BENEFITS REALISATION: SHARING INSIGHTS

GDHP White Paper on Evidence and Evaluation



GLOBAL DIGITAL HEALTH PARTNERSHIP



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We hope that this report provides both participant and nonparticipant countries with guidance on the use of standardised benefits categories and associated outcome measures used for evaluating the benefits of digital health technologies and services.

ABOUT THE GLOBAL DIGITAL HEALTH PARTNERSHIP

The Global Digital Health Partnership (GDHP) is a collaboration of governments and territories, government agencies and the World Health Organization, formed to support the effective implementation of digital health services.

Established in February 2018, the GDHP provides an opportunity for transformational engagement between its participants, who are striving to learn and share best practice and policy that can support their digital health systems. In addition, the GDHP provides an international platform for global collaboration and sharing of evidence to guide the delivery of better digital health services within participant countries.

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GLOBAL DIGITAL HEALTH PARTNERSHIP

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1 NOTE FROM THE GDHP WORK STREAM CHAIR

Digital health technologies and services offer the potential of enormous benefits for our health systems and improved healthcare outcomes for people around the world. All governments face the challenge of determining whether those benefits have been realised, which requires evaluation that applies suitable methods and analyses.

Without good evidence, governments and policy makers are unable to make informed decisions that guide future investment in digital health services. This is a shared global challenge, and learning from the successes and failures of others around the world is critical to improving our ability to make the better decisions on digital health investment for our populations.

The Evidence and Evaluation work stream of GDHP has previously considered methods and frameworks that support evaluation of digital health benefits, published in February 2019 in the white paper 'Measuring Benefits'. This work established some gaps that we needed to address in order to move towards an improved ability to share our evidence and insights about our digital health successes and failures internationally.

An important requirement for sharing evidence of benefit is understanding which benefit categories governments and policy makers require evidence about in order to guide their critical analysis of digital health technologies and services. This report presents our collective GDHP agreement on what these benefits categories are, and which ones should be prioritised in terms of undertaking evaluations of different digital health service or technology types. In addition, we investigated how these benefits categories had been represented in evaluation examples around the world, in terms of the variety of outcome measures that can be used for each specific category.

I would like to sincerely thank all those GDHP participants who contributed to creating this set of standard benefits categories recommended for sharing evidence. I hope that these findings will provide extra support for countries around the world as they contemplate the success of their digital health services, and make important digital health investment decisions that will result in people leading healthier and happier lives.

Clinical Professor Meredith Makeham

Chief Medical Adviser, Australian Digital Health Agency

Chair, Evidence and Evaluation work stream of the GDHP

2 EXECUTIVE SUMMARY

2.1. BACKGROUND

Digital health technologies and services currently represent a significant financial investment for many countries around the world. In particular, governments and non-government organisations (NGOs) are faced with challenges to justify their health expenditure on digital health technologies and services for their people. These challenges are due to the complex nature of evaluating the benefits of digital health technologies and services that change rapidly. Furthermore, governments and NGOs continually find it difficult to find *reliable* and *consistent* evaluation methodologies to determine whether or not the benefits of digital health technologies and services are realised.

There is a global need to demonstrate the benefits of digital health technologies and services with high-quality evidence. This evidence is required to guide investment and development decisions by governments and other organisations. Learning from the experiences of others through international collaboration can reduce the time and cost for policy makers sharing high-quality evidence. However, this can be a challenge where there is inconsistency with respect to evaluation approaches across different countries. A greater standardisation of evaluation approaches to support evidence-sharing across countries can assist governments and NGOs around the world at various stages of maturity in their implementation of digital health technologies and services.

In February 2019, the Evidence and Evaluation work stream of the Global Digital Health Partnership (GDHP) published an international overview of benefits measurement frameworks and approaches to the evaluation and benefits measurement of digital health technologies and services among GDHP participant countries. Countries provided an overview of their current approach along with case studies as examples of lessons learnt.

Key recommendations of this initial report, entitled <u>Measuring Benefits</u>, included the need to develop standard benefits categories to drive greater consistency between international evaluation approaches, develop standard benefits and outcome measurements, and the need to assist developing countries with evaluation approaches as they began programs of digital health benefits measurement.

The purpose of this white paper is to offer countries an agreed set of 'standard' benefits categories and potential outcome measures to support the international comparison of evidence relating to digital health technologies and services. This will assist with comparing evaluation results between GDHP participant countries and growing the international research and evidence base for different digital health technologies and services.

Addressing the barriers to sharing benefits evaluation methods and measures across different countries can also support developing countries with access to evidence and techniques that will support them in more rapidly adopting digital health solutions. This will benefit their people and accelerate their ability to achieve the targets set in the United Nations' Sustainable Development Goals.

All GDHP country participants who had joined before 1 August 2019 were offered the opportunity to contribute to the Evidence and Evaluation work stream white paper. To capture the information from participant countries, a survey using a nominal group

technique was distributed (a copy of the survey is at Appendix A). This approach sought to develop a consensus of important benefits and measurements categories for digital health evaluations, and to prioritise (or rank) responses into the most important benefits categories when evaluating digital health technologies. Concurrently, a rapid review of the international literature was undertaken during July and August 2019. This rapid review sought to identify international literature on the evaluation methods and proximal measurements used in the studies of digital health benefits categories. A range of academic databases and search engines were used to complete this literature review. The literature review data was supported with a nominal group technique to develop a pragmatic guide for policy makers in different countries who are considering evaluating the benefits of their digital health technologies.

2.2. KEY FINDINGS

The key findings from the nominal group survey and literature review are summarised below. These findings are discussed in sections 4, 5 and 6 of this report.

- 1. Digital Health Safety and Quality benefits categories were considered the highest priority for most GDHP countries, including the most highly rated standard categories to include in the global standard set of benefits categories.
- 2. Digital Health Efficacy was the most investigated benefits category in the literature, and Digital Health Equity was the least investigated benefits category in the literature.
- 3. The evidence from the literature review and nominal group study showed that evaluations of digital health technologies and services frequently included more than one or multiple overlapping benefits categories.
- 4. Standard benefits categories that were supported by GDHP participants for inclusion when undertaking benefits evaluations of digital health technologies and services include safety, quality, efficacy, equity, improved end-user experience, efficiency and population health improvements including health service planning and other secondary uses of data.
- 5. A conceptual model of benefits categories is proposed that groups benefits categories into three different areas of evaluation purpose, being: improving healthcare service delivery; improving adoption of digital health services; and supporting systems change. In this way, policy makers can prioritise the use of particular benefits categories depending upon the requirement to demonstrate different aspects of benefit for a given digital health technology or service.

2.3. RECOMMENDED NEXT STEPS

The Evidence and Evaluation work stream will continue to develop resources for countries around the world to effectively undertake evaluation of digital health technologies and services using standard approaches to benefits measurement.

To advance the report findings, the proposed next steps for the Evidence and Evaluation work stream are summarised below. A more detail description of these recommendations is included in Chapter 8.

6. Take a global approach to evidence building

Next steps should attempt to accelerate the international adoption of these agreed standard benefits categories to facilitate international comparisons of benefits and knowledge sharing among different GDHP countries.

7. Consider relative risk as a priority in digital health evaluation

Countries should compare new innovations to the current state, rather than evaluating without reference to a real-world context.

8. Harness lessons learnt by others

GDHP countries should continue to capture lessons learnt from countries that are more progressed in digital maturity.

9. Evolve the work stream; move towards 'Evidence Translation and Implementation'

Next steps for the Evidence and Evaluation work stream should relate to the translation of evidence, and consider practical ways of applying evidence in practice with a focus on key issues from other work streams (for example, citizen access to personal health information).

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3 INTRODUCTION: SHARING THE EVIDENCE FOR BENEFITS MEASUREMENT IN DIGITAL HEALTH EVALUATIONS

3.1. OVERVIEW

Measuring the benefits of digital health technologies and services is a challenge for countries around the world. The results of these evaluations are critical inputs for governments to consider their best use of limited resources to improve health outcomes for their people. Benefits evaluation may be complex and costly, and the ability of countries to share high-quality evidence in this field will reduce the time and investment required by individual governments to make informed decisions about how best to advance the development and adoption of digital health services for the benefit of their people.

The benefits of digital health technologies and services can be more easily compared across countries with a common understanding of the evaluation methodology and associated outcome measures that represent different types of benefit. In particular, governments and non-government organisations (NGOs) around the world are beginning to face significant challenges to supporting benefits realisation management to determine the value of their digital health implementation. Benefits realisation management is a process to measure the improvement resulting from the outcomes of the evaluation of a digital health technology or service (1, 2). Moreover, governments and NGOs are continually finding it difficult to find reliable and consistent evaluation methodologies to ensure the benefits of digital health are realised.

The World Health Organization (WHO) (3) recently released a draft global strategy on digital health to advance the Sustainable Development Goals and to enable governments to help improve health outcomes for populations globally through the use of digital technologies. To support the implementation of the global strategy, the WHO has created a framework for action that aims to assist countries in advancing digital health. Furthermore, the WHO defines digital health as a discipline related to any aspect of adopting digital technologies to improve the health of people around the world. The definition includes eHealth, medical informatics, health informatics, telemedicine, telehealth, mHealth, and precision medicine (3, 4).

The Global Digital Health Partnership (GDHP) report of February 2019 entitled Measuring Benefits (5) described international approaches to the evaluation of benefits measurement of digital health technologies and services among GDHP participant countries. Furthermore, the report identified significant variations in evaluation approaches used among GDHP participant countries (5). Advanced countries such as Canada, Australia, and the United Kingdom reported having national frameworks for evaluating digital health benefits, while other countries reported they did not. Indeed, the variation in evaluation approaches across different countries is representative of the inconsistencies that exist globally.

The report findings were subsequently discussed by participant countries at the 4th GDHP Summit in New Delhi, India. The outcome of these discussions was agreement to

develop greater standardisation of benefits management internationally. It was agreed that developing an agreed set of standard benefits measurement categories could assist countries that wished to accelerate their understanding of benefits related to digital health technologies and services through global sharing of benefits evaluation findings.

Seven benefits categories emerged from the socialisation of the Measuring Benefits report and have been tested among GDHP participants using a nominal group technique to form the recommendations within this current report. These are: 1) digital health efficacy, 2) digital health end-user experience, 3) digital health quality, 4) digital health efficiency and return on investment, 5) digital health safety, 6) population health trends and secondary uses, and 7) digital health equity.

These categories are also supported by findings in the grey and peer-reviewed scientific literature, demonstrating a variation in evaluation approaches related to these benefits categories. The literature review supports the proposed 'standard' benefits categories with examples of their application around the world. It also demonstrates which benefits categories are more commonly considered in evaluations and, by combining this with the results of GDHP participant feedback on the prioritisation of benefits categories, supports the recommendations in this report related to areas where further investment in benefits evaluation should be focused.

3.2. PROBLEM STATEMENT

Previous work that the GDHP has undertaken in this work stream provides an international comparison of benefits evaluation methods and applications of benefits evaluation frameworks. This has informed a preliminary hypothesis on the nature of potential benefits categories that are recommended for countries to consider when evaluating their digital health services, as well as potential outcome measures appropriate to these categories. By developing an agreed group of 'standard' benefits categories, countries will more easily be able to compare evaluation results and use these findings to guide future investment and development of digital health services more meaningfully within their local health economies.

3.3. AIM OF THE RESEARCH

The aim of the research is to develop an agreed group of 'standard' benefits categories supported by a synthesis of the international literature on benefits management in digital health, and to raise consensus of benefits categories among GDHP participant countries.

3.4. SIGNIFICANCE FOR POLICY MAKERS

This report should be a guide for policy makers to determine the appropriate approaches when developing a business case for a digital health technology or service. It should assist governments and NGOs to invest public funding into appropriate digital health products and services for their people.

3.5. SCOPE

The scope of the report is to examine evaluation methods and associated outcome measures used in the evaluation of digital health technologies and services. These include technologies such as patient portals, electronic health records, applications, application programming interfaces, medical devices, health information networks, telehealth, artificial intelligence, and remote monitoring.

3.6. METHODOLOGY

An integrative design and methodology was used (see Figure 1). The report consists of a rapid review of the international literature on the evaluation methods and proximal measurements used in the studies of digital health benefits. Literature review data was supported by a nominal group consensus process to develop a pragmatic guide for policy makers in different countries who are considering performing digital health evaluations and benefits measurement.

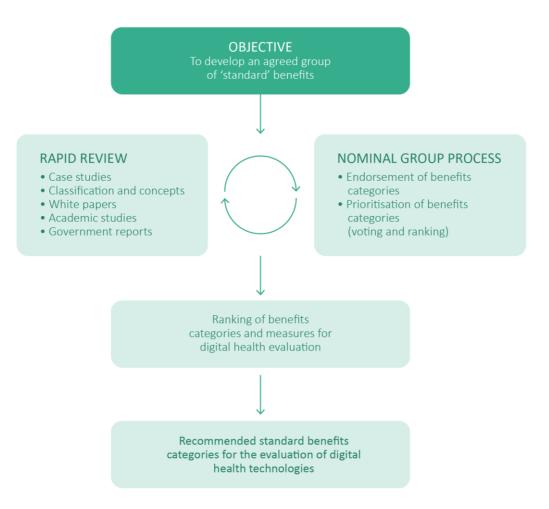


Figure 1: Design and methodology used to develop 'standard' benefits categories among GDHP participants

4 METHODS USED TO DETERMINE THE GDHP RECOMMENDED STANDARD BENEFITS CATEGORIES

4.1. METHOD: RAPID REVIEW OF THE LITERATURE

4.1.1. Search resources

To support the development of a recommended group of standard benefits categories with current evidence, a rapid review of the international literature was undertaken during July and August 2019 to identify publications relating to a range of digital health benefits categories and measures used to demonstrate these categories. Academic databases and search engines used included Academic Search Complete, CINAHL Complete, Health Business Elite, Nursing/Academic Edition, and PubMed. Grey literature sources used included Analysis & Policy Observatory (Australia), British Library Social Policy Collection (UK), Agency for Healthcare Research and Quality (US), the Canadian Agency for Drugs and Technologies in Health (CADTH) and Health Evidence (Canada), and the World Health Organization (WHO). In addition, we used Google site search to find related records in the websites listed in Appendix B then reviewed and added related records identified within these websites.

4.1.2. Search terms

All databases and search engines were searched for literature on methods and outcomes for digital health benefits management. Appendix C provides the list of specific search terms used. A combination of the following search terms was used:

- Digital health settings: digital health; digital medicine; electronic health; eHealth
- **Measures:** measure; proxy outcome; proxy measure; benefit; evaluation; assessment; realisation
- **Benefits:** based on the seven known benefits categories digital health safety; digital health quality; digital health efficacy; digital health efficiency and return on investment; population health trends and secondary uses; digital health equity

4.1.3. Screening criteria

The search was limited to literature published after 2015, and literature written in English. Literature was included if it: 1) referred to definitions of concepts based on evaluating and measuring benefits of digital health services and technologies (see Appendix D); 2) employed a qualitative, quantitative, or case study design; and 3) was published in a peer-reviewed scientific journal or in the grey literature.

4.1.4. Study selection and data extraction

Three researchers undertook the review of academic databases and two separate researchers reviewed the grey literature and identified websites. Screening and review

was performed by these five researchers and an additional researcher. Synthesis was independently conducted by three additional domain experts. For academic papers, researchers extracted metadata and literature references directly into the Covidence software (6).

4.2. METHOD: NOMINAL GROUP PROCESS

4.2.1. Sample

All GDHP participant countries that joined the GDHP before 1 August 2019 were invited and encouraged to contribute to the study.

4.2.2. Nominal group process

A nominal group technique was used to develop an agreement (or consensus) of important benefits and measurements categories for digital health evaluations. The modified nominal group technique was used for the current study to capture levels of agreement (with less focus on the need to reach high consensus for benefits categories). Hence, the ranking aspect of the technique was used to elicit and prioritise (or rank) responses into the most important benefits and measurements categories.

4.2.3. Instrument

A standardised questionnaire (see Appendix A) was sent to GDHP participants asking them to indicate their level of agreement for the inclusion of each hypothesised benefits category within the 'standard' set. This was undertaken by participants using a Likert scale of 1 to 5 to rank their agreement (1=strong disagreement, 3=neither agree nor disagree, 5=strong agreement). Additionally, participants were asked to prioritise each category from 1 to 7 where 1=most important and 7=least important. Participants were also given the opportunity to include any unknown (missing) benefits and measurements categories.

Furthermore, participants were asked to include a list of proximal measurements that have been used to measure the success of their digital health implementations. For each of the 'benefits' and 'measurements' categories, participants were invited to consider a range of open-ended questions. First, participants were asked to give a reason why they supported the inclusion of each benefits category. Second, participants were asked to provide comments about their experience of having used a benefits category, including what was evaluated? who was evaluated? how was it evaluated?

4.2.4. Analysis

For each of the benefits categories that were ranked by participants, the raw score ranking was summed across all participants combined to derive the rank order at the group level. The level of agreement for a benefits category within the group was indicated by the median. Medians of 4–5 were considered as strong support, 3 as moderate, and 1–2 as weak. Further analysis was undertaken to determine the level of

agreement within the group. Thematic content analysis was used to examine the free-text qualitative responses which complemented the quantitative responses.

5 RESULTS OF THE LITERATURE REVIEW AND NOMINAL GROUP PROCESS

5.1. RAPID REVIEW RESULTS

Figure 2 displays the PRISMA flow chart for the rapid review. A total of 14,698 records were retrieved from the database search. An additional 4,675 records were identified through grey literature sources, and the websites of GDHP participant countries. After duplicates were removed, the search revealed 7,100 relevant unique records. From these, the records of 1,945 titles and abstracts were screened, of which 1,305 were excluded. Of the remaining 640, the full text was assessed to determine eligibility, of which 308 articles were excluded because they did not cover benefits categories (41 studies), did not include measurements (65 studies), did not match source criteria (72 studies), or have access to the full text (130 studies). A total of 332 articles were included in the literature review.

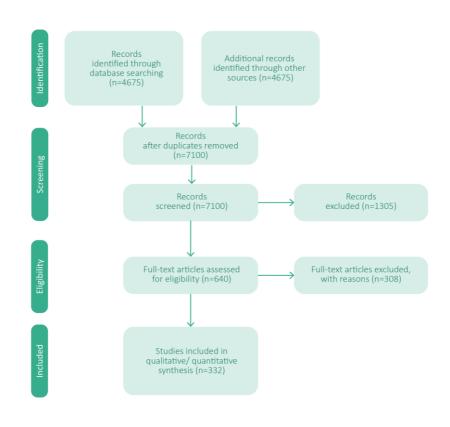


Figure 2: PRISMA flowchart of rapid review

The evaluation methods and associated outcomes identified within the literature were mapped into the following seven benefits categories: (1) digital health efficacy (n = 147); (2) digital health end-user experience (n = 138); (3) digital health quality (n = 115); (4) digital health efficiency and return on investment (n = 78); (5) digital health safety (n = 75); (6) population health trends and secondary uses (n = 62); and (7) digital health

equity (n = 25). The number of articles supporting one or more of the seven benefits categories is presented in Figure 3.

NUMBER OF STUDIES IN DIFFERENT CATEGORIES

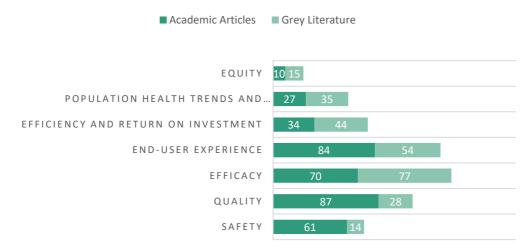


Figure 3: Number of articles supporting one or more of the seven benefits categories

The results of the literature review showed that, across the seven benefits categories, efficacy is the most investigated category with 147 articles (70 academic and 77 grey articles). In contrast, equity has been the least studied area with only 25 articles (10 academic and 15 grey articles). Furthermore, the results of the literature review showed there was a substantial overlap between these categories; for example, the majority of articles addressing digital health safety also address aspects of either digital health quality or efficacy. Figure 4 shows the graph of connections between various categories, where the number of articles in each group is presented in each node while the overlaps between various groups is represented by the value of each connecting line. For example, there were 138 articles about end-user experience, 78 articles about efficacy, and 25 articles which address both groups.

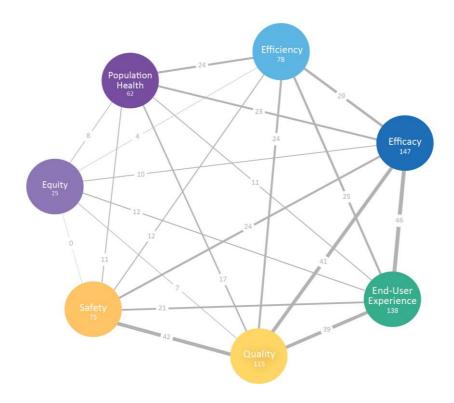


Figure 4: Relationships of articles between different benefits categories

5.2. NOMINAL GROUP RESULTS

Sixteen countries responded to the survey conducted in July 2019. Participants that responded to the survey were Australia, Argentina, Brazil, Canada, Estonia, Italy, Indonesia, India, Japan, Poland, the Kingdom of Saudi Arabia, Singapore, the Republic of Korea, Sweden, the United Kingdom, and the United States. All participants responded to all survey questions. Two issues were addressed from the quantitative analysis: (1) the strength of support to include a given benefits category within the group of 'standard' benefits categories; and (2) the priority that participants placed upon the importance of including particular benefits categories when evaluating digital health technologies.

5.2.1. Agreed benefits categories to include into standard

There was strong agreement to include digital health safety (median = 5.0, range 4–5) digital health end-user experience (median = 5.0, range 3–5), and digital health equity (median = 5.0, range 3–5) into the group of 'standard' benefits categories. Participants found moderate-to-strong agreement to include digital health efficiency and return on investment (median = 4.5, range 2–5), and population health trends and secondary uses (median = 4.5, range 2–5). Furthermore, participants found moderate agreement to include digital health efficacy (median = 4.0, range 2–5) into the group of 'standard' benefits categories. Figure 5 presents the percentage of GDHP participant countries in agreement to include each of the benefits categories into standard.

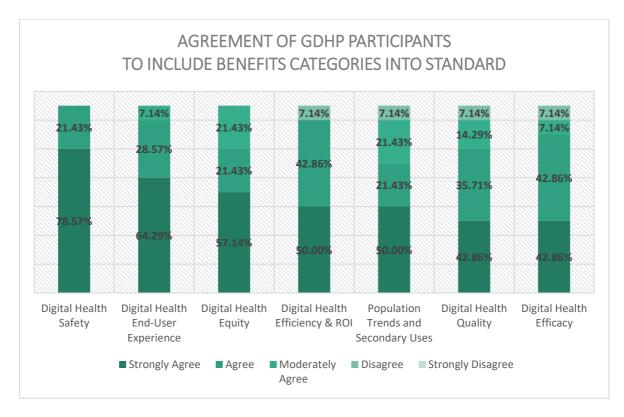


Figure 5: The percentage of GDHP participant countries in agreement to include each of the benefits categories into standard

5.2.2. Top benefits categories when evaluating digital health

Digital health safety was the highest ranked benefits category (ranked #1). This was followed by digital health quality (ranked #2), digital health efficiency and return on investment (ranked #3), digital health efficacy (ranked #4), digital health end-user experience (ranked #5), digital health equity (ranked #6), and population health trends and secondary uses (ranked #7). Table 1 presents the priority ranking of benefits categories by the sum of scores for each of the seven benefits categories.

Table 1:	Тор	benefits	categories	by	priority	(n = 16)
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Benefits Categories (7 = high, 1 = low)	Ranking (sum of scores)	Frequency of votes of the top 3 priorities (for each idea)	Ranked Priority
Digital Health Safety	88	12	#1
Digital Health Quality	65	9	#2
Digital Health Efficiency & ROI	63	8	#3

Benefits Categories (7 = high, 1 = low)	Ranking (sum of scores)	Frequency of votes of the top 3 priorities (for each idea)	Ranked Priority
Digital Health Efficacy	63	5	#4
Digital Health End-User Experience	57	4	#5
Digital Health Equity	50	4	#6
Population Health Trends and Secondary Uses	34	2	#7

6

SYNTHESIS OF THE EVIDENCE: SUPPORTING THE MEASUREMENT OF STANDARD BENEFITS CATEGORIES

This section presents an overview of the evidence that was gathered through literature review and survey of participants for each of the GDHP recommended standard benefits categories. Within each category, a further description of measures that were used in evaluations is presented, as well as some case studies that were provided by participant countries.

6.1. DIGITAL HEALTH SAFETY

This benefits category describes both improvements or threats to patient safety associated with the use of digital health services, and includes measures such as medication errors, other avoidable adverse events, and data quality improvements that could assist diagnosis. Process measures may include communication errors, or software and hardware problems.

6.1.1. Academic and grey literature supporting digital health safety (75 articles)

Most of the literature used various methods to evaluate the reduction of prescription errors as a safety outcome of digital health. Semi-structured interviews were used to evaluate safety by examining the decreases of medical errors and improvement of software features (7-9) and the value of digital interventions (10) over significant periods after implementing electronic health records (EHRs). In the United Kingdom, surveys were used to evaluate the quality of care delivered by online telehealth including key measures such as prescribing safety, the management of safety incidents and alerts, safeguarding, staffing and recruitment, monitoring health and safety, and responding to risky health practices (11). Canada also published a literature review that examined the reduction of prescribing errors and adverse drug events of electronic medical records (EMRs) rolled out nationally (12). Similarly, a literature review published in Australia evaluated the effect of Health Information Technology (HIT) systems on data integrity and security, and safer prescribing (13). Safer prescribing was a key outcome for improving the quality of care for patients.

Digital health safety was linked to improvements in data and intervention quality of health care. Internationally, frameworks (consisting of messages, surveys and interviews) and case studies were used to measure the impact of HIT or digital health via intervention quality, interoperability, and risk management including alert suitability (14-20). In Australia, case studies, surveys and literature reviews were used to evaluate five clinical HIT systems (electronic patient portals, electronic patient reminders via mHealth, electronic discharge, computerised provider order entry, and clinical decision-support systems) on reducing unwarranted variation and preventable harm, improved appropriateness and patient-centredness, and increased monitoring and quality improvement (16, 21). A roundtable discussion of experts was used to evaluate artificial intelligence (AI) applications (data types include administrative and claims, clinical, clinical trials, EHR, genomic, patient-generated, internet of things, social media, social determinants of health, surveillance, registry, survey, and vitals) to measure improvements in data quality and interoperability and cultural challenges of AI in health care by treating underlying bias in health data (22). Similarly, a systematic evaluation of digital health tools and data analysis assessed data quality, clinical quality and improved care (23, 24). Overall, improvements in the quality of health care and digital health safety was difficult to discern across the literature.

Several studies using literature reviews examined outcomes related to reducing the potential harm to consumers as an outcome to improve the safety of digital health technologies. A literature review used to evaluate the harms of online telehealth for psychiatry was published in Canada (25). A literature review of consumer HIT systems published in Australia examined internet use to improve health literacy as an approach to measuring safe health care (26). A literature review published by US authors proposed an evaluation of digital health solutions (telehealth and mHealth applications) in measuring the safety of technical, clinical, and usability factors of digital health products (27). Other reviews include methodological reviews and chart reviews that assessed digital health tool feasibility in terms of patient care undertaken in the Americas (28, 29). A review of case studies in New Zealand (30) and a review of methodologies in Latin America and the Caribbean (28) were used to evaluate national EHRs to improve decision support and risk management of care. Generally, the majority of the literature evaluated existing studies on consumer IT systems, such as telehealth and mHealth solutions. Below is a summary of methods and associated measures used in the literature for digital health safety.

Methods for digital health safety:

- Interview
- Survey
- Questioners
- Roundtable discussion of experts
- Literature review

Measurements for digital health safety:

- Intervention quality
- Impact on unwarranted variation and preventable harm
- Appropriateness and patientcentredness
- Alert sustainability
- Impact on recruitment
- Data integrity
- Data security
- Medication and prescription errors
- Impact on communication errors
- Software and hardware problems
- Improving risk management

6.1.2. GDHP participant countries' support for digital health safety (n = 16)

The qualitative analysis of the nominal group survey resulted in seven outcomes for digital health safety. Of the seven outcomes, 40 ideas were generated by the group of GDHP participants. Overall, most of the GDHP participant countries believed digital health safety to be the most important benefits category. As shown below, most of the GDHP countries believed digital health safety to be strongly related to digital health quality and/or digital health efficiency.

"This may need to incorporate a multi prong approach of 'Quality & safety standards' with an evaluation mechanism to ensure there are no threats to patient safety associated with the use of digital health services. In addition to evaluating intended outcomes such as improvements to patient safety associated with the use of digital health services." [GDHP participant country no. 5, 2019]

"The most important element of patient's interaction with the digital tools, besides clinical efficacy, is safety. From this perspective – the design of the digital services, procedures and tools should first and foremost constitute value added to the patient and not pose a threat." [GDHP participant country no. 6, 2019]

6.1.3. Preventing medication errors to improve patient safety

Many of the GDHP participant countries believe that reducing medication errors and adverse drug events are outcomes related to improving patient safety. They believe drug barcode labels, drug profile viewer, drug information systems, and e-Prescribing services were digital health solutions that can reduce medication errors. These solutions were found to support clinical workflow, decision-making, and clinician communication.

"The impact assessment of the national e-Prescription service was based on, among other things, its potential to reduce adverse drug events." [GDHP participant country no. 4, 2019]

"A well-designed, properly implemented, and responsibly used health IT system may improve patient safety and reduce user burden by better supporting clinical workflow and decision-making. Thus, it is important to measure how digital health services strengthen patient safety efforts and reduce medical errors through the effective use of health IT." [GDHP participant country no. 9, 2019]

"Agree, but this needs to be more specific, e.g., medicine safety." [GDHP participant country no. 11, 2019]

6.1.4. Avoid errors in pathology to improve patient safety

GDHP countries also supported the idea of digital health technologies avoiding errors in pathology. They consider that measuring these digital health outcomes could result in improving overall patient safety procedures for pathology.

"The possibility to analyse the relevant number of information connected to the pathology will allow the in-depth evaluation of the safety procedures and the data collected, through digital technologies, in order to avoid medical errors or to prevent adverse events." [GDHP participant country no. 7, 2019]

6.1.5. Evaluating diagnostic errors when using digital health

Evaluating diagnostic errors by users of digital health technologies was another outcome measurement for digital health safety. This outcome was associated with the potential harm of digital health on patient safety.

"Depending on the type of digital care service, it may be considered unlikely to directly harm the patient, but a diagnostic error caused by the digital device could ultimately lead to inappropriate testing or treatment for the patient and, consequently, serious harm to the patient's health." [GDHP participant country no. 7, 2019]

"Despite the beneficial associations between digital health interventions and patient safety, concerns like ... remote consultations not being able to scrutinise subtle diagnostic cues resulting in lapses, and data breaches for patient-owned data need to be reviewed in assessing the benefits of digital health services." [GDHP participant country no. 12, 2019]

6.1.6. Security and privacy as factors in digital health safety

Several countries believed digital health technologies could be a risk to patient safety. GDHP participant countries considered cybersecurity and information privacy as outcomes of improving digital health safety.

"Digital technologies also pose a risk to patient safety when the proper security and privacy measures are not applied. Cybersecurity and privacy are necessarily not always assessed by HTA [Health Technology Assessment] bodies, and dedicated security and privacy experts should be considered for this role." [GDHP participant country no. 4, 2019]

"The security of eHealth services should be given a top priority and therefore must be duly evaluated. A relevant consideration shall be given however to both realms of digital health safety – clinical safety and cybersecurity." [GDHP participant country no. 6, 2019]

6.1.7. Increasing trust of services as an outcome of digital health safety

A GDHP participant countries considered that increasing trust in health services was an outcome of improving digital health safety. Along with trust, improved data security was considered key factors to digital health safety.

"...Improving patient safety is one of the stated missions of [X], and it leads to a further mission: increased trust in the [X]. Many of the programmes in our current and historic portfolios include patient safety benefits. One would assume that it is one of the raison d'être of any health service." [GDHP participant country no. 16, 2019]

6.1.8. Improving patient-centric approaches via digital health safety

One of the GDHP participant countries considered digital health safety to be a critical precondition to adopting a patient-centric approach to delivery of health care.

"Digital health safety is a critical precondition to adopt a patient-centric approach to digital health. As payment models change, with more clinicians and healthcare entities accepting financial risk for outcomes, healthcare systems are using digital health to manage their populations and improve access, patient experience, and control costs. With this arises the need to review the implications of cost control on quality of care and health service delivery to every patient." [GDHP participant country no. 3, 2019]

6.1.9. Evaluating general threats of digital health

Some GDHP participant countries believed evaluating the threats to patient care as a consequence of using digital health was an outcome measurement for digital health safety – generally, reducing the risk to patient safety due to digital health, or reducing unintended consequences.

"...'Improvements' and 'Threats' may require very different evaluation approaches. The latter may benefit from consideration in a broader 'unintended consequences' category." [GDHP participant country no. 3, 2019]

"Patient safety is a core tenet of health care and insofar as a digital technology has the capacity to pose a risk to patient safety, these potential adverse effects need to be assessed." [GDHP participant country no. 4, 2019]

6.1.10. Case studies supporting digital health safety

Exemplar case studies in GDHP countries included digital health evaluations on e-Prescription service (Canada, United States, Argentina, Estonia), a national patient safety platform (Kingdom of Saudi Arabia, Poland), national digital health programs and live services (United Kingdom), electronic health records and meaningful use capabilities (United States), virtual reality for mental health treatment (the Republic of Korea), and electrical-medical equipment (India). Four of the exemplar case studies focused on the evaluation team (Republic of Korea, Kingdom of Saudi Arabia), diabetes patients and oncology practitioners (United States).

The exemplar case studies from the United States, Estonia and the Kingdom of Saudi Arabia deployed multiple methods to measure reports of adverse events and patient feedback to evaluate digital health safety. Estonia's case study on e-Prescription services also measures cybersecurity audits to evaluate digital health safety. The case study provided by the Republic of Korea used systematic reviews to evaluate post-traumatic stress treatment using virtual reality. The case study provided by India used certification safety standards to measure against safety hazards such as shock, harmful radiation, excessive temperature, implosion, medical instability and fire of electrical-medical equipment used in the National Digital Health Ecosystem. The case study by the United States used surveys to measure safety culture and quality of clinician-to-clinician communication on electronic health records. Many of the case studies from the GDHP countries have indicated that evaluation of the digital health technology has yet to be deployed, or the final digital health technology evaluated after approval by the country's food and drug administration.

The United Kingdom provided a benefits map that showed multiple methods and measures used to understand patient safety on multiple national digital health programs and live services. In particular, surveys and face-to-face interviews were used to obtain qualitative measures that took into account perspectives of clinicians, staff, and endusers of health care services. The United Kingdom will regularly evaluate a digital health program at 'initiation' (waterfall) or 'discovery' stages of the program lifecycle. These benefits are managed by 'benefits owners' during the delivery process and they are conducted on an ongoing basis, and based on need (that is, formative, summative, impact, outcome process evaluations). This form of evaluation helps to identify emerging benefits. Figure 6 provides a diagram of the United Kingdom's benefits map.

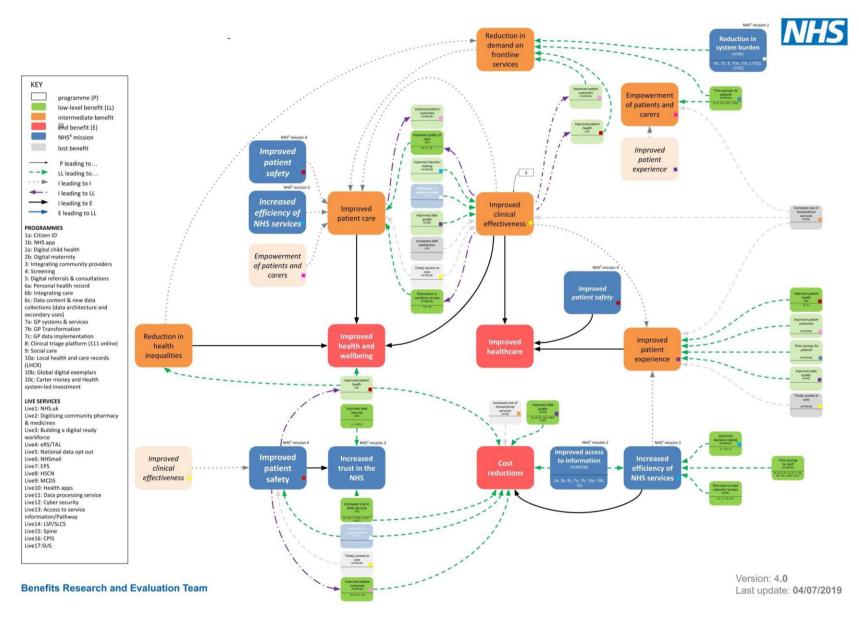


Figure 6: The NHS benefits map for digital health programmes and live services provided by the United Kingdom

Case study 1 | Canada

An evaluation case study on an e-Prescription service in Canada investigated the impacts of a centralised provincial Drug Profile Viewer (DPV) on the accuracy and comprehensiveness of patient medication history at the time of hospital admission.

Participants, setting, and study design

Surgery patients who had a pre-admission clinic appointment prior to elective surgical procedures participated in the study. The setting for this prospective, dual centre, randomised controlled trial was the pre-admission clinics of two tertiary care teaching hospitals. Eligible patients were randomly assigned to the intervention arm (DPV access) or standard care (control without DPV access).

Outcome measurements

Primary endpoints or outcomes included the number of patients with at least one best possible medication history medication discrepancy. Secondary endpoint or outcome included potential adverse drug events, classification of medication discrepancies, discrepancies prevented by the e-Prescription service, and clinician time to conduct medication history check.

Conclusions and results

Clinicians' proactive use of the e-Prescription service, using a structured process to view medication history, appears to enhance the quality of clinical practice by significantly reducing discrepancies and potential adverse drug events, and does not impact the clinician's time to complete a medication history check.

Source: Fernandes OA, Etchells EE, Lee AW, Siu V, Wong G, Holbrook A, Hamandi B, Harrison J, Wong M, Colquhoun M. Impact of a Centralized Provincial Drug Profile Viewer on the Quality and Efficiency of Patient Admission Medication Reconciliation. 2010. URL: <u>https://www.infoway-</u> inforoute.ca/en/component/edocman/resources/reports/benefitsevaluation/2936-impact-of-a-centralized-provincial-drug-profile-viewer-on-theguality-and-efficiency-of-patient-admission-medication-reconciliation

Case study 2 | Austria

In 2009, Austria launched the pilot project "e-Medikation". The program is a national e-Prescription service which was implemented to increase patient safety and to improve the effectiveness and efficiency of prescription and dispensing processes in Austria while maintaining data security.

Participants, setting, and study design

A formative evaluation study design was used to evaluate the e-Prescription service in three pilot regions, Tyrol West and Wels-Grieskirchen in Upper Austria, and two districts in Vienna. Surveys were developed and distributed to physicians, pharmacists, and patients. In addition, there was an analysis of e-Medikation log files.

Outcome measurements

Number of documented prescriptions, number of medication safety warnings, satisfaction of e-Medikation software, qualitative impact of e-Medikation on workflow of physicians and pharmacists, qualitative benefits and barriers, patient satisfaction, degree of success of e-Medikation, and lessons learnt from national rollout.

Conclusions and results

The results demonstrated high acceptance of the national e-Prescription service among pharmacists and patients. Results were mixed among physicians. Further design improvements to the software interface is needed before a national rollout.

Source: Ammenwerth E, Duftschmid G, Gall W, Hackl WO, Hoerbst A, Janzek-Hawlat S, Jeske M, Jung M, Woertz K, Dorda W. A nationwide computerized patient medication history: evaluation of the Austrian pilot project "e-Medikation". Int. J. Med. Inform. 2014 Sep 1;83(9):655-69.

6.2. DIGITAL HEALTH QUALITY

This benefits category describes the quality of healthcare services using digital health, such as potential quality concerns of services, service areas that need further study and investigation, and changes in service quality over time. Benefits categories include standardised, evidence-based measures that can be used with available hospital inpatient administrative data to measure and track clinical performance and outcomes. Measures may include preventive, inpatient, patient safety, and paediatric quality indicators.

6.2.1. Academic and grey literature supporting digital health quality (115 studies)

In the literature, data extracted from medical records were used to evaluate data quality and the quality of safe healthcare practices. For instance, data extracted from records assessed the completeness of EHRs (24), and surveys assessed the completeness of EMRs and EHRs (17). Furthermore, data extracted from EHRs were used to evaluate the data quality (such as missingness, breadth, plausibility, and density) of records (31) as well as the screening accuracy of an algorithm (32). Completeness and other measurements (such as computability and accuracy) have also been used to assess EHRs (33-35). Lexical approach has been used to evaluate the consistency of terms in a controlled terminology system (36). Lastly, a mixed method, using data extracted from health records and clinician questionnaires, was used to assess the number of handovers per day (37). While data extraction methods were used, questionnaires and surveys were also commonly used to evaluate the digital health quality.

Surveys and questionnaires were used to evaluate the quality of health care through the maintenance of high quality data in digital health systems. A data quality tool using questionnaires for two countries in Latin America and the Caribbean was used to assess EHRs in both regions (28). Surveys were used to assess an EMR ability to improve appointments or visits with caregivers (16). Also, surveys were used to assess primary healthcare providers using online telehealth safety to deliver high-quality health care for citizens in the United Kingdom (38). Similarly, surveys were used to evaluate national EHRs from multiple countries on safety of data in relation to delivering better quality auditing of clinical records and health practices (17, 36, 39). A survey of US clinicians was used to evaluate the impact of EHRs on clinician's performance in terms of quality of care, resource utilisation, and productivity measurements (40, 41). EMR appropriateness and patient safety were also assessed in a US survey-based study (42). Overall, surveys and questionnaires were used in the literature to evaluate outcomes such as improvement to the quality of care, safer healthcare practices, and improvements in appointments and visits to providers.

Interviews were also commonly conducted to evaluate the quality of healthcare services. For instance, interviews were used to evaluate the EMRs to assess quality of healthcare services (43). Additionally, interviews were used to evaluate healthcare data analytics applications on monitoring improvements of quality of health care in the United Kingdom (44), the United States (31, 45) and Israel (46). Some overlapping themes of time and workflow were also assessed using semi-structured interviews in a qualitative descriptive study of the Catalan national health system (47). Interviews were also used with other methods to evaluate the quality of health care in different countries.

The study by African Strategies for Health Project (48) provides a series of case studies that were used to evaluate mHealth in several African countries. Different methods were used: surveys, web traffic analytics, usage statistics, phone interviews and surveys, questionnaires, interviews, mixed method assessments, focus groups, interactive voice response, randomised control study, and iterative design process. Some of the measures and outcomes of these methods include:

- Better support for health workers
- Improved communication of health workers using mobile phones
- Infrastructure made more accessible in African crisis areas
- Time of health providers freed up

Literature reviews were commonly used to evaluate the quality of health care delivered by HIT systems for clinicians across the United States, Canada, Australia, New Zealand, the United Kingdom and Europe. A literature review commissioned by the United States Agency for International Development (USAID) evaluated multiple HIT systems for consumers and health workers based on reducing time and energy of training health workers, improving real-time reporting and decision-making, and enhancing leadership via better decision-making (49). The use of big data to improve reporting, decisionmaking and time use was also addressed by a mixed methods UK study (50). Furthermore, a literature review was conducted on HIT tools for multimorbidity care in Europe which evaluated improvements in healthcare systems by measuring reductions in the length of stay in hospital, improving integrated care, and supporting decision-making by clinicians (51).

The European Union also published an opinion paper on HIT systems that proposed an evaluation framework examining aspects of health system improvements (52). Reviews of case studies in New Zealand (30) and the United States (53) were used to evaluate national EHRs to improve service management and collaboration within integrated care, and improvements in information exchange. A literature review that was published in Australia was used to evaluate the impact of HIT systems on improvement in resource utilisation and guideline adherence (see also modelling study in the United States (54)), reduced interruption and workarounds, and improvements in organisational efficiency (13). A literature review was used to evaluate EMRs in Canada by measuring patient safety, appropriateness of EMRs, and health outcomes (12). Moreover, improvements in health service management and integrated care were outcomes for digital health quality.

Literature reviews were also used to evaluate consumer-based digital health services, such as telehealth and mHealth products. A literature review conducted in the United States evaluated home telehealth interventions using multiple study designs that measured reductions in admissions and emergency department visits (55). This adds to another US study (56) and a Dutch study (57) employing assessment of adoption, cost, and quality measures over an extended period of time. A literature review of evidence was used to evaluate telehealth and mHealth solutions on improvement in provider awareness (58). Another literature review was used to evaluate a telehealth system that measured improvements in existing healthcare services (59). Similarly, a literature review evaluated digital health products in relation to improvements on clinical workflows and laboratory values, and adherence to treatment (27). Overall, literature reviews were leveraged in many of the studies evaluating outcomes such as improvements in communication with consumers and healthcare providers, clinical workflow and usability of digital health, and reduction in hospital visits.

Secondary data analysis was used with literature reviews to evaluate telehealth, mHealth, and AI health applications. For instance, literature reviews and secondary data analysis were used to evaluate HIT systems by measuring the use of digital health technologies (24, 60). Furthermore, secondary data analysis was used to evaluate telehealth and mHealth services on outcomes related to reducing visits to providers (61-63). Secondary data analysis was also used to evaluate telehealth and mHealth systems in Brazil, Costa Rica, the Dominican Republic, Spain, the United States and the United Kingdom on improved early detection of disease, improved access to primary health care, and better interdisciplinary collaborative care (23, 63-65). Lastly, a literature review was used to evaluate AI health applications to measure impacts on improvements in screening and medication adherence to treatments (66). Medication adherence in the United States was also assessed via process mapping (20). Some of the outcomes that were measured in studies using secondary data analysis include improvements in the screening of diseases, better access to health care, better medication adherence, and reduced visits to providers. Below is a summary of methods used to evaluate digital health quality and associated measurements used in the literature.

Methods for digital health quality:

- Interview
- Data extraction
- Survey
- Questionnaires
- Web traffic analytic
- Usage statistics
- Focus groups
- Interactive voice response
- Randomised control study
- Literature review
- Secondary data analytics

Measurements for digital health quality:

- Quality of services
- Changes in service quality over time
- Improve standardisation
- Clinical performance and outcomes
- Impact on paediatric quality indicators
- Data quality including missingness, breadth, plausibility, density, computability and accuracy
- Number of handovers per day
- Improve appointments or visits with caregivers
- EMR appropriateness
- Quality of health care
- Better support for health workers
- Improve the communication of health workers
- Reducing time and energy of training health workers
- Making infrastructure more accessible
- Improve reporting and decision making
- Reduce length of stay in hospital
- Improving integrated care
- Interoperability and improvements in information exchange
- Better resource utilisation
- Guideline adherence
- Reduce interruption
- Reductions in admissions and emergency department visits
- Improving providers' awareness
- Improvements of clinical workflows
- Improve laboratory values
- Adherence to treatment
- Improving early detection of disease
- Better access to primary health care
- Better interdisciplinary collaborative care
- Screening improvements

6.2.2. GDHP participant countries' support for digital health quality (n = 16)

Qualitative analysis of the nominal group survey resulted in three outcome measures for digital health quality. Of the three outcome measures, 13 ideas were generated by the group of GDHP participants. Similar to digital health safety, most participants believed measuring digital health quality to require a multifaceted and global approach.

"The evaluation of health services using clinical quality and service quality indicators has been practised in many countries in the world. By tracking this it helps evaluate whether digital transformation indeed has improved healthcare delivery." [GDHP participant country no. 10, 2019]

"Measuring the quality of healthcare procedures is important. The assessment of procedures should be unified, both for procedures performed in a traditional way, as well as digital ones. In our opinion there is no necessity of additional system of assessment of digital procedures. Instead, we are of opinion, that both – traditional and digital procedures should be certified and assessed in the same way. What is more, the information on assessment of a given procedure shall be widely available and allow for making comparisons between healthcare providers. The quality assessment outcomes should be one of the decisive factors when choosing a given procedure (traditional/digital and a given provider)." [GDHP participant country no. 6, 2019]

"The evaluation of health services using clinical quality and service quality indicators has been practised in many countries in the world. By tracking this it helps evaluate whether digital transformation indeed has improved healthcare delivery." [GDHP participant country no. 10, 2019]

6.2.3. Technical aspects of technologies to enhance digital health quality

GDHP participant countries described the technical aspects of digital health technologies as an outcome of digital health quality. In particular, digital health quality was measured by the design of a medical database, functional completeness of software, and reliability and accuracy of software technology.

"Digital healthcare services will need to have 'technical completeness' to ensure 'reliability and accuracy.' The low confidence in the technology of digital healthcare services can be an important factor that impedes the activation of digital healthcare services. For the active introduction of services in the future, the selection of highquality digital healthcare services through testing for reliability, accuracy and functional completeness of digital healthcare services will be important." [GDHP participant country no. 2, 2019] "... medical database can lead to providing appropriate medical care, and quality could be a major factor that can improve the quality of medical services by promoting digital health." [GDHP participant country no. 1, 2019]

6.2.4. Improvement in healthcare processes to improve digital health quality

Some of the GDHP participant countries described the improvements of healthcare processes to be relevant for digital health quality. For instance, healthcare practice patterns and feedback of clinical teams can be measured to understand enhanced digital health quality.

"The process of enhancing care starts with measuring the results of current processes and practice patterns. Quality measurement provides tangible feedback to clinicians and other healthcare team members about care processes and outcomes. Teams can use this feedback to identify opportunities to improve care and outcomes for their patients. Therefore, it is extremely important to assess how health IT impacts the quality of healthcare services rendered." [GDHP participant country no. 9, 2019]

"Digital health interventions such as EHR, remote mobile-based consultations, frontline health worker aid through mobile apps have the potential to scale quality health interventions to the billion and upwards of people who need it. Given the demand for quality health services that is timely, efficient, and cost-effective, and the limited skilled manpower to respond to this demand, quality digital health interventions can increase the capacity of the health ecosystem to respond to needs without being as dependent on skilled manpower." [GDHP participant country no. 12, 2019]

"I think that the definition is confusing and is more outcome and performance management based than benefits-led. ... there are numerous benefits categories that fit into this theme, e.g. improved access to information, improved decision making, timely access to care." [GDHP participant country no. 16, 2019]

6.2.5. Digital health quality as part of other benefits categories

Several GDHP participants reported digital health quality to be linked with other benefits categories, such as digital health efficacy, efficiency, or safety. Furthermore, some of the participants commented on the difficulties to distinguish between quality and the other categories.

"We have difficulty understanding how this category meaningfully differs from efficacy or efficiency. It would appear that what is considered quality would be measured by either of the two." [GDHP participant country no. 4, 2019]

"Quality of the services should be part of any evaluation framework." [GDHP participant country no. 8, 2019]

"We strongly agree with adding quality as outlined under Safety above. We are not sure why the outcome measure here is also patient safety?" [GDHP participant country no. 4, 2019]

"We understand that assessing quality of health services is a multi-causal "black box". Both digital health and other factors can affect quality, and it is very difficult to assign just one cause." [GDHP participant country no. 14, 2019]

6.2.6. Case studies supporting digital health quality

Case studies from the GDHP participants reported on the evaluation of electronic health records and clinical decision-support systems (Canada, the United States), national eHealth platforms (Kingdom of Saudi Arabia, Poland), and digital devices for diabetes (Italy). The majority of the countries described these evaluations as being aimed at end-users, such as health providers or patients.

GDHP country participants such as the Kingdom of Saudi Arabia deployed disease mapping and analytics to measure the number of registered users for a service and number of completed sessions. Countries such as Poland used User Experience (UX) analysis to understand the technical and functional aspects of their digital health infrastructure to infer improvements in digital health quality. Several case studies from the United States and Canada used literature reviews and patient surveys to examine the impact of interoperable health information exchange on quality of health care for patients, including a randomised controlled trial (RCT) to evaluate clinical decisionsupport tools to improve healthcare process measures. GDHP country participants reported using these evaluation methods and outcomes on an ongoing basis.

Case study 3 | Switzerland

A mortality predictive model was evaluated based on Electronic Health Records (EHRs) data to enhance patient care by pointing physicians to patients at risks. The Acute Laboratory Risk of Mortality Score (ALaRMS) is a scoring system that uses statistical learning methodologies (or 'big data' strategies) to aid decision support and improve the quality of health care.

Participants, setting, and study design

Database of EHRs involving over 100,000 hospital admissions. Patient records of the Inselspital (University Hospital of Bern) from early 2012 to late 2015 were used. A total of 23 numeric laboratory test results were included in the ALaRMS model. Several statistical analysis methods were used, including linear classification methods, neural artificial network, and decision tree approach.

Outcome measurements

Area Under the ROC Curve (AUC) were used to evaluate prediction accuracy.

Conclusions and results

The study showed that statistical methods can perform well in predicting inpatient mortality compared to existing approaches. By predicting inpatient mortality, preventative measures can be used to improve quality of patient care.

Source: Nakas CT, Schütz N, Werners M, Leichtle AB. Accuracy and calibration of computational approaches for inpatient mortality predictive modeling. PloS one. 2016 Jul 14;11(7):e0159046. DOI: https://doi.org/10.1371/journal.pone.0159046

Case study 4 | Argentina and Brazil

This case study examined the "ePHC Assessment Framework" in Latin American and Caribbean countries. The ePHC Assessment Framework aims to support how eHealth is used to provide people-centred, integrated health care in primary health care (PHC) settings. The ePHC framework is based on the National eHealth Strategy Toolkit and the Primary Health Care Logic Model of the province of Alberta, Canada.

Participants, setting, and study design

Field work was conducted on experts in Argentina and Brazil. Local experts from both regions attended workshops before data collection. Questionnaires were used to collect data.

Outcome measurements

Enhancements of chronic condition prevention and management using the ePHC framework. A local site in Latin America satisfying the ePHC foundations.

Conclusions and results

The study found Argentina and Brazil engaged in eHealth initiatives as part of ePHC Assessment Framework. The research data suggest the ePHC framework provides person-centred and high-quality PHC services.

Source: Lima-Toivanen M, Pereira RM. The contribution of eHealth in closing gaps in primary health care in selected countries of Latin America and the Caribbean. Revista Panamericana de Salud Pública (Pan America Journal of Public Health). 2019 Jan 21;42:e188.. DOI: https://doi.org/10.26633/RPSP.2018.188

6.3. DIGITAL HEALTH EFFICACY

This benefits category describes the effectiveness of a digital health product or service, such as whether or not it produces the desired outcomes it was designed to deliver. Measures may include improved health status indicators, such as weight reduction for people with obesity, better HbA1c control in people with diabetes, a better understanding of how to follow healthcare advice, or improved health literacy. A process measure may be improving the quantity or frequency of reminders and recalls for preventive health interventions or other improved processes in the delivery of health care.

6.3.1. Academic and grey literature supporting digital health efficacy (147 studies)

Mixed methods were used to evaluate the impacts of telehealth and mHealth systems on digital health efficacy. Internationally, the World Health Organization (WHO) published a guideline using surveys, interviews, and literature reviews to evaluate mHealth and telehealth (digital health intervention) systems measured by improved communication to clients for behavioural change, and better monitoring of health status (67). Mixed methods were used to assess the health status of people with mental health problems using a telehealth system (65). Overall, the health status of people was used as a measure to evaluate many of the outcomes related to digital health efficacy.

Literature review and surveys or interviews were used to evaluate the impacts of different digital health systems. In Australia, surveys and two literature reviews were used to evaluate different HIT and telehealth systems including mHealth that measure improvements in high-quality data, enhanced models of care, greater innovation, improved access to health services, and increased capabilities of digital health in the workforce as key factors to patient efficacy (68, 69). Similarly, another literature review and interviews were used to assess the impacts of HIT and accompanying digital health systems that specifically examine factors relating to better management of chronic disease and mental health and wellbeing of citizens (70, 71). In particular, these methods were deployed to leverage other measures such as data quality, innovation and models of care, access to health care, workforce capabilities, and wellbeing outcomes to evaluate digital health efficacy.

More sophisticated methods such as simulation and statistical analysis were used to assess quality of life and improvements in patient communication. For instance, simulation methods were used to evaluate the quality of life in relation to cost-effectiveness of EHRs (72). Furthermore, statistical analysis and cross-sectional studies were used in US studies to assess improved patient-client communication and patient-centredness (73-75). These methods were often used on secondary data to evaluate the impacts of the efficacy of digital health on patients. Below is a summary of methods and associated measurements used in the literature for digital health efficacy.

Methods for digital health efficacy:

- Surveys
- Interviews
- Literature reviews
- Simulation and statistical analysis

Measurements for digital health efficacy:

- Improving health indicators such as weight reduction
- Improving health literacy
- Quantity or frequency of reminders
- Recalls for preventive health interventions
- Improving processes in the delivery of health care
- Better communication with clients
- Better monitoring health status
- Improving access to health services
- Better management of chronic disease
- Improving mental health and wellbeing of citizens
- Improving innovation in models of care
- Increasing access to health care
- Better workforce capabilities
- Improving wellbeing outcomes

6.3.2. GDHP participant countries' support for digital health efficacy (n = 16)

The nominal group survey resulted in four outcome measures for digital health efficacy. Of the four outcome measures, nine ideas were generated by the group of GDHP participants. A couple of GDHP participants reported the difficulties of disentangling digital health efficacy from other benefits categories such as quality and safety.

"Important topics included in the description, but may be hard to disentangle from Digital Health Quality. From the description, it reads like Digital Health Quality could lead to Digital Health Efficacy – if this is intentional, it could maybe be represented as such." [GDHP participant country no. 3, 2019]

"... we would include this as a process and/or impact indicator of Digital Health Safety above. We have no strong objection to including but am not sure of the reason for splitting them." [GDHP participant country no. 5, 2019]

GDHP participant countries believed a multi-method approach should be used to measure digital health efficacy. For instance, efficacy can be measured using clinical measurements and clinical consultation/health-seeking experience.

"Digital healthcare services may find it difficult to apply the already well-established methodology to validate clinical effects as it may be difficult to apply the traditional clinical verification methods applied to existing medicines or surgical treatment devices, but digital health care is also for the patient's health, and efficacy should be clearly verified." [GDHP participant country no. 2, 2019]

"Efficacy assessments are a pillar of Health Technology Assessment and should be applied to digital technologies as well. With limited funding, purchasers must be able to assess whether the technology they are acquiring produces the desired outcome. That being said, efficacy assessments should not be conducted on a one-size-fits-all basis, but should rather be based on the level of the digital intervention." [GDHP participant country no. 4, 2019]

6.3.3. Clinical measurements and patient experience to monitor digital health efficacy

Several GDHP participant countries believed digital health efficacy can be measured using multiple measurements displayed on dashboards as an evaluation method. In particular, digital health efficacy can be measured using clinical quality indicators, such as blood pressure, combined with service indicators, such as the patient experience.

"We use improvements to e.g. patient health, to patient outcomes, to clinical effectiveness. Improvements to health and wellbeing and to healthcare are two of the triple aim." [GDHP participant country no. 16, 2019]

"The evaluation of health services using clinical quality and service quality indicators has been practised in many countries in the world. By tracking this it helps evaluate whether digital transformation indeed has improved healthcare delivery. For example, one method of measure could be whether implementation of a diabetes dashboard in national systems has led to improvement in clinical measurements of control such as blood pressure and HbA1c over time, supplemented with use of surveys of clinicians and patient on whether the dashboard has facilitated their clinical consultation/health seeking experience." [GDHP participant country no. 10, 2019]

"Efficacy can be regarded as the penultimate evaluation of a digital health intervention, given its range of influence on the desired outcome of the intervention: in promoting health behaviours (smoking cessation, healthy eating etc.), improve outcomes in patients with long-term conditions (cardiovascular disease, diabetes, mental health conditions) and provide remote access to effective treatments (remote counselling services, for example)." [GDHP participant country no. 12, 2019]

6.3.4. Technology functionality to improve digital health efficacy

GDHP participant countries described measuring the functionality of a digital health technology as an outcome of digital health efficacy. Moreover, digital health technology functionality should account for the frequent use of digital health and improvements in patient-specific outcomes.

"It is important to assess whether technology is functioning as intended. Technology that doesn't function as required could impact the healthcare delivery, increase provider burden, and negatively impact patient outcomes." [GDHP participant country no. 8, 2019]

"The digital efficacy must be evaluated taking into account the frequency in using the digital technologies and the related results in terms of improvement of the main indicators related to the patient specific pathology." [GDHP participant country no. 7, 2019]

6.3.5. Enhanced support and guidance to clinicians as an outcome of digital health efficacy

A number of GDHP participant countries believed the quality of medical care can be measured by providing better health guidance, or enhancements in existing clinical procedures.

"For example, there are cases where health guidance based on the specific medical checkup database makes the effects that help prevent or aggravate, and Health efficacy could be a major factor that can improve the quality of medical services by promoting digital health." [GDHP participant country no. 1, 2019]

"Clinical efficacy of digital health procedures should be duly measured – as it is considered an important tool in public health sector. It shall be a viable source of information on day-to-day operational management as regards the contents of digital health procedures portfolio. The data collected should serve as a basis for updating the catalogue of performed procedures, as well as it should be used to decide on the contents of the catalogue, continuation, modification or withdrawal of a given digital procedure." [GDHP participant country no. 6, 2019]

6.3.6. Improving vaccine delivery as an outcome of digital health efficacy

One GDHP participant country noted the improvement of vaccine delivery as a result of digital health efficacy. The timing, coverage, and completeness of vaccination schedules were outcomes of improved digital health efficacy.

"...digital health systems may be used to optimize the delivery of vaccines in terms of timing, coverage and completeness of the vaccination schedule, while the vaccines themselves have already been previously tested for efficacy (i.e. they have been shown to reduce rates of infection or illness in prior studies) and administered through other programmes." [GDHP participant country no. 12, 2019]

6.3.7. Case studies supporting digital health efficacy

Exemplar case studies reported on the evaluation of different digital health systems, including telehomecare (Canada), general medical devices (Estonia), a digitalised call centre (Italy), admission, discharge, and transfer (ADT) notification system, and interoperable health information exchange (United States). Five of the case studies evaluated the impact of their systems on patients and physicians.

The case study by Estonia developed a framework (consisting of assessments and costbenefit analysis) to evaluate the medical efficacy of general medical devices, such as clinical systems or procedures that had a significant digital component, or stand-alone medical devices. In the United States, ADT notification systems were evaluated to measure improvements on provider communication and enhance support to patients with multiple or chronic conditions. Similarly, case studies on ADT notifications were evaluated to measure improvements between patients and providers in the United States.

Case study 5 | Argentina

This case study examines a text messaging intervention to promote adherence to tuberculosis (TB) treatment. There is evidence to suggest that text messaging interventions to consumers and patients for TB treatments is an effective communication strategy and can lead to health behaviour change. This pilot study aimed to examine initial results of the efficacy of TB intervention via promoting the adherence to TB treatment.

Participants, setting, and study design

A randomised, mixed method study design was conducted to evaluate the intervention against a usual care control group. The participants were patients recently diagnosed with TB, 18 years or older and with access to a mobile phone. They were recruited from a public pulmonary-specialised hospital located in the province of Buenos Aires, Argentina. The intervention supported the patients for the first two months of treatment.

Outcome measurements

Semi-structured interviews were conducted. Primary outcomes included the number of potential eligible participants, the number of patients with mobile phones, the use of the SMS intervention, perception of the SMS intervention, and queries from participants. Secondary outcomes evaluated sputum smear or culture conversion and treatment success using data collected from patients' medical records, as well as regional TB program records.

Conclusions and results

The results demonstrated a low rate of participant refusal and improved knowledge and understanding of TB. Patients reported they felt cared for and supported throughout the study. Patients also identified that they felt responsible for their own treatment and care plan. Treatment outcomes were similar in both groups.

Source: Iribarren S, Beck S, Pearce PF, Chirico C, Etchevarria M, Cardinale D, Rubinstein F. TextTB: a mixed method pilot study evaluating acceptance, feasibility, and exploring initial efficacy of a text messaging intervention to support TB treatment adherence. Tuberculosis research and treatment. 2013. https://doi.org/10.1155/2013/349394

Case study 6 | Australia

The Australian Digital Health Agency (ADHA) recently conducted a digital health evidence review which examined the registration, adoption, access and active use of the national electronic health record (EHR) system in Australia.

Participants, setting, and study design

The study conducted an extensive literature review of the case studies from around the world that showcase international evidence on national rollouts of EHRs. Additionally, the literature review presented an overview of the My Health Record system and provided a comparison of similar international experiences and policies.

Outcome measurements

The literature review focused on six main areas: 1) types of digital health record; 2) overview of digital health records in other countries; 3) benefits of shared digital health records; 4) adoption of digital health records; 5) people use of digital health records; and 6) health providers' use of digital health records.

Conclusions and results

A number of conclusions were drawn from the evaluation. First, national EHRs (such as the My Health Record) can provide individuals and healthcare providers with secure personal health information similar to personal health records in other countries. Second, online portals can extend existing functionality of national EHRs. Third, specific legislation on national EHRs can improve the rights of citizens to share health information with providers. Fourth, legislation of digital health records differs across different countries. Lastly, benefits of digital health records include improved patient safety and health outcomes, increased adherence to treatment, time savings for clinicians, and reduced duplication of visits and hospital admissions.

Source: Australian Digital Health Agency (2018) Safe, seamless and secure: evolving health and care to meet the needs of modern Australia. URL: <u>https://conversation.digitalhealth.gov.au/australias-national-digital-health-strategy</u>

6.4. DIGITAL HEALTH END-USER EXPERIENCE

This benefits category describes the experience of the end-user as they interact with a digital health technology or service. Measures may include satisfaction with the design of a digital health interface or other heuristic evaluation measures, such as the match between the system and the real world. Digital health end-users may include consumers, patients, and clinicians. Other healthcare stakeholders also include end-users not directly involved in the delivery of health care, such as healthcare administrators, digital health designers, policy makers, and researchers.

6.4.1. Academic and grey literature supporting digital health end-user experience (138 studies)

Surveys, questionnaires and interviews were used to evaluate the acceptability and usability of different digital health tools. Questionnaires were used to evaluate the acceptance of mobile phones among patients and consumers in a clinical setting (76). Patient and practitioner end-user experience was assessed in terms of acceptance and ease of use via surveys in Germany (76), the Kingdom of Saudi Arabia (77), and Taiwan (78). Interviews were used to access an interactive patient care (IPC) and EHR system on the satisfaction and usefulness of the digital health tool (79). End-user experience was evaluated by acceptance of a digital health tool or the ease of use for patients and consumers.

Mixed method approaches were also used to assess the usability of HIT and telehealth systems. In Australia (80) and the United States (79), surveys and literature reviews were used to evaluate HIT and telehealth (including mHealth) systems that measured the levels of clinical engagement to improve end-user experience of clinicians. Mixed method or qualitative methods were used to assess the usability factors of an EHR and telehealth system (7, 65). Multiple evaluation methods were commonly used to measure the usability of digital health for clinicians.

Video ethnography and analysing data access patterns of clinicians' use of a digital health system was used to evaluate end-user experience. For instance, video methods were used to assess the screen time of the clinician using an EHR (81). Data access patterns using a prototype test and usability testing were also analysed to show the importance of interface design and its impacts on physician use (8, 82). Similar to other approaches used in this category, these novel methods were used to measure outcomes related to improvements on user interface design and screen time use.

Literature reviews were commonly used to evaluate user satisfaction and other usability factors. A report published by the WHO used literature reviews and case studies to evaluate multiple HIT, mHealth, and algorithmic systems for tuberculosis (TB). It demonstrated the importance of consistent user interface design, ease of use, browser capability, and standardised clinical reporting as important measures for end-user experience (83). A literature review published in Canada used these methods to evaluate the national EHR on user satisfaction factors such as competency of using the system, user acceptance, and ease of use (84). Literature reviews were also used to evaluate the patient and clinician satisfaction with EMRs (41). Outcome measures such as user interface design, ease of use, improved clinical reporting, and user satisfaction were used to evaluate digital health end-user experience. Below is a summary of methods and associated measurements used in the literature for digital health end-user experience.

Methods for digital health end-user experience:

- Surveys
- Questionnaires
- Interviews
- Literature review
- Video ethnography

Measurements for digital health enduser experience:

- Heuristic evaluation measures such as the match between the system and the real world
- Acceptance and ease of use
- Usefulness of the digital health tool
- Levels of clinical engagement
- Screen time of the clinician
- Improving standardised clinical reporting
- Consistent user interface design
- Improving user satisfaction
- Competency of using the system

6.4.2. GDHP participant countries' support for digital health end-user experience (n = 16)

The qualitative analysis of the nominal group survey resulted in four outcome measures for digital health end-user experience. Of the four outcome measures, 13 ideas were generated by the group of GDHP participants. Similar to other benefits categories, enduser experience was associated with improvements in the digital health quality.

"For example, there are cases where data from National-Database and long-term care Database can be useful for policy makers and researchers, and the End-user experience could be a major factor that can improve the quality of medical services by promoting digital health." [GDHP participant no. 1, 2019]

6.4.3. Improving adoption of digital health as an outcome of digital health enduser experience

Many of the GDHP participants supported the idea of measuring adoption or uptake of digital health technologies as an outcome of digital health end-user experience. For instance, many of the GDHP participants reported that evaluating digital health end-user experience requires measuring the uptake of digital health, including measuring the adoption rate of digital health services.

"The end-user experience is ultimately a predictor of uptake, and therefore should be considered for the assessment of digital technologies, particularly national services. This is to avoid potentially very costly investments into technology that does not end up being used or is used in the wrong way." [GDHP participant no. 4, 2019]

"From a perspective of a central administration, introducing a new digital health procedure/service, a special consideration shall be given to the uptake of it. The pace of the uptake is strongly related to the benefit it offers, empowerment it makes possible and the ease of use/entry barriers." [GDHP participant no. 6, 2019] "Usability is one of the main barriers for adoption of eHealth tools in our environment." [GDHP participant no. 8, 2019]

"intuitive user experience design can simplify user interactions with an app, chatbot, or other services and reduce hesitation and confusion that comes with adoption of new technology, hence improving digital health efficacy." [GDHP participant no. 12, 2019]

6.4.4. Ease of use to improve end-user experience of digital health technologies

GDHP participants reported measuring ease of use of digital health technologies as an outcome of digital health end-user experience. Ease of use includes measuring the user-friendliness of a digital health interface, or the level of burden placed on the end-user while using digital health.

"A user-friendly interface helps to attract end-users. This is very important factor for making digital services popular. User-friendly solutions are a key enabler for patients' engagement in digital services and therefore deserve a special attention when evaluating digitisation efforts." [GDHP participant no. 6, 2019]

"To truly realize the benefits of health information technology, end-users must see the value in using the tool. Use of the technology mustn't be burdensome and provide the end-user with information they trust which can then be used to inform decision-making." [GDHP participant no. 9, 2019]

6.4.5. Convenience for users, and increased familiarity of a system to enhance end-user experience of digital health technologies

Some GDHP participants believed end-user experience should be measured by the additional convenience to end-users (or placing less burden on end-users). Additionally, evaluations should measure the increased familiarity of the system as an approach to understanding the benefits of digital health end-user experience.

"In other words, ease of use, familiarity, or convenience is the criterion of choice of technology in the measurement of end-users." [GDHP participant no. 2, 2019]

6.4.6. Patient satisfaction to improve end-user experience of digital health services

Numerous GDHP participants supported measuring patient satisfaction as an outcome of digital health end-user experience. In particular, one participant commented on using patient satisfaction as an indicator when evaluating consumer/patient-facing applications.

"This element is particularly relevant considering the enormous number of digital health apps already present in the market and that will appear in the next years. It will be important to assess the patient satisfaction in using these technologies, together with the other stakeholders involved in the delivery of health services (care givers, case managers, GPs)." [GDHP participant no. 7, 2019] "Strongly agree. [X] use this indicator as often as possible especially in all consumer/patient-facing applications." [GDHP participant no. 5, 2019]

"...improved patient experience is one of our main benefits, and it is the use of the product by the end-users that leads to interesting benefits such as improvements to clinical effectiveness." [GDHP participant no. 16, 2019]

6.4.7. Case studies supporting digital health end-user experience

Exemplar case studies for this category reported on the evaluation of EHRs (Canada and the United States), general digital technology in health (Canada, Italy), national digital health systems (Estonia, the Kingdom of Saudi Arabia), and patient experience measurement programs (the Kingdom of Saudi Arabia). The case studies evaluating these systems assess the impacts on health providers, patients and a healthcare facility.

The exemplar case studies from Canada used surveys to assess the clinician satisfaction with EHRs and general technology use across various health professionals, such as nurses, pharmacists, and physicians. Similarly, the United States sponsors the use of surveys to measure end-user experience by measuring people's access to digital health, and people's health behaviours. Case studies from the United States measured ease of use as an outcome of digital health end-user experience. The case studies by Estonia and the Kingdom of Saudi Arabia used national surveys to evaluate patient satisfaction of their national digital health system. The exemplar case study by the Kingdom of Saudi Arabia used measures to digital health, number of appointments, and patient satisfaction. The case studies by Italy and Argentina used researchers and software developer experts to evaluate patient experience levels of digital technologies in health care.

Case study 7 | Estonia

A report published in 2015 titled "Estonia eHealth Strategic Development Plan 2020" examined an eHealth strategy of Estonia. The strategy included measurements to evaluate several focus areas relating to developing healthcare e-services.

Participants, setting, and study design

The study used a literature review to evaluate the evidence to support the strategy. An eHealth task force was commissioned by the Government of Estonia. The taskforce included stakeholders from all over Estonia, including the health insurance sector, medical associations, hospital associations, the information technology sector, family doctor associations, the disability sector, the university and education sector, and the service industry sector.

Outcome measurements

Outcome measurements were related to development principles of healthcare e-services in Estonia. Focus areas included high-quality health information and data infrastructure, focus on persons and personal medicine, comprehensive case management and cooperation between organisations, and development of remote services. Under different focus areas, end-user experience measures included efficient user applications for data acquisition and data quality, development of digital data and information processing capabilities, empowerment of people and technology, development of personalised and user-focused e-services, effective decision-support solutions, and developing eHealth infrastructure for remote communities.

Conclusions and results

The literature review findings were approved at a cabinet meeting of the Estonian government on 3 December 2015.

Source: Government of the Republic of Estonia (2015) Estonian eHealth Strategic Development Plan 2020. URL: <u>https://www.sm.ee/sites/default/files/content-editors/sisekomm/e-</u> tervise strateegia 2020 15 en1.pdf

Case study 8 | Sweden

This case study evaluates nurse shift-to-shift handovers in an oncological inpatient setting. Person-centred handover (PCH) is a structured workflow involving shift-to-shift reports using EHRs between nursing staff and the patient.

Participants, setting, and study design

A cross-sectional study was conducted at the Department of Oncology, Karolinska University Hospital, Stockholm. In-patients with cancer received either the PCH intervention or non-verbal handover (standard care). Data was collected from September 2014 to May 2015 following the introduction of the PCH protocol.

Outcome measurements

Patient satisfaction questionnaires were used to measure the clinician's technical skills, interpersonal skills, information provision, and availability. Other factors include hospital staff interpersonal skills and information provision, exchange of information, and waiting time. Questionnaires also assessed hospital accessibility, comfort, and general satisfaction. Information on gender, age, length of stay, cohabitation, reasons for admission, and treatment intention was collected from the patient EHR.

Conclusions and results

Patient satisfaction was higher after receiving PCH intervention compared to patients in the control condition. The results suggest PCH intervention is feasible and it does not impact on oncology inpatient satisfaction.

Source: Kullberg A, Sharp L, Johansson H, Brandberg Y, Bergenmar M. Patient satisfaction after implementation of person-centred handover in oncological inpatient care–A cross-sectional study. PloS one. 2017 Apr 6;12(4):e0175397. URL: <u>https://doi.org/10.1371/journal.pone.017539</u>

6.5. DIGITAL HEALTH EFFICIENCY AND RETURN ON INVESTMENT

This benefits category describes whether digital healthcare resources are being used to get the best value for money. It examines the relationship between resource inputs (costs such as labour, capital and equipment) and either intermediate outputs (numbers treated, waiting times, etc.) or final health outcomes (lives saved, life years gained, etc.). Some examples of outcomes that may be measured to demonstrate greater efficiency include avoiding unnecessary tests or visits to healthcare services, saving time for clinicians in the delivery of health care, overall improvements in workforce productivity, economic growth, and innovation growth in the healthcare sector.



6.5.1. Academic and grey literature supporting digital health efficiency and return on investment (78 studies)

Simulation models and economic evaluation using secondary data were used to evaluate digital health efficiency. For instance, simulation methods were used to evaluate the cost per person using EHRs (72). Economic evaluation using trial data was used to evaluate the cost-effectiveness of EHRs (85). The report by the Organisation for Economic Cooperation and Development (OECD) used a literature review and secondary data analysis to evaluate HIT systems by measuring the adoption of medical technology, the balance of innovation value, access to pharmaceutical and medical devices, and the use of health data from technologies (60). Measurements included cost, innovation value, access to technology, and health data to evaluate digital health efficiency and return on investment for digital health.

Several countries used literature reviews to evaluate HIT and telehealth systems on digital health efficiency. In Australia, surveys and literature reviews were used to evaluate HIT and telehealth (including mHealth) systems to understand new models of care that will improve the efficiencies of different health systems across the world (68, 69). A systematic review published in Canada was used to evaluate telehealth systems for patients with heart failure to measure the cost-effectiveness of these systems on the health system and the impacts on patients/families (86). Overall, digital health efficiency was measured based on new models of care, and cost-effectiveness of digital health systems.

Interviews and surveys were used to evaluate the efficiency of digital health systems such as EHRs. For instance, interviews were used to evaluate the productivity of EHRs (43). Surveys on hospitals were used to evaluate the meaningful use of EHRs (87). Measures such as meaningful use and productivity were indicators for digital health efficiency and return on investment.

Mixed methods were used to evaluate the digital health efficiency and return on investment. The mixed method approach using interviews and surveys was used to evaluate the financial benefits of EMRs (88). Mixed method studies including longitudinal studies, data analysis, surveys and interviews were used across the United States, Italy and England to evaluate cost efficiencies (75, 88-90). Some of the measures include financial benefits, and the cost-effectiveness of digital health. Below is a summary of methods and associated measures used in the literature for digital health efficiency and return on investment.

Methods for digital health efficiency and return on investment:

- Simulation models and economic evaluation
- Literature reviews
- Interviews
- Surveys
- Longitudinal studies
- Data analysis

Measurements for digital health efficiency and return on investment:

- Avoiding unnecessary tests or visits to healthcare services
- Saving time for clinicians
- Overall improvements in workforce productivity
- Economic growth
- Innovation growth in the healthcare sector
- Adoption of medical technology
- Balance of innovation value
- Access to technology
- Cost-effectiveness of digital health systems
- Meaningful use of EHRs
- Financial benefits of EMRs

6.5.2. GDHP participant countries' support for digital health efficiency and return on investment (n = 16)

The qualitative analysis of the nominal group survey resulted in four outcome measures for digital health efficiency and return on investment. Of the four outcome measures, 12 ideas were generated by the group of GDHP participants. One GDHP participant considered digital health efficiency to be related to digital health efficacy.

"Much like efficacy, efficiency is a pillar of [X] that should also be applied to digital technologies to make informed decisions in a limited resource setting." [GDHP participant no. 4, 2019]

6.5.3. Reducing unnecessary cost as an outcome of digital health efficiency and return on investment

The majority of GDHP participant countries considered measuring the cost of delivering health care and managing healthcare resources to be outcomes in evaluating the benefits of digital health efficiency and return on investment. In particular, reducing unnecessary medical costs, better management of medical resources, and monitoring savings from digital health are all outcomes related to digital health efficiency and return on investment.

"It is critically important to measure (1) the cost of digital health tools and (2) potential cost savings associated with the use of these tools. However, because of the nature of the [X] health IT network, it is challenging to identify cost data and moreover connect the use of technology to potential cost savings." [GDHP participant no. 9, 2019]

"This aspect represents one of the main objectives of the digitalisation process happening in the healthcare sector. In other words, indicators on the better use of health resources, the increase in the efficiency of the health procedures and pathways and the reduction of the related cost, represent a focal point in the introduction of the digital health technologies." [GDHP participant no. 7, 2019]

"The introduction of digital health technology, which ultimately fails to help patients with treatment outcomes, leads to an increase in unnecessary medical costs. If benefits are provided for digital health that is not sufficiently validated, this could lead to a consumption of limited health insurance funds, which would make it more difficult to pay for essential medical practices." [GDHP participant no. 2, 2019]

6.5.4. Increased productivity as an outcome of digital health efficiency and return on investment

GDHP participant countries reported measuring productivity as an outcome in evaluating the benefits of digital health efficiency and return on investment. In particular, two GDHP country participants believed evaluating these measures may result in better investment and health system performance.

"Most significant area of early value in [X] experience, and efficiencies are important to demonstrate to drive further investment. It has also proven important to document efficiencies or productivity improvements to ensure they can be harvested and actually generate ROI [return on investment]." [GDHP participant no. 3, 2019]

"Cost of healthcare delivery (measure in terms of value) is one of the triple aims of [X] as an approach to optimising health system performance, and should be tracked as health systems go digital." [GDHP participant no. 10, 2019]

"Given that digital interventions replace otherwise labour-intensive model of care, one can expect it to replace costly healthcare professional time or hospital services." [GDHP participant no. 12, 2019]

6.5.5. Reducing unnecessary medication prescriptions as an outcome of digital health efficiency and return on investment

One of the GDHP countries reported that digital health technology should be evaluated on the basis of reducing unnecessary medication prescriptions. The decreases in duplicated drug prescription can result in efficient allocation of healthcare resources.

"For example, by making drug information visible among medical institutions, it is expected to reduce double dosing, which is considered to contribute to efficient allocation of medical resources, and efficiency could be a major factor that can improve the quality of medical services by promoting digital health." [GDHP participant no. 1, 2019]

6.5.6. Securing sponsorship as an outcome of digital health efficiency and return on investment

One of the GDHP countries reported that digital health efficiency and return on investment is important in terms of securing funding for future digital health initiatives. In particular, countries should be concerned about the financial sustainability of current digital health programs.

"We believe it is an important measure to secure sponsorship for certain digital health initiatives." [GDHP participant no. 14, 2019]

6.5.7. Case studies supporting digital health efficiency and return on investment

The exemplar case studies for the digital health efficiency and return on investment category reported on the evaluation of EMRs (Canada), interoperable health information exchange (the United States), the e-Prescription service (Estonia), and digital technology in health care (Italy). The case studies from the United States and Canada focused on evaluating their digital health systems on health providers and healthcare facilities, such as hospitals.

The case studies by Canada and the United States reported using a variety of methodologies, such as surveys, cost analysis and literature reviews. These case studies focused on measuring workflow efficiencies, physician-perceived impacts, cost benefits, and cost savings. The case studies by the United States evaluated specific costs, such as software licence fees, software maintenance fees, implementation fees, and transaction fees of hospitals. Interestingly, the case studies from Estonia evaluated efficiency by measuring the time savings of an e-Prescription service. Thus, the efficiencies led to the reduction of cost of medication to patients. Similarly, the case study by Italy measured reductions in duplicated visits to hospitals and treatments based on the evaluation of digital technologies.

Case study 9 | United States

A report published in the United States titled "Analyzing the public benefit attributable to interoperable Health Information Exchange" examined the development of a set of measurements and methods to quantify the public benefits of health information exchange.

Participants, setting, and study design

A literature review of the peer-reviewed and grey literature was conducted from 2009 to 2016. This included two rounds of phone conversations with subject matter experts.

Outcome measurements

Public benefit outcomes related to efficiency included start-up cost and shortterm efficiency measurements. Other measures included the utilisation cost of new technologies.

Conclusions and results

The report findings suggest significant data and methodological barriers when making links between the Health Information Exchange technology and outcomes.

Source: Blavin F, Ramos C, Lallemand NC, Fass J, Ozanich G, Adler-Milstein J. Analyzing the Public Benefit Attributable to Interoperable Health Information Exchange. Urban Institute, 2017. URL:

https://www.urban.org/sites/default/files/publication/97416/analyzingthepubli cbenefit 2001765 0.pdf

Case study 10 | New Zealand

The Minister of Health in New Zealand published a report on EHRs and EMRs policy in New Zealand.

Participants, setting, and study design

Case studies were used to evaluate a national policy on EHRs. As part of the review, New Zealand's health IT landscape was assessed in relation to the experience of implementing a digital health record in other countries.

Outcome measurements

As part of the analysis, the cost/benefits/risks of the current EHR approach versus moving towards a 'single' EHR approach were assessed.

Conclusions and results

Efficiency benefits were largely descriptive. For example, challenges of managing IT integration cost across different vendors, and the added financial cost to maintain legacy health IT systems.

Source: Deloitte New Zealand. Independent review of New Zealand's Electronic Health Records Strategy. 2015. URL: <u>https://www.health.govt.nz/publication/independent-review-new-zealands-</u> <u>electronic-health-record-strategy</u>

6.6. POPULATION HEALTH TRENDS AND SECONDARY USES

This benefits category describes the use of digital health services and technologies and their associated datasets for purposes that are beneficial to communities at a population level, as opposed to when a digital technology or service is used for the direct care of an individual. Big data analytics and the application of AI and machine learning to datasets in areas such as genomics and precision medicine are examples of secondary use that can benefit communities with particular conditions, or the broader population, as treatments can be tailored for specific cohorts of disease. The evaluation of the benefits of these emerging sciences may use measures at population or disease group level, such as reduced side effect profiles for medicines in the application of pharmacogenomics, improved life expectancy due to tailored cancer therapies through the application of precision or personalised medicine, or the preparedness of a country for an emergency response to a disease outbreak.

6.6.1. Academic and grey literature supporting population health trends and secondary uses (62 studies)

Case studies and literature reviews were used to evaluate different digital health systems. In New Zealand, case studies were used to evaluate EHRs in relation to monitoring trends and understanding the layout of the digital health ecosystem in the country (30). Internationally, case studies were used to assess multiple HIT systems on different types of secondary health data (32, 91). Similarly, a report by the World Economic Forum used multiple case studies, literature review, and secondary data analysis to evaluate the impacts of informatic algorithms on sharing and analysing outcome and other relevant information for each population segment (92). These case studies evaluated digital health systems, such as EHRs and algorithms for monitoring population health trends.

Questionnaires, interviews, and cross-sectional protocol-based testing was used to evaluate the impacts of digital health technologies in national, local and rural settings. In a report by African Strategies for Health (ASH) (93), interviews were used to evaluate the impacts of digital technologies, especially mHealth, across the African continent. These impacts include greater collaboration between governments and local organisations in Africa as a way to understand the impacts of digital technologies, such as mHealth. Rural experiences of mHealth applications were assessed via survey in Sudan (71) and the impacts of mHealth on attitudinal change were assessed via a control trial in Nigeria (18). In the United States, studies were undertaken to assess scenarios and patient willingness for their data to be used in a secondary manner – as well as the potential for secondary uses and issues relating to privacy – via questionnaires, interviews and cross-sectional protocol-based testing (89, 94, 95)

Other methods such as data extracted from medical records and stakeholder engagement were used to evaluate EHRs and complementing algorithms to improve treatment and prognosis of illnesses. Data extracted from medical records were used to assess an algorithm for EHRs to evaluate the accuracy of prognosis (96). Stakeholder engagement was used to assess EHRs and patient-reported outcomes (PROs) to evaluate the benefits of tailoring treatment (97). Overall, these methods were used in evaluating automation of existing digital health services. Below is a summary of methods and associated measurements used in the literature for population health trends and secondary uses.

Methods for population health trends and secondary uses:

- Literature reviews
- Interviews

56

- Cross-sectional protocol-based testing
- Questionnaires
- Data extracted from medical records

Measurements for population health trends and secondary uses:

- Better methods for monitoring population health trends
- Better understanding the layout of the health ecosystem
- Patient willingness for their data to be used in a secondary manner
- Issues relating to privacy
- Improving treatment and prognosis of illnesses
- Better evaluating the accuracy of prognosis
- Benefits of tailoring treatment

6.6.2. GDHP participant countries' support for population health trends and secondary uses (n = 16)

The qualitative analysis of the nominal group survey resulted in four outcome measures for population health trends and secondary uses. Of the four outcome measures, 20 ideas were generated by the group of GDHP participants. Generally, many of the GDHP participants agreed to include this category into the group of 'standard' benefits categories. In contrast to the other benefits categories, many of the GDHP participants were able to distinctly understand the difference between this category and other benefits categories.

"Understanding population health and secondary uses of EHR is critical to ensuring that we are building towards a learning health system. This is also important to understanding how health information technology advances health outcomes broadly." [GDHP participant no. 9, 2019]

"Population trends and secondary use of data are a little different than the other categories – perhaps they are applications of Digital Health, rather than impact of Digital Health. However, given the importance of this field, it does seem like it deserves inclusion in some form." [GDHP participant no. 4, 2019]

"Strongly agree. Improved access to information leads to increased efficiencies and cost reductions. Benchmarking leads to reductions in variations in care which leads to improved patient care etc. This benefits category and the health equity category are very similar." [GDHP participant no. 16, 2019]

6.6.3. Better genomics to contribute to population health trends and secondary uses

Genomics advances were important outcome measures for evaluating population health trends and secondary uses of digital health. Specifically, indicators of this category include development of advanced analytical tools, the development of new treatments for public health, and the discovery of new therapies.

"For example, it is thought that not only the genome information of a cancer patient can be used to treat the patient but also it can be accumulated to be useful for the development of a new treatment, and population trends and secondary uses could be a major factor that can improve the quality of medical services by promoting digital health." [GDHP participant no. 2, 2019] "The more data we collect, the better results for a given group of society we may have. However, we need to take into account that the concept of AI, machine learning and genomics analysis on gathered data sets is rather far-fetched, taking into consideration a systemic scale of operation. Furthermore, it requires development of very specific and advanced analytical tools and a functioning, well established national eHealth system in place." [GDHP participant no. 6, 2019]

6.6.4. Enhanced monitoring of disease and illness prevalence to monitor population health trends and secondary uses

Several GDHP participants commented on measuring better capabilities for monitoring the prevalence of disease and illness as outcomes of this category. These benefits may support detecting the health risks of a country's population, nationwide planning and policy decisions, and public health policies.

"The AI application on the database issued by the use of digital technologies represents another pillar of the effective application of these technologies to the health sector. The digital technologies should be considered as a continuous source of RWD [Real World Data] that enables the health authorities to better evaluate the different level of risks of the population, identifying the appropriate setting of services (form prevention to post-acute care) to offer to the patients." [GDHP participant no. 7, 2019]

"This should be measured because the use of standards for interoperability also allows for population level data to be harnessed to support nationwide planning and policy decisions." [GDHP participant no. 10, 2019]

6.6.5. Enhanced evidence-based decision making and policy

One of the GDHP participant countries believed the benefits of population health trends and secondary uses from digital health can improve evidence-based decision-making and policy implementation.

"Analytics that indicate health trends in the population and provide real-time feedback on health service delivery can be critical data for evidence-based decision-making and policy implementation. In the context of more than a billion data sets, having a bird's eye perspective of health metrics in a population can be the difference between a curative (yet reactive) and preventive health system." [GDHP participant no. 12, 2019]

6.6.6. Better emergency response to disease outbreaks

One of the GDHP participants stated the importance of measuring a country's emergency response to disease outbreaks. When evaluating digital health, the participant believed the benefits of public health messages should be evaluated based on the time needed to respond to any disease outbreak in a country.

"This is of outmost importance to [X] especially preparedness of a country for an emergency response to a disease outbreak including:

• during the Hajj to Mecca which is considered the world's largest human gathering with almost 2.4 million pilgrims in 2018 from all parts of the world visiting a very small geographic area for a very short time period approx. 5 days.

• Public health trends and alerts." [GDHP participant no. 5, 2019]

6.6.7. Case studies supporting population health trends and secondary uses

The exemplar case studies from Canada and Estonia focused on evaluating EMR and EHR systems; the case study from the United States evaluated the All of Us Research Program (All of Us) which is Health Level Seven International (HL7®)'s Fast Healthcare Interoperability Resources (FHIR®) genomics technology. The case study from the Kingdom of Saudi Arabia evaluated disaster management and ambulance monitoring systems using real-time dashboards. The case studies from Estonia and Italy evaluated machine learning algorithms and AI applications for health care. These evaluations were conducted on patients, clinics and hospitals, and regional citizens.

The case studies from Estonia measured the detection rates of patients with a diagnosis of familial hypercholesterolemia. Another case study evaluated prediction power of a machine learning algorithm on patients with acute eosinophilic asthma. The exemplar case study from the Kingdom of Saudi Arabia used measures such as immunisation coverage, communicable disease, hospital-acquired infections, and data quality of clinical reports. Prediction measures were used to evaluate AI applications in Italy. Search capabilities were used to evaluate the case studies in the United States.

Case study 11 | Kingdom of Saudi Arabia



The Government in the Kingdom of Saudi Arabia developed a series of real-time dashboards to monitor population trends of its citizens. These trends include the immunisation coverage of Hajj pilgrims at port of entry, immunisation coverage by geographical area, communicable disease by age, gender and region, hospital-acquired infections by microorganism, and data quality for all of the above report requirements.

Participants, setting, and study design

A case study was used to demonstrate the real-time use of population trends. The dashboards are used on all Hajj clinics and hospitals. They are evaluated in real-time.

Outcome measurements

Real-time dashboards are used to measure the number of visits by disease and clinical procedure. Outcome measurements include the number of clinic and hospital visits by disease or procedure during Hajj, resource utilisation status/numbers (operational numbers, for example, waiting times with alerts for any changes from the normal pattern and/or any suggestion of medical crisis, disaster management, and ambulance tracking and directing.

Conclusions and results

Real-time dashboards for emergency response have been in development, and they are regularly evaluated and monitored.

Source: Provided in the survey response by the Government of the Kingdom of Saudi Arabia, 2019.



6.7. DIGITAL HEALTH EQUITY

This benefits category relates to health equity, being the absence of avoidable, unfair or remediable differences among groups of people, whether those groups are defined socially, economically, demographically or geographically or by other means of stratification. Health equity implies that, ideally, everyone should have a fair opportunity to attain their full health potential and that no one should be disadvantaged from achieving this potential. Examples of measures that may be used here include access to digital health services among populations. Some of the variables that might be considered in contributing to digital health equity might include sociodemographic factors, such as place of residence, race/ethnicity/culture/language, occupation, gender, religion, education, disability, and socioeconomic status.

6.7.1. Academic and grey literature supporting digital health equity (25 studies)

Literature reviews and other methods were used to evaluate multiple digital health technologies on different disparate population groups. In Australia, literature reviews and interviews were used to evaluate HIT and accompanying digital health systems in relation to measuring various equity factors, such as health literacy and digital health literacy, remote and culturally diverse populations, populations with poor health outcomes, and equitable finance models (70). A literature review (98) and other studies (survey and interviews) (99-101) were used to assess the impacts of multiple digital health technologies (such as mHealth) on changes to health behaviours and engagement in disparate population groups. People with poorer health literacy, poorer health outcomes, low incomes, and who are from remote and culturally diverse populations were some measures that were considered in the evaluation of technologies under the digital health equity category.

Other approaches using multiple methods were used to evaluate digital health under this category. Multiple methods were used to evaluate EHRs to improve population with health disparities (102, 103). Furthermore, interviews and surveys were used to evaluate EHRs to improve rural health (63, 71). Similar methods were used to evaluate HIT and EHRs to improve access to health services (104, 105). While the methods of these studies were focused on EHRs, other digital health systems have also been evaluated.

Published literature using secondary data analysis was used to evaluate different eHealth systems. Conversely, a United States observational study assessed the impacts of belonging to a marginalised group and non-English language preference on eHealth registration (106). Internationally, secondary data analysis and surveys were used to evaluate medical devices (such as tools to diagnose, treat, and rehabilitate people living with illness or diseases) that measured various equity factors, such as the affordability of devices, adequate facilities and infrastructure in poorly resourced countries, sufficient regulation, sufficient workforce skills and expertise in devices, and sufficient amount of information available to citizens in poorly resourced countries (107). Overall, indicators for digital health equity included language preferences, affordability of devices, infrastructure, regulations, workforce skills, and literacy. Below is a summary of methods and associated measurements used in the literature for digital health equity.

Methods for digital health equity:

- Literature reviews
- Interviews
- Surveys
- Secondary data analysis

Measurements for digital health equity:

- Improving health literacy
- Better health outcome for remote and culturally diverse population
- Better health outcome for disadvantaged populations
- Equable finance models
- Better engagement in disparate population groups
- Better health outcome for low income communities
- Better access to health services
- Affordability of devices
- Better facilities and infrastructure in poorly resourced countries
- Improving regulation
- Improving workforce skills
- Increasing amount of information available to citizens in poorly resourced countries

6.7.2. GDHP participant countries' support for digital health equity (n = 16)

Qualitative analysis of the nominal group survey resulted in three outcome measures for digital health equity. Of the three outcome measures, 11 ideas were generated by the group of participants. There was some agreement to digital health equity being included in the agreed group of 'standard' benefits categories.

"Excellent topic to be included." [GDHP participant no. 3, 2019]

"We agree with this category. [X] current focus is on evaluation of Digital Health equity to healthcare facilities as we roll out the implementation of over 200 hospital information systems and 2,400 primary healthcare systems." [GDHP participant no. 5, 2019]

One GDHP country commented on the difficulties to see the difference between digital health equity and population health trends and secondary uses.

"This benefits category and the secondary uses category are very similar. If I had to choose one, I would choose this one." [GDHP participant no. 16, 2019]

6.7.3. Improving access to health care as an outcome of digital health equity

Several GDHP participant countries commented on measuring access to services as an outcome of digital health equity. This includes reducing barriers associated to access to health services and improving equal access to health services.

"For example, healthcare access is considered to be improved in on-line medical care, and equity could be a major factor that can improve the quality of medical services by promoting digital health." [GDHP participant no. 1, 2019]

"Excellent topic to be included. It is not sufficiently addressed in [X] framework. We include a component called 'access', which broadly speaks to improving access to care, but does not have a strong equity focus." [GDHP participant no. 3, 2019]

"On one hand, 'equity' is an important aspect of healthcare provision. On the other hand, digital health solutions by default aim to contribute to reducing social inequalities in health and removing the barriers of access to healthcare services. Therefore, a question should be raised whether it is necessary to additionally explore this particular aspect." [GDHP participant no. 6, 2019]

"It is important to understand the equity of digital health as a way of ensuring that the entire population has access to the health system, regardless of access to digital health, and to think of strategies to ensure access to digital health." [GDHP participant no. 14, 2019]

6.7.4. Better connectivity of health services as an outcome of digital health equity

GDHP participant countries reported on the connectivity of different health services as an indicator of digital health equity. This includes improving connectivity of multiple subsystems of health care as an outcome of achieving digital health equity.

"This aspect, connected to the previous one concerning the end user experience, represents another prerequisite for the general introduction of digital technologies. Indicators should be developed aimed at considering the interconnection among the different variables adopted in segmenting the population and the use of digital technologies. These technologies need an environment "ready" to accept and integrate them in the daily management of the citizens and the patients." [GDHP participant no. 7, 2019]

"This is an important category, especially in countries with private and public providers, the goal would be to ensure that all healthcare sub-systems can use the benefits of digital health tools." [GDHP participant no. 8, 2019]

6.7.5. Better digital health literacy as an outcome of digital health equity

One GDHP participant expressed the importance of measuring digital health literacy as an outcome of achieving digital health equity among all citizens. Addressing literacy may result in avoiding exacerbating inequities in healthcare delivery.

"... Numerous studies have demonstrated significant variety when it comes to digital health literacy and access to digital technologies, therefore it is not unreasonable to assume that the introduction of digital health technologies might exacerbate inequities in health care when not designed according to the reality on the ground. The opposite might also be true." [GDHP participant no. 4, 2019]

6.7.6. Case studies supporting digital health equity

The exemplar case studies from Canada focused on evaluating mHealth and telehealth. Case studies from Estonia and the United States evaluated health information technologies. These evaluations were conducted on healthcare facilities and hospitals.

Methods used by case studies from Canada, Estonia, and the United States measured a variety of outcomes, including number of facilities, nationwide interoperability, and exchanging information between partners. Many of the case studies conducted their evaluation regularly. Other countries have not yet conducted their evaluations on digital health equity.



Case study 12 | United Kingdom

The National Health Service (NHS) in the United Kingdom published a guide to digital inclusion aimed at local health and social care organisations to help them take practical steps to increase access to digital health services.

Participants, setting, and study design

A review of the literature helped inform the development of the guide which provides a range of resources which can help health providers take local action. The guide is targeted to commissioners of health and care services, including clinical groups.

Outcome measurements

Digital inclusion factors included improved digital skills, connectivity, and accessibility. Outcomes should also consider barriers to digital inclusion, such as access, confidence, skills, and motivation.

Conclusions and results

The guide described population groups who are at risk of digital exclusion – including older people, people in lower income groups, those without a job, in social housing, with disabilities or low education levels, people in rural areas, homeless people, and those from diverse language backgrounds. The guide also outlined strategies that can assist digital inclusion, such as widening digital participation, digital skills training, digital champions, intergenerational mentoring, assistive technologies, free public wi-fi, social prescribing, improving digital skills of staff, and raising awareness.

Source: National Health Service (NHS) United Kingdom Digital inclusion for health and social care – NHS Digital. 2019. URL: <u>https://digital.nhs.uk/about-nhs-digital/our-work/digital-inclusion</u>

7 KEY FINDINGS: GDHP RECOMMENDED STANDARD BENEFITS CATEGORIES

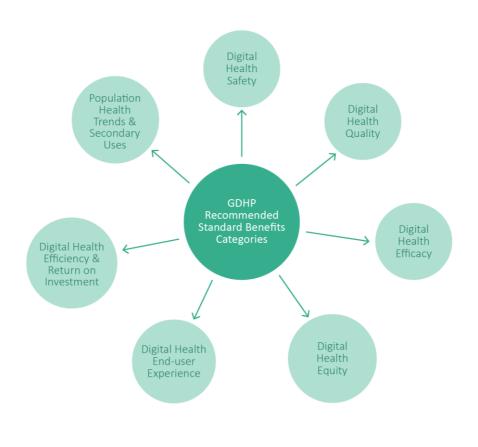


Figure 7: GDHP recommended standard benefits categories

The key findings suggest GDHP participant countries supported the inclusion of all seven standard benefits categories when undertaking the evaluation of digital health technologies and services. The literature review identified over 300 studies supporting each of the seven benefits categories of digital health. These were, in order of significance as rated by participants:

- 1. Digital health safety
- 2. Digital health quality
- 3. Digital health efficiency and return on investment
- 4. Digital health efficacy
- 5. Digital health end-user experience
- 6. Digital health equity
- 7. Population health trends and secondary uses

Additionally, the survey results demonstrated strong agreement to include most of the seven benefits categories into the global standard. Overall, the integrative results from

both studies showed that the evaluation of digital health technologies and services frequently included more than one or multiple overlapping benefits categories.

The report also outlined the methods and measurements that should be used to evaluate the benefits of safety, quality, efficacy, equity, improved end-user experience, efficiency and population health improvements, including health service planning, and other secondary uses of data. Depending on the purpose of the technology, countries should consider how the evaluation of their digital health technologies can impact one or more of the proposed standard benefits categories. This ensures the actual benefits of the technology are realised by governments and their citizens, and NGOs.

When looking to evaluate the benefits of digital health technologies, countries should consider aligning the use of these evaluation methods and measurements with the outcomes they wish to achieve with their digital health systems. In the report, GDHP participants outlined these outcomes across the seven benefits categories. For example, a digital health technology developed to prevent medication errors should deploy relevant methods and measurements, such as interviews that specifically measure medication and prescription errors. Essentially, countries that adopt these types of benefits standards will increase the robustness of the evidence for digital health technologies allowing for significant investments by different governments and multilateral funders.

8 MEASURING SUCCESS IN DIGITAL TRANSFORMATION

In order to guide countries in the use of the GDHP recommended standard benefits categories, a conceptual model was developed based on the synthesis of the findings from the literature review and nominal group survey of participant countries. The model was developed to help guide evaluation of digital health services by grouping benefits categories and measures with the key objective of an evaluation across three main areas: systematic change, adoption of services, and delivery of services.

8.1. A CONCEPTUAL MODEL OF DIGITAL HEALTH BENEFITS CATEGORIES

Figure 7 represents the conceptual model for each of the digital health benefits categories. The conceptual model is primarily based on the weight of evidence supporting each of the benefits categories, shown as individual clusters, and their ranking by GDHP participants.

The position of the benefits category circles along the horizontal (x-axis) continuum of the model relates to the rankings by GDHP participants. Benefits categories that are believed to be of high priority (with strong agreement among GDHP participants) were represented by the position of the clusters being placed further towards the right in the horizontal (x-axis) continuum. For instance, GDHP participants believed *safety* and *quality* benefits categories had the highest priority whereas *equity* and *population health trends* benefits categories had the lowest priority.

The size of the circle and its position in the vertical (y-axis) continuum for each cluster in the conceptual model was based on the weight of articles or quantum of evidence within each benefits category for the included studies within the literature review. Therefore, the largest (and highest in the vertical axis) benefits category circle was 'digital health efficacy', while the lowest (and smallest) representation was for the category of 'digital health ealth equity'.

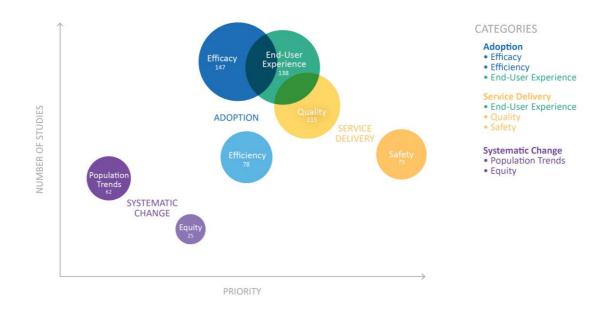


Figure 8: Conceptual model of digital health benefits categories

It is important to note that studies may have considered more than one benefits category and would therefore have been represented in more than one circle. While the majority of articles and evidence supported benefits categories for *quality*, *efficacy*, and *end-user experience* as seen by the size and position of their circles in the model, it should be noted that there were considerable overlaps in these areas – that is, articles simultaneously considered these benefits categories.

Therefore, in the final model, the distance between clusters and the position for each of the clusters in both the horizontal and vertical continuum of the conceptual model represent both their relative weight of evidence and the value or importance of these studies as rated by participants.

8.2. APPLYING STANDARD BENEFITS CATEGORIES FOR THE PURPOSE OF DIGITAL HEALTH EVALUATION

In addition to the representation of the weight of evidence from literature review, and the representation of priority as determined by the nominal group process that is provided by the size and position of clusters, this conceptual model adds a further element for the user – the **purpose of the evaluation** – to help guide those undertaking digital health evaluation in their consideration of which benefits categories and measures to prioritise. The key purpose or objectives of digital health evaluations that were included in the literature were considered across three main areas, as described below. Though not intended to be mutually exclusive, these three main themes for evaluation (service delivery, adoption and systematic change) are described here with the key benefits categories with which they were commonly associated in the literature:

 Service delivery: For many policy makers internationally, benefits categories (such as safety, quality, and end-user experience) were important to improving current practices in healthcare service delivery. Benefits categories for safety and quality were high priorities for most of the GDHP participant countries. Despite the smaller number of articles in support of the safety benefits category, there was high agreement for this benefits category to be included in

the standard across the different countries. While the evidence is not as strong compared to other categories, more investment in generating evidence on digital health safety and quality can occur internationally.

- 2. Adoption: This band of benefits categories (such as *efficacy, efficiency and return on investment,* and *end-user experience*) situated in the model can be related to how people adopt digital health in practice. These benefits categories were supported by many of the GDHP countries. While there was solid support for these categories, many of the GDHP participant countries also responded qualitatively on the difficulties in separating them as individual categories. This was also reflected in the number of articles in the literature review search.
- 3. Systematic change: Equity and population health trends and secondary uses categories will become important categories to measure systematic change of the healthcare system. Policy makers will require these outcomes to observe changes that digital health technology may bring. Also, observing the impact of systemic changes in equity and population health trends and secondary uses categories on the other categories (e.g., safety, quality) can inform policy makers. In the conceptual model, the proportion of the supporting articles and evidence was smaller than other benefits categories, especially those studies in the adoption band. Additionally, GDHP participant countries believed equity and population health trends categories were of a lower priority compared to other benefits categories.

For example, if the key purpose of an evaluation is to consider the success of the 'adoption' of a digital health technology or service, it would be important to prioritise the categories of *efficacy* and *efficiency and return on investment* when undertaking an evaluation. The examples of measures of these benefits categories can be further considered as outlined in chapter 5 of this report, 'Synthesis of the evidence: Supporting the measurement of standard benefits categories'.

9 RECOMMENDATIONS AND NEXT STEPS

This report outlines the evaluation methods, measurements and outcomes for seven benefits categories. It also provides a summary of the important (and most agreed upon) group of 'standard' benefits categories, and how these might be applied to digital health evaluation using a conceptual model.

A review of the literature and nominal group survey findings showed efficacy was the most investigated benefits category, equity was the least investigated benefits category, and safety and quality benefits categories were considered the highest priority among the GDHP participant countries.

Overall, the evidence suggests all benefits categories were interrelated, and all were considered to be of value for digital health evaluation.

To facilitate progress in the GDHP Evidence and Evaluation work stream, the following next steps are recommended:

1. Take a global approach to evidence building

The current work has developed practical guidance with an agreed set of benefits categories. Additionally, the report provides a list of outcome measures under each of the categories that GDHP countries have prioritised for use in their digital health evaluations. Next steps should attempt to accelerate the international adoption of these agreed standard benefits categories. This will facilitate international benefits comparisons and knowledge sharing among different GDHP countries, which is a core principle of GDHP.

2. Consider relative risk as a priority in digital health evaluation

When considering the positives and negatives of a digital health service and technology, countries should compare new innovations to the current state, rather than evaluating without reference to a real-world context. Therefore, evaluation of digital health technologies should ask questions relating to health outcomes or increasing benefits and compare these to current health service delivery. Ultimately, GDHP countries should take a pragmatic approach to improving health services.

3. Harness lessons learnt by others

As a priority, GDHP countries should continue to capture lessons learnt from countries that are more progressed in digital maturity. Lessons should include both successes and failures on the implementation of digital health in any given setting. This may also consider practices where training and preparation is required and how this might be customised to be implemented in different country contexts. When understanding failures, GDHP countries should be given support earlier in the process of their digital transformation. Sharing the experiences of other countries can help others learn from and avoid costly implementations, which have previously been shown not to work.

4. Evolve the work stream; move towards 'Evidence Translation and Implementation'

To date, this report has developed a shared understanding of frameworks,

methods, and benefits categories with practical guidance on outcome measurements for GDHP countries to apply when undertaking evaluation of digital health services. Next steps for the Evidence and Evaluation work stream should address GDHP priorities. These priorities should relate to the translation of evidence, and to considering practical ways of applying evidence in practice with a focus on key issues from other work streams (for example, citizen access to personal health information).

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11 APPENDIX A: EVIDENCE AND EVALUATION SURVEY

Below is a list of known benefits categories identified by our previous research. As you move through the questionnaire, the focus of these categories is on essential beneficial outcomes that a digital health service will deliver. So far, we have identified seven benefits categories;

- 1. Digital health safety
- 2. Digital health quality
- 3. Digital health efficacy
- 4. Digital health end-user experience
- 5. Digital health efficiency and return on investment
- 6. Population health trends and secondary uses
- 7. Digital health equity

If you have further suggested benefits categories that are not included in the current list, please provide additional categories in the last question of the survey.

For each benefits category, please rate the level of agreement as to their appropriateness to be included in our GDHP recommended 'standard' benefits categories. Use the 5-point scale, where;

- 1 = Strongly disagree with this category being included in the standard
- 3 = Neither agree nor disagree
- 5 = Strongly agree with this category being included in the standard

There are additional questions to provide more comments.

01 Digital Health Safety

This benefits category describes both improvements or threats to patient safety associated with the use of digital health services, and includes outcome measures such as medication errors, other avoidable adverse events, and data quality improvements. Process measures may include communication errors, or software and hardware problems.

Using the 5-point scale, please tell us how much you agree with the appropriateness of including '*digital health safety*' as part of the recommended group of 'standard' benefits categories.

Strongly disagree				Strongly agree
1	2	3	4	5

Please provide a reason for why you believe 'digital health safety evaluation' will be appropriate (or not appropriate) to be included into the agreed group of 'standard' benefits categories?

Please provide your experience of using digital health safety evaluation in context.

If possible, please provide details of an example, including (where relevant);

- What was the digital service that was evaluated and what was the problem it was trying to solve?
- Who was evaluated?
- How was the evaluation undertaken, (such as the methods and <u>outcome measures or</u> <u>process measures</u> that were used)?
- When was the evaluation done in the course of implementing the digital health product or service?

If there are relevant resources such as journal articles or online resources that describe your example, please include these in your response.

02 Digital Health Quality

This benefits category describes the quality of health care services using digital health, such as potential quality concerns of services, service areas that need further study and investigation, and changes in service quality over time. Benefits categories include standardised, evidence-based measurements that can be used with available hospital inpatient administrative data to measure and track clinical performance and outcomes. Outcome measurements may include preventive, inpatient, patient safety, and paediatric quality indicators.

Using the 5-point scale, please tell us how much you agree with the appropriateness of including '*digital health quality*' as part of the recommended group of 'standard' benefits categories.

Strongly disagree				Strongly agree
1	2	3	4	5

Please provide a reason for why you believe '*digital health quality*' will be appropriate (or not appropriate) to be included into the recommended group of 'standard' benefits categories?

Please provide your experience of using digital health quality evaluation in context.

If possible, please provide details of an example, including (where relevant);

- What was the digital service that was evaluated and what was the problem it was trying to solve?
- Who was evaluated?
- How was the evaluation undertaken, (such as the methods and <u>outcome measures or</u> <u>process measures</u> that were used)?
- When was the evaluation done in the course of implementing the digital health product or service?

If there are relevant resources such as journal articles or online resources that describe your example, please include these in your response.

03 Digital Health Efficacy

This benefits category describes the effectiveness of a digital health product or service, such as whether or not it produces the desired outcomes it was designed to deliver. Outcome measures may include improved health status indicators, such as weight reduction for people with obesity, better HbA1c control in people with diabetes, and a better understanding of how to follow health care advice or improved health literacy. A process measure may be improving the quantity or frequency of reminders and recalls for preventive health interventions or other improved processes in healthcare delivery.

Using the 5-point scale, please tell us how much you agree with the appropriateness of including '*digital health efficacy*' as part of the recommended group of 'standard' benefits categories.

Strongly disagree				Strongly agree
1	2	3	4	5

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Please provide a reason for why you believe '*digital health efficacy*' will be appropriate (or not appropriate) to be included into the recommended group of 'standard' benefits categories?

Please provide your experience of using digital health efficacy evaluation in context.

If possible, please provide details of an example, including (where relevant);

- What was the digital service that was evaluated and what was the problem it was trying to solve?
- Who was evaluated?
- How was the evaluation undertaken, (such as the methods and <u>outcome measures or</u> <u>process measures</u> that were used)?
- When was the evaluation done in the course of implementing the digital health product or service?

If there are relevant resources such as journal articles or online resources that describe your example, please include these in your response.

04 Digital Health End-User Experience

This benefits category describes the experience of the end-user as they interact with a digital health technology or service. Outcome measures may include satisfaction with the design of a digital health interface or other heuristic evaluation measures, such as the match between the system and the real world. Digital health end-users may include consumers, patients, and clinicians. Other health care stakeholders also include end-users not directly involved in health care delivery, such as health care administrators, digital health designers, policy makers, and researchers.

Using the 5-point scale, please tell us how much you agree with the appropriateness of including '*digital health end-user experience*' as part of the recommended group of 'standard' benefits categories.

Strongly disagree				Strongly agree
1	2	3	4	5

Please provide a reason for why you believe 'digital health end-user evaluation' will be appropriate (or not appropriate) to be included into the recommended group of 'standard' benefits categories?

Please provide your experience of using digital health end-user evaluation in context.

If possible, please provide details of an example, including (where relevant);

- What was the digital service that was evaluated and what was the problem it was trying to solve?
- Who was evaluated?
- How was the evaluation undertaken, (such as the methods and <u>outcome measures or</u> <u>process measures</u> that were used)?
- When was the evaluation done in the course of implementing the digital health product or service?

If there are relevant resources such as journal articles or online resources that describe your example, please include these in your response.

05 Digital Health efficiency and return on investment (ROI)

This benefits category describes whether digital healthcare resources are being used to get the best value for money. It examines the relationship between resource inputs (costs, such as labour, capital and equipment) and either intermediate outputs (numbers treated, waiting times etc) or final health outcomes (lives saved, life years gained, etc). Some examples of outcomes that may be measured to demonstrate greater efficiency include avoiding unnecessary tests or visits to healthcare services, saving time for clinicians in health care delivery, overall improvements in workforce productivity, economic growth, and innovation growth in the health care sector.

Using the 5-point scale, please tell us how much you agree with the appropriateness of including '*digital health efficiency and ROI*' as part of the recommended group of 'standard' benefits categories.

Strongly disagree				Strongly agree
1	2	3	4	5

Please provide a reason for why you believe '*digital health efficiency and ROI evaluation*' will be appropriate (or not appropriate) to be included into the recommended group of 'standard' benefits categories?

Please provide your experience of using digital health efficacy and ROI evaluation in context.

If possible, please provide details of an example, including (where relevant);

- What was the digital service that was evaluated and what was the problem it was trying to solve?
- Who was evaluated?
- How was the evaluation undertaken, (such as the methods and <u>outcome measures or</u> <u>process measures</u> that were used)?
- When was the evaluation done in the course of implementing the digital health product or service?

If there are relevant resources such as journal articles or online resources that describe your example, please include these in your response.

06 Population Trends and Secondary Uses

This benefits category describes the use of digital health services and technologies and their associated datasets for purposes that are beneficial to communities at a population level, as opposed to when a digital technology or service is used for the direct care of an individual. Big data analytics and the application of AI and machine learning to datasets in areas such as genomics and precision medicine are examples of secondary use that can benefit communities with particular conditions, or the broader population as treatments can be tailored for specific cohorts of disease. The evaluation of the benefits of these emerging sciences may use outcomes at population or disease group level, such as reduced side effect profiles for medicines in the application of pharmacogenomics, improved life expectancy due to tailored cancer therapies through the application of precision or personalised medicine, or the preparedness of a country for an emergency response to a disease outbreak.

Using the 5-point scale, please tell us how much you agree with the appropriateness of including '*population trends and secondary uses*' as part of the recommended group of 'standard' benefits categories.

Strongly disagree		Strongly agree		
1	2	3	4	5

Please provide a reason for why you believe '*population trends and secondary use evaluation*' will be appropriate (or not appropriate) to be included into the recommended group of 'standard' benefits categories?

Please provide your experience of using population trends and secondary use evaluation in context.

If possible, please provide details of an example, including (where relevant);

- What was the digital service that was evaluated and what was the problem it was trying to solve?
- Who was evaluated?
- How was the evaluation undertaken, (such as the methods and <u>outcome measures or</u> <u>process measures</u> that were used)?
- When was the evaluation done in the course of implementing the digital health product or service?

If there are relevant resources such as journal articles or online resources that describe your example, please include these in your response.

07 Digital Health Equity

This benefits category relates to health equity, being the absence of avoidable, unfair or remediable differences amongst groups of people, whether those groups are defined socially, economically, demographically or geographically or by other means of stratification. Health equity implies that ideally everyone should have a fair opportunity to attain their full health potential and that no one should be disadvantaged from achieving this potential. Examples of outcome measures that may be used here could include access to digital health services amongst populations. Some of the variables that might be considered in contributing to digital health equity might include sociodemographic factors, such as place of residence, race/ethnicity/culture/language, occupation, gender, religion, education, disability, and socioeconomic status.

Using the 5-point scale, please tell us how much you agree with the appropriateness of including '*digital health equity*' as part of the recommended group of 'standard' benefits categories.

Strongly disagree			Strongly agree	
1	2	3	4	5

Please provide a reason for why you believe '*digital health equity evaluation*' will be appropriate (or not appropriate) to be included into the recommended group of 'standard' benefits categories?

Please provide your experience of using digital health equity evaluation in context.

If possible, please provide details of an example, including (where relevant);

- What was the digital service that was evaluated and what was the problem it was trying to solve?
- Who was evaluated?
- How was the evaluation undertaken, (such as the methods and <u>outcome measures or</u> <u>process measures</u> that were used)?
- When was the evaluation done in the course of implementing the digital health product or service?

If there are relevant resources such as journal articles or online resources that describe your example, please include these in your response

Prioritising Benefits Categories

For the seven benefits categories presented, please number these from 1 to 7 in order of priority when evaluating a digital health service or technology.

Benefits category	Order of priority (please number 1 to 7)
Digital health safety	

Benefits category	Order of priority (please number 1 to 7)
Digital health quality	
Digital health efficacy	
Digital health end-user experience	
Digital health efficiency and return on investment	
Population trends and secondary uses relating to digital health	
Digital health equity	

Please provide any additional comments relating to your prioritisation of these benefits and categories. For example, are there health priorities or other issues in your country that may influence your perspective?

Additional benefits categories

Please provide any missing or additional benefits categories that you believe is important to be included in our recommendations, and if possible please include some context or examples to support your suggestion.

12 APPENDIX B: LIST OF GDHP COUNTRIES AND REVIEW OF ORGANISATION WEBSITES

Organisation	Website	Country	English?	Search terms used ¹	Search results	ltems for review
Ministry of Health	<u>https://www.arg</u> <u>entina.gob.ar/sal</u> <u>ud</u>	Argentina	No	General review	0	0
Australian Digital Health Agency	<u>https://www.digi</u> <u>talhealth.gov.au/</u>	Australia	Yes	Digital health, eHealth, evaluation	39	5
Federal Ministry of Health and Women's Affairs	https://www.sozi alministerium.at /en.html. https://www.sozi alministerium.at /Themen/Gesun dheit/eHealth.ht ml	Austria	Yes	General review	0	0
Ministry of Health, Cabinet of the Minister, Office for International Affairs	<u>http://www.saud</u> e.gov.br/	Brazil	No	General review	0	0
Canada Health Infoway	<u>https://www.inf</u> <u>oway-</u> inforoute.ca/en/	Canada	Yes	Digital health, eHealth, evaluation	160	9

¹ Terms may vary due to search systems.

Organisation	Website	Country	English?	Search terms used ¹	Search results	ltems for review
Ministry of Health	<u>https://www.min</u> <u>sal.cl/</u>	Chile	No	General review	0	0
Hong Kong Hospital Authority, Food and Health Bureau and Department of Health	<u>https://www.fhb</u> .gov.hk/en/index .html	Hong Kong SAR	Yes	General review	47	0
Ministry of Health and Family Welfare	<u>https://mohfw.go</u> <u>v.in/</u>	India	Yes	General review	6	1
Ministry of Health	<u>http://www.kem</u> <u>kes.go.id/</u>	Indonesia	Yes	General review	0	0
Ministry of Health	<u>http://www.salut</u> e.gov.it/portale/h ome.html	Italy	No	General review	0	0
eHealth, Ministry of Social Affairs	<u>https://www.sm.</u> <u>ee/en/e-health</u>	Estonia	Yes	General review	0	1
Ministry of Health, Labour and Welfare	<u>https://www.mhl</u> w.go.jp/english/	Japan	Yes	General review	176	0
Ministry of Health	<u>https://www.hea</u> <u>lth.govt.nz/</u>	New Zealand	Yes	Digital health, eHealth, evaluation	3	2

Organisation	Website	Country	English?	Search terms used ¹	Search results	ltems for review
Ministry of Health, Welfare and Sport	https://www.gov ernment.nl/minis tries/ministry-of- health-welfare- and-sport	Netherlan ds	Yes	Digital health, eHealth, evaluation	3	0
Ministry of Health	<u>https://www.gov</u> <u>.pl/web/zdrowie</u> _	Poland	No	General review	0	0
Shared Services of the Ministry of Health	<u>https://spms.min-</u> <u>saude.pt/</u>	Portugal	No	General review	0	0
National Health Information Center	<u>https://nhic.gov.</u> <u>sa/en/Pages/def</u> <u>ault.aspx</u>	Kingdom of Saudi Arabia	Yes	General review	0	0
Integrated Health Information Systems	<u>https://www.ihis.</u> <u>com.sg/</u>	Singapore	Yes	General review	8	0
Health Information Standardizati on Department, Social Security Information Service (SSIS)	<u>http://www.ssis.</u> or.kr/eng/index. do	Republic of Korea	Yes	General review	0	0

Organisation	Website	Country	English?	Search terms used ¹	Search results	ltems for review
eHalsomyndi gheten (the Swedish eHealth Agency)	<u>https://www.ehal</u> <u>somyndigheten.s</u> <u>e/</u>	Sweden	Yes	General review	0	0
NHS Digital, NHS England and Department of Health and Social Care	<u>https://digital.nh</u> <u>s.uk/</u>	UK	Yes	Digital health, eHealth, evaluation	122	5
Ministry of Health	<u>http://moz.gov.u</u> <u>a/</u>	Ukraine	Yes	General review	0	0
Department of Health and Human Services	<u>https://www.hhs</u> .gov/	USA	Yes	General review	55	0
Office of the National Coordinator and Chief Technology Officer's office in the Department of Health and Human Services	https://www.heal thit.gov/	USA	Yes	Digital health, eHealth, evaluation	45	2
Ministry of Public Health	<u>https://www.gub</u> .uy/ministerio- salud-publica/	Uruguay	No	General review	0	0
AGESIC	<u>https://www.ages</u> <u>ic.gub.uy/</u>	Uruguay	Yes	General review	5	0

Organisation	Website	Country	English?	Search terms used ¹	Search results	ltems for review
WHO	<u>https://www.wh</u> <u>o.int/</u>	Worldwid e	Yes	Digital health, eHealth, evaluation	449	30

13 APPENDIX C: SEARCH TERMS USED IN THE RAPID REVIEW

The following search terms were used for the rapid review of the literature.

(*) = wildcard

Digital Health

- "digital health"
- "digital medicine"
- "electronic health"
- "ehealth"

Measure

- measur*
- "proxy outcome*" ∖
- "proxy measur*"
- benef*
- evaluat*
- assess*
- realis*
- realiz*

Benefit: The benefit terms are based on the benefits categories as follows:

- Safety: safe*
- Quality: quality
- Efficacy: efficacy
- End-user experience: "end-user" experience or "consumer experience" or "patient* experience"
- Efficiency and return on investment: efficien* AND "return on investment" OR "economic growth" OR productiv*
- Population health trends and secondary uses: "population trend*" OR "secondary use*" OR "big data" OR "data base" OR "machine learning" OR "artificial intelligence" OR genom*
- Equity: equity

The following academic sources used the below search terms:

Academic search term = Digital health terms AND Measure terms AND Benefit

For example, for *digital health safety* we search:

("digital health" or "digital medicine" or "electronic health" or "ehealth") AND (safe*) AND (measur* OR "proxy outcome*" OR "proxy measur*" OR benef* OR evaluat* OR assess* OR realis* OR realiz*)

14 APPENDIX D: DEFINITIONS OF BENEFITS EVALUATION AND MEASUREMENT CONCEPTS FOR DIGITAL HEALTH

Terms	Definitions
Evaluation	The systematic and objective assessment of an ongoing or completed project, program or policy, its design, implementation and results. The aim is to determine the relevance and fulfilment of objectives, development efficiency, effectiveness, impact and sustainability.
Benefit	A measurable improvement or change resulting from an outcome perceived as important by one or more stakeholders which may include quality, access and productivity outcomes. Measurement of benefits may be used to justify both initial and ongoing investment in digital health technologies and services by government.
Benefits measurement	The process of identifying, defining, tracking, realising and optimising the benefits delivered by business investment.
Benefits evaluation	Examines the degree to which target benefits have been achieved and lessons learnt from implementation and rollout.
Economic evaluation	Aims to determine a probable value for money from an investment.
Effectiveness	The ability of a digital health intervention to achieve the intended results in a non-research (uncontrolled) setting.
Efficacy	The ability of a digital health intervention to achieve the intended results in a research (controlled) setting.
Feasibility	The ability of a digital health system to work as intended in a given context.
Financial evaluation	Deals with whether the organisation and digital health users can afford the digital health system, and how it will be financed.

Terms	Definitions
Impact evaluations	Studies that aim to assess the effect the intervention has on outcomes and the impact on the intended beneficiaries or clients. These evaluations require a counterfactual and draw on data generated internally (that is, inputs, processes and outputs) as well as data on outcomes external to the project.
Implementation research	Research that seeks to understand and work in real-world or usual practice settings, paying particular attention to the audience that will use the research, the context in which implementation occurs, and the factors that influence implementation.
Usability	The degree to which a product or system can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use.



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