

Refinement and Prioritisation of Key Performance Indicators for Digital Health Interventions Using Consensus Methodology

Catherine McCabe, Leona Connolly, Yuri Quintana, Arielle Weir, Anne Moen, Martin Ingvar, Koen Nauwelaerts, Margaret McCann, Carmel Doyle, Mary Hughes, Maria Brenner

Submitted to: Journal of Medical Internet Research
on: November 13, 2024

Disclaimer: © The authors. All rights reserved. This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on its website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressly prohibit redistribution of this draft paper other than for review purposes.

Table of Contents

Original Manuscript..... 5

Supplementary Files..... 28

 Figures 29

 Figure 1..... 30

 Figure 2..... 31

Refinement and Prioritisation of Key Performance Indicators for Digital Health Interventions Using Consensus Methodology

Catherine McCabe¹; Leona Connolly¹; Yuri Quintana²; Arielle Weir¹; Anne Moen³; Martin Ingvar⁴; Koen Nauwelaerts⁵; Margaret McCann¹; Carmel Doyle¹; Mary Hughes¹; Maria Brenner⁶

¹ Trinity College Dublin Dublin IE

² Beth Israel Deaconess Hospital Harvard Medical School Plymouth US

³ University of Oslo Oslo NO

⁴ Karolinska Institutet Stockholm SE

⁵ Bayer (Belgium) Diegem BE

⁶ University College Dublin Dublin IE

Corresponding Author:

Catherine McCabe

Trinity College Dublin

D'Olier street

Dublin

IE

Abstract

Digital health interventions (DHI's) have the potential to improve health care and health promotion. However, there is a lack of guidance in the literature for the development, refinement, and prioritisation of Key Performance Indicators (KPI's) for evaluation of DHI's. This paper presents a 4-stage process used in the Gravitate Health project based on stakeholder consultation and consensus for this purpose.

The Gravitate Health consortium comprises private and public partners from across Europe and the U.S, which is developing innovative digital health solutions in the form of Federated Open-Source Platform (FOSP) and G-Lens®, to present users with individualised digital information about their medicines. The 1st stage was the consultative process for the development of the KPI's involved stakeholder (Gravitate Health project leads) consultations at the planning stages of the project which resulted in an extensive list of KPI's organised into 7 categories. The 2nd stage was conducting a scoping review which confirmed the need for extensive stakeholder consultation in all stages of the KPI development, refinement, and prioritisation process. The 3rd stage was a period of further consultation with all consortium members which resulted in the elimination of 1 category of KPI's. The 4th stage involved using the Delphi technique for refining and prioritising the remaining 6 categories of KPI's. It is unusual to use this in a non-research exercise, but it provided a clear consultative framework and structure that facilitated the achievement of consensus within a large consortium of 250 members, on a substantial list of KPI's for the project. Consortium members ranked the relevance and importance of each KPI. The final list of KPI's provides substantial indicators sensitive to the needs of a broad group of stakeholders that are being used to capture real-world data in developing and evaluating DHI's.

(JMIR Preprints 13/11/2024:68757)

DOI: <https://doi.org/10.2196/preprints.68757>

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

Please make my preprint PDF available to anyone at any time (recommended).

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.

Only make the preprint title and abstract visible.

✓ **No, I do not wish to publish my submitted manuscript as a preprint.**

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain visible to all users.

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <http://www.jmir.org/preprint/68757>, I will be able to make my manuscript PDF available to anyone. No. Please do not make my accepted manuscript PDF available to anyone.



Original Manuscript

Refinement and Prioritisation of Key Performance Indicators for Digital Health Interventions Using Consensus Methodology

Catherine McCabe¹, Leona Connolly¹, Yuri Quintana²; Arielle Weir ¹, Anne Moen³; Martin Ingvar⁴; Koen Nauwelaerts⁵, Margaret McCann¹, Carmel Doyle¹; Mary Hughes¹, Maria Brenner⁶.

¹School of Nursing and Midwifery, Trinity College Dublin; Dublin, Ireland

²Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, Massachusetts, USA

³Institute for Health and Society, Faculty of Medicine, University of Oslo; Oslo, Norway

⁴Integrative Medicine, Karolinska Institute; Stockholm, Sweden

⁵Bayer; Berlin, Germany

⁶School of Nursing, Midwifery and Health Systems, University College Dublin; Dublin, Ireland

***Corresponding author:**

Professor Catherine McCabe

Email: CAMCCABE@tcd.ie

Keywords: Digital Health Interventions, Key Performance Indicators, Delphi Technique, Consensus methodology, Drug related side effects and adverse reactions, referral, and consultation.

Refinement and Prioritisation of Key Performance Indicators for Digital Health Interventions Using Consensus Methodology:

ABSTRACT

Digital health interventions (DHI's) have the potential to improve health care and health promotion. However, there is a lack of guidance in the literature for the development, refinement, and prioritisation of Key Performance Indicators (KPI's) for evaluation of DHI's. This paper presents a

4-stage process used in the Gravitare Health project based on stakeholder consultation and consensus for this purpose.

The Gravitare Health consortium which comprises private and public partners from across Europe and the U.S, is developing innovative digital health solutions in the form of Federated Open-Source Platform (FOSP) and G-Lens®, to present users with individualised digital information about their medicines. The 1st stage was the consultative process for the development of the KPI's involved stakeholder (Gravitare Health project leads) consultations at the planning stages of the project which resulted in an extensive list of KPI's organised into 7 categories. The 2nd stage was conducting a scoping review which confirmed the need for extensive stakeholder consultation in all stages of the KPI development, refinement, and prioritisation process. The 3rd stage was a period of further consultation with all consortium members which resulted in the elimination of 1 category of KPI's. The 4th stage involved using the Delphi technique for refining and prioritising the remaining 6 categories of KPI's. It is unusual to use this methodology in a non-research exercise, but it provided a clear consultative framework and structure that facilitated the achievement of consensus within a large consortium of 250 members, on a substantial list of KPI's for the project. Consortium members ranked the relevance and importance of each KPI. The final list of KPI's provides substantial indicators sensitive to the needs of a broad group of stakeholders that are being used to capture real-world data in developing and evaluating DHI's.

Keywords: Digital Health Interventions, Key Performance Indicators, Delphi Technique, Consensus methodology, Drug related side effects and adverse reactions, referral, and consultation.

INTRODUCTION

Recent advancements in digital technology have enhanced many aspects of health care, allowing for digital monitoring, and support of health-related behaviours and enabling communication. [1] One way this has been achieved is through the use of digital health interventions (DHI's) which have the potential to improve health care through illness prevention and health promotion. [2, 3] DHI's are defined as a “discrete functionality of digital technology designed to improve health system processes in order to achieve health sector objectives”(p25). [4] For example, DHI's may help facilitate tailored health solutions such as providing targeted support and education, and enhancing treatment adherence [5] while reducing the burden on healthcare providers where time and resources are already limited. [6] However evidence regarding the efficacy of DHIs to improve health outcomes has been mixed. [7, 8]

The Gravitate Health consortium comprises private and public partners from across Europe and the U.S, drawing on expertise from within academia and research institutes, knowledge transfer experts, European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Innovative Medicines Initiative 2 (IMI2) partners, health care providers and payers, patient organisations and consumer groups, regulators and product information providers and the digital technology industry. Gravitate-Health is developing innovative solutions in the form of Federated Open-Source Platform (FOSP) and G-lens® which is an app (App), to present users with individualised digital information about their medicines which is adapted to their personal needs and context. These solutions will access the Electronic Product Information (ePI) for each medicine that users are taking. It will use additional health data such as a personalised Patient Summary to focus and highlight the most personally relevant content from the ePI. The intended use of the Gravitate-Health solutions is to enable users to understand their medicines in an individualised way, for example, understand why they are taking each medicine, what effects to anticipate, what precautions to take whilst consuming the medicine and how best to follow recommendations and adhere to their ongoing treatment. It is

anticipated that by being informed, users will better adhere to their medication schedule which will lead to better health outcomes, fewer complications and reduce healthcare utilisation.

The Gravitare-Health project work plan will see these solutions deployed and scaled across four demonstration sites using key performance indicators (KPI's) as a baseline for evaluation. KPI's are measures or variables that provide a means of observing and optimising achievement and reflect changes connected to performance. [9, 10] They deliver relevant information to stakeholders regarding the progress and sustainability of complex interventions. [11] One issue with selecting KPI's for the evaluation of innovative DHI's is that there is a lack of evidence for relevant performance indicators. This is because DHI's are by their very nature new and therefore have not previously been assessed. A recent scoping review by Brenner et al (2023) concluded that there is a lack of evidence for a standardised approach to development and prioritisation of KPI's for DHI's. This paper highlighted that although most studies recognised and included the input of key stakeholders as a starting point for identifying potential KPI's, a common, rigorous process for the development and prioritisation of KPI's for innovative DHI's is needed.[12] This paper addresses this lack of guidance within the literature for developing relevant KPI's for meaningful evaluation by presenting a novel use of the well-established Delphi technique as a process for refining and prioritising KPI's for novel digital health interventions.

METHODS

Process for refinement and prioritisation of KPI's

Three potential approaches were considered as potentially suitable process refining and prioritising the KPI's for evaluation in this project. The main criteria for consideration was the need for a process that would include all key stakeholders in coming to a consensus in refining and prioritising KPI's. These were 1. the Sheffield Elicitation Framework[13], 2. a factorial survey approach [14], or

3. the Delphi technique [15]. The Sheffield Elicitation Framework and factorial survey approach rely on having a clearly defined group, and a limited, strong evidence-based list of KPI's. therefore, neither were regarded as appropriate due to the uniqueness of the Gravitare Health solutions and subsequent absence of supporting evidence. The list of KPI's for this project was produced at the outset of the project by key stakeholders based on their expertise/role in the project and reflected their aspirations for the digital solutions developed by the Gravitare-Health project. Due to the novel nature of the solutions, the list of KPI's identified was lengthy and were not evidence based. This meant that further refinement and prioritisation of the KPI's was required at a more advanced stage of the project and needed to include all consortium members.

The Delphi technique was regarded as the most appropriate method to achieve consensus across all stakeholders in terms of refining and prioritising the KPI's for evaluation of the Gravitare-Health digital solutions. This technique, developed by Dalkey and Helmer (1963), is a widely accepted process commonly used in research studies for converging opinions on a specific topic from experts within the discipline. [15, 16] The Delphi technique is a systematic and interactive approach in research that involves a panel of experts coming together to share information and experience in order to achieve consensus as an outcome. [17, 18] Consensus was an essential feature of refining and prioritising the existing KPI list in the Gravitare-Health project, therefore, using the Delphi technique as a consultative process rather than a research methodology provided a structured and rigorous framework to achieve this.

Development of initial KPI's and evaluation

Based on the initial anticipated impact of the Gravitare-Health Digital solutions, a preliminary list of KPI's was created and classified according to anticipated areas of impact, during a face-to-face informal brainstorming session by key stakeholders when the initial grant proposal was being prepared. This key stakeholder group comprised early Consortium members representing medicine,

patient representative groups, academia, technology, and pharmaceutical industry. The areas of expected impact of the KPI's included: access and use; understanding; user experience; patient compliance/adherence; two-way communication; and risk minimisation. This classification of the KPI's and allocation of percentage thresholds for the achievement of these KPI's were based on expert opinion only and conducted using an informal consultative process at a very early stage in the proposal development. There was no specific evidence to support the any other particular process for developing relevant KPI's in DHI's.[12]

Measurement of KPI's throughout the project is an iterative process (3 intervals) using relevant tools at key stages throughout the project (minimal viable products (MVP) 1, 2 & 3) to measure digital health literacy (of educational material), patient empowerment, user trust of the platform, usability, accessibility, and satisfaction with the platform. For example, systems data will be used to measure usage of the platform and to gauge user engagement. The Systems Usability Scale will be used to measure usability and the Medication Adherence Report Scale – 10 to measure medication adherence.[19, 20] Qualitative data will be collected via focus group interviews to obtain subjective accounts of user experiences related to trust, accessibility, usability and user experience with the digital solutions. The Findings from each interval is used by the technical teams for product refinement and development throughout the project. Figure 1 describes the process of mapping KPI's to evaluation tools and evaluation time points.

Stakeholder consultation

Stakeholder consultation included a presentation of the initial KPI's at several internal meetings (monthly) within the Gravitare Health consortium which had expanded in numbers significantly (n=250) since the initial list of KPI's was created. Each consortium member consulted during these meetings represented a key expert group involved in the ongoing design and evaluation of the

Gravitate-Health digital health solutions, for example, healthcare users, healthcare practitioners, academic institutes, pharmaceutical and technology industry and all were from high income EU countries. These meetings aimed to seek expert advice and perceptions on the initial KPI's and explain and discuss the use of the Delphi technique to refine and prioritise the KPI's. Overall, this consultative process demonstrated support for the preliminary list of KPI's with the exception of the category on "Value for the industry and society". These are specific deliverables for the project, and therefore it was perhaps not surprising that these KPI's were regarded as not applicable as they would not be measurable by evaluation tasks in the project. This was an essential and supportive exercise in communicating the work of consortium evaluation team to the broader stakeholder group and subsequently getting consensus on the process to be used.

Delphi survey and consensus

Value statements were created for each of the KPI's and the list was revised to ensure that the wording was clear in terms what the KPI was anticipated to measure in order to meet the SMART criteria defined in the WHO guide for indicators: Specific, Measurable, Attainable, Relevant, and Time-Bound. [21] All members of the Gravitate Health consortium were then invited by email to contribute to the Delphi survey (n=250). The decision for inclusion of all members was made on consideration of the results from a previous scoping review which highlighted a significant gap in the evidence-based knowledge in this domain, and strongly emphasized the involvement of stakeholders in developing KPI's for digital health interventions.[12] A two-round ranking style Delphi was performed, using the Qualtrics online platform to identify and rank the final KPI's for use in the project (Figure 2).[22, 23] In round 1, all potential consortium members were sent a cover letter advising them of the purpose of the exercise. Survey items were presented as two questions for each of the six KPI categories. In the first question, consortium members were presented with the list of proposed KPI's for the category and asked to choose one KPI from the list they felt most represented

the category, and one KPI they felt least represented the category. This is in line with the commonly used and reliable approach of developing rank order in Delphi survey responses. [24-26] The second question was a free-text box asking consortium members if they would like to suggest an additional KPI that could be reflective of the category. In the first round of the survey, KPI's were listed in random order for each of the categories. Consortium members had ten days to respond to round 1 and a further 10 days to respond to round 2 of the survey.

In round 2, Consortium members were presented with the KPI's in ranked order based on results from the first round and again asked to rank the list in order of most to least relevant. There were no differences in how consortium members ranked the KPI's in terms of relevance and priority in round 2. Minor wording edits were made during data analysis by study authors to some of the KPI's in round 2 based on a small number of free-text feedback to increase the clarity and precision of the KPI's.

Outcome of consultative process

There were 40 respondents in the first round of the project and 41 respondents in the second round which represents a response rate of 16%. As a research methodology, the Delphi technique has been criticised in health research for methodological issues such as low response rates.[27] However, as a process for consensus achievement in refining and prioritising KPI's, the characteristics of the consortium members who responded in this process is representative of all key stakeholders in the Gravitate Health Consortium. Just over 41% from pharmaceutical industry and 32% from digital technology companies provided feedback in round 1 and 2. Other consortium members represented academic/research institutes (n=14, 34.1%) (Table 1). Respondents listing their role as other (n=13, 31.7%) included the following: medical doctor, patient advocate, medicine agency, health professional working in academia, regulatory authority, user advisory group member, member

organisation in digital and telehealth, patient representative, and gerontologist/dementia specialist.

Ethical considerations

The conduct of this consultative process was solely intended for decision making in relation to refining and prioritising a predetermined list of KPI's. Therefore, ethical approval was not required. Participation in this process was voluntary and participant engagement in this consultative process was regarded as consent. The Qualtrics online platform was used to ensure all responses were anonymous. No compensation was given for engagement in the consultative process.

Table 1. Characteristics of respondents

Role, n (%) * (could indicate more than 1 role)	Round 1 (n=40)	Round 2 (n=41)
Industry	16 (40)	17 (41.5)
Academic/Research Institute	14 (35)	14 (34.1)
Healthcare providers	5 (12.5)	3 (7.3)
Patient representatives	6 (15)	5 (12.2)
Private partners	4 (10)	7 (17.1)
Digital technical expertise	14 (35)	13 (31.7)
Other	9 (22.5)	13 (31.7)

The results of the class ranks (the percentage of responses in which each KPI was listed as first in order of importance) and mean ranks (average number of ranks for each KPI) for each of the six categories for the first and second Delphi rounds are presented in Table 2.

Key Performance Indicators for Digital Health Interventions

Table 2. Class and mean rank for rounds 1 & 2 of KPI refinement and prioritisation

Category 1: Access and use					
Round 1			Round 2		
Class rank	KPI	Mean rank	Class rank	KPI	Mean rank
1	Measure citizens' use of Gravitate Health to manage health information - 85% of test users will complete the pilot trial scenarios.	2.38	1	Measure how usable and accessible the Gravitate Health platform is - Over 50% of users will evaluate Gravitate Health solutions as usable/accessible.	2.02
2	Measure how usable and accessible the Gravitate Health platform is - Over 50% of users will evaluate Gravitate Health solutions as usable, /accessible.	2.25	2	Measure citizens' use of Gravitate Health to manage health information - 85% of test users will complete the pilot trial scenarios.	2.07
3	Measure if the platform is accessible on the web and personal devices - The platform is accessible on the web and personal devices.	3.48	3	Measure if the platform is accessible on the web and personal devices - The platform is accessible on the web and personal devices.	2.98
4	Measure citizen awareness of the importance of self-management - Citizens will receive a 15% annual increase in time on the website/users	3.28	4	Measure citizen awareness of the importance of self-management - There will be a 15% annual increase in time on the website by users.	3.69
5	Measure EU citizens' awareness of Gravitate Health - There will be a 10% annual increase in unique contacts globally.	3.62	5	Measure EU citizens' awareness of Gravitate Health - There will be a 10% annual increase in unique contacts globally.	4.24
Category 2: Understanding					
Round 1			Round 2		
Class rank	KPI	Mean rank	Class rank	KPI	Mean rank
1	Measure if the Gravitate Health platform has educational material at a digital literacy level that is understandable - >75% of information is accessible to a middle school level 9-year-old.	2.88	1	Measure if the Gravitate Health platform has educational material at a digital literacy level that is understandable - >75% of information is understandable to a middle school level 9-year-old.	2.02
2	Measure if the Gravitate Health platform provides users with an understanding of the medication benefits and how and why to take medication - The Gravitate Health platform will achieve a 25% improvement over the baseline.	2.88	2	Measure if the Gravitate Health platform provides users with an understanding of the medication benefits and how and why to take medication - The Gravitate Health platform will achieve a 25% improvement over the baseline.	2.21
3	Measure if the Gravitate Health platform addresses users who are physically, auditorily, visually challenged, and have dyslexia requirements - 50% of physically challenged users will express satisfaction with the digital services above baseline.	3.08	3	Measure if the Gravitate Health platform addresses users who are physically, auditorily, and visually challenged - 50% of physically challenged users will express satisfaction with the digital services above baseline.	3.52
4	Measure if the Gravitate Health	3.10	4	Measure if the Gravitate Health	3.52

Key Performance Indicators for Digital Health Interventions

	platform has the multilingual capability - The platform will have >5 languages supported.			platform has the multilingual capability - The platform will have >5 languages supported.	
5	Measure if the Gravitare Health digital solution provides notifications and updates on prescription/ over-the-counter ePI - The Gravitare Health digital solution will achieve a 10% annual increase in knowledge/use of platform features.	4.50	5	Measure if the Gravitare Health digital solution provides notifications and updates on prescription/ over-the-counter ePI - The Gravitare Health digital solution will achieve a 10% annual increase in knowledge/use of platform features.	4.29
6	Measure if the Gravitare Health platform has reached the maturity of the technology platform at the end of the project - The platform will reach Technology Readiness Level 4 to 8 for parts of the platform and digital solution.	4.58	6	Measure if the Gravitare Health platform has reached the maturity of the technology platform at the end of the project - The platform will reach Technology Readiness Level 4 to 8 for parts of the platform and digital solution.	5.43
Category 3: User experience					
Round 1			Round 2		
Class rank	KPI	Mean rank	Class rank	KPI	Mean rank
1	Measure if the Gravitare Health platform increases patient empowerment and activation - The Gravitare Health platform will provide a 25% baseline increase in self-efficacy, motivation, and activation.	2.90	1	Measure if the Gravitare Health platform increases patient empowerment and activation - The Gravitare Health platform will provide a 25% baseline increase in self-efficacy, motivation, and activation.	2.64
2	Measure if the Gravitare Health platform facilitates patient empowerment and activation - The Gravitare Health platform will facilitate 75% of users with empowerment to manage their medication and find relevant, easily understood information on drugs, symptoms, and risks.	3.58	2	Measure if the Gravitare Health platform facilitates patient empowerment and activation - The Gravitare Health platform will facilitate 75% of users in managing their medication and facilitate finding relevant, easily understood information on drugs, symptoms, and risks.	2.88
3	Measure if users trust the Gravitare Health platform - There will be a medium to strong effect size on trust in health providers and the health system and satisfaction in doctor/patient relation/communication.	4.22	3	Measure if users trust the Gravitare Health platform - There will be a medium to strong effect on trust in health providers and the health system and satisfaction in doctor/patient relation/communication.	2.93
4	Measure if the Gravitare Health platform improves the patient-provider interaction using G-lens® - The Gravitare Health platform will provide a 25% baseline improvement in patient-provider interaction.	3.85	4	Measure if the Gravitare Health platform improves the patient-provider interaction using G-lens® - The Gravitare Health platform will provide a 25% baseline improvement in patient-provider interaction.	4.57
5	Measure if the Gravitare Health platform provides user empowerment through digital	5.18	5	Measure if the Gravitare Health platform is assessed by users as not providing information overload or	5.36

Key Performance Indicators for Digital Health Interventions

	solution features - The Gravitate Health platform will provide a 25% increase in awareness of features (e.g., notifications, active search, interaction, and queries.			missing relevant data - 60% of users report satisfaction with the content in the Gravitate Health digital solution.	
6	Measure if the Gravitate Health platform provides carers (informal/non-professional) with the satisfaction of the experience - 65% of carers report that the Gravitate Health digital solution has improved their knowledge and engagement with G-Lens.	5.30	6	Measure if the Gravitate Health platform provides user awareness through digital solution features - The Gravitate Health platform will provide a 25% increase in awareness of features (e.g., notifications, active search, interaction, queries.	5.93
7	Measure if users assess the Gravitate Health platform as providing no information overload or missing data - 60% of users report satisfaction with digital solution features.	5.45	7	Measure if the Gravitate Health platform provides carers (informal/non-professional) with a satisfactory experience - 65% of carers report a satisfactory experience with the Gravitate Health digital solution.	5.50
8R	Measure if the Gravitate Health platform provides satisfaction to health providers and is trusted - 65% of health providers report high satisfaction and trust with Gravitate Health digital solution.	5.33	8	Measure if the Gravitate Health platform provides health providers with a satisfactory experience - 65% of health providers report a satisfactory experience with the Gravitate Health digital solution.	6.19
Category 4: Patient compliance and adherence					
Round 1			Round 2		
Class rank	KPI	Mean rank	Class rank	KPI	Mean rank
1	Measure if the Gravitate Health platform leads to better patient outcomes - The Gravitate Health platform will lead to a 10% improvement in health outcomes.	2.02	1	Measure if the Gravitate Health platform leads to better medication compliance/adherence by users - The Gravitate Health platform will lead to a medium to strong effect size on medication compliance/adherence by users.	1.98
2	Measure if the Gravitate Health platform leads to better medication compliance/adherence by users - The Gravitate Health platform will lead to a medium to strong effect size on medication compliance/adherence by users.	2.22	2	Measure if the Gravitate Health platform leads to better patient health outcomes - The Gravitate Health platform will lead to a 10% improvement in health outcomes.	2.12
3	Measure if the Gravitate Health platform leads to a safer use of medication/therapy administration - 50% of users will find that the Gravitate Health platform/ G-lens® provides tailored information that helps them safely adhere to therapy in their lifestyle.	2.22	3	Measure if the Gravitate Health platform leads to a safer use of medication/therapy administration - 50% of users will find that the Gravitate Health platform/ G- lens® provides tailored information that helps them safely adhere to therapy in their lifestyle.	2.60
4	Measure if the Gravitate Health platform leads to improved user preferences and co-creation - The	3.52	4	Measure if the Gravitate Health platform leads to an increased partnership between the patient and	3.31

Key Performance Indicators for Digital Health Interventions

	Gravitate Health platform will lead to > 90% of users have tried the possibility of shaping cooperation with the health team, and > 50% will use it repeatedly.			the health team - The Gravitate Health platform will lead to > 90% of users participating in improved collaboration between the patient and the health team.	
Category 5: Two-way communication					
Round 1			Round 2		
Class rank	KPI	Mean rank	Class rank	KPI	Mean rank
1	Measure if the Gravitate Health platform leads to increased provider awareness of bias and understanding of users' attitude towards medication compliance/adherence - The Gravitate Health platform will lead to a 25%-50% increase over baseline on changing provider bias	1.73	1	Measure if the Gravitate Health platform leads to increased provider awareness of bias and understanding of users' attitude towards medication compliance/adherence - The Gravitate Health platform will lead to a 25%-50% increase over baseline on changing provider bias	1.76
2	Measure if the Gravitate Health platform will meet legal and privacy requirements while balancing "need to know," usability, and accessibility, and will have a no-harm policy - Data Processing Agreement will accept the Gravitate Health platform for all tests.	1.98	2	Measure if the Gravitate Health platform will meet legal and privacy requirements while balancing a need to know, usability, and accessibility, and will have a no-harm policy - Data Processing Agreement will accept the Gravitate Health platform for all tests.	1.83
3	Measure if the Gravitate Health platform leads to an increase in patient opt-ins for providing real-world data - The Gravitate Health platform will lead to a 10% increase in users who opt into a report/donate their data to the Gravitate-Health platform.	2.30	3	Measure if the Gravitate Health platform leads to an increase in patient opt-ins for providing real-world data - The Gravitate Health platform will lead to a 10% increase in users who opt into a report/donate their data to the Gravitate-Health platform.	2.40
Category 6: Risk minimization					
Round 1			Round 2		
Class rank	KPI	Mean rank	Class rank	KPI	Mean rank
1	Measure if the Gravitate Health platform leads to a risk minimization function - 85% of providers will receive alerts for adverse interfering effects and can prepare information about safe medication use.	1.95	1	Measure if the Gravitate Health platform leads to a risk minimization function - 85% of providers will receive alerts for adverse interfering effects and can prepare information about safe medication use.	1.83
2	Measure if the Gravitate Health platform achieves lower risks across populations - The Gravitate Health platform will achieve a 50-75% confirmation of better user understanding of risks.	1.98	2	Measure if the Gravitate Health platform provides alerts to users to avoid prescribed and over-the-counter drug interactions - The Gravitate Health platform will lead to a 20% increase over the baseline of users taking notice of alerts to avoid prescribed and over-the-counter drug	1.98

Key Performance Indicators for Digital Health Interventions

				interactions.	
--	--	--	--	---------------	--

The mean rank was calculated for each KPI within each category. These show the rankings for each KPI and the changes which occurred in the prioritisation of individual KPI's between rounds 1 and 2. No additional KPI's emerged that were to be added to the list during this process. The overall final list of prioritised KPI's for the project is presented in Table 3.

Table 3. Final list of refined and prioritised KPI's using consensus methodology

Class rank	Key Performance Indicator
Access and Use	
1	Measure how usable, and accessible the Gravitare Health platform is.
2	Measure citizens' use of Gravitare Health to manage health information.
3	Measure if the platform is accessible on the web and personal devices.
4	Measure citizen awareness of the importance of self-management.
5	Measure EU citizens' awareness of Gravitare Health.
Understanding	
1	Measure if the Gravitare Health platform has educational material at a digital literacy level that is understandable.
2	Measure if the Gravitare Health platform provides users with an understanding of the medication benefits and how and why to take medication.
3	Measure if the Gravitare Health platform addresses physically, auditorily, and/or visually challenged users.
4	Measure if the Gravitare Health platform has the multilingual capability.
5	Measure if the Gravitare Health digital solution provides notifications and updates on prescription/ over-the-counter ePI.
6	Measure if the Gravitare Health platform has reached the maturity of the technology platform at the end of the project.
User Experience	
1	Measure if the Gravitare Health platform increases patient empowerment and activation.
2	Measure if the Gravitare Health platform facilitates patient empowerment and activation.
3	Measure if users trust the Gravitare Health platform.
4	Measure if the Gravitare Health platform improves the patient-provider interaction using G- lens®.
5	Measure if the Gravitare Health platform is assessed by users as not providing information overload or missing relevant data.
6	Measure if the Gravitare Health platform provides user awareness through digital solution features.
7	Measure if the Gravitare Health platform provides carers (informal/non-professional) with a satisfactory experience.
8	Measure if the Gravitare Health platform provides health providers with a satisfactory experience.
Patient compliance/adherence	
1	Measure if the Gravitare Health platform leads to better medication compliance/adherence by users.
2	Measure if the Gravitare Health platform leads to better patient health outcomes.
3	Measure if the Gravitare Health platform leads to a safer use of medication/therapy administration.

Key Performance Indicators for Digital Health Interventions

Class rank	Key Performance Indicator
4	Measure if the Gravitare Health platform leads to an increased partnership between the patient and the health team.
Two-way communication	
1	Measure if the Gravitare Health platform leads to increased provider awareness of own bias and understanding of users' attitude towards medication compliance/adherence.
2	Measure if the Gravitare Health platform will meet legal and privacy requirements while balancing a need to know, usability, and accessibility, and will have a no-harm policy.
3	Measure if the Gravitare Health platform leads to an increase in patient opt-ins for providing real-world data
Risk Minimization	
1	Measure if the Gravitare Health platform leads to a risk minimization function.
2	Measure if the Gravitare Health platform provides alerts to users to avoid prescribed and over-the-counter drug interactions.
3	Measure if the Gravitare Health platform achieves lower risks across populations.

DISCUSSION

Consortium members ranked the usability, accessibility of the G-lens, digital literacy, and patient empowerment as fundamental issues in this project. This reflects the drive for more accessible technology in healthcare, which had gained traction before the COVID-19 pandemic.[28-30] The most important KPI identified, risk minimisation, relating to alerts for adverse interfering effects, is not surprising given the previous work completed by the European Union's Innovative Medicines Initiative WEB-RADR.[31] However, the third ranked most important item in this category was the need to achieve lower risks across populations. This reflects the importance of developing a health solution that enhances equity of care in medication management. Changes in KPI's were not observed during the refinement process in round 1 and 2 of the Delphi technique. This is not surprising as the Gravitare-Health digital solution did not exist prior to this exercise, therefore, consortium members had no prior experience of them.

The Delphi technique framework provides a complementary approach to the WHO Framework for Monitoring and evaluating digital health interventions and to existing health systems frameworks such as the Donabedian's Framework on Quality of Care, the RE-AIM Framework for public health, the logic model, and the Balanced Scorecard.[32-36] While these

Key Performance Indicators for Digital Health Interventions

frameworks agree that setting indicators for planning and evaluation in DHI projects is important, they do not offer guidance on how this should be achieved. The process used for KPI development, refinement and prioritisation in the Gravitare Health project provides such guidance. It provides a standardised approach to achieving consensus between large groups of stakeholders, therefore, can be used in many types of Digital Health solution projects in identifying and prioritising KPI's.

The use of a Delphi technique in the Gravitare Health project provided a well-established framework for a structured approach to achieving consensus in developing, refining, and prioritising KPI's in DHI initiatives involving large groups of diverse stakeholders where there is limited supporting evidence. [12] Current literature in this area shows that most previous initiatives for DHI evaluation used health assessment frameworks that were adapted for DHI evaluation focused on the usability and clinical outcomes of the interventions.[12] However, as Bradway et al noted, new initiatives should be created with the unique properties of DHI's in mind[37]. Though the specific KPI's identified by this project may not be generalisable to all DHI evaluations, this paper offers a useful first step toward a common methodology for the development of KPI's for DHI's.

This consultative process has some limitations. Firstly, although the response rate was low (41 consortium members out of 250 contributed), it has been noted that a minimum of 20 participants can achieve response stability in Delphi research studies. [27] The list of KPI's was mapped against feedback from healthcare users in the broader project, however the project may have benefitted from wider engagement with a greater number of healthcare professionals, healthcare users and healthcare organisations. This limitation is mitigated somewhat by all KPI's being measured regardless of the ranking as the purpose of this project was to refine the initial

Key Performance Indicators for Digital Health Interventions

KPI list and to develop an order of priority. For example, no additional KPI's were identified for inclusion. However, having a greater number of healthcare professionals and healthcare users may have led to a different outcome. In addition, limitations to this methodology include a limited number of items that can be included in a list, with some suggesting that the number of items be restricted to three to five, with a maximum of seven, resulting in potential bias due to ties among items, response bias, and issues with standardisation.[22, 38-41] Future work will conduct an external validation to measure the feasibility, reliability, or validity to demonstrate the robustness and applicability of the developed KPI's. This could be done by conducting more pilot testing of the indicators in real-world settings, assessing inter-rater reliability, and exploring the relationship between the KPI's and relevant outcomes.

Conclusions

The objective of this paper was to present a consensus approach to refining and prioritising candidate KPI's to measure the success of novel digital health solutions produced by the Gravitare-Health project. The Delphi technique provided a structured framework for this, and albeit, a very novel context, it proved to be an effective approach. The final list of KPI's provides a list of substantial indicators sensitive to the needs of a broad group of stakeholders that can be used to capture real-world data in developing and evaluating DHI's. This consultative approach offers a suitable 4 stage process to enable the setting of evaluation indicators for the assessment of DHI's (Figure 2).

ACKNOWLEDGEMENTS

Data availability

Key Performance Indicators for Digital Health Interventions

Anonymised data may be made available upon reasonable request.

Author contributions

MB and AW conducted the Delphi project. MB, CMcC and AW reviewed and interpreted Delphi project findings. MB and CMcC wrote the first draft of the manuscript. AM, MI, MB, CMcC, YQ, MH, CD, MMcC, KN and LC reviewed and edited the manuscript.

Funding

The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 945334. The JU receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA and Datapharm Limited. This communication reflects the views of the authors and neither the IMI nor the European Union, EFPIA, or Datapharm Limited are liable for any use that may be made of the information contained herein.

Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Abbreviations

DHI: Digital health intervention

KPI: Key performance indicator

Key Performance Indicators for Digital Health Interventions



Key Performance Indicators for Digital Health Interventions

REFERENCES

1. Zeeb H, Pigeot I, Schüz B. [Digital public health-rapid technological progress, but many open public health questions]. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz*. 2020 2020/02//;63(2):135-6. PMID: 31960072. doi: 10.1007/s00103-020-03092-0.
2. Wienert J, Jahnel T, Maaß L. What are Digital Public Health Interventions? First Steps Toward a Definition and an Intervention Classification Framework. *J Med Internet Res*. 2022;24(6):e31921. PMID: 35763320. doi: 10.2196/31921.
3. Schoeppe S, Alley S, Van Lippevelde W, Bray NA, Williams SL, Duncan MJ, et al. Efficacy of interventions that use apps to improve diet, physical activity and sedentary behaviour: a systematic review. *International Journal of Behavioral Nutrition and Physical Activity*. 2016 2016/12/07;13(1):127. doi: 10.1186/s12966-016-0454-y.
4. Organization WH. Digital health platform handbook: building a digital information infrastructure (infostructure) for health. 2020.
5. Sieben A, Bredie SJ, van Laarhoven CJ, Schoonhoven L, Burger DM, van Onzenoort HA. [e-Health interventions and improvement in treatment adherence]. *Ned Tijdschr Geneesk*. 2014;158:A8460. PMID: 25534266.
6. Pouls BP, Vriezেকolk JE, Bekker CL, Linn AJ, van Onzenoort HA, Vervloet M, et al. Effect of interactive eHealth interventions on improving medication adherence in adults with long-term medication: systematic review. *Journal of medical Internet research*. 2021;23(1):e18901.
7. Wang Z, Zhu Y, Cui L, Qu B. Electronic Health Interventions to Improve Adherence to Antiretroviral Therapy in People Living With HIV: Systematic Review and Meta-Analysis. *JMIR Mhealth Uhealth*. 2019 Oct 16;7(10):e14404. PMID: 31621641. doi: 10.2196/14404.
8. Jeminiwa R, Hohmann L, Qian J, Garza K, Hansen R, Fox BI. Impact of eHealth on medication adherence among patients with asthma: A systematic review and meta-analysis. *Respir Med*. 2019 Mar;149:59-68. PMID: 30803887. doi: 10.1016/j.rmed.2019.02.011.
9. Organization WH. Handbook on health inequality monitoring: with a special focus on low-and middle-income countries: World Health Organization; 2013. ISBN: 9241548630.
10. Khalil H, Kynoch K. Implementation of sustainable complex interventions in health care services: the triple C model. *BMC health services research*. 2021;21:1-10.
11. Varela T, Zamorano P, Muñoz P, Rain C, Irazoqui E, Sapag JC, et al. Evaluation of the implementation progress through key performance indicators in a new multimorbidity patient-centered care model in Chile. *BMC Health Services Research*. 2023 2023/05/04;23(1):439. doi: 10.1186/s12913-023-09412-9.
12. Brenner M, Weir A, McCann M, Doyle C, Hughes M, Moen A, et al. Development of the key performance indicators for digital health interventions: A scoping review. *Digital Health*. 2023;9:20552076231152160.
13. Oakley J, O'Hagan, A. SHELF: the Sheffield elicitation framework (version 2.0). 2014 [cited 2025 29th January]; Available from: <https://shelf.sites.sheffield.ac.uk/>.
14. Rossi PaA, A. The Factorial Survey Approach: An Introduction. In: Rossi PaN, S., Eds., editor. Beverly Hills, CA: Sage; 1982.
15. Dalkey N, Helmer O. An Experimental Application of the DELPHI Method to the Use of Experts. *Management Science*. 1963;9(3):458-67. doi: 10.1287/mnsc.9.3.458.
16. Allen J, Brenner M, Hauer J, Molloy E, McDonald D. Severe Neurological Impairment: A

Key Performance Indicators for Digital Health Interventions

- delphi consensus-based definition. *European Journal of Paediatric Neurology*. 2020 2020/11/01/;29:81-6. doi: <https://doi.org/10.1016/j.ejpn.2020.09.001>.
17. Nasa P, Jain R, Juneja D. Delphi methodology in healthcare research: how to decide its appropriateness. *World Journal of Methodology*. 2021;11(4):116.
 18. Steel M, Seaton P, Christie D, Dallas J, Absalom I. Nurse perspectives of nurse-sensitive indicators for positive patient outcomes: A Delphi study. *Collegian*. 2021;28(2):145-56.
 19. Horne R, Weinman J. Self-regulation and self-management in asthma: exploring the role of illness perceptions and treatment beliefs in explaining non-adherence to preventer medication. *Psychology and Health*. 2002;17(1):17-32.
 20. Brooke J. SUS-A quick and dirty usability scale. *Usability evaluation in industry*. 1996;189(194):4-7.
 21. Organization WH. Monitoring and evaluating digital health interventions: a practical guide to conducting research and assessment 2016.
 22. Strasser A. Design and evaluation of ranking-type Delphi studies using best-worst-scaling. *Technology Analysis & Strategic Management*. 2019;31(4):492-501.
 23. Qualtrics. Copyright year (2020). Version 082024. Provo, Utah, USA: Qualtrics; 2005.
 24. Beiderbeck D, Frevel N, von der Gracht HA, Schmidt SL, Schweitzer VM. Preparing, conducting, and analyzing Delphi surveys: Cross-disciplinary practices, new directions, and advancements. *MethodsX*. 2021 2021/01/01/;8:101401. doi: <https://doi.org/10.1016/j.mex.2021.101401>.
 25. Robertson M, Line M, Jones S, Thomas S. International students, learning environments and perceptions: A case study using the Delphi technique. *Higher education research & development*. 2000;19(1):89-102.
 26. Del Grande C, Kaczorowski J. Rating versus ranking in a Delphi survey: a randomized controlled trial. *Trials*. 2023 Aug 18;24(1):543. PMID: 37596699. doi: 10.1186/s13063-023-07442-6.
 27. Shang Z. Use of Delphi in health sciences research: a narrative review. *Medicine*. 2023;102(7):e32829.
 28. Ahern DK, Woods SS, Lightowler MC, Finley SW, Houston TK. Promise of and potential for patient-facing technologies to enable meaningful use. *American journal of preventive medicine*. 2011;40(5):S162-S72.
 29. Alessa T, Abdi S, Hawley MS, de Witte L. Mobile Apps to Support the Self-Management of Hypertension: Systematic Review of Effectiveness, Usability, and User Satisfaction. *JMIR Mhealth Uhealth*. 2018;6(7):e10723. PMID: 30037787. doi: 10.2196/10723.
 30. Whitehead L, Seaton P. The Effectiveness of Self-Management Mobile Phone and Tablet Apps in Long-term Condition Management: A Systematic Review. *J Med Internet Res*. 2016;18(5):e97. PMID: 27185295. doi: 10.2196/jmir.4883.
 31. Initiative IM. WEB RADR Recognising Adverse Drug Reactions. 2017 [cited 2023 Sept 15th].
 32. World Health O. Monitoring and evaluating digital health interventions: a practical guide to conducting research and assessment. Geneva: World Health Organization; 2016 2016. ISBN: 9789241511766.
 33. Donabedian A. The Quality of Care: How Can It Be Assessed? *JAMA*. 1988;260(12):1743-8. doi: 10.1001/jama.1988.03410120089033.

Key Performance Indicators for Digital Health Interventions

34. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *American journal of public health*. 1999;89(9):1322-7.
35. Kellogg W. Logic model development guide. Michigan: WK Kellogg Foundation. 2004.
36. Kaplan RS, Norton DP. Using the balanced scorecard as a strategic management system. *Harvard Business Review*. 1996;74(1 (January - February 1996)):75-85.
37. Bradway M, Carrion C, Vallespin B, Saadatfard O, Puigdomènech E, Espallargues M, et al. mHealth Assessment: Conceptualization of a Global Framework. *JMIR Mhealth Uhealth*. 2017 May 2;5(5):e60. PMID: 28465282. doi: 10.2196/mhealth.7291.
38. Azzara C. Qualitatively Speaking: The focus group vs. in-depth interview debate. *Quirk's Media*. 2010;24(6):16.
39. Cohen SS, Di Minin A, Motoyama Y, Palmberg C. The persistence of home bias for important R&D in wireless telecom and automobiles. *Review of Policy Research*. 2009;26(1-2):55-76.
40. Cohen S, Orme B. What's your preference? Asking survey respondents about their preferences creates new scaling decisions. *MARKETING RESEARCH*. 2004;16:32-7.
41. Okoli C, Pawlowski SD. The Delphi method as a research tool: an example, design considerations and applications. *Information & management*. 2004;42(1):15-29.

Supplementary Files

Figures

Process of mapping KPI's to evaluation tools and timepoints.

Figure 1. Process of mapping final list of KPI's to evaluation tools and time points

Category	Key Performance Indicator	Evaluation tool	MVP1	MVP2	MVP3
Access and Use					
EU User awareness about the project	10% annual increase in number of unique contacts globally	Systems data, platform/ website logs			
User awareness of importance of self-management	15% annual increase of time on website/users, 25% increase in webinars attendance	Systems data, platform/ website logs			
Users use solution to manage health information	85% of test users complete the pilot trial scenarios	Evaluation framework: Systems data, platform/ website logs			
Platform availability, usability, and accessibility	>50% of users evaluate <i>Gravitate health solutions</i> as useful, usable, and accessible	SUS, focus groups/ Interviews			
Platform availability and accessibility	Accessible platform available in web and personal devices	Adherence to WCAG 2.1 or GPII			
Understanding					
Platform addresses physically, auditorily, visually, challenged, dyslexia requirements	50% of physically challenged express satisfaction with the digital services, above baseline	SUS and Qualitative data			
Multilingual capability	>5 languages supported	Selection of data			
Digital literacy level of educational material	>75% information accessible for middle school level (9-year-olds)	Formal tests in scenarios, SUS (system usability scale), focus groups/ interviews			
Maturity of the technology platform at end of project	TRL 4 to 8 for parts of the platform and digital solution				
Digital solution provides notifications and updates on prescription/OTC ePI	10% annual increase in knowledge / use of platform features	Systems data, platform/ website logs, Online survey, interviews/ focus groups.			

Flow diagram of consensus process for KPI development, refinement, and prioritisation for evaluation of the Gravitate - Health project.

Figure 2. Flow diagram of consensus process for KPI development, refinement, and prioritisation for evaluation of the Gravitate – Health project

