certain population groups in the context of technological progress [3]. Such discrepancies not only exacerbate socio-economic and health disparities but also underscore the potential for DPHI to widen existing gaps. Identifying approaches to mitigate the digital divide and promote equitable technology utilization is paramount [3]. In case of the digital divide, the populace may therefore be more negatively impacted by the technology [19]. If access to new technologies is restricted, it may limit opportunities in life, such as ignorance of one´s own health and illness, alternative therapies and care techniques, or care options. Digital inequality may also lead to social inequality and ultimately health inequality [11].

An excerpt from the framework by Odone et al. [5, p. 30] illustrates (Table 1) the potential added value of digitalization for public health in the pillars for practice, research, training, and education and in policy. It highlights the broad spectrum of DHI for public health and the leading advantages of DPHI.

Table 1 Potential added value of DPH: Excerpt from a conceptual framework
Source: Based on [5, p. 30]

Public health domains	*DHT*	*Features*	*Potentials public health*
Health prevention Health communication Health promotion Epidemiology Risk management Surveillance Food safety Impact assessment	mHealth Telehealth Social media Internet of things Big Data AI Drones Robotics Virtual Reality Genomics Wearables and sensors	Personalization and Precision Prediction Data analytics Interaction	Shift from cure to prevention Care closer to people Safer, faster, and more efficient services Less expensive care

Overall, Odone et al. [5] breaks down aspects of digital technologies that support and potentially enhance public health practice into five main features. Data analytics and Prediction are presented in one section as the recent literature shows a high interaction between these features.

Automation

Automation is the process of making a process run automatically by using information technologies and control systems. Automation is being used in healthcare administration through drug dispensing systems, automated adverse clinical event detection, decision support systems, and health services scheduling. Additionally, data from HER can greatly simplify automated reporting of chronic illnesses and diseases to public health agencies [5]. It should be noted that these systems can only be counted as DPHI, if a clear public health goal emerges from the technology, these are then often understood as the special software that leads to decision-making.

Data analytics and Prediction

The Robert-Koch-Institute [69] as the national public health institute in Germany sees the opportunities of DHI primarily in digital epidemiology. When used effectively, digital epidemiology, with digital data sources can offer fast and localized information about the dynamics of health and illness in people all over the world [70]. Using digital epidemiology as the foundation for DPH has yielded several insights into pandemics as well as new opportunities for the visualization of fundamental epidemiological data,

which could be crucial for contemporary public health communication [4]. Murry et al. [45] identified further potentials for DPHIs in response to the COVID-19 pandemic focusing on the use of data. Data is typically used to achieve two goals: First, to optimize the delivery of healthcare services and patients´ access to health information and second, to carry out research, policymaking, and regulatory activities.

The timely surveillance of the COVID-19 pandemic can be significantly enhanced by the digital gathering of administrative data. Visualization tools like data dashboards and interactive maps have facilitated pandemic monitoring and informed decision-making about appropriate PHI [64]. These kinds of technology might be employed in tandem with the dedication of laboratories and hospitals worldwide to establish a 21st-century surveillance network to identify the resurgence of infectious illnesses and the next pandemic. This infrastructure could serve the subsequent use of health data and could supports data management, data analysis and medical decisions [3]. Rapidly gaining these insights is made considerably more efficient and successful by linking different data sources [45]. Policymakers have benefited from the creation of instruments for global real-time public health data as they plan and improve containment tactics. These instruments made it possible to assess the efficacy of therapies in real time [1].

The data collected has so far been used in particular to monitor health problems in the area of communicable diseases, but it is conceivable that it could be extended to changes in risk factors for chronic diseases, such as apps or fitness trackers, on mobile devices [55]. It entails gathering personal health information from the population. This provides rich information for the population data pool. Characteristics found in extensive public health data, will serve as a point of reference for individuals and connect them to similar cohorts in the community according to factors like age, gender, ethnicity, etc. risk assessment and illness prediction are made possible by longitudinal data collected over months and years. Examples of this include calculating the likelihood of disease development or evaluating the response to various treatments [71]. It confirms the goal of promoting efficiency and equity in prevention and care in order to increase the quality-of-service provision [72]. However, as of right now, emergency, and pandemic response, population health monitoring, and disease surveillance are the primary fields of DPHIs. A great deal of effort has gone into creating and promoting applications and other DHI-related tools in the field of health promotion, especially to promote lifestyle choices and behavioral changes [65].

The power of using big data models in public health also offers the possibility of tracing sensitive health data and can therefore endanger privacy. Thus, it's important to strike a balance between the advantages of using data and privacy protection. This is crucial in

the case of DPHIs since it takes a lot of data to identify or prevent diseases in their early stages, which can only benefit a small number of people. For this reason, ideas about data sovereignty are being put forth, such as in Germany by the German Ethics Council [73], to be able to preserve their privacy on their own, people should be able to handle their personal data in a self-determined and accountable sovereign manner. The objective is to strike a balance between the potential benefits of big data for population healthcare and the preservation of individual personal rights, an area in which DPHI still must catch up [68].

Personalization and precision

The feature personalization and precision suggest concentrating on the living space [72]. The ability to identify links between social determinants of health and the design of living environments that promote health is made possible by new methods of data collection and linking [70]. DT are crucial for the tailored identification of disease risk factors and the subsequent personalized recommendations for behavioral modification or the use of preventive medical services, especially in the prevention of lifestyle-related diseases [3]. Specialization for personalized medicine in care through digital technologies and data therefore represents great potential for public health [72].

However, unresolved, and potentially crucial aspects in this area are concerns regarding the protection of privacy and property rights to health data. In addition, many stakeholders warn that socio-economic inequalities and, consequently, health inequalities could worsen due to different levels of competence in the use of DT [3]. Concerns about a return to paternalistic relationship structure (but with data holders, who may not be doctors) are sparked by the often-opaque data flows and processing algorithms, as well as the unequal distribution of skills and knowledge in society when it comes to the new technologies. To this end, questions about the responsibility and validity of the knowledge base must be clarified when medical decisions or decision support for the healthcare worker are made or applied based on AI models [68]. Thus, "information transparency" or informational self-determination plays a key role in the healthcare industry's data processing and "big data" discourse. [11, p. 5]. It is important to ensure autonomy for the user. Too much monitoring and the automated collection of data (without conscientious consent) through sensor technology (e.g. wearables) could make people forget the feeling of being "at home" in their own care. Excessive self-control also poses the risk of medicalizing otherwise natural life processes, which is caused by an exaggerated desire to optimize one´s own health [72].

According to Lupton [37], the use of personal data by software providers (or other unapproved third parties) creates an imbalance whereby the private user may

occasionally be denied access to their own data, while the industry has access to an almost limitless amount of potentially commercially exploitable data. For instance, a comparative analysis of fitness trackers revealed a deficiency in the security of users´ private health information. Practically all the devices under consideration offered insufficient movement data encryption and protection, leaving it vulnerable to theft by outside parties [8]. Users may have immediate negative effects from this, or at the very least, concerns may arise [74].

The legal framework for data protection and data security that applies in the respective country must also be observed, considered, and complied with, especially in Germany and Europe, data protection guidelines pose challenges. According to the European Court of Human Rights, data protection is enshrined in fundamental rights [75]. Other aspects include individual patient rights and data accountability [48]. For DPH and the use of ICT, the focus is on the exchange and communication of health data for preparation and further processing. The requirements for the quality of this data consist of the properties of confidentiality, integrity, authenticity, availability, validity, and auditability as healthcare date are sensitive data that requires special protection [3], [72].

Integrative care as a building block for the healthcare of the future, with the networking of healthcare stakeholders and the mutual exchange of health information, not only has the challenge of interoperability of the individual health information systems, but also data protection and information security. The data can then be used effectively and a relationship of trust with the user is established [76]. This also applies to the challenge of DPH research, where data that has already been collected is to be made available to other researchers. The sharing of this data and research data management, however, must be subject to the FAIR (F = Findable, A = Accessible, I = Interoperable, R = Reusable) data principles. Furthermore, worries about the fine line that health data automation must draw between autonomy and outside control highlight the moral issues that are fundamental to DPH [3, p. 3]. The ethical concerns created by the digitalization of individual healthcare which is often referred to as digital health partially overlap. The fact that the same technology tools, like health apps, can be applied to both the person and the population is one explanation for this [68].

Interaction

Effective communication with the public, media, policymakers, and decision-makers is essential to public health. Storytelling and data visualization, particularly interactive data visualization, can be more successful in delivering important messages and enhancing public health awareness [45]. Health communication is divided into three types: Peer to peer, informational offers, and entertainment-oriented content. Websites that provide

information on illnesses, their progression, management, and treatment through text, graphics, and video content are considered informative services [62]. Besides that, public health event notifications for preparedness and planning for emergencies via formal (international organizations) and informal information channels (e.g. WhatsApp) are considered helpful in crisis situations for the rapid dissemination of information [3]. The aim of entertainment-oriented content with a focus on digital formats that contain health-related content is the low-barrier integration of health-related topics into invented entertainment shows. This entry can raise citizens´ knowledge of how their own behavior and the environment they live in affect their health and involve them in decisions about care, prevention, and promotion of health [77]. Thus, health education through the dissemination of health knowledge leads to a strengthening of community and empowerment over one´s own health [72].

Peer-to-peer related content formats, in conclusion, highlight the potential for networking, exchange, and involvement in health-related communication. This also applies to online communities, such as web forums, which allow for private or public discussions on diseases as well as trends and lifestyles related to health [62]. Social media, as opposed to conventional unidirectional mass communication, offers a wide range of interaction choices, such as liking, sharing, and commenting, as well as the ability to create original material (such as on video platforms). Further research shows that public health organizations are increasingly using social media advertising campaigns in pursuit of public health goals. Results mark that PHIs via digital advertising are an effective way to change key self-reported beliefs and attitudes about COVID-19 [78]. These campaigns are also a cost-effective approach to increase e.g. vaccination rates. This approach can make them attractive to a wide range of organizations around the world. More generally, the use of social media advertising could help achieve other public health goals, such as hand washing and children vaccinations [78]. However, the advantage of new forms of communication through ICT is also seen as one of the biggest challenges for public health in the coming years. The main concern is the fight against misinformation, which is why it is important to acquire and strengthen skills in health communication [58].

2.2 Digital public health in low-resourced settings

First, a definition of LRS is given, then the goals and obstacles in this environment are explained. Examples of the implementation of DPHIs in LRS are described.

2.2.1 Definition of low-resourced settings

Before the specific opportunities and challenges of DPHIs in LRSs can be discussed, a definition of the term "low-resource setting" is required. This term is not yet widely used in research and academia. In research reports dealing with applications of digital technologies in healthcare, the term LMIC, developing country or the global south (as the opposite of the global north) is often used [79]. Thus, the reproduction of the state of research almost always refers to the countries that fall under the terms currently in use. However, a widely held view is that a country's ability to provide adequate healthcare depends on a variety of interrelated factors rather than government spending. The term "low-resource-settings" could be expanded to nine themes, including (1) financial pressure, (2) suboptimal healthcare service delivery, (3) underdeveloped infrastructure, (4) paucity of knowledge, (5) research challenges and considerations, (6) restricted social resources, (7) geographical and environmental factors, (8) human resource limitations and (9) influence of beliefs and practices, showing that these environments are not one-dimensional or dichotomous but rather reflect a complex web of interconnected resource constraints and concepts [79, p. 12]. DPHIs and the associated potential "digital divide" that could further divide health equity must consider the fact that health inequalities persist in developed and HICs, leading researchers to increasingly use the term "LRS". A further indication of the concept's complexity is the convergence of "low-resource" countries, some of which are also high-income countries according to the World Bank [79]. This means that the description of LRSs can also apply to HIC, among others, and thus includes the fact that certain lessons can also be learned from HIC that have gaps or deficiencies in resources in some settings [15]. As a result, high-resource nations also confront significant obstacles such the aging population, the rising incidence of non-communicable diseases, the impact of special interests on behavioral risk factors, the viability of national health systems, and the disparity in health between and across nations. The in-depth potential of digitalization in public health therefore needs to be explored also in these high-resource setting areas [5].

2.2.2 Aims and barriers of DPHIs in LRSs

The implementation of digital health presents a variety of challenges across different countries. HIC and developed countries prioritize patient mobility and interoperability, while LMIC and developing countries struggle with issues such as a shortage of healthcare providers, difficulty accessing healthcare services, inadequate education

opportunities for healthcare providers, increased disease transmission, inadequate surveillance, and unconfident data management [80].

The field of DPH could be a critical component of achieving the 17 SDGs and is essential to the UHC that countries with LRSs are constantly striving for [81]. Because it has the potential to provide universal access to healthcare (SDG3), reduce inequalities (SDG10), and contribute to poverty reduction (SDG1). Digital health also encourages investment in ICTs and research (SDG 9), fosters cross-sectoral collaboration partnerships between health and IT (SDG 17), and contributes to quality health worker education [82]. The prevalent disease burden in LRSs are still infectious diseases [83] followed by non-communicable diseases (NCDs) [84], [85] which are above average and increasing in this setting compared to the rest of the world, and mental diseases due to the COVID-19 epidemic in four LRSs a depression prevalence of nearly 25% was found [86].

Application of DPHI in LRSs

Among the ICT, the use of mobile phones in the context of public health for prevention and health promotion stands out and forms an interesting interface of enabling equal health possibilities [72]. As the proportion of smartphone owners has also risen sharply in LRSs countries, while the cost of use is falling, offering a relatively low-resource platform [87]. However, this since this technology can be used in a wide variety of ways in healthcare, in addition to being easily accessible. It can be used for remote patients care in rural areas with the help of telemedicine, which allows patients to consult with healthcare providers remotely, eliminating travel and waiting [88] or the use of telephone calls and SMS for the treatment of HIV patients [89]. One technical option that has proven successful in other cases is to retrieve and play the messages asynchronously when the user has an Internet connection [90].

The use of analyzing tools for EHR improves healthcare efficiency and serve public health objectives like disease surveillance and health trend monitoring. They facilitate easy patient information sharing, leading to coordinated care and fewer tests. The WHO´s ICD-11 adoption in 2019 standardized global health data, and a successful pilot project in Rwanda integrated ICD-11 into OpenMRS, (open-source EHR system for resource-constrained environments) demonstrating its potential for improved data collection, harmonization, reporting, and insurance reimbursement processes [91]. Moreover, advanced AI and data analytics technology analyze vast amounts of health data, enabling clinical decision-making by anticipating disease outbreaks and detecting patterns [35]. One quickly emerging technology that could offer new alternatives for supporting health system responses in LRSs to cardiovascular and other NCDs is the use of wearable health monitors [92]. At the same time, implementation is hampered by

a lack of internet access, coupled with a lack of technical usability or cultural acceptance [92]. By connecting recorded data with the use of AI algorithm for detecting early health issues, personalized care options would rise. A Tanzanian scoping review highlights the potential of AI, particularly machine learning and deep learning, in transforming healthcare services. However, it emphasizes the need for Tanzania to establish national AI policies and regulatory frameworks in line with WHO guidelines for ethical AI adoption [93]. In general the use of DHIs in LRSs can be seen in six areas (Table 2) [94].

Table 2 Summary of Applications of DHTs in LRS
Source: Based on [94, p. 887]

Application	*Description*
Disease diagnosis and treatment	Can be used to improve the diagnosis and treatment of diseases, such as HIV/AIDS, tuberculosis, and family planning. This can be done using telemedicine, mobile health apps, and other digital tools.
Patient communication	Can be used to improve patient communication, such as by providing patients with access to educational materials, appointment reminders, and other resources. This can help to improve patient adherence to treatment and overall health outcomes.
Healthcare workforce	Can be used to improve the healthcare workforce, such as by providing training and support to healthcare workers in rural areas. This can help to improve the quality of care in LRSs.
Healthcare delivery	Can be used to improve the delivery of healthcare, such as by providing access to healthcare services in remote areas. This can help to improve access to care and reduce disparities in health outcomes.
Healthcare financing	Can be used to improve healthcare financing, such as by providing patients with access to financial services and insurance. This can help to make healthcare more affordable and accessible.
Healthcare research	Can be used to improve healthcare research, such as by collecting and analyzing data on the use of digital health tools. This can help to improve the understanding of diseases and the development of new treatments.

The doubt about the impact of DPHI in LRSs is also evident in the evidence base on the use of mHealth interventions for prevention and health promotion, where studies show significantly weaker effectiveness of mHealth interventions in LMIC [95]. This opacity highlights the need for additional assessment research. While the negative effects need to be acknowledged and eliminated, they need to pinpoint the elements that explain the good outcomes.

Problem of pilotitis

The growing expansion of DPHIs could help to prevent these disease patterns in the population through preventive and health-promoting measures. But despite the well documented reports on the benefits of digital health, adoption remains low in developing countries [96]. Academic literature indicates that the United States of America (19.1% of implemented digital innovations), China (12.7% of implemented digital innovations), and

India (5% of implemented digital innovations) were the countries with the highest number of implemented digital innovations [10, p. 9]. The problem of developing countries like India is that the DPHIs lack in scalability, reproducibility, transferability, sustainability, cost and logistical difficulties [65], [97].

That's why one major issues in digital health, especially in LRSs are pilotitis and siloed interventions. Pilotitis in digital health refers to the phenomenon where multiple small-scale digital health pilots or projects are started but few, if any, are scaled up to a level where they have significant, sustainable impact. These projects are often not integrated with other projects and are often overlapping. Pilotitis is fueled by siloed funding streams for small-scale disease specific projects rather than holistic healthcare funding. This effect is often amplified by cost problems because many projects are dependent on donor funding [98], [99]. In addition to the high number of pilot projects, siloed projects are another major issue. Many DPH projects are not integrated into existing information systems or are not interoperable with them. This issue leads to siloed information systems with limited to no data sharing [57]. The deployment of digital health services e.g. in Africa is also hindered by various challenges, including inadequate coordination of numerous pilot projects, but also by feeble health systems, insufficient awareness and knowledge about the field, inadequate infrastructure, including unstable power supplies and poor internet connectivity, and a lack of interoperability among various digital health systems [57].

Increased ethical problems

Looking at the literature, Health information Systems (HIS) in particular shows that there is very little ethical consideration in LRSs. Thus, technical progress quickly overtakes progress in ethical issues, and it is precisely these that require the implementation of strategies and procedures that ensure the ethical collection and use of data for the population. Thomas et al. call for closing this research gap in LMIC [100].

The intersection of health equity and the digital divide presents a multifaceted challenge in the realm of DPHI. The urgency emphasized by Chauvin and Rispel [65] underscores the imperative for global public health entities to lead discussions on the integration of DT for fostering health equity. The high health inequalities in LRSs are mainly influenced by poverty, education, and the place of residence [101], [102], [103]. In addition, the lack of literacy and computer literacy exacerbates the digital divide [16]. In its global strategy for digital health, which was adopted in 2020, the WHO pointed out that digital health must support equal and universal access to high-quality health services. These high ideals are particularly difficult to achieve for LMIC [39]. Otherwise more possible consequences like in Kenya can be seen, where despite the high mobile phone

penetration, mHealth adoption in rural areas remains low due to factors like ease of use, perceived usefulness, disease threat, user age, language literacy, and social influence [90]. This underscores the need for a systematic approach for ensure meaningful, sustainable impact of DPHIs. These factors and promoting digital literacy skills development to prevent the digital health gap and ensure vulnerable people are not left behind [89]. Otherwise the digital divide may restrict access to crucial digital health solutions for certain populations, widening existing health disparities [64]. Semaan et al. points out that the risk of infodemics is widespread among vulnerable groups worldwide (e.g. low socio-economic status). In the process, correct as well as incorrect and inaccurate (health) information will quickly become widespread [90].

Further problems of DPHIs are to ensuring data privacy and security [64]. A strong legal and regulatory framework around the use of personal data, with clearly defined roles for data governance for equitable data sharing, must be created and implemented at national and international levels by countries to protect data privacy and ensure data security [39]. Only 31 of the 55 African countries have passed explicit data protection legislation, and not all of them are enforced [104, p. 6]. The laws in place in several African nations are either out-of-date or overly restrictive in light of the advancements provided by DPHIs [105].

2.3 Concepts of health technology assessments for DPHIs in LRSs

The main theoretical basis for this master thesis is based on existing theories of health technology assessment for DPHI. Therefore, the status of assessment methods for DPHI is presented. In addition, a comparison between traditional and digital HTA is shown. After that the complexity and challenges in assessing DPHI are illustrated. In the end the application of HTA in LRSs is displayed.

2.3.1 Traditional HTA vs. digital HTA

HTA is an evidence-based review of the suitability of methods for use in healthcare. The assessment serves as a decision-making aid when the introduction of new devices and methods or the abolition of old methods is being considered [106]. The common HTA methods are focusing on economic and medical efficacy. HTA is a multidisciplinary procedure that provides a systematic, transparent, unbiased, and rigorous summary of the data that has been gathered. It addresses nine areas (Figure 6) [106].

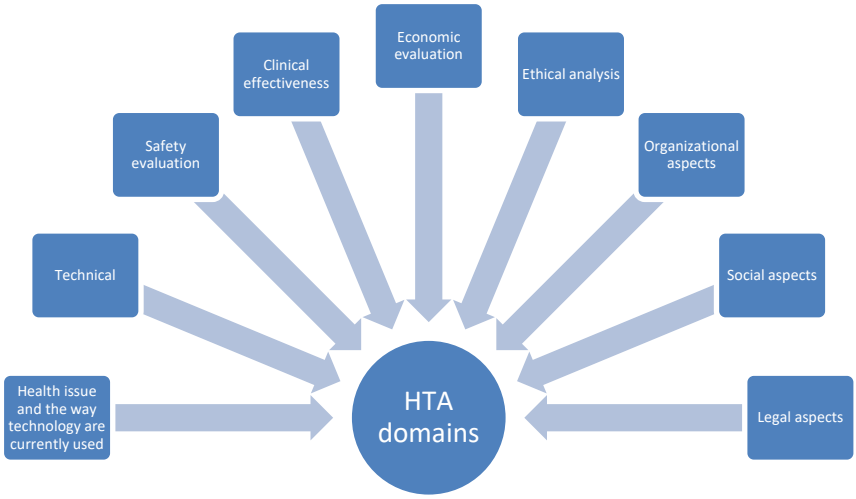

Figure 6 HTA core domains
Source: Based on [107]

A full HTA report, a quick review, a contextualization of assessment reports from other sources, and a mini-HTA report are the many types of assessments reports. While a fast evaluation only includes the first four domains and is therefore transferable from one nation to another, a comprehensive HTA report covers all nine domains [107].

The use of HTA to evaluate non-pharmaceutical technologies is increasing in various healthcare systems. HTA primarily suggests the cost per quality-adjusted life year (QALY) approach and allows for the simultaneous assessment of a health technology´s clinical and economic benefits. The gold standard for determining a pharmaceuticals worth is thought to be the QALY method. By estimating the cost per extra health outcome, or QALY, payers are able to allocate funds across various therapeutic areas using a consistent technique and make pricing and reimbursement decisions based on

a straightforward cost per QALY criterion [108]. Vis et al. identified in their review on assessment frameworks for DHI that the focus was mostly on technical and economic aspects [109]. However, it begs the interesting question of whether the field of digital health can benefit from such a streamlined approach that concentrates only on clinical outcome. It emphasizes a need for a new assessment framework for the value of DHI instead of a QALY approach [7]. Further results show that the economic evaluation of DHI is not meaningful in terms of the overall benefit [110].

The evolving landscape of HTA reflects a growing interest in evaluating novel technologies like AI. The literature underscores a need for updated HTA frameworks tailored to these innovations, in recognizing DHIs as a new frontier in HTA requiring distinct criteria and processes [111]. Notably, established evaluation frameworks for DHIs have been heavily influenced by HTA methodologies, highlighting HTA´s role in guiding assessments within this domain [112]. However, many DHI that usually fall into lower risk categories are excluded from the recent European Union legislation on HTA [113]. This highlights a present mismatch between the speed of innovation in digital health and the regulations [9].

The comparison between conventional HTA and digital HTA reveals distinct challenges and considerations for evaluating emerging technologies. Conventional HTA faces limitations in effectively assessing DHIs due to several factors. The rapid development of numerous technologies, reliance on small-scale pilot studies, and the iterative nature of DHTs disrupt traditional HTA practices. This highlights the need for adapted frameworks to address these unique properties [114]. The evaluation should be a continuous process [115]. The Model for Assessment of Telemedicine (MAST) [116] is an example for the iterative continuous assessment process [117]. Besides that the phase of maturity (can be read from the product lifecycle) and the objective of the assessment should be considered [118]. According to recent research, DHI should be approached differently from traditional HTA since it represents a care process rather than a single product [9], [119]. Technology Readiness Levels are the finest tool for determining the level of technological maturity. The nine stages are separated into three distinct phases: deployment, development, and research. In each phase, different end-user, clinical and societal activities, and outcomes are of different importance. It is recommended to combine the end-user, health, and societal perspectives rather than focusing on just one. In the research and development phase the end user perspective is the dominant factor whereas in the deployment phase the social and health perspective are in the focus [115].

Unlike traditional HTA, digital HTA must contend with assessing novel technologies that may impact decision satisfaction rather than traditional clinical outcomes like QALYs. Patients´ preferences and satisfaction with DHIs are critical factors that may not be adequately captured by standard utility measures. Society´s willingness to pay for incremental gains from DHIs is relatively low, underscoring the importance of low acquisition costs for these technologies. Furthermore, there is a risk of overvaluing new technologies solely due to novelty, potentially skewing their perceived impact versus actual value. Digital HTA processes are also time-intensive, requiring robust data, economic evaluations, and expert validation [114]. This becomes clear when looking at the overview of classification of digital health indicators (Figure 7) listed in the WHO Guide to Monitoring and Evaluation [56]. The aspects of how users interact with the technology come before the evaluation of how the technology can improve the existing process. It shows how important it is to make sure that the user can use the technology correctly and according to their capabilities. This results in an iterative loop between the adaptation of technical and organizational factors after the exchange of user feedback [56].

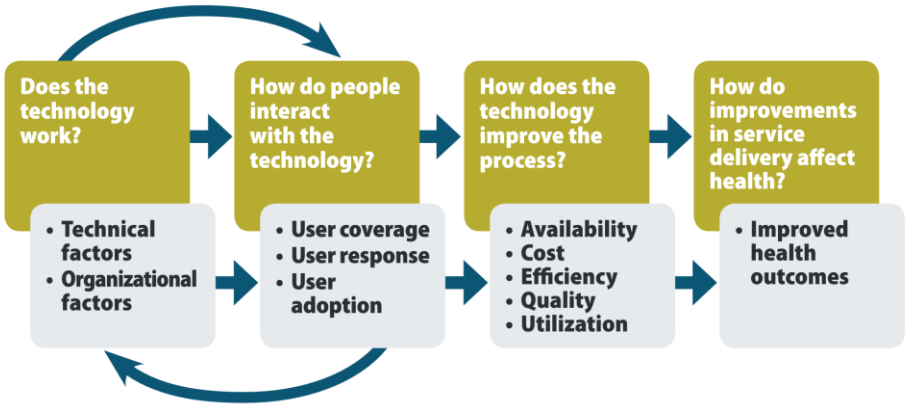

Figure 7 Categorization of digital health indicators
Source: Original from [56, p. 33]

Conventional HTA usually compares innovative interventions to a gold standard of care and emphasizes cost in relation to stable clinical outcomes across the course of an illness from the perspective of society. On the other hand, Digital-HTA assesses technologies based on their unpredictable and changing future worth and impact, comparing them to either one or more comparators. This method stresses patient perceptions in addition to social ones. HTA agencies frequently do not assess DHIs that are largely commercial or not recommended for patient populations since they might not meet the requirements of commercial insurers and single-payer health systems for payment [114]. Furthermore, existing HTA methodologies lack specific items tailored for DT and public health purposes, necessitating the development of specialized

frameworks to adequately assess these innovative technologies [120]. A review by Kowatsch et al. [121, p. 256] examined consolidated categories for DHIs. The leading categories (mentioned to 26,3%) were the “ease of use”, which described the degree to which effort is required to take advantage of the DHI. Followed by the degree to which the content of a DHI is accurate, timely, complete, relevant, and consistent (“content quality”), and the degree to which the DHI considers legal requirements and aspects with respect to privacy and security aspects (“privacy and security”), both categories mentioned to 12,4% in evaluation studies. Ethical aspects (1,5%) and Safety (0,9%, extent to which the usage of a DHI is safe with respect to side effects) were the least investigated. Even the “effectiveness” was represented in only 5,4% of the studies.

In global health programs, traditional benchmarks for intervention validity emphasize evidence of direct improvements in health outcomes. However, the focus with DHIs has been on leveraging digital systems to enhance and optimize existing health service delivery. This approach aims to broaden population coverage and enhance service quality, with claims that digital interventions promote positive health behaviors and reduce service delivery costs through efficient data transfer and communication channels. DHIs often complement existing effective interventions rather than acting as standalone solutions. In cases where measuring direct impact is challenging, effectiveness is assessed using proxy and process indicators. The WHO guide for Monitoring and Evaluating DHI is demonstrating in a “barometer” that the selection digital health indicators depend on the existing evidence and efficacy. For novel interventions lacking strong evidence, outcomes are prioritized, whereas, for established interventions (e.g., vaccines or clinical care), the focus shifts towards improving reach and delivery timeliness, building upon existing evidence of efficacy [56].

2.3.2 Current assessment of DPHIs

The first review of the use of DT within the public health domain was conducted by the WFPHA [21] and examined several issues related to the population health and health equity. The problems relate to the scalability, replicability, transferability, and sustainability of DPHIs. Although the focus on personalized medicine and healthcare, there is a chance that one will become engrossed in the buzz surrounding technology and disregard community perspectives and demands. The strong industry drive for the creation and use of DHIs connected to health and a disregard for the limitations of local resources. So that the predominance of efforts driven by the north or west that may not be able to fit in with local circumstances, but rather the profit that drives innovation [65]. The question of the needs-based use and implementation of DPHIs should not be based on what is technically possible, but on what is technically necessary. This is because

technical progress is developing too quickly, meaning that the debate about social and health-related consequences is only conducted afterwards [11]. One reason for this is that large companies carry out the evaluation and development of DHIs without seeking contact with the associated healthcare personnel. Regarding DPHI, many innovations suffer from the fact that although they ensure low-threshold provision and access to health information, the quality of the service and information is lacking. Companies want to maximize markets and use the data for business goals. The focus on the health needs of a population is often lost in the process. Regulation and evaluation are therefore necessary in order to curb the self-dynamics of profit orientation, but also to redirect the target orientation of interventions to the public health context [68].

This is also reflected in the problem already described that there are no standardized definitions in the field of eHealth, digital health and certainly not for this master thesis relevant category of DPHI to conduct clear debates on development, implementation, execution and evaluation [11]. When considering the challenges of developing DPHIs, a distinction can be made between technical and non-technical challenges. The quality of evidence, funding gaps, health equity, policy and governance, and ethics were among the nontechnical obstacles to digital integration in public health. Technical difficulties included personnel capacity shortages, disjointed and unsustainable systems, unclear standards with missing interoperability as one of the crucial issues in case of technological difficulties, and the unreliability of data that was provided [13].

Assessment frameworks in this case form a necessary part of the framework for the digitalization of health [122], can serve both as a strategic tool for digital transformation [49] and contribute to the required faster decision-making in the area of public health in crisis management [69]. This trend is also reflected in Germany, as one of the important tasks of the planned "Federal Institute of Public Health" is the evaluation of public health measures, among other things, the evaluation also serves to strengthen public health research [123]. Moreover, one pillar of a successful European strategy for the digitalization of healthcare is therefore "monitoring and evaluation". This suggests that technology evaluations based on focused, reliable, and shareable HTA models should assist the implementation and oversight of DPH solutions in many domains [5]. The European eHealth Action Plan for 2012-2020 also set out to improve the assessment of the added value of DHT through closer cooperation between member states and stakeholders in HTA. This has resulted in the establishment of the EUnetHTA network [11].

Traditionally, assessment methods have focused on medical devices, pharmaceuticals, and clinical procedures. DHIs are intricate interventions, and conventional evaluation

techniques such as randomized controlled trials (RCTs) have limitations in their suitability for these interventions [17], [124]. Whereas for public health it is important to ensure topics like health equity or data security as well [17]. Adaptation of study design is already underway, for example the CONSORT e-health checklist which can be used to overcome the challenges of reporting RCTs of web-based and mHealth interventions. The aim is to improve reporting quality through feedback and before-and-after studies [125]. As DPHIs interact with everyday life, such as work, education, urban development, and democratic processes, a new assessment of DHPIs is necessary to ensure their effectiveness and promote a more inclusive and sustainable approach [72]. There is a lack of validated DPH assessment tools addressing the nuances of DPHIs compared to standard frameworks. The Expert Panel on effective ways of investing in Health [112] encourages further synthesis and development of assessment tools and frameworks to address this gap. Setting precise and significant parameters for the efficacy of the new DPHIs is made even more interesting [13].

There are already many frameworks for evaluating DHI that specialize in the respective technology, the coronavirus pandemic has brought the evaluation of telemedicine [107], contact tracing apps [108], and health surveillance systems [109] into focus. However, there are many different frameworks for evaluating the quality of applications and software in the field of mHealth [126]. Namely mentioned for example the Mobile App Rating Scale (MARS) [127] or Enlight [128] which is used for mHealth and web-based eHealth interventions. But despite their popularity the MARS still fails to address important key aspects for DPHI of quality which are data security and privacy [126]. In addition, mHealth has shown that very specific questions are also necessary for the evaluation, particularly for specific disease-related applications. However, concerns regarding accessibility, data protection, clinical basis and interoperability are non-specific but more relevant for success in the area of public health [129]. Other assessment frameworks for DHI are orientated towards benchmarking individual areas such as digital literacy [130], data security [131], and usability [132] (e.g. System Usability Scale). This heterogeneity leads to a specialization in certain technologies, processes, and assessment domains, but does not provide an overall view of a DPHI.

The view of the population is usually omitted, so that the basis for evaluating the supposed success is based on the effectiveness of the intervention for the individual. More and more opinions are calling for a more far-sighted view of the evaluation of digital technologies, not least because of the risks already mentioned [1]. From a global perspective, the lack of appropriate evaluation models is one of the main limitations in the promotion of m-health [133]. The primary focus is the clinical and quality approach

which presently involves conducting systematic reviews of e-health and m-health interventions. While this approach is commendable for its commitment to evidence-based evaluation, there's a pressing question about whether the methodology needs adaptation and supplementation given the rapid pace of technological advancement [55]. By the time an assessment is completed, the evaluated digital intervention may have undergone updates or become outdated, threatening the relevance and utility of the assessments. This can lead to unchecked technological advancements and inadequate evaluation [24]. One opposing viewpoint suggests that only e-health and m-health interventions that see sustained and prolonged use can be integrated into public health practices, thus making them amenable to evidence synthesis. However, even with such interventions, the evaluation often faces significant constraints due to limited follow-up periods, which hinder the assessment of both long-term positive and negative effects [55]. To enhance the value and effectiveness of DPHI, it is crucial to develop comprehensive frameworks that consider the complexity of how these tools may influence health on individual, organizational, and societal levels [3].

DPHI face significant challenges in achieving widespread adoption and effectiveness. Despite the availability of numerous applications and solutions, their underutilization cannot solely be attributed to this factor, as identified by Arnold, Scheibe, and Müller [134]. Implementation is feasible across both primary and secondary healthcare markets, with the latter offering fewer restrictions, however, the low willingness of users to pay complicates the development of sustainable business models. In the primary healthcare market, mere approval and demand are insufficient for successful diffusion. Demonstrating tangible benefits, medical necessity, and cost-effectiveness is critical for securing financing from statutory health insurance. This necessitates a robust evidence base and scientific evaluation to translate the theoretical potential of interventions into measurable outcomes [24]. Specifically, within DPHIs, there is a dearth of evidence on their efficacy and economic value across various stakeholders. Practical evaluation of DPHIs is particularly challenging due to their inherent complexities, posing obstacles to adopting established DPH evaluation methods. Companies operating in this space lament the absence of guidelines for designing adequate evaluation studies. Furthermore, the current evaluation processes are characterized as ambiguous, opaque, and protracted [135], highlighting the need for clearer, more efficient evaluation frameworks to support the uptake and successful implementation of DPHI [24].

2.3.3 Complexity of DPHIs and challenges for their assessment

As the implementation of HTA for traditional, non-technology-enabled public health interventions is rare and therefore the evidence base in health services is insufficient, the use of DT for public health increases complexity. Hence, it is imperative to give priority to and reinforce the introduction and growth of collaborative HTA approaches in public health practice and policy [136]. In global health initiatives, proof of direct gains in health outcomes is usually used to assess the validity of an intervention. Nonetheless, the main goal of DPHIs has been to increase population coverage and raise service quality by utilizing DT to improve and expedite the delivery of current health services. These treatments are frequently thought of as enhancing or stimulating already successful interventions [56]. Health and medical apps can potentially reach large sections of the population with evidence-based content and thus improve health promotion and prevention [62], [74]. However, the evidence mostly relates to the individual detection effects of the user, so that there is no holistic view of the population health [65]. Based on a socio-ecological model of health, Schütz and Urban [74] distinguish the undesirable effects of health and medical apps on three different levels of impact (Table 3): the individual level, the relationship level and the care level. When creating DHIs and assessing preventative and health-promoting interventions based on them, these factors need to be considered. It does not show the classic cause-effect relationship, in which, for example, malfunctions, misuse, misdiagnosis, incorrect treatment and incorrect use of DPHIs lead to direct health risks but extends this to undesirable effects that can occur when using DT in the public health context, illustrating the complexity of such interventions [74].

Table 3 Undesirable effects of digital health technologies on three levels
Source: Based on [74, pp. 193–197]

Individual level • Lack of quality of the recorded and entered data, which leads to incorrect recommendations and diagnoses by the technology • Negative emotions because of, programming errors or poorly designed or inaccessible interfaces • The processing and use of personal health data by third parties, for commercial use
Relationship level *Analog social environment:* • Awareness of the disease can lead to stigmatization on individuals. • "Corrupting effects" through pursuit of physical outcomes, so that physical activity that was previously driven by intrinsic factors is now driven by extrinsic factors. concerns about an impersonal doctor-patient relationship. • concerns about an impersonal doctor-patient relationship

Online social interactions: • The intended health promotion and prevention can be undermined by derogatory and stigmatizing information, e.g. through the comment functions
Care level • Misuse of personal health information leads to rejection of the technology by consumers or justification by private healthcare providers or insurance companies, for instance, to refuse to offer treatments. • Unequal access to and interpretation of digital technologies (digital divide) if DPHIs are planned based on biased data (e.g. underrepresentation of population groups) • Increase in health inequalities by not considering the inclusion of digital health literacy in the development of technology and the exclusion of population groups due to cognitive and physical requirements

Complex interventions are characterized by a range of interactive and interdependent components, targeting multiple behaviors across various groups or organizations [137]. The field of DPHI exhibits extensive variability in objectives, target audiences, and technical approaches, leading to a wide range of potential applications. Consequently, the degree of innovation and process integration varies significantly, resulting in a lack of identifiable standardization or defined typology for DPHIs [24]. The complexity of these interventions is further compounded by their interaction with the surrounding context, encompassing all circumstances from conception to evaluation. Understanding the mechanisms of change within these interventions, including causal links between components and outcomes, is crucial. Contextual factors play a pivotal role in shaping outcomes. Effective complex intervention research considers not only the intervention design but also the conditions necessary for realizing its mechanisms of change and supporting its implementation in real-world settings. Properties such as emergence, feedback, adaptation, and self-organization characterize these interventions, highlighting the need for comprehensive consideration of their dynamic nature in research and decision-making processes [137].

Dockweiler and Fischer illustrate high complexity of a DPHI [24] using three dimensions (Figure 8). These also apply to non-digital applications but are particularly pronounced here. The dimension of the intervention is complex, as it consists of several technical components that require direct interaction with the user in various forms. The effect of the DPHI is only achieved through several parallel mechanisms and several target groups are addressed. As a result, effects are achieved at several end points. Comparability (e.g. as in the evaluation of a drug), which has a singular focus and thus primarily serves a targeted benefit, is therefore more difficult [138]. The complexity of the system is characterized by the large number of stakeholders involved in the service

process (Figure 3). These include both professionals and non-professionals such as patients (e.g. through self-reporting apps). This results in individual requirements of the user groups regarding a specific application and e.g. technical experience can differ greatly. In addition, the care context is tied to social, institutional, organizational, and legal framework conditions that can have an impact on the design and use of interventions. This is particularly the case with DPHIs, as the entire population is involved and DPHIs are used across professions and sectors [24].

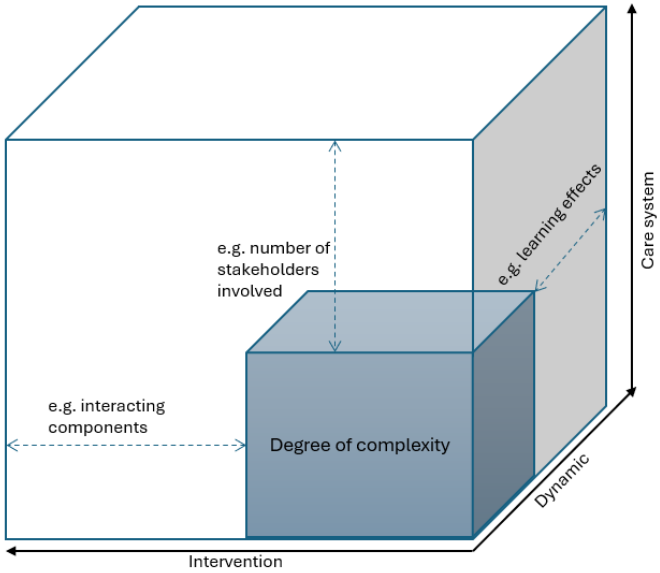

Figure 8 Complexity cube
Source: Based on [24, p. 110]

Complex intervention research requires methods that are sensitive to context, implementation challenges, and system dynamics. Refining the intervention involves fine-tuning or making changes based on preliminary development, aligning with the program theory and transparently reporting rationale for changes [137]. In principle, DPHIs are highly dynamic in terms of development. This is because there is a constant process of change in technical interventions as well as in human-machine interaction. Human-machine interaction is subject to a process of change and normalization. This is because the time required for technical integration into processes and structures is increased and users must first get used to the changed processes (handling must be learned before the full potential can be developed) In addition, digital interventions have short development and life cycles. There is no completion of development after approval (e.g. as with medication), but rather further adjustments and optimizations (e.g. software updates or new functions), so the application can be fundamentally changed and the change process must be reintroduced if the innovations are too large [24].

One of the challenges in the evaluation of DPHIs is the transferability of the results in conjunction with compliance with established evaluation requirements. In addition, the new challenges arise from the additional complexity, which should also be considered when making reimbursement decisions. When evaluating DPHIs, the requirements for an adaptive study design increase due to the high development dynamics (RCTs are based on fully developed interventions). Classic study designs provide a high level of evidence through strict adherence to the study protocol, but this requires a clear definition of the intervention. The time required for RCTs is also too long compared to the short development cycles of DPHIs, so there is a risk that the DPHI will already be technically outdated by the time the evaluation is completed. Blinding and randomization are further problems that cannot be guaranteed if personal data must be collected. The necessity of RCTs for less high-risk interventions should therefore be reconsidered and the study design should be made more flexible (e.g. allowing prospective planned changes based on interim analyses of the study data without compromising the integrity or validity of the study) [24].

When recording the costs and benefits of a DPHIs, specific effect measures must be used depending on the type of application, which are determined based on specific objectives and expected impact channels. This in turn leads to compromises in generalizability and comparability due to the high level of specification. In addition, the unintended effects of DPHI on third parties listed in Table 3 and other relevant unintended effects must be considered. This requires an overall societal perspective, which, however, faces major challenges. This is because benefits can cause undistributed positive and negative effects through the involvement of different actors. (e.g. teleconsultation: Beneficiaries requesting services, service providers providing advice must incur costs) Ultimately, an intensive multi-perspective cost-benefit analysis of the stakeholders is required [24].

Consideration of synergy effects is crucial due to the way DPHI typically integrate multiple components into a comprehensive solution, resulting in non-linear effects. While primary pathways of impact can be discerned, DPHIs also exhibit parallel effects branching out to individuals beyond the target group, with potential feedback loops and learning effects. This complexity poses the risk that the overall benefit of the solution may not simply equate to the cumulative sum of its individual components, as some effects may be amplified or inhibited. Therefore, DPH evaluations play a critical role in uncovering the intricate interplay of these components to identify tangible benefits and actionable insights. An adaptive study approach may be a viable strategy for addressing the challenges inherent in such evaluations. Furthermore, DPHIs relying on network

effects for scalability, such as those facilitating faster and more informative communication among users (e.g., through documentation software connecting various healthcare professionals), highlight the potential for indirect benefits like improved medication management and error prevention [24].

The challenge in developing tailored evaluation paradigms for DPHIs may stem from the historical focus on technology or target behaviors rather than central functions within public health [3]. Current frameworks predominantly emphasize the clinical aspects of digital health applications, overlooking broader public health considerations [120]. In addition to technical development processes, the implementation and participatory design of DHI are crucial [139]. It is essential to involve potential users in research, development, and implementation processes early on and to identify hindering factors systematically that could affect the adoption and acceptance of DPHIs. This inclusive approach ensures that DPHIs are aligned with user needs and address potential barriers effectively [139]. To establish a clear agenda for the field´s further development, the fundamental pillars (Figure 9) of DPH and the fundamentals of public health practice must be carefully considered [13].

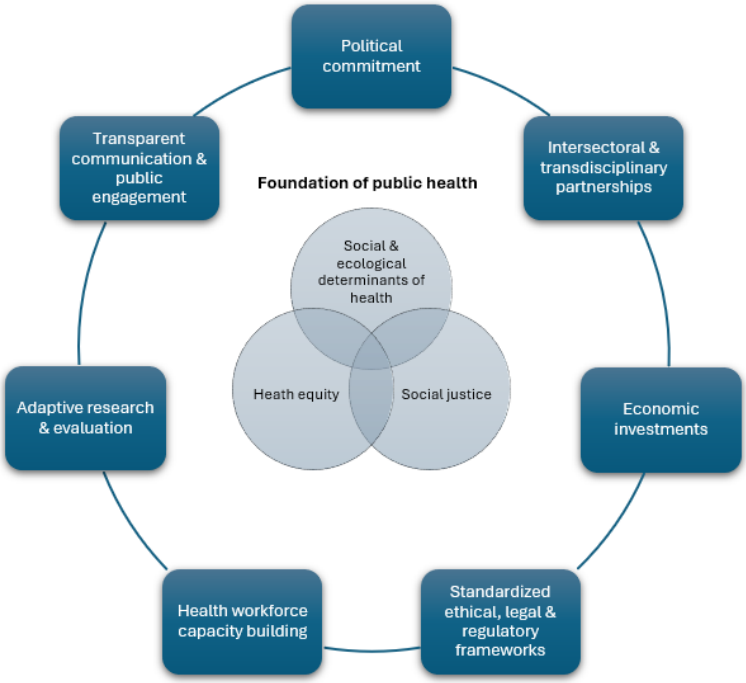

Figure 9 Mutually reinforcing pillars of digital public health
Source: Based on [42, p. 11]

2.3.4 Health technology assessments in LRSs

Existing frameworks, designed for high-resourced settings, lack resonance with the specific needs of low-resourced countries, particularly in public health, and remain untested for effective application. They may not fully understand the intricacies of health systems and PHI in LRSs [120], [140]. The ethical, social, organizational, and legal implications of DHTs are becoming increasingly important for decision-making in the public health sector. Data protection and informational health self-determination are also playing a significant role, but these are linked to increasing implementation challenges. This pertains to LRSs and includes restricted mobile phone usage, low coverage and network connectivity, a lack of technological know-how, a lack of power supply, and difficulties with application design [141]. The use of policies or legislation to define medical jurisdiction, liability, or reimbursement of digital health by World Bank income group showed that in HIC over 50% have such a framework whereas in LIC under 10% do. Overall, the statistics showed that richer countries reported a higher incidence of such laws than poorer countries [142, p. 116]. A 2020/2021 conducted WHO survey [26] which did an overview on the use of HTA in the world, revealed that systematic existence of a formal process to gather information to support healthcare decisions in 44 of 55 LMICs were established. The WHO highlighted HTA as a valuable tool to drive the implementation of UHC and make decisions about who receives which health interventions and at what cost. But only 18 referred to this process as HTA. The main barriers to HTA have been that there is a lack of awareness of the importance and the institutionalization of HTA. Other issues were political support and qualified human resources. The main aspects covered in the assessment process for population level health interventions were the feasibility (e.g. availability of budget and human resource), safety and acceptability of patients. The stakeholder with the less voice in the assessment process were representatives of the citizens and vulnerable and marginalized groups. Hollingworth et al. [143] and Babigumira et al. [144] found similar result with the little use of evidence for policymaking and the lack of local data and appropriate tools to conduct HTA e.g. in Tanzania, panels of experts made choices regarding the selection of necessary medicines mostly based on experience and subjective judgment; the role of evidence in the decision-making process was minimal. So that specialized interests pose a threat to Tanzania´s efforts to reform the country´s pharmaceutical laws [143].

The relationship between HTA and healthcare spending (GDP per capita) appears to be moderately correlated, while the degree of centralization (government effectiveness) shows a strong association with HTA implementation. The results do not, however,

conclusively demonstrate whether the application of HTA successfully supports interventions of high public health priority. Even though studies are classified as HTA, they are frequently not routinely used to support national policy decisions and are usually motivated by the interests of organizations rather than the government or the health system. There has been worldwide success in this area, with the WHO emerging as a pioneer in implementing HTA programs in LMICs [144].

In LMIC, for example, such HTA tools correspond to the KNOW ESSENTIALS tool (alternative that facilitates evidence-based decision making by stakeholders without formal expertise in HTA). As a stopgap solution, the tool may be especially helpful for healthcare systems building their HTA capabilities. Additionally, it can be helpful anywhere quick decisions about health technology based on evidence are needed [145]. The ability of foreign data and information to be transferred to a local context is its most significant constraint. In addition, rapidly reviewing the evidence for several technologies without the appropriate competence may cover a disproportionate amount of expensive technologies, placing needless strain on the ability of public finances to support themselves [146]. Therefore, additional assessment to decide on financial decisions in the digital health is needed. Broomhead et al. developed such a framework after realizing that there are no appropriate ones in Africa [147]. It serves to assists decision-makers in evaluating and choosing effective eHealth investments in resource-constrained settings and has potential for applicability beyond Africa [148].

3 Methods

The selection of the methodology is first explained, then the search strategy and the evidence selection criteria are described and visualized.

3.1 Data collection methods

The scoping review methodology was chosen because DPH is a new field of research [24]. The purpose of the scoping review was to get an orientation on the status of existing frameworks for the assessment of DPHIs and to see what points of contact already exist in the assessment of DHPI in LRSs. It therefore also serves to differentiate holistic DHIs assessment frameworks from assessment frameworks that have been explicitly designed for DPH and to work out which criteria, factors or indicators influence DPHIs in LRSs by analyzing existing reviews of DPHI application in LRSs. The master thesis uses a nine-step scoping review framework. This includes defining objectives and questions, developing inclusion criteria, describing the evidence search, selection, data extraction, and presentation approach, searching for evidence, selecting evidence, extracting evidence, analyzing evidence, presenting results, summarizing evidence, making conclusions, and noting implications. The “Covidence” software was used support the scoping review, following the Joanna Briggs Institute (JBI) scoping review methodology guidelines [149].

3.2 Search strategy

The search strategy aim to locate both published and unpublished studies. The text words contained in the titles and abstracts of relevant articles, and the index terms used to describe the articles were used to develop a full search strategy for Pubmed, Healthcare Administration Database and Google Scholar. The search strategy, including all identified keywords and index terms, was adapted for each included database, a librarian was brought in to advise on the selection of databases and search strings. The reference list of all included sources of evidence was screened for additional studies, the inclusion of these references is highlighted in the summery of each excluded publication (Appendix 8). Only sources published in *English* and published since *2020* are considered, as the spread of DPHIs has accelerated during the COVID-19 pandemic which revealed recent forms for DPH practice [10]. A total of 1095 sources were screened by title and abstract.

The search strings are shown in Table 4. Due to a lack of direct hits (more hits in references), the search for the identification of existing frameworks for the assessment of DPHIs was extended via Google Scholar on 17th of April 2024. By using the search string “"Digital public health" AND "assessment framework". The search string "digital

public health" AND "evaluation" produced too large and imprecise results, which may limit the findings of the scoping review by excluding potential sources.

Table 4 Scoping review search strings

Search string (date)	*Amount of search hits (extracted evidence)*	*Database*
"Digital public health" AND "assessment" (02/08/2024)	16	Healthcare Administration Database
"Technology assessment" AND ("digital" OR "eHealth") AND ("framework" OR "tool") AND "public health“ (02/08/2024)	263	Healthcare Administration Database
"Technology assessment" AND ("digital" OR "eHealth") AND ("developing countries" OR "LMIC") (02/08/2024)	64	Healthcare Administration Database
"Digital public health" AND ("evaluat*" OR "assess*") (02/08/2024)	82	Pubmed
(("Digital health" OR "eHealth") AND "public health" ("assessment" OR "evaluation") AND ("framework" OR "tool") (02/08/2024)	454	Pubmed
("Digital health" OR "ehealth") AND "public health" AND ("developing countries" OR "LMIC") (02/08/2024)	101	Pubmed
"Digital public health" AND "assessment framework" (04/17/2024)	115	Google Scholar

3.3 Source of evidence selection

Following the search, all identified citations were collated and uploaded into Covidence software and duplicates were removed. Titles and abstracts were then screened for assessment against the inclusion criteria for the review. A total of 143 sources were screened by full text. Potentially relevant sources were fully researched, and their citation details listed in Appendix 8. Reasons for exclusion of sources of evidence at full text that did not meet the inclusion criteria were recorded in the scoping review and are represented in the following and is visible in the PRISMA-flowchart (Figure 10). The exclusion criteria can be seen in Table 5. The reasons for exclusion are listed using the keywords "Wrong Setting",” Wrong Intervention” "Wrong Outcomes" and "Wrong Study Design", each of which has one or more exclusion criteria. The inclusion criteria are listed below:

Inclusion criteria for possible DPHI assessment framework:

- Generic assessment framework for DHTs
- Framework application of an assessment for a DPHI

- *Functional frameworks for DPH*

Inclusion criteria for LRSs:

- Holistic DPHI assessment in LRSs
- Lessons learned/recommendations or limitations for the development or assessment of DPHIs

Table 5 Exclusion criteria

Exclusion Criteria	*Assessment Framework*	*Assessment in LRSs*
Wrong Setting	• No direct link to the healthcare sector • Framework for special technology (e.g. AI)	• No LRSs application context
Wrong Intervention	• No DPHI or no public health context • Assistance systems or technical basis (such as HIS)	
Wrong Outcomes	• No full text • No application of the assessment • Implementation, Scale-Up or process evaluation frameworks	• No full text • No recommendations • Only cost effectiveness or quality reviews of DPHIs
Wrong Study Design	• Only evaluation of specific technology • Proof of effectiveness and quality/clinical study	• Development process without reflection or critical appraisal

3.4 Data extraction

Data was extracted from papers included in the scoping review using the data extraction tool “Covidence”. The extracted data contains specific information on the most important results that are relevant to the research questions of the master thesis (Appendix 8). This data contains *general information*: Study ID, Title, Lead author, Publication year, Aim of study. In addition, the *characteristics of the extracted studies* were included: Database, Research Question, Search string, Inclusion notes. Under the "Inclusion notes", in addition to the justification for the inclusion of the paper, the reference from which the content for the scoping review was taken is also included. This is also cited in the "Inclusion notes".

3.5 Data presentation

The Data presentation is illustrated by the PRISMA flowchart developed by Moher et al. [150]. The studies included were divided according to the aim of answering the research questions. A total of 20 sources were extracted from which ten sources [7], [27], [109], [114], [151], [152], [153], [154], [155], [156] have been relevant for the first research question, eight sources [15], [94], [157], [158], [159], [160], [161], [162] for the second research question and two sources for both [9], [163] (Figure 10).

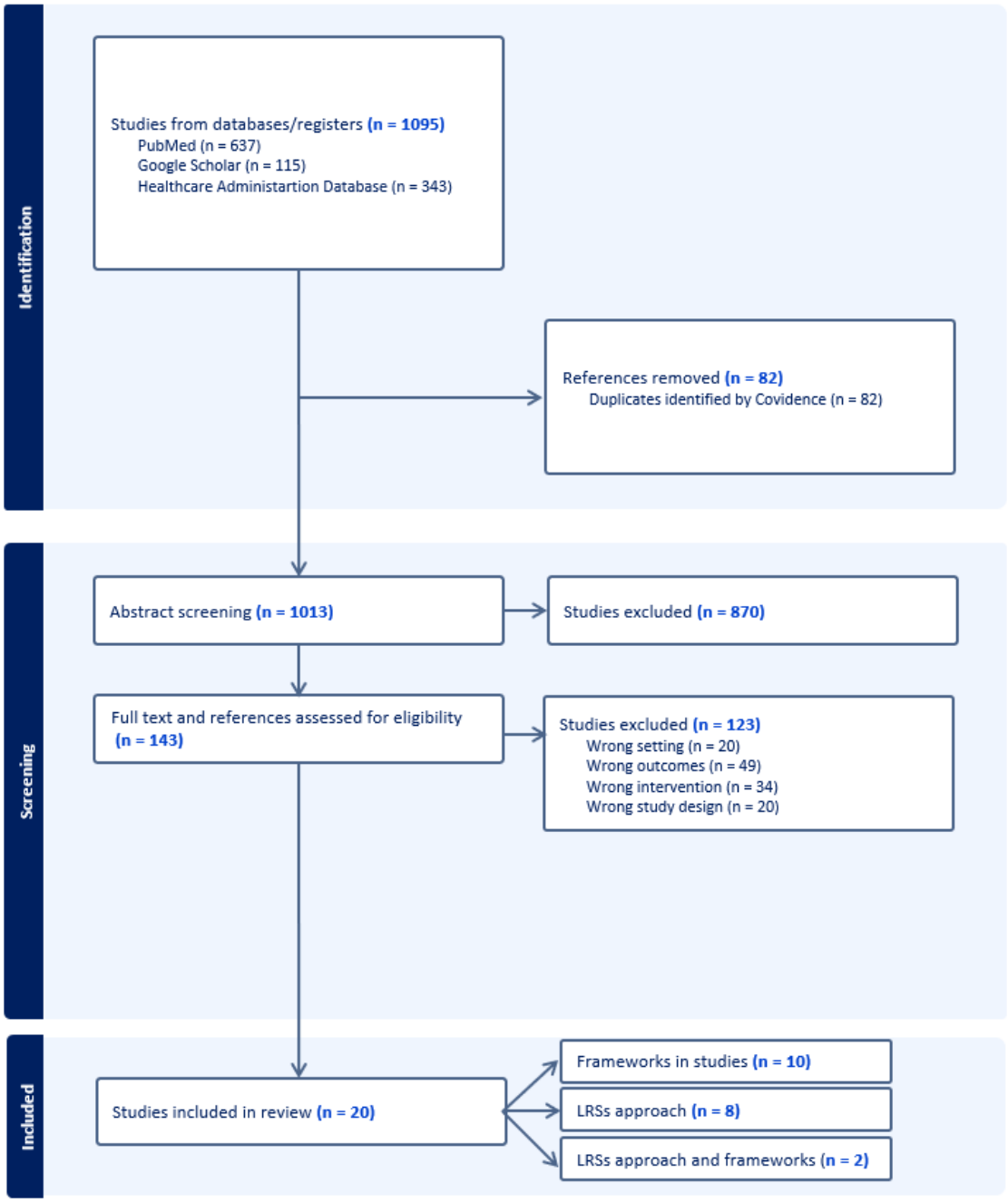

Figure 10 PRISMA Flow-chart of extracted evidence

4 Results

The results are divided into the two sections to answers the first research questions and the second research question afterwards. The second part compared the suitability of the frameworks which have been suitable for the assessment of DPHI.

4.1 Identified frameworks for possible DPHIs assessments

Regarding the first research question, it should be noted that not all the frameworks identified are directly focused on the assessment of DPHIs, as the two results of the search string with “digital public health” contained remarkably few amounts of 16 and 82 hits. Consequently, the frameworks that take a holistic and fundamental view on the evaluation of DHI were included, insofar as an assessment of potential DPHI would be conceivable or scientific assessments that corresponds to the characteristics of a DPHI already exists.

The scoping review revealed different viewpoints on the assessment of DPHIs. Different authors tried to provide a novel framework for the evaluation of these emerging technologies. The frameworks identified in the scoping review with their functionality, use and characteristics are listed in Table 6. The frameworks are examined in the discussion part to determine their suitability for assessing DPHI in LRSs. A total of "five" [60], [111], [152], [156], [164] frameworks were found, only "one" [156] emerged directly from the extracted evidence source. In contrast, the majority of "four" [60], [111], [152], [164] frameworks were taken from the references of the scoping review hits that match the inclusion and exclusion criteria. To examine the comparability of the frameworks for the assessment of DHI, the adapted EUnetHTA core model by Kolasa and Kozinski [7], which adds the three new criteria usability, interoperability and data security to the nine core criteria was used to compare core functionalities of HTA (Appendix 9). First, the objectives of the frameworks and the development process with the usage of the framework are outlined. Then the selection of the assessment criteria, domains and parameters are compared.

Of the identified frameworks, the NICE Evidence Standards Framework (ESF) for DHT was extracted most frequently. It was used, named or referenced in a total of eight [7], [9], [27], [109], [114], [151], [154], [155] different studies. Thereafter, the RE-AIM framework was mentioned three [152], [153], [163] times in relation to the assessment of a DPHI. This study [152] resulted in an adapted version of the RE-AIM framework for DHI. This version is primarily referred to in the following for the context of DPH. The Digi-HTA was also mentioned three times [9], [114], [151]. The DigiPHrame was the only framework which could be found directly [156] whereas the other frameworks were

extracted manually from the references. The Digital Health Technology Evaluation for Health Organizations (DHTEfHO) was identified in only one source [114].

Table 6 Overview extracted assessment frameworks

Framework	*Content/Focus area*
DigiPHrame [156] (1st version, 2023)	Checklist which assists developers, evaluators, policymakers and researchers in the systematic development and evaluation of DT in public health by providing an overview of criteria to assess DPHI.
Evidence standards framework for digital health technologies [60] (1st version 2019, latest update 2022: AI, data-driven technologies)	Standardized approach to guide developers and commissioners on the levels of evidence needed for the clinical and economic evaluation of DHTs by health and care systems in the United Kingdom.
Digi-HTA [111] (1st version, 2019)	A set of standards for judging whether digital health services are appropriate for usage in medical settings. It supports the evidence-based deployment of new digital technologies like mHealth applications, AI, and robotics in Finnish healthcare by integrating information security and data protection into the evaluation of digital healthcare solutions.
Digital Health Technology Evaluation for Health Organizations: An evaluation framework for early-stage technologies [164] (1st version, 2021)	It poses questions on the technology value alongside questions about the feasibility of its implementation and the risks inherent to its progress, while emphasizing the role of healthcare professionals as design partners of the technology in development.
RE-AIM adapted version [152] (1st version 1999, [165]**)**	Assessing and promoting interventions´ reach, effectiveness, adoption, implementation, and maintenance for improved public health impact.

4.1.1 Purpose and scope

A look at the aims and purposes of the frameworks shows that all frameworks are used to support decision-making for the selection and improvement of DHIs. The Intended audience of the frameworks differ in detail, for example, the DigiPHrame is designed for any decision maker (developers, evaluators, policy makers and researchers) responsible for the systematic development and evaluation of DPHIs. The use of the framework is intended to create a holistic overview of the use of the targeted DPHI [156]. The NICE evidence standards framework for DHTs can be used by evaluators and innovation teams in the National Health Service (NHS) and care system when assessing a DHT for a commissioning or purchasing decision. The aim is to demonstrate that evidence

standards are available to reinforce the value of DHTs to the United Kingdom (UK) health and social care system. It also aims to help DHT organizations understand what types of evidence need to be provided to inform commissioning or purchasing decisions in the NHS and care system. The ESF is not mandatory and therefore not a legal requirement when commissioning DHIs [60]. The Digi-HTA framework´s main goal is to assist DHTs with their HTA initiatives, to support the introduction of novel technologies into Finnish healthcare [111]. For example, by serving as a tool for the early HTA method, it may be able to direct the development of a product and foresee its subsequent development and market access [166].

The framework for DHT evaluation for health organizations (DHTEfHO) intends to give a way for determining the feasibility of industry partnerships for research and development (R&D) and piloting, as well as a useful tool for innovation advocates in health organizations to assess DHI in the premarket stage. The intended audience for this resource is technology managers and innovators in health organizations, it might serve as a springboard for industry discussion. It serves as a framework for the development of regional or internal assessment procedures and methodologies by organizations [164].

The RE-AIM offers a framework for figuring out which projects are worth ongoing funding, and which ones are effective in real-world settings. RE-AIM is consistent with evidence-based medicine and can be used to assess studies of various designs as well as randomized controlled trials. It states that evidence should be expanded to encompass aspects in addition to efficacy [165]. By concentrating investigation on each of these problems, the model can also be utilized to direct qualitative research activities and is therefore also used as a data extraction tool [152]. Above all, however, it is a framework for planning and evaluation that makes recommendations for improving the use of DPHI [153]. It thus serves decision-makers to generate comprehensive information which is used as a basis for the adoption or abolition of DPHIs [165].

The included technologies and interventions targeted by the assessment differ. The RE-AIM framework was originally designed for PHI [165]. The evidence found in the scoping review, was a study conducted to optimize the implementation of digitally supported interventions for secondary prevention of heart disease using an adapted RE-AIM framework for DHIs [152]. Reference is also made to this adapted RE-AIM framework for DHIs during the presentation of results and the discussion. DigiPHrame is the only framework that concentrates solely on the evaluation of DPHIs. The other three [60], [111], [164] can be used to evaluate a wide range of various digital health solutions. These could include mHealth, stand-alone software, internet resources for treatment or

diagnosis, health promotion, or applications that analyze data from medical equipment like monitors, scanners, or sensors. They are used to assess the suitability of digital products and services for social and health care and well-being for customers and employees in the health sector. The intended benefit could therefore be at the population levels as well as on the individual level or the healthcare system. Only the ESF explicitly not intended to be used for evaluating the following types of DHT [60, p. 6]:

- “Software that is integral to, or embedded in, a medical device or in vitro diagnostic (IVD), also called software in a medical device”
- “DHTs designed for providing training to health or care professionals (such as virtual reality)”
- “DHTs that facilitate data collection in research studies.”

4.1.2 Development process

The development process includes the organizations and people involved, as well as the development methodology and the foundations used for development. The background of the frameworks is thus depicted. The latest changes are also highlighted.

The DigiPHrame was developed in three steps, starting with a literature review of existing frameworks for public health and DPH that assess health interventions in the field of primary prevention and health promotion. Then all criteria from the scoping review were analyzed and grouped into domains based on the HTA Core Model from EUnetHTA. Each domain was then discussed with DPH experts from the Leibnitz Science Campus at the University of Bremen. The first version was published in July 2022. The framework was designed as a living framework so that further changes can be made after the framework has been applied to different use cases for DPHI (as in the latest version from June 2023) [156].

The development of the RE-AIM was originally based on the fact that the impact of PHI depends on the reach and efficiency (I=R×E) [167]. This thesis was extended by Glasgow et al. who included the setting of the intervention (adoption, implementation, and maintenance) [165]. The existing RE-AIM framework was subsequently adapted to the conditions of DHI, however, the validity and reliability of such modifications have not yet been examined [152].

The other three frameworks [60], [111], [164] were developed by the national HTA organizations of the countries in England (NICE), Finland (Finnish Coordinating Center for Health Technology Assessment (FinCCHTA)) and Israel (Israeli Center for Technology Assessment in Health Care). The ESF was the first HTA body globally which publish an ESF for DHT in 2018, since that it has been updated regularly the recent one

was in 2022, when updated the framework to include AI and data-driven technologies with adaptive algorithms, but also deployment considerations and design factors [9], [60]. The selection of the foundation domains were examined by expert consultations, by representatives of NICE, National Health Service England, Public Health England, and other government, academic, and private sector stakeholders and actively commissioned public input [60].

The Dig-HTA was performed by an integrative literature review to identify the state-of-the-art frameworks and their HTA domains to assess digital healthcare services focusing on mHealth, AI and robotics. After that unstructured interviews with seven technology companies and five healthcare service providers were done. In the end four multiprofessional workshops were held the participants consisted of a senior planning officer from the FinCCHTA and an HTA specialist, AI specialist, and medical doctor from the Faculty of Medicine, University of Oulu [111]. The first version was published in 2019 which covered a broad range of DHTs [9].

The DHTEfHO for early-stage DHTs has been released in 2021. It was developed by the basis of the insights from about 400 evaluations of DT which throughout the last five years have been planned for research and evaluation, pilot, or introduction programs by the Health Ministry's Division for Digital Health, as well as interviews with innovators in the health sector and industry. The framework is flexible designed to fit the particular requirements of every healthcare organization [164].

4.1.3 Framework utilization

The use of the frameworks is presented and, where appropriate, explained based on structure and methods used. In general, it can be said that each framework provides information and data that is used for the assessment. However, the frameworks differ in the further use of the data.

Each of the extracted frameworks is divided into several evaluation domains. Which contain further sub-categories. In the structure of these sub-categories, there are two different ways of expression among the frameworks. The ESF and the RE-AIM framework contain the specific requirements that a domain must fulfill, which are formulated as an order in the case of the ESF [60] or as descriptive content in the case of the adapted RE-AIM [152].

The other three frameworks [111], [156], [164] contain a number of open questions for each subcategory of a domain, which serve to guide the user through the assessment process.

DigiPHrame draws attention to the fact that not all questions are equally important or relevant to all interventions. Some questions may not be applicable and there may be no robust evidence to answer the question or no information available at all [156].

The ESF shows a preselection of which evaluation standard should be used. This classifies the health interventions into ten functional categories. These are divided into "Tiers" according to the degree of potential risk associated with the respective function. The term "potential risk" describes the extent of harm to the user that could result, for example, from unintended negative consequences for the user's health and well-being using the DHI. Some DHIs fit into several functional categories, then the highest risk category is used [154].

The DigiPHrame [156] and the DHTEfHO [164] initially only serves as an initial orientation for the DPHI developers to understand whether it is worth pursuing the development strategy or whether it needs to be adapted. DigiPHrame does not offer any methods for extracting evidence. There is a need for expert opinion to answer the questions when common sense reaches its limits on some issues. So that the elaboration and answering of the questions are primarily user-lead [156]. The feature of a checklist for reviewing the key criteria is also included in the ESF, but specific methods used in the NHS for evidence and effectiveness monitoring are advertised as recommendations for use in the framework. For example, the Digital Technology Assessment Criteria (DTAC) for health and social care which gives staff, patients, and citizens confidence that the DHI they use meet the national clinical safety, data protection, technical security, interoperability and usability and accessibility standards [60]. The DHTEfHO also provides options for quantitative surveys [164].

In the Digi-HTA, the domains of data security and protection issues are dealt right from the start with the help of external documents "Preliminary task of data security and data protection" and "Requirements for information security and data protection" and are also carried out by experts from this field [111, p. 323]. The HTA report is then again prepared by the HTA experts. Based on the home outcomes, FinCCHTA and the University of Oulu assess the product (Figure 11) [9].

A score for a numerical final overall assessment of the DHI which shows the impact and utility is provided by the RE-AIM [165] through the public health impact score (population based affects, reaches from 0-1), which is the product of the five dimensions. The data collected via the RE-AIM framework serves for several evaluation purposes [165, p. 3]:

- “Assessing an intervention's overall public health impact”

- “Comparing the public health impact of an intervention across organizational units or over time”
- “Comparing 2 or more interventions across RE-AIM dimensions”
- “Making decisions about redistributing resources toward more effective programs”

A traffic light model is used to rate the key areas in the Digi-HTA [111], wherein the various areas are evaluated. In partnership with the company, FinCCHTA posts the assessment on its website, using the overall point total as the basis for its conclusion [9]. In the DHTEfHO [164], the key-questions from every assessment category gets a score from 1-5, based on the parameters collected responses. A spider chart is recommended to visualize the DHI advantages and disadvantages (Appendix 7). The ESF[60] and DigiPHrame [156] do not offer an approaches for scoring. The DigiPHrame [156] follows the project management approach using an assessment indicator scheme (Appendix 5).

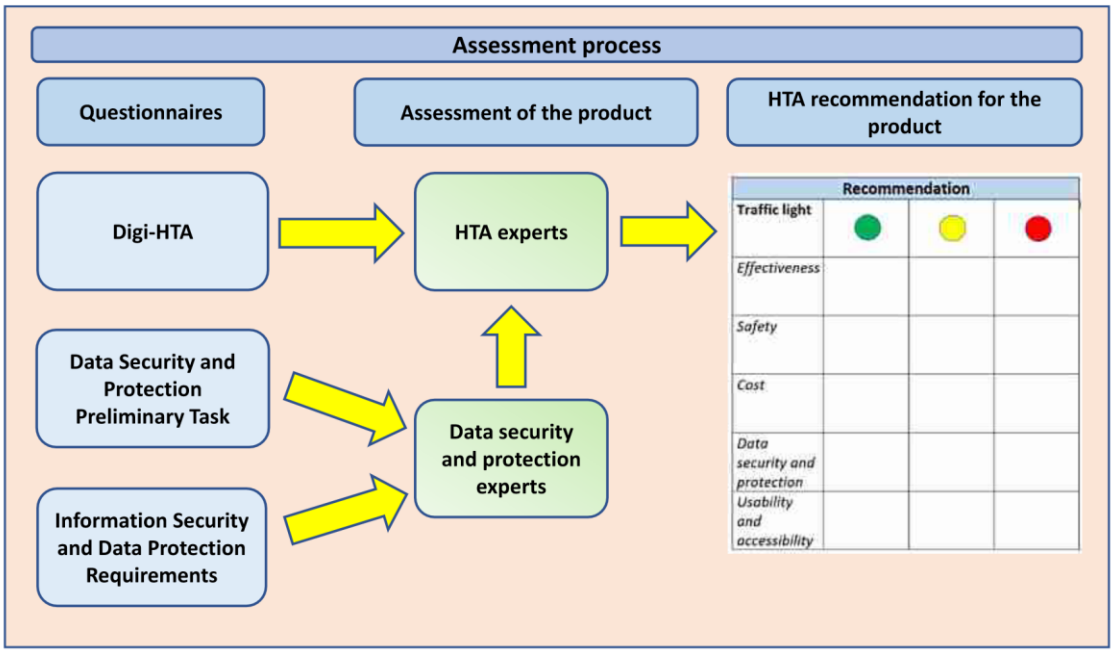

Figure 11 Assessment process for digital healthcare services in Finland
Source: Original from [111, p. 332]

4.1.4 Assessment criteria

To give an overview on the structure of each framework the full assessment criteria of each framework are listed in Appendix 6. In the following the applied assessment criteria are compared to the adapted EUnetHTA core model from Kolasa and Kozinski [7].This should serve as a point of reference for the subsequent discussion in order to provide a basis for comparison (Appendix 9)

The *Health Problem and Current Use of the Technology* are treated in four cases [156], [111], [164]. The DigiPHrame also determines under this point which health inequalities occur with the current technology [156] and the ESF draws attention to the expected costs of the new technology [60]. The RE-AIM makes no clear reference to the existing technology, but only describes the new users for the technology of the population [152]. The *Description (of the technology) and technical characteristics* are represented in two cases [111], [156]. Whereas in the Digi-HTA the view on the technology and its functions is done, the DHTEfHO only focuses on company capabilities to invest which includes the technological ones of the ability to develop the technology in case of missing expertise or experience of the company [164]. The ESF refers to the DTAC for assessing technological standards like an interoperability toolkit [60]. Further technical checks are not discussed as with the RE-AIM, where this category is missing [152]. The patient and providers *safety* is included by [60], [111], [164] mainly focusing on clinical safety for patients. The ESF also includes environmental aspects and the perspective of relevant health care professionals on outputs to give a professional oversight in throughout the design of the DHI [60]. Risk management and analysis are focus points in [111]. Intended and unintended health-related effects and negative outcomes are described in [152],[156] which should reveal potential harms and dangerous patient safety. To ensure clinical effectiveness in a systematic way is contained in all identified frameworks, except for the DigiPHrame which is not referring to a clinical study or method to provide valid, accurate or reviewed results. Instead, it focused on the impact of the DPHI on e.g. knowledge and behavior and quality of life and well-being [156]. *Cost and economic effectiveness* is in [60], [111], [164], [156] a main domain with a view several parameters like budget impact analysis (direct and indirect costs), implementation costs or cost-benefit analysis. The RE-AIM only discussed maintenance costs [152].

An holistic ethical analysis is not done in [111], ,[152] and in the ESF the ethical focus is vulnerable groups using the DHI, and eliminating unlawful discrimination (ensure access and measures for safe peer-to-peer communication, promoting equity according to the national equalities act) [60]. In DHTEfHO [164] the access for all to reduce inequalities and ethical consideration that could challenge the realization of the clinical potential needs to be secured. The ethical assessment in the DigiPHrame [156] is based on the influential “Principles of Biomedical Ethics” by Beauchamp Childress (Autonomy, Harm/non-maleficence, Beneficence, Justice) [168]. The *organizational aspects* are investigated by [60],[164],[156] which includes intra-organizational aspects (e.g. how information about a new technology is provided to the patients in the organization), inter-organizational aspects (e.g. how the communication between different organizations

occur), and health care system level aspects (e.g. how to set national objectives)[107]. The RE-AIM [152] only considers the setting and staff in a broad way to make sure that the adoption of the technology is possible. The Digi-HTA [111] only includes the perspective from the provider company (Integration of technology based on business model), stakeholder or system level perspectives are not taken into account. *Patient and social aspects* is represented in [156] it includes the patient and caregivers view on the technology. Besides the involvement of and co-creation with users in the development process, the DigiPHrame [156] pins out social, cultural and gender aspects which could be relevant to affecting the utilization of the DHI. In [111], [152] social parameters are not included. Social considerations from [164] are included to look at the target population its suitability, but the involvement to strengthen the empowerment of the users is not provided. In the ESF [60] it must be demonstrated that health experts are involved in the development, testing or design of the technology. During the implementation phase, care must be taken to ensure that communication about the result reaches the end user and that end user education and training is guaranteed.

A broad investigation of *legal aspects* is only included by the DigiPHrame [156] which focus points are on consumer protection, data security and data protection, medical device regulations and reimbursement legislation. As data security and protection is a solo criterion in the adapted EUnetHTA core model [7], regulations to this topic are examined in further parts. Accordingly, no further legal aspects are included in [111], [152]. The ESF [60] refers to meet the medical device regulations and care quality standards in the UK, but has no own domain for it. In DHTEfHO [164] it is undetailed which regulations should be met, it is just mentioned that the company should be able to meet any regulation demands.

The three new assessment domains in the adapted HTA core model *Usability, Interoperability and Data Security* are represented by all frameworks except from the RE-AIM [152] which only includes some aspects to meet usability standards by ensuring the satisfaction of the users with the technology and the DHTEfHO [164] which do not integrated interoperability. Besides the usability context, accessibility for the users plays a vital role in this domain. In the area of data security, the focus is on the quality, processing, transfer of data and transparency of the data creation process are in focus. In addition, the necessary data protection precautions must be taken, e.g. to prevent the use and disclosure of data by third parties. The suitability of DHI to databases and health information systems and the privacy concern are outlined.

The identified frameworks also have additional evaluation categories that have not yet been mentioned. The Digi-HTA [111] has additional categories tailored to the areas of

robotics and AI. To ensure scalability (e.g. through required infrastructure and resources) is one additional domain in [60]. Maintenance for long-term effects, sustainability and implementation approaches are extra domains in [152], [156]. The DHTEfHO [164] does not have a specific extra domain, but it focuses on evaluation from the perspective of the developing organization, thus preparing the company for the requirements needed to provide funds and resources.

4.2 Recommendations for an assessment of DPHIs in LRSs

The second part of the presentation of results lists the recommendations for the assessment of DPHI in LRSs. A total of eight publications were extracted from the scoping review, which provided information on the recommendations for the development, evaluation, and sustainable implementation of DPHI in LRSs. An overview of the selected studies can be found in Appendix 8. The recommendations and findings can relate to the strategic orientation of the assessment process as well as to individual domains that are necessary for the assessment.

4.2.1 Strategic-related factors

First, it should be noted that the process of assessment and evaluation is important to reach a consensus on the DHI. In the end, the process of assessment should serve to inform decisions on funding, implementation, and development (serve like an HTA report [106]). This is possible, for example, by carrying out validated studies and identifying obstacles to use. It is therefore about serving the information needs of decision-makers [9], [15].

In order to obtain the correct and targeted information, the involvement of stakeholders in the development process were considered important from six [94], [159], [161], [162], [163] [94]. For example, when supporting digital tools for a vaccination campaign, the HCD approach was important in empowering local stakeholders, e.g. to identify interdependencies with other systems. The strategic partnership and local collaborations, which is intended to succeed by involving users in the development process, can thus strengthen the sustainable access to hardware and software [161], [162]. In addition, developers should partner with local government, non-governmental organizations, technical sector operators to secure funding, guidance and infrastructure [163].

Cooperation between the government and providers during development and evaluation is mentioned by six [9], [94], [160], [161], [162], [163]. By [94] even as one of the most important factors. Accordingly, this collaboration is intended to strengthen the ability to scale in the long term. In order to develop and advance the instruments, the COVID-19

pandemic´s most effective solutions benefited from solid, long-term partnerships with dedicated governments [160], [162]. Therefore, the establishment of a network of digital health testing labs was also recommended. This network would include researchers, innovators, health service providers, and public institutions in charge of health policy, such as the state health ministry, to create a realistic and long-lasting environment for the development, testing, and validation of innovations in the field of digital health [9].

4.2.2 Domain-related factors

These are criteria categories or domains which are of particular importance in the evaluation of DPHI in LRSs. The planning and creation of an implementation strategy for the DPHI was taken up by three authors [159], [160], [161]. The implementation should be designed on a system-based approach where needs and practices of each setting must be taken into account [161]. The understanding of the socioeconomic context, stable electricity infrastructure, reasonably priced internet service, and supportive policies needs to be ensured. Additionally, because of these factors, the intervention can be tailored to the target users´ needs in order to make it practical, accessible, user-friendly, and trustworthy [159]. Mason et. al recognized from the experience of using digital tools against the COVID-9 pandemic in LRSs that, the implementers can concentrate on the content rather than the technology by using flexible digital tools. A DPHI should be implemented with the help of digital global goods (DGG) [169] or tools that are adaptable and useful in a variety of settings. So that the implementers can concentrate on user-centered design and scaling because of this flexibility. For instance, a lot of the DT were in use years prior to the pandemic, so users already possessed the resources and expertise needed to begin utilizing COVID-19 solutions right away [160].

Securing the technical requirements and functionalities was explained in six [15], [157], [158], [159], [162], [163] cases. The study by Steinman et al. stated that the barriers to better management of diabetes and/or hypertension through mHealth were firstly power outages which limited the mobile phone infrastructure in Cambodia, and secondly there are numerous competing providers, forcing patients to change phones frequently as each provider requires a different system to send mHealth messages [163]. Thus, while it is important to consider national data regarding internet and energy availability, it is also important to look at the actual situation, which may be marked by erratic or uneven supply, particularly in rural areas. Therefore, when assessing the DPHI, it is necessary to consider the implementation of a plan that enables the digital health solution to function offline and/or on battery power. For instance, employing SMS technology to apply technology in places with poor internet connectivity, or using renewable energy as a backup power source [159]. Despite the high penetration of smartphones, the actual

technical equipment of these differs between owners in urban areas and owners in rural areas, who have a low-tech device in comparison (e.g. with no Internet access) [157]. To increase the range and chances of technical implementation, the interoperability of the software and hardware with the central health system should be considered during development. This ensures open access to the DPHI [159]. For software decision it is mentioned by Mc Kenna et al. [162] that tools which are labeled as Digital Public Good (DPG) are good options to consider. Because besides the open-source status, the DPG or the DGG also were assess by their maturity, quality, and sustainability. This software-tools can be found in the digital good registries [170]. Furthermore, digital health platforms can be registered with pertinent use-case examples on the WHO's Digital Health Atlas [171] for more information for developers and implementers.

In addition to technical access, the financial aspect of use for the individual and ensuring the sustainability of a DPHI was emphasized in five cases [9], [15], [159], [162], [163] as a domain of evidence. The initial hurdles are the high investment costs for the provider and the inability to secure sustainable financing [15]. To assess the implementation cost, for instance, one must comprehend the local pricing structure for fixed internet versus low usage mobile data and phone bundles. This is due to the possibility that the latter is the only reasonably priced option for LRSs, and technology must be developed accordingly [159]. Besides that, even opensource software which are free of license cost still requires investments e.g. in software customization, personnel training which must be considered in the assessment of the DPHI. For the user, on the other hand, the affordability of mobile phones can already be a barrier, so many families in LRSs share a smartphone [163]. The evaluation in the LRS should show, from a financial perspective, that DPHI can be superior to standard care in the long term if it achieves the same health benefits but is cheaper because it improves health outcomes due to better adherence or even replaces significant staff capacity [9].

Summarizing the ethical considerations regarding data handling, McKenna et al. emphasize the importance of transparency in data collection and usage, proactive security measures to prevent breaches, and safeguarding against harmful or inappropriate data use. They highlight guidelines from various organizations, such as the WHO Global Strategy on Digital Health [39], DPG standard maintained by the Digital Square [172], and Digital Global Good standard by the DPG Alliance [173], which stress privacy protection and data security at the design stage of digital tools. Furthermore, the authors assert that proactive measures in data privacy are crucial for ethical preparedness, particularly during health emergencies, to ensure the rapid adoption of

digital health technologies while upholding privacy and security standards for individuals. This discussion appears in only one [162] out of eight articles analyzed [162].

The assessment considerations of evidence-based and safety aspects of DPHI in LRSs, was highlighted about half of the authors [9], [94], [161], [163] the following recommendations are particularly noteworthy:

- Evidence-based alignment: Authors emphasized the importance for manufacturers/suppliers to clarify how their interventions align with evidence-based clinical guidelines or existing protocols.
- Technical documentation: There is a need for comprehensive technical documentation regarding the reliability and stability of the technology. This documentation should include essential details such as minimum user thresholds required to maintain the effectiveness of DPHI and plans for technology lifecycle management, demonstrating functionality and long-term viability.
- Robust monitoring system: It was noted that a robust monitoring system, where stakeholders can report malfunction or misuse and share solutions, is essential. Collaboration between national and international organizations and leading digital industry players is crucial for effective monitoring.
- Demonstrated Role of DPHI: The identification of priority areas for public health, with a focus on therapeutic equivalency and safety and efficacy standards, where the use of technology can result in substantial social and economic gains.
- Conformity assessment procedure: Authors suggested a conformity assessment procedure for DPHI as medical devices before HTA, e.g. like a CE certification demonstrating overall safety and performance.
- Transparency and safety: Developers and suppliers should inform about risks associated with DPHI fully, including potential misuse, adverse effects, specificity, and sensitivity of DPHI used for diagnosis and monitoring.

The assessment of DPHI involves understanding and incorporating the contextual structures, with five [15], [157], [159], [162], [163] authors recognizing the regulatory characteristics of legislation, social norms and the diversity of the primary care system as an important element in the assessment of DPHI in LRSs. For example, it's critical to evaluate the disparities in the ways that organizational structures, regulations, standards, and community or public health components operate [15]. Especially when there is a lack of regulation, attention should be paid to how this is dealt with [159]. It is important to determine and possibly ensure the ideal option for a particular setting and community. In addition to legal requirements, Mc Kenna et al. are also concerned with recognizing social norms and, for example, using accepted identification options in the event of a

vaccination campaign. In this case, e.g. iris and fingerprint scanners turned out to be the best tool [162].

Alongside the social norms of society, user centricity is the most frequently mentioned point and was listed as a domain by all eight evidences [15], [157], [158], [159], [160], [161], [162], [163]. The role of the end user in the development of a DPHI should therefore be considered in the evaluation. This is because user-centered design is a key factor for the dissemination of DPHIs, both for the health worker and for the people in the population [15], [159], [160]. When developing DPHI, usability must consider the physical, mental, socio-economic, racial, and linguistic barriers that a community or individual may face [15], [158]. Since the DPGs are intended to help achieve the SDG, they could serve as a standard for developing inclusive and equitable DHI [174]. Because digital literacy and skills of ICT are important to use DPHI. Which means that “the assessment of a community or person’s ability to effectively interact with digital technology, understand and apply information,” is vital [158, p. 12]. The feeling of empathy for the use of DPHI should be able to be created, for example when looking at the design of a website to disseminate health information [157]. So that there is certainty about the trust that can be built in relation to the DHI in order to increase the intrinsic use of a DPHI by the population [158].

Access to health services and information should be equal an visible for the whole population [15]. Thus, the evaluation must take into account that the local context must be understood, especially in LRSs, in order not to exclude disadvantaged groups (e.g. older people, disadvantaged communities, minorities, illiterate people) [159]. The healthcare decision-makers should therefore focus on the ease of use, with accommodations for patient language, literacy and disability, and the community access to the infrastructure to ensure the effective usage for vulnerable groups and communities in LRSs [157], [163]. This could include for example to use multiple communication strategies in case of communicable disease outbreaks [162]. The special community structure in LRSs should be taken into account [15]. Regarding the application of AI, it is also important to consider the degree to which the underlying data and algorithms appropriately account for underrepresented and varied communities or individuals [158].

Monitoring and ensuring that healthcare personnel have proper training in using DPHI is also necessary for its implementation. Any new digital solutions offered in public health should concentrate on quick yet efficient training programs to properly educate health workers, given the current insufficient staff in LRSs. This is important, and solutions can be adopted quickly if there is a steep learning curve [159], [162]. In LRSs, there is a limited culture of data-driven decision-making in healthcare [15]. Thus, all stakeholders

need training in the fundamental AI "language" and culture addressing permission, privacy, and responsible use of AI technology [161]. However, using population healthcare data can be crucial to developing suitable governance plans and pinpointing crucial areas for funding and intervention to steer clear of funding "miracle solutions" that the media has pushed, such as expensive medical devices without adequate local infrastructure and knowledge [161].

5 Discussion

The promise of DT within public health rests on the ability to reach a vast audience at minimal expense, diminishing face-to-face interactions and their attendant expenses in executing public health initiatives. Simultaneously, it tackles various facets of efficient PHI and produces extensive data and unbiased metrics. These datasets can then be leveraged for assessing, overseeing, and ultimately refining public health schemes [3]. At the same time, the healthcare system is evolving from an individual approach to a population-based approach, making public health even more important. The new technologies in this field should help to solve problems of geographical access, facilitate the provision of appropriate interventions, reduce the cost of interventions and even raise public awareness of how to deal with health problems and promote healthy lifestyles, which in turn will help to increase patient empowerment [48].

Nevertheless, there exist several unresolved and possibly crucial issues linked to DPH. These primarily involve apprehensions regarding safeguarding privacy, ownership rights concerning health data stemming from technological utilization, and the overarching dependence on technological advancements over personal connections and community engagement. Moreover, numerous voices caution that disparities in socio-economic status and consequently health outcomes are prone to exacerbation due to differing levels of proficiency in utilizing digital technologies [3]. It highlights the presence of various obstacles hindering the effective deployment and development of DPHIs. Developing comprehensive frameworks that take into account the complexity of how these technologies may influence health on an individual, organizational, and societal level is essential to improving the value and efficacy of digital interventions for public health [3]. For LRSs the WHO has shown that there is a lack of standard for HTA or similar process where data systematic data collection leads to decision-making support [26]. Major concern about the pilotitis problem and increased ethical issues (e.g. accessibility) must be integrated in the assessment process. Ignoring these elements could lead to greater inequalities in health outcomes and the digital divide, which would eventually undermine the goals of public health programs [3].

This scoping review was conducted to identify appropriate assessment frameworks for DPHIs and to incorporate the LRS approach by compiling recommendations for the development and assessment of DPHIs in LRSs. In the following, the results of the first research question are discussed first, followed by the second research question where the identified frameworks for DPHI are tested for their suitability for an LRS approach.

5.1 Framework suitability for DPHIs

The results regarding the existence of assessment frameworks for DPHIs reveal a major research gap. The scoping review resulted in only one direct hit for such an assessment framework (DigiPHrame [156]). The other results, while not specifically focused on DPHIs, were organized holistically enough that they could be potentially used as a framework for DPHIs assessments. These were all taken from the scoping review search hit references and aim to review digital health or eHealth interventions. The fact that more hits were taken from this area could be due to the familiarity of these terms or the lack of establishment of DPH [27]. In addition, there were limitations in the search methods as the term “evaluation framework” and similar terms were not included in the Google Scholar search as this was beyond the scope of a master’s thesis, therefore further research may be required. By limiting the search to “digital public health”, any assessment frameworks that have a holistic approach to DHIs or eHealth may be unintentionally excluded from the scoping review.

Overall, it is therefore not yet possible to speak of sufficient research in the field of DPH assessment. Nevertheless, DHIs need to be integrated into public health concepts. The use of standards assessment framework for evaluation could be used as a comparative measure, for example to find out why certain innovations have not achieved a sustainable impact [3], [49]. National strategies, and mechanisms for DPH need to be developed by policy makers to enable intersectoral cooperation. Thus, one goal is to include medical professionals from the beginning, look for sources of funding as needed, and modify academic courses to reflect the changes brought about by the introduction of DPHIs [48]. If DPHIs are not conceptualized properly, it may lead to fragmented and diverse digitization efforts that may have little effect on the public and health systems and restricted interoperability [42]. For DPH, this means that the ubiquitous technological progress and the constantly expanding possibilities for the design, dissemination and communication of health topics should be contrasted with an approach that is primarily concerned with achieving public health goals such as the general improvement of health and the reduction of health inequalities [3]. From the theoretical foundations of DPH and the evaluation of DHI, methodological, strategic, and domain-specific characteristics crystallize that are indispensable for the evaluation of DPHI to carry out a validated, comprehensive, and meaningful technology assessment (Table 7).

Table 7 Most needed assessment techniques and scopes for DPHI
Source: Extraction based on [5], [13], [27]

Methodological prerequisites: • Function of the framework and clarity through targets • Scoring mechanism

Strategic prerequisites: • Holistic approach • Consideration of stakeholder interests • Flexibility and adaptability of the framework and its methods
Content requirements: • Effectiveness and evidence base • Data protection and security • Accessibility and user-friendliness • Sustainability and scalability

5.1.1 Methodological prerequisites

These approaches form the methodological basis for supporting targeted decisions. From a methodological perspective, it is important to formulate a clear objective, especially for DPHIs, to carry out an assessment it must be clearly defined which technologies DPH includes [27]. There should also be clear objectives in the desired areas such as evaluation of effectiveness, accessibility, cost-effectiveness, and user acceptance of DPHI. The presentation of the results must ultimately be understandable for the decision-makers. Following an assessment by users, the ESF shows that there is still a need for more precise definitions and terminology, as well as a more thorough description of the integration of standards into the current legal framework and their role in market access agreements [154]. Based on this example, the other frameworks must also provide a clear explanation of the context and goal of the framework´s role in the statutory reimbursement process. Even though these frameworks are not intended to substitute regulatory approval requirements or to assess adherence to pertinent technical standards for information governance, security, resilience, or interoperability [60]. Moreover to define the DPHI the framework should refer to which extend the DPHI fulfill one of the ten essential public health goals [27]. Regarding this, all frameworks target the expected influenced population and overall goal but not the specific public health objective.

Specific and measurable indicators should be defined to evaluate the performance of the DPHI. This could include, for example, utilization rate, improvement in health outcomes or cost-effectiveness. These results should be finalized using a score or visualized scale, a lack of clear scoring mechanisms would affect interpretation and comparability in the evaluation process [126]. Of the frameworks identified, RE-AIM, Digi-HTA and DHTEfHO have such a methodology. The RE-AIM, which is primarily used for reporting research results of health promotion programs and is a data extraction tool, but can also be used

for planning and development, refers to the five domains, reach, efficiency, adaptation, implementation, and maintenance for the translation of research results into practice (benefits for e.g. health care decision makers) [139]. These five dimensions are weighted equally in the evaluation, as in the DHTEfHO [164] where the answer to key questions (in health value and feasibility, organizational benefits and suitability, economic value and feasibility, usability and social considerations, company capabilities) gives an overview on the DHI. Critics of the RE-AIM mentioned that the assessment categories need to be reweighted when evaluating them because they differ based on the rapidly changing environments in technology development and environmental conditions [152]. The Digi-HTA [111] uses a traffic light model for each assessment category which mainly generate evidence through expert interview and literature reviews. The DigiPHrame and the ESF list specific methodological tools for individual questions or domains that can be used for data extraction or evaluation (e.g. disadvantaged groups identified: according to PROGRESS-Plus [156], budget impact analysis: Patient level information and costing system [60]). However, these are not listed comprehensively in the framework but only as examples and do not follow a coherent scheme that can lead to an overall result.

5.1.2 Strategic prerequisites

Due to the different types of implementations (hardware and software) and target areas that DPHI entails, the framework should take a holistic approach [109]. This aspect was already defined in the inclusion and exclusion criteria of a scoping review. However, there is a difference in the ESF which already pre-selects the required assessment criteria and needed level of evidence by dividing the technology according to the degree of risk for the patient (Figure 12). From the authors perspective it can be currently considered to be the most comprehensive DHT specific HTA framework [60].

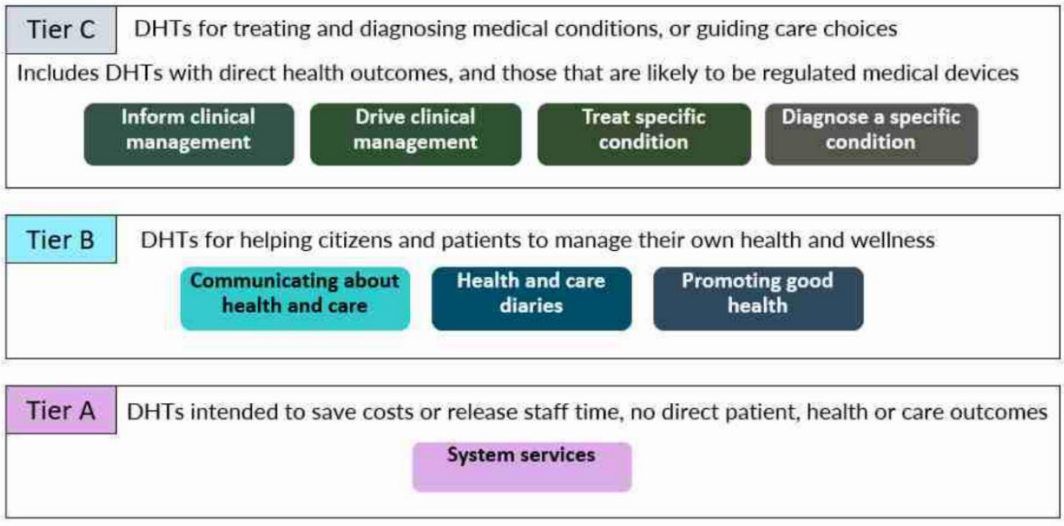

Figure 12 DHTs classified by intended purpose and stratified into risk tiers
Source: Original from [60, p. 8]

The lowest standard is tier A, with vertical DHT which have system impact, these are system services which services patients to the healthcare system without direct measurable patient outcome (e.g. EHR) [27]. The second highest level of evidence, Tier B, consists of communication and understanding following a horizontal function of PHI. This includes health diaries, which generally record health data such as wearables or symptom diaries, as well as providing information to the public, e.g. about a healthy lifestyle. Furthermore, the techniques for digital communication between patient and doctor or other health care professionals belong in this category (e.g. in telemedicine) In this tier, the focus is not on a specific health outcome (i.e. a specific treatment), but on communication and the transfer of information and data on general health. The highest level of evidence is Tier C, which includes specific digital measures for preventive behavior change for public health, e.g. against alcohol, cigarettes. It also includes, for example, apps that help manage specific conditions through personal responsibility (self-management) and may also include behavior change techniques. DHI that provide treatment suggestions, have an influence on diagnosis and care through their own calculation from collected data, make a diagnosis themselves or is actively recording health data in order to intervene in a specific condition are also classified in the highest category [154]. All three prevention varieties (primary, secondary, tertiary) are represented in here [27].

According to Digi-HTA authors [111] it is the first framework which combines novel technologies like mHealth, AI and robotics which are key drivers for the need of a new HTA framework. It enables HTA activities for a wide range of DHIs, and not a particular technology. This also applies to DHTEfHO, DigiPHrame and the adopted RE-AIM framework, whereby the latter two have their origin and orientation in the PHI sector. The author of the DigiPHrame mention, that the DigiPHrame is the first framework which combines the assessment of DHT and PHI. It is a comprehensive framework, so that users do not need to use multiple frameworks for their assessment, because it considers one the one side the technical aspects and on the other side e.g. ethics and data security. In fact, that it is the most recent framework released, it has not yet been tested and validated. As a result, a scientific justification is still lacking. The ESF is not directly geared toward PHI and lack at the population and prevention focus [120] nor is it relevant for technologies that are directly available by the public population, e.g. for apps through the Apple or GooglePlay store [154]. But it is oriented towards the purposes of DT for specific health goals. Such a function-based approach is also very useful for research purposes [3]. In general, the question whether the assessment serves for regulated DHT

or unregulated DHT which are available on the secondary healthcare market (e.g. wellness apps) should be clarified for DPHI.

For DPHIs, it is important to include the needs and perspectives of various stakeholders (e.g. healthcare providers, government authorities, patients) in the framework to ensure broad acceptance and applicability [13]. The participatory development with key stakeholders is an important basis for consolidating this multilateral approach to solution development [24], [139]. Up to now, the public health perspective, which considers the needs, attitudes, values, concerns, or reservations of the various user groups, has not been considered in the development of DHI. In the case of PHI in particular, acceptance of DHI among the general population must be ensured and the desired target group of DPHI must be addressed [11]. Lessons to deal with the complexity at early stage of DPHI design can also be learned from existing implementation strategies aimed at the HCD [139].

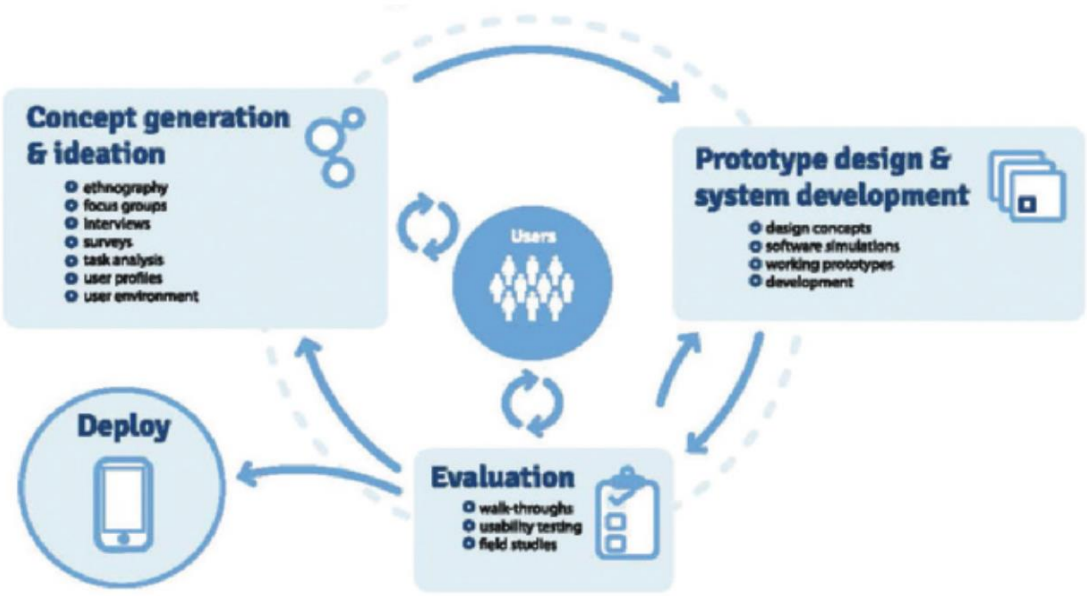

Figure 13 User-Centered Design Process
Source: Original from [175, p. 50]

The UCD process starts at the concept generation stage, as shown in Figure 13 on the example of a mHealth. The intended usage and purpose of the mHealth application are understood by doing a comprehensive requirements analysis once users have been identified. In this user requirements assessment process, human factors research techniques like as focus groups, in-context field studies, and one-on-one interviews are used. Potential cognitive biases, the social or organizational culture of the user group, the setting in which the application will be utilized, and the group´s chosen communication style are all significant additional considerations [175]. According to the definition of a DPHI by Wienert et al. [27] for DPHI assessment the inclusion of the user

perspective in the development process of a DPHI through participatory methods is crucial to support effectiveness and implementation with the aim of improving the health of the population.

With regard to the identified frameworks it can be stated that the ESF lacks of patient and public engagement [154], DigiPHrame does not include mandatory involvement of multiple stakeholders and was developed namely by DPH experts which does not rule out the involvement of several stakeholders but does not clearly confirm the extent to which they were involved. The Digi-HTA, DigiPHrame and DHTEfHO are also based on literature review and/or expert opinion from several technology providers, which could potentially distort the perspective, so that the methodological approach for the selection of evaluation criteria suppressed population perspective aspects and emphasized the provider perspective. However, the DHTEfHO emphasizes cooperation with start-ups, which can have a positive effect on the evaluation perspective, as they are usually closer to the end users in the development process also through the use of advanced evaluation methods such as usability testing [176]. A key component of the RE-AIM is stakeholder-driven practical application of the framework, which determines which features should be measured, which can be disregarded, which should be operationalized, and which should be improved first. [177], [178]. The integration of expanding cost criteria by including stakeholder perspective and stakeholder engagement are already under development [179, p. 8].

The assessment framework for DPHI should be adaptable to new technologies and changing healthcare needs [13]. The ESF shows this feature, as it was recently updated to include AI technology. This is also due to the fact that an iterative framework was iteratively modified through feedback before and after implementation [114]. The DigiPHrame [156], DHTEfHO [164] are designed as a living framework to keep up pace with the rapidly evolving field of DPH. In addition to the DigiPHrame, the ESF [60] and the Digi-HTA [111] see themselves as a holistic framework. Whereas the Digi-HTA is the only frameworks which can carry out fast comprehensive HTA [111]. However, this does not appear to be suitable for DPHI, as important criteria such as ethical and social aspects are not considered. The DHTEfHO can be adapted to the respective organization in order to improve the evaluation process, e.g. a health organization that treats a large proportion of patients from disadvantaged communities might concentrate on the framework's parameters related to social concerns and health equity [164]. The RE-AIM is also an adaptive framework that has already been adapted for DHI and was used for many evaluations for various PHI [152]. The methodologies employed in digital health assessment are diverse. Due to their significant context dependence, DPHIs

should be evaluated with consideration for both the assessment´s goal and maturity stage (Technology Readiness Level) [118]. For this master thesis, the searched assessment framework should aim at the assessment at the time of development and before implementation and therefore serves for technology impact assessment like an HTA report which is applied at this point of the technology level where the end user perspective is dominant [115]. For complex DPHIs the social considerations should be included at the same time, as the risks in this area are greatest for weakening rather than strengthening the health of the population.

An assessment framework should clarify which data sources are used and how data is collected, analyzed, and interpreted to make meaningful assessments. But for DPHIs there are still the paradox to overcome that if there is no evidence than there is no implementation which means that without implementation there is again no more evidence [24]. Innovative approaches to gathering evidence are needed to break this problem. Gaining faster, less expensive, and higher-quality insights is possible using simulation-based research [176]. End users will be encouraged to conduct research by taking these ways into consideration, as opposed to being put off by the time, expense, and complexity of more conventional methods. The gold standard of “RCT” will be retained for final evaluation, but new methods will be needed to justify implementation (early secured refinancing) and further development to counter rapid technological and environmental change [176]. When there is little chance of health danger, fewer RCTs are required. Therefore, the German Federal Joint Committee (which is in charge of determining refund decisions for the statutory health insurance) , reiterates that process improvements should be made to a larger degree and that the amount of evidence needed to prove benefit should be decided based on the kind of application [24]. It creates a tension field for DPHI where obstacles must be built on one side for diffusion to occur. It is imperative that the evaluation requirements based on science be refined in the core [24]. The NICE ESF is used to identify clinical evidence for "Tier A and B" DHTs can come from observational research, expert opinion, real-world evidence, or evidence synthesis studies. trials on test accuracy, concordance, intervention, retrospective, or prospective trials are included as potential sources of clinical evidence for Tier C DHTs. Level C DHTs also welcome qualitative research on patient or healthcare professional experiences.

Since DPHIs appear to span a range of evidence levels, different assessment criteria are consequently applied based on the required degree of evidence, making risk-level-based pre-selection deemed appropriate [9]. There is no such preliminary categorization for the other identified frameworks. The Digi-HTA has a specific domain for AI which

could be relevant for DPHIs, but it does not show a specific method for the data extraction. Moreover, neither the DigiPHrame nor the DHTEfHO show which techniques are applied. The RE-AIM as a date extraction tool focuses on literature reviews and RCT for evidence extraction [152]. A critical look should be taken at the already successfully completed assessment of scoping and systematic reviews, where the results of the study should be interpreted cautiously due to the paucity of empirical data demonstrating the causal relationship between certain practice factors and implementation success [180]. Moreover another exemplary problem in the RE-AIM was the risk of bias due to the small sample size and insufficient blinding of several studies for digital diabetes self-management [181]. This confirms that there is still some catching up to do in terms of structured evidence generation for DHIs and increasingly for DPHIs as the data sources used and the how the data was collected and interpreted are not specifically noted.

5.1.3 Content requirements

In order to help achieve public health goals, health-related, digitally enabled activities should be grounded on the greatest available scientific knowledge [44]. The framework should therefore aim to evaluate the effectiveness of digital health solutions. This can be done through clinical studies, real-time data analysis and evidence-based assessments. Clinical effectiveness is described as an evaluation criterion in all frameworks. In the DigiPHrame [156] it is this described rather vaguely as expected and unexpected health-related effects. In addition to the classic efficacy (e.g. influence on mortality), the overall quality of life is also addressed, including aspects such as behavioral change or the influence of the function of a DPHI on, for example, everyday working life.

Even with DHIs, comparing the effectiveness of two interventions is difficult because it includes other factors such as digital literacy or usability in addition to traditional medicines and medical devices, which are difficult to compare. An approach such as the DigiPHrame therefore seems more comprehensive, as these factors can be even more pronounced in DPH because they are not individually tailored on the user. All frameworks consider the economic benefits and advantages of DPHIs, except for the RE-AIM, which just takes maintenance expenses into account. Like clinical efficiency, there is still a lack of substantiation, as there have been few studies completed in this manner before the year 2024. As a result, it is challenging to draw conclusions regarding the economic benefits of DPHIs that are supported by science [4]. According to Darmann-Finck et al. [44], DPHIs should not just be evaluated based on efficacy and efficiency data. Instead, to reinforce or prevent them, it is vital to consider the unintended positive and negative impacts. For instance, the detrimental effects of societal pressure on one´s health to maximize oneself, the advantages of DPHI for groups, or the rise in heteronomy.

Once the benefits of DPHI have been demonstrated, they must also be assessed in terms of their impact on the foundations of public health. This includes social justice, health equity and social and environmental determinants of health (e.g. ethical aspects) [13]. The impact must be analyzed and, where appropriate, the conditions identified under which the use of DT can prevent existing health inequalities between social groups from being exacerbated due to differences in access to and competence in the use of the technology in question [44]. Thus, a variety of living situations at various levels can be linked to these disparities in access to DPHIs. These are mostly influenced by geographic variables, such as poor infrastructure, socioeconomic level, sociodemographic characteristics, and the culture surrounding digital health solutions. We should consider the following, for example, how simple is it for users to use DPHIs and are they open to all demographic groups and devoid of barriers? Either a digital technological positivism and determination or the necessity to address pressing public health issues should be critically evaluated prior to development and implementation apart from pressure [22]. A suitable guidance for public health officials, policymakers, and researchers to think through digital technologies in public health, is restricted to the three areas of social justice, ethics, and health equity (Table 8).

The RE-AIM framework will be adopted to health equity issues in the future [179], at this point it only considers the user satisfaction and acceptance [152]. For all other frameworks, user acceptance and accessibility are addressed. including the topic of transparent handling of data usage, which is also neglected in the RE-AIM framework. Based on these facts alone, the RE-AIM framework [152] is not suitable for the overall assessment of DPHIs in this adapted version.

This should raise the question of the perspective from which the evaluation takes place and for what purpose. The same applies to the Digi-HTA which was used, for example, for web-based applications (digital service for self-monitoring of symptoms for citizens) or digital therapeutics solutions for patients (mHealth application, which has wireless connection with a measuring and monitoring device) [111]. There it was already reflected by the author [111] himself that the most important improvement in the review is needed for usability and accessibility to apply it holistically for all DHIs. This is why the Digi-HTA is not yet suitable for DPHI at this stage. In addition, the assessment should consider ethical, social, and legal requirements, which are also not considered holistically, but are only focused on data protection. The reason is that these seem too time-consuming, as the aim of Digi-HTA is a rapid assessment to keep up with rapid technological progress [111]. The trigger for utilizing adaptive HTA rather than complete HTA is one of three things: low budget effect, safety, and urgency. It has been discovered that adaptive HTA

is quicker, more effective, helpful for decision-makers, and lessens effort duplication. But there is a lack of uniformity, openness, and uncertainty quantification, particularly in HTA systems that are still in their infancy. [182].

According to the authors Kolasa and Kozinski [7] and Vis et al. [109], the ESF does not address the impact on the healthcare system as a whole and lacks guidelines for evaluating organizational, ethical, legal, and technical needs and functionalities. Rather, it ignores the usability of DPHI assessments and instead concentrates only on the clinical efficacy and economic impact of the DHIs.

Another important evaluation criteria should consider the protection of sensitive health data and the security of the technologies to ensure data protection standards. This is addressed by every framework, except the RE-AIM. Some general recommendations to reduce the chance of health data breaches were that the health organization backs up the health data regularly, the software should be screened for loopholes and software should bet updated to latest patches. Besides the technical issues it is also important to introduce data security problems to health care workers e.g. by logging out of the account when entries of patient data or viewing patient reports have been completed. Perhaps the most crucial factor for the DPHI evaluation is that data and privacy concerns are integrated from the start by limiting the quantity of personal information gathered, determining how long the information must be kept, encrypting information when it can, and deleting it as soon as possible [183].

Table 8 Considerations for public health officials, policymakers, and researchers to think through digital technologies in public health
Source: Based on [22, p. 414]

Domain	*Guiding example*
Ethics:	
Justification	E.g., the DT being used should achieve an explicit and unambiguous public health goal or function, rather than a technological end on its own.
Impact	E.g., an evaluation plan of the short- and long-term implications should be developed when using a DT for public health goals and/or functions, as well as a concrete and feasible plan to ensure rapid and effective de-implementation when the DT engenders more unintended health equity and social justice harms than benefits.
Transparency	E.g., the process should be open and inclusive of all relevant public health stakeholders and members of society. Transparency also entails meaningfully including impacted populations in the decision-making.
Health equity:	
Benefits	E.g., the analyses of benefits should consider whether, when, for whom, and under which circumstances the internal and/or public-facing DT can equitably benefit populations and countries.
Burdens	E.g., burdens must be both justifiable and distributed equitably.

Root causes	E.g., ideally, a DT should purposefully be developed and implemented to help address the root causes of inequities in health.
Upstream action	E.g., ideally, a DT should purposefully be developed and implemented to help enable upstream (vs. downstream) action to foster public health.
Social justice:	
Context	E.g., public health practice has, intentionally and unintentionally, affected certain communities disproportionately. Given such past and present histories, the local and global context in which new DTs in public health are implemented should be front and center in considering the implications of these technologies.
Profit distribution	E.g., given the increasing participation of corporate, non-state actors in creating and implementing DTs and in public health more broadly, direct and/or indirect forms of equitable compensation and profit redistribution should be devised.
Misuse	E.g., potential redirection of the data or DT use for corporations' profit, political gain, government surveillance, privacy erosion, or social control, rather than public health purposes, should be prevented.
Public good	E.g., the foundational spirit of public health of advancing the health of the people and that population health is a public good should prevail and be safeguarded.

A final important point to consider when evaluating DPHIs is how sustainable the implementation of the digital health solution is and how it can be transferred to larger populations or other regions. Scalability and the implementation of DPHIs is very much related to how political commitment is ensured, cross-sectoral collaboration between stakeholders is achieved, economic investment is given, capacity building for health workers can be enabled and transparency of the provision of DPHIs to the population exists [13]. In view of climate change and the consumption of resources caused by digital technologies, the question of the ecological dimensions also arises when evaluating a DPHI [44]. The ESF [60] and the DigiPHrame [156] fulfil the points by paying attention to the implementation as well as the scaling of the DPHI. Whereas the DHTEfHO [164] only focuses on unintended effects, the proposed budget impact and business capabilities for the implementation.

Lessons can be learnt from the DHI assessment frameworks. A categorization of the DPHI appears to be difficult due to the broad field of application [61] (e.g. mHealth for health prevention and health promotion, health information websites and portals, surveillance systems, telemedicine, or wearable monitoring). Therefore, a categorization should be made as per the ESF which prescribes evidence standard for the DPHI depending on the risk for the user. The capabilities and capacities of the developer company are particularly important in connection with the dissemination and implementation of a DPHI. The DHTEfHO provides insights into what financial, human, material and social resources are necessary for healthcare organizations to design a

successful implementation for DHIs. The Digi-HTA provides important information that is relevant to the emerging technology of AI (e.g. data sovereignty and data transparency), as well as the role of an assessment framework in an HTA process. This should be defined by a clear objective when applying the framework.

Nevertheless, in conclusion, it can be stated that the DigiPHrame is the only framework that includes the evaluation criteria for DPHIs but has some catching up to do in terms of methodology. For example, there is a lack of prescribed means for generating evidence and a mechanism that enables weighting between the individual areas and makes a result quantifiable to establish comparability. The DHTEfHO only looks at the evaluation of the development and implementation of a DHI from the perspective of a healthcare organization. This means that only the resources and means that are important for the healthcare organization are examined. However, it does not analyze the technical characteristics of the DPHI, particularly regarding interfaces for integrating the DPHI. Interoperability is not a subject of the study, which could significantly influence the implementation and realization of the intervention in the further course. The ESF, on the other hand, assesses the technological requirements since specific guidelines that apply in the UK. The exclusion criterion for DPHI is that the ethical and social user-related aspects are insufficiently described. In the end, the suitability of the frameworks for DPHI is poor; none of the assessment frameworks designed for DHIs fulfils all the important points required for an assessment of DPHIs. The gap is only closed by the DigiPHrame, which has not yet been tested and has therefore not yet been validated. However, it has the necessary prerequisites to provide a comprehensive overview of the DPHIs. For scientific use in the sense of HTA, it requires more systematic methods and evaluation mechanisms.

5.2 Frameworks suitability for DPHIs in LRSs

After checking the suitability of the assessment frameworks identified for DPHIs, only the DigiPHrame was found to be eligible. Therefore, it will be reviewed below for its further suitability for LRSs. Lessons learnt from DPHIs in LRS could also be helpful globally when designing and implementing DHIs to address acute or chronic public health emergencies, such as the detrimental effects of large population movements and the rapid spread of infectious viruses and global pandemics [15]. This is why the “DigiAfya” project was chosen in collaboration with countries where resource constraints are greater than in HIC. By transferring recommendations on DPHI assessments to LRSs, it is possible to identify possible weaknesses in the identified frameworks. Alternatively, methodologies such as the HTA, which is not yet so widespread in Africa and is less used, should also be made useful. The scoping review therefore serves as a starting

point on which further research can build to improve the quality of DPHI assessments in LRSs. To answer the research question, the choice of a literature review as basic research therefore seemed appropriate.

The results highlight key considerations for the assessment of DPHIs in LRSs (Figure 14). It emphasizes system-based planning tailored to local needs, including factors like stable electricity and affordable internet for accessibility. Technical requirements should account for varying smartphone capabilities and interoperability with existing health systems. Financial sustainability is crucial, with evaluation of deployment costs and affordability for users. Ethical concerns stress transparency in data handling and proactive security measures. Assessment should focus on evidence-based alignment, robust monitoring, and adherence to safety standards. Understanding regulatory and social contexts is essential, alongside user-centric design for equitable access and usability. Training healthcare personnel is critical given limited data-driven decision-making culture in LRSs. Overall, stakeholder collaboration and inclusive development are key to successful DPHI realization in these settings. Mugu and Nzuki [184] and other research in LRSs [185], [186], who analyzed the health determinants in the introduction of e-health services in developing countries, came to similar conclusions. Encounters to low adoption rates for new systems often boils down to the key challenges of achieving user engagement at all levels, establishing necessary infrastructure, and ensuring security and integrity measures are in place. These factors are critical for overcoming adoption barriers and successfully integrating new technologies into operations.

Figure 14 Key considerations for the assessment of DPHI in LRSs
Source: Own illustration based on result of the second research question

The conspicuousness of the required different assessment of DPHIs in the LRS is shown by the fact that in LRSs, potential digital health strategies and solutions should meet the specific needs of the country´s healthcare system and culture. They should also be technologically sound, respect the social, cultural, environmental, and economic constraints of the region in which they are implemented, and promote self-sufficiency. [48]. Opinions differ on the application of the common assessment framework in HIC and LMIC. Kowatsch et al [121], on the one hand, show in the development of a design and assessment framework for DHIs that the most important evaluation criteria and implementation barriers can be the same globally and thus possibly also apply universally. One the other hand the RE-AIM framework used to guide evaluations in Cambodia [163], Mexico [187] and India [188] with limitations found. From this it emerged that the next steps by putting the RE-AIM framework into practice will require modifying the RE-AIM technique to evaluate programs that build on existing resources, require little upfront planning, and are relatively easy to implement with existing resources [187]. Non-contextual issues have also been raised, stating that the definitions of outreach and adoption overlap at the individual level and it is difficult to distinguish between the two [188]. The ESF has also shown interest by governments, academic groups and national technology assessment institutions in HIC to transferring it to their countries, but also LMIC like Indonesia and India are interested [154]. The ESF might not be directly applicable in other nations with different health systems and contexts, but the method that groups DHI according to how they interact and how risky they are for patients could be a helpful place to start when looking for pertinent frameworks for these kinds of systems, or if none already exist, to create your own [27]. In addition, an improvement has already been made to the ESF, which better analyses the vulnerable groups and their access to DHI [154].

This shows that frameworks for LRSs must also be customizable, to specific needs. This supported by the findings of Mc Kenna et al. that the DHIs functionalities differ when used for a large-scale vaccination process in LMIC. There are several aspects of each of these DHIs that need to be evaluated considering the criteria and conditions unique to each country [162]. Also, the results from the assessment of a DPHI from HIC cannot always be transferred to LMIC, but they are probably generalizable to countries where an HTA approach is used to make decisions about public financing of health care [151].

A comparison of the most important assessment criteria (Figure 14) with the DigiPHrame identified in the scoping review is intended to show the extent to which these have been analyzed and addressed. For DPHIs, infrastructure, access to the internet and electricity in LRSs is particularly crucial. Research shows that in areas with unequal access, a

quarter of community members and patients/carers have access to the internet for ten or fewer hours per day [151]. The DigiPHrame [156] includes this aspect, furthermore the question is asked how fast the Internet is and whether a broadband connection is available. The importance of speed naturally depends on the data transfer rate required for the proper functioning of the intervention.

The technical equipment is also addressed and the issue of available open-source software, which favors the use of digital public goods, is included. An open programming interface for all public health goods is another crucial factor e.g. for wearables to take into account in order to customize them to the needs of the healthcare system and local communities [92] using international standards will help to support interoperability [162]. In LRSs, prioritizing cost-saving DPHI that achieve similar health outcomes at lower costs can be beneficial [9]. This is ensured in DigiPHrame by applying possible economic evaluation methods. The implementation, sustainability and utilization costs are also considered. The possibility of long-term reimbursability through legal requirements is also analyzed. The regulatory and social requirement contexts are presented very well overall.

The necessity of long-term fixes and precise guidelines for data security and protection are crucial in LRSs and must be considered right away. Open-source methods appear to provide greater accessibility when choosing a tool [162]. In this approach, a distinct domain for data security incorporates ethical issues of data confidentiality, enforcement of data integrity, authenticity, and availability, and a transparent presentation of the data handling is documented. There is a noticeable risk of bias in evaluation studies in LRSs, e.g. to prove effectiveness, as groups of people are often excluded in LRSs due to instrumental disadvantages (e.g. no internet connection) or language barriers that prevent participation [155]. Proactive measures against this and other health inequality issues are also ensured in the DigiPHrame. The review takes place according to the required digital literacy. Targeting illiterate and low-literate people is a challenge for digital media since they may not be suitable for standard text-based designs, which need for whole different strategies, an example for that could be serious games like MANTRA which improves knowledge of maternal health, neonatal health, and geohazards in women in rural Nepal [97]. According to a review of mental health app evaluation frameworks, frameworks that include diversity, equality, and inclusion criteria have the ability to identify apps that do not cater to the needs of marginalized groups and, as a result, it motivate app developers to make improvements that would help these groups [189]. Ensuring safety standard for an evidence-based alignment and the data needed are included in the DigiPHrame but there is a lack in robust monitoring, as monitoring is

taken for granted as an overall goal of the framework there is no recognition of plan in future and sustainable follow-up check of health effects. Same problem is seen within the workforce capabilities which are mentioned at the implementation process. Where a successful integration depends on health professionals and staff involved having at least basic computer (or data scientist),skills which creates the need for training and education [190], [191],[185]. In the further course of the utilization of a DPHI, no plans are considered to issue the necessary personnel resources.

The most important overarching goal in the evaluation of DPHIs in LRSs is the increased co-operation and involvement of relevant stakeholders and government in the development, implementation, and evaluation process. As a result, this patient-centered strategy helps to close the gap in health. Under “Intraorganizational Relationship”, the DigiPHrame includes collaboration with public and private partners to ensure sustainable financing and local ownership. The most important stakeholders are included through “co-creation empowerment”. There is no obligation to involve them, but the orientation of the framework shows the proximity to the end users through the extensive evaluation of usability, accessibility, and equitable access. For example, ISO 9241-11 for “Ergonomics of human-system interaction” [192] is listed as a standard for review. It is currently unknown which technology breeds widespread inequality because of its technical features. However, when selecting a platform or device, it is preferable to choose ones that are user-friendly, have been developed in collaboration with potential end users, have been integrated into users' daily routines and workflows, and have been tailored to the local context, culture, language, and literacy levels [185]. HCD is extremely essential since it simplifies the evaluation of a community's or individual's capacity to use DT, comprehend information, and apply it [98], [193]. Thomas et al. [193] state that while HCD is well established in commercial smartphone apps, it is absent in DHIs in LRSs. The trust of a person or organization in the DPHI, which must be established in LRSs, as listed by Holmes Fee et al [158] is also mapped in the DigiPHrame.

The DigiPHrame comprehensively addresses critical factors such as internet and electricity access, speed, availability of open-source software, technical equipment, data security, regulatory requirements, and social contexts. It also emphasizes stakeholder collaboration and user-centered design which plays a vital role in the assessment of DPHIs in LRSs. However, there are some gaps when applying the DigiPHrame in LRSs. It lacks detailed plans for ongoing and sustainable monitoring of DPHI health impacts, treating monitoring as an overarching goal without specifying future measures. While implementation relies on the competence of health professionals, there are no comprehensive plans for providing necessary training and resources. Additionally,

considerations for the long-term provision of required personnel resources and structured strategies for continuous review and adjustment of interventions based on collected data and experiences are missing. These gaps could affect the long-term effectiveness and sustainability of DPHIs in LRSs. The DigiPHrame reflects the main important aspect, but it needs methodological improvements to promote practical usefulness (e.g. scoring mechanism), as well as consider sustainable factors for strategic planning. It is therefore not fully suitable for LRSs, further research in testing the DigiPHrame in LRSs is necessary to validate and adapt fine modifications.

6 Conclusion

Digitalization has the potential to transform public health efforts fundamentally. The goal of DPHIs is to expand analytical and intervention capacities to improve the health opportunities of all population groups and enhance social cohesion. Digitalization offers significant potential for fulfilling public health tasks, such as health surveillance (e.g., digital epidemiology methods), prevention including early detection (e.g., health apps on mobile devices), and communication and social mobilization (e.g., social media). Key prerequisites for realizing the potential of digitalization in public health include independent funding, consistent implementation research, and a crucial shift in perspective toward user orientation. It is essential to substantially promote sensitivity to social and ethical challenges and accountability arising from using health-relevant data, integrating these aspects into the education and training of all relevant stakeholders. The assessment of DPHIs presents significant challenges, particularly in goal orientation and classification for evidence generation. These difficulties stem from the variety and complexity of DPHIs, as well as the different stakeholders and interactions they involve, generating different direct interactions with users. This diversity complicates the transferability of evaluation results. Additionally, the delivery system where the intervention occurs is another complex factor with many actors, including healthcare laypeople. Without embedding DHIs within a broader public health framework and ensuring a solid evidence base, technological advances may lead to non-evidence-based and need-driven public health strategies being overlooked. Therefore, a suitable assessment framework for DPHIs is necessary.

The development of assessment frameworks for DPHIs varies, incorporating methods from HTA institutes, literature reviews, expert interviews, and companies, each bringing unique approaches. This diversity leads to a wide range of criteria and evaluation metrics, which are often not comprehensive enough, e.g. tailored to the national health and care system and less applicable to global public technologies like app store offerings. The master thesis reveals a notable gap in the development of appropriate assessment frameworks for DPHIs, although holistic DHI frameworks exist. This gap in DPH research is further highlighted by the remarkably few hits in the initial search for suitable frameworks, underscoring the need for more research efforts in this area. One reason for the few results could be due to limitations in search methods. Therefore, further research may be required, as the need for specific assessment frameworks for DPHIs was proven. Among the identified assessment frameworks, DigiPHrame stands out as the only framework that includes all necessary assessment criteria for DPHIs.

However, the DigiPHrame lacks by the fact that methods for extracting evidence are not systematically represented, and content decision often relies on expert opinions for specific issues. Moreover, to use it for decision support, it needs an overall quantitative assessment method (e.g. scoring mechanism) to make comparisons possible. For instance, DigiPHrame describes clinical effectiveness vaguely. Adhering to established evaluation requirements is difficult as it necessitates a clear definition of the intervention and strict adherence to the study protocol. Like other DT, DPHIs are subject to a high development dynamic, involving continuous evolution in both technical intervention and human-machine interaction. Users must adapt to new procedures and learn how to handle them before their full potential is unlocked. Short life cycles of interventions make it challenging to conduct long RCTs. Thus, new adaptable study designs and criteria have been introduced to DHIs and are needed for DPHIs to address the lack of evidence regarding the benefit or risk to society and individual users.

The effects of DPHIs are influenced by social, institutional, organizational, and legal frameworks. In LRSs digital health has significant potential for substantial gains, as there are less affected by oligopolistic practices, proprietary procedures, entrenched interests, and outdated regulations than wealthy nations [194]. The problems of DPHIs in LRSs are like those of HICs, but the scale is greater and leads to far more detrimental health consequences for the population. In addition, resource problems and lack of co-operation with the government make the introduction of DPHIs more difficult. The second research question of the scoping review highlights the key considerations for assessing DPHIs in LRS. These include stable power supply, affordable internet, and ICT compatibility. Financial sustainability, transparent data processing, robust monitoring and security standards are crucial. In addition, user-centered design, training of healthcare staff and collaboration with stakeholders are crucial for success. The DigiPHrame provides a solid foundation for the transfer and application of assessment frameworks for DPHIs in LRS, which could be extended through targeted improvements e.g. ensuring the sustainability of resources by strategic planning. Overall, this master's thesis highlights the inadequate research and lack of a framework for the assessment of DPHIs in LRS and the call for verification of existing ones.

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Bibliography

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Appendix

Appendix 1 Digi-HTA framework extraction [111, p. 333]

HTA-Domain and Criteria
Company information
Contact information of company.
What is the company's business model?
Are quality management systems in use? Which ones?
Product information
The name of the product.
Short description of the product.
What is the product's readiness level (TRL levels 1–9)?
Which platforms and platform versions of the product are available?
Does the product have CE and/or FDA approval?
Is the product a medical device, and what classification does it have?
Is the product classified according to MDD or MDR requirements?
Does the product meet the electrical safety requirements for medical devices (if applicable)?
Does the use of the product require registration or login?
Does the use of the product require strong identification?
Does the company have any plans for post-market surveillance of the product?
What kind of product support does the company offer?
What is the intended use of the product?
What are the intended user groups?
What problem in the healthcare system is the product trying to solve?
Is the aim of the product to replace any existing healthcare services?
Does the introduction of the product cause any changes to the premises, information systems, or care processes?
Is the product already in use elsewhere in Finland or worldwide? Where, and for how long?
What kind of support does the end user need to use the product?
If users need training, who organizes it? When? What is the language of training?
Does the company have instructions (e.g., a project plan) for healthcare service providers to ensure fluent introduction of the product?
Technical stability
What is the company's testing process?
What is the company's process for handling error messages?
Does the company have the capacity to roll back to previous versions of the product?
Does the company have a process to proactively monitor the running of systems and system components to automatically identify faults and technical issues?
Does the company have a plan for decommissioning the product?
Has there been any downtime or impairment time in the use of the product during the last six months?

Appendix 2 ESF for digital health technologies framework extraction [60, p. 39]

Delivering value

Standard 17: provide a budget impact analysis

Applies to DHTs in tiers A, B and C.

Information that can be used to meet standard 17

Provide a budget impact analysis relevant to the setting the DHT is used in. This can be done using information about the value proposition given in response to standards 10 to 13, and the outcomes from studies shown in standard 14, or the real-world evidence in standard 15.

For tier B and C DHTs, the budget impact analysis should include:

- size of target population and uptake estimates
- all direct costs associated with the technology and implementing the technology, including cost of the technology (purchasing, updating, maintenance), costs of staffing and training, costs of supportive IT infrastructure needed to implement the technology
- all direct costs associated with the comparator
- relevant indirect costs associated with the technology and the comparator, reference test or current practice.

For tier A DHTs, a simpler analysis may be more appropriate. This would include a comparison of direct and indirect costs and resource impacts between the DHT and current practice.

Estimates of resource use should include:

- length of hospital or care home stay
- number of hospitalisations
- outpatient or primary care consultations
- changes in infrastructure, use and maintenance.

Appendix 3 Digital health technology evaluation for health organizations framework extraction [164, p. 19]

Health value and feasibility

Parameter	Guiding questions
Scope of the affected population	What is the prevalence of the disease or health condition in Israel, and in your organization? If the technology is relevant to diagnostic processes, it is advisable to also take into account incidence rates. If this information is not available in Israel, can the scope be evaluated based on data from other countries?
Severity of the unmet need	For what unmet need does the technology offer a solution? Which health (or other) outcomes are affected by this need, and in what way?
Comparison to current standard of care	What is the current standard of care? How would you describe the current treatment process or patient journey? Where in this process will the new technology be incorporated? Will it replace existing procedures? To what extent will the technology improve or offer a better alternative to the current standard of care?
Clinical potential and feasibility of realization	Is the technology based on sound clinical rationale? Is the success of the technology scientifically plausible? What studies or testing have been done so far in order to provide proof of concept, and how trustworthy are they? How was the technology's performance measured, and is there a clear relation between these indicators and effectiveness? Are there any regulatory or ethical considerations that are likely to challenge the realization of any clinical potential? Are there any expected barriers to the compliance of end users? You may use the parameters below in the **Usability and social considerations** section in order to evaluate usability and likelihood of compliance.
Risks to patient health	With respect to both the R&D as well as implementation stages: Is the technology likely to risk the health or safety of patients (or other users)? In the event that the technology produces inaccurate results, how is this expected to affect the treatment process and patient health? Is there a risk of incorrect use that might affect the quality of care? Are there controls for ensuring quality of care and identifying errors?

Appendix 4 Adopted RE-AIM for DHI framework extraction [152, p. 4]

Reach—Individual level	**The number, proportion, and representativeness of participants**
Target population	The process by which the target population was identified and recruited for participation in the intervention
Inclusion criteria	Characteristics that determined if a potential participant was eligible to participate
Exclusion criteria	Characteristics that determined if a potential participant was not eligible to participate
Participation rate	Sample size divided by the number of eligible participants exposed to recruitment strategies
Reasons for not participating	Reasons provided for not participating in intervention
Representativeness	Comparison of characteristics of the study participants to target population
Effectiveness—Individual level	**The impact of the intervention on important individual outcomes, including quality of life, negative outcomes and on attrition**
Primary outcome of intervention	Description of primary outcome measure
Secondary outcome of intervention	Description of secondary outcome measure
Quality-of-life as secondary outcome	The study includes a measure of the quality of life as secondary outcome measure
Results for at *least* one follow-up	The study reports on study variable(s) measured at specific time point(s) after baseline measures
Intent-to-treat analysis utilised	The study reports it analyses all participants, regardless of whether they received or adhered to the allocated intervention, or if it only includes participants that were present at follow-up
Satisfaction with intervention	The study includes a patient satisfaction survey or monitors patients' feedback
Negative outcomes	Negative outcomes are assessed to evaluate unanticipated consequences that may be a direct product of the intervention (barriers to participate)
Percent attrition	The proportion that was lost to follow-up or dropped out of the intervention (including deaths)
	Provided reasons for dropping out of the intervention

Appendix 5 DigiPHrame framework extraction [156, p. 12]

Framework Domains

1. Health Conditions and Current Public Health Interventions

This domain involves background information for the digital public health intervention describing the population, the conditions and the observance of health inequities. Furthermore, this domain addresses current public health interventions and common alternatives.

		Assessment indicator scheme				
Criteria	*Question*	*NA*	*Assessment result*	*Assessment completed & sufficient*	*Assessment done but improvement needed*	*Assessment only partially done or not possible yet*
Population	1.1 Who is the target population of the digital public health intervention?					
	1.2. How many people are affected by or exposed to the target disease, health conditions or health behavior?					
	1.3. What are the health-related needs and priorities of the target population?					
	1.4. What is the relevant context to reach the target population?					
	1.5. What is the expected level of digital literacy of the target population?					
Conditions	1.6. What conditions (disease, health conditions or health behavior) are addressed in the digital public health intervention (basic epidemiological assessment)?					
	1.7. What are the relevant determinants of health for the conditions?					

Appendix 6 Criteria overview extracted assessment framework

DigiPHrame [156]*: 13 domains, 210 questions*

1) Health conditions and current PHI

- Population
- Conditions
- Observance of health inequities.
- Current public health interventions and common alternatives

2) Functionality of the health technologies

- Health technology features
- Design
- Evidence bases for primary prevention and health promotion

3) Software properties

- Launch, update and rating
- Provider
- Interoperability
- Data integration
- Open source
- Stability
- Internet connectivity

4) Human-Computer interaction

- Accessibility
- Languages
- User-friendliness
- Usability

- Co-creation and empowerment
- Credibility and trustfulness
- Feasibility
- Design quality

5) Infrastructure and organization

- Structure of the setting
- Infrastructure
- Inter-organizational relationships
- Health system interaction

6) Implementation

- Implementation theory
- Implementation structure
- Implementation process
- Implementation strategy
- Implementation agent
- Implementation outcome
- Complexity (practical implementation difficulties)

7) Health-related effects

- Mortality
- Effects on health
- Function
- Quality of life and well-being
- Knowledge and behavior change

8) Social, cultural and gender Aspects

- Context/setting
- Social and societal Impact
- Impact on societal Groups
- Impact related to gender
- Socio-cultural acceptability
- Social sustainability
- Community capacity
- Community participation

9) Cost and Economics

- Prior to the economic assessment
- Economic evaluation methods potentially relevant

10) Legal and Regulatory

- Data protection
- Data security
- Consumer protection
- Medical (Device) regulations
- Health system financing

11) Ethics

- Autonomy
- Harm/non-maleficence
- Beneficence

- Justice

12) Data Security and Data Protection

- Data confidentiality
- Data integrity
- Data authenticity
- Data availability
- Data controllability
- Handling of personal data

13) Sustainability (long-term effects)

- Environmental
- Social
- Economic

Evidence Standards Framework for Digital Health Technologies [60]*: 21 standards arranged in 5 groups*

1) Design factors (7-9: not in Tier A)

- 1: Safety and quality standards
- 2: Intended user group acceptability in the design
- 3: Environmental sustainability
- 4: Health and care inequalities and bias mitigation
- 5: Good data practices in the design
- 6: Define level of professional oversight
- 7: Processes for creating reliable health information
- 8: Credibility with UK professionals
- 9: Safeguarding assurances where users are considered to be in vulnerable groups, or where peer-to-peer interaction is enabled

2) Describing value

- 10: Intended Purpose and target population
- 11: Current pathway or system process
- 12: Proposed pathway or system process
- 13: Expected health, cost and resource impacts compared with standard or current care or system processes

3) Demonstrating performance (14: only Tier C)

- 14: Evidence of effectiveness to support its claimed benefits
- 15: Real-world evidence that the claimed benefits can be realised in practice
- 16: Company and evaluator should agree a plan for measuring usage and changes in the performance over time

4) Delivering value

- 17: Budget impact analysis
- 18: Cost-effectiveness analysis (when higher financial risk)

5) Deployment considerations

- 19: Transparency about requirements for deployment
- 20: Strategies for communication, consent and training processes to allow the DHT to be understood by end users
- 21: Appropriate scalability

Digi-HTA [111]*: 11 domains*

1) Company information

- Business model
- Quality management systems

2) Product information

- Intended purpose
- Maturity level of the product
- CE and/or FDA approvals
- Medical device classification
- Need for changes and training

3) Technical stability

- Processes for testing and handling error messages
- Previous reported downtime or impairment in the use

4) Cost

- Of using for healthcare customers and organization
- Initial and maintenance costs

5) Effectiveness

- Clinical benefits
- Benefits for end-users and/or organization
- Evidence for the effectiveness claims

6) Clinical safety

- Risks, possible side effects, or other undesirable effects
- Reported or identified adverse events and how those are handled

7) Data security and protection

- In the technical and organizational implementation of the product
- During the product lifecycle

8) Usability and accessibility

- Testing with different user groups,
- Company process for evaluating and developing usability and accessibility
- Compatibility with available usability guidelines

9) Interoperability

- Product interfaces into website, other software, healthcare services, electronic patient records, and/or to other companies' services
- Formats of data transfer and storage

10) AI

- Problem solved by the AI, machine learning or neural network,
- Possibility for retraining and used data sources
- AI solution decision logic transparency for healthcare personnel,
- Access rights for data in every use case

11) Robotics

- Safety risks for healthcare personnel or customers and how those are avoided in the design
- Needed arrangements for teaching or programming the robot
- Battery-life of the robot

Digital Health Technology Evaluation for Heath Organization (DHTEfHO) [164]*: 5 domains and 26 parameters*

1) Health value and feasibility:
   - Scope of the affected population
   - Severity of the unmet need
   - Comparison to current standard of care
   - Clinical potential and feasibility of realization
   - Risks to patient health
2) Organizational benefits and suitability:
   - Organizational benefits
   - Suitability to databases and information systems
   - Integration into existing workflows
   - Preparedness and necessary resources
3) Economic value and feasibility:
   - Target population
   - Impact on budget – preparing for deploying the product
   - Impact on budget – expected operating costs
   - Identifying economic benefit and its components
   - Economic measures and targets
   - Cost-benefit evaluation
   - Missing information
4) Usability and social considerations:
   - Characterizing the target population
   - Core suitability of the technology to the target population
   - Usability
   - Health equity considerations
5) Company capabilities:
   - Motivation
   - Professional and teamwork skills

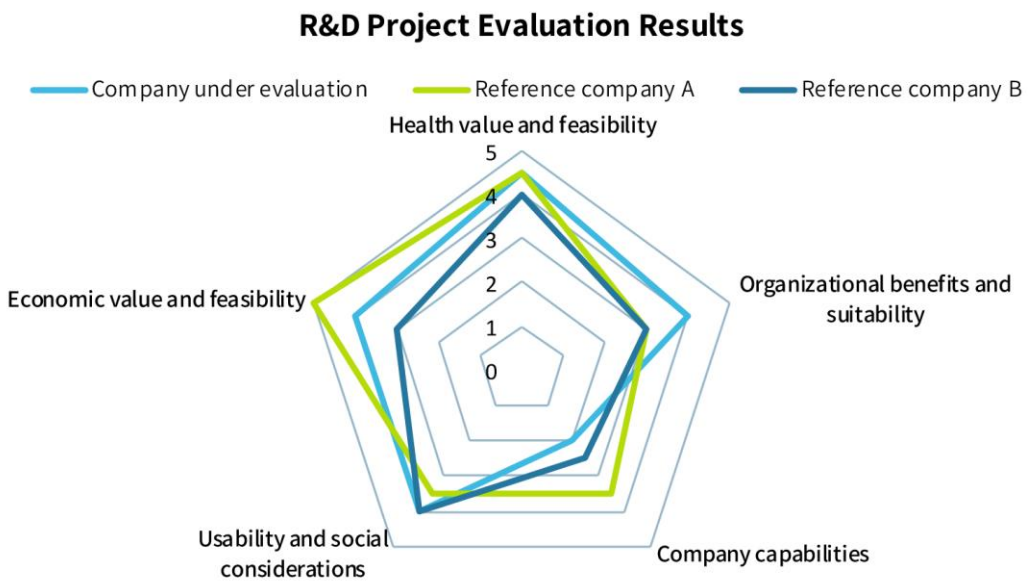
- Technological capabilities
- Business capabilities
- Technological maturity and company preparedness to complete development
- Advantages over competitors

Adapted RE-AIM [152]*: 5 domains*

Dimension	*Adaption*
Reach – Individual Level: • Target population • Inclusion criteria • Exclusion criteria • Participation rate • Representativeness	+ Reasons provided for not participating in intervention
Efficacy – Individual Level: • Primary outcome of intervention • Secondary outcome of intervention • Quality-of-life as secondary outcome • Results for at least one follow-up • Intent-to-treat analysis utilized • Satisfaction with intervention • Negative outcomes • Percent attrition	-
Adoption —Settings and staff levels: • Description of intervention location • Staff required to deliver the intervention	+ Further details of staff providing intervention (if applicable): • Characteristics of these intervention delivering staff members • Level of expertise of these intervention delivering staff members Uptake/Adoption rate of staff
Implementation—Settings and staff levels: • Intervention duration and frequency • Measures of cost of implementation	+ Fidelity: Details provided of amended protocol if applicable (type, timing, and reasons) + Theory-based approach: • Was the implementation informed by theory? • Name of theory used if applicable

Maintenance—Individual and setting levels: • Indicators of program maintenance • Program adaptation in other settings • Measures of cost of maintenance	+ Indicators of maintained behavior: • Report on outcome measures of individuals at some duration after intervention termination • Description of assessed outcomes post-intervention

Appendix 7 Spider chart for project evaluation results [164, p. 27]



Appendix 8 Extracted evidence from Scoping Review

General information	
Study ID	https://doi.org/10.1007/s12553-023-00792-w
Title	Significance of Digital Health Technologies (DHTs) to manage communicable and non-communicable diseases in Low and Middle- Income Countries (LMICs)
Lead author	Aizaz, Muhammad
Publication Year	2023
Aim of study	To summarize different categories of DHTs that can be used to decrease the spread of infectious diseases, including CDs and NCDs in LMICs
Characteristics of included studies	
Database	Healthcare Administration Database
Research Question	☐ Assessment Framework ☑ LRS recommandation
Search string	"Technology assessment" AND ("digital" OR "eHealth") AND ("developing countries" OR "LMIC")
Inclusion notes	Identification of important prerequisites for the use of DPHI in LMIC

General information	
Study ID	https://doi.org/10.1186/s12992-020-00584-1
Title	Artificial intelligence in health care: laying the Foundation for responsible, sustainable, and inclusive innovation in low- and middle-income countries
Lead author	Alami, Hassane
Publication Year	2020
Aim of study	Discussion of potential benefits as well as risks and challenges raised by AI-based health care
Characteristics of included studies	
Database	Pubmed
Research Question	☐ Assessment Framework ☑ LRS recommandation
Search string	("digital health" OR "ehealth") AND "public health" AND ("developing countries" OR "LMIC")
Inclusion notes	Recommandation with five building blocks for the development of sustainable and inclusive AI health care technologies in LMIC

General information	
Study ID	https://doi.org/10.1017/S0266462323000089
Title	Stakeholder preferences for attributes of digital health technologies to consider in health service funding
Lead author	von Huben, Amy
Publication Year	2023
Aim of study	Aims to understand the community, patient/carer, and health professionals' preferences to help inform a prioritized list of evaluation criteria for DHT
Characteristics of included studies	
Database	Healthcare Administration Database
Research Question	☑ Assessment Framework ☐ LRS recommandation
Search string	"Technology assessment" AND ("digital" OR "eHealth") AND ("framework" OR "tool") AND "public health"
Inclusion notes	Referenced two generic DHT assessment frameworks: 1. UK ESF 2. Digi-HTA (two references) References: 1. National Institute for Health and Care Excellence (UK). Evidence standards framework for digital health technologies [Internet] [updated 09 August 2022; cited 2022 August 15]. 2022. Available from: https://www.nice.org.uk/corporate/ecd7. 2.1 Haverinen J, Keränen N, Falkenbach P, et al. Health technology assessment framework for digital healthcare services. FinJeHeW. 2019;11: 326–341. 2.2 Haverinen J, Turpeinen M, Falkenbach P, Reponen J. Implementation of a new Digi-HTA process for digital health technologies in Finland. Int J Technol Assess Health Care. 2022;38:e68.

General information	
Study ID	DOI:10.1002/hpm.3064
Title	Telemedicine is an important aspect of healthcare services amid COVID-19 outbreak: Its barriers in Bangladesh and strategies to overcome
Lead author	Chowdhury, Saifur Rahman
Publication Year	2021
Aim of study	Described the importance of telemedicine service amid the outbreak of COVID-19 in Bangladesh, the barriers and challenges that the country is facing to implement this approach and the strategies to overcome these barriers in this developing country.
Characteristics of included studies	
Database	Pubmed
Research Question	☐ Assessment Framework ☑ LRS recommandation
Search string	("digital health" OR "ehealth") AND "public health" AND ("developing countries" OR "LMIC")
Inclusion notes	Barriers and recommandations for the implementation of telemedicine in developing countries with focus on COVID-19 response

General information	
Study ID	https://doi.org/10.1186/s12913-023-10361-6
Title	Optimising the implementation of digital-supported interventions for the secondary prevention of heart disease: a systematic review using the RE-AIM planning and evaluation framework
Lead author	de Moel-Mandel, Caroline
Publication Year	2023
Aim of study	Aims to evaluate the extent to which RE-AIM dimensions and associated internal and external validity indicators are reported in the included studies offer guidance to improve the wider implementationnand optimisation of digitalenabled secondary prevention programs.
Characteristics of included studies	
Database	Pubmed
Research Question	☑ Assessment Framework ☐ LRS recommandation
Search string	(("digital health" OR "eHealth") AND "public health" ("assessment" OR "evaluation") AND ("framework" OR "tool")
Inclusion notes	Reference and application of adopted RE-AIM framework for DHI Reference: original RE-AIM Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. Am J Public Health. 1999;89:1322. https://doi.org/10.2105/ajph.89.9.1322.

General information	
Study ID	https://doi.org/10.1371/journal.pdig.0000314
Title	Strategies and solutions to address Digital Determinants of Health (DDOH) across underinvested communities
Lead author	Holmes Fee, Casey
Publication Year	2023
Aim of study	Gain a preliminary understanding of current academic knowledge of DDOH mitigation strategies and solutions, including their potential effectiveness

Characteristics of included studies	
Database	Pubmed
Research Question	☐ Assessment Framework ☑ LRS recommandation
Search string	(("digital health" OR "eHealth") AND "public health" ("assessment" OR "evaluation") AND ("framework" OR "tool")
Inclusion notes	Proposed framework for DDOH assessment for underinvested communities

General information	
Study ID	doi: 10.7189/jogh.12.04094
Title	Mapping national information and communication technology (ICT) infrastructure to the requirements of potential digital health interventions in low- and middle-income countries
Lead author	Hui, Chi Yan
Publication Year	2022
Aim of study	Aimes to identify and describe the evidence available in open-source data and existing literature regarding implementation of digital health applications in five exemplar LMICs (Bangladesh, India, Indonesia, Malaysia, Pakistan)
Characteristics of included studies	
Database	Pubmed
Research Question	☐ Assessment Framework ☑ LRS recommandation
Search string	("digital health" OR "ehealth") AND "public health" AND ("developing countries" OR "LMIC")
Inclusion notes	Shows checklist of contextual factors that developers of digital health initiatives in LMICs should consider at an early stage in the development process

General information	
Study ID	doi:10.3390/ijerph17062119
Title	How to Value Digital Health Interventions? A Systematic Literature Review
Lead author	Kolasa, Katarzyna
Publication Year	2020
Aim of study	Systematic literature review of published DHIs' assessment guidelines and analysis with the 12-item checklist based on a EUnetHTA core model, enriched with addiitional criteria such as usability, interoperability, and data security
Characteristics of included studies	
Database	Pubmed
Research Question	☑ Assessment Framework ☐ LRS recommandation
Search string	(("digital health" OR "eHealth") AND "public health" ("assessment" OR "evaluation") AND ("framework" OR "tool")
Inclusion notes	Reference of NICE Evidence Standards Framework for Digital Health Technologies: Evidence Standards Framework for Digital Health Technologies March 2019. Available online: https://www.nice.org.uk/Media/Default/About/what we-do/our-programmes/evidence-standards-framework/digital-evidence-standards-framework.pdf

General information	
Study ID	doi:10.3390/ijerph17124538
Title	A Mixed Methods Evaluation of a Digital Intervention to Improve Sedentary Behaviour Across Multiple Workplace Settings
Lead author	MacDonald, Bradley
Publication Year	2020
Aim of study	Understand the potential of a digital health promotion application which targets reducing and breaking up sedentary behaviour (across multiple workplace settings

Characteristics of included studies	
Database	Pubmed
Research Question	☑ Assessment Framework ☐ LRS recommandation
Search string	(("digital health" OR "eHealth") AND "public health" ("assessment" OR "evaluation") AND ("framework" OR "tool")
Inclusion notes	Reference of RE-AIM framework: Glasgow, R.E.; Vogt, T.M.; Boles, S.M. Evaluating the public health impact of health promotion interventions:The RE-AIM framework. Am. J. Public Health 1999, 89, 1322–1327.

General information	
Study ID	doi: 10.3389/fpubh.2022.859941
Title	Lessons Learned From Implementing Digital Health Tools to Address COVID-19 in LMICs
Lead author	Mason, Caitlyn
Publication Year	2022
Aim of study	Review on digital health solutions in lower- and lower middle-income countries across three user groups—healthcare providers, health system managers, and health system clients to conclude lessons learned from the implementation.
Characteristics of included studies	
Database	Pubmed
Research Question	☐ Assessment Framework ☑ LRS recommandation
Search string	("digital health" OR "ehealth") AND "public health" AND ("developing countries" OR "LMIC")
Inclusion notes	Summary of strengths and challenges across the assessed digital tools in respondance to COVID-19 in LMIC

General information	
Study ID	https://doi.org/10.1080/14760584.2023.2184091
Title	Digital health technology used in emergency large-scale vaccination campaigns in low- and middle-income countries: a narrative review for improved pandemic preparedness
Lead author	Mc Kenna, Paula
Publication Year	2023
Aim of study	To provide a resource for LMICs that consider introducing the use of digital tools health tools in future large-scale vaccination campaigns for outbreak response based on the experience in similar settings. Additionally, to consider topics such as data security and safety, tool availability, costs, challenges specific to LMICs, and options in ensuring sustainability of tools.
Characteristics of included studies	
Database	Pubmed
Research Question	☐ Assessment Framework ☑ LRS recommandation
Search string	("digital health" OR "ehealth") AND "public health" AND ("developing countries" OR "LMIC")
Inclusion notes	Lessons learned from digital tools for large scale vaccination programm in LMIC

General information	
Study ID	doi: 10.3389/fpubh.2023.1197949
Title	International practices in health technology assessment and public financing of digital health technologies: recommendations for Hungary
Lead author	Mezei, Fruzsina
Publication Year	2023
Aim of study	Overview of international practices on public financing and health technology assessment of digital health technologies (DHTs) in five European Union (EU) countries and outlines recommendations for country-level action that relevant stakeholders can consider in order to support uptake of digital health solutions in Hungary.
Characteristics of included studies	
Database	Pubmed
Research Question	☑ Assessment Framework ☑ LRS recommandation
Search string	(("digital health" OR "eHealth") AND "public health" ("assessment" OR "evaluation") AND ("framework" OR "tool")
Inclusion notes	References Digi-HTA (1) and Evidence Standards Framework for Digital Health Technologies (2): 1. Haverinen J, Turpeinen M, Falkenbach P, Reponen J. Implementation of a new Digi-HTA process for digital health technologies in Finland. Int J Technol Assess Health Care. (2022) 38:e68. doi:10.1017/S0266462322000502 2. National Institute for Health and Care Excellence. Evidence standards framework for digital health technologies Corporate document Published: 2018, updated August 2022 (2022). Available at: https://www.nice.org.uk/corporate/ecd7/resources/evidence-standards-framework-for-digital-health-technologies-pdf-1124017457605(Accessed January 31, 2023). + Recommandation for evaluating DHI in MIC (Hungary)

General information	
Study ID	https://doi.org/10.1080/13814788.2023.2241987
Title	SERIES: eHealth in primary care. Part 6: Global perspectives: Learning from eHealth for lowresource primary care settings and across high-, middle- and low income countries
Lead author	Rakers, Margot
Publication Year	2023
Aim of study	To outline the contributions and challenges of eHealth in low-resource primary care settings.
Characteristics of included studies	
Database	Pubmed
Research Question	☐ Assessment Framework ☑ LRS recommandation
Search string	("digital health" OR "ehealth") AND "public health" AND ("developing countries" OR "LMIC")
Inclusion notes	Recommandation for developing and evaluating eHealth interventions for LRSs in primary care

General information	
Study ID	DOI:10.17605/OSF.IO/UB3W4
Title	Developing and Assessing Digital Public Health Interventions: A Digital Public Health Framework (DigiPHrame)
Lead author	Pan, Chen-Chia
Publication Year	2023
Aim of study	Illustration of a framework for developing and assessing Digital Public Health Interventions
Characteristics of included studies	
Database	Google Scholar
Research Question	☑ Assessment Framework ☐ LRS recommandation
Search string	"digital public health" AND "assessment framework"
Inclusion notes	Study shows DigiPHrame: Framework for assessing and evluating digital public health interventions

General information	
Study ID	http://dx.doi.org/10.21037/mhealth-19-249
Title	Can mHealth and eHealth improve management of diabetes and hypertension in a hard-to-reach population? —lessons learned from a process evaluation of digital health to support a peer educator model in Cambodia using the RE-AIM framework
Lead author	Steinman, Lesley
Publication Year	2020
Aim of study	Aim is to share findings and lessons learned from a process evaluation of mHealth to improve NCD management for persons living with diabetes and/ or hypertension in Cambodia.
Characteristics of included studies	
Database	Pubmed
Research Question	☑ Assessment Framework ☑ LRS recommandation
Search string	(("digital health" OR "eHealth") AND "public health" ("assessment" OR "evaluation") AND ("framework" OR "tool")
Inclusion notes	Application of adopted RE-AIM framework for DPHI in LRSs

General information	
Study ID	DOI: 10.1177/20552076211018617
Title	The NICE Evidence Standards Framework for digital health and care technologies Developing and maintaining an innovative evidence framework with global impact
Lead author	Unsworth, Harriet
Publication Year	2021
Aim of study	To describe the agile policy research approach used to develop the ESF, outline how the ESF works, and describe its impact to date and ongoing work to ensure that the ESF remains up to date with the rapidly changing field of digital healthcare.
Characteristics of included studies	
Database	Pubmed
Research Question	☑ Assessment Framework ☐ LRS recommandation
Search string	(("digital health" OR "eHealth") AND "public health" ("assessment" OR "evaluation") AND ("framework" OR "tool")
Inclusion notes	Description on how the NICE Evidence Standards Framework for digital health and care technologies works

General information	
Study ID	https://doi.org/10.1016/j.cjca.2021.08.015
Title	Health Technology Assessment for Cardiovascular Digital Health Technologies and Artificial Intelligence: Why Is It Different?
Lead author	Vervoort, Dominique
Publication Year	2022
Aim of study	Discuss HTA in light of DHTs and AI applications in cardiovascular medicine, describe existing DHT/AI HTA frameworks, and highlight unique opportunities for Canada to better evaluate, promote, and reimburse meaningful new technologic innovations.
Characteristics of included studies	
Database	Pubmed
Research Question	☑ Assessment Framework ☐ LRS recommandation
Search string	(("digital health" OR "eHealth") AND "public health" ("assessment" OR "evaluation") AND ("framework" OR "tool")
Inclusion notes	Referenced: Digi-HTA(1), NICE Evidence Standard Framework for DHT (2), Digital Health Technology Evaluation for Health Organisations: an evaluation framework for early-stage technologies (3): 1. Haverinen J, Keränen N, Falkenbach P, et al. Digi-HTA: health technology assessment framework for digital healthcare services. Finn J eHealth eWelfare 2019;11:326-41 2. National Institute for Health and Care Excellence. Evidence Standards Framework for Digital Health Technologies. December 10, 2018; updated April 23, 2021. Available at: https://www.nice.org.uk/about/ what-we-do/our-programmes/evidence-standards-framework-for-digitalhealth-technologies. 3.Digital Health Division, Israel Ministry of Health. Digital health technology evaluation for health organizations: an evaluation framework for early-stage technologies. June 2021. Available at: https://www.gov.il/ BlobFolder/generalpage/digital-health-guide-062021/he/files_publications_ digital_health_digital-health-hta-062021.pdf.

General information	
Study ID	https://doi.org/10.1017/S026646232000015X
Title	Health technology assessment frameworks for eHealth: A systematic review
Lead author	Vis, Christiaan
Publication Year	2020
Aim of study	To identify frameworks and methods for assessing eHealth's impact on healthcare.
Characteristics of included studies	
Database	Healthcare Administration Database
Research Question	☑ Assessment Framework ☐ LRS recommandation
Search string	"Technology assessment" AND ("digital" OR "eHealth") AND ("framework" OR "tool") AND "public health"
Inclusion notes	Referenced NICE Evidence Standard Framework for DHT: National Institute for Health and Care Excellence (NICE). Evidence Standards Framework for Digital Health Technologies. 2019. p. 1–35. Available from: https://www.nice.org.uk/Media/Default/About/whatwedo/our-programmes/evidence-standards-framework/digital-evidencestandards-framework.pdf.

General information	
Study ID	https://doi.org/10.1017/S0266462321001665
Title	Application of a health technology assessment framework to digital health technologies that manage chronic disease: a systematic review
Lead author	von Huben, Amy
Publication Year	2021
Aim of study	To summarize current trends in primary research on DHTs that manage chronic disease at home, particularly the coverage of content recommended for DHT-specific and comprehensive HTA
Characteristics of included studies	
Database	Healthcare Administration Database
Research Question	☑ Assessment Framework ☐ LRS recommandation
Search string	"Technology assessment" AND ("digital" OR "eHealth") AND ("framework" OR "tool") AND "public health"
Inclusion notes	Referenced NICE Evidence Standard Framework for DHT: National Institute for Health and Care Excellence (UK). Evidence standards framework for digital health technologies. London, UK: NICE (UK);2021

General information	
Study ID	doi: 10.2196/31921
Title	What are Digital Public Health Interventions? First Steps Toward a Definition and an Intervention Classification Framework
Lead author	Wienert, Julian
Publication Year	2022
Aim of study	Aims to provide the first definition of digital public health interventions
Characteristics of included studies	
Database	Pubmed
Research Question	☑ Assessment Framework ☐ LRS recommandation
Search string	"digital public health" AND ("evaluat*" OR "assess*")
Inclusion notes	Referenced NICE Evidence standards framework for DHT: Evidence standards framework for digital health technologies. National Institute for Health and Care Excellence. URL: https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/digital-evidence-standards-framework.pdf

Appendix 9 Framework comparison to the adapted EUnetHTA core model for DHT [7]

Framework	*Health Problem and Current Use of the Technology (CUR)*	*Description and technical characteristics (TEC)*	*Safety (SAF)*	*Clinical effectiveness (EFF)*
UK ESF (Number of Standard) [60]	Describing Value (10-13)	Design Factors (1): Refers to the Digital Technology Assessment Criteria (DTAC) for UK	Design Factors (1,3,6,9)	Demonstrating Performance (14-16)
Digi-HTA [111], [195]	Product Information	Technical Stability: Check if the company has the resources to react in case of errors.	Clinical Safety	Effectiveness
RE-AIM (Adopted for DHI) [152]	Reach: Population		Efficiency: Focus on negative outcomes and attrition	Efficiency
DigiPHrame [156]	Health Conditions and Current Public Health Interventions: + Health Inequality	General Description of the DPHI Technical Aspects: + Data Integration + Open-Source + Stability and internet connectivity	Intended and Unintended Health-related Effects	Health-related Effects: Quality of Life and Well-being
Digital Health Technology Evaluation for Health Organisations (DHTEfHO) [164]	Health value and feasibility	Company capabilities: Point of view of the company resources, and not on the technology itself	Health value and feasibility: Risk to patient health	Health value and feasibility

Legend:

- Missing
- Undetailed
- Detailed

Framework	*Cost and economic effectiveness (ECO)*	*Ethical analysis (ETH)*	*Organizational aspects (ORG)*	*Patient and social aspects (SOC)*
UK ESF (Number of Standard)	Delivering value (17,18)	Design Factors (4,9): Focus on health equity and care inequalities especially for vulnerable groups. Design Factors (4): Eliminating unlawful discrimination	Design Factors (2,8): User group involved in development process. Describing Value (12) Delivering Value (18)	Design Factors (8): Credibility with UK professionals Deployment Considerations (20): Communication, consent, and training of end-users
Digi-HTA	Cost		Company Information: Superficially only business model, no more detailed input on stakeholders	
RE-AIM (Adapted for DHI)	Maintenance Cost		Adoption: Setting and staff required for the adoption of the DHI	
DigiPHrame	Cost and Economics	Ethics (Autonomy, Harm/non-maleficence, Beneficence, Justice)	Infrastructure and Organization	Co-creation and Empowerment +Social, Cultural and Intersectional Aspects:
Digital Health Technology Evaluation for Health Organisations (DHTEfHO)	Economic value and feasibility	Only in connection with health inequality and access and in consideration of realization of the clinical potential	Organizational Benefits and Suitability	Social considerations: Suitability for target population

Framework	*Legal aspects (LEG)*	*Usability*	*Interoperability*	*Data security*	*Additional criteria (ADD)*
UK ESF (Number of Standard)	Medical device regulations and care quality standards in the UK	Design factors (2): Incorporate intended user group acceptability in the design of the DHT	Design Factors (1): Interoperability	Design Factors (4,5,7): • High quality of data • Transparency of procedures for maintaining the quality of health information. • Refers to national guidance for projects that use data	• Ensure appropriate scalability
Digi-HTA		Usability and accessibility	Interoperability	Outsourcing of Data Security	• Robotics • AI
RE-AIM (Adapted for DHI)		Satisfaction with intervention			• Maintenance: Long-term effects of the DHI • Implementation
DigiPHrame	Legal and Regulatory	Usability	Technical Aspects: + Interoperability	Data Security and Data Protection	• Implementation • Sustainability
Digital Health Technology Evaluation for Health Organisations (DHTEfHO)	Focus on regulatory requirements to meet for the company	Focus domain which is on usability		Suitability to databases and information systems	• Point of view is from developing involved organization

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Declaration

I declare that I have prepared this thesis independently, have not submitted it for examination purposes, have not used any sources and aids other than those specified, have labelled verbatim and analogous quotations as such, and tolerate verification using anti-plagiarism software.

Dornstadt, 21.05.2024

Place, date

Henrik Hüsmann

Signature