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Published in:
HEALTH SERVICES MANAGEMENT RESEARCH

DOI:
10.1177/0951484820971447

Published: 08/12/2020

Document Version
Early version, also known as pre-print

Please cite the original version:
Halminen, O., Chen, A., Tenhunen, H., & Lillrank, P. (2020). Demonstrating the value of digital health: Guidance on contextual evidence gathering for companies in different stages of maturity. *HEALTH SERVICES MANAGEMENT RESEARCH*, *34*(1), 13-20. [0951484820971447]. https://doi.org/10.1177/0951484820971447

Title:

Demonstrating the Value of Digital Health: Guidance on Contextual Evidence Gathering for Companies in Different Stages of Maturity

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Abstract

Application of value-based healthcare policies affects all actors in social and health care field, including the Digital Health Intervention (DHI) providers aiming to enter the industry or expand their market. Apparent lack of fit between evidence and expectations inhibits the growth of DHI companies. The companies need efficient and credible methods to access and demonstrate the value of their DHIs. Building on the stage-of-maturity logic presented in World Health Organization's (WHO) guide of monitoring and evaluating digital health interventions and Context-Intervention-Mechanism-Outcome (CIMO) logic, we provide a potential approach for DHI companies to assess the evidence needed in their current situation. The proposed approach takes into account the company's future development goals and the business environment, reflecting for every stage of technology maturity according to the WHO guidelines and through the CIMO lens. The focus is on specific intervention and its fit for different organizational and national contexts. The solution guides the research process of the company to understand which evidence-gathering topics should be addressed. This evidence can be beneficial for companies to enter into, occupy, expand or sustain in the domestic or international market.

1. Introduction

Challenges in demonstrating the value of Digital Health Interventions

Application of value-based healthcare policies[1,2] affects all actors in social and health care industry, including the Digital Health Intervention (DHI) providers aiming to enter the field or to expand their market. Based on extant literature[3–6], we understand DHIs as products or services (e.g. apps, software and online platforms) that use digital, mobile and wireless technologies and approaches, as well as advanced computing sciences in big data, genomics and artificial intelligence, to address health and healthcare issues and support the achievement of health objectives. Several trends are driving care providers to improve value assessment of DHIs. These include ageing populations, cost inflation, and increasing emphasis on value-based healthcare management practices[7–9]. The economic impact of DHIs is vast: the global digital health market is expected to reach USD 509.2 billion by 2025, with an annual growth rate at 27.7%[10]. DHI companies are endowed with unprecedented opportunities to transform the healthcare sector. It is a highly competitive market where the ability to create and demonstrate new value to care delivery and well-being is more crucial than ever.

Although it is widely accepted that digital health has become the frontline of healthcare, the non-adoption and abandonment of DHIs by care provider organizations is frequent, and uptake and scaling of implementations remain relatively slow[11]. This has been attributed to a lack of efficient and credible methods to evaluate and demonstrate the value of various types of DHIs. Despite the rapid development of digital health, the evidence on the effectiveness, outcomes and impacts of DHIs remains insufficient and of varying quality[12]. The difficulty in evaluating DHIs may be attributable to the sheer complexity of the organizational context in healthcare where DHIs are applied[13]. Implementation of DHIs in a specific healthcare context is an inherently complex socio-techno-economic process, which presents special challenges for the evaluation process. As compared with traditional interventions, DHIs are often "rapidly developed and tend to iterate, update, and improve"[14] and "evolving through several stages of maturity during which the evaluation needs of the intervention are also changing rapidly"[3]. Therefore, the established standards and processes for evaluating new drugs or devices may fail to keep up with the dynamic nature of digital health development and delivery[15,16]. Especially for the companies, existing summative evaluation models, such as the widely used RE-AIM model[17], may fail to bring value in the iterative development practices, and formative evaluation practices are also needed[18]. Technology companies typically go through several development phases from prototyping to routine use in the use environment, and different types of evidence are in focus in each of these phases. Iterative design methods that include both formative and summative evaluation practices, typically common in software development[19], are increasingly being applied also in healthcare field[20].

WHO's guide of monitoring and evaluating Digital Health Interventions

An effort to create an evaluation model for DHIs was launched by the World Health Organization (WHO) in their recent guidebook *Monitoring and Evaluating Digital Health Interventions: A practical guide to conducting research and assessment*[3]. It provides stepwise guidance to develop an evaluation plan and improve evaluation efforts and activities specifically for DHIs. The guide stresses the importance of defining the stage of maturity for technology, stage of already-gathered evidence, and specific claims provided by stakeholders, before planning evaluation activities. The roadmap model of moving from prototyping to national implementation focuses on explaining how different methodologies should be used by companies in different stages of maturity to gather evidence and monitor their effectiveness. The guide summarizes seven stages of the intervention maturity from pre-prototype to international level deployment:

- Pre-prototype: Conceptual design and initial needs assessment for the DHI.
- Prototype: Creation and testing of design, technical stability and usability in an iterative process.
- Pilot: Examination of whether the digital health intervention can produce the desired effect under controlled circumstances.
- Demonstration: Testing of DHI in uncontrolled yet still limited environment.
- Scale-up: Optimization and scaling-up across multiple subnational, national or population levels.
- Integration: Integration into the broader health system.
- Internationalization: Implementation in more than one country and integration into multiple health systems.

The overall model provided by WHO concerns the usual variation in evaluation goals during the development and implementation of DHIs by taking the stakeholders' values, preferences and expectations into account. However, it is still not practical enough for DHI companies to define the appropriate level of evidence and evaluate what they develop and/or implement. Most importantly, WHO model does not pay enough attention to the context of intervention. In their model, the importance of contextual fit is only discussed in relation to the prototyping and piloting stages, implying their view of the context is on clinical specialty level, not on the organizational level. The analysis of ideal vs. real contexts of use and getting relevant evidence is highly important since even 60% of organizational change initiatives have been found to fail[21], and often it is not the ineffectiveness of technology but the poor innovation-system fit[22] that lead to interventions being useless and fail in practice. In transferring the technology to a new organizational context, new factors affecting the implementation process are bound to arise. Furthermore, the WHO model is not specifically developed from DHI companies' point of view but from the care providers', and DHI companies' strategy and growth goals may poorly align with their efforts of collecting evidence. Thus, this could downplay the role of variability in each implementation context-of-care, and exaggerate the importance of stability and quality of the DHI in regional expansion.

Aim of the study

The apparent lack of fit between evidence and expectations inhibits the growth of DHI companies. For DHI companies wanting to enter the industry or expand their market, there is a need for a straight-forward, efficient, and credible sense-making model guiding the activities of collecting evidence and evaluating DHIs, helping to identify the appropriate value proposition for each part of the intervention, and demonstrating the overall value of DHIs. WHO's guide of monitoring and evaluating digital health interventions is a step in this direction, but lacks context-based thinking. In this paper, we apply the Context-Intervention-Mechanism-Outcome (CIMO) logic, widely used in organizational research, to understand which organizational components of the DHI should be in evaluation focus in each stage of technology maturity. We discuss how to contextually apply WHO's guide for DHI companies to collect evidence of and communicate the value of their innovations and to help companies to enter into, occupy, expand or sustain in the domestic or international market. We illustrate our considerations with examples from the real-life cases of evaluation practices in different stages of technology maturity. We also discuss the theoretical and practical implications arising from the consideration of bringing the CIMO and WHO models together.

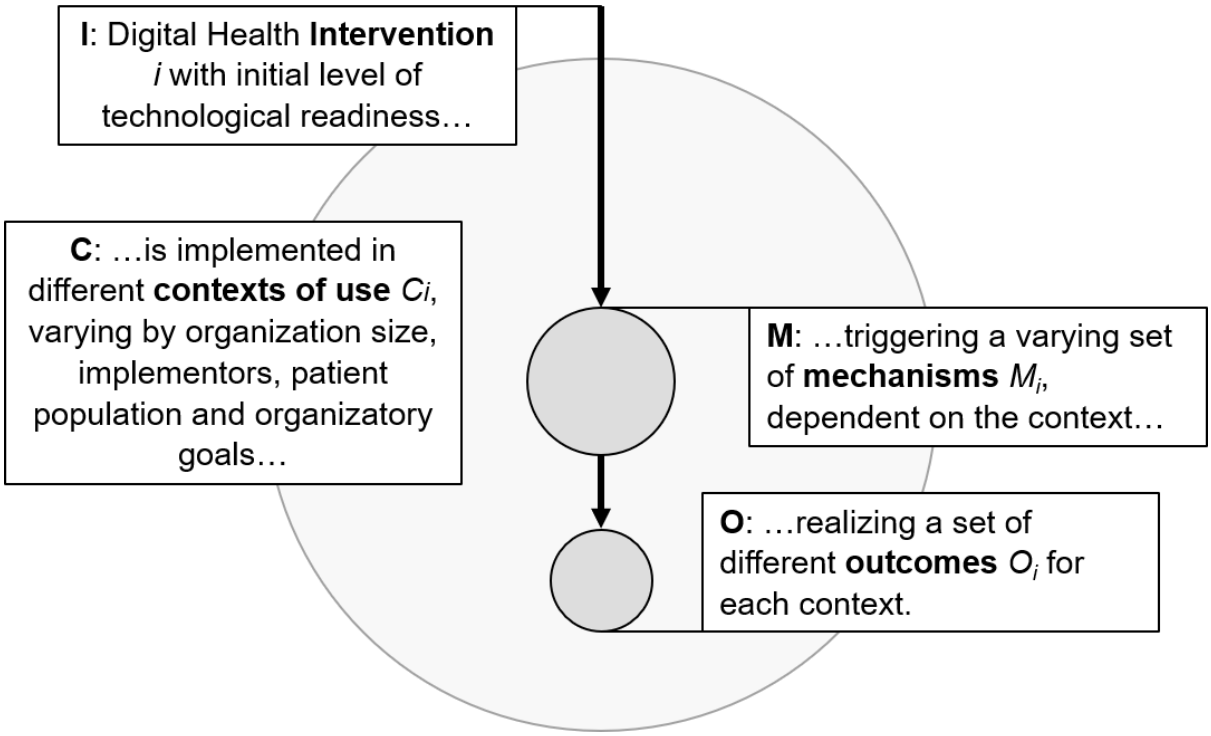
2. Methodology: Context-Intervention-Mechanism-Outcome (CIMO) logic

We use CIMO-logic[23] to improve the context-specific application of WHO guide. According to Murray et al.[5], "*as with any complex intervention, consideration of the likely benefits of a digital health intervention starts with a detailed and often theory-based characterization of the nature of the problem and the context in which the intervention will be used*". The CIMO framework focuses on analyzing the characteristics of the intervention, the basic functions and outcomes of the intervention that is designed for certain contexts, the contextual factors and the mechanisms determining the outcomes.

The CIMO-logic stems from the concept of realistic evaluation[24], emerging from design science. The idea is to recognize the *context* of a given situation where a particular *intervention* takes place producing an *outcome* based on a *mechanism* (see Picture 1). *Contex*t is a set of unique factors that frame an environment for a DHI. The *Intervention* could be a new technological solution affecting the clinical or care pathway, while implementation could be defined as all the means applied to adopt the new solution into use. *Mechanisms* explain the reasoning why the intervention causes certain outcomes in a given context. These might include improved timing of care procedures, competence level of caregivers and patients, integration and coordination of care practices within and between different care organizations, and the use of evidence-based care practices. *Outcome* is described as the end results that the intervention produces. On a practical level, the outcome could be cost savings, more efficient treatment or improved work satisfaction for caregivers[25].
It can be assumed that when the DHI's context of implementation changes from one organization to another, the organizational details of the mechanisms that cause the intervention to work also change, resulting potentially in different outcomes from those observed in the previous context. Generic CIMO analysis helps identifying the ideal outcomes of interest for evaluation. To understand and evaluate intervention and its implementation, the following should be considered:

- Context: which context is the intervention aimed for? Who are the supposed actors using the intervention, and for what purpose?
- Intervention: what is the technology of DHI? How is it implemented in the context?
- Mechanism: what causal or stochastic mechanisms are expected to bring out the expected outcomes of the intervention?
- Outcomes: what are the expected, or ideal, outcomes of the intervention?

CIMO analysis can help clarify and explain why applying the same digital health intervention in a new context may fail and what key conditions are required for implementation to succeed[26]. The CIMO configuration can be tailored to the evaluation needs of DHIs. In the following, we discuss which parts of the CIMO configuration should be focused into when studying DHIs with different stages of technology maturity.



Picture 1: The different parts of the Context-Intervention-Mechanism-Outcome (CIMO) logic.

3. Results: Applying WHO guide with CIMO-logic

In this section, we will go through the stages of maturity of the DHI and explain which factors of CIMO-logic are in key focus in each of them.

Pre-prototype and prototype

In the pre-prototype and prototype stages, the goal is to develop a working proof of concept for a DHI. The product-development process, assuming a relatively user-centered approach, will start from an initial exploration and market research to uncover a need for a new technological solution. A sufficient market size or the gravity of the problem needs to be ensured to justify the upcoming development costs. After this follows the design of the technology and its development with field experts, such as medical professionals and hospital technicians, in order to have a first functioning product. For example, Yardley et al.[27] describe how they have employed a person-based approach in the beginning of developing a behavior-changing app. In this stage, the technical stability and usability in laboratory settings needs to be proven.

As there is not yet a set use context to be considered, these two initial stages typically center around the *technological innovation* itself, but also focus on the ideal *implementation* of the innovation in a generic, non-real context. Together these two form the core design of the DHI, meaning the technology and its ideal implementation plan. In this stage, the evidence gathered mostly concerns the I part of CIMO-logic: developing an ideal intervention and ensuring its functioning in a laboratory setting.

Pilot

In the piloting stage, the goal is to test the product in a real but restricted context of use, simulating an ideal use environment. This stage is usually performed with real future users of the product in a real use locus, while minimizing the distorting effects of the context-related factors. Examples of piloting stage include testing the DHI in a restricted use context or a restricted clinical group, e.g., only with voluntary non-acute patients such as in Tenhunen et al.[28], or testing a heart monitor with healthy patients or in parallel with the existing technology. Control groups may be used, like in a piloting-stage study of a student mental-health app by Lee and Jung[29]. In this stage, the effectiveness of a DHI is tested in an ideal use context with usual real-life variance excluded. For example, all the care personnel involved in the study should be well acquainted with the use of DHI, even in a better manner than they normally would be in the regular use of the DHI.

In piloting stage, the evidence gathered mostly concerns the question of whether the DHI is able to trigger the expected mechanisms and consequently the outcomes in a restricted setting yet as a part of the real care process. The focus is in the combination of intervention, mechanism and outcome parts of the CIMO-logic.

Demonstration

Demonstration is the first stage when the technology is applied in a real context with no restrictions on the patient selection or the contextual factors. This stage typically last for a predetermined period of time, e.g., 2 months, after which the results of the technology testing may be assessed. Usually the demonstration stage continues with the actual implementation of the product in the use context – after all, the evidence of this stage should be enough for the using organization to assess the level of the "ideal" outcomes and estimate the probability of achieving them in a real environment. An example of a demonstration of DHI in real-use environment, Goldin et al.[30] report

the use of their smartphone-based mental health application to be effective in treating depression symptoms. Furthermore, for example of a demonstration of an extension to a current implementation, a study by Economides et al.[31] performed a first demonstration of feasibility and effectiveness of including a heart rate variability-biofeedback component in the same application.

In the demonstration stage the whole C-I-M-O configuration is in use showing evidence of the DHI performance for a specific organization. It should be noted that the demonstration stage shows "real" evidence only for some specific context, and might not be generalizable to e.g. other organizations, as care organizations have different personnel knowledge bases and organizational-level practices and goals. Thus, demonstration-stage might occur more than once – for example, when a city hospital is implementing a DHI previously used in a university hospital.

Scale-up

In the scale-up stage, the DHI is being implemented in several use contexts at the same time. These implementations typically take place in parallel and with slight adjustments for each implementing organization. The CIMO focus of this stage is to understand the logic of how different use contexts (C_i) result in different outcomes (O_i), and what kind of common preconditions do the successful implementations have. At the same time, for each separate organization, a demonstration process will be ongoing. It should be understood that the amount of complexity increases drastically as the amount of organizations begin to grow, which requires a balance between the needs of individual organizations, and the strengths of standardized implementation: for example: Robertson et al.[32] discuss several challenges associated with the implementation of a detailed electric health records system in several UK hospitals.

The evidence sought for in scale-up stage is two-fold: firstly, for the company, understanding the requirements for efficient implementation is key to enable swift adjustment for each different new implementation context. On the other hand, this stage might provide evidence of economies of scale: when implemented in several organizations, the costs of scalable background processes might lower significantly. Also, as an example, the care coordination between two organizations that have implemented similar DHIs might be easier in the future.

Integration

In the Integration stage, the viewpoint is in establishing the DHI as a part of national or regional care practices, or legitimize its use as an accepted solution on a wider regulatory level. The evidence must show that the integration of the DHI throughout the whole wider level care system would provide a satisfactory outcome level.

The integration stage typically concerns national level institutions, such as National Institute for Health and Care Excellence (NICE) in the United Kingdom, which evaluate the gathered evidence from the DHI to create clinical practice recommendations.

Internationalization

In the internationalization stage, the technology is implemented in a context of use that cuts across different health systems, infrastructure and spending levels. This might affect the implementation process, for example due to the differences in stability requirements of the DHI. As an example of internationalization, Ouhbi et al.[33] introduce a standard framework for the evaluation of internationalization potential of a DHI solution. The evidence in this stage should show that the DHI may be implemented in an organization which is working under a different regulatory framework.

The CIMO focus of internationalization stage is in the micro-level effects of the change of the wider, macro-level context.

In the Integration and Internationalization stage, the focus is, instead of the CIMO parts of the integration, more on whether the solution fits in to the wider regulatory context and whether it is able to achieve the expected outcomes on a wider scope. These could be described as a wider context – big C –, and a wider level outcome – big O. They are separate from the daily functioning of the intervention but are needed in shifting from micro- and meso-level evaluations in the past stages of maturity to macro-level evaluation.

The process of evidence-gathering moves gradually from the core of the intervention towards the wider context. In each stage of the implementation, both summative and formative evaluation might take place: summative in the sense of answering a specific closed-form evaluation questions and formative in the sense of supporting the design and scale-up processes. The findings for each stage of the implementation of DHI and the possible summative and formative evaluation results are described in table 1.

Table 1: CIMO focus in each stage of maturity of DHI.

Stage	Focus of evaluation	Environment	CIMO focus (what is studied)	Ideal CIMO focus	Evaluation outcomes
Pre-prototype and prototype	Designing the Intervention, Testing Intervention and Mechanisms	No real context, lab environment	I / I+M	Designing the ideal of CIMO, or the core I	Summative: validation of prototype Formative: Knowledge of implementation practices
Pilot	Intervention and Mechanisms + Outcomes	Restricted, selected, "ideal-like" context	I+M+O	Comparing outputs with ideal	Summative: validation of pilot version of the DHI Formative: discover new factors which separate the testing environment from ideal
Demonstration	Full C+I+M+O for one specific context	Real specific context, no controlled conditions	C+I+M+O	Comparing outcomes in specific context against the ideal	Summative: validation of DHI in a specific environment Formative: iterative development ideas for implementation context; development ideas for the DHI
Scale-up	Optimizing I+M and use in different Contexts and Outcome expectations	Several real contexts	Changes in O by varying Cs	Updating the ideal of context and outcomes	Summative: evidence on meso-level performance Formative: design suggestions to improve scalability
Integration	Implementation into broader Context C and larger-level outcomes O	Broader health system	Big C +C+I+M+O +big O	Understanding differences between big C&O and small c&o	Summative: validity for national-level implementation Formative: design suggestions towards integration
Internationalization	Changing the broader Context C and larger-level outcomes O	One or several different broader health systems	Changes in big O by varying big Cs	Updating the ideal C&O	Summative: evidence on performance in other national context Formative: design suggestions to enable internationalization

4. Discussion and conclusions

DHI companies have to be straight-forward and cost-efficient when evaluating their innovations and products. In this paper we described how analyzing the stage-of-maturity-logic, proposed in WHO's recently published guide, through the lens of CIMO-logic, introduced by Denyer et al., can help DHI companies to efficiently assess and present the value of their technology in different stages of maturity and in varying contexts. In order for DHI companies to succeed in their commercialization and internationalization initiatives, the goal of each evaluation project has to be aligned with the company's current situation.

Implications from a stage-of-maturity perspective

On theoretical level, when analyzing the CIMO focus in each stage of maturity, it becomes evident that as the technological readiness of the DHI increases, the focus of the evaluation activities moves from the ideal functioning of the innovation towards the context of the implementation. Piloting in a restricted context gives the baseline estimate of DHI's performance in ideal-like conditions, with which the functioning-in-context of the DHI may be compared in demonstration stage. For each new context of use, some level of demonstration is needed to see whether the DHI in question is applicable in this context of use. However, as more evidence is gathered through more implementations and scale-up, the amount of demonstration required should be expected to decrease. Each stage of maturity has both a specific summative goal for evaluation, but also creates formative implications relevant for both the organizational context at hand and for future stages of maturity.

On practical level, the analysis implies that skipping a stage in the evaluation pathway might hinder the proper evaluation and growth prospects of a technology company. Although the DHI company might start their evaluation activities in the demonstration-stage without first implementing a pilot study, there is a risk that contextual factors in the implementation organization would disturb the evaluation project. In a similar vein, regional or national care organizations, such as National Health System in the United Kingdom, might require evidence from several previous implementation sites before allowing a regional-level implementation in all of their organizations. Ideally, technology providers should have a separate and deep understanding of all the relevant parts of CIMO configuration, achieved by a set of micro-studies throughout the development and scaling of the product.

Implications from a CIMO-logic perspective

As a theoretical contribution, when reflecting stages of maturity via CIMO-logic, we begin to see a distinction between the macro and micro-level contexts. A macro-level evaluation is only needed when the implementation of a DHI has to consider national care practices. The effect of macro-level regulatory framework on the micro-level functioning of the DHI has to be understood when integrating into a health system, or when changing from one macro-level framework to another. This reflection also suggests that the CIMO-logic could be expanded to include also a wider macro-level contexts Big C and Big O. On practical level, we also could see that the macro-level integration of a DHI will likely need evidence that is more general than implementation in any narrower context. This macro-level evidence may not naturally be created through market logic, but might need governmental, proactive research funding to ensure that widely applied innovations in the health system also fulfill the requirements set by national health bodies.

Limitations and conclusions

Some limitations need to be noted in the application of our considerations. As the stages of maturity are abstractions of the real-world product-development process, they do not necessarily happen in the similar procession in practice. For example, some simple DHIs such as online scheduling applications might already be deemed to be ultimately harmless to the patients and have proofs-of-concept from other industries, sharply reducing the need for additional evidence before implementation. It should also be noted that although the piloting stage should give the "ideal" performance baseline for the DHI, there are several reasons why the performance of the DHI might be drastically different when implemented. For example, some technologies need much use experience from the care personnel to work smoothly, or integration with other information systems of the use context which might not be achievable at the time of pilot.

Combining CIMO-logic with the stage-of-maturity perspective creates additional insight in the application of both frameworks. Our work contributes to the literature on evaluation of DHIs and addresses the evidence-gathering challenge commonly faced by DHI companies, i.e., what kind of evidence is needed to assess, communicate, and demonstrate the value of DHIs in different technology development stages and implementation contexts, and help companies to enter into, occupy, expand or sustain in the domestic or international market. The considerations in this paper are on a general level, meaning they do not state what would the specific organizational challenges faced by the companies be, but stress the importance of considering contextual challenges when creating a mid- and long-term fit between the technology developers' growth strategy and evidence-gathering activities. The conceptual implications presented here are currently being tested in our ongoing research projects. In the future, more empirical studies should be performed which study technology transfer challenges posed by changing the organizational context.

Funding

The study was part of the Evaluation of Digital Healthcare Solutions (DiRVa) research project, funded by Business Finland.

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