Developing evidence guidelines for eHealth Small and Medium-sized Enterprises

Towards feasible yet convincing evidence

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***Abstract*—eHealth applications hold many promises, for instance to improve the quality of health care, to increase its accessibility, or to reduce the cost. Yet, many eHealth innovations never reach the stage where they get embedded into routine health care. This is due in part to a lack of evidence that these innovations indeed deliver what they promise. For small and medium-sized enterprises (SMEs) in particular, collecting convincing evidence for eHealth innovations proves to be a challenge as the available time, resources and expertise to do so are often limited. In response to this challenge, the research group *ICT Innovation in Health Care* initiated the project *Successful Entrepreneurship in eHealth*. The project is a cooperation between 24 parties in The Netherlands: eHealth SMEs, health care providers, patient organizations, health insurance companies, and national health care authorities. Its aim is to speed up eHealth innovation by providing eHealth SMEs with guidelines for collecting feasible yet convincing evidence. In this paper the project's approach is introduced and some preliminary results and lessons learnt are discussed.**

Keywords: eHealth; innovation; evidence; guidelines; SME

I. INTRODUCTION

Getting an eHealth innovation embedded into routine health care often turns out to be a challenge. Several causes can be identified, including a narrow focus on technological aspects of the innovation, too little involvement from key stakeholders during design and implementation, or lack of a good underlying business model [1]. The research group *ICT Innovation in Health Care* at Windesheim University of Applied Sciences (Zwolle, The Netherlands) has dedicated itself to study these issues and to support small and medium-sized enterprises (SMEs; in The Netherlands defined as companies with up to 250 employees) in overcoming them. For instance, the research group recently published the first version of the eHealth Innovation Matrix [2]; an online assessment and library that offers eHealth SMEs (i.e., SMEs offering eHealth products and services to health care providers and the public) guidance in developing and evaluating a business model for their eHealth innovations.

A. Collecting evidence for eHealth innovations

In a recent series of workshops organized for eHealth SMEs and health care parties, an inventory was made of the problems encountered when getting eHealth innovations embedded in routine health care. Among the list of problems, collecting *evidence* for an innovation came out first. To get their innovation accepted by patients and care providers, reimbursed by health insurance companies, endorsed by patient organizations, or approved by national health care authorities, innovators often need to show evidence for the innovation's effectiveness, for instance to increase treatment quality or reduce the cost of delivering health care.

For a typical eHealth SME it is often unclear what kind of evidence is expected and by whom, and according to which standards this evidence should be collected. In other cases, the standard may be clear (e.g., a randomized controlled trial) yet practically unfeasible for an SME due to a lack of available time, (financial) resources, or expertise. To complicate matters further, care providers, insurance companies and care authorities offer no clear guidelines for eHealth innovators. They recognize that this discourages eHealth adoption and that it impedes innovation within the Dutch care system [3].

B. Towards feasible yet convincing evidence

At the beginning of 2012 the project *Successful Entrepreneurship in eHealth* (SEE) was initiated by the research group to address these challenges. The project constitutes a cooperation between 24 eHealth SMEs, health care providers, patient organizations, health insurance companies, and national health care authorities in The Netherlands. The project's aim is to establish guidelines for collecting evidence in such a way that (i) it is practically feasible for eHealth SME's to do so and (ii) the resulting evidence is acceptable and potentially convincing for care providers, health insurers, or care authorities. Hence the project's motto: *towards feasible yet convincing evidence*.

To achieve its aim, the project will address the following research questions:

1. What kinds of evidence for eHealth innovations are generally recognized? Are there any commonly accepted evaluation frameworks?
2. What are relevant outcome indicators and methods to collect specific kinds of evidence? How do these compare in terms of methodological quality and practical feasibility?

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3. Which parties in the Dutch care system (patients, care providers, health insurance companies, national care authorities, others) will need to be convinced of the effectiveness of an eHealth innovation before it can be embedded into routine practice?
4. How do these parties value the kinds of evidence mentioned earlier? What typically constitutes "convincing evidence" for these parties?

By generating answers to these questions the project will offer guidance to eHealth SMEs: which parties will need to be convinced of the effectiveness of an innovation, what evidence will be required, and how to collect this evidence in a feasible yet acceptable way.

II. APPROACH

The project is structured into four phases which are briefly outlined in this paragraph.

A. Inventory

During this phase an inventory is made of generally recognized types of evidence. This is done by means of a literature review, interviews with health care experts in The Netherlands, and workshops with representatives of Dutch health care providers, insurers, patient organizations, and national health care authorities. Questions to be answered include: Which parties are involved when getting an eHealth innovation embedded in routine health care? What kind of evidence is generally needed, and how should it be collected? How do parties value various kinds of evidence? What criteria are typically used? The results will include:

- An initial overview of commonly required types of evidence, possibly clustered into themes or categorized by type of eHealth application;
- A series of fact sheets, one for each type of evidence, containing purpose, relevance for various parties, methods, criteria, and practical feasibility.

B. Case studies

Whereas the analysis during the Inventory is top-down, the analysis during the case studies is deliberately bottom-up – to involve the SMEs and to enrich the analysis with examples of concrete situations, dilemmas and obstacles encountered. Cases from the participating eHealth SMEs will be selected for a detailed study by means of analysis of available documentation, workshops with experts, and in-depth, semi-structured interviews. Questions to be answered include: How are SMEs trying to get their innovations embedded into routine care? Which stakeholders do they identify and involve? What kinds of evidence do these stakeholders require? What evidence did the SMEs collect so far, and in what ways? How did stakeholders evaluate the evidence, against what criteria? The results will include:

- Detailed, in-depth descriptions of successful and unsuccessful strategies followed by SMEs to get their eHealth innovations embedded in routine health care;
- Specific examples of evidence that was required, whether and how it was collected and, if applicable, how it was evaluated by health care providers, insurers, patient organizations, or national health care authorities.

C. Guidelines and best practices

In this phase, the case studies will serve as input to a series of workshops with health care experts and representatives of health care providers, insurers, patient organizations, and national health care authorities. Learning lessons from these specific examples, and building on the results of the Inventory, best practices for embedding eHealth innovations in routine health care will be identified. Furthermore, guidelines will be developed for collecting and evaluating the required evidence. Best practices and guidelines will then be combined into a systematic approach for collecting and evaluating evidence for eHealth innovations. To validate the newly developed systematic approach it will be applied and evaluated in a second series of case studies. Thus, the results of this phase will include:

- An initial, systematic approach for collecting and evaluating evidence as required for getting an eHealth innovation embedded in routine health care;
- Validation of the systematic approach, including an inventory of practical issues and points for improvement.
- A revised, final systematic approach.

D. Consolidation and tool development

In this final project phase, the systematic approach described above will be consolidated in a web-based tool and documented in a handbook:

- The web-based tool will offer eHealth SMEs guidance in planning and implementing evidence collection for their eHealth innovation;
- The handbook will document the various types of evidence for eHealth innovations, including methods for collecting evidence and criteria for evaluating it.

III. PRELIMINARY RESULTS

The project *Successful Entrepreneurship in eHealth* started at the beginning of 2012 and will conclude at the end of 2013. At the time of writing, the first project phase, Inventory, is nearing completion while the second phase, the case studies, has just been started with the first in-depth interviews. This paragraph highlights some preliminary results and lessons learnt.

A. No generally accepted standards for collecting evidence

During the literature study several articles and reports offering proposals for evaluation frameworks were found, with guidelines for the evaluation of eHealth applications, lists of outcome indicators, and descriptions of methods to collect evidence [e.g., 4, 5]. However, the general consensus in the literature is that there are currently no commonly accepted standards for collecting evidence for eHealth applications [6, 7]. The assumptions, methods, and study designs of experimental science may altogether be less suited for application in the socio-political context in which eHealth evaluations usually take place, and alternative approaches

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that view evaluation as social practice rather than scientific testing need to be considered [8]. Moreover, the tendency to focus on "hard" evidence provided by randomized controlled trials (RCTs) may result in disregard for the interests and experiences of the individual patient [9]. Some researchers therefore argue for a contextualized approach in which all relevant stakeholders are actively involved in the definition of the outcome indicators that will be used for evaluation [10, 11].

B. Stakeholders recognize three themes for evidence

During the interviews with health care experts and the workshop with representatives from health care providers, insurers, patient organizations, and national health care authorities, three dominant themes were recognized by the participants within the larger concept of evidence: *effectiveness* ("did health care get any better?"), *cost efficiency* ("did it get any cheaper?") and *labor savings* ("did it get any less labor intensive?"). Below we briefly describe each theme, including a few relevant issues mentioned by the participants.

1) Effectiveness

This kind of evidence relates to clinical effectiveness, quality of care, safety, accessibility, timeliness, and patient satisfaction. However, eHealth's primary purpose may not always be patient recovery; frequently, eHealth is directed at retaining autonomy, strengthening the involvement from relatives, maintaining social participation, or improving a patient's wellbeing. Although these aspects are hard to measure, they are important from the patient's perspective and also valued by care professionals and society as a whole.

2) Cost efficiency

This includes evidence with regard to cost savings, cost control, and efficiency in terms of time, money, and other resources. eHealth applications have traditionally been considered as a promising way to reduce the cost of delivering health care. With the growing emphasis on budget control in health care, evidence for eHealth's cost efficiency is becoming increasingly relevant for decision makers. The current Dutch health care policy, for instance, is directed at stimulating cost-efficient eHealth applications that are replacing (instead of supplementing) traditional forms of care [3].

3) Labor savings

This relates to evidence that the same number of patients can be treated with the same quality, but with fewer hours worked by health care professionals. Although labor savings might be considered a special case of cost efficiency, the predicted labor shortage in the Dutch health care system justifies this kind of evidence to be considered separately. Labor savings also occur when an eHealth application reduces the complexity of a particular task, allowing highly schooled professionals to delegate part of their work to less skilled staff.

Various indicators and methods relating to the above types of evidence have been identified during the interviews and workshop and also from the literature. They are currently being complied into three sets of fact sheets, i.e., one set for each theme.

C. How stakeholders value evidence

From the interviews and workshop it has become clear that "heavy" forms of evidence (obtained using, e.g., randomized controlled trials) are certainly not always necessary to facilitate the uptake of eHealth applications. The participants agreed that RCTs are not always useful, necessary or practically feasible. Furthermore, care providers and health care insurers indicated that they will still rely on their own patient data to support any decisions they make about embedding eHealth applications.

National care authorities, on the other hand, hold the view that eHealth applications typically only change the way in which health care is being delivered. As long as there are no indications that clinical effectiveness is at stake, and within the limits defined by the health care system, care providers and health care insurers are free to negotiate and decide about the use (and reimbursement) of eHealth applications.

D. "Innovation routes" for embedding eHealth innovations

One topic which arose very prominently during the workshops, is that it is not straightforward which path an SME should follow within the care system to get an eHealth innovation embedded into routine care. In part this is due to the wide variety of applications that fall under the common denominator of eHealth, but it is also due to the complexity of the Dutch care system, which is highly regulated and in which various authorities and other parties each play a distinct role. From a myriad of options an SME should consider very carefully which "innovation route" to follow, as the chosen route will determine which stakeholders to address and involve. Stakeholders will have their own roles, responsibilities and interests, and hence will need their own arguments to get convinced of an eHealth application's added value. It is, therefore, the chosen innovation route that determines the context in which evidence will be collected and the purpose for which it is collected.

IV. CONCLUDING REMARKS

Returning to the project's slogan, *towards feasible yet convincing evidence*, it has become clear that it is absolutely essential to consider the purpose for which the evidence will be used. Any collected evidence effectively constitutes the foundation beneath a business model in which all relevant stakeholders and their interests have been accounted for. Although this conclusion may perhaps be obvious, the first case study interviews with SMEs indicate that they do not always realize this or act accordingly. SMEs should therefore identify and involve stakeholders as early as possible, and preferably define and collect any required evidence in a cooperative effort together with all relevant stakeholders.

The preliminary results clearly point out that eHealth SMEs require a "map" – not just to find the most promising innovation routes within the Dutch care system, but also to identify relevant stakeholders and their interests. Creating such a map, and embedding the evidence fact sheets within

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it, will provide SMEs with essential information they need to collect convincing evidence in a feasible way. In the coming months, this will therefore be the project's highest priority.

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