Developing and Evaluating Digital Public Health Interventions: The Digital Public Health Framework (DigiPHrame)

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Abstract

Background: Digital Public Health (DiPH) interventions may help us tackle substantial public health challenges, present valuable opportunities to improve and complement existing services, and reach historically underserved populations. However, DiPH interventions are often triggered through technological advancements and opportunities rather than public health needs. In order to develop and evaluate interventions designed to serve public health needs, a comprehensive framework is needed that systematically covers all aspects relevant to public health. This includes taking into account the complexity of the technology, the context in which the technology is supposed to operate, its implementation, and its effects on public health including ethical, legal, or social aspects.

Objective: We aimed to develop such a framework with a comprehensive list of core principles to be considered throughout the development and evaluation process of any DiPH intervention.

Methods: The resulting Digital Public Health Framework “DigiPHrame” is based on a scoping review of existing digital health and public health frameworks. After extracting all assessment criteria from these frameworks, we clustered the criteria. During a series of multidisciplinary meetings with experts from the Leibniz ScienceCampus Digital Public Health, we restructured each domain to represent the complexity of digital public health.

Results: The current framework consists of 182 questions nested under 12 domains. In this article, we use a COVID-19 contact tracing app as a use case to illustrate how the framework may be applied to assess DiPH interventions.

Conclusions: DigiPHrame may help avoid overlooking important aspects that would otherwise result in low-value interventions that are not user-friendly, violate (data protection) law, or are not sustainable. As a living framework, DigiPHrame will be updated regularly as new public health needs and technological advancements emerge.

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Background: Digital Public Health (DiPH) interventions may help us tackle substantial public health challenges, present valuable opportunities to improve and complement existing services and reach historically underserved populations. However, DiPH interventions are often triggered through technological advancements and opportunities rather than public health needs. In order to develop and evaluate interventions designed to serve public health needs, a comprehensive framework is needed that systematically covers all aspects with relevance for public health. This includes taking into account the complexity of the technology, the context in which the technology is supposed to operate, its implementation, and its effects on public health including ethical, legal, or social aspects.

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Results: The current framework consists of 182 questions nested under 12 domains. In this article we use a COVID-19 contact tracing app as a use case to illustrate how the framework may be applied to assess DiPH interventions.

Conclusions:
DigiPHrame is a comprehensive framework for the development and assessment of digital technologies designed for public health purposes. It is a living framework and will therefore be updated regularly and as new public health needs and technological advancements emerge.

Key terms: Digital Public Health, Digital Health, Public Health, Framework, Development, Evaluation, Guidance, Program Evaluation, Telemedicine

Introduction

The overarching goal of public health is to promote and improve the health and well-being of people and communities. In recent years, digital interventions specifically designed for public health purposes have emerged on a large scale. Digital Public Health (DiPH) interventions may help us tackle substantial public health challenges, including aging populations [1], the dual burden of noncommunicable and communicable diseases [2], and the health impacts of climate change [3]. Moreover, DiPH interventions present valuable opportunities to improve and complement existing healthcare services and reach historically underserved populations.

With the COVID-19 pandemic, we have seen how digital technologies may accelerate responses to public health emergencies. For example, digital contact tracing apps have become a major component to monitor community transmission and curb the spread of the virus in a population [4]. Further, the development of information platforms for international real-time public health data has supported policy and decision-makers in planning and executing containment strategies. Another relevant field that became more visible during the pandemic concerns public health education. Digital platforms of health authorities and national agencies played a critical role in rapidly engaging and educating the population through prompt dissemination of trusted and tailored public health information while limiting the visibility of information from unreliable sources [5].

As with other health technologies, DiPH interventions need to be developed through an iterative process considering a multitude of factors right from the beginning of the conceptualization process. However, these factors (e.g., acceptability, usability, data security, or sustainability) are sometimes not well-thought-out during the development or not at all considered, often resulting in low-value interventions that are ineffective, burdensome, and reduce both quality and efficiency. In turn, the development of DiPH interventions is often triggered through technological advancements (i.e., what is possible) rather than current public health needs [6].

Although vast amounts of new health apps are launched in app stores regularly, the number of downloads for many of these apps generally stay notoriously low [7]. Individual decisions around the initial use, adoption, rejection, and continued use of an app might be influenced by concerns regarding data security and data protection issues, costs to purchase an app, or user-friendliness for different user groups [8,9]. Other societal aspects, such as sustainable financing, regulatory requirements, are described as challenges to fulfill public health functions. Thus, these aspects may influence the design of a DiPH intervention and need to be considered from the beginning of the development process [10].

During the development and evaluation process, a number of different stakeholders assess the potential impact of DiPH interventions (e.g., tech companies, health insurances, governments, or health organizations). As such for each DiPH intervention a great variety of potential users and user environments must be considered. In order to systematically develop and evaluate DiPH interventions, a comprehensive framework is needed that systematically covers all aspects with relevance for public health. This includes taking into account the complexity of the technology, the context in which the technology is supposed to operate, its implementation and its effects on public health including ethical, legal, or social aspects. Such a comprehensive framework would cover all phases, from conceptualization to evaluation of all types of DiPH interventions and all parties [11].

Existing frameworks for digital health interventions, health technologies, and public health Interventions

Interventions are often developed without a systematic method and without drawing on the evidence and theories. This point was made by Martin Eccles, Emeritus Professor of Clinical Effectiveness in the UK, in referring to a frequently used principle of intervention design, the ‘ISLAGIATT’ principle. The letters stand for ‘It Seemed Like A Good Idea At The Time’! This means that we jump straight to intervention and crucially miss out understanding the behaviours we are trying to change or do not consider contextual facilitators and barriers for a successful implementation of the intervention. Frameworks that integrate a wide range of domains allow us to think ahead and help us to avoid potential pitfalls before they occur so that we can design appropriate interventions based on this analysis [12].

While frameworks for digital health interventions, health technologies, and public health interventions have been developed previously, to the best of our knowledge, no framework for the systematic development and assessment of digital interventions for public health purposes exists today. Assessment criteria for health-related technologies have been developed previously, although their focus generally lies on either, health technology [13,14] or digital health-relevat [15] aspects.

One prominent example of assessing various health technologies is the Health Technology Assessment (HTA). “HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.” (https://www.inahta.org/). Based on this methodology, various organizations developed frameworks with different foci [13, 14, 17]. For instance, the European Network For Health Technology Assessment (eunethta) developed the health technology core model for assessing dimensions of value to facilitate production and sharing of health technology assessment information, such as evidence on efficacy, effectiveness and patient aspects, to inform decisions. The model has a broad scope and offers a common ground to various stakeholders through offering a standard structure and a transparent set of proposed HTA questions [13]. HTA frameworks are generally applied to already developed technologies rather than providing standards for evaluation aspects that should be considered throughout development. However, this is important because existing interventions would likely be outdated by the time their assessment is finished.

Assessment frameworks specifically designed for the evaluation of digital health technology also exist. The National Institute for Health and Care Excellence (NICE) recently developed an Evidence Standards Framework (ESF) for Digital Health Technologies [15], aiming at providing standards for clinical evidence of (novel) health technology's (cost-) effectiveness within the UK health and care system. Similar to other frameworks [18-21] it lacks applicability to public health technologies due to its focus on clinical outcomes. Other frameworks focus on evaluation and assessment criteria along the life cycle of digital health interventions yet still lacking a public health focus [22].

Digital interventions heavily rely on user interaction and engagement. However, public health frameworks generally do not include specific measures to assess usability, user experience, and the design aspects crucial for promoting sustained user engagement [23]. Further digital public health interventions often require integration into existing healthcare systems, which can be complex and fraught with interoperability, data security, and data protection challenges; issues that are often not properly addressed in public health frameworks [24]. While these are just a few examples they illustrate how unique aspects of digital public health interventions may fall short in existing public health frameworks.

Together, we identified the following gaps: 1. Absence of a framework for digital interventions in public health: While frameworks for health technologies and public health

interventions exist, there is no established framework specifically tailored for the systematic development and assessment of digital interventions in public health. 2. Limited applicability of existing assessment frameworks. 3. Inadequate consideration of usability and integration challenges. Addressing these gaps requires the development of a comprehensive framework specifically tailored for digital interventions in public health, integrating diverse domains and considering usability, user experience, and integration challenges throughout the development and assessment process so that developers and assessors need not draw on multiple frameworks. The main focus of this article is to present the current form of Digital Public Health framework (DigiPHrame) and describe its development process followed by a use case to illustrate its application. More detailed information on the scoping review which served as a starting point to develop DigiPHrame can be found in the protocol, which we preregistered on OSF [25]. The German contact tracing app “Corona-Warn-App” (CWA) as a digital public warning system with a clear public health focus was deemed as a suitable use case to illustrate the application of DigiPHrame.

Methods

We developed the framework in several steps (Figure 1).

(1) We conducted a scoping review to identify existing frameworks for public health and digital health interventions (*Protocol and registration*: OSF https://osf.io/ku38m/). *Eligibility criteria*: see table 1. *Information sources*: We searched journal articles in the electronic literature databases MEDLINE (via PubMed), Scopus, IEEE, CINAHL (via EBSCO), and PsycINFO (via Ovid). *Search*: Our search strategy was first developed around our core concepts as our primary search keywords specific search fields, and Boolean operators: (“Public Health” [Title/Abstract] OR “Digital Health” [Title/Abstract]) AND Evaluation [Title] AND Framework [Title]. The search syntax was then expanded to include the synonyms, wildcards, and the relevant subject terms of above primary keywords to increase the sensitivity of our searches. We then modified the subject terms and search field of the search syntax to adopt to each database (see Appendix 1). We also manually searched relevant reviews’ reference lists. The final search was completed on April 12, 2022, with no publication date limitations. *Selection of sources of evidence*: After deduplication, 4,830 titles and abstracts were screened by two researchers independently, resulting in 433 full texts, which were then assessed by two independent researchers. Disagreements among researchers were resolved through dialogue, with involvement of a third party if necessary although a definitive agreement score was not established. In total, 68 articles were included for data extraction (see PRISMA Flowchart in Appendix 2).

Table 1. Eligibility criteria for the scoping review to identify existing frameworks for public health and digital health interventions.

Inclusion criteria	Exclusion criteria
1. Development or evaluation framework for health interventions related to Public Health or Digital Health. **2. The report should describe a framework or guidance to outline the standards, principles, criteria, or properties needed to support the systematic development or evaluation of health interventions aim for health promotion or prevention with or with out digital technologies.**	1. No framework or guidance in the report 2. The framework or guidance is not focusing on developing, monitoring, validating or evaluating health interventions 3. The framework or guidance does not provide specific standards, principles, criteria, or properties 4. The framework or guidance is only deigned for one specific tool, and not applicable to other health interventions 5. The framework or guidance can only apply to pharmaceutical/ surgical/ clinical/ rehabilitation interventions
3. Publication type: a) journal articles; c) study/policy/program reported in grey literature	6. Other publication type: comment, correction, letter, editorial, protocol, oral presentation, poster
4. Language: English	7. Other language than English
5. Access to full-text of studies selected for data coding	8. No access to full-text

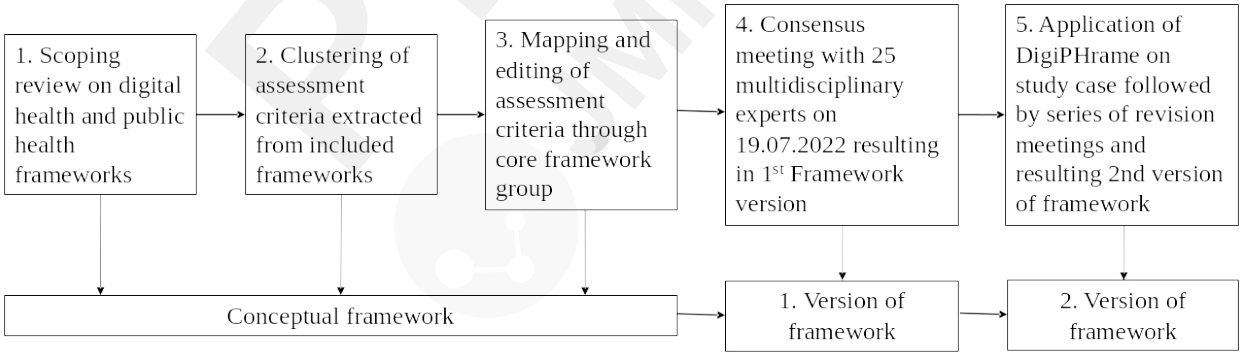
(2) *Data charting process & Data items*: We extracted all pertinent assessment criteria from these frameworks. Criteria were extracted from the frameworks identified through the scoping review. Initially, these criteria were assigned to the HTA domains/subdomains [13], although several criteria could not be assigned due to thematic misfit (akin to deductive coding). Subsequently, new categories were formed (akin to inductive coding). One researcher performed the coding initially, followed by a collaborative examination of the coded sections by two researchers, leading to adjustments during the discussion process (e.g., reassignment to other domains, reassignment to other subdomains within a domain, summarization of subdomains, deletion of irrelevant domains or subdomains). Questions describing the subdomains were devised by us based on the criteria (here, too, a proposal was made by one person, followed by verification by a second person). We consulted

additional literature for the categorization of ethical principles [16].

(3) A group of multidisciplinary experts from the Leibniz ScienceCampus Digital Public Health (LSC DiPH) were assigned to the domains corresponding to their expertise for counselling. Each domain was restructured with proficient inputs to represent the complexity of digital public health. Where necessary additional literature was consulted, especially when the included frameworks fell short of offering criteria specific to digital public health.

(4) A first draft of the proposed framework was sent to an interdisciplinary expert panel consisting of 105 members of the LSC DiPH. The feedback was gathered as unrestricted comments on the domains we developed. We reached out to experts from diverse fields including medicine, public health, global health, psychology, sociology, human-computer interaction, (health) economics, informatics, sports science, medical biometry, architecture, urban planning, statistics, ethics, oicy analytics and law, assigning them domains based on their respective expertise. A deadline for feedback submission was set for July 18, 2022. Additionally, the same members of the LSC DiPH were invited to partake in a consensus meeting held on July 19, 2022. Participants were grouped into domain-specific discussions according to their areas of expertise, with these discussions being moderated by the DigiPHrame team. This resulted in the first version of the framework [26].

(5) The same experts were invited to a workshop on the February 23, 2023, where the proposed framework was applied to a study case and tested for face validity. The case study was a digital application under development with the aim to promote mental health among informal caregivers. Followed by several revision meetings by the framework team between February and May 2023 the second version of the proposed framework was finalized in May 2023 [28].



Results

DigiPHrame comprises a set of criteria framed as open-ended questions clustered within domains that will lead interested parties through a broad spectrum of crucial elements when developing and evaluating DiPH interventions.

The evolution of domains and subdomains through the stepwise process including the number of questions per subdomain in each version can be found in Appendix 3. The framework in its current form was uploaded on the LSC DiPH website and the open science framework [29] in May 2023 and is a revised version of the original framework that was first published in July 2022. In total, DigiPHrame consists of 182 questions, structured by 12 domains (Figure 2).

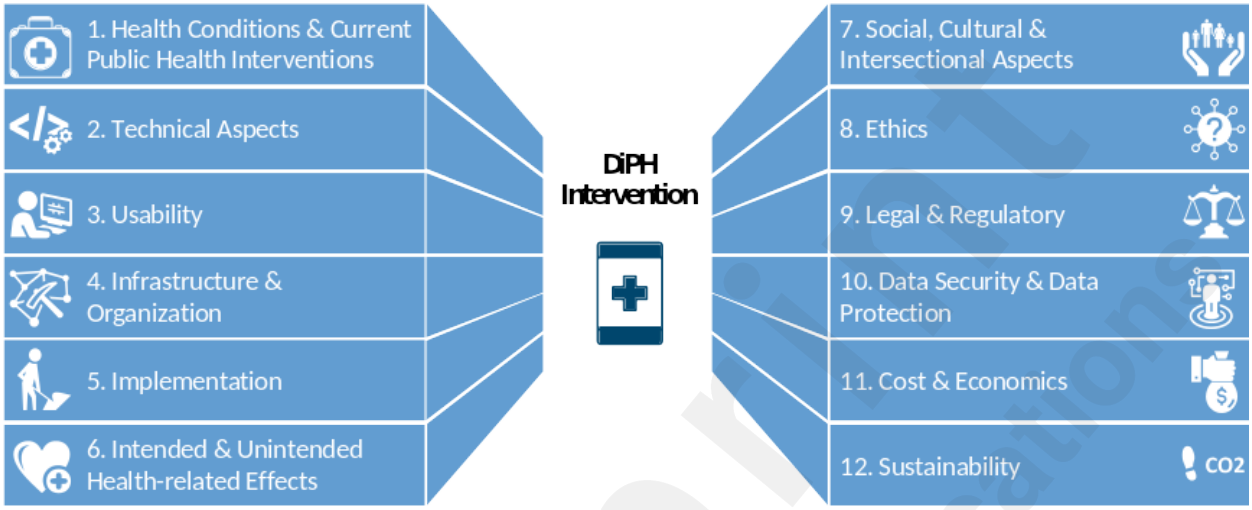


Figure 2: Summary of the DigiPHrame framework domains for developing and evaluating digital public health interventions

While the first domain describes the current status of health needs and existing interventions, domains 2 and 3 aim at the DiPH technology under assessment and aspects related to human-computer interaction. Domains 4 and 5 aim at structural and process aspects, and domains 6-12 assessment criteria address contextual conditions as well as the outcomes of the DiPH intervention from broad perspectives.

In the following, we define the domains and illustrate them using the German contact tracing app “Corona-Warn-App” (CWA) as a use case. The CWA is a digital public warning system that was designed and developed during the COVID-19 pandemic and has a clear public health focus. Below we briefly outline the purpose and characteristics of the CWA. Further, we will illustrate how DigiPHrame can be applied, taking the CWA as an example. From each domain, we apply one assessment question as examples.

Use Case: The German “Corona-Warn-App”

Shortly after COVID-19 pandemic in 2020 numerous digital tracing applications have been developed or proposed, with official government support in some territories and jurisdictions. The rationale behind it: Contact tracing is an important tool in infectious disease control, but as the

number of cases rises, time constraints make it more challenging to trace transmissions effectively. Digital contact tracing, especially if widely deployed, may be more effective than traditional methods of contact tracing [30].

COVID-19 apps include mobile applications for digital contact tracing – i.e., identifying persons ("contacts") who may have been in contact with an infected individual – deployed during the COVID-19 pandemic. Privacy concerns have been raised, especially about systems tracking users' geographical location. Alternatives include co-opting Bluetooth signals to log a user's proximity to other smartphones. For example, the open-source CWA funded by the German government was based on proximity tracing using Bluetooth signals. The app provided a function for users to warn other users by uploading their positive test results anonymously on a voluntary basis to the CWA server. Users would then get notified about any contacts with infected persons and could get tested on a voluntary basis.

Health Conditions and Current Public Health Interventions

The 1st domain (*Health Conditions and Current Public Health Interventions*) involves background information for the DiPH intervention describing the population, conditions, and observance of health inequities. Furthermore, this domain addresses current public health interventions and common alternatives.

Question 1.5. asks: "What is the expected level of digital literacy of the target population?". In the case of the CWA, the target population comprises the entire population within a geographically delimited space. Therefore, the whole spectrum of digital literacy is to be expected. Thus, different forms of representation (e.g., graphics, text, sound, etc.) of risk exposure and other information related to the COVID-19 pandemic must be available, which was not the case and might have hindered people to use it.

Technology and Usability

The 2nd domain *Technical Aspects* guides one through assessing general technical aspects of the health technology of interest. The questions focus on what digital tools are applied and how aspects such as interoperability, data integration, internet connectivity, and others are integrated.

Question 2.17. is "Does the software require an internet connection (e.g., all the time, once in a while, once)?" In the use case of the CWA, an internet connection is necessary, as the major functionality of warning people is distributed via the internet. Only a fraction of the available functions is working completely without an internet connection, such as the contact diary. Generally,

it does not need a continuous internet connection. However, the device on which the application is installed needs to be connected to the internet at best multiple times a day, but at least once a day to sync the contacts and update on test results.

The 3rd domain (*Usability*) focuses on how usable the health technology system is in order to ensure that its users can perform the required tasks (i.e., the intended function) safely, effectively, and efficiently, and with satisfaction. Therefore, accessibility, user empowerment, credibility, and trustworthiness are also considered in this domain.

Question 3.3. asks: “Are the health technology and digital public health intervention available in relevant languages?” When the CWA was first launched, it was available only in German and English. Russian, one of the most spoken immigrant languages in Germany, was not provided in the CWA until much later versions. Since version 2.20.0 for iOS and version 2.20.4 for Android, the CWA was available in German, English, Turkish, Bulgarian, Polish, Romanian, and Ukrainian.

Structural Aspects

The 4th domain (*Infrastructure and Organization*) considers the structure of the context in which the DiPH intervention is developed and implemented, as well as the involved stakeholders.

Question 4.4. asks: “Is the digital public health intervention flexible to suit local, cultural, or social needs?” Initially, the German government promoted centralized storage of user data, which, according to the Federal Ministry of Health, would allow it to better track the spread of infections. However, this had led to resistance from digital experts and data protectionists. As a consequence, the CWA was developed with the decentralized data collection across various servers. This approach ensured that the data could be decoupled, thereby hindering any potential tracing of app users.

The 5th domain (*Implementation*) describes aspects to consider before and during integrating the DiPH intervention into the health care system to ensure that the intervention is delivered properly. The domain focuses on the theory used for implementing the digital public health intervention, implementation infrastructure, process, and agents, as well as implementation outcomes and dissemination.

Question 5.9. asks: “Which implementation difficulties (e.g., duration, scope, disruptivity, centrality, complexity, and the number of steps required) did the digital public health intervention encounter?” In case of the CWA, necessary features (e.g., sharing of test results, embedding vaccination certificates) were not initially available when the app was first launched in June 2020 but had to be continuously added to the app.

Contextual conditions and outcomes-related domains

The 6th domain *Intended and Unintended Health-related Effects* considers the positive and negative effects on physical, mental, and social health, quality of life, well-being, and the knowledge, beliefs, and behavior of individuals and the population in the short, intermediate, and long term.

Question 6.2. asks, “To what extent is the digital public health intervention expected to impact the physical, mental, and/or social health of the individual and the population?” With its goal to prevent infections, the CWA was expected to positively affect individuals’ and, ultimately, population health. It is unclear how the large red warning sign displayed on users' smartphones when a high-risk contact with an infected person occurred would affect their mental health. Although generally accepted, the CWA was not used by the majority of the population and was widely discussed in terms of data privacy concerns prior to the launch of the app. With some individuals using the CWA and some not (including sometimes strong opinions in favor or against the benefit of the app within a social circle), this may have affected an individual’s relationships and social health.

The 7th domain *Social, Cultural and Intersectional Aspects* examines the societal, cultural, and intersectional dimensions pertinent to communities and groups of individuals, such as ethnic or demographic groups, people residing in the same neighborhood, those sharing common interests, or individuals with specific physical or mental conditions.

Question 7.5. asks, “Which factors in the society/community are relevant for the digital public health intervention implementation?” In the case of the CWA, it is the availability of compatible smartphones (e.g., older smartphones were not compatible), trust that data will be protected and not used for other purposes (e.g., analog data from guests of restaurants (not the data from the app) were used to identify suspects of thefts), and willingness to enter one’s data in case of infection.

The 8th domain (*Ethics*) addresses the moral considerations that arise from the implementation of DiPH interventions. The categorization of ethical principles is based on the influential 'Principles of Biomedical Ethics' by Tom L. Beauchamp and James F. Childress [16].

Question 8.20. asks: “Does the digital public health intervention discriminate against particular segments of the target population?” While efforts were successively visible to avoid discrimination, it took too much time to offer the app in different languages frequently spoken in Germany. People using phones with older operating systems were also excluded from applying the app.

The 9th domain *Legal and Regulatory* generates awareness about which areas of law must be considered when developing or evaluating DiPH interventions. It is not the purpose of the domain to pose every specific legal question that has to be answered in order to develop or evaluate DiPH interventions. Since laws differ from country to country, the domain helps to detect fields of law and typical problems in these fields that could be relevant for developers and evaluators. The applicable law and its requirements depend on the country.

Question 9.6. “Have you considered the potential reimbursement of digital public health interventions in a national health system (some countries may have specific requirements for reimbursement)?” raises awareness about what are the requirements for reimbursement of the DiPH interventions in a national health system or for other payers. Regarding the German CWA, the provider offered the intervention for free (without reimbursement option) because the free-of-charge offer of the CWA promises a broader and quicker distribution of the app.

The 10th domain provides information relating to *Data Security and Data Protection*. Data security focuses on the technological protection of data and, therefore, combines the aspects of data confidentiality, data integrity, data authenticity, data availability, and data controllability. Data protection relates to whether it is allowed to process personal data.

If personal data is transferred to third parties, question 10.25. asks “Is there is a legal basis for the transfer and are the requirements of the legal basis fulfilled?”. Regarding the case of the CWA, T-Systems International GmbH and SAP Deutschland SE & Co. KG are acting on the Robert Koch Institute’s behalf. The legal basis is a contract that is binding on the processor with regard to the controller and that sets out the subject matter and duration of the processing, the nature and purpose of the processing, the type of personal data and categories of data subjects and the obligations and rights of the controller (Art. 28(3) GDPR). Otherwise, the Robert Koch-Institute only passes on data to third parties if the Robert Koch-Institute is legally obliged to do so or if this is necessary for legal action or criminal prosecution in the case of attacks on the app’s technical infrastructure.

The 11th domain *Cost and Economics* assesses DiPH interventions regarding whether they can be considered a rational use of scarce resources.

Question 11.1. asks, “Which relevant costs and effects can be identified?”. Considering costs and effects of the intervention from the beginning could help comparing it with other interventions and show that it is economically dominant, i.e., it provides at least as effective but costs less than the alternative interventions. Further, this information might be the basis for health economic evaluation (see question 11.4 to 11.6) to see whether it costs per health gain is considered acceptable by the

payer. In the example of the CWA, there are various relevant costs of the intervention itself, like development and operation (2020: € 52.8 Mio; 2021: € 63.5 Mio) and promotion (2020 and 2021: € 13.7 Mio) of the CWA [31]. Taking a broader (societal) perspective, they might be further costs, such as costs of further testing when the CWA received a warning and costs for unrelated survival gains or benefits such a reduction in the loss of earnings, reduction of hospitalizations, rehabilitation measures and reduction of deaths [29]. However, to our knowledge, the pandemic context and the decision process about the CWA lead to a situation where a decision was made without formally considering cost-effectiveness in comparison with alternative decision options.

The 12th domain *Sustainability* asks for environmental, social, and economic sustainabilty.

Given the goal to reduce carbon emissions in healthcare, question 12.1. “Which resources are necessary to develop and maintain the digital public health intervention?” would be of relevance. In the case of the CWA servers need to run which produce carbon emissions and computers to ensure compatibility of health offices with the CWA need to be obtained. Measuring and evaluating these resource consumptions also allows decision-makers to consider more climate-friendly design alternatives for DiPH interventions.

Application of DigiPHrame for the development and evaluation of digital public health interventions

In this use case, we highlighted a number of questions relevant during the development of the CWA but also important for assessors once the CWA was available. For example, developers needed to consider how the data would be collected and shared without interfering with data privacy and data protection law. Similarly, assessors needed to find ways of evaluating the effectiveness of the CWA (e.g., Did the CWA prevent infections?) without the relevant data (due to de-centralized data storage, data from different individuals could not be connected, and thus only estimates could be determined). In future scenarios, DigiPHrame can serve both developers and assessors as a checklist that helps avoid overlooking key issues with relevance to the performance of the intervention. While for some questions, it might be enough to use common sense (in the case of the CWA, it could be questions surrounding the usability of the app); for others, specialist expertise may be necessary (e.g., questions regarding legal and regulatory issues).

The application of DigiPHrame is agile and primarily user-led (Box 1). We have deliberately included the option of feedback loops in the framework to support the agile development process

(Table 1). Although it is advised to consider all domains and respective questions, developers may decide which domains are assessed at what stage of their development process and which questions are relevant for the respective DiPH intervention. For an intervention under development, a first orientation might be enough to understand if it is worth continuing along the determined path or if adjustments might be necessary. Developers may also decide to put specific questions “on hold” and revise them at a later stage in case any changes or additions need to be made to the DiPH intervention. Similarly, assessors may delay answering certain questions in case no robust evidence is available at the time to answer the question.

Box 1: How to use DigiPHrame

Users of DigiPHrame are firstly encouraged to answer a list of questions regarding a general description of their DiPH intervention. Providing general characteristics will help assessors better understand the DiPH intervention under assessment. DigiPHrame is further equipped with a standardized answer scheme to help developers in answering the questions and if necessary, plan the next steps in the development process. For assessors the answer scheme can serve as a checklist to tick off all relevant criteria.

DigiPHrame users can respond to each question using the provided answer scheme. The first two assessment indicators are "Not applicable" when the question is irrelevant to the particular DiPH intervention, and "Assessment result" to provide the answer or additional information to the assessor. The last three columns of the answer scheme focus on the current status of the DiPH intervention during the assessment. These columns include "Assessment completed and sufficient" when the assessment is finished and satisfactory, "Assessment done but improvement needed" when the assessment is complete but indicates the need for improvements or changes to the DiPH intervention, and "Assessment only partially done or not possible yet" when the assessment is incomplete or not feasible at the moment.

Table 1: Example answer scheme

		Assessment indicator scheme				
		NA*	Assessment result	Assessment completed and sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
Criteria	Question					
e.g., Population	e.g., Who is the target population of	e.g., ✓	e.g., entire population	e.g., ✓	e.g., Briefly outline the necessary	e.g., (Insert specific steps to be

	the digital public health intervention?		at risk of getting infected with SARS-CoV-2		changes/expected date for revising the question	taken/expected date of completion)

*Not applicable

Discussion

A unified framework for digital interventions with a public health focus

While health-related digital technologies hold great potential for enhancing public health and addressing health-related inequalities at a relatively low cost, new developments are often driven by technological advancements and assessments and primarily revolve around clinical aspects of health. To the best of our knowledge, no existing frameworks consider digital interventions specifically designed for public health purposes. Additionally, previous frameworks primarily emphasize clinical aspects when addressing digital health technologies, neglecting the public health perspective. As an example, although the Evidence Standards Framework [15] emphasizes clinical outcomes, crucial for any intervention's success, it omits essential aspects such as sociocultural, ethical, legal, and sustainability factors vital for effectively implementing DiPH interventions. DigiPHrame includes aspects regarding clinical outcomes (e.g., Domain 6. Intended and Unintended Health-related Effects), among others derived from the Evidence Standard Framework but also the abovementioned factors. Moreover, while HTA frameworks [13] are often designed for evaluating existing technologies, our objective was to devise a comprehensive framework applicable across all stages of development and evaluation. DigiPHrame adopts a comprehensive public health perspective and can serve as a guide specifically for developers and assessors throughout the entire development and assessment of DiPH interventions. DigiPHrame provides users with criteria concerning clinical effectiveness, technical functions, usability, organizational, legal, ethical, economic, and socio-cultural aspects. Users have the flexibility to determine the relevant domains and assessment questions based on their specific needs and the stage of the process without relying on multiple development and assessment frameworks. Furthermore, the users of DigiPHrame are encouraged to take a broader view and may be inspired to include other perspectives that were not initially within their scope (e.g., social-cultural aspects, ethics, sustainability).

A holistic framework covering relevant domains for digital public health interventions

Additionally, deeper understanding of contextual factors is necessary to assess what will work in one country versus another. These factors can either enhance or hinder the adoption and diffusion of DiPH technologies. While many frameworks tend to overemphasize the technical aspects, it is essential to acknowledge that various other factors influence success or failure. These factors include disparities in health expenditure, demographic conditions, health infrastructure, information and communication technology (ICT) skill levels, digital health literacy, clinical and patient engagement, and many more. Recognizing and understanding these key differences within and across countries is crucial for policymakers and other stakeholders in public health and DiPH. While our framework takes these factors into consideration, future work needs to apply DigiPHrame in diverse contexts and countries to validate and continuously update the current version of the framework. Although our framework aims to be universally applicable to various DiPH technologies, it will require revision as new public health needs and DiPH technologies emerge. Therefore, our framework can serve as the foundation for a development and assessment toolkit that developers, decision-makers, and other users alike can utilize.

As we illustrated with the German contact-tracing app that was launched during the first wave of the Covid-19 pandemic, DigiPHrame can be applied for all stages including the design, implementation and evaluation. This may have helped to avoid potential pitfalls from the beginning that would have otherwise occurred further down the development process.

Strengths and Limitations

Our framework has several key strengths that set it apart. Firstly, it is based on a comprehensive scoping review of digital health and public health frameworks (OSF, https://osf.io/n8jge), ensuring a robust foundation. Additionally, we conducted scientific consensus meetings involving interdisciplinary experts, ensuring a breadth of perspectives in its development. Secondly, the assessment themes within our framework were derived from existing frameworks developed in various western countries, including Germany, the UK, and the US. This demonstrates the broad applicability of DigiPHrame across different geographical contexts, making it adaptable to diverse settings in developed countries. Another strength of our framework is its universality. It is not limited to specific types of DiPH interventions, therefore, can be applied to any digital intervention with the overarching aim of improving public health outcomes. This flexibility allows for its widespread application across a wide range of interventions.

Furthermore, DigiPHrame is designed as a living framework that will evolve and adapt as technology advances. To do so, we will continue to revise the domains and questions and regularly test any changes for face validity using a variety of use cases. This ensures that it remains relevant and up-to-date in the fast-paced DiPH landscape, accommodating emerging technologies and methodologies. Lastly, we incorporated input and expertise from various research fields throughout the entire development process of DigiPHrame. We fostered an interdisciplinary perspective by involving experts from different disciplines, including public health, epidemiology, psychology, philosophy, law, economics, human-computer interaction, and sociology, enriching the framework with diverse insights and knowledge.

While our framework has several strengths, it is important to acknowledge certain limitations. Firstly, going through the proposed framework might require significant time and expertise due to its complexity and depth. Nevertheless, it is flexible; it is up to the assessor to decide which domains and criteria are applicable to their specific case. This flexibility is advantageous, allowing the framework to be adapted to diverse contexts and DiPH interventions. However, it may also introduce subjectivity in the evaluation process, as different assessors may choose different domains and criteria, leading to varying outcomes. Ensuring transparency and consistency in domain selection could help mitigate this concern. Additionally, we intend to develop a condensed version of the framework focusing on the most critical domains and questions. Secondly, we engaged experts from diverse research fields to address potential inconsistencies during the development process. However, it is worth noting that the majority of our consultations did not extend to a broader geographical range, particularly in terms of incorporating specific aspects from low- and middle-income countries. It is crucial to recognize that contexts may differ significantly, including factors such as technology accessibility, digital health literacy, and legal requirements. While DigiPHrame aims to be applicable across different geographical contexts, users of the framework are advised to consider and adhere to their local requirements and nuances. Furthermore, in our scoping review we focused on primary prevention and health promotion, but not on secondary and tertiary prevention (e.g., rehabilitation). This could have have limited the frameworks and criteria found we found. Although as per our definition, DiPH focusses on primary prevention and health promotion, future research may also include frameworks focused on secondary and tertiary prevention. Lastly, we did not provide any evaluation methods along with the framework. As DigiPHrame evolves however, our goal is to provide suitable existing and develop novel evaluation methods for DiPH interventions.

Conclusion

DigiPHrame is a comprehensive framework for the development and assessment of digital technologies designed for public health purposes. Our framework may assist to design and evaluate DiPH interventions that serve public health needs rather than displaying technological advancements. Moreover, DigiPHrame may help avoid overlooking important aspects such as acceptability, usability, data security, or sustainability, which would otherwise result in low-value interventions that are not user-friendly, violating (data protection) law, or are not sustainable. We aim to revise and improve DigiPHrame as new technologies emerge and encourage developers and assessors to utilize and contribute to improving DigiPHrame.

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

Author contributions:
TJ and AG conceived of the concept of the manuscript. TJ drafted the first version of the manuscript. All authors contributed to the literature search, writing and editing of the manuscript. All authors read and approved the final manuscript.

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List of Abbreviations

CWA	Corona-Warn-App
DigiPHrame	Digital Public Health Framework
DiPH	Digital Public Health
ESF	Evidence Standards Framework
HTA	Health Technology Assessment
ICT	Information and Communication Technology
LSC DiPH	Leibniz ScienceCampus Digital Public Health
NICE	National Institute for Health and Care Excellence

Supplementary Files

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Multimedia Appendixes

Developing and Assessing Digital Public Health Interventions: A Digital Public Health Framework (DigiPHrame) Version 1.1, 05/2023.
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Evolution Domains and Subdomains through steps process.
URL: http://asset.jmir.pub/assets/5125a55f351892cbc820e7e2ce679bb3.docx

CONSORT (or other) checklists

PRISMA flow diagram revised.
URL: http://asset.jmir.pub/assets/3d66a9d8b2779f66b497825a6512e8d1.pdf

PRISMA Scr Checklist revised.
URL: http://asset.jmir.pub/assets/2cd84c984ce39980a1414eafaa2b5e43.pdf