



Towards a better risk analysis and validation of e-health applications in Care and Prevention

Management summary

Existing methods for risk assessment for medical aids are being surpassed by the rapid rise and availability of apps, serious games and online e-health applications. There is a lack of transparency for end users (consumers, patients, care professionals and consultants, and health insurers) regarding the status, operation and effectiveness of these new tools. At the same time, existing filters for risk assessment of medical aids often lead to excessively strict validation requirements for these new tools, which inhibits their possible contribution to better and more affordable care for the patient. It also erects barriers to new entrepreneurial entrants to the care market and their innovative ideas. This all requires an improved system of risk analysis and validation of e-health applications. A vital condition for an improved system is the introduction of the shortest possible assessment period for this form of quality care, considering the tempo of technological developments in both technical platforms and the applications that run on them (critical time-to-market), so that products do not lose their value before they are released to the market.

1. Introduction

Care in transition

Health care in the Netherlands is a sector that faces major challenges. As a result of an aging population and longer life expectancies, the cost of care in general is increasing. Over the long term, the sector will face a shortage of personnel, while short-term cost reductions will result in layoffs and restructuring in health care. Institutional care faces pressure from cost reductions and budget cuts. Care professionals will have to undergo a massive change in mentality from 'caring for the patient' to 'ensuring that the patient...'. As a result of this transition, people are becoming more aware of self-management for patients. As the population ages, family care and individual care are given greater priority, but self-management during and after an illness, and healthy living, are also receiving more attention. The focus will have to be placed on the patient. These transition processes have a major influence on health care as a system. Technology is increasingly considered to be an integral part of a package of solution strategies, which are often combined together under the term 'e-health'. But the term 'm-health' is also used to describe technological solutions on mobile platforms, such as smartphones and tablets. These names cover a wide range of solutions, varying from online platforms for communication and care support, serious games or apps, whether or not combined with special hardware solutions.

E-health: a matter of appreciation (validation)

The tempo at which these solutions are becoming available for professionals and consumers is too high. Every day, new health care-related apps appear in the app stores for iOS and Android platforms. In almost every case, it is unclear what the status of these products is, exactly. Several apps have been proven not to be based on valid interventions, or to have no clear effect. There are no standard



instructions for these kinds of products, and it is often unclear who produced them, whether they have been validated or not, and how or to what degree doctors or patient organisations have contributed to their development. This makes it difficult for care consumers and professionals to assess which tools may or may not be used in the care process, and if so, in which way. The rapid rise of these new solutions has placed considerable pressure on the policy systems intended to assess these products. The same applies to the parties responsible for managing the basic insurance package and compensation system, such as legal agencies or health insurers.

Position

Existing systems for evaluating new digital health care products are often insufficiently specific to these new digital developments, which often results in the formulation of unnecessarily strict validation requirements.

Purpose of this position paper

In this position paper, we will first explain the background for this statement and the negative consequences that traditional validation methods for e-health applications have on care and prevention. We will then provide an insight into validation by listing elements that may be important for new e-health methods (especially games) in this field. By formulating the problem, we will make an urgent call for changes and we will sketch a scenario for the desired solution. In conclusion, we will identify who would benefit from a solution.

2. Analysis of the current e-health validation and negative consequences for innovation

Existing validation methods, especially in Cure

Many of the validation instruments that are currently used or requested, even for these new digital solutions, originate in the medical tradition of evaluating medication or medical intervention research. Long-term research using control groups (Randomised Controlled Trials, RCT) in order to measure effectiveness are the norm for such evaluation, which makes validation expensive and time-consuming. The decision-making processes for evaluating and categorising these products were designed for traditional care interventions and/or focused on Cure. In the Cure domain, this strict form of validation is of course vital, but in Care and Prevention this is much less necessary.

Risk assessment: insufficient differentiation with negative consequences

We have determined that the demand for validation of new digital tools does not differentiate enough. Since existing regulations are not optimally adapted to this differentiation, in practice the apps, games and online interventions are quickly confronted with a strict, or even the strictest, medical validation regime. This is undesirable for several reasons.

The absence of a dedicated system means that there is a possible risk that the development, and especially the upscaling, of many of the innovative products will be hindered by the unnecessarily strict validation requirements. This in turn unnecessarily raises the threshold for small and young innovative companies in the health care sector to contribute to innovation. Since the filters currently used for health care tools have fairly 'generous' margins for these new forms, almost everything is immediately placed in the strictest validation category.

Due to the lack of a balanced system for risk analysis, many tools will not be able to find their way to acceptance or implementation by the care consumer or professional.

This excessive demand from innovative tools will inhibit the drafting of a profitable business case in the care sector. The strict validation requirements will unnecessarily delay and hinder the development of e-health solutions. But in addition to the financial repercussions, an entirely different category of problems will also play a role.



The time required to undergo this type of strict validation procedure is especially undesirable due to the tempo with which platforms and standards develop in the technology domain. The time-to-market for digital products is linked to a digital platform's life expectancy. From this perspective, long-term validation processes will be especially detrimental, because the products will have completely lost their relevance due to new developments in the underlying platforms (especially iOS, OS X, Android and Windows). By the time these products make it through the strict validation process, they may need to be completely rebuilt due to the continued development of the underlying platforms.

The goal of any form of validation system should be to keep the time-to-market as short as possible, without compromising on thoroughness or safety. A strict, but moderate system is therefore needed.

Summary of negative consequences

Hindrances pertaining to:

lack of transparency for:

1. *care consumers and their caregivers*
2. *health care professionals*
3. *care financers*

but primarily:

1. *development and upscaling of innovative new e-health products*
2. *the entry of small, young innovative companies to the health care sector*
3. *the possibility (or impossibility) of drafting of a profitable business case*
4. *relevance of a new product vs. time-to market: technology develops faster than the current validation process; original product has no value/relevance after a long validation process*
5. *implementation*

Layered validation is needed, especially for Care and Prevention

Some parties are experimenting with other forms of evaluation. One example is 'Routine Outcome Monitoring', in which surveys are regularly conducted of the user or patient's situation, but monitoring is often focused on adjusting treatment, not on validating the application.

Validation can deal with a variety of aspects of the application:

- 1) how is the game positioned in the market (for whom? by whom?)
- 2) how playable is the game (usability?)
- 3) is the interaction validated as an intervention (does it work?)
- 4) what is the user experience? (is it fun to use?)
- 5) what effect does coaching or intervention have? (measuring effects)

It is clear that every future validation system will have different levels that reflect the diversity of the various aspects. Moreover, decisions will be made in the design process that determine the end result, and may be evaluated (involvement of experts, involvement of users, choice of procedure and scenario, etc.). Each of these categories will need its own validation method and practice.



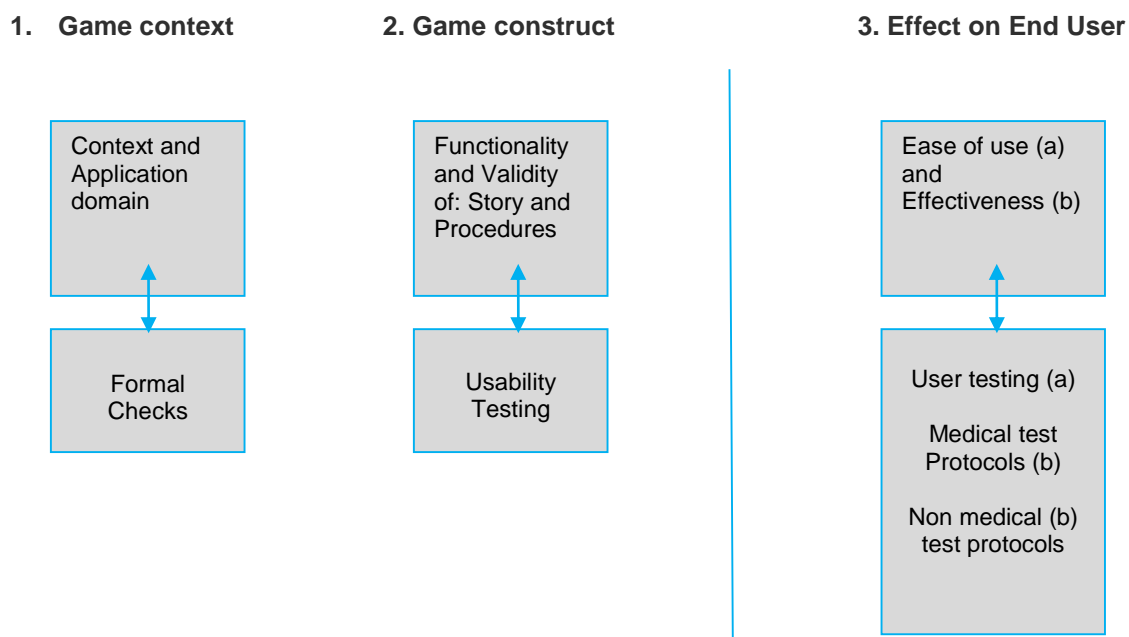
3. Missing elements in the risk analysis of e-health innovations

For medical serious games (Cure), extensive research is already being conducted into suitable validation methods. This paper focuses mainly on the lack of research into and development of methods for Care and Prevention. Naturally, we can also include proven methods in this search.

In their paper “How to systematically assess Serious Games Applied to Health”, Graafland et al. [2014] describe the criteria by which a game should be validated. We will also utilise comparable levels described in this article:

1. **Applicability and context of use**
2. **The chosen form of game play and**
3. **The effect on the end user**

Ad 1. Applicability and context of use



The previous figure shows an overview of the various aspects and the validation methods used in practice.

The current risk assessment system leaves out many aspects that are vital for a good assessment of the proper degree of validation for an e-health application.

Below is an initial and incomplete inventory of the aspects that we believe may contribute to a more balanced assessment of the estimated risk of an e-health application, in order to link it to a more suitable validation regime.

A. Application

For which domain is the application intended?

- I prevention
- II public health
- III less-complex care, treatment or training
- IV more-complex care, treatment or training

The higher the number, the greater the likelihood that the risk profile should be made stricter.

B. Target group

For whom is the application intended? Only the care consumer and/or caregiver, or for care professionals? Or a combination of the above? Is the care professional in the loop in the use of the application?

C. Purpose

Is the application intended for the care consumer as a patient? Is the care professional the end user in his or her role of providing treatment? Or is it a training application to help the professional develop and practice new knowledge or skills? There is a fundamental difference in purposes such as 'empowerment', 'diagnostics' and 'monitoring'; each has its own level of severity in the risk profile. We differentiate here between medical applications and non-medical applications. A game is considered a medical application if it is intended to facilitate a medical tool or is used for diagnostic or therapeutic purposes [Ekker et al., 2013].

D. Level of intervention

What is the application's level of intervention? Is it about information and prevention? Instructing on how to conduct minor medical activities at home (ex.: rehabilitation exercises, measurements, measuring levels, etc.)

Are there measurements on or of the body? Where is the intervention in the chain of care? A surgeon practicing a new surgical technique in a simulation will go on to treat hundreds of patients. If he or she learns the technique wrong, that will have far-reaching consequences for people in the future. This is of a completely different order than a patient who practices a rehabilitation exercise less than optimally at home.

E. user status

If the end user is a care consumer, then the user's health status is important:

- healthy (general lifestyle intervention / information / influencing)
- healthy, with risk of becoming ill (specific lifestyle intervention / information / influencing)
- temporarily ill (promoting / supporting recovery)
- chronically ill (lifestyle changes, constant monitoring and acute intervention in event of escalation)
- surroundings involved with care consumer (relatives, friends, caregivers, etc.)

If the end user is a health care professional, then the user's status is also important:

- involved in the provision of treatment (monitoring, support, reporting)
- responsible for planning treatment (deciding, communicating, following up, monitoring)
- responsible for the coordination of various stakeholders in treatment (outpatient and home care, but also in an intramural multidisciplinary setting)
- responsible for implementing complex medical intervention (doctors, surgeons, psychiatrists, etc.)

F. data profile

Privacy is currently a serious consideration for the security of online and digital products and services. And yet here too, perspective is needed, such as the degree in which the data transported can be traced back to a specific person and/or condition. The nature of the data should be seen separately from the fact that data is transferred over a network.

G. integration

Finally, we must recognise that many applications have combinations of these elements. An app can contain both awareness information as well as facilitate monitoring or support treatment interventions. An important question is therefore how to deal with these combinations of aspects. Another possible pitfall would be to determine the risk profile for an entire combined application exclusively by the element of the application with the highest risk profile.



Ad 2. The chosen form of game play

In the section above, we dealt with the first criteria: the context of use. If the app is a serious game, then the form of game play chosen is also important. This second criterion includes the manner in which the intervention is formulated in the game. The game play in a serious game can also be differentiated by:

a. functionality: is the computer game 'playable' (without software or procedural errors).

One can also consider

b. the validity of the construct (the design of the game).

Graafland et al. [2014] differentiate a variety of forms of validity. We have included the most important below.

- | | |
|-----------------------|--|
| 1) Face validity | which examines whether the game play corresponds to the therapy or solution in reality |
| 2) Content validity | which examines whether the game adequately and correctly offers these solutions, and |
| 3) Construct validity | in which the game intervention's effectiveness is compared to other possible solutions or therapies. |

Ad 3. Effectiveness

The effectiveness of a selected game as an intervention has two aspects:

- 1) user convenience, and
- 2) the effect that the serious game has on the end user within the chosen therapy, context or application domain.

This last aspect is the main bottleneck in the current practice, in which a good risk analysis is vital (see above). The first aspect is usually conducted in the form of 'user tests', in which a certain hypothesis is studied quantitatively or qualitatively.

4. Towards a new risk assessment system and corresponding validation requirements

The main problem is

"How can a good risk assessment be designed for these new categories of care interventions and support, in such a way that a justified link can be made to the necessary and suitable validation mechanisms?"

Appeal for differentiation in validation

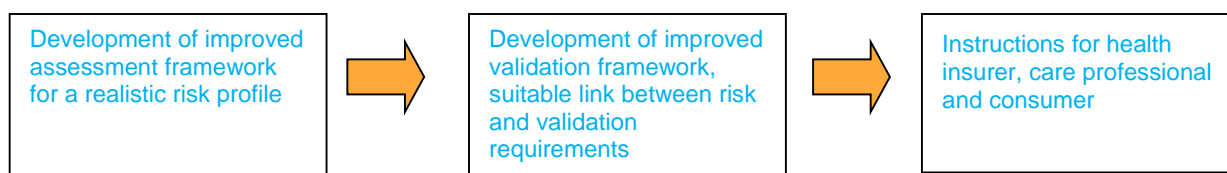
We advocate for the development of a balanced, updated system for risk analysis that clarifies which validation requirements are placed on each solution in order to prevent the requirements from being formulated too strictly or too loosely.

This initiative is emphatically not an attempt to negate the importance of validation. On the contrary: it is a plea to formulate proportional validation requirements in the systems for validation and certification of digital care tools that are informed by a careful risk analysis of the app, game or other digital intervention to be developed for the care and welfare domain. We will hereafter refer to these variants as 'application's'.



Such an evaluation framework must be flexible and future-proof with regard to new technological developments (think of biofeedback sensors that are increasingly finding their way into consumer products), as the integration of hardware and software progresses.

As stated above, the scope of this position paper does not include the presentation of a solution. Our goal is to spark a discussion about this issue and to elaborate several characteristics of the problem pertaining to differentiation that may serve as building blocks for the further development of a solution to this issue.



5. Conclusion: What needs to be done, and who will benefit from the solution?

We advocate for a fully elaborated framework for risk assessment, which also refers to a thorough system of validation requirements and methods, which will lead to a well-founded assessment or result.

Such an elaborated framework will be valuable for the following important stakeholders:

1. Care consumers and their caregivers, who will develop greater demand for tools to help them assume an increasing amount of responsibility for their care as it is delegated to them due to developments in the health care system.
2. Medical professionals, due to their responsibility to provide treatment, information, supervision and mediation.
3. Health insurers or other interested parties who bear final responsibility for the repayment/acceptation of care tools.
4. Policy workers and other government officials who design legislation and regulations.
5. Developers and researchers, both in knowledge centres and in industry, who wish to contribute to improving health care from their position as pioneers and innovators.
6. **Distribution parties** who host and provide apps, games and care portals for the users (think of Apple iOS store, Android app store, etc.)

Next steps

We are of the opinion that this problem must be given greater priority on the agenda, in order to lead to an improved situation. This paper therefore strives to emphasise that there are critical preconditions which an improved system must meet if it is not to unnecessarily hinder the innovation potential in health care.

More research is also needed, both nationally and internationally, to combine the knowledge and expertise needed in this area in order to prevent unnecessary duplication of the same work in too many places.

The consortium parties united in the Growing Games project have made it their goal to raise awareness of this issue and to contribute to a solution. By starting on the next phase of research, they hope to find critical stakeholders in the Netherlands and abroad and involve them in order to achieve the desired result.

This paper was drafted as part of the Growing Games project. Growing Games is a long-term stimulus programme (2013-2016) to promote the sustainable growth of the Dutch applied games sector. See www.growinggames.nl.

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