World Health
Organization

European Region

Equity across the regulation, implementation and evaluation of digital health

Scoping review

World Health Organization

European Region

Equity across the regulation, implementation and evaluation of digital health

Scoping review

Abstract
Digital health has the potential to improve health-care delivery and population health outcomes. To ensure equitable benefits, its development and implementation must address potential health inequities arising from biased technologies and systemic factors. A scoping review used a sociotechnical lens to examine how equity is considered in digital health regulation, implementation and evaluation within the WHO European Region. Equity is increasingly acknowledged in digital health, but its integration into practice remains inconsistent. Regulatory frameworks primarily emphasize safety, privacy and performance, with limited focus on inclusion of underserved populations or adaptability to low-resource settings. Implementation strategies often overlook structural barriers. Standardized equity metrics and robust bias auditing for artificial intelligence-driven technologies are lacking. The review highlighted the need for an equity-by-design approach to embed equity throughout the digital health life cycle. Advancing equity requires inclusive governance, participatory design and cross-sectoral collaboration. Recommendations include establishing a shared understanding of equitable digital health, integrating equity metrics into maturity models, and reinforcing regulation, governance and sustainable financing. The Region is positioned to lead harmonization efforts and support Member States to embed equity within digital health policies and practices, ensuring that digital health contributes to improved health outcomes, stronger health systems and reduced health inequities.

Keywords
DIGITAL HEALTH, HEALTH EQUITY, SCOPING REVIEW, DELIVERY OF HEALTH CARE

Document number: WHO/EURO:2026-13153-52927-82472 (PDF)

© World Health Organization 2026

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; https://creativecommons.org/licenses/by-nc-sa/3.0/igo).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition: Equity across the regulation, implementation and evaluation of digital health: scoping review. Copenhagen: WHO Regional Office for Europe; 2026".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization (http://www.wipo.int/amc/en/mediation/rules/).

Suggested citation. Equity across the regulation, implementation and evaluation of digital health: scoping review. Copenhagen: WHO Regional Office for Europe; 2026. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Sales, rights and licensing. To purchase WHO publications, see http://apps.who.int/bookorders. To submit requests for commercial use and queries on rights and licensing, see https://www.who.int/about/policies/publishing/copyright

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Designed by: PELLEGRINI

Contents

Acknowledgements

This document was developed by the Data and Digital Health Unit, Division of Country Health Policies and Systems of the WHO Regional Office for Europe. The main authors were Diana Bright, Alisha Davies, Kirsty Little, Claire Morgan and Sana Shaikh of the Public Health Data, Knowledge and Research Directorate, Public Health Wales, Cardiff, United Kingdom. Clayton Hamilton and David Novillo Ortiz (Data and Digital Health Programme) provided technical advice and direction during the production process. WHO would also like to thank Natasha Azzopardi-Muscat, Director of the Division of Country Health Policies and Systems, for her strategic guidance.

WHO wishes to thank the external experts, Louise Holly (Policy and Research Coordinator, Digital Transformations for Health Lab, Utrecht, Netherlands (Kingdom of the)), Eric Sutherland (Senior Health Economist, Organisation for Economic Co-operation and Development, Paris, France), Adnan Hyden Hyder (Senior Associate Dean for Research and Innovation and Professor of Global Health, Milken Institute School of Public Health, George Washington University, Washington, United States of America) and Saif Khairat (Professor of Digital Health and Informatics, University of North Carolina, Chapel Hill, United States of America) for their insightful feedback on the initial draft of the report. Thanks also go to Enfys Preece (Public Health Research Officer, Public Health Wales, Cardiff, United Kingdom) and Helen Morgan (Information Specialist, Public Health Wales, Cardiff, United Kingdom) for their support with data extraction and the search strategy, respectively.

This publication was co-funded by the European Union. Its contents are the sole responsibility of WHO and do not necessarily reflect the views of the European Union.

Abbreviations

AI	artificial intelligence
COVID-19	coronavirus disease
DHT	digital health technology
EU	European Union
FAIR	findability, accessibility, interoperability and reusability (principles)
GDPR	General Data Protection Regulation (European Union)
LMIC	low- and middle-income countries
m-health	mobile health
PROGRESS-Plus	place of residence, race/ethnicity/culture/language, occupation, gender/sex, religion, education, socioeconomic status and social capital, plus other key characteristics (framework)
NHS	National Health Service (United Kingdom)
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
RE-AIM	reach, effectiveness, adoption, implementation, maintenance (framework)
SAFE-D	sustainability, accountability, fairness, explainability and data responsibility (principles)
STANDING	STANdards for data Diversity, INclusivity and Generalisablity

Executive summary

Introduction

The digital transformation of health systems has rapidly accelerated since the coronavirus disease (COVID-19) pandemic, reshaping how people connect, access information and engage with health services. Digital health and artificial intelligence (AI) offer a transformative potential to prevent poor health and improve health-care access and efficiency, as well as patient outcomes. Ensuring equity in digital health systems is essential to avoid further marginalizing disadvantaged populations and to support innovation that can help reduce health inequities.

WHO highlights equity as a priority in the *Global strategy on digital health 2020–2025* and *Regional digital health action plan for the WHO European Region (2023–2030).* While regulations, frameworks and guidance for digital health increasingly reference equity, it is unclear whether the narratives are limited to high-level statements of principles or effectively embedded into digital health design and implementation.

To address this gap, Public Health Wales (United Kingdom), conducted a scoping review to assess how equity is incorporated into the regulation, implementation and evaluation of digital health systems. The review aims to provide insights to support efforts to strengthen equitable digital health systems across the WHO European Region.

Methods

A thematic appraisal based on a sociotechnical framework was conducted to examine the consideration of equity across technical (digital infrastructure, data and digital tools) and social (access to digital technology, digital skills and user engagement) components of a digital health system. A search of peer-reviewed and grey literature published between 2015 and 2024 identified 154 relevant articles. A scoping review was conducted to answer the following three questions.

1. To what extent is equity incorporated into regulations for digital health across the WHO European Region and globally?
2. To what extent is equity incorporated into the implementation or evaluation of digital health across the WHO European Region and globally?
3. What are the implications of the findings towards ensuring equitable benefit from digital health innovation?

Types of evidence

A total of 154 publications (50% each academic and grey literature) were included in the review, of which the majority focused on a single topic (28% on implementation of digital health, 14% on evaluation and 6% on regulation), and 40% featured both implementation and evaluation. The publications primarily originated from the WHO European Region (45%), followed by North America (34%), global organizations (14%) and Member States of other WHO regions (8%).

Across the publications, no consistent terminology or framework was used to describe disadvantaged or marginalized populations. Discussions of equity most commonly referred to ethnicity (63%), age (60%), disability (55%) and urban/rural residence (51%). Some articles considered the intersectionality of equity, reflecting a growing awareness of the compound effects of the multiple overlapping forms of disadvantage. However, equity in digital health largely focused on demographic groups in silos, with little consideration of interactions between groups or with the social and digital determinants of health.

Although some publications discussed equity in terms of digital health development and deployment, the emphasis varied from high-level generic statements to guidance on the specific technical/social components of a digital health system. The principles of a whole-system approach (e.g. equity by design) were inconsistently applied, which may inhibit the systematic integration of equity into digital health development and deployment in practice.

Results

Equity in digital health regulation

Regulations often considered the hardware and software resources needed to deploy digital health innovation effectively but lacked consideration of equity in the digital infrastructure. Interoperability was recognized as good practice, but it is not yet mandated. Regulatory frameworks for data emphasized individual privacy protections and accountability (such as the European Union (EU) General Data Protection Regulation and EU Artificial Intelligence Act and the United States of America Health Insurance Portability and Accountability Act). However, they lacked consideration of the meaningful involvement of vulnerable or marginalized populations in personal data protection.

Within the regulation of digital health technologies (DHTs), equity was primarily considered within safety, effectiveness and performance, with equity in bias and fairness largely limited to ethnicity and gender. Recently, several legislative efforts, including the EU's Data Governance Act and Artificial Intelligence Act, have aimed to enhance transparency, promote ethical data use and reduce algorithmic bias. These regulatory frameworks are promising steps towards equity-aware governance, but lack enforceable mechanisms for equity in the design and implementation of digital health tools. No evidence was identified on equity in digital health tools post deployment, even though post-market surveillance of digital health tools is mandatory to monitor safety and effectiveness. Without specific requirements for equity-focused monitoring and evaluation, potential equity issues may go unrecognized or unaddressed, thereby reinforcing exiting health disparities.

Current regulations for digital health tools do not address the inclusion of digital access or skills in patients and health professionals. Although some regulatory frameworks do address accessibility, trust and usability, they do not fully incorporate equity considerations, particularly for marginalized populations. There is a need for regulations that explicitly ensure accessibility, build trust and promote sustained use, with a focus on inclusivity and cultural sensitivity across diverse groups.

Equity in digital health implementation

Implementation frameworks incorporating the technical and social aspects of a digital health system were identified, but varied considerably in their emphasis on equity and methods for improving equity.

Guidance to support the implementation of digital health frequently acknowledges the importance of having the appropriate digital infrastructure. For example, DHTs should be designed to function on basic digital systems and in low-bandwidth settings to ensure their usability in resource-limited environments and among marginalized populations.

Complementary initiatives that promote the implementation of inclusive digital health, including guidance on data governance (e.g. STANDING Together's collaborative recommendations and the sustainability, accountability, fairness, explainability and data responsibility (SAFE-D) principles) and digital systems (e.g. the findability, accessibility, interoperability and reusability (FAIR) principles), increasingly emphasise equity by design. Numerous implementation frameworks have also been developed to support equitable access to technology, digital skills and user engagement.

Although several implementation frameworks focus on equity (e.g. the Digital Healthcare Equity Framework and the Health Equity Impact Assessment tool), evidence on their effectiveness in driving change towards equitable digital health systems remains limited.

While the available implementation guidance spans the technical and social domains of a digital health system, the examples identified represent good practice only. There are no common minimum requirements for equity across the implementation of digital health, and accountability for ensuring equity in digital health implementation is unclear (e.g. quality improvement roles, regulatory oversight).

Equity in digital health evaluation

Evaluation frameworks did not consistently or comprehensively include interoperability across different digital infrastructures, and few considered equity in adaptability (e.g. how well a tool can adapt to the needs of diverse users) or scalability (e.g. whether a tool remains accessible and effective for underserved groups as its reach is expanded).

Underrepresentation of those at greater risk of experiencing inequity makes it difficult to evaluate the effectiveness of digital health across different populations. AI-driven health technologies require more rigorous equity evaluations, but bias audits, fairness checks and transparency mechanisms for AI-driven health care remain largely aspirational.

Equity-focused indicators are often lacking in routine monitoring and evaluation frameworks for digital health, reducing the ability to detect and track disparities, or adjust interventions for inclusive impact. The use of approaches such as the Health Equity Impact Assessment tool, may inform a framework to capture both the technical and social domains of digital health, but representative data and qualitative insights from diverse user groups are essential to support the evaluation of more inclusive and equitable digital health system.

Use of the evaluation of digital health to inform implementation drew largely on health technology assessments, which focus on clinical effectiveness, cost–effectiveness and safety. Strengthening such tools to better embed equity considerations would also support more inclusive and equitable evaluation of digital health systems.

The lack of real-world impacts of equity-focused digital health evaluations highlights the importance of case studies and shared learning on how evaluation frameworks influence equity in digital health deployment within complex systems.

Considerations

As the understanding of equity in the context of digital health continues to evolve, regulators, policy-makers and health systems are increasingly adopting measures to prevent and address potential inequities arising within digital health systems. This review highlights the complexity of achieving digital transformation in health while ensuring equity, and considers the need for a whole-system approach that moves beyond high-level principles towards actionable strategies and measurable outcomes to promote equity in digital health transformation. To support this effort, the review identified the following considerations across key cross-cutting areas to advance equity in digital health across the WHO European Region.

Moving towards an equitable digital health system

- Develop a shared understanding of what an equitable digital health system consists of to address fragmentation and lack of coherence in digital health policies and support a comprehensive approach to ensuring equity is embedded into digital transformation. Without coordinated efforts, there is a risk that fragmented interventions will contribute to a cumulative digital health equity gap.
- Develop a common definition of core equity domains and measures of equity in digital health systems, to facilitate evaluation and shared learning across the Region.

Using tools and frameworks to operationalize equity

- Develop a maturity matrix for an equitable digital health system to support countries to identify and address equity gaps within their unique digital and health system contexts.
- Define interoperable minimum equity standards across the technical and social components of a digital health system (e.g. data standards for equity, user-centred design), and ensure effective governance structures for implementation.
- Promote the use of tools to support the development of equitable digital health systems (e.g. equity-by-design principles, equity impact assessment tools), and facilitate shared learning and knowledge transfer to support scalability.

Strengthening regulation, governance and financing for digital health equity

- Promote the harmonization of equity-focused regulatory frameworks and strengthen requirements for inclusive design and deployment (e.g. equity by design) to ensure that digital health innovation prioritizes equity.
- Strengthen governance and accountability for equity in digital health systems by:
  - ensuring oversight of digital health tools after deployment through standardized monitoring and evaluation frameworks for access and outcomes across population groups, and capturing the underlying drivers of differences in real-world settings.
  - implementing sustainable financing and reimbursement mechanisms to promote inclusive innovation, for example, by incentivizing developers to demonstrate how their tools address the needs of underserved populations and reduce health disparities.
- Address technological and market power imbalances to ensure equitable access to digital health solutions for all.

Building capacity and cross-sectoral collaboration for digital health equity

- Bring together interdisciplinary teams across digital, data, clinical, social, lived experience to ensure representation across diverse backgrounds (e.g. gender, ethnicity) to protect against unconscious bias.
- Establish communities of practice and implementation science networks to share learning and support equity-focused implementation of digital health through dissemination of standardized frameworks, tools and lessons learned.
- Collate and implement best practice approaches to support active engagement in the development and implementation of digital health tools and systems to ensure equity and build trust across the public, professionals and communities.
- Advocate for digital health equity by levering international research and supporting policy experimentation and engagement across government, academia and public sector to build more equitable digital health systems.

1. Introduction

1.1 Background

Digital transformation is reshaping health systems across the WHO European Region. As digital technologies become increasingly central to how people access information, connect with services and engage in their own care, digital health has emerged as a key enabler of health system strengthening *(1,2)*. It offers the potential to improve health outcomes, increase efficiency and improve access to health services. However, without explicit considerations on equity, digital health innovation risks reinforcing or exacerbating existing health inequities *(3–6)*. Box 1 contains the definitions of digital health and equity used in this report.

Box 1. Definitions used in the report

Digital health: the field of knowledge and practice associated with the development and use of digital technologies to improve health. It expands the concept of ehealth to include digital consumers and a wider range of smart and connected devices. It also encompasses other uses of digital technologies for health such as the internet of things, advanced computing, big data analytics and AI, including machine learning and robotics *(2,4)*. Within this review, specific terminology related to digital health is used as follows.

- **Digital health innovations:** this refers to novel or emerging DHTs, methods or approaches that represent advancements over existing technologies or practices.
- **Digital health tools:** this term is used broadly to cover technologies that support health and health-care delivery.
- **DHTs:** this term is used specifically when referring to tools that are evaluated or discussed within regulatory, implementation or evaluation frameworks.
- **Digital health solutions:** this term is used to emphasize integrated or user-facing applications of DHTs that provide health services or interventions.

Equity: the absence of unfair, avoidable or remediable differences among groups of people, whether they are defined socially, economically, demographically, geographically or by other dimensions of inequity (e.g. gender, sex, ethnicity or disability) *(7)*.

AI: artificial intelligence; DHT: digital health technology.

WHO has a critical leadership role in building consensus across the field of digital health. Building on its *Global strategy on digital health 2020–2025*, which has equity as a core principle *(2)*, WHO has developed a suite of technical guidance and regional initiatives to support countries in implementing inclusive, rights-based digital health systems *(8,9).* Central to these efforts is the understanding that accessible, ethical and inclusive digital health innovations are critical to advancing universal health coverage and achieving the health-related Sustainable Development Goals *(10,11)*. In the WHO European Region, this commitment is further reinforced through the Regional Digital Health Action Plan for the WHO European Region 2023–2030 (document EUR/RC74/8) *(9)*, as adopted by the Seventy-second session of the Regional Committee for Europe in resolution EUR/RC72/R2 *(12)*. The Action Plan prioritizes raising awareness of equity in digital environments and proposes the development of a European framework to measure digital health equity.

In support of this vision, Public Health Wales (United Kingdom) conducted a comprehensive scoping review of the extent of digital health inequities across the Region across 10 different domains of equity, extending beyond age, deprivation and sex *(4)*. The review highlighted that populations with greater health needs and language barriers experience significant obstacles to engaging with digital health technologies (DHTs) due to limited access to technology, digital literacy challenges and poor engagement with DHTs and services that often fail to meet user needs.

Rapid advancements in digital health systems require continued efforts to better understand how digital health can impact health equity. Beyond issues of digital exclusion and literacy, the growing integration of data-driven tools and artificial intelligence (AI) brings new challenges to ensuring equitable digital health across health systems *(13)*. For example, certain populations are underrepresented in health-care data, resulting in the development of biased DHTs that do not perform well across different population groups *(14)*. Additionally, disparities in digital infrastructure can cause regional inequities in the implementation of innovations *(4)*. Achieving an equitable digital health system requires consideration of factors at the individual, community and system levels to ensure that the development, deployment and funding of DHTs serve all population groups *(15,16)*.

In recent years, there has been an important increase in guidance, frameworks and regulatory initiatives designed to support the development of equitable digital health systems *(1,17–21).* While this growing recognition is encouraging, it remains unclear whether the narrative is limited to high-level statements of principles or whether these principles are being translated into practical tools to ensure that equity is effectively embedded into digital health innovation.

In response to this challenge, this scoping review examines how equity is incorporated into the regulation, implementation and evaluation of digital health systems. By applying a sociotechnical approach *(22,23)*, the review explored equity considerations across six digital health components to identify gaps and opportunities for strengthening equity in digital health systems across the WHO European Region and beyond.

1.2 Methodology

A scoping review of peer-reviewed literature published in English between January and June 2024 was conducted to identify articles on the regulation, implementation and evaluation of digital health systems. The time frame was selected to align with adoption of the Sustainable Development Goals *(10)* and capture the accelerated advancements in digital health innovation following the coronavirus disease (COVID-19) pandemic. The geographical scope focused on the WHO European Region, but relevant publications from other regions or countries that had an abstract or executive summary published in English were included.

The database search yielded 6671 papers and a further 110 sources were obtained from grey literature searches of relevant websites and suggestions from stakeholders. After removal of duplicates, 5236 academic papers were screened by title and abstract, of which 4920 were excluded. Including grey literature, a total of 424 full-text records were assessed, of which 77 academic articles *(5,6,15,20,24–96)* and 77 grey literature sources *(1–4,13,17–19,97–165)* met the inclusion criteria. Annex 1 provides full details of the methodology.

2. Results

2.1 Overall findings

Equity was considered across six key components of a digital health system (Fig. 1). Of these, the three technical components (Digital infrastructure and systems, Data, and Digital health tools) influence the development, deployment and outcomes of digital health innovations. The three social components (Access to digital technology, Digital skills for health, and Use and engagement) consider how digital health impacts individuals, communities and societies and determine the uptake, adoption and overall effectiveness of digital health innovations.

Fig. 1. Technical and social components of a digital health system

[a]Considered across the general public, patients, carers and health professionals.

It is important to consider that progress towards digital health systems will be limited by financial barriers, both at system level, through health-care financing, and at individual level, particularly for direct-to-consumer DHTs. Inadequate funding for digital infrastructure, procurement and deployment of DHTs, and access to digital platforms can hinder digital transformation. Without sustained public investment and equitable reimbursement mechanisms, these financial limitations risk reinforcing existing health inequities and restricting the reach and impact of digital health innovations *(2,98,99)*.

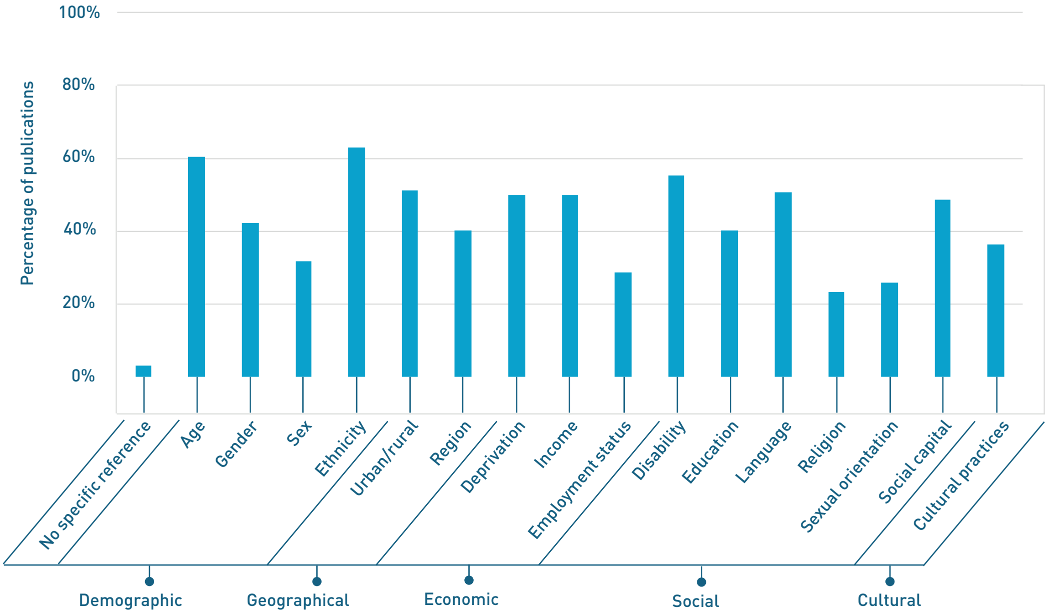
2.1.1 Overview of search results

The most common article types included in the scoping review were technical guidance (25.3%), literature reviews (20.1%) and implementation frameworks (16.9%). The publications were primarily from WHO European Region (44.8%), including the European Union (EU), Austria, Denmark, Finland, France, Germany, Greece, Israel, the Netherlands (Kingdom of the), Norway, Spain, Sweden, Switzerland and the United Kingdom. Other articles were from the WHO Region of the Americas (33.8%), global organizations (13.6%) and other countries, including Australia, India, Japan, Republic of Korea, Singapore and South Africa (7.8%). Most publications focused on implementation only (27.9%) or evaluation only (13.6%), with fewer addressing regulation (4.8%). Over one third focused on both implementation and evaluation (39.6%).

Although all publications included in the review considered equity, they did not use the same terms to describe the population groups of interest within the context of equity. Of the publications that explicitly referred to specific population groups, 26.0% reported on 10 or more equity domains, 35.7% on between five and 10, and 38.3% to less than five. The most frequently addressed equity domains were ethnicity (63.0%) and age (60.4%), followed by disability (55.2%) and urban/rural residence (51.3%). Other commonly considered domains were language (50.6%), deprivation (50.0%), social capital (48.7%) and gender (42.2%) (Fig. 2).

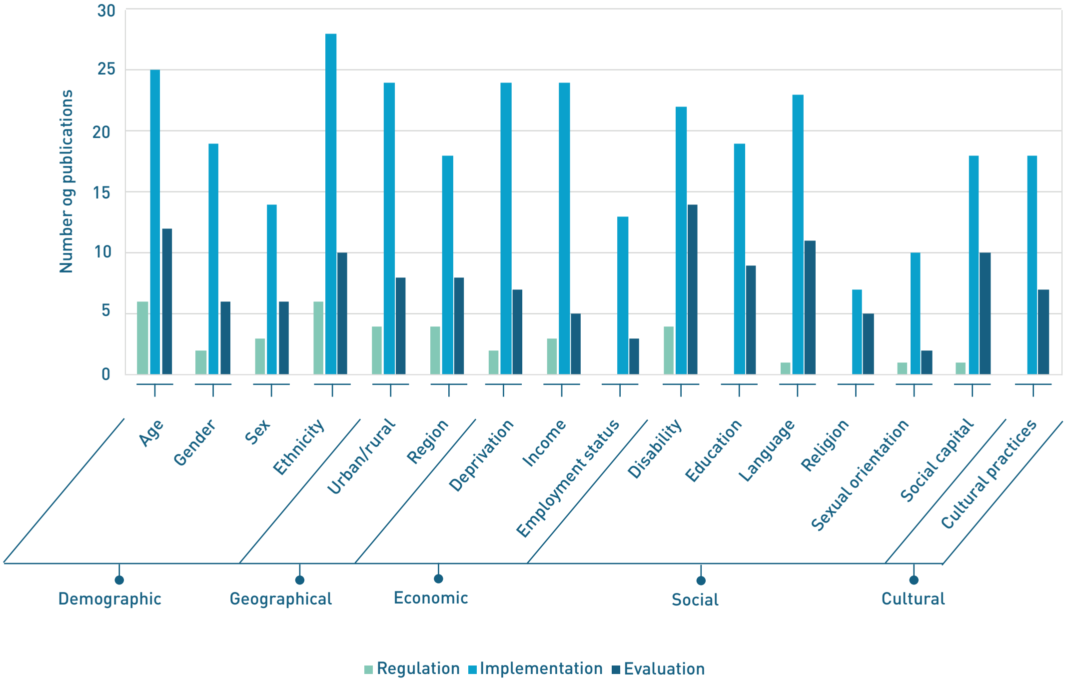
In publications focused on regulation, the main subdomains considered were age, ethnicity, disability and urban/rural residence. Publications focused on implementation most commonly included ethnicity, age, deprivation and disability. Those focused on evaluation also frequently included disability, age, language and ethnicity. In contrast, domains such as employment status, religion and sexual orientation received less attention, highlighting persistent gaps in how equity is addressed in digital health research. While this review analysed sex and gender as separate domains, both were both frequently combined and reported together as sex/gender as a main equity domain. This highlights challenges around the nuanced use of these terms (i.e. the difference between sex and gender is not clearly understood and defined) and also the limitations in disaggregated reporting in the existing literature (Fig. 3).

Fig. 2. Coverage of equity domains in the identified publications



Note: each publication may have referred to multiple equity domains.

Fig. 3. Coverage of equity domains and subdomains in publications on the regulation, implementation or evaluation of digital health systems



2.1.2 Equity considerations in digital health

The review investigated how equity is considered within the existing regulatory, implementation and evaluation guidance for digital health across six key components of a digital health system:

- digital infrastructure and systems
- data
- digital health tools
- access to digital technology
- digital skills for health
- use and engagement.

Equity by design was identified as a cross-cutting theme. Annexes 2 and 3 provide overviews of the challenges, current approaches and recommendations for the regulation, implementation and evaluation of digital health systems.

2.2 Digital infrastructure and systems

The infrastructure and systems component of digital health relates to the foundational hardware, software, networks and systems that enable the operation, integration and delivery of digital health solutions or services. These support the collection, storage, processing and transmission of health-related data, and facilitate interactions between patients and health-care providers.

The review identified three subthemes that consider equity: digital and computing infrastructure (section 2.2.1), interoperability (section 2.2.2) and adaptability and scalability (section 2.2.3).

2.2.1 Digital and computing infrastructure

Definition

This subtheme relates to the technological foundation that supports the development, deployment and integration of DHTs. The infrastructure includes both the hardware (e.g. servers, networks, devices) and software (e.g. platforms, applications, databases) that enable these technologies to operate smoothly, securely and at scale, while also allowing for continuous innovation and improvement *(1).*

Why is this important for digital health equity?

The underpinning digital infrastructure is key to ensuring digital health equity, given that it determines who can access, use and benefit from digital health innovations. High-quality infrastructure enables broader accessibility, better usability, and more reliable and secure services, thereby ensuring that digital health solutions reach and benefit diverse populations, including those who are often excluded from traditional health services *(100)*.

How is equity considered in the current approaches?

Regulatory bodies and frameworks, standards and evaluation tools often consider the essential hardware and software resources needed to effectively implement or deploy digital health innovations *(1,2,19,100–108)*. However, there was little mention of equity in terms of digital and computing infrastructure requirements. Equity considerations around the digital and computing infrastructure for implementation of digital health systems highlight the importance of designing DHTs that promote digital inclusion to better serve marginalized populations *(103,109)*. This includes creating tools that work with simpler technology, are compatible across operating systems, support multiple users on a single device and do not rely on a high internet bandwidth *(25,110,111)*. Implementation of digital health within large health systems requires systematized tools to prevent resource disparities, alongside a thorough understanding of the local infrastructure, government policies and existing initiatives *(110,166)*. Developers need to clearly specify the infrastructure and technology requirements for deployment, given that regional capabilities and field conditions may impact system functionality *(100,102,103,108,112,113)*. This includes the necessary expertise for operating these systems, particularly in environments where infrastructure is limited or data systems are still maturing *(1,104)*. This is particularly important for data-driven technologies because inter-country disparities can widen the gap between low- and middle-income countries (LMIC) and high-income countries *(13,104,114)*. For example, limited data availability in LMIC increases the risk of bias. Many AI models are trained on datasets from high-income countries that do not accurately represent LMIC populations, especially in areas concerning ethnic minorities and women's health *(26,114,115)*.

Health equity assessment tools for digital health services such as the Health Equity Impact Assessment tool *(103)*, evaluate both strengths and barriers of the infrastructure needed to implement digital health services. Equity assessment tools can help to identify gaps and propose solutions to help to ensure that digital health tools are accessible, inclusive and equitable *(5)*.

What else needs to be done?

A few guidelines highlighted the importance of including information on the minimum infrastructure requirements for implementing or deploying DHTs *(107,110,116,117).* However, they did not provide specific details on what this entails. Clearly defining these requirements is valuable for assessing the feasibility, generalizability and replicability of DHTs to support equity, especially in contexts where the infrastructure may be less advanced than in the original setting *(2)*. Based on the existing evidence, key infrastructure requirements may include:

- **expanding digital access** in underserved areas to ensure reliable and affordable broadband services for all populations (e.g. policies to subsidize or regulate pricing for high-speed broadband internet, reimbursement mechanisms) *(25,27, 110,118–120)*;
- **public Wi-Fi access** via digital hubs or free Wi-Fi in health and care settings *(28,29, 111,117)*;
- **device provision or purchase/lending programmes** to improve access *(6,27, 30,121)*;
- **interoperable and accessible platforms** to facilitate seamless data exchange *(17,18,31–39,99,105–107,122–126)*;
- **multilingual** resources to support diverse populations *(4,5,28,40,41,108,116, 120,127)*;
- **assistive technology** (e.g. screen readers, closed captions, read-aloud options) for accessibility *(29,42–46,120,124,127–130)*;
- **robust cybersecurity and privacy measures** to protect patient data *(19,20,26, 27,123,131,132); and*
- **community support,** such as digital champions or patient navigators and digital literacy training, especially for individuals with limited digital skills *(25,28,36,41,47,129,133,134)*.

Key message

Digital infrastructure is an important contributory factor for equitable access to digital health innovation. Although some guidelines for the development and deployment of DHTs do consider this, no common standards or minimum requirements for equity within the digital infrastructure were found to support the scalable implementation of DHTs towards creating an equitable digital health system.

2.2.2 Interoperability

Definition

Interoperability is the ability of different systems and technologies to share data seamlessly, thereby ensuring that health-related information is accessible, meaningful and usable across various components of the health system. Such interconnectedness is crucial for delivering coordinated care, empowering patients and improving equity *(2)*. However, the digital health landscape remains fragmented: many health systems still rely on disconnected small datasets, which hinders effective data exchange, processing and interpretation *(1,167)*. As the world becomes more interconnected, health-care information must be accessible across borders and beyond traditional care settings *(17)*. WHO's *Global strategy on digital health 2020–2025* promotes syntactic and semantic interoperability, that is, the ability of systems to exchange data using common structure (syntactic) and to interpret and understand the meaning of the data consistently across systems (semantic) *(2)*.

Why is this important for digital health equity?

Interoperability can promote digital health equity through a number of routes including by enabling data aggregation across systems to identify health inequities; informing targeted interventions for marginalized or stigmatized groups (e.g. patients with HIV/AIDS) *(100,115)*; supporting comprehensive care delivery for underserved populations *(167)*; and enabling patients to access their health records (e.g. through health apps linked to health-care data), thus empowering them to manage their health more actively *(168)*.

How is equity considered in the current approaches?

Interoperability is becoming an increasingly key factor in the regulation and implementation of digital health. Regulatory frameworks *(124)*, organizations *(2,100,118,135)* and standards *(105–107)* are placing greater emphasis on ensuring that digital health systems can communicate and share data securely and seamlessly. While standard compliance is not mandatory, it is often considered during the implementation of digital health systems to facilitate the use of digital public goods across different platforms and systems *(10,131)*. Europe is taking significant steps towards improving interoperability through both EU-wide and national policy initiatives *(99)*. For example, in Germany, in order to be listed in the Digital Health Applications directory, manufacturers must demonstrate interoperability in areas such as data exportability and integration with electronic patient records *(124)*. The European Health Data Space aims to create a unified framework for securely sharing health data across EU Member States. By improving access to health data, it seeks to reduce disparities in health-care resources, research, and digital health innovations, fostering equitable access for all Member States *(99)*. The interoperability of DHTs is often evaluated in health technology assessments (e.g. whether the DHT complies with regional standards and regulations and system compatibility, and how well it integrates with existing health-care information technology systems) *(33,131,136)*.

What else needs to be done?

Incentivizing interoperability is a proposed approach to encourage the seamless integration of systems. This would involve establishing a strong legal and regulatory framework that guarantees data protection, confidentiality and integrity of personal health data, and system availability *(99)*, all of which are particularly important for marginalized and stigmatized populations *(100)*. Data exchange can be greatly improved through multistakeholder cooperation on issues such as the correct use of terminology that defines unambiguous vocabularies for the communication of health-related information (e.g. 11th revision of the International Classification of Diseases *(169)*) *(48)* and globally aligned open standards (e.g. Fast Healthcare Interoperability Resource standards *(170)*) *(49,99,113,137)*. Incorporating data on social needs and social determinants of health into these standards has been proposed as a strategy to promote health equity *(49,50)*.

While interoperability is an important consideration across implementation and evaluation, there needs to be clearer frameworks to assess interoperability readiness between digital health systems. The wider adoption of a global interoperability maturity model that considers digital inclusion as a core aspect of interoperability is needed to ensure that no one is left behind due to systemic barriers such as access to technology and low-resource environments *(126)*.

Key message

Interoperability is key to advancing digital health equity by enabling seamless data exchange, coordinated care and patient empowerment; along with the collection and integration of data on the social determinants of health, it can be a powerful tool for tackling health inequities. While interoperability is increasingly recognized, globally aligned standards are needed to support good practice and ensure data protection and equitable access.

2.2.3 Adaptability and scalability

Definition

Adaptability and scalability are interrelated subcomponents that are key to the effectiveness and sustainability of digital health solutions. Adaptability relates to the ability of health technologies, systems and practices to adjust and respond effectively to changing conditions, user needs and emerging technologies *(104).* Scalability relates to the capacity of health technologies and interventions to expand effectively to accommodate growing numbers of service users, data or geographical areas without compromising performance or quality. Scaling up digital health tools requires consideration of the need to increase the size and complexity of the infrastructure and data, alongside a potential increase in support to address user needs *(34,104,127,138)*. For example, scaling up digital mental health services to meet the rising demand among young people illustrates how scalability intersects with equity and resource allocation *(171)*.

Why is this important for digital health equity?

Both subcomponents enable DHTs to meet the evolving demands of health systems and users, support equitable access to care, and improve outcomes for all, regardless of socioeconomic status or geographical location *(172)*. Scalability efforts commonly focus on easy-to-reach populations, with hard-to-reach groups coming last. In contrast, an equity-first approach that prioritizes interventions for the most underserved populations from the outset can be both more inclusive and more cost-effective in reducing health disparities, thereby strengthening the case for equitable investment *(173).*

How is equity considered in the current approaches?

Ensuring that DHTs can perform at scale (referred to as load testing) is not explicitly required by regulations. However, it is considered best practice and supports compliance with security, performance and reliability standards *(105–107,138,139)*. Implementation guidance is limited and mainly focuses on ensuring that DHTs can be scaled up effectively, particularly in LMIC where the technical infrastructure is less mature *(102,104)*. The mHealth Assessment and Planning for Scale Toolkit is a valuable resource for scaling mobile health (m-health) interventions in low-resource settings *(104)*. It helps implementers and policy-makers to plan for large-scale, sustainable m-health programmes that are accessible, equitable and impactful. The Toolkit emphasizes the importance of assessing the current status of the m-health initiative, including infrastructure, human resources and funding, identifying key barriers to scalability, and providing solutions. It also highlights the importance of capacity-building for long-term success, offers guidance on monitoring and evaluating progress, and prioritizes equity to ensure that interventions reach marginalized and underserved populations *(102)*.

Although the identified literature highlighted the importance of designing DHTs to be adaptable to the needs of different populations or users *(6,25,36,127)*, these tended to be described at high level with limited practical guidance on how to design for adaptability or implement it effectively.

What else needs to be done?

WHO's *Global strategy on digital health 2020–2025* promotes the appropriate use of digital technologies as "digital public goods which are adaptable to different countries and contexts to help address key health system challenges to support equity in access to digital resources" *(2).* To achieve this aspiration, there needs to be greater emphasis on adaptability of digital health tools to meet the usability needs of populations at risk of health inequities (section 2.4.1). This includes technical factors (e.g. network coverage), accessibility factors (e.g. auditory, motor or visual disabilities) and social factors (e.g. language, literacy, ethnic minorities, sexual and gender minorities, socioeconomically disadvantaged communities, rural populations) *(36,127)*. For AI/machine learning technologies, minimizing the risk of bias is crucial before deployment at scale to prevent exacerbating health inequities (e.g. ethnicity disparities) *(51–53)*. As technology evolves, regulatory frameworks should allow for iterative improvements and updates to data-driven systems, particularly as they expand into new regions or health-care settings.

Key message

Considerations of scalability and adaptability are essential to ensuring that digital health innovations are accessible to all, equitable, and effective across diverse populations and settings. While the guidance highlights the importance of scalability, there is limited practical direction on designing adaptable DHTs. Clearer guidelines are needed to ensure that DHTs can be modified, tested and approved to suit different contexts while maintaining their safety and effectiveness.

2.3 Data

The data component of digital health relates to patient and public data within electronic health records, administrative systems or public/user-generated data such as wearable devices.

The review identified three subcomponents that consider equity: data governance, privacy and security (section 2.3.1); transparency and accountability (section 2.3.2); and data quality (section 2.3.3).

2.3.1 Data governance, privacy and security

Definition

Data governance encompasses the frameworks, policies and procedures that ensure that health data are accurate, reliable and accessible while maintaining their integrity and quality *(174–176)*. Privacy safeguards an individual's rights to control their personal health information by ensuring that it is collected, used and shared with their consent and in compliance with data regulations *(127)*. Security involves safeguards such as encryption and access controls to protect data from breaches and misuse *(54)*. Together, these principles ensure ethical data management in digital health.

Why is this important for digital health equity?

Data governance, privacy and security are essential for achieving digital health equity by ensuring accessibility, inclusivity and trust across diverse populations *(177)*. These principles safeguard marginalized communities from data misuse and discrimination while fostering trust through privacy-by-design standards established by regulations such as the EU General Data Protection Regulation (GDPR) *(178)*, United States of America Health Insurance Portability and Accountability Act *(179)* and EU Artificial Intelligence Act *(17,124,127,140,180)*. Clear, transparent standards developed with community engagement and guided by user-centred design principles further strengthen this trust (section 2.4.1).

Without effective data governance, data-driven DHTs risk excluding vulnerable groups and exacerbating health inequities. For example, low-income populations, minority groups and individuals with chronic conditions face increased risks from poor governance, security breaches and privacy violations *(100,127)*. Inadequate governance can also enable data use that does not contribute to health equity or broader public value, such as applications driven by commercial interests rather than public health goals *(55,104)*. Implementing equitable data governance frameworks not only protects these groups but also fosters trust and promotes ethical data management throughout the data life cycle *(181)*.

How is equity considered in the current approaches?

Digital health governance remains highly fragmented, with varying regulatory, implementation and evaluation approaches across different regions. While some frameworks prioritize privacy, consent and security, the broader equity dimensions of digital governance, including collective community rights, accessibility and protections for vulnerable populations, are often overlooked.

Regulations such as the European GDPR *(119,124,178)*, United States Health Insurance Portability and Accountability Act *(100,127,179)*, and the EU Artificial Intelligence Act *(21,35)* emphasize the importance of embedding privacy protections into the design and deployment phases of digital health systems and of ensuring compliance with privacy standards, transparency and ethical considerations, particularly for AI-driven applications. However, while these frameworks provide essential safeguards, they do not consider equity in data governance, particularly in ensuring community-level protections and equitable access to digital health innovations. There is growing recognition of the need for equity- and rights-based principles to balance individual and collective perspectives *(20,56,57)*. This shift is reflected in frameworks such as WHO's *Regulatory considerations on artificial intelligence for health*, which emphasizes safeguarding the dignity and autonomy of vulnerable groups by mitigating the risk of discrimination and economic exploitation *(19)*.

Despite progress in digital health, significant gaps in global governance remain *(2)*. Many LMIC lack strong regulatory oversight, making them vulnerable to data exploitation by wealthier nations *(20,58)*. Some national policies, such as the one implemented by India's National Health Systems Resource Centre, have begun incorporating ethical governance principles to promote fair data use *(58)*. Additionally, the integration of indigenous governance models in Australia into digital mental health programmes demonstrates how community-led approaches can strengthen data stewardship and trust *(42)*.

Despite regulations, their inconsistent implementation may exacerbate inequities. Governance models for AI-driven technologies raise concerns over autonomous decision-making, bias and patient consent *(20,53,59)*. Privacy-by-design approaches (such as data protection impact assessments and encryption) offer safeguards *(43)*, but marginalized communities remain underserved due to limited digital literacy and trust issues *(60)*. Participatory approaches are crucial for equitable implementation, yet many governance models assume fairness without proactive enforcement, leaving barriers intact *(3,18,109,117,141)*. This gap is further compounded by a lack of bias-auditing mechanisms in governance for AI-driven technologies, which risks reinforcing existing disparities *(26,61)*. Disaggregated data collection (e.g. by gender, ethnicity or rurality) is essential for identifying inequities *(142)*[1], with guidelines such as the sustainability, accountability, fairness, explainability and data responsibility (SAFE-D) principles (section 2.4.3) and people-centred digital health strategies promoting data fairness, accountability and inclusive design *(114,119,142)*.

What else needs to be done?

Global governance frameworks must go beyond individual protections to include collective data rights to ensure community-driven decision-making *(20,62,63)*. This broader approach is essential to advancing equity in digital health because it promotes community participation, addresses structural power imbalances, and strengthens legitimacy and accountability in data use *(62).* Embedding collective rights ensures that digital health systems are responsive to the needs of underserved and historically marginalized populations, thus ultimately supporting more inclusive and equitable health outcomes *(43)*.

Regulatory measures should address commercialization risks by preventing corporations from prioritizing profit over public health goals *(20).* This includes preventing data exploitation and reinforcing ethical AI use in health. Strengthened security and ethical safeguards such as anonymization, encryption and localized storage are vital to protect patient privacy and uphold data sovereignty *(17,43,58,64,123)*.

Current frameworks often provide generic protections but fail to address practical barriers for marginalized or vulnerable groups, including children. Privacy protections should prioritize transparency, with consent mechanisms that accommodate individuals with low literacy or visual impairments and align with regulations such as the EU's GDPR and United States Health Insurance Portability and Accountability Act *(43,178,179)*. Participatory governance is essential, with underrepresented populations playing a role in shaping how their data are collected, used and protected *(43,62)*.

---

[1] The reference relates to two publications on the same topic that were publishedsimultaneously *(182,183)*.

Building public trust requires user-centred design and culturally sensitive approaches to ensure that digital health tools are accessible, usable and relevant across diverse populations *(30,97,109,114,117).* Governance for AI-driven technologies must prioritize transparency, explainability and accountability by incorporating audit trails and bias mitigation measures *(13,17,18,39,61,64,65,66,104,132,143)*. Ongoing monitoring and evaluation are essential to ensure that digital health systems remain unbiased and continue to meet equity goals *(67,68).*

Lastly, the use of plain language in data policies can enhance public understanding and trust *(3,144)*, while disaggregated data collection will help to reduce engagement barriers and enhance representation in digital health systems and, ultimately, advance equity *(97,109,114,142).*

Key message

Strong data governance, privacy and security frameworks are key to achieving digital health equity by ensuring inclusivity and trust across diverse populations. They must protect marginalized communities from data misuse and discrimination while promoting transparency and accountability. Beyond individual protections, governance should uphold collective data rights and embed community-driven decision-making structures that share power with the populations they serve. Digital health systems should centre community voices in shaping data practices and oversight. Governance for AI must emphasize transparency, accountability and continuous monitoring to align with equity goals. Prioritizing disaggregated data collection will improve representation and promote digital health equity.

2.3.2 Transparency and accountability

Definition

Transparency relates to openness and clear communication about the gathering, processing, sharing and safeguarding of health data and the tools and algorithms using these data. This requires well-documented data and processing protocols, supervision and ethical compliance systems to be in place and open to all *(143)*. Accountability ensures that stakeholders are held responsible for their actions through legislative regulations and supervision frameworks, open communication, public examination, and unrestricted access to information *(2,145)*.

Why is this important for digital health equity?

Transparency and accountability are crucial to foster trust and address inequities in digital health innovation. Without transparency, mistrust can grow, particularly among marginalized communities who may be subject to widespread stigma and discrimination, such as women and those seeking confidential sexual and reproductive health support *(64,114,115)*. Transparent and clear communication on data use, system operations and decision-making can reduce concerns about prejudice, discrimination and privacy issues while also building trust among various user groups. Accountability ensures that all stakeholders, including developers, regulators and health-care providers, are responsible for creating and maintaining inclusive systems that serve all users, especially those from underrepresented communities.

How is equity considered in the current approaches?

Translating transparency principles into enforceable mandates remains a challenge because many frameworks rely on voluntary compliance rather than having legally binding requirements *(34,101,105,119,143)*. Many AI-driven systems operate as black boxes, with limited requirements for transparency or bias auditing, thus increasing the risk of inequities *(64,66,68,69)*. Legal frameworks for AI liability remain unclear. They mainly focus on human accountability (e.g. of developers, health-care providers) but struggle to define AI-driven harm, particularly in contexts where AI functions autonomously or makes decisions without human input *(35,64)*.

In Europe, the Organisation for Economic Co-operation and Development's AI principles *(184)*, GDPR *(178)* and other initiatives emphasize transparency. However, their impact is weakened by inconsistent enforcement and varying implementation across Member States, lack of patient/public involvement, and conflicting commercial interests that restrict data-sharing and equitable governance *(19,69,99,118,124)*. Recently, several legislative efforts, including the EU's Data Governance Act *(185)* and Artificial Intelligence Act *(180)*, have aimed to enhance transparency, promote ethical data use and reduce algorithmic bias *(35,98)*. These regulatory frameworks represent promising steps towards equity-aware governance but lack enforceable mechanisms for equity accountability and remain regionally focused, with limited applicability beyond the EU.

The implementation of transparency and accountability in digital health faces significant challenges, primarily due to limited algorithmic explainability *(18,19,26,54,61,65,119)*, inconsistent bias auditing *(48,61,65,65,67,122)* and insufficient patient involvement *(3,26,27,62)*. Data transparency remains a key issue because users are often unaware of how their sensitive health data are collected, used and/or shared *(26,54,66,67,69,100,120)*. While efforts to improve AI transparency are emerging, they remain incomplete. For example, some AI systems now use saliency maps that help to visualize decision-making and some hospitals have started establishing AI accountability departments. However, these initiatives are not yet widely adopted and remain vulnerable to bias *(61)*. Stakeholder engagement is increasing, with models such as m-health governance frameworks integrating patient participation into data usage decisions; however, these remain the exception rather than the norm *(62)*.

Ethical guidelines, such as the United Kingdom's Data Ethics Framework *(145)*, advocate for transparency through user feedback and explainability but fall short in making equity a central focus, particularly regarding how digital health tools and systems impact underserved populations. In contrast, frameworks such as the *Ethics guidelines for trustworthy AI (17)* place a stronger emphasis on equity considerations *(69,145)*. Bias audits and fairness checks remain largely aspirational, as most regulatory-approved AI tools lack public documentation on how their models were trained, thus limiting scrutiny and replicability. While some guidelines emphasize transparency, many are more focused on procedural fairness rather than ensuring equitable outcomes *(54,61,66)*.

Current recommendations emphasize transparency and accountability through user-friendly designs and secure data handling. However, these guidelines often lack clarity on how to operationalize equity beyond mere compliance with existing privacy and security laws *(129)*. Despite increasing discussions about transparency and accountability, most evaluation frameworks rely on periodic reviews and ethical recommendations rather than legally mandated oversight. This creates gaps in AI governance, bias mitigation and stakeholder inclusion that limit the potential of digital health systems to build trust, fairness and equitable participation *(98,107,108)*.

What else needs to be done?

Ensuring equitable digital health governance requires moving beyond generic protections and addressing operational gaps in transparency and accountability. While current legislative frameworks emphasize accountability in principle, they lack clear mechanisms to define who is responsible for AI-driven decisions *(61,64)*. Accountability must extend beyond governance structures to encompass patient rights and autonomy by ensuring that individuals can access and challenge AI-driven medical recommendations *(66).* Operationalizing transparency at system-wide level is equally critical. For example, privacy, consent and data processes must be accessible and understandable for all users, particularly marginalized groups. Alternative or complementary approaches such as community consent may offer more equitable ways to support community participation and understand community needs *(121,146,147)*.

A participatory governance model is essential for preventing exclusionary decision-making *(70)*. Marginalized and underrepresented communities must be actively involved in shaping AI and digital health policies to ensure that governance aligns with equity-focused goals and does not perpetuate existing disparities *(13,18,62,148)*. Accountability mechanisms must incorporate continuous feedback loops from these communities to ensure meaningful oversight and the ongoing adaptation of governance practices *(13,19,114,149)*. More robust regulatory frameworks, enforceable equity measures and systematic bias audits are needed to fully integrate equity into digital health governance.

Key message
Transparency and accountability are essential for building trust, ensuring equity and supporting ethical AI use in digital health. However, governance frameworks lack clear enforcement, leading to bias and patient distrust. Strengthening regulatory oversight, implementing external AI audits and requiring explainable models are crucial steps towards accountability. Equitable digital health governance must actively engage underserved communities in decision-making and embed enforceable mechanisms to ensure fairness, inclusivity and long-term resilience in health systems.

2.3.3 Data quality

Definition
In the context of digital health, data encompasses all aspects related to the acquisition, curation, validation, documentation and utilization of data to support digital health innovations. Data quality relates to the reliability, accuracy, completeness, relevance and integrity of the data used to develop, deploy and evaluate digital health tools. It encompasses dimensions such as dataset composition, data labelling and validation processes, accuracy and sensitivity in representation, mitigation of bias, and transparency in data handling and documentation *(186,187)*. Data quality is a key factor in the algorithmic bias of DHTs (section 2.4.4).

Why is this important for digital health equity?
High-quality data are critical to enabling digital equity because they shape the design, validation, implementation and performance of tools across population groups. Poor-quality data, including incomplete or biased datasets, can exacerbate health inequities and lead to inequitable outcomes by misrepresenting or excluding

certain populations. For example, missing data or a lack of diverse demographic representation in training datasets can skew AI-driven health interventions and, thereby, disadvantage underrepresented groups including ethnic minorities, people with disabilities, or those living in rural settings *(61,71,72,119)*. Ensuring high data quality through careful data curation and robust validation mechanisms allows for equitable health interventions, builds trust in digital health solutions and, ultimately, reduces health inequities *(4,19,33)*.

How is equity considered in the current approaches?

Despite a growing awareness of data-related risks *(3,103,104,139,150)*, current regulatory and governance frameworks do not consistently mandate standards for equity in data practices. Most existing policies do not provide enforceable mechanisms for addressing data bias or evaluating algorithmic fairness *(35,69,73,118).* Frameworks such as the GDPR *(178)* provide critical protections for individuals but may also hinder equitable data-sharing due to restrictions that disproportionately affect marginalized communities with limited data representation *(137).*

Health data poverty driven by structural barriers to data collection, digitization, and barriers to obtaining informed consent continues to limit representation of some communities *(67,74)*. The identified articles commonly focused on ethnic minorities, low-income groups, rural populations and people with disabilities *(3,121,144,147)*, and more rarely on groups such as women and older adults *(18,115,121)*. Current recommendation stress the importance of dataset localization (i.e. adapting data to reflect specific demographic groups, cultures and contexts) to address underrepresentation and mitigate structural bias *(3,4,97,99,109,114,117,119,124,143–145,151,188)*. For example, even when datasets include diverse populations, evaluation processes may reproduce bias through unrepresentative variable selection, use of non-transparent proxies and limited external validation *(68,74)*. Most AI innovations are tested on the same datasets used for training and, therefore, fail to assess real-world performance across diverse populations *(13,54)*.

Furthermore, AI models often prioritize accuracy for majority groups, typically those from high-income populations, while underperforming for others *(26,51,67)*. Certain populations are excluded from models based on data availability rather than clinical relevance, leading to biased AI predictions and inequitable health outcomes *(3,13,39, 97,119,142,144,145,150)*. To address these issues, experts recommend oversampling marginalized groups to ensure that datasets reflect diverse populations and call for data localization, transparency and accountability in data curation *(104,114,121,150)*. Transparency is essential for ensuring that AI models are not only accurate but also inclusive, with an increasing focus on clear reporting of dataset attributes, bias and limitations *(1,3,19,139,142,150)*. However, the lack of participatory governance means that those communities most affected by AI-driven health-care decisions are rarely involved in dataset creation or model validation, leading to further alienation of underrepresented populations *(34,42)*. To date, bias mitigation strategies tend to focus on technical fixes, such as statistical adjustments, rather than on addressing the systemic root causes of inequities, such as limited health-care access *(26)*.

What else needs to be done?

Regulatory frameworks should establish clear standards for data quality by ensuring that DHTs rely on accurate, complete and reliable datasets. They should also focus on bias mitigation by mandating diverse and representative data collection from marginalized and underserved populations *(13,17,74,118)*. Privacy regulations such as the GDPR should continue to protect sensitive data while facilitating the data-sharing necessary for equitable innovation. Additionally, enforceable accountability mechanisms such as regular audits and risk assessments should ensure that stakeholders are held responsible for ensuring equitable outcomes *(35,64,65,75,118,142)*.

In terms of implementation, policies are needed to support the inclusion of underrepresented groups in health data collection *(142)*. Training and capacity-building for developers, health-care providers and regulators are crucial to increase the understanding of what bias is and how to mitigate it *(104)*. Furthermore, participatory governance models are needed to ensure that those communities affected by health disparities are involved in decision-making, particularly around data curation, AI model development and health-care delivery *(34,42).*

Evaluation frameworks should extend beyond technical performance to assess the equity impact of digital health innovations, including whether they reduce disparities and effectively meet the needs of marginalized groups *(51,54,67)*. Feedback from users and affected communities should be built into the evaluation process to ensure that systems adapt to real-world needs *(97)*. Transparent reporting on data sources, bias and limitations is also essential for accountability and to provide stakeholders with all the information needed to understand the capabilities and risks of DHTs *(39,74,142).*

Key message

Data quality is essential for ensuring the accuracy, reliability and inclusivity of DHTs. Regulatory frameworks must move beyond technical compliance by incorporating enforceable measures for mitigating data and algorithmic bias, as well as ensuring fair data collection practices. To promote the development of more equitable digital health solutions, it is crucial to ensure diverse representation, support participatory governance and user feedback, evaluate DHTs with a focus on equity outcomes, and encourage data-sharing.

2.4 Digital health tools

The digital health component relates to the development and deployment of a digital health tool (such as a mobile app, wearable device, telemedicine platform, health management software or health-AI) and how effectively the tool performs against the intended goals or functions under varying conditions.

The review identified five subthemes that consider equity: user-centred design (section 2.4.1), validity and reliability (section 2.4.2), safety (section 2.4.3), algorithmic bias (section 2.4.4) and monitoring and evaluation for equity (section 2.4.5).

2.4.1 User-centred design

Definition

User-centred design is an approach that involves end users throughout the development of digital health to ensure that the tools are of value to, and operable by, the intended users *(189).*

Why is this important for digital health equity?

A key driver of engagement with digital health is whether the tool meets the needs of the intended user. User-centred design ensures that a people-centred approach is used to develop digital health to take into account the lived experience, cultures, skills and capabilities of multiple social groups *(101)*. User-centred design has an important role in ensuring digital health equity by considering the views and needs of marginalized or underrepresented populations at the outset in the design process. For individuals to perceive digital health as useful, they must see the value of the digital product/service to them and feel they have a voice and a choice *(144)*. This is especially important for groups such as people with disabilities or with language barriers *(4)* and in contexts where consideration of language is needed to ensure that tools do not unintentionally contribute to stigma and disempowerment *(49,101)*.

How is equity considered in the current approaches?

User-centred design is not explicitly mandated as a standalone regulatory requirement by regulatory bodies such as the Medicines and Healthcare products Regulatory Agency, Food and Drug Administration, and European Medicines Agency. However, the principles of user-centred design are integrated into broader regulatory recommendations for DHTs such as involving stakeholders in the development and deployment of these technologies *(19,152–154)*. User-centred design features prominently in the implementation *(4,97,141,144)* and evaluation *(127,131,155)* of digital health, including an emphasis on diversity in those developing and testing DHTs in order to better understand needs that may not be represented in clinical data *(97).*

Across user-centred design, no single definition of underrepresented groups is used, but reference is commonly made to representation across age, health/physical condition, education, language and technical aptitude. The evidence generated can support equity considerations in the ability to use and benefit from digital health, as intended *(131)*, and in action to mitigate the social barriers to digital health engagement once deployed (section 2.8).

Many different methods are employed in user-centred design, including co-design, public participation research, user research, citizen panels, focus groups and qualitative methods. The identified articles highlighted the importance of user feedback in ensuring that designs meet the needs and values of the intended users *(3,13,49,97,100,101,116, 128,144)*. For example, practical recommendations for user-centred design are provided in the Digital Healthcare Equity Framework *(49)*. Each stage of the digital health tool planning and development process provides an opportunity to employ the principles of user-centred design by engaging with multiple stakeholders, including potential end users.

To promote equity, recommendations for user-centred design include realigning power dynamics by positioning underserved population members in leadership roles and elevating their perspectives in research *(34,57,146)*. Additionally, avoiding user participation in formal institutional settings and instead utilizing community spaces could help to rebalance the power dynamic *(146)*. Clear communication about the benefits or added value of digital health and care should use written and alternative formats and highlight how these benefits have supported similar populations *(133)*. Co-designing easy-to-use security features (e.g. secure authentication) with service users, including carers, may help to remove barriers that discourage people from using DHTs *(76)*.

In some cases, user-centred design has led to the development of DHTs that are more inclusive and targeted to user needs. For example, co-design with marginalized communities (including older people; African indigenous, or Nova Scotian populations; homeless people; people experiencing domestic violence; and migrants) has supported inclusive and relevant m-health services in Canada *(117)*. Similarly, meaningful engagement with indigenous young people facilitates better research practices and increases the chance of producing more acceptable, culturally responsive tools to address the current unmet need *(42)*. Usability testing by people with auditory, motor and/or visual disability within the intended target group to assess the usability of an app helps to ensure the app's viability and adoption. Such testing must be relevant to the target population and demonstrate reasonable product usability *(105)*. The evidence suggests that digital health systems can be successfully implemented for vulnerable groups, including people with disabilities and those with substance use disorders *(38,57).*

When it comes to deployment, evaluation of user experiences of digital health across population groups can provide a feedback loop to ensure that user-centred design is effective and address any new or unseen challenges for digital health equity. For example, a United States economic-focused framework suggests that user experience should be measured among a diverse set of prospective or active end users to anticipate real-world conditions *(128)*. Furthermore, the evaluated population should not be highly selective in terms of age, gender, comorbidity level, language or other factors that may influence the user experience.

Whereas user-centred design focuses on end users, diversity within the teams designing and evaluating digital health is also recognized as a critical factor for digital health equity *(6,37,75,120)*. Technological solutions are most effective when informed by diverse voices, including those of women, gender-diverse individuals, and representatives from the populations they aim to serve *(6,17,27,37,120,122)*. Since women and gender minorities are often underrepresented in technology fields, it is especially important to include these groups as stakeholders in the planning and development of digital health innovations *(4,155)*.

What else needs to be done?

Given the extensive guidance on user-centred design, the challenge is to encourage its application in practice from development to digital health deployment in health systems. A United Kingdom report recommended that developers should publish clear pathways for incorporating input from underrepresented groups into the decision-making process *(149).* Regulators such as the United Kingdom's Medicines and Healthcare products Regulatory Agency have stipulated that developers must state the intended users of the digital health tool *(153)*. However, regulatory bodies could set compliance with user-centred design as a condition for market approval. In addition, governments and health services could support this by only funding (including reimbursement mechanisms) or adopting DHTs that meet user-centred design criteria. This could include following international standards *(15,24,34,77,78, 105,125,127,128,136)* such as the International Organization for Standardization's multipart standard 9241 for usability *(190)* and the Web content accessibility guidelines for accessibility *(191)* (section 2.7). Notably, to achieve equity, developers need to focus on the specific needs of disadvantaged populations separately rather than grouping them together with the general population.

Robust research is needed into the impact of user-centred design on health outcomes and inequities. To date, the use of user-centred design appears limited in digital health interventions that target socially disadvantaged groups. A systematic review found no papers that discussed user-centred principles *(79)*. Similarly, a scoping review on mitigating racial and ethnic bias found minimal or no information on the involvement of non-physician stakeholders in the design, evaluation, deployment or reporting of clinical algorithms *(75)*. Another scoping review found that a low degree of user participation in people with impairments early in the development of digital health solutions may, in fact, introduce additional barriers and exclusion because people with impairments do not fully benefit from the deployed solutions *(78)*. Another study found that while participatory approaches using community-engaged methodologies have been successful, digital intervention studies have yet to use similar strategies *(6)*. It reported that by integrating real-time quality improvement and prototype testing in partnership with users, user-centred digital interventions can reduce development time, improve functionality, increase the likelihood of promoting positive outcomes, sustain user engagement and address health disparities.

Key message

User-centred design should place the population using digital health tools at the centre of all phases, including planning, design, implementation and evaluation. Co-design with marginalized communities can result in more inclusive and relevant digital health tools and services. To create effective guidelines, robust research is needed into the impact of user-centred design on health outcomes and inequities. Ensuring that user-centred design is required for the funding and adoption of digital health tools, providing clear pathways for input from underrepresented groups, and measuring user experiences across diverse populations are essential steps for improving the impact of digital health interventions on health equity.

2.4.2 Validity and reliability

Definition

Validity relates to what the digital health tool measures and how well it does so, whereas reliability relates to the accuracy of the data obtained and the degree to which the measuring tool controls for random error *(192)*. A reliable AI system is one that works properly over a range of inputs and situations so that the system can be scrutinized to prevent unintended harms *(115)*. A reliable AI system behaves exactly as the designer intended and anticipated; it adheres to the specifications it was programmed to carry out *(124)*.

Why is this important for digital health equity?

Examining the validity and reliability of DHTs is essential to determine whether their performance (e.g. measurement and outcomes) is consistent across both time and population groups *(115)*.

How is equity considered in the current approaches?

Validity and reliability are considered in the regulation of DHTs, although the extent to which they are explicitly addressed can vary by region and regulatory framework, Validation studies are often required as part of pre-market approval to demonstrate that the DHT performs as intended and is safe to use. Regulatory bodies may require ongoing performance data and post-market surveillance to ensure that the DHT maintains its intended function *(124)*.

Literature on the reliability and validity of digital health tool performance did not explicitly discuss equity domains or equity for vulnerable populations. Instead, considerations of reliability were related to determining building confidence among all users of DHTs through assessing reproducibility, evaluation and assurance. For example, the United Kingdom's National Institute for Health and Care Excellence guidelines and their Spanish (Catalonia) adaptation include considerations of validity and reliability that provide good practices for developers *(106,107)*. In addition, digital health developers are recommended to review and update the health-related content at defined periods (at least every 12 months) *(101,128)*, ideally by relevant experts (e.g. health and care professionals working in the relevant field) *(1)*.

To ensure reliability, digital health innovations, including AI systems, should be reproducible *(22)*. Measures of reproducibility involve determining whether an AI experiment exhibits the same behaviour when repeated under the same conditions. Replication files can facilitate the process of testing and reproducing behaviours *(19)*. The Alan Turing Institute (United Kingdom) suggests building trust and confidence in a system by applying assurance processes to AI. The assurance process involves measuring, evaluating and communicating the properties and evidence that contribute to AIs trustworthiness *(143)*. Developers should provide comprehensive, reliable information to patients using DHTs in the form of text, video or other educational material to help them to better understand their health and care. Developers should have valid and accurate processes in place to maintain the health information gathered by DHTs *(23)*. Accuracy is also an important aspect of valid and reliable DHTs. European Commission guidelines state that for AI systems accuracy is defined as the ability to make correct judgements (e.g. to correctly classify information into the proper categories) or correct predictions, recommendations or decisions based on data or models *(17)*. The Commission suggests that robust development and evaluation processes can help to mitigate the risks of inaccurate AI extrapolations to ensure a high level of accuracy when dealing with human health *(19)*.

What else needs to be done?

In machine learning health-care applications, accuracy depends on the clinical context. Validation studies are necessary both in clinical trials and within the general population. To be equitable, machine learning in health-care applications should provide equivalent levels of accuracy within the intended-use population across multiple patient subgroups or characteristics *(65)*. Accuracy may also require balancing different test characteristics that carry ethical implications, as influenced by the designer's value judgements. For example, this could involve a trade-off between correctly identifying more people with a specific condition and misclassifying more people without (false positives) or with (false negatives) the condition. The key ethical consideration is whether the potential benefits of these inaccuracies (and any resulting harms) justify their impact and are fairly distributed among patients, without disproportionately affecting vulnerable groups *(65).*

One review identified two possible issues with AI validity and reliability: (i) that AI advancements may not keep pace with real-world medical procedures and, therefore, have limited ability to function in novel conditions; and (ii) that AI models may fail to account for unforeseen changes, such as emergent strains of disease, meaning that results derived from AI tools may not be completely reliable and valid. To address these issues, developers should disclose the methodologies used for validation. Transparent reporting of results from such validation studies, including limitations and bias, is also vital to inform decision-making by regulatory bodies, health-care providers and users *(64)*.

As equity was not explicitly discussed in the identified literature on the reliability and validity of digital health tool performance, consideration of the part that equity plays in this area of digital health tool performance may be needed. There should be a way to test whether digital health tool performance is valid and reliable for underrepresented populations, as well as for general users. This may involve consideration of what else is needed for vulnerable populations when providing reliable information to patients using digital health, in the form of text, video or other educational health-care material *(107)*. User feedback and stakeholder involvement are necessary to ensure that digital health tools are valid, reliable and fit for purpose in real-world health-care settings *(23)*.

Key message

Ensuring that digital health innovations are valid and reliable requires robust testing, continuous monitoring, transparent methodologies, stakeholder involvement, regulatory oversight and attention to ethical concerns. Equity considerations should be factored into the criteria for determining the validity and reliability of digital health tools.

2.4.3 Safety

Definition

Digital clinical safety relates to the avoidance of harm to patients and staff from technologies manufactured, implemented and used in the health service *(156)*. In the EU, Regulation (EU) 2017/745 on medical devices *(193)* and Regulation (EU) 2017/746 on in vitro diagnostic medical devices *(194)* ensure that devices used for health and medical purposes perform consistently for their intended purpose and comply with the general safety and performance requirements. Two recent EU policies for the digital sector are the Digital Markets Act *(195)* and the Digital Services Act *(196)*. The latter prohibits the design, organization or operation of online interfaces in a way that could deceive or manipulate the user *(35)*.

Why is this important for digital health equity?

Safety in digital health tool performance is important for equity because underserved population groups may be more vulnerable to harm from digital health compared with other populations. Safety plays a crucial role in achieving equity because unsafe or poorly regulated digital health tools can exacerbate disparities rather than close gaps in health-care access.

How is equity considered in the current approaches?

The safety of digital health products, in terms of minimizing risk or harm and ensuring human welfare, was referenced substantially in the identified literature in terms of their regulation, implementation and evaluation *(1,19,30,35,54,61,65, 69,71,80,81,118,129)*. Regulation of DHTs requires developers to take measures to guarantee product safety and provide the necessary information about the security measures to protect users *(124,147,172)*. Evaluation frameworks and tools *(132,142,146)* assess whether a DHT poses any risks to users' health or safety. They also recommend keeping users informed about potential risks and providing guidance on how to mitigate them.

For data-driven technologies, WHO's regulatory considerations for AI suggest assessing safety as part of a clear-use case description, alongside demonstrating the clinical validation and assessment of possible bias in the AI system. Consideration of the context of use is also important in assessing the safety of an AI system. It should cover the setting (e.g. geographical location, type of care facility), population (age, ethnicity, race, gender, disease type, disease severity, comorbidities), intended user (health-care provider or patient) and clinical situation for which it is intended. These guidelines further suggest that regulators reflect on possible situations in which a tool should not be used and potential risks from its use outside the intended settings *(19)*.

The SAFE-D principles framework: this was developed was developed by the United Kingdom's Alan Turing Institute to provide an ethical approach to evaluating data-driven technologies (including AI technologies) to ensure that they are safe, fair and accountable *(143)*. The principles focus on sustainability, safety, accountability, fairness, explainability and data stewardship (responsible management and oversight of data throughout its life cycle). Safety is a key component in building trustworthy AI systems by ensuring that they do not cause harm. The framework also stresses the importance of fairness to avoid bias, transparency to ensure understanding, and responsible data handling to protect privacy and security, thereby promoting the long-term, ethical development of AI technologies.

Safety processes: robust processes are important for maximizing safety in the use of digital health. The processes include reviewing research results, patient safety incident reports and ongoing risk management plans. A responsible entity should be assigned to identify, report and address safety issues related to the digital health product. Additionally, companies must be aware of the required safety-related notification processes for medical devices *(147)*. Evaluations of safety testing should ask whether the sample group was representative of the target population (e.g. in terms of demographic, geographical and healthy literacy considerations) and whether the test results can be generalized to the target population *(142).* United States assessment tool criteria determine (i) how frequently the information in the app will be updated in line with health research and (ii) safeguarding measures in communication functions of the app, if relevant *(136)*.

Safety, law and standards: a European network for health technology assessment framework suggests that the safety requirements of laws or other binding rules should be considered in the implementation of digital health *(146).* Similarly, recommendations of the United Nations Educational, Scientific and Cultural Organization on ethics in AI propose that Member States implement appropriate safeguards to protect the right to privacy in accordance with international law, including addressing concerns such as surveillance *(18)*. Creating testing grounds (or regulatory sandboxes) where developers and health-care providers can test and evaluate products and services to assess risk may help to safeguard against unintended harmful consequences *(69)*. In the context of telehealth, the United States National Committee for Quality Assurance recommends that policy-makers and telehealth experts collaborate to identify the minimum standards for telehealth safety *(30)*. More broadly, policy-makers and practitioners must work together to anticipate and mitigate harms, such as digital repression and the widening of existing digital divides associated with disability, income or geographical location *(157)*.

What else needs to be done?

User profiles for vulnerable populations: United Kingdom guidelines state that digital health may be unsuitable for at-risk populations, including people being trafficked and young people who are vulnerable to sexual exploitation. Using apps instead of face-to-face consultation might allow abusers to keep these groups hidden and limit their interactions with health-care professionals *(143)*. A Spanish assessment tool proposes that health systems should provide safeguarding assurances where digital health users are members of vulnerable groups, such as children or at-risk adults, and especially where peer-to-peer interaction is enabled through the DHT *(106)*. Health systems should also state who has access to the platform and their role, why they have access and what other measures are in place to ensure the safety of vulnerable users in peer-to-peer communication, for example, through user agreements or moderation *(22)*. An Australian assessment framework suggests that developers should question whether an app has objectionable content that may increase the risk of abuse or exploitation or diminish the dignity of users or whether their devices may be used in a way that risks harm (physical, mental, social or financial) *(128)*. Evaluators must also apply the do-no-harm principle and use trauma-sensitive methods. This principle applies all the time and is an important general guiding principle throughout the evaluation process. Depending on context, sensitivity and protection issues need to actively account for the specific risks for women and girls, and for other marginalized groups *(158)*.

Safety for children and young people: a United Nations Children's Fund framework proposes that the digital space should be made safer for children through a number of interventions such as digital skills training, curriculum development, awareness campaigns and online learning content for children, in addition to regulatory measures *(150)*. A WHO report on youth-centred digital health interventions suggests ensuring that digital technology is the correct approach to achieving the intended health outcomes, especially when there are privacy and confidentiality concerns around young people accessing digital health *(112)*. Social media platforms operated by private companies can reinforce harmful social norms and generate new forms of inequity *(157)*. The United Nations *Global digital compact* commits to prioritizing the development and implementation of national online child safety policies and standards in compliance with international human rights law *(118)*, including the Convention on the Rights of the Child, as adopted by the United Nations General Assembly in resolution 44/25 *(197)*.

Data protection included as a part of safety: United Nations Educational, Scientific and Cultural Organization guidelines recommend Member States to establish or reinforce data policies to protect personal and sensitive data that, if disclosed, may cause significant harm, injury or hardship to individuals. This includes data related to criminal offences, legal proceedings and related security measures, as well as biometric, genetic and health data. It also covers personal data related to race, colour, descent, gender, age, language, religion, political opinion and national, ethnic and social origin *(18)*. Similarly, United Kingdom consensus-based recommendations on diversity in datasets advise data users to review pre-existing assessments on datasets to identify whether there is any risk of harm to the intended-use population *(142)*.

Key message

Digital health tools should prioritize the safety of vulnerable populations by ensuring protection through user agreements or moderation. Developers must implement robust data policies to safeguard personal and sensitive data. The safety requirements outlined in law should be fully integrated into the implementation and evaluation of digital health tools.

2.4.4 Algorithmic bias

Definition

Algorithmic bias refers to the to the presence of systemic errors in a digital health tool or system that results in the generation of information or decisions that unfairly discriminate against certain population groups. Algorithmic bias is closely linked to the quality of the source data (section 2.3.3). AI bias can arise because of systemic inequities in dataset curation, inequitable opportunities to participate in research and inequalities of access *(13,17,65,67,74,98,142,151)*.

Why is this important for digital health equity?

Minimizing algorithmic bias in digital health is crucial to achieve digital health equity because biased algorithms can reinforce existing disparities in health care, leading to inequitable outcomes for certain groups, particularly those who are already marginalized or underserved *(13,64)*. Addressing this bias for health may help to ensure that all digital health users are accessing tools, apps and systems on an equitable basis.

How is equity considered in the current approaches?

A United Kingdom report on AI ethics highlights fairness-aware design as best practice in achieving equitable outcomes *(119)*. The principle of discriminatory non-harm is central to this approach. A companion report proposes adopting the findability, accessibility, interoperability and reusability (FAIR) principles to improve data management and governance to ensure that data remain accessible to both human users and computers *(143)*. Unlike other fields, where race-neutral approaches might be ideal, clinical AI must account for individual physical attributes to avoid compromising accuracy and patient outcomes. One effective fairness strategy is risk correction, where the risk levels for one population are adjusted to match those of another *(68)*.

Source data integrity: a United Kingdom Data Ethics Framework suggests consideration of the source data being used to train a model to determine whether they reflect biased historical practice *(176)*. It further cautions that the use of proxy variables for protected characteristics in a model could lead to indirect discrimination. Similarly, a United Kingdom report on ethics in AI suggests that bias mitigation should start at the beginning of data collection and that ensuring that the data-gathering processes employ suitable, reliable and impartial sources of measurement is key *(119)*. The performance of a device is likely to be poorer and less reliable for groups that are underrepresented in datasets, and this can result in harm for minority groups *(98)*. Therefore, use of datasets that are appropriately diverse and representative of their intended-use population is essential to ensuring algorithmic safety *(67,142)*.

Auditability and oversight: AI auditing is important to monitor is important to monitor changes in system operation and ensure that changes aimed at improving performance for a broad population do not introduce inequities for specific population groups *(64,75,82,143)*. A United Kingdom report on ethics in AI proposes that "all AI systems must be designed to facilitate end-to-end answerability and auditability", with humans involved across the design and implementation of AI tools to ensure oversight and review *(119)*. It further suggests that accessible information and record keeping are important for auditability. A bias audit assesses the inputs and outputs of algorithmic systems to determine whether there is unfair bias in the outcome of a decision, classification made by the system or input data used in the system *(107)*. European Commission guidelines state that bias in AI can be mitigated by putting in place oversight processes to analyse and address the system's purpose, constraints, requirements and decisions in a clear and transparent manner *(17)*. In addition, recruiting AI developers from diverse backgrounds, cultures and disciplines can ensure a diversity of opinions and should be encouraged *(37,75)*. One of the most commonly adopted approaches to bias auditing is the scoping, mapping, artefact collection, testing, and reflection (SMACTR) method *(64)*.

Data documentation in AI: according to United Kingdom recommendations for diversity in AI, data documentation should describe how bias may be introduced, highlight known or potential differences in data across groups or in the uncertainty of measurements between groups, and describe any attempts to mitigate bias *(142)*. Developers should identify and document AI sources as part of their policy for detecting, reporting and removing bias from the AI system *(132)*. Data sources should be preserved and any adjustments documented for traceability. It may be useful to identify in advance contextualized groups of interest, who may be at risk of harm from AI, using evidence review and collaboration with experts with lived experiences *(142)*. The conscious curation of data, such as careful cohort selection and definition, may help to reduce algorithmic bias *(74,142)*.

What else needs to be done?

Consideration of equity in laws, standards, regulations and policies: keeping pace with rapid changes in AI is a challenge for legal and regulatory frameworks. Regulatory frameworks should require AI models to undergo equity-focused evaluations before approval, thus ensuring transparency, explainability and demographic reporting *(13,153)*. Establishing a specialized regulatory body for AI in medicine, comprising a range of stakeholders, may help to set and oversee standards and prevent misuse of AI *(66)*. An independent regulatory body could also monitor AI performance in real-world settings and track disparities over time. Developers should be required to submit periodic reports on bias and fairness, with corrective measure if disparities are identified. Currently, there are no comprehensive standards that are unanimously applied to the datasets used in developing medical AI models. As a result, potential sources of bias often go unaddressed *(54)*. To mitigate such risks, regulators should define inequitable outcomes in a manner that is fair, clear, specific and quantifiable. Mandating the transparent reporting of key equity domains such as race, ethnicity, income and sex within AI/machine learning datasets would allow for better assessments of representativeness *(51)*. The proposed MINimum Information for Medical AI Reporting framework outlines the essential details required to understand the predictions made by medical AI models, the populations they are intended for and potential hidden bias *(48)*. It also emphasizes the importance of assessing how well these technologies can generalize. This framework can be a valuable tool in identifying ways to collect data and information that ensure that models are trained with minimized bias and reduced equity concerns. Member States of the WHO European Region should establish, evaluate and adjust Regional regulatory frameworks as needed to ensure accountability and responsibility for the content and outcomes of AI systems throughout all phases of the life cycle *(114).* Beyond dataset transparency, regulators and policy-makers should require AI developers to disclose their methodologies and performance metrics. Ideally, these should be equity sensitive and related to the target outcomes. Such measures would enable more effective evaluation and ongoing monitoring of AI systems. Additionally, increased funding and research should be directed not only towards AI innovation but also towards fairness in AI applications *(61,75)*. Overall, policy recommendations for AI include:

- ensuring diversity within the professional workforce and adequate equity training *(6,37,75,120,145)*;
- a requirement for algorithm auditing *(2,13,17,35,51,54,56,61,64–69,75,82,104, 118,131,132,141)*;
- fostering a transparent organizational culture *(75)*;
- implementing a health equity-by-design approach throughout development and deployment of algorithms *(49,75)*;
- funding and accelerating research *(18,97–99)*;
- establishing governance structures and evaluation schemes to prevent harms *(75)*; and
- amplifying patients' voices in AI decision-making *(37,75,97)*.

Better awareness of equity and AI: a United Kingdom review of equity in medical devices suggested a need for better recognition of the issue of bias in AI-assisted medical devices *(13)*. It proposes that professional practice bodies should carry out an audit of devices used in the National Health Service (NHS) to identify those with a particular risk of racial bias with the potential for harm, such as dermatological devices. The review further suggested insufficient awareness and understanding of the issues affecting equity in AI development and deployment. It proposed an online–offline academy for stakeholders of equity in AI-assisted medical devices to consider and promote equity issues.

Key message

Mitigating bias requires a comprehensive approach that includes user-centred design, fairness-aware design, technical strategies such as pre-processing and monitoring, and ensuring unbiased source data. Auditability and oversight are vital to prevent inequities in algorithm updates. Regulatory bodies must enforce transparency and require equity-focused evaluations, including monitoring real-world performance to track disparities. Standardizing data reporting and thoroughly documenting algorithm performance can improve representativeness and reduce bias. Additionally, promoting diversity in AI teams and fostering equity-focused organizational cultures are key to creating fairer digital health systems.

2.4.5 Monitoring and evaluation for equity

Definition

Monitoring is the ongoing process of collecting and analysing data to assess how well an intervention is being implemented in comparison to expected results. On the other hand, evaluation focuses on determining what works, what does not and why by gathering data to assess the effectiveness of a digital health intervention *(156).* Whereas monitoring ensures the fidelity, quality and reach of the intervention, evaluation assesses its outputs, outcomes and economic value *(124)*.

Why is this important for digital health equity?

Monitoring and evaluation are key to ensuring that digital health design and implementation do not reinforce bias or inadvertently discriminate against individuals and groups. They help to ensure that digital health systems achieve the desired outcomes while being non-discriminatory and aligned with the public interest, including human rights and democratic values *(145).*

How is equity considered in the current approaches?

Although monitoring and evaluation are crucial for ensuring that DHTs remain safe, effective and equitable once implemented, the consideration of equity-related monitoring and evaluation is still evolving. Existing regulations such as those of the European Medicines Agency, United States Food and Drug Administration and United Kingdom Medicines and Healthcare products Regulatory Agency focus on general safety, performance and privacy concerns rather than on equity-related metrics such as health disparities based on race, gender, income or geographical location *(152–154)*. The EU's Artificial Intelligence Act proposes the creation of risk-based categories for AI, with stronger monitoring for high-risk AI applications in sectors such as health. The Act encourages ongoing performance assessments but, while it addresses bias mitigation and transparency, it lacks specific mandates for equity-focused evaluation *(35,198)*.

Current guidance on monitoring disparities in digital health suggests measuring the usage of digital health solutions (e.g. internet access, device use or portal engagement) and evaluating differences based on sociodemographic and health characteristics *(27)*. WHO's regulatory considerations for AI recommend regular checkpoints to assess the performance of digital health tools, thereby ensuring continuous evaluation and tracking of changes over time *(19)*. Additionally, WHO's mHealth Assessment and Planning for Scale toolkit highlights the reach, effectiveness, adoption, implementation, maintenance (RE-AIM) framework as a comprehensive approach for consolidating various data sources during monitoring and evaluation *(102)*. Moreover, WHO's *Global strategy on digital health 2020–2025* highlights that existing metrics and indicators must evolve to keep pace with the rapid advancements in digital health, thus reinforcing the need for adaptive and forward-looking evaluation frameworks *(2)*.

Routine and continuous evaluation: continuous evaluation was a key theme in articles on the ethical use of digital health *(100,146)*. Both formative and summative evaluations are crucial for ensuring digital health equity *(83)*. The United Kingdom's Data Ethics Framework advocates for ongoing evaluation at all stages of a project – before, during and after implementation *(145)*. Similarly, the United Kingdom's Digital Inclusion Framework calls for regularly assessing populations at risk of digital exclusion by considering factors such as service access, technology use, clinical outcomes, and safety *(121)*. Evidence standards highlight the importance of continuous evaluation for understanding broader policy implications and ensuring that data insights are used responsibly *(106,138)*. Ongoing monitoring is also essential to maintain trust in users and prevent them from becoming dependent on services or technologies that decline in quality or effectiveness over time (e.g. apps that initially offer free services but later require mandatory subscriptions) *(188)*.

Plan for equity in evaluation data: metrics for success in digital health often lack an equity perspective, for example, the implementation of new platforms or services without specific goals related to race, ethnicity, language proficiency or age *(60)*. A Canadian framework emphasizes that equity should be incorporated into quality improvement and evaluation plans for digital health. The framework highlights the importance of equity in both access and outcomes to ensure that all intended populations have inequitable access to and achieve similar success in a programme *(101)*. It also suggests that tracking sociodemographic data (e.g. age, language, race, socioeconomic status) is useful for examining how different subgroups access digital health services and whether access and outcomes are equitable when compared with the general population. Similarly, the United Kingdom's Health Equity Assessment Tool *(147)* encourages developers to assess the impact of interventions on health inequities, whereas a Canadian assessment tool advocates for the use of standardized metrics and benchmarks for collecting equity-based virtual care data across the country *(109)*.

When mitigation strategies for inequities are included in improvement plans, they should be actively monitored, with relevant outcomes (e.g. changes in digital literacy) tracked and measured *(101)*. Evaluating the broader context, such as racially diverse communities, is essential to understanding disparities *(6,34,84)*. Studying the trends in and frequency of diversity in sample populations can also form part of a fairness analysis during the data-cleaning process *(74)*. Disaggregating datasets to more accurately evaluate communities that live with inequity was a prominent theme in the literature *(3,109,117).* GAVI Alliance guidelines for monitoring digital health interventions recommend incorporating gender-specific indicators into monitoring, evaluation and learning plans to advance gender equity in digital health *(155)*. Similarly, the United Kingdom's Digital Health and Rights project advocates for developing assessment tools to evaluate digital health policies that integrate gender and human rights to ensure the inclusion of women, girls, young people and other vulnerable populations *(114)*. Additionally, ensuring the diversity of those involved in evaluating digital health tools is crucial for building community trust *(126)*.

Engagement and feedback from underserved populations: seeking feedback from end users through clear and appropriate channels was a key theme in the literature *(42,49, 97,157)*. Engaging targeted end users in developing outcomes that are relevant to them is good practice when defining monitoring and evaluation strategies *(34).* Effective evaluation for underserved communities requires identifying those measures that are most meaningful to these populations *(47)*. A United Kingdom report on socioeconomic inequities in digital health highlighted the importance of gathering feedback from disadvantaged populations on the reasons why they use (or do not use) NHS apps. It suggested that such feedback should be flagged within the system and used to update or improve the digital health solution *(97)*. Similarly, an NHS England framework recommends considering how excluded groups provide feedback on technology and measuring the impact of such feedback and other inequities *(97)*. Utilizing an equity dashboard to assess equity intentionality in digital health is considered good practice to ensure that the technical characteristics of a proposed solution meet the current needs of users *(49)*.

What else needs to be done?

Better monitoring and safety signals in datasets: a United Kingdom Government review of equity in medical devices highlighted the challenges of monitoring the performance of optical devices once approved and in use by the NHS *(13)*. Adverse outcomes in specific populations should be identified at an early stage to allow for timely mitigation measures requires a comprehensive, whole-system approach. Both the devices and the broader system in which they are used should be considered, including health-care providers, patients, regulatory bodies and the technology infrastructure. Similarly, the impact of AI technologies must be continuously monitored and evaluated, particularly when they may disproportionately affect certain groups by reinforcing existing bias and discrimination *(97,119)*. In AI monitoring and evaluation, it is important to identify populations at risk of harm (i.e. groups of interest) before deployment *(3)*. For machine learning in health-care applications, evaluation processes should ensure that the technology continues to benefit people over time, regardless of race, ethnicity, sex and age. Additionally, ongoing monitoring is needed to ensure that machine learning systems are not inadvertently repurposed inappropriately *(65)*.

The unfairness of fairness metrics: concerns have been raised about the use of fairness metrics in AI for health that aim to help disadvantaged groups by adjusting algorithms. However, these metrics can sometimes mistakenly conflate equity and equality and, therefore, attempt to equalize outcomes by levelling down and ultimately making all groups equally worse off rather than effectively reducing health disparities *(13)*. To improve overall performance and maximize outcomes for each subgroup, creating separate models tailored to different groups can be more effective. Additionally, newer methods such as transformation learning improve accuracy and fairness by training models specifically for each group while incorporating relevant data from the broader population *(68)*.

Key message

To ensure that digital health tools are effective and inclusive, evaluation metrics must track equity-related outcomes, including access to services, health outcomes across diverse populations, and disparities in intervention effectiveness based on social determinants of health. For data-driven technologies, identifying and addressing bias in digital health tools requires strategies such as disaggregating datasets, conducting ongoing evaluations and actively gathering feedback from underserved populations to ensure inclusivity and fairness. Existing metrics and indicators need to evolve to keep up with the rapid changes in digital health.

2.5. Access to digital technology

Definition

Access to technology depends on having an internet connection and a digital device such as a smartphone, computer or tablet. More broadly, access can also operate at a collective level, where geographical location, finance and infrastructure may impose limits *(4)*.

Why is this important for digital health equity?

Access to the internet is crucial for achieving the Sustainable Development Goals *(26)* and is increasingly recognized as a fundamental human right *(199)*. Access to the internet and technology directly influences the ability to access, use, engage and benefit from digital health tools or services. Governments and health systems are shifting towards a digital front door policy, that is, a centralized, user-friendly digital access point designed to streamline health services and improve efficiency and innovation *(3)*. Although this approach aims to enhance access to digital health tools, it can exacerbate inequities through perpetuating a digital divide in which many people lack access or capability to use these resources *(3)*. In today's internet-enabled world, digital determinants of health are increasingly intersecting with and complicating the traditional determinants of health *(2,4,15,50,85,101,130,159,200)*. For example, access to health services is now being shaped by the accessibility and usability of digital tools and platforms *(3)*.

How is equity considered in the current approaches?

Suitable access to devices and/or internet connection is an important component of digital health. While regulatory bodies aim to ensure that DHTs are safe and effective for all users, they also collaborate with diverse stakeholders (e.g. national health authorities, health-care providers and nongovernmental organizations) to shape policies that advocate for affordable treatments for vulnerable populations and address digital exclusion *(13).* Implementation guidelines and diverse toolkits and frameworks recommend assessing whether the necessary prerequisites to access are met before implementing a digital health innovation and considering how to overcome any identified barrier *(16,42,86,87,98,101,102,109, 111–113,119,121,129,131,136,146,158)*. For example, in the United Kingdom, the Good Things Foundation and NHS provide useful resources to assess digital exclusion.

Recommendations include using digital inclusion heatmaps and data from mapping exercises (e.g. mapping neighbourhoods by internet user classification) to better understand the levels of digital inclusion and guide local strategies for inclusion *(121,133,134,160)*.

Appraisal of the potential bias for or against specific groups of the population could be done by collecting demographic data and implementing a social determinants of health screen *(34)*. Directing people to voluntary, community and social enterprise organizations, library services, or community support is a common strategy to improve access to technology *(76,133)*. Additionally, equity-focused guidance emphasizes the need to consider potential discrimination based on factors such as geographical location, gender, ethnicity, disability, and employment status that may affect access to digital health services and what specific actions can be taken to maximize the potential for positive impacts and/or mitigate negative impacts on health inequities *(15,34,49,88,101,109,113,147,150,161)*.

What else needs to be done?

Providing people with digital devices and internet connectivity addresses only one aspect of the broader issue of inequitable access to health care *(4,13,138,150)*. More efforts are needed to develop governmental regulations to foster the expansion of broadband access to underserved populations *(6,76)* and subsidize internet costs for these populations *(47,118,135)*. Potential strategies also include securing a zero rating (e.g. no data connectivity charges to patients), providing free internet access in health and care settings *(134)*, and supporting device purchase or loan programmes *(6,27,30,121)* and the use of devices that do not require individual data plans *(34)*. A common approach to improving access is to collaborate with different agencies to enable access to data plans and devices to people who cannot afford them (e.g. libraries or voluntary, community and social enterprise organizations) *(76,133)*. In addition, governmental agencies, the voluntary sector and internet service providers should also collaborate to fund digital inclusion initiatives with a focus on ensuring sustainability *(101,109,112,117,121,146)*. To date, there is a lack of robust research on the effectiveness of such digital inclusion initiatives, which makes it difficult to build the evidence base needed to secure long-term funding *(4)*. Learning from successful digital health initiatives in other countries can help to scale up solutions that address needs in the local context *(102)*. Lastly, providing a non-digital option remains essential to advance equity in access to health care *(1,25,97,100,101,111,117,129,144,146)*.

Key message
Although the digital front door approach aims to improve health-care efficiency and innovation, ensuring equitable access requires addressing both social and digital determinants of health, fostering cross-sectoral collaboration, and maintaining non-digital alternatives. Ongoing research and integrated policy, regulation, and community initiatives are crucial to ensure digital health benefits all, particularly disadvantaged populations.

2.6 Digital skills for health

This component considers the digital skills of the public, patients and professionals.

Definition
To effectively access, use and engage with digital health, individuals need a combination of digital literacy (the ability to use information and communication technologies to find, evaluate, create and communicate information, which requires both cognitive and technical skills), health literacy (the ability to access, interpret, evaluate and act on health information) and digital health literacy (the ability to find, understand and use health information from digital sources) *(166,201).*

Why is this important for digital health equity?
These skills help to ensure that all individuals, regardless of background and circumstances, have the knowledge and ability to access, understand and use DHTs and digital health services effectively, leading to better access to care, improved health outcomes and reduced health inequities. Building digital literacy and digital health literacy is also essential for health professionals who develop, implement, recommend and prescribe digital health tools and services. Ensuring that both groups have strong skills allows everyone to fully benefit from digital health innovations and, therefore, leads to better access to care, improved health outcomes and reduced health inequities *(3,46).*

How is equity considered in the current approaches?

Considering users' skills beforehand is key to the successful implementation of a new DHT or digital health service *(29,30,36,37,49,86,88,89,110,116).* The evidence suggests that digital health interventions that provide training to end users and their support network (e.g. family members or carers) enhance access to and engagement with DHTs and digital health services *(25,36,60,63,69,83,90,91, 110,116,159,162)*. As a result, improving users' skills was identified as an important consideration to improve access to, use of and engagement with digital health *(6,25, 27,29,31,37,42,49,86,87,88,99,102–104,106,108,113,117,118,129,134,137,144,163,164)*.

Providing community support through the use of digital champions, community health workers or patient navigators is a common approach to disseminate skills and knowledge to digitally excluded communities *(28,41,47,133,162)*. Developing a support framework is also a good way of upskilling individuals. For example, in Wales (United Kingdom), a digital support framework that is accessible to public health organizations features over 50 companies and voluntary, community and social enterprises that specialize in digital skills training and technical support *(166)*. The framework is designed to provide a faster and more efficient way to access these resources by avoiding the need for a full procurement process. Whereas digital health literacy is increasingly recognized as a critical factor in the success of digital health initiatives, its evaluation is rarely standardized. For example, a recent review found that only a few randomized controlled trials assessed digital health skills using validated tools (e.g. eHealth Literacy Scale) *(90)*. Without these data, opportunities to optimize DHTs and digital health services to better meet users' needs may be missed.

Ensuring that health professionals have the skills and knowledge to use, implement and support patients with DHTs and services is key to encouraging patients to use and engage with digital health services *(25,99,101–103,106,108,113,117,129,144,164)*. This includes not only assisting patients with digital health tools but also guiding them to technical support when issues arise, addressing any questions about security and privacy, and referring them to community support services *(134)*. However, the challenge is that the additional time needed to provide this kind of support is often perceived as extra workload by professionals *(25,89,90)*.

New educational approaches have been implemented to support health and care professionals. For example, the Association of American Medical Colleges has established guidelines for medical school curricula to incorporate telehealth competencies *(48)*. They aim to ensure high-quality care by emphasizing patient safety, equitable access, appropriate telehealth use and adherence to ethical and legal standards. In the United Kingdom, the NHS Digital Academy has incorporated digital inclusion into its training and development programme *(160)*. The initiative aims to equip health-care leaders with the skills needed to drive digital transformation across the NHS *(160)*.

What else needs to be done?

Ideally, training for end users should also include cyber-safety education and digital consumer awareness to help people to critically evaluate online content, navigate security risks and make informed choices that support their health and well-being *(117,150)*. Specific training for vulnerable population, such as children and young people, may also be required to ensure that they understand how their information is used and to whom it is available. Consideration should be given to providing the tools needed to ensure that they can find trusted health-related information even when they are digitally competent *(48,150)*. Plans to upskill vulnerable groups should take into account the wider context of a person's life to understand what they want to achieve by engaging with online platforms (e.g. managing a chronic condition) *(99,129)*. They should also consider looking deeper into the digital divide to make cultural adjustments to target support and address specific needs. The social network of end users, including training for family members or carers *(101,113,124,129,146,147,156)* and community and peer-to-peer learning (e.g. digital champions, community health workers) *(25,28,117, 121,129,143,146,162)*, is likely to have a continued role in advancing equity in digital health.

Education for health-care professionals should extend beyond digital literacy to include training on cultural sensitivity, accessibility and equity in digital health *(49,81,101, 109,151,165)*. Equity-oriented training, resources and competencies should be developed to support service providers in offering compassionate and destigmatized care to stigmatized or marginalized communities such as people with mental health conditions or substance use disorders and people living with HIV *(27,42,81,101,159)*. For emerging technologies such as AI, there is a call for educational programmes to improve developers' and health professionals' understanding of equity in AI-assisted medical devices *(13,15,61,64,151)*, discrimination awareness *(119,159)* and ethical considerations in AI data-driven systems. Basic AI literacy should be promoted across society, but its effectiveness depends on first ensuring that professionals (e.g. ethicists) receive proper training and skills in this field *(17,48,67,188)*. Establishing shared goals and standards for integrating digital health education into both pre-registration and ongoing professional training is essential. This can be facilitated via continued professional development and continued medical education opportunities, along with dedicated time and support for health and care professionals to attend, assimilate and apply their new knowledge *(1,2,13,62,109,126)*.

Recently, there has been growing recognition across the WHO European Region of the need to invest in developing digital rights literacy, that is, the knowledge, skills and understanding that individuals need to navigate the digital world in a way that protects their rights. Strengthening digital health literacy is essential for promoting equitable access to digital health and safeguarding vulnerable populations against discrimination or digital exclusion. However, this is likely to require a strong collaboration between multiple partners and agencies across Member States *(114)*.

Key message

To benefit from digital health, individuals need a set of digital literacy, health literacy and digital health literacy skills. These skills enable equitable access to digital health, improve health outcomes and reduce disparities. Training for both patients and health-care professionals, along with support for vulnerable groups, is crucial for bridging the digital divide. Cross-sectoral collaboration and investment in providing skills will ensure equitable access and protect vulnerable populations from digital exclusion.

2.7 Use and engagement

This digital health component relates to how actively and meaningfully users interact with technologies to support their health, and how these interactions lead to better health behaviours and outcomes.

The review identified three subcomponents that consider equity: accessibility and ease of use (section 2.7.1), acceptability and trust (section 2.7.2), and user satisfaction and sustained use (section 2.7.3).

2.7.1 Accessibility and ease of use

Definition

Accessibility relates to whether DHTs are developed and implemented in a way that facilitates ease of use (how simple it is for individuals to interact with a platform, system or interface) for the widest user base possible, regardless of background, geographical location, and physical or mental ability *(127)*. It encompasses the concepts of inclusivity, affordability and adaptability to diverse users *(111,120)*.

Although the primary emphasis is on racial and ethnic groups, older adults, and people with physical disabilities, it is also important to consider low-income populations, underserved rural communities, and sexual and gender minority groups *(127)*.

Why is this important for digital health equity?

Even when people are able and willing to use technology, many DHTs are not sufficiently flexible to serve those with higher health burdens or multiple disadvantages, which could increase inequities in access to care *(78,97)*. As DHTs and digital health services grow in importance, ensuring their accessibility will become crucial for improving health-care outcomes, reducing disparities and fostering more inclusive health systems *(4,127)*. DHTs that are intuitive and easy to use become more accessible to a broader and more diverse range of users, thus helping to reduce health inequities in health-care access and outcomes.

How is equity considered in the current approaches?

Accessibility is a regulatory requirement for medical devices *(124,153,202)*. Developers are requested to provide product support and written information to end users on how to use DHTs *(106,107,113,124,131)*. For example, German-language support for users is a mandatory requirement for digital health applications to receive market approval for use within Germany's statutory health insurance system *(124)*. Accessibility is also a key consideration for the implementation *(4,13,17,27,34, 43,49,78,90,92,101,112,120,134,144,160,163)* and evaluation of DHTs *(24,27, 29–31,47,48, 60,76,84,87,92,101,108,118,121,128,133,135,146)*. Recommendations focus on reducing the necessary skill level of users, particularly those with low digital literacy or physical and cognitive disabilities. For example, key aspects of this digital health subcomponent are using plain language and a single login, lowering the system demands of DHTs, and making DHT intuitive, user-friendly, translatable and adaptable to other languages and cultural contexts *(34,44,84,144,146,203)*. Providing plain language materials and instructions to end users is recommended by several evaluation frameworks, tools and guidelines – this includes providing information in multiple languages *(4,108,127)* and, in the case of data-driven technologies, information to end users on how such technologies may impact them *(98,141)*. Conducting a specific accessibility assessment in terms of the target population and usage is important to ensure that DHTs address the needs of intended users *(106,124,136,138,140,144)*.

What else needs to be done?

While accessibility is considered a key digital health component, few frameworks specifically recommended following specific standards such as the Web Content Accessibility Guidelines *(15,24,34,78,105–107,127,128,136,140)* or the NHS Accessible Information Standard *(144,160)* to ensure that everyone can fully benefit from digital health and the information provided by DHTs. Online accessibility checklists such as the Web Accessibility Evaluation Tools *(204)* can also provide a quick view of how accessible digital health services are *(160)*. It is also important to consider accessibility from the perspective of health professionals. For example, 20% of the United Kingdom's NHS staff are also NHS users with a disability *(144)*. One potential solution is to create policies that incentivize the development and adoption of accessible and inclusive DHTs by setting minimum accessibility standards (e.g. ensuring proper alternative text, colour contrast, keyboard navigation and content adaptability) *(6,127)*.

Evaluating technology at an early stage provides an opportunity to consider inclusive design. Additionally, it helps to develop a clearer understanding of the potential benefits and risks associated with adopting the technology, particularly in terms of its impact on health equity *(93,164)*.

Key message

Accessibility and ease of use are essential to ensure that DHTs are affordable and adaptable for diverse users, including people with disabilities and underserved communities. Designing intuitive and user-friendly DHTs is key to reducing health-care disparities and improving outcomes. Clear standards, accessibility assessments and inclusive design practices to promote equitable health care should be considered when regulating, implementing and evaluating DHTs and digital health services.

2.7.2 Acceptability and trust

Definition

Acceptability relates to the willingness of users to adopt, use and engage with DHTs and digital health services such as apps, virtual care and wearable devices to address their health-care needs or practices *(106)*. It encompasses how well these technologies align with the preferences, needs and values of users, as well as how comfortable and confident they feel in using them. For individuals to have confidence in such tools, they must feel assured that their data are protected and that the technology is functioning as intended and that it will provide accurate and reliable health information.

Why is this important for digital health equity?

Both acceptability and trust are critical for the widespread adoption and effective use of digital health tools and services, especially in underserved populations with varying levels of digital literacy and health-related needs. If certain population groups do not accept or engage with digital health tools, use of such tools may inadvertently widen existing health inequities *(97).*

How is equity considered in the current approaches?

Regulatory bodies include usability testing as a critical part of pre-market approval and may assess usability post market if any issues arise. Regulations follow international usability standards such as International Electrotechnical Commission 62366-1 (Application of usability engineering to medical devices) *(124,153,202,205)*. Standards and evaluation frameworks and tools are commonly aligned with regulations and emphasize adherence to usability international standards *(101,105,106,113,131,136,138,140)*. A key consideration for digital health implementation is ensuring end-user acceptability, which should be assessed during the evaluation of DHTs. This involves providing evidence from usability evaluations, including user feedback, ease of use and adoption rates *(124)*. Designing culturally appropriate DHTs that take into consideration context and cultural awareness is a key factor in increasing acceptability for population groups who live with inequities (e.g. older adults, homeless people, people experiencing domestic abuse, and migrant and ethnic minority groups) *(4,19,49,90,101,102,109,117,128,144,146,161,164,203)*. Creating DHTs through an iterative process with target users (user-centred design) and usability testing, including the use of validated tools (scales, questionnaires, surveys) and qualitative research (focus groups or interviews) is common strategy to address acceptability (section 2.4.1) *(24,25,34,42,81,124,127,140)*.

Security and privacy concerns are significant barriers for minoritized groups to engaging with digital health. Historical feelings of mistrust in the health system and fears of surveillance or data misuse contribute to this issue *(15,37,40,57,63,94,101,161)*. Addressing such concerns by involving trusted intermediaries or messengers (e.g. community leaders or navigators) is often a key strategy to increase the use and adoption of digital health services by these communities *(84,101,134,144)*. However, despite these efforts, best practice guidelines for participatory design among these communities, knowledge-sharing and consistent reporting of outcomes are lacking. As a result, evidence is limited on the impact of digital health tools and services in addressing the needs of underserved groups and improving digital health equity *(42)*.

What else needs to be done?

Although the field is still developing a consensus on the best ways to measure acceptability as a domain (and related terms such as usability or user experience), there are validated instruments to measure usability, such as the System Usability Scale *(206)*. However, to facilitate progress in this field and allow for robust indirect comparisons, developers should strive to use the same standards and measure(s) that have been previously used to evaluate similar DHTs *(127)*. Measuring acceptability (or usability) should be part of the minimum requirements for the approval and implementation of digital health innovations *(100)*.

Better engagement with communities, including trusted intermediaries and end-user feedback, will provide useful information for developers to ensure that digital health tools and services are culturally sensitive and adaptable to the specific values, beliefs and needs of the target population *(4,101,108,109,112,117)*. Information about engagement activities with end users should be clearly documented so that it can be used as a guide for similar DHTs and digital health services, but more formal guidelines on assessing acceptability or usability might also be needed. The provision of clear communication and information for end users is vital to address trust issues, particularly in population groups that have historically been marginalized in health care (e.g. ethnic minority groups, people with disabilities, and rural communities) *(100,143)*. Fostering a sense of autonomy, addressing confidentiality and privacy concerns, and offering culturally appropriate DHTs and digital health services are key to overcoming mistrust and encouraging engagement *(17,29,97,100,106)*. For certain populations such as those experiencing domestic violence or those who worry about being overheard, privacy concerns relate to having a safe-space environment to engage with digital health services. Providing access to a digital hub in the community or health-care setting may address this issue *(43,159)*.

Sharing success stories where digital services have created value, addressed a barrier to care or positively impacted health could also address trust issues *(95,117)*. For data-driven technologies, developers must ensure that they adopt ethical AI practices, mitigate bias and ensure transparency to maintain public trust *(17,61,119,143)*. Additionally, building public trust in and understanding of AI in health care requires targeted education and communication strategies (section 2.3.2) *(66)*.

Key message

End users must trust that their needs are met, their data are secure and the information they receive is reliable. DHTs and digital health services should be culturally appropriate, user centred and undergo acceptability or usability testing. For AI- and data-driven technologies, transparency, fairness and accountability are essential to build public trust. Clear communication, privacy protection and engagement with marginalized communities are key to building trust and preventing health inequities.

2.7.3 User satisfaction and sustained use

Definition

User satisfaction plays a key role in driving user engagement with and adoption of DHTs and digital health services *(207)*. To achieve this, developers need to focus on creating easy-to-use, effective and reliable DHTs that meet the needs and expectations of end users. When users are highly satisfied, their motivation and experience improve, leading to more consistent and long-term use of the DHTs or digital health services.

Why is this important for digital health equity?

User satisfaction ensures that health technologies are accessible, effective and inclusive for all users, regardless of personal background, socioeconomic status or health condition. When DHTs are designed to be user friendly and reliable, are tailored to diverse needs, and offer value to patients or end users, they promote greater adoption and engagement, ultimately reducing health inequities and improving health outcomes across populations *(31,91,95,134).*

How is equity considered in the current approaches?

User satisfaction is often considered as part of the broader assessment of a tool's acceptability and usability *(8,87)*. For example, regulatory bodies *(127, 153,202) and* frameworks *(124)*, standards *(106)* and evaluation frameworks and tools *(113, 121,140,146)* require developers to show how their technology improves health outcomes and how easily and effectively users can interact with DHTs. However, only a few guidelines recommend considering the users' holistic experience (i.e. physical, cognitive, emotive, beliefs, preferences, motivations, or behaviours) *(1)* and the context of use *(24,31,92,112,128,129,150,164)*.

What else needs to be done?

While information about the perceived value and benefit of DHTs is relevant and should be integrated into the regulation, implementation and evaluation of DHTs, a deeper understanding is needed of user satisfaction and what motivates people to use DHTs and digital health services *(4,31)*. Social dimensions commonly focus on access and skills but tend to overlook the underlying factors (or hooks) that motivate people to actively engage with DHTs and digital health services *(94,129).* Understanding user satisfaction is key to ensuring that people are ready to engage with and continue to be involved with digital health. Additionally, user satisfaction should be constantly monitored to improve quality and promote well-being to ensure ongoing engagement and positive outcomes *(137)*.

Key message

DHTs must be user friendly, reliable and tailored to diverse needs. Current approaches focus on evaluating usability, but a deeper understanding is needed of the holistic user experience, including motivation and social factors, to enhance sustained engagement with DHTs and digital health services.

2.8 Cross-cutting theme: equity-by-design

Definition

Equity by design is a proactive approach to developing digital health that specifically aims to address and reduce health inequities *(208)*. The concept emphasizes integrating equity considerations into every stage of the design process to ensure that digital health solutions are accessible, usable and beneficial for diverse populations, particularly marginalized or underserved groups *(6,15,101, 106,120)*. The approach moves beyond a superficial description of factors to an ecologically comprehensive framework that accounts for the complex interplay of sociodemographic, cultural and economic determinants of health and well-being. By intentionally embedding equity throughout the digital health-care life cycle, this approach seeks to improve clinical outcomes (e.g. mortality, morbidity and quality of life), process outcomes (e.g. care continuity, coordination and quality), and health-care experiences (e.g. patient/provider satisfaction and engagement) *(6,15,49,165)*.

The International Organization for Standardization highlights the need for digital health innovations to not only leverage technology for improved health care but to do so in ways that actively address systemic inequities. The term **tecquity** highlights the need to prioritize accessibility, inclusivity, transparency and fairness in preventing the reinforcement of existing disparities and working towards a more just health system *(120)*. Ultimately, the aim is to ensure that technology requirements are driven by a commitment to achieving both equitable access to high-quality digital health-care solutions for all *(6,13,49,109,120)*.

How is equity considered in the current approaches?

Evaluation frameworks and tools *(113,127,128,147)*, standards *(106,107)* and diverse implementation guidelines *(6,18,34,100,129,134,145,158)* recommend that developers should design DHTs with inclusion in mind. Guidelines also recommend that digital health tools should be developed and deployed in a way that respects human rights and promotes social justice *(18,89,122,143,161)*. For example, national guidance such as the United Kingdom's National Institute for Health and Care Excellence evidence standards for DHTs includes a specific standard (Standard 4) focused on addressing health inequities and bias in DHT design *(107)*. The adaptation of these standards by the Spanish Ministry of Health and the Agency for Health Quality and Assessment of Catalonia goes further by incorporating human and sociocultural factors that could affect technology use, including acceptability, ease of use, digital health literacy, user engagement, perceived benefits and patient empowerment. They also emphasize the importance of evaluating the sociocultural impact of DHTs through assessing factors such as accessibility to health services, potential changes to workflows and roles, and the impact on the doctor–patient relationship *(106).*

For data-driven DHTs, including those with AI, the emphasis is on mitigating against algorithmic bias that could lead to inequitable health outcomes between different population groups *(17,18,32,98,105–107,119,132,142,143,145,151)*; promoting the diversification of datasets *(19,99,127,141,151)*; and matching funding for AI with funding for research into how data-driven health systems and digital health services affect health inequities *(3)*. This may involve funding dedicated teams to oversee post-deployment monitoring of the impacts of DHTs on inequities *(75,97)* and the impact of digital health services on wider health services (i.e. by reallocation of resources) *(113,149)*. While there is increasing focus on inequities based on gender *(18,19,114,155,158)*, race or ethnicity *(3,13,98,101,109,127,142)*, failing to consider other social determinants of health, as well as digital determinants of health (and how they interact with one another), may exacerbate health inequities, especially for those who have historically been underserved.

A concerted and intentional effort is needed at both the national and Regional levels to develop systems and infrastructure that reduce inequities and to monitor their impact and adapt them based on feedback with the goal to ensure that everyone has equitable access to the benefits of digital health.

What else needs to be done?

To create tools and services that foster digital health equity, good practice could involve conducting an Equity Impact Assessment *(49,97,116,117,141,144,145)* that complies with legislation on discrimination, equity and diversity such as the United Kingdom's Equality Act 2010 *(209)*. Inequities may be identified by using a framework such as place of residence, race/ethnicity/culture/language, occupation, gender/sex, religion, education, socioeconomic status and social capital, plus other key characteristics (PROGRESS-Plus) *(4,34,210)*. This would ensure that digital health innovations are inclusive, equitable and fair for all users. However, additional funding may be needed for regulatory bodies to implement this as part of the approval process for new DHTs *(13)*. For data-driven systems, there is a call for increased certainty and clarity in regulations and standards to address the immediate needs of the growing number of AI-driven applications *(13,19,64,98,211)*. In addition, it is essential to develop governance structures to continuously evaluate and mitigate bias in AI-driven technologies *(75)*. From the European perspective, harmonizing rules on conformity assessment procedures across the EU, eliminating regulatory duplication and ensuring the effective exchange of information between notified bodies on market authorization of the same product for digital health use are needed to advance digital transformation in health care equitably across the continent *(99)*.

Policies that mandate equitable design in digital health solutions are essential to ensure that public health systems prioritize equity alongside innovation *(60)*. However, equity in digital health cannot be achieved in isolation: a multistakeholder, systems-based approach is crucial to integrating digital health initiatives with the existing health-care infrastructure, addressing the concentration of technological and market power that restricts equitable access, and upholding health care as a fundamental right, with digital inclusion as a core principle *(118,135,157)*.

Key message

Equity by design proactively and intentionally integrates equity into every stage of DHT development and deployment. This includes considering equity across the infrastructure, ensuring diverse data to minimize bias, employing user-centred design for inclusivity, establishing equity-focused standards and fostering collaboration among stakeholders. However, there is no universally agreed method to implement this approach, making consistency in application a challenge at both the national and international levels. The lack of standardized monitoring frameworks makes it difficult to assess the impact of digital health and integrate equity into every stage of development to ensure that the benefits reach everyone.

3. Discussion

3.1 Strengths and limitations of the review

The review was underpinned by a comprehensive search strategy, but there were some limitations. First, the quality of the included sources was not assessed. However, as the purpose of this study was not to validate methodological rigor but to gain an overview of the integration of equity into the regulation, implementation and evaluation of digital health, the lack of a quality assessment does not undermine the validity of the review. Secondly, although the searches were not limited by language, only two academic papers published in languages other than English were identified and only one met the criteria for inclusion. Most of the academic literature came from the WHO Region of the Americas (United States of America/Canada), whereas European evidence predominantly derived from high-income western European countries such as the United Kingdom, limiting its generalizability to all Member States of the WHO European Region. The review included a wide range of grey literature to capture ongoing or emerging work that may not yet be part of the established academic discourse. However, emerging frameworks may have been missed if they were published as commentary or viewpoint article. Lastly, due to the rapidly evolving nature of the field, it is possible that some emerging literature, including recent studies, frameworks or regulatory updates, may have been overlooked in the review. Nonetheless, the review identified important areas where a lack of frameworks and guidelines have created uncertainty and considerations are proposed to address these gaps.

3.2 Promoting equity in digital health

Ensuring that equity is considered during the development and deployment of digital health innovation is a priority across many Member States of the WHO European Region. Yet, equity in digital health is a significantly complex challenge, given that the drivers may relate to the underlying technical infrastructure, data systems and digital health tool performance, and the broader social inequities reflected in digital access, skills and literacy, and engagement across population groups. Addressing these interconnected challenges is critical to ensuring that digital health benefits all and does not inadvertently exacerbate existing inequities.

This scoping review examined how equity is reflected in recent literature across regulation, evaluation and guidance frameworks for digital health. Adopting a whole-system, sociotechnical approach, equity was considered across six technical and social domains of a digital health system, and opportunities for embedding equity were identified. While most publications had high-level principles, they did not explicitly embed actionable equity considerations. The report drew together key themes to guide health systems, regulators and innovators on embedding equity in digital health systems.

3.2.1 Equity in digital infrastructure and systems

The digital infrastructure is the foundation upon which digital health innovations are developed and deployed, yet the importance of designing digital data and operating systems (including infrastructure, interoperability, adaptability and scalability) to support an equitable digital health system was not emphasized. The literature largely referred to the necessity to consider the infrastructure, digital maturity and scalability to enable deployment in low-resource settings *(2,87,126,135,157).* However, while the importance of adaptability to support user needs was highlighted, actionable steps to action were lacking. Areas for further consideration are as follows.

- Adopt minimum digital infrastructure and open interoperability standards in line with data protection legislation to support the design of health systems to mitigate against bias in DHTs and enable more equitable development and deployment of digital health tools *(2,87,126,135,157).*
- Embed data solidarity into interoperability standards and governance to ensure that health data are shared and used in ways that benefit all, particularly underrepresented groups, while respecting privacy, autonomy and social good *(212)*.
- Define and integrate equity metrics into infrastructure maturity models to identify gaps and examine and monitor scalability from an equity perspective *(212)*.
- Apply user-centred design principles to best practice guidance to develop and deploy DHTs that are truly adaptable to the unique needs (such as language, literacy, and accessibility) of disadvantaged groups *(38,44,126)*, and incentivize developers to integrate these to reach all population groups *(99,213)*.

3.2.2 Equity in data

While existing legislative frameworks provide robust foundations for data governance alongside guidance to support, for example, culturally sensitive governance and consent, gaps remain in the practical implementation for equity. Addressing these gaps is essential to protect vulnerable populations and remove barriers to engagement with digital platforms. Improved engagement with digital health systems can reduce the exclusion of underrepresented populations (and bias) in the underlying source data.

The review found a greater emphasis on equity within quality assurance and bias, but the connection to embedding equity-by-design principles into the underlying digital and data infrastructure and systems of care and the involvement of participatory approaches were not always evident. Areas for further consideration are as follows.

- Promote consent, trust and cultural sensitivity: embedding user-centred design into data governance processes (data collection, share and use and value) to reflect diverse cultural background or needs to support clear communication. Building trust through participatory governance and community engagement is essential for equitable and sustainable digital health innovation *(38,121,146, 147,161,214,215)*.
- Ensure accessible mechanisms for individuals with low literacy, visual impairment or other barriers such as by using simplified consent forms and alternative or complementary formats (e.g. audio, interactive designs, community consent) *(29,42–45,120,124,127–129)*.
- Define core equity indicators/domains to support an approach that addresses underrepresentation in data and bias. Work with engineers, digital infrastructure and data specialists to develop systems to ensure disaggregated data collection for equity (e.g. collect once, use many times), regularly examine the reporting of bias, and incorporate intersectional analysis into routine practice *(4,85,142)*.

3.2.3 Equity in digital health tool performance

Understanding the performance of digital health tools across population groups is critical to achieving equitable health outcomes. While there was a strong narrative for equity in some areas, for example user-centred design, safety and algorithmic bias, the equity-specific implications were lacking in others (validity and reliability) *(13,54,66)*. Areas for further consideration are as follows.

- User-centred design is integral to the design, implementation and evaluation phases of digital health tools, but a standard approach to its practical application is needed to ensure that equity considerations are not generalized and to demonstrate how feedback informed development and deployment;
- Ensuring that equity considerations are embedded in the validation, reliability and safety of digital health tools before and after deployment to ensure consistent and accurate performance across intended users. Regulatory frameworks should also support the development of digital health tools that are generalizable and inclusive of underrepresented groups.
- Standard evaluation frameworks for DHTs should place a greater focus on equity.

3.2.4 Equity in digital access

Across DHT regulation, implementation and evaluation, addressing equitable access to devices and/or the internet connection is recognized, but there is a lack of focus on addressing the broader social and digital determinants of health such as digital infrastructure (e.g. geographical location), disability, gender and poverty. Despite multiple examples of programmes operating across sectors to address digital access, robust evaluation is needed to ascertain the sustainability of the impact *(4,27)*. Areas to consider are as follows.

- Support collaboration and the potential to work across public, private and voluntary sectors to address the underlying drivers of inequities in digital access *(28,47,76, 90,133,162)*.
- Evaluate and share best practice in digital exclusion to support collective success *(4)*.
- Recognize that for some groups, improving access alone will not address digital health equity due to a lack of skills or perceived value of engaging with digital platforms, hence the need to preserve a non-digital route to care *(25,149)*.
- Promote a wider focus that extends to variations in digital access for health and care staff, linked to the digital infrastructure of the health system *(102)*.

3.2.5 Equity in digital skills for health

Ensuring that users (both the public and professionals) have the skills to effectively understand and engage with DHTs is a key component of achieving digital health equity. While several frameworks support the development of digital health skills, including those focused on end-user and professional competencies, knowledge gaps remain in how to practically apply and tailor these frameworks to ensure equity in digital skills implementation. Limited digital literacy and skills among certain population groups present significant barriers to equitable engagement with digital health innovations. Tailored interventions are needed to support individuals with varying levels of digital proficiency or with cultural or other contextual concerns. Areas to consider are as follows.

- Provide training for health-care professionals (capacity-building) to effectively use digital health and to support their patients, with an emphasis on understanding cultural and other contextual barriers to participation in a digital health system, including discrimination awareness and ethical considerations in data-driven technologies *(13,15,18,48,61,64,67,81,114,119, 151,159,188)*.

- Identify groups that need support to develop digital literacy (across the public, patients, carers and health and care professionals) and test approaches to address these gaps *(90)*. Share insights from approaches to mitigate digital literacy.

3.2.6 Equity in engagement and use of digital health

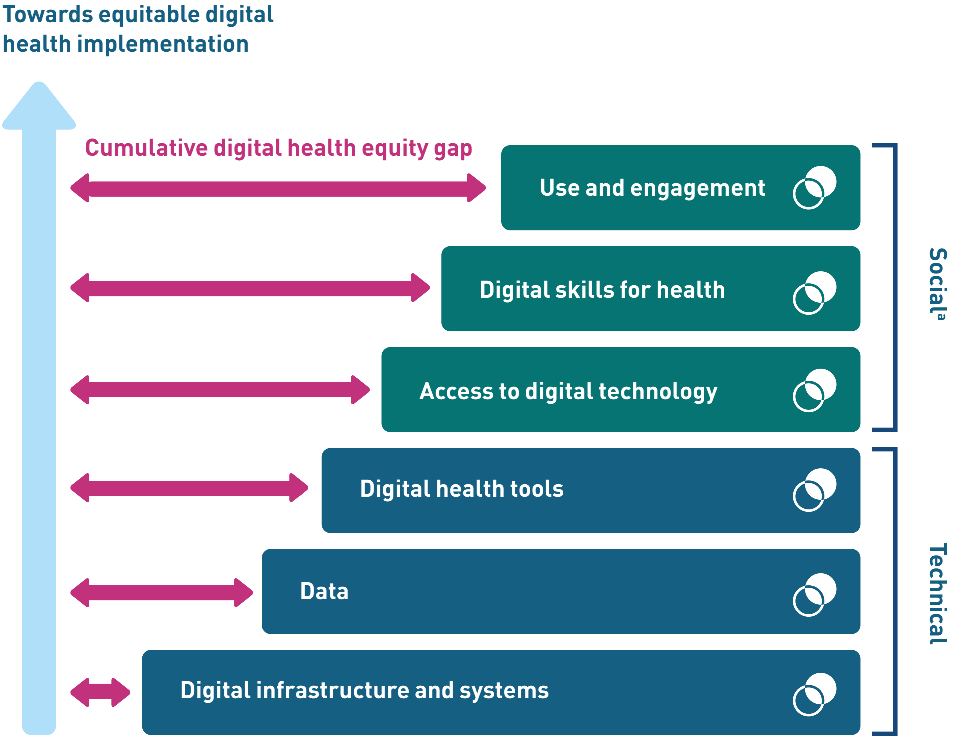
Active and meaningful use of digital health is essential to deliver the intended benefits and health outcomes, yet some communities are less likely to engage with DHTs, even when access and skills barriers are addressed. While current frameworks address components such as accessibility and user satisfaction, an equity lens should be used to understand the social and behavioural determinants of low engagement with DHTs *(4)*. Such low engagement can stem from mistrust, perceived irrelevance and poor user-centred design; consequently, certain groups less likely to engage or benefit *(48,120).* Areas for consideration are as follows.

- Adopt user-centred design approaches to develop DHTs that align with user needs by improving usability, engagement and the overall impact on health outcomes, thus supporting equity in digital health *(49,57,76,117)*.
- Promote the incorporation of behavioural insights to identify and address barriers to engagement, and support action to achieve more equitable and sustained use of DHTs *(4)*.
- Strengthen monitoring and evaluation frameworks to assess the uptake, utilization and impact of DHTs across different population groups, paying specific attention to disparities across equity domains *(34,48,120)*.

3.3 Considerations to ensure equitable benefits from digital health innovation across the WHO European Region

As the understanding of equity within the context of digital health improves, regulators, health policy and health systems are putting in place initiatives to mitigate against potential inequities in a digital health system. This review highlights the complexity of the challenge across the different components of a digital health system, and the need to move beyond generic protections towards embedding equity through action across a digital health system. Emerging areas for consideration to inform a Regional strategy for digital health equity are outlined in the following sections (Fig. 4).

Fig. 4. Inequity in technical and social components of a digital health system creates a cumulative digital health equity gap



[a] Considered across public, patients, carers and professionals.

Moving towards an equitable digital health system

- Develop a shared understanding of what an equitable digital health system consists of to address fragmentation and lack of coherence in digital health policies and support a comprehensive approach to ensuring equity is embedded into digital transformation. Without coordinated efforts, there is a risk that fragmented interventions will contribute to a cumulative digital health equity gap.
- Develop a common definition of core equity domains and measures of equity in digital health systems to facilitate evaluation and shared learning across the Region *(4,27,34)*.

Using tools and frameworks to operationalize equity

- Develop a maturity matrix for an equitable digital health system to help countries to identify their most significant barriers to achieving equity in a digital health system and guide solutions. By recognizing that countries have diverse digital landscapes, health systems and population needs, this approach would facilitate tailored action to close digital health equity gaps.
- Define interoperable minimum equity standards across the technical and social components of a digital health system and ensure effective governance structures for implementation. This could include:
  - inclusive digital/data infrastructure principles, including public engagement, consent and trust *(18,119,124)*;
  - data standards for equity (e.g. STANdards for data Diversity, INclusivity and Generalisablity (STANDING) Together collaborative recommendations) to promote inclusive data collection/engagement with digital health systems *(142,145,146)*;
  - minimum accessibility standards for equity in digital health access *(121,127, 139)*; and
  - digital skills standards for public and professionals *(100,151)*.
- Promote the use of tools to support the development of equitable digital health systems and facilitate shared learning and knowledge transfer to support adoption and scalability in a fast-paced digital health landscape. This could include:
  - embedding equity-by-design principles throughout the design, development, implementation and evaluation phases of digital health systems by adopting a user-centred design approach that actively involves diverse end users, particularly those from marginalized groups, in the co-design and testing of digital health innovations *(109,139,143,156)*; and
  - using structured tools such as equity impact assessment tools to evaluate the potential impact of digital health on health equity *(15,34,49,101)*.

Strengthening regulation, governance, and financing for digital health equity

- Promote the harmonization of equity-focused regulatory frameworks across the Region and encourage consistency in embedding inclusivity within DHTs. This includes balancing universal principles of equity with context-specific considerations to ensure that digital health innovations are both fit for purpose and responsive to the needs of intended users.

- Strengthen governance and accountability for equity in digital health systems by:
  - ensuring oversight of DHTs post deployment through standardized monitoring and evaluation frameworks for access and outcomes across population groups, and capturing the underlying drivers of differences in real-world settings (spanning access, use, outcomes, bias and emerging risks, e.g. implication of data drift in AI/machine learning tools and equity) – building on existing evaluation frameworks will enable robust comparisons. *(107,146,147)*; and
  - implementing sustainable financing and reimbursement mechanisms to promote inclusive innovation, for example, by incentivizing developers to demonstrate how their tools address the needs of underserved populations and reduce health disparities *(213)*.

- Address technological and market power imbalances to ensure equitable access to digital health solutions for all, for example, by ensuring that public procurement strategies and pricing policies are leveraged to improve equitable access, particularly for underserved populations *(56)*.

Building capacity and cross-sectoral collaboration for digital health equity

- Develop interdisciplinary teams – while each specialist team may focus on one component (e.g. digital architects, data engineers, clinicians, patient-engagement teams), there needs to be better integration across specialists through drawing on user-centred design involving social scientists, ethicists and community engagement to achieve a whole-system integration of equity. Teams should also aim to include specialists from diverse backgrounds (e.g. gender, age and ethnicity) to protect against unconscious bias *(27,55,96,145)*.

- Establish communities of practice and implementation science networks to share learning and support equity-focused implementation of digital health through dissemination of standardized frameworks, tools and lessons learned.
- Collate and implement best practice approaches to support active engagement in the development and implementation of DHTs and digital health systems to ensure equity and build trust across the public, professionals and communities.
- Foster cross-partnership collaborations (across government, academia, industry and civil society) to identify best practices for meaningful engagement in the field.
- Advocate for digital health equity by levering international research and supporting policy experimentation and engagement across government, academia and the public sector to build more equitable digital health systems *(22,46,47,71,104,151,175,186)*.

4. Conclusions

Achieving health systems that deliver equitable benefits for all populations remains a central priority for the WHO European Region. To fulfil this goal, equity must be established as a core principle throughout all stages of health system transformation. This requires a comprehensive, whole-system approach that goes beyond the technological aspects of digital health to address the broader societal determinants and structural inequities influencing digital inclusion.

Progress towards equitable digital health requires an intentional and coordinated effort to build systems that are inclusive, culturally responsive and adaptable to varied contexts and populations. Through these actions, the Region can lead the way in harnessing the transformative potential of digital health innovations to reduce health inequities and improve health outcomes for all.

References[2]

1. WHO guideline: recommendations on digital interventions for health system strengthening. Geneva: World Health Organization; 2019 (https://iris.who.int/handle/10665/311941). Licence: CC BY-NC-SA 3.0 IGO.
2. Global strategy on digital health 2020–2025. Geneva: World Health Organization; 2021 (https://iris.who.int/handle/10665/344249). Licence: CC BY-NC-SA 3.0 IGO.
3. Studman A. Access denied? Socioeconomic inequalities in digital health services. London: Ada Lovelace Institute; 2023 (https://www.adalovelaceinstitute.org/report/healthcare-access-denied/#:~:text=This%20situation%20can%20exacerbate%20inequalities,to%20use%20digital%20health%20services.).
4. Equity within digital health technology within the WHO European Region: a scoping review. Copenhagen: WHO Regional Office for Europe; 2022 (https://iris.who.int/handle/10665/365326). Licence: CC BY-NC-SA 3.0 IGO.
5. Were MC, Sinha C, Catalani C. A systematic approach to equity assessment for digital health interventions: case example of mobile personal health records. J Am Med Inform Assoc. 2019;26(8–9):884–90 (https://doi.org/10.1093/jamia/ocz071).
6. Nair US, Kue J, Athilingam P, Rodríguez CS, Menon U. Application of the ConNECT Framework to achieve digital health equity. Nurs Outlook. 2023;71(4):101991 (https://doi.org/10.1016/j.outlook.2023.101991).
7. Health equity [website]. World Health Organization; 2025 (https://www.who.int/health-topics/health-equity#tab=tab_1).
8. Digital health in the European Region: the ongoing journey to commitment and transformation. Copenhagen: WHO Regional Office for Europe; 2023 (https://iris.who.int/handle/10665/372051). Licence: CC BY-NC-SA 3.0 IGO.
9. Seventy-fourth Regional Committee for Europe: Copenhagen, 29–31 October 2024: leveraging digital transformation for better health in Europe: Regional digital health action plan for the WHO European Region 2023–2030. Copenhagen: World Health Organization; 2024 (EUR/RC74/8; https://iris.who.int/handle/10665/378406).
10. Transforming our world: the 2030 Agenda for Sustainable Development. New York, NY: United Nations; 2015 (https://sdgs.un.org/2030agenda).
11. Universal health coverage [website]. World Health Organization; 2025 (https://www.who.int/health-topics/universal-health-coverage#tab=tab_1).
12. Seventy-second Regional Committee for Europe: Tel Aviv, 12–14 September 2022: resolution: leveraging digital transformation for better health in Europe: Regional digital health action plan for the WHO European Region 2023–2030. Copenhagen: WHO Regional Office for Europe; 2022 (https://iris.who.int/handle/10665/362959).
13. Equity in medical devices: independent review. London: Department of Health and Social Care; 2024 (https://www.gov.uk/government/publications/equity-in-medical-devices-independent-review-final-report).
14. Gardiner T, Abraham S, Clymer O, Rao M, Gnani S. Racial and ethnic health disparities in healthcare settings. BMJ. 2021;372:n605 (https://doi.org/10.1136/bmj.n605).

---

[2] All references were accessed on 10 June 2025.

15. Richardson S, Lawrence K, Schoenthaler AM, Mann D. A framework for digital health equity. NPJ Digit Med. 2022;5(1):119 (https://doi.org/10.1038/s41746-022-00663-0).

16. Geracitano J, Barron L, McSwain D, Khairat S. How is digital health suitability measured for communities? A systematic review. Digit Health. 2024;10:20552076241288316 (https://doi.org/10.1177/20552076241288316).

17. High-Level Expert Group on AI. Ethics guidelines for trustworthy AI. Brussels: European Commission; 2019 (https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai).

18. Thagard P. Recommendation on the ethics of artificial intelligence. Paris: United Nations Educational, Scientific and Cultural Organization; 2021 (https://www.unesco.org/en/articles/recommendation-ethics-artificial-intelligence).

19. Regulatory considerations on artificial intelligence for health. Geneva: World Health Organization; 2023 (https://iris.who.int/handle/10665/373421). Licence: CC BY-NC-SA 3.0 IGO.

20. Goodman KW, Litewka S, Malpani R, Pujari S, Reis AA. Global health and big data: the WHO's artificial intelligence guidance. S Afr J Sci. 2023;119(5–6):14725 (https://doi.org/10.17159/sajs.2023/14725).

21. EU AI ACT: first regulation on artificial intelligence. Brussels: European Parliament; 2025 (https://www.europarl.europa.eu/topics/en/article/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence).

22. Jacob C, Lindeque J, Müller R, Klein A, Metcalfe T, Connolly SL et al. A sociotechnical framework to assess patient-facing eHealth tools: results of a modified Delphi process. NPJ Digit Med. 2023;6(1):232 (https://doi.org/10.1038/s41746-023-00982-w).

23. Fanta GB, Pretorius L, Erasmus L. A system dynamics model of eHealth acceptance: a sociotechnical perspective. In: Proceedings of the 25th International Conference of the International Association for Management of Technology, Orlando, 15–19 May 2016:256–70 (https://www.researchgate.net/publication/304177193_A_System_Dynamics_Model_of_eHealth_Acceptance_A_Sociotechnical_Perspective).

24. Jonsson M, Johansson S, Hussain D, Gulliksen J, Gustavsson C. Development and evaluation of ehealth services regarding accessibility: scoping literature review. J Med Internet Res. 2023;25:e45118 (https://doi.org/10.2196/45118).

25. Greenhalgh T, Rosen R, Shaw SE, Byng R, Faulkner S, Finlay T et al. Planning and evaluating remote consultation services: a new conceptual framework incorporating complexity and practical ethics. Front Digit Health. 2021;3:726095 (https://doi.org/10.3389/fdgth.2021.726095).

26. Lau PL, Nandy M, Chakraborty S. Accelerating UN Sustainable Development Goals with AI-driven technologies: a systematic literature review of women's healthcare. Healthc. 2023;11(3):401 (https://doi.org/10.3390/healthcare11030401).

27. Holmes Fee C, Hicklen RS, Jean S, Hussein NA, Moukheiber L, de Lota MF et al. Strategies and solutions to address Digital Determinants of Health (DDOH) across underinvested communities. PLOS Digit Health. 2023;2(10):e0000314 (https://doi.org/10.1371/journal.pdig.0000314).

28. Rodriguez JA, Charles JP, Bates DW, Lyles C, Southworth B, Samal L. Digital healthcare equity in primary care: implementing an integrated digital health navigator. J Am Med Inform Assoc. 2023;30(5):965–70 (https://doi.org/10.1093/jamia/ocad015).

29. Veras M, Labbé DR, Furlano J, Zakus D, Rutherford D, Pendergast B et al. A framework for equitable virtual rehabilitation in the metaverse era: challenges and opportunities. Front Rehabil Sci. 2023;4:1241020 (https://doi.org/10.3389/fresc.2023.1241020).

30. Kobeissi MM, Hickey JV. An infrastructure to provide safer, higher-quality, and more equitable telehealth. Jt Comm J Qual Patient Saf. 2023;49(4):213–22 (https://doi.org/10.1016/j.jcjq.2023.01.006).

31. Kayser L, Kushniruk A, Osborne RH, Norgaard O, Turner P. Enhancing the effectiveness of consumer-focused health information technology systems through ehealth literacy: a framework for understanding users' needs. JMIR Hum Factors. 2015;2(1)e9 (https://doi.org/10.2196/humanfactors.3696).

32. Dimitri P, Fernandez-Luque L, Banerjee I, Bergadá I, Calliari LE, Dahlgren J et al. An ehealth framework for managing pediatric growth disorders and growth hormone therapy. J Med Internet Res. 2021;23(5):e27446 (https://doi.org/10.2196/27446).

33. Fernandes FA, Chaltikyan G, Adib K, Caton-Peters H, Novillo-Ortiz D. The role of governance in the digital transformation of healthcare: results of a survey in the WHO Europe Region. Int J Med Inform. 2024;189:105510 (https://doi.org/10.1016/j.ijmedinf.2024.105510).

34. Groom LL, Schoenthaler AM, Mann DM, Brody AA. Construction of the digital health equity-focused implementation research conceptual model: bridging the divide between equity-focused digital health and implementation research. PLOS Digit Health. 2024;3(5):e0000509 (https://doi.org/10.1371/journal.pdig.0000509).

35. Schmidt J, Schutte NM, Buttigieg S, Novillo-Ortiz D, Sutherland E, Anderson M et al. Mapping the regulatory landscape for artificial intelligence in health within the European Union. NPJ Digit Med. 2024;7(1):229 (https://doi.org/10.1038/s41746-024-01221-6).

36. Goswami A, Poole L, Thorlu-Bangura Z, Khan N, Hanif W, Khunti K et al. The use of digital health interventions for cardiometabolic diseases among South Asian and Black minority ethnic groups: realist review. J Med Internet Res. 2023;25:e40630 (https://doi.org/10.2196/40630).

37. D'Elia A, Gabbay M, Rodgers S, Kierans C, Jones E, Durrani I et al. Artificial intelligence and health inequities in primary care: a systematic scoping review and framework. Fam Med Community Health. 2022;10(suppl 1):e001670 (https://doi.org/10.1136/fmch-2022-001670).

38. Ha S, Ho SH, Bae YH, Lee M, Kim JH, Kim JH et al. Digital health equity and tailored health care service for people with disability: user-centered design and usability study. J Med Internet Res. 202328;25(1):e50029 (https://doi.org/10.2196/50029).

39. Drukker K, Chen W, Gichoya J, Gruszauskas N, Kalpathy-Cramer J, Koyejo S et al. Toward fairness in artificial intelligence for medical image analysis: identification and mitigation of potential biases in the roadmap from data collection to model deployment. J Med Imaging. 2023;10(6):061104 (https://doi.org/10.1117/1.JMI.10.6.061104).

40. Blanc J, Hahn K, Oliveira B, Phillips RM, Duthely LM, Francois L et al. Bringing health care equity to diverse and underserved populations in sleep medicine and research through a digital health equity framework. Sleep Med Clin. 2023;18(3):255–67 (https://doi.org/10.1016/j.jsmc.2023.05.009).

41. Greene LK, Song G, Palma AV, Santarelli C, Wetzel C, Spillane J et al. A case series study assessing an equity-focused implementation of self-monitoring blood pressure programs using telehealth. J Public Health Manag Pract. 2024;30:S71–9 (https://doi.org/10.1097/PHH.0000000000001897).

42. Povey J, Raphiphatthana B, Torok M, Nagel T, Mills PPJR, Sells JRH et al. An emerging framework for digital mental health design with Indigenous young people: a scoping review of the involvement of Indigenous young people in the design and evaluation of digital mental health interventions. Syst Rev. 2023;12(1):108 (https://doi.org/10.1186/s13643-023-02262-w).

43. Garani-Papadatos T, Natsiavas P, Meyerheim M, Hoffmann S, Karamanidou C, Payne SA. Ethical principles in digital palliative care for children: the MyPal project and experiences made in designing a trustworthy approach. Front Digit Health. 2022;4:730430 (https://doi.org/10.3389/fdgth.2022.730430).

44. Schwamm LH, Chumbler N, Brown E, Fonarow GC, Berube D, Nystrom K et al. Recommendations for the implementation of telehealth in cardiovascular and stroke care: a policy statement from the American Heart Association. Circulation. 2017;135(7):e24–44 (https://doi.org/10.1161/CIR.0000000000000475).

45. Bounds DT, Stiles-Shields C, Schueller SM, Odgers CL, Karnik NS. Ethical considerations for developing pediatric mhealth interventions for teens with socially complex needs. J Child Adolesc Psychiatr Nurs. 2023;36(1):7–16 (https://doi.org/10.1111/jcap.12396).

46. Johnson EE, Kruis R, Verdin R, Wells E, Ford DW, Sterba KR. Development of an implementation science telehealth toolkit to promote research capacity in evaluation of telehealth programs. Telemed Rep. 2023;4(1):286–91 (https://doi.org/10.1089/tmr.2023.0039).

47. Shaw J, Brewer LC, Veinot T. Recommendations for health equity and virtual care arising from the COVID-19 pandemic: narrative review. JMIR Form Res. 2021;5(4):e23233 (https://doi.org/10.2196/23233).

48. Koehle H, Kronk C, Lee YJ. Digital health equity: addressing power, usability, and trust to strengthen health systems. Yearb Med Inform. 2022;31(1):20-32 (https://doi.org/10.1055/s-0042-1742512).

49. Hatef E, Hudson Scholle S, Buckley B, Weiner JP, Austin JM. Development of an evidence- and consensus-based Digital Healthcare Equity Framework. JAMIA Open. 2024;7(4):ooae136 (https://doi.org/10.1093/jamiaopen/ooae136).

50. Badr J, Motulsky A, Denis J-L. Digital health technologies and inequalities: a scoping review of potential impacts and policy recommendations. Health Policy. 2024;146:105122 (https://doi.org/10.1016/j.healthpol.2024.105122).

51. Uche-Anya E, Anyane-Yeboa A, Berzin TM, Ghassemi M, May FP. Artificial intelligence in gastroenterology and hepatology: how to advance clinical practice while ensuring health equity. Gut. 2022;71(9):1909–15 (https://doi.org/10.1136/gutjnl-2021-326271).

52. Brahmania M, Rogal S, Serper M, Patel A, Goldberg D, Mathur A et al. Pragmatic strategies to address health disparities along the continuum of care in chronic liver disease. Hepatol Commun. 2024;8(5):e0413 (https://doi.org/10.1097/HC9.0000000000000413).

53. Gama F, Tyskbo D, Nygren J, Barlow J, Reed J, Svedberg P. Implementation frameworks for artificial intelligence translation into health care practice: scoping review. J Med Internet Res. 2022;24(1):e32215 (https://doi.org/10.2196/32215).

54. Daneshjou R, Smith MP, Sun MD, Rotemberg V, Zou J. Lack of transparency and potential bias in artificial intelligence data sets and algorithms: a scoping review. JAMA Dermatol. 2021;157:1362–9 (https://doi.org/10.1001/jamadermatol.2021.3129).

55. Denecke K. An ethical assessment model for digital disease detection technologies. Life Sci Soc Policy. 2017;13(1):16 (https://doi.org/10.1186/s40504-017-0062-x).

56. Bente BE, Van Dongen A, Verdaasdonk R, van Gemert-Pijnen L. Ehealth implementation in Europe: a scoping review on legal, ethical, financial, and technological aspects. Front Digit Health. 2024;6:1332707 (https://doi.org/10.3389/fdgth.2024.1332707).

57. Claborn KR, Creech S, Whittfield Q, Parra-Cardona R, Daugherty A, Benzer J. Ethical by design: engaging the community to co-design a digital health ecosystem to improve overdose prevention efforts among highly vulnerable people who use drugs. Front Digit Health. 2022;4:880849 (https://doi.org/10.3389/fdgth.2022.880849).

58. Tiffin N, George A, LeFevre AE. How to use relevant data for maximal benefit with minimal risk: digital health data governance to protect vulnerable populations in low-income and middle-income countries. BMJ Glob Health. 2019;4(2):e001395 (https://doi.org/10.1136/bmjgh-2019-001395).

59. Floridi L, Cowls J. A unified framework of five principles for AI in society. In: Carta S, editor. Machine learning and the city: applications in architecture and urban design. Hoboken: John Wiley; 2022:535-45 (https://doi.org/10.1002/9781119815075.ch45).

60. Lyles CR, Nguyen OK, Khoong EC, Aguilera A, Sarkar U. Multilevel determinants of digital health equity: a literature synthesis to advance the field. Annu Rev Public Health. 2023;44:383–405 (https://doi.org/10.1146/annurev-publhealth-071521-023913).

61. Ueda D, Kakinuma T, Fujita S, Kamagata K, Fushimi Y, Ito R et al. Fairness of artificial intelligence in healthcare: review and recommendations. Jpn J Radiol. 2024;42(1):3–15 (https://doi.org/10.1007/s11604-023-01474-3).

62. Hussein R, Griffin AC, Pichon A, Oldenburg J. A guiding framework for creating a comprehensive strategy for mHealth data sharing, privacy, and governance in low- and middle-income countries (LMICs). J Am Med Inform Assoc. 2023;30(5):787–94 (https://doi.org/10.1093/jamia/ocac198).

63. Kim KK, Backonja U. Perspectives of community-based organizations on digital health equity interventions: a key informant interview study. J Am Med Inform Assoc. 2024;31(4):929–39 (https://doi.org/10.1093/jamia/ocae020).

64. Marotta A. When AI is wrong: addressing liability challenges in Women's healthcare. J Comput Inf Syst. 2022;62(6):1310–19 (https://doi.org/10.1080/08874417.2022.2089773).

65. Char DS, Abràmoff MD, Feudtner C. Identifying ethical considerations for machine learning healthcare applications. Am J Bioeth. 2020;20(11)7–17 (https://doi.org/10.1080/15265161.2020.1819469).

66. Sakhare NN, Limkar S, Mahadik RV, Phursule R, Godbole A, Shirkande ST et al. Ethical considerations of AI applications in medicine: a policy framework for responsible deployment. J Krishna Inst Med Sci Univ. 2023;12(4):15–26 (https://jkimsu.com/jkimsu-vol12no4/JKIMSU,%20Vol.%2012,%20No.%204,%20October-December%202023%20Page%2015-26.pdf).

67. Arora A, Alderman JE, Palmer J, Ganapathi S, Laws E, McCradden MD et al. The value of standards for health datasets in artificial intelligence-based applications. Nat Med. 2023;29(11):2440–9 (https://doi.org/10.1038/s41591-023-02608-w).

68. Agarwal R, Bjarnadottir M, Rhue L, Dugas M, Crowley K, Clark J et al. Addressing algorithmic bias and the perpetuation of health inequities: an AI bias aware framework. Health Policy Technol. 2023;12(1):100729 (https://doi.org/10.1016/j.hlpt.2022.100702).

69. Hashiguchi TCO, Oderkirk J, Slawomirski L. Fulfilling the promise of artificial intelligence in the health sector: Let's get real. Value Health. 2022;25(3):368–73 (https://doi.org/10.1016/j.jval.2021.11.1369).

70. Godinho MA, Jonnagaddala J, Gudi N, Islam R, Narasimhan P, Liaw S-T. Mhealth for integrated people-centred health services in the Western Pacific: a systematic review. Int J Med Inform. 2020;142:104259 (https://doi.org/10.1016/j.ijmedinf.2020.104259).

71. Van Kolfschooten H. EU regulation of artificial intelligence: challenges for patient's rights. Common Mark Law Rev. 2022: 59(1):81–112 (https://doi.org/10.54648/cola2022005).

72. Jeanselme V, De-Arteaga M, Zhang Z, Barrett J, Tom B. Imputation strategies under clinical presence: impact on algorithmic fairness. Proc Mach Learn Res. 2022;193:12–34. (https://pubmed.ncbi.nlm.nih.gov/36601036/).

73. Adams TL, Leslie K. Regulating for-profit virtual care in Canada: implications for medical profession regulators and policy-makers. Healthc Manag Forum. 2023;36(2):113–18 (https://doi.org/10.1177/08404704221134872).

74. Kidwai-Khan F, Wang R, Skanderson M, Brandt CA, Fodeh S, Womack JA. A roadmap to artificial intelligence (AI): methods for designing and building AI ready data to promote fairness. J Biomed Inform. 2024;154:104654 (https://doi.org/10.1016/j.jbi.2024.104654).

75. Cary MP, Zink A, Wei S, Olson A, Yan M, Senior R et al. Mitigating racial and ethnic bias and advancing health equity in clinical algorithms: a scoping review. Health Aff. 2023;42(2):1359–68 (https://doi.org/10.1377/hlthaff.2023.00553).

76. Wilson S, Tolley C, Mc Ardle R, Lawson L, Beswick E, Hassan N et al. Recommendations to advance digital health equity: a systematic review of qualitative studies. NPJ Digit Med. 2024;7(1):173 (https://doi.org/10.1038/s41746-024-01177-7).

77. Giebel GD, Speckemeier C, Schrader NF, Abels C, Plescher F, Hillerich V et al. Quality assessment of mhealth apps: a scoping review. Front Health Serv. 2024;4:1372871 (https://doi.org/10.3389/frhs.2024.1372871).

78. Henni SH, Maurud S, Fuglerud KS, Moen A. The experiences, needs and barriers of people with impairments related to usability and accessibility of digital health solutions, levels of involvement in the design process and strategies for participatory and universal design: a scoping review. BMC Public Health. 2022;22(1):35 (https://doi.org/10.1186/s12889-021-12393-1).

79. Cheng C, Beauchamp A, Elsworth GR, Osborne RH. Applying the electronic health literacy lens: systematic review of electronic health interventions targeted at socially disadvantaged groups. J Med Internet Res. 2020;22(8):e18476 (https://doi.org/10.2196/18476).

80. Hassanaly P, Dufour JC. Analysis of the regulatory, legal, and medical conditions for the prescription of mobile health applications in the United States, the European Union, and France. Med Devices. 2021;14:389–409 (https://doi.org/10.2147/MDER.S328996).

81. Kaplan B. Revisiting health information technology ethical, legal, and social issues and evaluation: telehealth/telemedicine and COVID-19. Int J Med Inform. 2020;143:104239 (https://doi.org/10.1016/j.ijmedinf.2020.104239).

82. Trewin S, Basson S, Muller M, Branham S, Treviranus J, Gruen D et al. Considerations for AI fairness for people with disabilities. AI Matters. 2019;5(3):40–63 (https://doi.org/10.1145/3362077.3362086).

83. Cresswell K, Rigby M, Georgiou A, Wong ZSY, Kukhareva P, Medlock S et al. The role of formative evaluation in promoting digitally-based health equity and reducing bias for resilient health systems: the case of patient portals. Yearb Med Inform. 2022;31(1):33–9 (https://doi.org/10.1055/s-0042-1742498).

84. DeWitt A, Kientz J, Coker TR, Liljenquist K. Mhealth technology design and evaluation for early childhood health promotion: systematic literature review. JMIR Pediatr Parent. 2022;5(4):e37718 (https://doi.org/10.2196/37718).

85. Allana S, Norris C, Hussain A, Clark A. A scoping review and intersectionality-based analysis of heart failure telehealth interventions for vulnerable populations. J Adv Nurs. 2023;79(11):4097–111 (https://doi.org/10.1111/jan.15756).

86. Marckmann G. Ethische fragen von digital public health [Ethical implications of digital public health]. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2020;63(2):199–205 (https://doi.org/10.1007/s00103-019-03091-w) (in German).

87. von Huben A, Howell M, Howard K, Carrello J, Norris S. Health technology assessment for digital technologies that manage chronic disease: a systematic review. Int J Technol Assess Health Care. 2021;37(1):e66 (https://doi.org/10.1017/S0266462321000362).

88. Antonio MG, Petrovskaya O. Towards developing an ehealth equity conceptual framework. Stud Health Technol Inform. 2019;257:24–30 (https://doi.org/10.3233/978-1-61499-951-5-24).

89. Heinsch M, Tickner C, Kay-Lambkin F. Placing equity at the heart of ehealth implementation: a qualitative pilot study. Int J Equity Health. 2022;21(1):38 (https://doi.org/10.1186/s12939-022-01640-5).

90. Hamilton FL, Imran S, Mahmood A, Dobbin J, Bradbury K, Poduval S et al. Design and deployment of digital health interventions to reduce the risk of the digital divide and to inform development of the living with COVID recovery: a systematic scoping review. Health Soc Care Deliv Res. 2025;13(39):1–18. (https://doi.org/10.3310/GJHG1331).

91. Campbell JI, Aturinda I, Mwesigwa E, Burns B, Santorino D, Haberer JE et al. The Technology Acceptance Model for Resource-Limited Settings (TAM-RLS): a novel framework for mobile health interventions targeted to low-literacy end-users in resource-limited settings. AIDS Behav. 2017;21(11):3121–36 (https://doi.org/10.1007/s10461-017-1765-y).

92. Faber JS, Al-Dhahir I, Kraal JJ, Breeman LD, van den Berg-Emons RJG, Reijnders T et al. Guide development for eHealth interventions targeting people with a low socioeconomic position: participatory design approach. J Med Internet Res. 2023;25(1):e48461 (https://doi.org/10.2196/48461).

93. Li MM, Rising KL, Goldberg EM. Transitioning to telehealth? A guide to evaluating outcomes. Health Policy Technol. 2022;11(3):100623 (https://doi.org/10.1016/j.hlpt.2022.100623).

94. Kaihlanen A-M, Virtanen L, Buchert U, Safarov N, Valkonen P, Hietapakka L et al. Towards digital health equity: a qualitative study of the challenges experienced by vulnerable groups in using digital health services in the COVID-19 era. BMC Health Serv Res. 2022;22(1):188 (https://doi.org/10.1186/s12913-022-07584-4).

95. Almond H, Cummings E, Turner P. An approach for enhancing adoption, use and utility of shared digital health records in rural Australian communities. Stud Health Technol Inform. 2017;235:378–82 (https://doi.org/10.3233/978-1-61499-753-5-378).

96. Davis MA, Lim N, Jordan J, Yee J, Gichoya JW, Lee R. Imaging artificial intelligence: a framework for radiologists to address health equity, from the AJR Special Series on DEI. Am J Roentgenol. 2023;221(3):302–8 (https://doi.org/10.2214/ajr.22.28802).

97. Studman A, Machirori M. Access denied? Inequalities in data-driven health systems and digital health services. London: Ada Lovelace Institute; 2023 (https://www.adalovelaceinstitute.org/policy-briefing/healthcare-access-denied/).

98. Regulatory Horizons Council. Regulatory Horizons Council Report on the regulation of AI as a medical device. London: United Kingdom Government; 2022 (https://www.gov.uk/government/publications/regulatory-horizons-council-the-regulation-of-artificial-intelligence-as-a-medical-device).

99. Recommendations of the Council on Artificial Intelligence. Paris: Organisation for Economic Co-operation and Development; 2025 (OECD/LEGAL/0449; https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0449).

100. Guidance on the rights-based and ethical use of digital technologies in HIV and health programmes. New York, NY: United Nations Development Programme; 2021 (https://www.undp.org/publications/guidance-rights-based-and-ethical-use-digital-technologies-hiv-and-health-programmes).

101. Evidence standards framework for digital health technologies. London: National Institute for Health and Care Excellence; 2018 (https://www.nice.org.uk/corporate/ecd7).

102. Monitoring and evaluating digital health interventions: a practical guide to conducting research and assessment. Geneva: World Health Organization; 2016 (https://iris.who.int/handle/10665/252183). Licence: CC BY-NC-SA 3.0 IGO.

103. Crawford A. Health equity impact assessment (HEIA): digital health supplement. Toronto: Centre for Addiction and Mental Health; 2022 (https://www.camh.ca/-/media/professionals-files/conditions-and-disorders/heia-digital-health-supplement2022-pdf.pdf).

104. World Health Organization, United Nations Foundation, United Nations Development Programme/United Nations Population Fund/World Health Organization/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, Johns Hopkins University. The MAPS toolkit: mHealth assessment and planning for scale. Geneva: World Health Organization; 2015 (https://iris.who.int/handle/10665/185238).

105. Medical technologies evaluation methods and process guide. Singapore: Agency for Care Effectiveness; 2024 (https://isomer-user-content.by.gov.sg/68/53adb002-9122-496b-8e44-394bd4a8a935/ace-mte-methods-and-process-guide-(version-3-01).pdf).

106. Ethics and governance of artificial intelligence for health: WHO guidance. Geneva: World Health Organization; 2021 (https://iris.who.int/handle/10665/341996). Licence: CC BY-NC-SA 3.0 IGO.

107. HL7 consumer mobile health application functional framework (cMHAFF), release 1. Standard for trial use 2. Ann Arbor: Health Level Seven International; 2023 (https://www.hl7.org/documentcenter/public/standards/dstu/HL7_CMHAFF_R1_STU2_2023APR.pdf).

108. Segur-Ferrer J, Moltó-Puigmartí C, Pastells-Peiró R, Vivanco-Hidalgo RM. Health technology assessment framework: adaptation for digital health technology assessment. Barcelona: Agency for Health Quality and Assessment of Catalonia; 2023 (https://aquas.gencat.cat/web/.content/minisite/aquas/publicacions/2023/framework-adaptation-digital-hta-redets-aquas2023.pdf).

109. Enhancing equitable access to virtual care in Canada: principle-based recommendations for equity. Ottawa: Government of Canada; 2021 (https://www.canada.ca/en/health-canada/corporate/transparency/health-agreements/bilateral-agreement-pan-canadian-virtual-care-priorities-covid-19/enhancing-access-principle-based-recommendations-equity.html).

110. Gauvin FP, Wilson MG, DeMaio P, Alam S, Drakos A, Lavis JN. Identifying and harnessing the potential of technology in long-term care settings in Canada. Hamilton: McMaster Health Forum; 2021 (https://www.mcmasterforum.org/about-us/products/project/identifying-and-harnessing-the-potential-of-technology-in-long-term-care-settings-in-canada).

111. Tackling inequality and disadvantage: key actions policy makers, commissioners and provider organisations can take when developing an approach with a digital component. London: Voluntary, Community and Social Enterprise Health and Wellbeing Alliance; 2023 (https://www.nationalvoices.org.uk/publication/tackling-inequality-and-disadvantage-key-actions-policy-makers/).

112. Youth-centred digital health interventions: a framework for planning, developing and implementing solutions with and for young people. Geneva: World Health Organization; 2020 (https://iris.who.int/handle/10665/336223). Licence: CC BY-NC-SA 3.0 IGO.

113. Kristensen FB, Lampe K, Wild C, Cerbo M, Goettsch W, Becla L. The HTA Core Model® – 10 years of developing an international framework to share multidimensional value assessment. Value Health. 2017;20(2):244–50 (https://doi.org/10.1016/j.jval.2016.12.010).

114. Serra F, West T, Simms S, Davis SLM. Towards people-centred approach digital health strategies: gender, equity, rights and inclusion. Coventry: University of Warwick; 2024 (https://warwick.ac.uk/fac/cross_fac/cim/research/digital-health-rights/publications/dhrp_2024_-_gender_equity_rights_and_inclusion_in_digital_health_strategies.pdf).

115. The role of artificial intelligence in sexual and reproductive health and rights: technical brief. Geneva: World Health Organization; 2023 (https://iris.who.int/handle/10665/376294). Licence: CC BY-NC-SA 3.0 IGO.

116. Trudelle P. Assessment of apps in the mobile health (mhealth) sector: overview and quality criteria of medical content for referencing digital services in the digital health space and the professional service package. Paris: French Health Authority; 2021 (https://www.has-sante.fr/upload/docs/application/pdf/2021-09/assessment_of_apps_in_the_mobile_health_mhealth_sector._overview_and_quality_criteria_of_medical_content.pdf).

117. Digital equity for mental health and addictions in Nova Scotia: a situational assessment. Halifax: National Collaborating Centre for Determinants of Health, Nova Scotia Health; 2021 (https://mha.nshealth.ca/sites/default/files/2021-07/Digital%20equity%20mental%20health%20sit%20ax_Final_May%2011%202021.pdf).

118. Global digital compact [website]. United Nations; 2021 (https://www.un.org/techenvoy/global-digital-compact).

119. Leslie D. Understanding artificial intelligence ethics and safety: a guide for responsible design and implementation of AI systems in the public sector. London: The Alan Turing Institute; 2019 (https://www.turing.ac.uk/sites/default/files/2019-06/understanding_artificial_intelligence_ethics_and_safety.pdf).

120. The path to techquity: an introduction to key issues impacting equitable design and deployment of technology in the US healthcare system. London: Ipsos; 2022 (https://www.ipsos.com/en/path-techquity).

121. NHS Sussex, University of Sussex. The digital inclusion framework (DIF) for health and care. Lewes: NHS Sussex; 2023 (https://www.digitalinclusionframework.co.uk/).

122. Burr C, Powell R. Trustworthy assurance of digital mental healthcare. London: The Alan Turing Institute; 2022 (https://doi.org/10.5281/zenodo.7107200).

123. Shared guiding principles for digital health inclusion. Geneva: World Economic Forum; 2021 (https://www.weforum.org/publications/shared-guiding-principles-for-digital-health-inclusion/).

124. The fast-track process for digital health applications (DiGA) according to Section 139e SGB V. Berlin: Federal Institute for Drugs and Medical Devices; 2020 (https://www.bfarm.de/SharedDocs/Downloads/EN/MedicalDevices/DiGA_Guide.html).

125. Voutilainen M, Kaksonen R, Haverinen J. Comparison report of Digi-HTA and DiGAV ordinance. Oulu: Finnish Coordinating Center for Health Technology Assessment; 2023 (https://finccht a.fi/wp-content/uploads/2023/04/comparison-report-of-digi-hta-and-digav-ordinance.pdf).

126. Healthcare Information and Management Systems Society, Ministry of Social Affairs and Health. European cooperation solutions to promote digital inclusion and increase the resilience of society. Digital Health Advisory Group for Europe: report from annual high-level meeting. Helsinki: Ministry of Social Affairs and Health; 2021 (https://gkc.himss.org/resources/european-cooperation-solutions-promote-digital-inclusion-and-increase-resilience-society).

127. ICER-PHTI Assessment Framework for Digital Health Technologies. Boston: Institute for Clinical and Economic Review; 2023 (https://icer.org/assessment/icer-phti-assessment-framework-fordigital-health-technologies/).

128. Assessment framework for mHealth apps. Canberra: Australian Digital Health Agency; 2022 (https://www.digitalhealth.gov.au/about-us/strategies-and-plans/assessment-framework-for-mhealth-apps).

129. Slater A, French T. From pillars to practice: developing a framework for embedding digital inclusion in health and social care. Edinburgh: Digital Health and Care Scotland; 2023 (https://www.tec.scot/wp-content/uploads/Digital-Pillars-Paper-July-2023.pdf).

130. Digital inclusion in mental health: a guide to help increase choice and improve access to digital mental health services. Glasgow: Mental Health Network, NHS Confederation; 2020 (https://www.nhsconfed.org/publications/digital-inclusion-mental-health).

131. United States Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, Oncology Center of Excellence. Digital health technologies for remote data acquisition in clinical investigations: guidance for industry, investigators, and other stakeholders. Silver Spring, MD: Food and Drug Administration; 2023 (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations).

132. AI governance framework for boards [website]. Anekanta AI; 2020 (https://anekanta.co.uk/our-services/anekanta-responsible-ai-governance-framework-for-boards/).

133. Supporting digital inclusion in general practice: 10 top tips [website]. NHS England; 2023 (https://www.england.nhs.uk/long-read/supporting-digital-inclusion-in-general-practice-10-top-tips/).

134. Mitigating risks of digital exclusion [website]. Good Things Foundation; 2021 (https://www.goodthingsfoundation.org/policy-and-research/research-and-evidence/research-2024/health-inequalities-digital-exclusion.html).

135. The age of digital interdependence: report of the UN Secretary-General's High Level Panel on Digital Cooperation. New York, NY: United Nations; 2019 (https://digitallibrary.un.org/record/3865925?ln=en&v=pdf).

136. Digital health assessment framework (DHAF) [website]. Organisation for the Review of Care and Health Apps; 2022 (https://www.orchahealth.com/resources/assessment-frameworks/dhaf).

137. The future of virtual health and care: driving access and equity through inclusive policies. Geneva: Broadband Commission for Sustainable Development; 2022 (https://broadbandcommission.org/working-groups/virtual-health-and-care/).

138. Behaviour change: digital and mobile health interventions. London: National Institute for Health and Care Excellence; 2020 (https://www.nice.org.uk/guidance/ng183).

139. Digital technology assessment criteria for health and social care (DTAC). Leeds: NHS England; 2021 (https://transform.england.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/).

140. Digi-HTA [website]. Finnish Coordinating Center for Health Technology Assessment; 2025 (https://fincchta.fi/en/digi-hta-eng/arvioinnit-eng/).

141. Ethics, transparency and accountability framework for automated decision-making [website]. Government of the United Kingdom; 2023 (https://www.gov.uk/government/publications/ethics-transparency-and-accountability-framework-for-automated-decision-making/ethics-transparency-and-accountability-framework-for-automated-decision-making#what-the-framework-is-for).

142. The recommendations [website]. STANDING Together; 2025 (www.datadiversity.org/recommendations).

143. Burr C, Arana S, Gould Van Praag C, Habli I, Kaas M, Katell M et al. Trustworthy and ethical assurance of digital health and healthcare. The Alan Turing Institute; 2024 (https://www.turing.ac.uk/research/research-projects/trustworthy-and-ethical-assurance-digital-healthcare).

144. Inclusive digital healthcare: a framework for NHS action on digital inclusion. Leeds: NHS England; 2024 (https://www.england.nhs.uk/long-read/inclusive-digital-healthcare-a-framework-for-nhs-action-on-digital-inclusion/).

145. Government Digital Service, Central Digital and Data Office. Data and AI ethics framework. London: Government of the United Kingdom; 2020 (https://www.gov.uk/government/publications/data-ethics-framework).

146. NHS Sussex, University of Sussex, Health Innovation Kent Surrey Sussex. Digital inclusion assessment tool. Lewes: NHS Sussex; 2024 (https://www.digitalinclusionframework.co.uk/s/Assessment-tool-DIF-V11-January-2024.docx).

147. Office for Health Improvement and Disparities. Health equity assessment tool (HEAT). London: Government of the United Kingdom; 2020 (https://www.gov.uk/government/publications/health-equity-assessment-tool-heat).

148. Guidance of the Secretary-General. Human rights due diligence for digital technology use: call to action for human rights. Geneva: United Nations Office of the High Commissioner for Human Rights; 2024 (https://www.unhcr.org/handbooks/informationintegrity/practical-tools/human-rights-due-diligence).

149. Rosen R, Leone C. Getting the best out of remote consulting in general practice: practical challenges and policy opportunities. London: Nuffield Trust; 2022 (https://www.nuffieldtrust.org.uk/research/getting-the-best-out-of-remote-consulting-in-general-practice-practical-challenges-and-policy-opportunities).

150. Towards a child-centred digital equality framework: key messages. New York, NY: United Nations Children’s Fund; 2022 (https://www.unicef.org/innocenti/projects/advancing-digital-equality-children).

151. A knotted pipeline: data-driven systems and inequalities in health and social care. London: Ada Lovelace Institute; 2022 (https://www.adalovelaceinstitute.org/report/knotted-pipeline-health-data-inequalities/).

152. Discussion paper: health equity for medical devices. Silver Spring, MD: Food and Drug Administration; 2024 (https://www.fda.gov/media/180608/download?attachment).

153. Medicines and Healthcare products Regulatory Agency. Medical devices: how to comply with the legal requirements in Great Britain. London: Government of the United Kingdom; 2025 (https://www.gov.uk/guidance/medical-devices-how-to-comply-with-the-legal-requirements).

154. European Medicines Agencies Network strategy to 2025: protecting public health at a time of rapid change. Amsterdam: European Medicines Agency; 2024 (https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network/european-medicines-agencies-network-strategy#previous-network-strategies-and-roadmaps-11065).

155. Mechael P, Chaney S. Gender-intentional digital health intervention and enablers: a rapid guide for analysis, planning, and monitoring. Geneva: GAVI Alliance; 2022 (https://www.healthenabled.org/resource-library/gender-intentional-dhi-and-enablers-a-rapid-guide-for-analysis-planning-and-monitoringpdf-njmoj).

156. WHO guideline on self-care interventions for health and well-being, 2022 revision. Geneva: World Health Organization; 2022 (https://iris.who.int/handle/10665/357828). Licence: CC BY-NC-SA 3.0 IGO.

157. The principles for digital development: a compass for those working to promote sustainable and inclusive development in today’s complex digital landscape [website]. Principles for Digital Development; 2024 (https://digitalprinciples.org/).

158. Applying a human rights and gender equality lens to the OECD evaluation criteria. Paris: Organisation for Economic Co-operation and Development; 2023 (https://doi.org/10.1787/9aaf2f98-en).

159. Dassieu L, Harnum J, De Moor C. Fostering equity in virtual care for substance use: what we heard. Ottawa: Canadian Centre on Substance Use and Addiction; 2023 (https://www.ccsa.ca/en/fostering-equity-virtual-care-substance-use-what-we-heard).

160. Digital inclusion for health and social care. Leeds; NHS England; 2019 (https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/digital-inclusion).

161. Toolkit for digital health equity: bridging the digital divide: increasing reach to older adults with mental illness and adapting approaches with Latino/a communities. Boston, MA: Centre of Excellence for Telehealth and Aging, Massachusetts General Hospital; 2022 (https://ce4ta.org/doc_resources/toolkit-for-digital-health-equity-bridging-the-digital-divide/).

162. Aldridge S. Improving digital health inclusion: evidence scan. Leyland: NHS Midlands and Lancashire; 2020 (https://www.strategyunitwm.nhs.uk/sites/default/files/2021-04/Digital%20Inclusion%20evidence%20scan.pdf).

163. Digital health and inclusion in palliative and end of life care. London: Hospice UK; 2024 (https://www.hospiceuk.org/publications-and-resources/digital-health-and-inclusion-palliative-and-end-life-care).

164. Digital health technology evaluation for health organizations: an evaluation framework for early-stage technologies. Jerusalem: Ministry of Health; 2021 (https://www.gov.il/BlobFolder/generalpage/digital-health-guide-062021/he/files_publications_digital_health_digital-health-hta-062021.pdf).

165. Barriers and strategies to equity in digital health programs and services. Toronto: Public Health Ontario; 2023 (https://www.publichealthontario.ca/-/media/Documents/E/2023/eb-barriers-strategies-equity-digital-health-programs-services.pdf).

166. Honeyman M, Maguire D, Evans H, Davies A. Digital technology and health inequalities: a scoping review. Cardiff: Public Health Wales; 2020 (phw.nhs.wales/publications/publications1/digital-technology-and-health-inequalities-a-scoping-review/).

167. Lehne M, Sass J, Essenwanger A, Schepers J, Thun S. Why digital medicine depends on interoperability. NPJ Digit Med. 2019;2:79 (https://doi.org/10.1038/s41746-019-0158-1).

168. Canali S, Schiaffonati V, Aliverti A. Challenges and recommendations for wearable devices in digital health: data quality, interoperability, health equity, fairness. PLOS Digit Health. 2022;1(10):e0000104 (https://doi.org/10.1371/journal.pdig.0000104).

169. International classification of diseases 11th revision [website]. World Health Organization; 2019 (https://www.who.int/standards/classifications/classification-of-diseases).

170. FHIR (HL7 Fast Healthcare Interoperability Resources) [website]. HL7 International; 2022 (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=491).

171. World mental health report: transforming mental health for all. Geneva: World Health Organization; 2022 (https://iris.who.int/handle/10665/356119). Licence: CC BY-NC-SA 3.0 IGO.

172. Ben Charif A, Zomahoun HTV, Gogovor A, Abdoulaye Samri M, Massougbodji J, Wolfenden L et al. Tools for assessing the scalability of innovations in health: a systematic review. Health Res Policy Syst. 2022;20(1):34 (https://doi.org/10.1186/s12961-022-00830-5).

173. Narrowing the gaps: the power of investing in the poorest children. New York, NY: United Nations Children’s Fund; 2017 (https://www.unicef.org/reports/narrowing-gaps).

174. World Health Organization data principles. Geneva: World Health Organization; 2020 (https://www.who.int/data/principles).

175. Data sharing governance framework [website]. Government of the United Kingdom; 2022 (https://www.gov.uk/government/publications/data-sharing-governance-framework/data-sharing-governance-framework).

176. Buttner P, Meyer M, Mikaelian R, Miller N, Ruhnau-Gee B. Healthcare data governance. Am Health Inf Manag Assoc. 2022;1:1–15 (https://www.ahima.org/media/pmcb0fr5/healthcare-data-governance-practice-brief-final.pdf).

177. Carroll SR, Garba I, Figueroa-Rodríguez OL, Holbrook J, Lovett R, Materechera S et al. The CARE principles for indigenous data governance. Data Sci J. 2020;19(1):1–12 (https://doi.org/10.5334/dsj-2020-043).

178. European Union. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). Off J Eur Union. 2016;L119:1–88 (http://data.europa.eu/eli/reg/2016/679/oj).

179. 104th United States Congress. Health Insurance Portability and Accountability Act. Washington, DC: Government of the United States; 1996 (https://aspe.hhs.gov/reports/health-insurance-portability-accountability-act-1996).

180. European Union. Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act). Off J Eur Union. 2024;L16899:1–144 (PE/24/2024/REV/1; http://data.europa.eu/eli/reg/2024/1689/oj).

181. Data governance in health. Washington, DC: World Bank; 2015 (https://documents1.worldbank.org/curated/en/099081723223522777/pdf/P175075036726f0a00832307b7ae23a06a6.pdf).

182. Alderman JE, Palmer J, Laws E, McCradden MD, Ordish J, Ghassemi M et al. Tackling algorithmic bias and promoting transparency in health datasets: the STANDING Together consensus recommendations. Lancet Digit Health. 2025;7(1):e64–e88 (https://doi.org/10.1016/S2589-7500(24)00224-3).

183. Alderman JE, Palmer J, Laws E, McCradden MD, Ordish J, Ghassemi M et al. Tackling algorithmic bias and promoting transparency in health datasets: the STANDING Together consensus recommendations. NEJM AI. 2025;2(1):2401088 (https://doi.org/10.1056/AIp2401088).

184. AI principles [website]. Organisation for Economic Co-operation and Development; 2025 (https://www.oecd.org/en/topics/sub-issues/ai-principles.html).

185. European Union. Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act). Off J Eur Union. 2022;L152:1–44 (PE/85/2021/REV/1; http://data.europa.eu/eli/reg/2022/868/oj).

186. What is data quality? [website]. IBM; 2021 (https://www.ibm.com/topics/data-quality).

187. A guide to good practice for digital and data-driven health technologies [website]. London: Government of the United Kingdom; 2021 (https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology).

188. Charlton V. NICE and fair? Health technology assessment policy under the UK's National Institute for Health and Care Excellence, 1999–2018. Health Care Anal. 2020;28(3):193–210 (https://doi.org/10.1007/s10728-019-00381-x).

189. Holeman I, Kane D. Human-centered design for global health equity. Inf Technol Dev. 2020;26(3):477–505 (https://doi.org/10.1080/02681102.2019.1667289).

190. Standards [website]. International Organization for Standardization; 2025 (https://www.iso.org/standards.html).

191. Web content accessibility guidelines (WCAG) 2.2 [website]. World Wide Web Consortium; 2024 (https://www.w3.org/TR/WCAG22/).

192. Crawford A, Serhal E. Digital health equity and COVID-19: the innovation curve cannot reinforce the social gradient of health. J Med Internet Res. 2020;22(6):e19361 (https://doi.org/10.2196/19361).

193. European Union. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. Off J Eur Union. 2017;L117:1–175 (http://data.europa.eu/eli/reg/2017/745/oj).

194. European Union. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. Off J Eur Union. 2017;L117:176–332 (http://data.europa.eu/eli/reg/2017/746/oj).

195. Regulation (EU) 2022/1925 of the European Parliament and of the Council of 14 September 2022 on contestable and fair markets in the digital sector and amending Directives (EU) 2019/1937 and (EU) 2020/1828 (Digital Markets Act). Off J Eur Union. 2022;L265:1–66 (PE/17/2022/REV/1; http://data.europa.eu/eli/reg/2022/1925/oj).

196. Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act). Off J Eur Union. 2022;L277:1–102 (PE/30/2022/REV/1; http://data.europa.eu/eli/reg/2022/2065/oj).

197. Convention on the rights of the child. Geneva: Office of the United Nations High Commissioner for Human Rights; 1989 (https://www.ohchr.org/en/instruments-mechanisms/instruments/convention-rights-child).

198. Busch F, Kather JN, Johner C, Moser M, Truhn D, Adams LC et al. Navigating the European Union Artificial Intelligence Act for healthcare. NPJ Digit Med. 2024;12;7(1):210 (https://doi.org/10.1038/s41746-024-01213-6).

199. Faturoti B. Internet access as a human right and the justiciability question in the post-COVID-19 world. Eur J Law Technol. 2024;15(1) (https://ejlt.org/index.php/ejlt/article/view/994/1083).

200. Kickbusch I, Piselli D, Agrawal A, Balicer R, Banner O, Adelhardt M et al. The Lancet and Financial Times Commission on governing health futures 2030: growing up in a digital world. Lancet. 2021;398(10312):1727–76 (https://www.thelancet.com/article/S0140-6736(21)01824-9/fulltext).

201. van Kessel R, Wong BLH, Clemens T, Brand H. Digital health literacy as a super determinant of health: more than simply the sum of its parts. Internet Interv. 2022;27:100500 (https://doi.org/10.1016/j.invent.2022.100500).

202. Watson A, Chapman R, Shafai G, Maricich YA. FDA regulations and prescription digital therapeutics: evolving with the technologies they regulate. Front Digit Health. 2023;5:1086219 (https://doi.org/10.3389/fdgth.2023.1086219).

203. Li Y, Albarrak AS. An informatics-driven intelligent system to improve healthcare accessibility for vulnerable populations. J Biomed Inform. 2022;134:104196 (https://doi.org/10.1016/j.jbi.2022.104196).

204. WAVE web accessibility evaluation tools [website]. Utah State University; 2025 (https://wave.webaim.org/).

205. IEC 62366-1:2015. Medical devices: part 1: application of usability engineering to medical devices. Geneva: International Organization for Standardization; 2015 (https://www.iso.org/standard/63179.html).

206. Brooke J. SUS: a "quick and dirty" usability scale. In: Usability evaluation in industry. London: CRC Press; 1996:189–94 (https://www.taylorfrancis.com/chapters/edit/10.1201/9781498710411-35/sus-quick-dirty-usability-scale-john-brooke).

207. Oudbier SJ, Smets EM, Nieuwkerk PT, Neal DP, Nurmohamed SA, Meij HJ et al. Patients' experienced usability and satisfaction with digital health solutions in a home setting: instrument validation study. JMIR Med Inform. 2025;13:e63703 (https://doi.org/10.2196/63703).

208. Wong WF, LaVeist TA, Sharfstein JM. Achieving health equity by design. JAMA. 2015;313(14):1417–18 (https://doi.org/10.1001/jama.2015.2434).

209. Equality Act 2010: guidance [website]. United Kingdom Government; 2010 (https://www.gov.uk/guidance/equality-act-2010-guidance).

210. O'Neill J, Tabish H, Welch V, Petticrew M, Pottie K, Clarke M et al. Applying an equity lens to interventions: using PROGRESS ensures consideration of socially stratifying factors to illuminate inequities in health. J Clin Epidemiol. 2014;67(1):56–64 (https://doi.org/10.1016/j.jclinepi.2013.08.005).

211. Panch T, Duralde E, Mattie H, Kotecha G, Celi LA, Wright M et al. A distributed approach to the regulation of clinical AI. PLOS Digit Health. 2022;1(5):e0000040 (https://doi.org/10.1371/journal.pdig.0000040).

212. El-Sayed S, Kickbusch I, Prainsack B. Data solidarity: operationalising public value through a digital tool. Glob Public Health. 2025;20(1):2450403 (https://doi.org/10.1080/17441692.2025.2450403).

213. Incentives and rewards [website]. Organisation for Economic Co-operation and Development; 2025 (https://www.oecd.org/en/toolkits/access-to-research-data-from-public-funding-toolkit/incentives-and-rewards.html).

214. Consent for use of personal data [website]. Organisation for Economic Co-operation and Development; 2025 (https://www.oecd.org/en/toolkits/access-to-research-data-from-public-funding-toolkit/data-governance-for-trust/consent-for-use-of-personal-data.html).

215. Health data governance principles [website]. Transform Health; 2022 (https://healthdatagovernance.org/principles/).

Annex 1. Search strategy

An electronic search of the Applied Social Sciences Index and Abstracts, Embase, MEDLINE, PsycINFO and Scopus databases was conducted to identify academic papers on the regulation, implementation and evaluation of digital health. The search was limited to publications published between January 2015 and June 2024 to align with adoption of the Sustainable Development Goals *(1)* and capture the accelerated advancements in digital health innovation following the coronavirus disease (COVID-19) pandemic. To include emerging evidence outside traditional academic channels, additional searches were conducted in Google Scholar and of the websites of relevant think tanks and technical agencies.

The search strategy considered academic and grey literature published from 2015 to June 2024. The database search yielded an initial 6671 papers and a further 110 sources were obtained from grey literature searches of relevant websites and suggestions from stakeholders (Table A1.1). After removing duplicates, 5236 papers were screened at title and abstract, of which 4920 were excluded. A total of 424 full-text records were assessed, of which 77 grey literature sources and 77 academic articles met the inclusion criteria (Table A1.2). Studies were selected according to Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines (Fig. A1.1) *(2)*.

Table A1.1. Sample search terms for MEDLINE and Embase

Search concept	Set	Search terms
Digital health technologies	**S1**	(“digital health*” or “digital healthcare” or “digital intervent*” or mhealth or m-health or “mobile health*” or ehealth or e-health or ehealthcare or e-healthcare or telehealth or telehealthcare or telemedicine or tele-health or tele-healthcare or “health technolog*” or tele-medicine or teleconsultat* or “patient portal*” or “virtual health*” or “virtual healthcar*” or “virtual care” or “virtual medicine” or “electronic health*” or teleconsultation* or “digital consult*” or “virtual consult*” or “remote care” or telecare or “video consult*” or “electronic consult” or “e-consult” or “e consult*” or “smart health*” or “electronic personal record*” or “electronic patient record*”).ti,ab.
	S2	exp Digital health/ or exp Telemedicine/

Table A1.1 contd

Search concept	Set	Search terms
	S3	(“digital technolog*” or “digital health technolog*” or “digital tool*” or “digital platform*” or “digital solution*” or “digital innovation*” or “health* data” or “health* information system*” or “big data” or blockchain* or “artificial intelligence*” or AI or “machine learning” or “deep learning” or “neural network*” or “internet of things” or interoperability or “internet-based intervention*” or “Internet of Things” or “integration” or “clinical decision support system*” or CDSS or “natural language processing” or “generative AI”).ti,ab.
	S4	exp Digital Technology/ or exp Patient Portals/ or Mobile Applications/ or Internet-Based Intervention/ or Health Information Interoperability/
	S5	((“effective* framework*” or “efficacy adj4 framework*” or “impact* adj4 framework*” or “outcome* adj4 framework*” or “evaluat* framework*” or “evaluat* model*” or “evaluat* adj4 metric*” or “evaluat* criteri*” or “evaluat* adj4 measure*” or evaluat* or “Health Equity Assessment Tool”) adj4 (digital* or telehealth* or ehealth* or “mobile health*” or mhealth* or virtual* or remote*)).ti,ab.
	S6	((guidance or regulat* or regulator* or “white paper*” or legislation*) adj4 (digital* or telehealth* or ehealth* or “mobile health*” or mhealth* or virtual* or remote*)).ti,ab.
Evaluation frameworks or assessment tools	**S7**	((evaluat* or framework* or model or taxon* or tool*) adj4 (digital* or telehealth* or ehealth* or “mobile health*” or mhealth* or virtual* or remote*)).ti,ab.
	S8	exp Program Evaluation/
Equity and access	**S9**	exp Health Equity/
	S10	((health adj4 equit*) or (health adj4 equalit*) or equit* or “inclus* health” or (health* adj4 bias*) or “health inequalit*” or “health disparit*” or “digital divide*” or “equit* digital health*” or (“social determinant*” adj4 health) or vulnerable or marginali?ed or disadvantag* or “hard to reach” or underserv* or minorit* or exclus* or migrant* or “migrant typolog*” or refugee* or “asylum seeker*” or “excluded population*”).ti,ab.
	S11	((AI or “AI ethic*” or “AI fairness” or “AI bias*” or “algorithm* bias*” or “machine learning fairness” or algorithm* or accountab*) adj4 (digital* or telehealth* or ehealth* or “mobile health*” or mhealth* or virtual* or remote*)).ti,ab.
	S12	((fair* or impartialit* or justice or equit* or equalit*) adj4 (digital* or telehealth* or ehealth* or “mobile health*” or mhealth* or virtual* or remote*)).ti,ab.

Table A1.1 contd

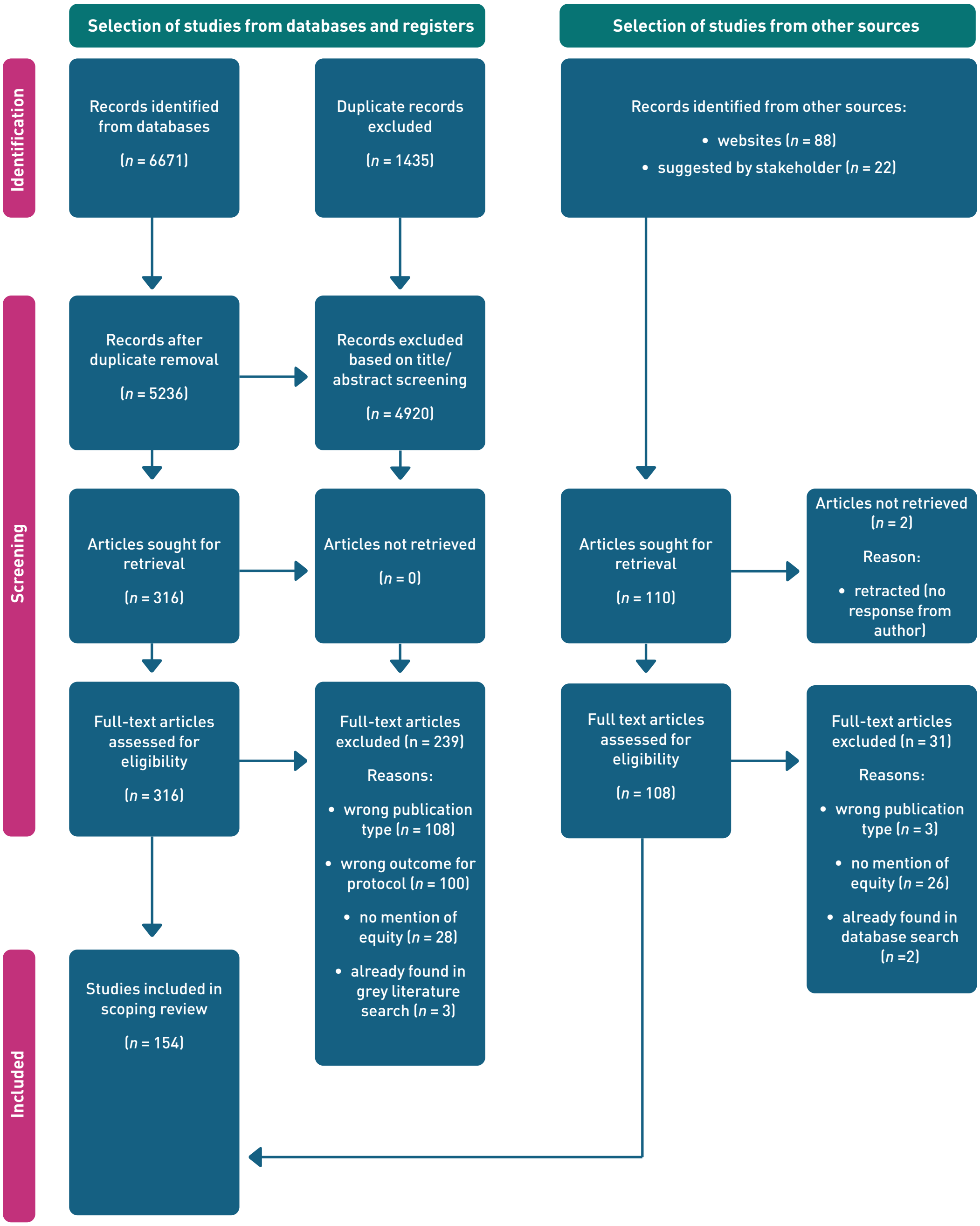
Search concept	Set	Search terms
	S13	((ethic* or exclusion* or inclusion* or inequalit* or "social determinant*") adj4 (digital* or telehealth* or ehealth* or "mobile health*" or mhealth* or virtual* or remote*)).ti,ab.
	S14	("Health* Qualit*" or "health* access*" or "health* evaulat*" or "health technology assess*" or "digital health technology framework*" or "Delivery of Health Care" or "Health Services Accessibilit*" or "Access to Primary Care" or "Health Equit*" or "Right to Health" or "health* Diversit*" or "health* Inclusion" or "Health* Disparit*" or "Ethic* factor*" or "Epidemiologic Factor*" or "Health Care Evaluation Mechanism*" or "Quality of Health Care" or "Social Inclus*" or "Social Deprivat*" or "Discriminat*" or "Socioeconomic Factor*" or "Social Determinants of Health" or "health influenc*").ti,ab.
	S15	((trust* or accept* or rural* or connectivit* or affordabilit* or "digital literac*" or "socioeconomic status*" or geograph*) adj4 (digital* or telehealth* or ehealth* or "mobile health*" or mhealth* or virtual* or remote*)).ti,ab.
Equity (including fairness terms)	**S16**	((intersection* or ageism or sexism or xenophobia or homophobia or racism or "racial bias*" or "gender bias*" or "political landscape*" or "local view*" or "algorithm* bias*" or justice or "clinic* bias*" or algorithm* or data) adj4 (bias* or ethic* or fairness or justice or injustice or impartial* or discriminat* or accountab*)).ti,ab.
	S17	exp culturally competent care/ or health services accessibility/ or exp healthcare disparities/ or exp Intersectional Framework/
	S18	S1 or S2 or S3 or S4
	S19	S5 or S6 or S7 or S8
	S20	S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17
	S21	S18 and S19 and S20
	S22	limit S21 to yr="2015-Current"

AI: artificial intelligence; CDSS: clinical decision support system.

Table A1.2. Inclusion and exclusion criteria

Criterion	Included	Excluded
Population	Any	–
Language	All	Sources without an abstract or executive summary in English
Publication date	2015–June 2024	Published before 2015 or after June 2024
Type of source	Academic literature and grey literature, including policy briefings, government reports, regulations, guidelines or evidence standards, and frameworks or assessment tools of digital health technologies	Commentaries, opinion articles, press releases, news articles, abstracts without full text, product reviews, editorials, advertisements and marketing materials, any literature not specifically addressing equity, and conference proceedings
Equity	Resources that incorporate equity in the regulation, implementation and evaluation of digital health. This will be considered across equity domains	Resources that do not address equity in the context of digital health regulation, implementation or evaluation
Digital health	Includes telemedicine, m-health, e-health, digital health, electronic health records, smart health, patient portals, health information systems, remote patient monitoring, Internet of Things, AI, big data, machine learning within health, and software as a medical device	General well-being or lifestyle-oriented technologies such as fitness trackers, meditation apps and consumer-based wellness technology

Fig. A1.1. PRISMA flowchart of selection of articles



The search identified any publications reporting on the regulation, implementation or evaluation of digital health systems. The geographical scope focused on the WHO European Region, but relevant publications from other regions or countries that had an abstract or executive summary published in English were included. Articles in languages other than English *(2)*, were translated using DeepL Translator *(3)*. Commentary or opinion pieces, viewpoints, editorial articles, abstracts without full text, product reviews, and publications focused on general well-being or lifestyle-oriented technologies (e.g. fitness tracker or consumer-based wellness tech) were excluded. Table A1.3 shows the characteristics of the included publications. Countries and regions/areas are ordered by descending percentage; those with the same percentage are ordered alphabetically.

Table A1.3. Characteristics of included publications

Characteristic	***n***	**%**
Type of publication		
Technical guidance	39	25.3
Literature review	32	20.1
Implementation framework	26	16.9
Evaluation frameworks/assessment tools	20	13.0
Observational study	11	7.1
Descriptive case study	9	5.8
Systematic review	6	3.9
Regulatory framework	6	3.9
Standard	3	1.9
Experimental study	2	1.3
Region/Member State		
WHO European Region	69	44.8
United Kingdom	36	23.4
EU countries	5	3.2
Finland	5	3.2
Spain	5	3.2
Netherlands (Kingdom of the)	4	2.6
France	3	1.9
Germany	3	1.9
Sweden	2	1.3

Table A1.3 contd

Characteristic	*n*	%
Austria	1	0.6
Denmark	1	0.6
Greece	1	0.6
Israel	1	0.6
Norway	1	0.6
Switzerland	1	0.6
WHO Region of the Americas (United States of America/Canada)	52	33.8
Global organizations	21	13.6
Other region	12	7.8
Australia	7	4.5
India	1	0.6
Japan	1	0.6
Republic of Korea	1	0.6
Singapore	1	0.6
South Africa	1	0.6
Focus of the publication		
Implementation	43	27.9
Evaluation	21	13.6
Regulation	9	5.8
Overlapping focus		
Implementation and evaluation	60	39.6
Regulation, implementation and evaluation	10	6.5
Regulation and implementation	8	5.2
Regulation and evaluation	2	1.3

EU: European Union.

A systems approach to considering equity across digital health system components

The consideration of equity across the complex array of literature, regulations and guidance for digital health required a whole-system approach spanning the different areas of a digital health system. The review adopted a sociotechnical approach *(5)* that considered equity across the components of a digital health system, as informed by existing frameworks (e.g. by drawing on a guide to good practice for digital and data-driven health technologies) *(6)*).

The digital health ecosystem includes multiple stakeholders across the health sector such as health-care providers, government agencies, academic institutions, public health organizations, patient advocacy groups and the private sector (e.g. startups, technology developers). The analysis specifically focused on the public and government sectors, including national health systems, regulatory bodies and publicly funded digital health initiatives. Although the private sector plays a significant role in digital health development, the review primarily considered frameworks, policies and interventions that are publicly governed and regulated. In addition, it focused on digital health within health systems and national health services, and did not analyse public health programmes or the broader digital health ecosystem.

Data extraction and analysis

The scoping review used the Arksey and O'Malley framework *(7)* and the PRISMA Extension for Scoping Reviews *(8)*. The protocol was registered on the Open Science Framework *(9)*. The key review questions were as follows.

1. To what extent is equity incorporated into regulations for digital health across the WHO European Region and globally?
2. To what extent is equity incorporated into the implementation or the evaluation of digital health across the WHO European Region and globally?
3. What are the implications of the findings towards ensuring equitable benefit from digital health innovation?

The review considered digital health equity across five domains (demographic, geographical, economic, social and cultural) and associated subdomains (Table A1.4), as informed by the Sex and Gender Equity in Research guidelines *(10)*, the United Kingdom's Equality Act 2010 *(11)* and the place of residence, race/ethnicity/culture/language, occupation, gender/sex, religion, education, socioeconomic status and social capital, plus other key characteristics (PROGRESS-Plus) framework (Table A1.5) *(12).*

Table A1.4. Digital health equity domains and subdomains considered in the review

Demographic	Geographical	Economic	Social	Cultural
Age Ethnicity Gender Sex	Region Urban/rural	Deprivation Employment status Income	Disability Education Education level Language Marital status Religion Sexual orientation Social capital	Cultural practices

Table A1.5. Equity domains and subdomains mapped against key frameworks

Equity domain (WHO equity classification)[a]	Subdomain	PROGRESS-Plus	SAGER guidelines	United Kingdom Equality Act 2010
Demographic	Age	Plus (age)	Age	Age
	Gender	G (gender/sex)	Gender	Gender
	Sex	G (gender/sex)	Sex	Sex
	Ethnicity	–	–	Ethnicity
Geographical	Urban/rural	P (place of residence)	–	–
	Region			

Table A1.5 contd

Equity domain (WHO equity classification)[a]	Subdomain	PROGRESS-Plus	SAGER guidelines	United Kingdom Equality Act 2010
Economic	Deprivation	S (socioeconomic status)	–	–
	Income		–	–
	Employment status	O (occupation)	–	–
Social	Education level	E (education)	–	-
	Disability	PLUS (disability)	–	Disability
	Language	S (language)	–	-
	Religion	R (religion)	–	Religion/belief
	Sexual orientation	S (sexual orientation)	–	Sexual orientation
	Social capital	S (social capital)	–	-
	Marital status	PLUS (marital status)	–	Marriage/civil partnership
Cultural	Cultural practices	R (race/ethnicity/ culture/language)	-	Religion/belief

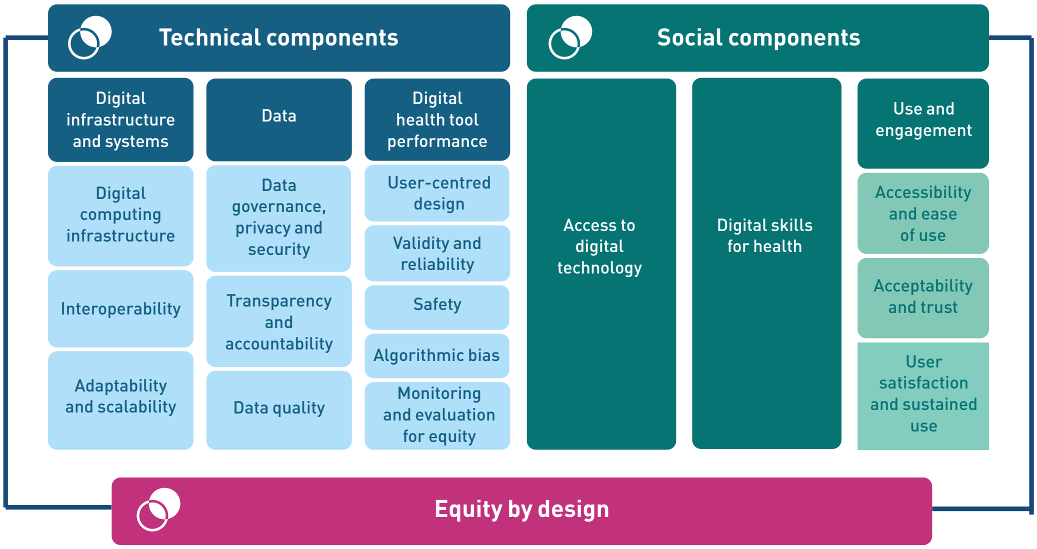
PROGRESS: place of residence, race/ethnicity/culture/language, occupation, gender, sex, religion, education, socioeconomic status and social capital; Plus: other key characteristics; SAGER: Sex and Gender Equity in Research.

[a] World Health Organization *(4)*.

The following data were extracted: (i) author/organization and publication date; (ii) country of first author/organization; (iii) publication type; (iv) scope (regulation, implementation or evaluation); (v) equity considerations related to the components and subcomponents of a digital health system; (vi) any other relevant information about equity; and (vii) specific equity domains addressed or discussed in the publication. Since the scoping review focused on providing a comprehensive picture of what is currently known about digital health, the evidence was not critically appraised.

Records were uploaded to NVivo 14 software (Lumivero) for data extraction and thematic coding. For each publication, text related to digital health equity was coded according to the digital health components (Table A1.4). Emergent themes under each component were recorded in an iterative codebook that included definitions and examples from the sources. Through consensus discussions among three reviewers, themes and subthemes were refined and merged, resulting in 14 final subcomponents of the technical and social digital health components and one cross-cutting theme. This framework was used to structure the thematic narrative review to ensure that equity considerations were examined across each sociotechnical component of the digital health system (Fig. A1.2).

Fig. A1.2. Digital health components and subcomponents used to inform the data extraction proforma for the review



Notes: blue indicates technical digital health components and subcomponents; green indicates social digital health components and subcomponents; and pink indicates a cross-cutting theme.

References[3]

1. Transforming our world: the 2030 Agenda for Sustainable Development. New York, NY: United Nations; 2015 (https://sdgs.un.org/2030agenda).
2. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71 (https://doi.org/10.1136/bmj.n71).
3. DeepL translator [website]. DeepL; 2025 (https://www.deepl.com/translator).
4. Health inequality monitor [website]. World Health Organization; 2025 (https://www.who.int/data/inequality-monitor/about#:~:text=Health%20equity%20is%20the%20absence,in%20health%20across%20population%20subgroups).
5. Jacob C, Lindeque J, Müller R, Klein A, Metcalfe T, Connolly SL et al. A sociotechnical framework to assess patient-facing eHealth tools: results of a modified Delphi process. NPJ Digit Med. 2023;6(1):232 (https://doi.org/10.1038/s41746-023-00982-w).

---

[3] All references were accessed on 10 June 2025.

6. A guide to good practice for digital and data-driven health technologies [website]. London: Government of the United Kingdom; 2021 (https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology).
7. Jonsson M, Johansson S, Hussain D, Gulliksen J, Gustavsson C. Development and evaluation of ehealth services regarding accessibility: scoping literature review. J Med Internet Res. 2023;25:e45118 (https://doi.org/10.2196/45118).
8. Tricco CA, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D et al. PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation. Ann Intern Med. 2018;169(7):467–73 (https://doi.org/10.7326/M18-0850).
9. Incorporation of equity across the regulation, implementation, and evaluation in digital health innovations: a scoping review protocol [website]. Open Science Framework; 2024 (https://osf.io/cy65f).
10. Heidari S, Babor TF, De Castro P, Tort S, Curno M. Sex and Gender Equity in Research: rationale for the SAGER guidelines and recommended use. Res Integr Peer Rev. 2016;1:2 (https://doi.org/10.1186/s41073-016-0007-6). Erratum in: Res Integr Peer Rev. 2024;9(1):15 (https://doi.org/10.1186/s41073-024-00155-7).
11. Equality Act 2010: guidance [website]. United Kingdom Government; 2010 (https://www.gov.uk/guidance/equality-act-2010-guidance).
12. O'Neill J, Tabish H, Welch V, Petticrew M, Pottie K, Clarke M et al. Applying an equity lens to interventions: using PROGRESS ensures consideration of socially stratifying factors to illuminate inequities in health. J Clin Epidemiol. 2014;67(1):56–64 (https://doi.org/10.1016/j.jclinepi.2013.08.005).

Annex 2. Overview of the regulation of a digital health system: challenges, current approaches and recommended actions

The review identified the relevant regulation of a digital health system for each of its components and subcomponents (Table A2.1).

Table A2.1. Regulation of a digital health system mapped to components and subcomponents

Digital health component and subcomponents	Challenges and gaps	Current approaches	Recommended actions
Digital infrastructure and systems • Digital computing and infrastructure • Interoperability • Adaptability and scalability	Regulations rarely address underinvestment in digital infrastructure and, while interoperability is good practice, it is not yet mandated. There are no requirements to adapt DHTs to the cultural, linguistic or infrastructural needs of diverse populations. The absence of equity metrics may limit the ability of underserved populations to benefit from scalable solutions	Regional bodies such as the EU have made efforts to harmonize digital health regulations to ensure secure, standardized and ethical access, sharing and use of health data across Member States	Establish standards that address investment in inclusive digital infrastructure, mandate interoperability and require DHTs to be adaptable to the cultural, linguistic and infrastructural needs of diverse populations and settings Integrate equity-focused indicators into infrastructure maturity models to support Member States in assessing and improving the inclusivity and scalability of digital health systems

Table A2.1 contd

Digital health component and subcomponents	Challenges and gaps	Current approaches	Recommended actions
Data • Data governance, privacy and security • Transparency and accountability • Data quality	Current governance frameworks lack explicit mechanisms to uphold collective community rights and ensure the meaningful involvement of vulnerable and marginalized populations in decision-making processes related to digital health There are no regulatory requirements to mitigate bias beyond general risk assessment in AI-driven innovations, prevent data-driven discrimination, or prevent data exploitation by wealthier nations	Legislation such as the GDPR *(1)* and HIPAA *(2)* safeguard individual rights, thus encouraging accountability and limiting harmful data practices In Europe, the EU Data Governance Act and Artificial Intelligence Act, aim to strengthen trust, transparency and accountability in data use, including requirements for data quality and bias mitigation in high-risk applications	Complementary regulatory oversight and guidance are needed to address equity, including community-centred governance frameworks Governments and relevant stakeholders should strengthen regulations and standards to ensure accountability and transparency in the use of health data, including the implementation of regular audits. Special attention must be given to safeguarding the rights and privacy of vulnerable populations
Digital health tools performance • User-centred design • Validity and reliability • Safety • Algorithmic bias • Monitoring and evaluation for equity	Regulatory frameworks for DHT performance focus on safety, effectiveness and performance monitoring, with varying degrees of attention to equity considerations such as UCD.	The principles of UCD are broadly integrated into regulatory frameworks for DHTs, including requirements such as usability testing and end-user engagement in the development of these technologies	Develop and enforce requirements for equity-focused monitoring and evaluation of digital health innovations Governments and health services should prioritize funding, adoption and reimbursement mechanisms that support DHTs that meet global usability and accessibility standards through UCD

Table A2.1 contd

Digital health component and subcomponents	Challenges and gaps	Current approaches	Recommended actions
Digital health tools performance (contd)	There is a lack of specific requirements for equity-focused monitoring and evaluation, which can reinforce existing disparities, produce biased outcomes, erode trust and exclude historically marginalized communities from the benefits of digital health		
Access to digital technology	Without regulatory support for equitable access, digital health systems risk exacerbating existing health disparities, particularly among underserved and marginalized populations	Regulatory bodies collaborate with diverse stakeholders, including national health authorities, health-care providers, internet service providers and NGOs, to shape policies that promote affordable treatments for vulnerable populations and address digital exclusion	Strengthen cross-sectoral collaboration and develop policies that ensure that DHTs are accessible, affordable and tailored to the needs of underserved and marginalized communities, thereby promoting equity in health access and outcomes
Digital skills for health	The inclusion of digital literacy or skills for both patients and health professionals is not addressed in regulations and not consistently linked to regulatory safeguards such as informed consent or data governance,	Digital health strategies recognize digital literacy as a priority, with some policies setting targets for basic skills as non-binding recommendations	Build cross-sectoral partnerships to support long-term investment in digital literacy initiatives Encourage regulatory bodies to define minimum standards for digital competencies in professional training curricula

Table A2.1 contd

Digital health component and subcomponents	Challenges and gaps	Current approaches	Recommended actions
Digital skills for health (contd)	thus limiting users' ability to understand data practices and engage in data governance processes		
Use and engagement • Accessibility and ease of use • Acceptability and trust • User satisfaction and sustained use	Regulatory frameworks often address accessibility, trust and usability, but do not fully incorporate equity considerations, particularly for marginalized populations. There is a need for regulations that explicitly ensure accessibility, build trust and promote sustained use, with a focus on inclusivity and cultural sensitivity across diverse groups	Some regulations address accessibility and usability through standards, usability testing and UCD principles, but may not fully consider the specific needs of underserved or marginalized populations, thus potentially limiting equitable access to digital health	Regulations should mandate compliance with minimum accessibility and usability standards to ensure equitable access to digital health innovations for all populations Public health systems should incentivize the development and adoption of accessible and user-friendly DHTs to promote equity and inclusivity

DHT: digital health technology; EU: European Union; GDPR: General Data Protection Regulation; HIPAA: Health Insurance Portability and Accountability Act (United States); NGO: nongovernmental organization; UCD: user-centred design.

References[4]

1. European Union. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). Off J Eur Union. 2016;L119:1–88 (http://data.europa.eu/eli/reg/2016/679/oj).
2. 104th United States Congress. Health Insurance Portability and Accountability Act. Washington, DC: Government of the United States; 1996 (https://www.govinfo.gov/content/pkg/BILLS-104s1028is/pdf/BILLS-104s1028is.pdf).

---

[4] All references were accessed on 10 June 2025.

Annex 3. Overview of the implementation and evaluation of a digital health system: challenges, emergent solutions and recommended actions

The review identified the relevant methods of implementation and evaluation of a digital health system for each of its components and subcomponents (Table A3.1).

Table A3.1. Implementation and evaluation of a digital health system mapped to components and subcomponents

Digital health component/ subcomponents	Challenges and gaps	Efforts/emergent solutions	Recommended actions
Digital infrastructure and systems • Digital computing and infrastructure • Interoperability • Adaptability and scalability	Persistent gaps in digital infrastructure, inconsistent interoperability across the Region and limited guidance on adaptability and scalability of digital health innovations prevent equitable implementation and evaluation	Some equity impact assessment tools include considerations of the infrastructure needed to implement digital health interventions Interoperability is commonly assessed in HTAs, with a focus on compliance with regional standards and the integration of DHTs into existing health systems	Establish minimum digital infrastructure standards, including accessibility, affordability and multilingual support Advocate for the integration of social and digital determinants of health into interoperability frameworks to enable more targeted, equitable and context-sensitive digital health interventions

Table A3.1 contd

Digital health component/ subcomponents	Challenges and gaps	Efforts/emergent solutions	Recommended actions
Data • Data governance, privacy and security • Transparency and accountability • Data quality	Implementation and evaluation of digital health systems often prioritize technical and individual-level safeguards, while overlooking collective rights, equitable data governance and inclusion of marginalized communities, resulting in gaps in transparency, accountability and data quality that risk reinforcing health inequities The underrepresentation of certain demographic groups (e.g. ethnic minority groups, people with disabilities, women, low-income communities) in health datasets can result in algorithms and systems that fail to address their specific needs	Existing non-binding regulatory frameworks and guidelines emphasize fairness and transparency for AI-driven technologies, including inequitable access to data, insufficient governance frameworks and structural power imbalances There is growing recognition of the importance of collecting equity-related data (e.g. ethnicity, gender, sex, disability status) in a harmonized manner and to consider intersectional analysis	Prioritize participatory governance to actively involve underserved populations in decision-making to build trust and ensure that accessible, culturally sensitive consent mechanisms are in place for diverse communities Promote the integration of ethical and culturally sensitive practices into the systematic collection of disaggregated equity-related data in a standardized way to support equitable digital health outcomes

Table A3.1 contd

Digital health component/ subcomponents	Challenges and gaps	Efforts/emergent solutions	Recommended actions
Digital health tools performance • User-centred design • Validity and reliability • Safety • Algorithmic bias • Monitoring and evaluation for equity	Limited engagement with underserved populations in development stages, scarce validation across diverse settings, gaps in safety mitigation for vulnerable groups and inadequate frameworks to address algorithmic bias hinder equity efforts Equity-focused indicators are often absent from routine monitoring and evaluation, thus reducing the ability to detect disparities, track progress or adjust interventions for inclusive impact	There is increased recognition of the importance of applying inclusive principles and co-design methods and of the need to increase efforts to identify and address structural barriers to digital health inequity Frameworks and guidelines have been developed to promote ethical, inclusive and equitable design of AI-enabled digital health systems, with an emphasis on data fairness, transparency and responsible stewardship	Standardize UCD approaches in the life cycle of DHTs to ensure that equity is addressed and user feedback informs development and deployment Implement processes to identify and mitigate algorithmic bias in digital health tools by using representative data, conducting equity-focused impact assessments and reporting performance across standardized equity domains (e.g. using the PROGRESS-Plus framework) Incorporate equity-focused validation and usability testing of DHTs pre and post deployment to support the development of technologies that are both generalizable and inclusive of underrepresented populations

Table A3.1 contd

Digital health component/ subcomponents	Challenges and gaps	Efforts/emergent solutions	Recommended actions
Access to digital technology	Despite ongoing efforts, evidence is limited on the effectiveness of digital inclusion strategies to inform long-term investment or enable cross-country comparisons of successful digital health initiatives for adaptation and learning in the WHO European Region	Device subsidy programmes, digital hubs offering access to digital health services, and support through VCSE organizations, libraries and community networks are widely adopted strategies to improve equitable access to technology	Assess local levels of digital exclusion to better understand population needs and ensure that DHTs are appropriately targeted and inclusive Maintain accessible, non-digital care pathways to ensure equitable access to health services for individuals and communities who may be unable or unwilling to engage with digital tools
Digital skills for health	Limited digital skills among users and health-care professionals, insufficient standardized assessment of these skills prior to implementation and a lack of tailored training, especially for vulnerable populations, prevent equitable access, effective use and sustained engagement with DHTs and digital health services	Current strategies emphasize assessing user skills prior to digital health implementation and providing tailored training for end users and their support networks Community-based models such as digital champions are widely used to support digital skills literacy efforts	Incorporate standardized assessments of digital health skills among users and health-care professionals prior to the implementation of digital health interventions Design and deliver tailored, culturally sensitive digital skills training programmes that address the needs of vulnerable and underserved populations.

Table A3.1 contd

Digital health component/ subcomponents	Challenges and gaps	Efforts/emergent solutions	Recommended actions
Digital skills for health (contd)		Some countries have incorporated digital health competencies into educational curricula, with the aim to enhance the digital skills of health professionals through structured programmes	For health professionals, this should also include training on cultural sensitivity, equity, discrimination awareness and ethical considerations in AI data-driven systems to support inclusive and equitable services
Use and engagement • Accessibility and ease of use • Acceptability and trust • User satisfaction and sustained use	Engagement disparities persist due to mistrust, poor design and perceived irrelevance. There remains a lack of standardized and validated approaches to assess acceptability, usability and trust to better understand and address user motivation, satisfaction and engagement across diverse populations	A range of non-binding recommendations and practice guidelines stress the importance of designing digital health tools that accommodate users with limited digital literacy, language barriers, and physical or cognitive disabilities Some initiatives engage trusted messengers or community leaders during rollout to improve trust	Strengthen and adapt existing monitoring and evaluation frameworks to systematically assess the use, adoption and impact of digital health innovations on health outcomes, and disaggregate by equity domains to identify and address disparities Strengthen the usability and accessibility of digital health innovations by applying UCD principles to assess and monitor ease of use and engagement

Table A3.1 contd

Digital health component/ subcomponents	Challenges and gaps	Efforts/emergent solutions	Recommended actions
Use and engagement (contd)			Integrate behavioural insights into the design, implementation and evaluation of digital health interventions to identify and address barriers to engagement and support sustained use across diverse populations

DHT: digital health technology; HTA: health technology assessment; PROGRESS-Plus: place of residence, race/ethnicity/culture/language, occupation, gender/sex, religion, education, socioeconomic status and social capital, plus other key characteristics; UCD: user-centred design; VCSE: voluntary, community and social enterprise.

The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

Member States

Albania
Andorra
Armenia
Austria
Azerbaijan
Belarus
Belgium
Bosnia and Herzegovina
Bulgaria
Croatia
Cyprus
Czechia
Denmark
Estonia
Finland
France
Georgia
Germany
Greece
Hungary
Iceland
Ireland
Israel
Italy
Kazakhstan
Kyrgyzstan
Latvia
Lithuania
Luxembourg
Malta
Monaco
Montenegro
Netherlands (Kingdom of the)
North Macedonia
Norway
Poland
Portugal
Republic of Moldova
Romania
Russian Federation
San Marino
Serbia
Slovakia
Slovenia
Spain
Sweden
Switzerland
Tajikistan
Türkiye
Turkmenistan
Ukraine
United Kingdom
Uzbekistan

WHO/EURO:2026-13153-52927-82472 (PDF)

World Health Organization
Regional Office for Europe
UN City, Marmorvej 51,
DK-2100 Copenhagen Ø, Denmark
Tel.: +45 45 33 70 00 Fax: +45 45 33 70 01
Email: eurocontact@who.int
Website: www.who.int/europe