Developing and Assessing Digital Public Health Interventions: A **Digi**tal **P**ublic **H**ealth F**rame**work (DigiPHrame)

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Overview

Why use this framework?

In order for digital public health interventions to be successfully developed, implemented and scaled up, it is curial to take interdisciplinarity and broader organizational and social contexts into account. Therefore, the **Digi**tal **P**ublic **H**ealth F**rame**work (DigiPHrame) is a comprehensive framework that takes into account the challenges of developing and implementing technology, considering the technical, social, legal, economic, and organizational aspects.

For whom is this framework useful?

DigiPHrame may be useful for everyone interested in developing and evaluating digital public health interventions including digital public health intervention developers, evaluators, policymakers and researchers.

When to use the framework?

DigiPHrame can be used throughout the whole development and evaluation process of a digital public health intervention. To avoid potential pitfalls that may otherwise arise along the development process of the digital public health intervention, DigiPHrame should be applied right from the beginning of the development process. This may help save time, money and other resources in a highly competitive and rapidly evolving field and may guide digital public health intervention developers and evaluators in making more informed decisions about which tools to use, endorse to users, invest in, partner with, or reimburse based on their potential quality and impact.

How to use this framework?

Firstly, users of DigiPHrame are encouraged to provide a brief abstract of the digital public health intervention under assessment. Secondly, users may answer each question by utilizing the provided answer scheme. DigiPHrame consists of 12 domains with 182 criteria framed as questions. Not all questions will be equally important or pertinent for all interventions, and some may not be applicable to all cases. However, it is important to consider them all at least once right at the beginning of the development process.

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About this framework

Purpose and scope of the framework

Public health aims to promote and enhance the health status of individuals and communities through collective societal efforts. Recently, several digital technologies have emerged, pursuing the same goal, developing a novel concept: digital public health. Given the rapidly increasing number of health-related digital technologies, a systematic framework is necessary to assess their values from a public health perspective.

The framework 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 digital public health interventions.

In total, it consists of 182 questions, structured by 12 domains: 1) Health Conditions and Current Public Health Interventions, 2) Technical Aspects, 3) Usability, 4) Infrastructure and Organization, 5) Implementation, 6) Intended and Unintended Health-related Effects, 7) Social, Cultural and Intersectional Aspects, 8) Ethics 9) Legal and Regulatory, 10) Data Security and Data Protection, 11) Cost and Economics, and 12) Sustainability.

Why use this framework

Currently, there are frameworks that systematically assess the use of health-related technologies such as the Health Technology Assessment Core Model (Lampe et al. 2009, EUnetHTA 2016), frameworks on digital health (without considering specifically public health) and frameworks on public health. Given the rapidly increasing digital technologies designed for public health interventions, a framework for digital public health interventions is deemed necessary.

DigiPHrame aims to be comprehensive; therefore, users need not draw on multiple frameworks for their assessments. Further, we acknowledge, that digital public health interventions cannot be successfully developed, implemented and scaled in isolation from broader organizational and social contexts in which it is being used. Therefore, we developed this framework that considers development and implementation challenges in light of the complexity of the sociotechnical structure and interplay between the technical, social, legal, economic and organizational aspects.

For whom is this framework useful?

DigiPHrame aims to assist digital public health intervention developers, evaluators, policymakers and researchers in the systematic development and evaluation of digital health interventions in public health by providing an up-to-date and comprehensive overview of criteria to assess digital public health interventions.

When to use this framework?

DigiPHrame is designed to assist digital public health intervention developers in considering aspects of the digital public health intervention lifecycle that usually occur along the different stages of the development process such as implementation, infrastructure or legal implications etc. right from the beginning of the development process. This will help to avoid potential pitfalls that may otherwise arise at a later development stage of the digital public health intervention saving time, money and other resources in a highly competitive and rapidly evolving field. Further, this may guide digital public health intervention developers and evaluators in making more informed decisions about which tools to use, endorse to users, invest in, partner with, or reimburse based on their potential quality and impact.

How to use this framework

In the beginning of DigiPHrame a list of questions regarding a general description of the digital public health intervention is provided. Users are encouraged to use these questions as a basis for creating an abstract describing their digital public health intervention. Providing general characteristics will help better understand and evaluate the digital public health intervention under assessment.

Each criterion in the framework is framed as a question. Users are encouraged to apply these questions to the digital public health intervention they want to develop and assess. Not all questions will be equally important or pertinent for all interventions, and some may not be applicable. There may not be any robust evidence available at the time to answer the question or no available information at all.

Users of DigiPHrame may answer each question by utilizing the provided answer scheme. The first two assessment indicators comprise *not applicable* in cases the question is irrelevant to the respective digital public health intervention and *assessment result* for the answer to each question or additional information to the evaluator.

The last three columns of the answer scheme focus on the current status of the digital public health intervention at the time of assessment and are comprised of: *assessment completed & sufficient, assessment done but improvement needed* and *assessment only partially done or not possible yet*. In cases where *assessment done & completed* applies, users may indicate this for the respective question and no further action is needed. In cases where the assessment is completed but the results indicate improvements or changes to the digital public health intervention, the user of the framework may specify so under *assessment done but improvement needed*. Here, any necessary changes and expected dates of completing the changes may be indicated. Similarly, if *assessment only partially done or not possible yet* applies, the user may provide information on specific steps to be taken in order to answer the question and indicate a date for revising the respective framework question. In the latter two

cases, the framework should be consulted again, once the changes to the digital public health intervention were made or the assessment could only be completed at a later stage.

The color codes indicate whether a question is sufficiently answered (blue), or whether any actions need to be taken in the form of an improvement to the intervention (yellow) or assessing the question at a later stage of the intervention development (purple). Ideally, at the end of the development and/or evaluation of the digital public health intervention all questions will be answered with *assessment done & sufficient* (blue) or *not applicable*.

Table 1: Example answer scheme

Domain Description					
e.g., "Health Conditions and Current Public Health Interventions" 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*
e.g., Population	e.g., Who is the target population of the digital public health intervention?	e.g., ✓	e.g., Inactive adults	e.g., ✓	e.g., Briefly outline the necessary changes/expected date for revising the question	e.g., (Insert specific steps to be taken/expected date of completion)
e.g., Accessibility (& Languages)	Are the health technology and digital public health intervention available in relevant languages?	e.g., ✓	Yes, Languages include: English, German, Turkish, Spanish	e.g., ✓	e.g., Intervention available in all necessary languages, but final check by native speakers of respective languages still under way. Expected completion by (DATE)	e.g., The intervention will be rolled out in multiple countries but is not yet translated into all necessary languages. Translation will be completed by (DATE)

*Not applicable

The framework does not provide methodologies related to the questions. For some questions, it might be enough to use common sense; for others, specialist expertise may be necessary.

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.

In summary, the application of the framework is primarily user-led. At a minimum, it can serve as a checklist that helps avoid overlooking key issues with relevance to the performance of the intervention.

How this framework was developed

DigiPHrame is the result of a three-step process. First, a scoping review was conducted to identify existing public health and digital health frameworks for developing and evaluating health interventions in primary prevention and health promotion and their assessment criteria (OSF scoping review protocol registration: https://osf.io/ku38m/). Second, all assessment criteria collected from the scoping review were analyzed and mapped into domains based on the structure of the Health Technology Assessment (HTA) Core Model (Lampe et al. 2009; EUnetHTA, 2016). Finally, multidisciplinary digital public health experts from the LSC were invited to a scientific consensus meeting to discuss and validate each framework domain.

The information sources for the scoping review included articles published in scientific journals. Journal articles were identified using the electronic literature search function of international bibliographic databases alongside the manual search of relevant reviews' reference lists. The electronic bibliographic databases used for the literature search were MEDLINE (via PubMed), Scopus, IEEE, CINAHL (via EBSCO) and PsycINFO (via Ovid). The search syntax in the bibliographic databases included the following basic 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 included synonyms and the most relevant subject terms of our primary keywords in each concept. A truncated term with the wildcard character was used when appropriate to maximize sensitivity while striving for reasonable precision. The final search was executed on the 12th of April 2022 with no language or publication date limitations.

The inclusion criteria included English-written journal articles, reports or thesis that depicted a descriptive framework. The aim of the frameworks had to be to develop, monitor, validate, evaluate, or implement interventions related to public health or digital health, focusing on primary prevention or health promotion at a population level. A total of 9,011 articles were identified after searching in the databases. After deduplication, 4,830 titles and abstracts were screened by two researchers independently. Following, 433 full texts were assessed by two independent researchers for potential extraction. Disagreements between the two researchers at both stages were discussed among them. If no agreement was achieved, a third researcher was involved in making a conclusive decision. After the full-text screening, 68 articles were included for data extraction.

Data from all 68 articles were extracted, specifically including the framework criteria and sub-criteria. These were inductively analyzed as a first step into clustered domains suggested by the EUnetHTA Health Technology Assessment (HTA) Core Model (Lampe et al. 2009,

EUnetHTA 2016). The multidisciplinary experts from the *Leibniz Science Campus Digital Public Health* (LSC DiPH) were assigned to domains to which they conferred and restructured according to specific characteristics of digital public health interventions. Where necessary additional literature was consulted.

A first version of the framework was sent to a multidisciplinary expert panel consisting of 105 members of the LSC DiPH. They were invited to give written feedback and to participate in an online scientific consensus meeting to discuss and validate each domain of the framework. A total of 25 members participated in the meeting on the 19th of July 2022.

After a multidisciplinary workshop applying a use case to the framework on 23rd of February 2023 and multiple consensus meetings with the framework team between February and May 2023 an updated version of the framework (V1.1) has been finalized.

Current status of this framework and outlook

As the field of digital public health is rapidly evolving, DigiPHrame has been designed as a living framework. The framework will be updated on a regular basis and be applied and tested on a heterogeneous set of digital public health interventions. As this occurs, additional literature will be integrated, and experts beyond the LSC DiPH will be consulted.

How you can participate

If you find items missing, questions difficult to understand or operationalize or if you have applied DigiPHrame and would like to share your experiences, we are very keen to hear from you.

In these cases, or if there is other relevant feedback, please send an e-mail to: framework@lsc-digital-public-health.de

General Description of the Digital Public Health Intervention

Please provide a description of the digital public health intervention. The questions listed below are intended to assist you in creating a short abstract including background information on the population's needs of this intervention and a brief description of the intervention.

- Why is this digital public health intervention needed?

- What is the goal of the digital public health intervention?

- What is this health technology (or technologies)? e.g., a device, a webpage, an app, or a plug-in like a chatbot?

- Who is the subject of the digital public health intervention?

- Who administers the health technologies in the digital public health intervention?

- Who is the provider of this software? (e.g., government, for-profit company, not-for-profit-company, trusted healthcare institution, academic institution)

- What are alternative health technologies or health interventions to this digital public health intervention.

- What are the components of the digital public health intervention (e.g., behavior change techniques, consultation, education, supervision, reminders, and regulations) and execution of intervention (timing and duration, dose and intensity)?

Insert abstract here:

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?					

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
			Assessment indicator scheme			
Conditions	1.8. What strength of association rating (at least in order) between the determinant(s) and health conditions are there, and what is the quality of the evidence?					
	1.9. What is the impact of the health conditions on society?					
Health Inequities	1.10. Are disadvantaged groups identified (e.g., according to PROGRESS-Plus)?					
	1.11. Is there an intersectional approach rather than a single variable approach on the identification of the target population (i.e., combination of different social factors such as gender, race/ethnicity, language, social class, migration background, age, sexual orientation, occupation, education and disability)					
	1.12. Is the target group of the intervention representative of the diverse experiences of people for whom the issue under study is relevant?					
	1.13. How are health inequities quantified or otherwise described?					

			Assessment indicator scheme			
Criteria	*Question*	NA	*Assessment result*	*Assessment completed & sufficient*	*Assessment done but improvement needed*	*Assessment only partially done or not possible yet*
Current Public Health Interventions	1.14. What is the current management of the health conditions in this context?					
	1.15. What are common alternative public health interventions?					
	1.16. Is there effectiveness evidence from alternative public health interventions?					

2. Technical Aspects

This domain assesses the general technical aspects of a health technology or a combination of health technologies used in a digital public health intervention (i.e., digital tools applied in the intervention, e.g., health app, wearable device, chatbot, or social media platform).

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
			Assessment indicator scheme			
Functionality	2.1. What is this health technology? e.g., a device, a webpage, an app, or a plug-in like a chatbot?					
	2.2. What are the functions offered by this health technology?					
	2.3. What is the rationale for choosing this health technology, and what are the expected (non-health related) benefits of using this particular health technology (compared to traditional public health intervention or other technologies)?					
	2.4. What is the relevant context to reach the target population?					
	2.5. What is the expected level of digital literacy of the target population?					
Interoperability	2.6. To what extent is the software interoperable (e.g., different hardware/software platforms or versions) and standardized?					

			Assessment indicator scheme			
		NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
Criteria	*Question*					
Interoperability	2.7. How is interoperability considered in the development and implementation (as in: realized in software/hardware) process?					
	2.8. Is the ability to move across different platforms (e.g., mobile and desktop) while maintaining profile preferences and information desired, and if so, how is it designed?					
	2.9. To what extent can the software part of the health technology be updated (e.g., to fix security issues, improve stability, etc.)?					
Data Integration	2.10. Does the software share data with other apps, networks, and medical record systems?					
	2.11. Does the software integrate data from other sources such as medical record systems?					
Open-source	2.12. Is this software/application open source? If yes, which parts?					
	2.13. Which open-source license is used?					
	2.14. Which open-source standards are used?					
	2.15. Which open-source standards are used (HTML is an					

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
			Assessment indicator scheme			
	open-source standard for example)?					
Stability	2.16. How often does the software crash?					
Internet Connectivity	2.17. Does the software require an internet connection (e.g., all the time, once in a while, once)??					
	2.18. If the internet is required, is broadband internet needed, or are there options for slow connections?					
	2.19. What amount of data usage does the use of the health technology imply – taking into account data per use and frequency of use (e.g., multiple times a day, once daily, once every few days, once a month, etc.)?					
	2.20. To what extent can the user influence the data usage?					
Feasibility	2.21. Can the health technology be tested under real conditions (e.g., during a pilot study)?					

3. Usability

This domain focuses on the usability of the health technology system in order to ensure that its users can perform the required tasks (i.e., the intended function) safely, effectively and efficiently, and with satisfaction.

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
			Assessment indicator scheme			
Accessibility (& Languages)	3.1. How accessible is the health technology (e.g., technically/in terms of literacy)?					
	3.2. Does the health technology support the operating's accessibility features (e.g., Windows', Apple's or Android's standard accessibility support)? If not, which accessibility features (such as adjusting text size, text to voice, or color-blind color scheme adjuster, …) are provided by the technology itself?					
	3.3. Are the health technology and digital public health intervention available in relevant languages?					
	3.4. Do the health technology and intervention provide easy language (for literacy) or an option for people who can´t read?					

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
			Assessment indicator scheme			
Usability	3.5. How is usability and user experience considered in the development and implementation (as in: realized in software/hardware) process (e.g., Nielson's 10 heuristic guidelines)?					
	3.6. How does the health technology respond to users´ needs?					
	3.7. How can the health technology be tailored according to users´ needs?					
	3.8. How can the health technologies be adapted to suit local, cultural, or social needs?					
	3.9. Are the usability criteria from ISO 9241-11 met?					
	3.10. How is usability considered in the development and implementation process (e.g., Nielson's 10 heuristic guidelines)?					
	3.11. Was the usability and user experience of the current design assessed (e.g., with SUS, MeCUE, UMUX, UEQ,...)?					

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
			Assessment indicator scheme			
Usability	3.12. How easy is it for users to accomplish basic tasks the first time they encounter the design?					
	3.13. Once users have learned the design, how quickly can they perform tasks?					
	3.14. How many errors do users make, how severe are these errors, and how easily can they recover from the errors?					
Co-creation and Empowerment	3.15. To what extent and how are potential end users involved in developing the digital public health intervention?					
	3.16. To what extent and how are different stakeholders involved in developing the digital public health intervention?					
	3.17. How does the health technology support users' empowerment?					
Credibility & Trustfulness	3.18. Are legal information (such as legal notice, contact person, relevant regulations, etc.) integrated and easily accessible for the user?					
	3.19. Are the evidence Is the information about the claimed health benefits of the health technology integrated and easily accessible for the user?					

4. Infrastructure and Organization

This domain considers the structure of the context in which the digital public health intervention is developed and implemented as well as the stakeholders that are involved in the development and implementation.

| | | Assessment indicator scheme | | | | |
| | | NA | Assessment result | Assessment completed & sufficient | Assessment done but improvement needed | Assessment only partially done or not possible yet |
Criteria	Question					
Structure of the Context	4.1. Which are the facilitators of the context where the digital public health intervention is implemented (i.e., political structure, distribution of power, budget allocation, health system structure, digital health strategy, market situation)?					
	4.2. Which are the barriers of the context where the digital public health intervention is implemented (i.e., political structure, distribution of power, budget allocation, health system structure, digital health strategy, market situation)?					
	4.3. Which aspects of the context interact with the development and implementation of the digital public health intervention?					
	4.4. Is the digital public health intervention flexible to suit local, cultural, or social needs?					

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
			Assessment indicator scheme			
Intra-organizational Relationship	4.5. Which stakeholders are involved in the development, implementation, and evaluation of the digital public health intervention?					
	4.6. Which capabilities (e.g., funds, human resources, skills) are required among stakeholders (e.g., governments, health professionals, local agencies, local communities, health providers) to develop and evaluate the digital public health intervention?					
	4.7. What is the nature of the relationship between stakeholders (e.g., dependency, power structure, intensity of connection)?					
	4.8. How is the communication between stakeholders (e.g., regularity, intensity, mechanisms for conflict management)?					
	4.9. Which is the degree of alignment between stakeholders (e.g., shared vision, common goals, mutual acceptance)?					

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
			Assessment indicator scheme			
Health System Interaction	4.10. How does the digital public health intervention impact the organization of the health system?					
	4.11. How does the digital public health intervention impact the efficiency of the health system?					

5. Implementation

This domain signifies each element of the intervention implementation (i.e., implementation theory, implementation infrastructure, implementation process, implementation agents, implementation outcome, and dissemination) of the digital public health intervention.

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
Implementation Theory	5.1. What implementation theory was used for the implementation of the digital public intervention?					
	5.2. How does this theory interact with the context?					
Implementation Infrastructure	5.3. Which financial resources are needed to implement the intervention?					
	5.4. What equipment (e.g., rooms, office material, computer, mobile phones, hardware) is needed to implement the intervention?					
	5.5. What data, records, or registry are needed to monitor the implementation of the intervention?					
	5.6. What requirements in terms of qualification and quality assurance processes are needed for the implementation and maintenance of the intervention?					

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
			Assessment indicator scheme			
	5.7. Which human resources (i.e., personnel) are necessary for implementing the digital public health intervention?					
Implementation Infrastructure	5.8. What training resources and information should be provided to the intervention subject or their care givers?					
Implementation Process	5.9. Which implementation difficulties (e.g., duration, scope, disruptivity, centrality, complexity, and the number of steps required) did the digital public health intervention encounter?					
	5.10. How does the implementation process interact with the context?					
	5.11. Was the digital public health intervention implemented as intended?*					
	5.12. What intervention components were modified during the implementation of the digital public health intervention?*					
Implementation Agent	5.13. Which implementation agents (i.e., those delivering the intervention) are involved in the implementation of the digital public health intervention?					

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
			Assessment indicator scheme			
	5.14. How do these implementation agents interact with the context?					
Implementation Outcome	5.15. Which implementation outcomes are reported?					
Implementation Outcome	5.16. How do these implementation outcomes interact with the intervention outcomes?					
Dissemination	5.17. Which information about the intervention should be provided to the general public (i.e., intervention dissemination)?					
	5.18. How do the evaluators ensure their findings are accessible to the concerned population?					
	5.19. How is the transparency compliance accounted for (e.g., honesty, trustfulness, disclosure and public justification)?					

*only to be answered in the evaluation phase

6. Intended and Unintended Health-related Effects

This domain 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.

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
			Assessment indicator scheme			
Mortality	6.1. To what extent is the digital public health intervention expected to impact mortality?					
Health outcome	6.2. 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?					
Function	6.3. To what extent is the digital public health intervention expected to impact on functioning (e.g., ability to work, daily life activities, autonomy)?					
Quality of Life and Well-being	6.4. To what extent is the digital public health intervention expected to impact the general quality of life?					
	6.5. To what extent is the digital public health intervention expected to impact the specific quality of life?					
	6.6. To what extent is the digital public health intervention expected to impact the physical, mental, and social well-being?					

| | | Assessment indicator scheme | | | | |
Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
Knowledge and Behavior Change	6.7. Which theory or behavioral framework was used for intervention development?					
	6.8. How is the digital public health intervention expected to affect knowledge?					
	6.9. How is the digital public health intervention expected to affect beliefs (e.g., outcome expectancies)?					
	6.10. How is the digital public health intervention expected to affect attitude(s)?					
	6.11. How is the digital public health intervention expected to affect skills or competencies?					
	6.12. How is the digital public health intervention expected to affect capabilities?					
	6.13. How is the digital public health intervention expected to affect motivation?					
	6.14. How is the digital public health intervention expected to affect opportunities?					
	6.15. How is the digital public health intervention expected to affect behavior?					

7. Social, Cultural and Intersectional Aspects

This domain analyses the social, cultural, and intersectional aspects related to societies, communities, and groups of people, e.g., ethnic groups, demographic groups, people sharing the same neighborhood, interests, or a specific physical or mental condition.

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
			Assessment indicator scheme			
Context	7.1. In which context is the digital public health intervention supposed to be employed?					
Social and Societal Impact	7.2. How will the digital public health intervention affect societal and cultural values, attitudes, norms and perspectives?					
Impact on Intersectional Social Positions	7.3. How will the digital public health intervention affect relevant intersectional social positions and their relationships with each other?					
Socio-cultural Acceptability	7.4. How is the digital public health intervention in accordance with societal and cultural values, attitudes, norms and perspectives of the intended population?					
Community Capacity	7.5. Which factors in the society/community are relevant for the digital public health intervention implementation?					

			Assessment indicator scheme			
Criteria	*Question*	NA	*Assessment result*	Assessment completed & sufficient	*Assessment done but improvement needed*	*Assessment only partially done or not possible yet*
Community Capacity	7.6. Is there a political will for the development/implementation of the digital public health intervention?					
Community Participation	7.7. How is the society/are communities involved in the development and implementation of the digital public health intervention?					

8. Ethics

This domain addresses the ethical considerations that arise from the implementation of digital public health interventions. The following categorization of ethical principles is based on the influential 'Principles of Biomedical Ethics' by Tom L. Beauchamp and James F. Childress.

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
Autonomy	8.1. Does the digital public health intervention have a positive or negative impact on freedom of choice?					
	8.2. Does the digital public health intervention promote health literacy in the target population?					
	8.3. Does the digital public health intervention adequately respect the privacy of the target population?					
	8.4. Are there alternatives to the digital public health intervention that the target population can choose?					
	8.5. Does public access to information about the digital public health intervention promote informed decision-making and transparency about the digital public health intervention?					

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
			Assessment indicator scheme			
Autonomy	8.6. Is there an institution to which target subjects or groups of the digital public health intervention can turn with concerns?					
	8.7. Can individuals drop out of the digital public health intervention, or is coercion being applied?					
Harm/ non-maleficence	8.8. Does the digital public health intervention have the potential to harm the target population?					
	8.9. Is the digital public health intervention featured by functionality, safety, and low error susceptibility?					
	8.10. Will sufficient data security be ensured?					
	8.11. Can accountability be assigned in cases of harm?					
	8.12. Are third parties outside the target population potentially affected/harmed by the digital public health intervention?					
	8.13. Is the digital public health intervention harmful to the environment?					

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
					Assessment indicator scheme	
Harm/ non-maleficence	8.14. Is research being conducted to replace the digital public health intervention with lower harms and risks?					
Beneficence	8.15. Is the digital public health intervention beneficial for the target population?					
	8.16. Do the benefits align with the initial goals of the digital public health intervention?					
	8.17. Do the benefits outweigh the harms?					
Justice	8.18. Does the digital public health intervention help address local, regional, and global health inequities?					
	8.19. Are the benefits, harms and risks of the digital public health intervention equitably distributed in the target population?					
	8.20. Does the digital public health intervention discriminate against particular segments of the target population?					

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
				Assessment indicator scheme		
Justice	8.21. Is non-discriminatory access to digital public health intervention available?					
	8.22. Are vulnerable groups protected to a distinctive measure?					
	8.23. How is the impact on future generations considered?					
	8.24. Did a fair and legitimate decision-making process precede the digital public health intervention?					

9. Legal and Regulatory

This domain generates awareness about which areas of law have to be taken into account when developing or evaluating digital public health 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 digital public health 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.

Criteria	Question	NA	Assessment indicator scheme			
			Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
Data Protection	9.1. Have you considered international or national data protection laws that could impose requirements for the intervention?					
Data Security	9.2. Have you considered national or international requirements for data security that could be relevant to the intervention (e.g., appropriate technical and organizational measures or provisions for risk management)?					
Consumer Protection	9.3. Have you considered national or international consumer law duties that could set rules for the intervention?					

		Assessment indicator scheme				
Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
Medical (Device)	9.4. Have you considered international or national regulations the intervention must comply with in order to access the market (e.g., medical device regulation and CE marking)?					
	9.5. Have you considered international or national medical laws relevant to the intervention?					
Health System Financing	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)?					

10. Data Security and Data Protection

This 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 the question of whether it is allowed to process personal data.

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
Data Confidentiality	10.1. Are stored or transmitted data protected from unauthorized access (e.g., through encryption)?					
	10.2. Are user authentication and identification complemented in combination with authorization for access?					
	10.3. Who manages/is allowed to grant access rights?					
	10.4. Are there different levels of confidentiality (all data, subset, …)?					
Enforcement of Data Integrity	10.5. Have cryptographic measures been taken (e.g., message authentication code, digital signature)?					
	10.6. Is remote downloading of programs done from a secure system (e.g., a specially secured secure server)?					

| | | Assessment indicator scheme | | | | |
Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
Enforcement of Data Integrity	10.7. Are there access controls assigned to computers, data carriers and data lines? Is there assignment of rights?					
Data Authenticity	10.8. Is there a digital signature as proof of the authenticity and its unambiguous assignment to the signatory by means of a digital certificate?					
	10.9. Do measures exist for the authentication of computers, programs, users and data?					
Data Availability	10.10. Which measures exist for physical data protection?					
	10.11. Which measures exist for error detection and correction?					
	10.12. Do redundant systems or system components exist?					
	10.13. Are security copies made for the fast recovery of destroyed data (backup)?					
	10.14. Is there protection against automated attacks (e.g., by botnets, SQL injections, …)?					

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
			Assessment indicator scheme			
Data Controllability	10.15. Is there a logging process?					
	10.16. Which standards or certifications for IT security are fulfilled?					
Data Protection	10.17. Is data processed lawfully, fairly and in a transparent manner in relation to the data subject?					
	10.18. Is data collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes (purpose limitation)?					
	10.19. Is data processing limited to what is necessary in relation to the purposes of data processing (data minimization)?					
	10.20. Is data kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed (storage limitation)?					

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
			Assessment indicator scheme			
Data Protection	10.21. If the intervention asks for consent: How is informed consent regarding data processing guaranteed (consider specifically minors and vulnerable groups)?					
	10.22. Is there appropriate information for the users regarding data processing?					
	10.23. If the intervention processes health data: Are there specific safeguards for processing these sensitive health data?					
	10.24. If there are automatic decisions: Are there specific measures to protect users against biased automatic decisions (e.g., decisions based on AI)?					
	10.25. If personal data is transferred to third parties: Is there a legal basis for the transfer, and are the requirements of the legal basis fulfilled?					

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
			Assessment indicator scheme			
Data Protection	10.26. If personal data is transferred to third countries: Is there a legal basis for the transfer, and are the requirements of the legal basis fulfilled?					
	10.27. Are user rights regarding data processing realized (such as erasing personal data, right of access)?					
	10.28. If there are several processors: Is the processing governed by a contract or another legal act, for the case that the processing is to be carried out on behalf of a controller. Or does an arrangement exist for the case that the processors are joint controllers?					
	10.29. Do procedures exists for the notification of a personal data breach to the supervisory authority and to the data subject without undue delay?					

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
			Assessment indicator scheme			
Data Protection	10.30. Do you maintain a record of processing activities under your responsibility and have you carried out an assessment of the impact of the envisaged processing operations on the protection of personal data?					

11. Cost and Economics

This domain assesses digital public health interventions with regard to the question of whether they can be considered a rational use of scarce resources.

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
Prior to the Economic Assessment	11.1. Which relevant costs and effects can be identified?					
	11.2. For which payer are these costs and effects relevant? (e.g., private individuals, health care reimbursement agencies, or public entities with other/additional considerations than health)					
	11.3. What are the payer's decision criteria and corresponding requirements for health economic evaluation? (e.g., individuals might acquire the intervention for aesthetic reasons or other personal considerations; health care reimbursement agencies are typically interested in health gains; other public policymakers may consider other/further aspects such as education or community building)					

Criteria	Question	Assessment indicator scheme					
		NA	Assessment result		Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
Economic Evaluation Methods Potentially Relevant	11.4. What is the cost of the targeted disease (cost of illness analysis)?						
	11.5. How cost-effective is the digital public health intervention in relation to: ▪ individual considerations of added value (no formal evaluation necessary but individual evaluation of costs vs. willingness to pay) ▪ specific health endpoints (cost-effectiveness analysis, of particular relevance if different interventions with similar clinical outcomes are compared) ▪ generic health endpoints (cost-utility analysis, of particular relevance if the digital public health interventions are assessed against other uses of scarce healthcare and public health resources)						

Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
			Assessment indicator scheme			
Economic Evaluation Methods Potentially Relevant	▪ social willingness to pay (cost-benefit-analysis, of particular relevance if various benefits are relevant and acquisition of the digital public health intervention can or should not be left to private decisions and budgets)?					
	11.6. What is the total cost of implementing the digital public health intervention over time (budget impact analysis)?					

12. Sustainability

This domain accounts for long-term impacts of digital public health interventions on an environmental, social and economic level.

		Assessment indicator scheme				
Criteria	*Question*	NA	*Assessment result*	*Assessment completed & sufficient*	*Assessment done but improvement needed*	*Assessment only partially done or not possible yet*
Environmental Sustainability	12.1. Which are the resources needed to develop and maintain the digital public health intervention?					
	12.2. What are the environmental impacts associated with these resources?					
	12.3. Which are the strategies for reducing the environmental impacts of the digital public health intervention?					
	12.4. What are the strategies for guaranteeing the enhancement of the environment throughout the digital public health intervention?					

| | | | Assessment indicator scheme | | | |
Criteria	Question	NA	Assessment result	Assessment completed & sufficient	Assessment done but improvement needed	Assessment only partially done or not possible yet
Social Sustainability	12.5. How is the satisfaction of the different stakeholders involved in the digital public health intervention measured (e.g., the continuity of the intervention can be better assured when stakeholders are satisfied with the intervention and its outcomes)?					
	12.6. Which are the unintended social impacts of the digital public health intervention?					
Economic Sustainability	12.7. How and by whom is the financing of the digital public health intervention continuity assured?					
	12.8. What are the economic effects of the digital public health intervention for future generations (e.g., is the intervention financially burdening the upcoming generations)?					