An eHealth Innovation Map for 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 its 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 Innovations in Health Care* at the Windesheim University of Applied Sciences initiated a joint research project, *Successful Entrepreneurship in eHealth*, with 28 eHealth SMEs, care providers, and other stakeholders in the Dutch health care system. The project's main result is an *eHealth innovation map*. This map consists of a diagram showing eHealth SMEs which parties in the Dutch health care system to involve, their roles and their mutual relations, their interests in eHealth innovation, and the kinds of evidence that may convince them of the added value of an eHealth innovation. A set of corresponding fact sheets was developed to provide eHealth SMEs with concise yet easily accessible information for choosing an appropriate "innovation route" and for determining what evidence to collect for relevant stakeholders. Preliminary findings show that the innovation map is indeed a useful instrument, and that the corresponding fact sheets manage to capture all the essential information needed to guide an eHealth SME along a chosen innovation route.**

Keywords - eHealth; innovation map; innovation route; evidence guidelines; health care system; stakeholder

I. INTRODUCTION

Getting an eHealth innovation embedded into routine health care often turns out to be a challenge, in particular for small and medium-sized enterprises (SMEs). Several causes can be identified, for instance a lack of a good underlying business model [1]. The research group *ICT Innovations in Health Care* at the Windesheim University of Applied Sciences (Zwolle, The Netherlands) has dedicated itself to study these issues and to support eHealth SMEs in overcoming them. Note that eHealth SMEs are defined here as small and medium sized enterprises offering eHealth products and services to patients, health care providers, and the general public. All SMEs participating in the project had less than 10 employees.

During a series of workshops organized by the research group, an inventory was made of the problems encountered when SMEs are trying to get eHealth innovations embedded into routine health care. 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 improve 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.

Other researchers have also identified this barrier to eHealth implementation, although not specifically for SMEs. For instance, Mair et al. [2, 3] conclude in a meta-review of eHealth implementation studies that lack of validation and evaluation is frequently presented as a barrier to eHealth implementation: *"Without strong data demonstrating that a system works, improves standards of care, can be used efficiently and easily, and is cost-effective to implement, it is unlikely to win the confidence of policy makers and users."* [2, p. 23].

The project *Successful Entrepreneurship in eHealth* was initiated by the research group to address these challenges. The project constitutes a cooperation between 28 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 SMEs to do so and (ii) the resulting evidence is acceptable and potentially convincing for care providers, health insurers, or care authorities.

The project's main aim is to offer guidance to eHealth SMEs: which parties will need to be convinced of the

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effectiveness of an innovation, what evidence will be required, and how to collect this evidence in a feasible yet acceptable way.

The structure of the remainder of this paper is as follows. In Section II the approach followed will be introduced, including the four phases in which the project was structured. Next, Section III will discuss the main findings and lessons learned. Section IV describes the eHealth innovation map and the accompanying sets of fact sheets. Finally, Section V summarizes the main conclusions.

II. APPROACH

The project *Successful Entrepreneurship in eHealth* started at the beginning of 2012 and will conclude at the end of 2013. At the outset the project was structured into four phases; these phases are briefly outlined in this section. More details about the approach followed are given in [4] and [5].

A. Phase 1: Inventory

During this phase an inventory was made of generally recognized types of evidence. This was done by means of a literature review and a workshop with representatives of Dutch health care providers, insurers, patient organizations, and national health care authorities. Questions to be answered included: 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? And what criteria are typically used?

B. Phase 2: Case studies

Whereas the analysis during the inventory phase was top-down, the analysis during the case studies was 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 were subjected to a detailed study by means of in-depth, semi-structured interviews and an analysis of available documentation. Questions included: 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?

C. Phase 3: Guidelines and best practices

In this phase, the insights gained from the inventory and the case studies were combined. Best practices for embedding eHealth innovations in routine health care were identified, and guidelines for collecting required evidence were developed. Best practices and guidelines were then combined into a systematic approach for collecting evidence for eHealth innovations. To validate the newly developed approach it was applied and evaluated in a second series of case studies.

D. Phase 4: Consolidation and tool development

In this final project phase, the systematic approach described above was consolidated into an "eHealth innovation map". The map consists of a diagram showing eHealth SMEs which parties in the Dutch health care system to involve, their roles and their mutual relations, their interests in eHealth innovation, and the kinds of evidence that may convince them of the added value of an eHealth innovation. As part of the map, a set of corresponding fact sheets was developed to provide eHealth SMEs with concise yet easily accessible information for choosing one of four possible "innovation routes", and for determining what evidence to collect for relevant stakeholders encountered along each route. The map and fact sheets have been made available to a wide audience in The Netherlands, by means of a convenient booklet and a corresponding interactive web-based tool.

E. Ongoing dialogue

Next to the activities in the above four phases, regular project meetings were organized to stimulate an ongoing dialogue between the participating organizations. During these meetings, SMEs introduced their cases, representatives of health care organizations discussed procedures or criteria used to evaluate eHealth innovations, and the research team presented the project's latest results. To collect feedback from the project's participants, mini-workshops were organized to evaluate the usefulness and correctness of the developed tools, typically by applying them to cases at hand.

III. OVERVIEW OF FINDINGS

This section briefly highlights the main findings and lessons learned. A complete overview, including a detailed discussion of the case study results, is provided in [5].

A. Existing frameworks offer little guidance for SMEs

During the literature study more than a few reports and scientific papers offering proposals for eHealth evaluation frameworks were found, most of them containing guidelines for setting up a proper evaluation study, lists of outcome indicators and measures for various aspects of eHealth's impact, and descriptions of methods and instruments to collect data. Examples are the *National Telehealth Outcome Indicators Project* [6], *Model for the Assessment of Telemedicine Applications* [7], and *Guidelines for the Economic Evaluation of Health Technologies* [8]. However, these frameworks seem to be directed mostly at academic experts. The *Health Information Technology Evaluation Toolkit* [9] is one of the very few examples primarily aimed at the non-expert. It provides step-by-step guidance for project teams who are developing evaluation plans for health IT projects.

Although these frameworks indeed offer guidance with regard to setting up a proper study, none of the frameworks found provide the same kind of guidance with regard to identifying the various stakeholders involved in embedding an eHealth innovation into routine care, including their possible interests in the innovation, and subsequently the aim of an evaluation and the kinds of evidence that may be

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required. This is especially striking since researchers have argued for a contextualized approach in which all relevant stakeholders are actively involved in the definition of the outcome indicators that will be used [10, 11].

B. Stakeholders' views on evidence

During an expert session 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?"), including respective outcome indicators and methods. During the session it became clear that strong forms of evidence (obtained using, for instance, randomized controlled trials) are certainly not always necessary to facilitate the uptake of eHealth applications. The participants agreed that randomized controlled trials 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, held 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 safety or clinical effectiveness are at stake, and within the limits defined by regulations governing the provision of health care, care providers and health care insurers are free to negotiate and decide about the use (and reimbursement) of eHealth applications.

C. Four "innovation routes" for eHealth innovations

One topic which arose very prominently during the same expert session, is that it is not straightforward which path an SME should follow within the Dutch 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. 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, the purpose for which it is collected, and the requirements that it should satisfy.

Based on the above findings, a review of online documentation pertaining to innovation in the Dutch health care system took place (e.g., [12-16]), and follow-up interviews with representatives of the participating health care organizations were organized. These efforts resulted in a comprehensive description of the Dutch health care system, including the roles of the parties involved, their interests in eHealth innovation, and criteria they use to evaluate eHealth innovations. Four main innovation routes were identified and described, including the specifics of each route and criteria for when to choose which route:

- The *consumer route* where an eHealth application is offered to and paid by patients/consumers. For example, a medical translation app that can be used when visiting a doctor abroad.
- The *provider route* where an application is offered to and paid by health care providers. For instance, an online treatment plan which allows clients to consult their plan and report about their progress.
- The *insurer route* where an application becomes part of an existing treatment that is offered by a care provider and reimbursed by a health insurance company. For example, a real-time medication monitoring service to improve the medication adherence of a diabetes patient. (In this case, the medication is the existing treatment and real-time monitoring becomes part of it.)
- The *government route* where an application leads to a new treatment not yet offered by care providers or reimbursed by health insurance companies, and where health care authorities need to decide whether it should be admitted to publicly insured care. Here, an example might be the introduction of telemonitoring of epilepsy patients in the home environment, to respond quickly in the event of a major seizure.

D. The paths followed by eHealth SMEs

During the case studies phase, eight cases submitted by seven SMEs were selected for in-depth, semi-structured interviews. During each interview, the path followed by the SME to get its eHealth innovation embedded into routine care was reconstructed. Particular attention was paid to the stakeholders that had been identified and involved, and (if applicable) the evidence that had been collected. Where available, underlying documentation was used to analyze the collected evidence, in particular the outcome indicators and methodology used, the conclusions drawn, and, if applicable, how these conclusions were translated into a business case for stakeholders.

A detailed discussion of the case study results is outside the scope of this paper. We briefly summarize a few highlights here, more details are reported in [5].

- Entrepreneurs with little or no experience in the health care sector often had difficulties in identifying a successful innovation route. The paths they followed were frequently based on trial and error, during which they steadily built up a better understanding of how the health care system works.
- The role of health insurance companies in the health care system, their interests in health care innovations, and the criteria by which they evaluate eHealth innovations were often unclear to SMEs.
- SMEs tended to involve health insurance companies too early, when strong support among care providers, endorsements from patient organizations,

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or approvals from professional associations were still lacking. Insurance companies, on the other hand, used these as principal criteria for the selection of promising innovations.

- Health care providers and health insurance companies often had partly conflicting interests, making it difficult to come up with a business case which was compelling to both parties at the same time.
- Within the "insurer route", clinical trials were often essential to build up evidence for an innovation's effectiveness. SMEs lacked the expertise and financial resources to carry out a proper trial, forcing them to involve experts and to find sponsoring. Furthermore, it was not always clear exactly what evidence was required.
- In cases where evidence had been collected in trials, this had been done using randomized controlled trials – the "golden standard" [17]. These trials were designed and performed by academic experts. These experts assumed responsibility for deciding which evidence was to be collected and how this should be done. However, it remained unclear to which extent external stakeholders had been consulted before these choices were made.
- The results from a trial had sometimes been developed into a business case for stakeholders. One case was especially illustrative: the effect that was found on an intermediary outcome measure used in the trial was first translated into an effect on a relevant end measure (a reduction in health related costs) using the results of a systematic review found in the scientific literature. This was then translated into a reduction in insurance claims for a health insurance company, based on the results of an internal study performed by the insurer. In this way, the clinical trial could focus on an intermediary outcome measure where effects could be measured on a much shorter time scale.

Judging from the cases under study, it was clear that decision makers (for instance in health insurance companies, but also in other stakeholders) should be more closely involved when an evaluation is being planned. In this way, the criteria that play a role in the decision process can be clarified early on, when they can still be taken into account in the development of evaluation plans or business cases, or in the design of clinical trials.

E. The criteria used by the insurance company

In the Dutch health care system, the insurance company often plays a crucial role in the reimbursement of eHealth based care. Based on three cases that were monitored closely during the project, it became clear that three criteria are essential for the insurer: (i) is there sufficient support for the innovation among care providers (for instance, does it address any evident needs or demands), (ii) does the innovation fit into existing health care processes, and (iii) will it be able to substitute for existing forms of care. Other important criteria were: (iv) is the innovation fully developed, (v) is it fully interoperable with existing systems

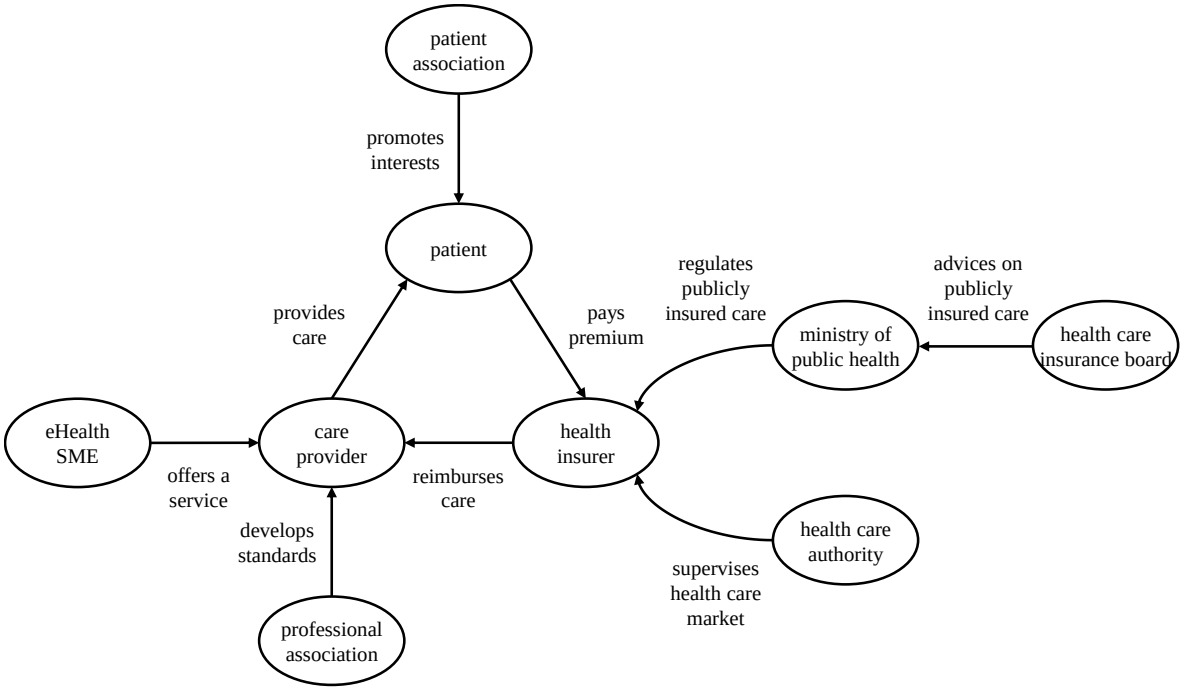

Figure 1: Elementary version of the eHealth innovation map, showing the main parties in the Dutch health care system. Each of these parties and their interests in eHealth innovations are further described in accompanying fact sheets.

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(for instance, systems in use by general practitioners), and (vi) is the potential for a nationwide adoption clear.

The criteria used by the insurer seem to be driven by a concern to identify early on which innovations will most likely be successfully implemented. However, the principal criterion is cost reduction by means of substitution: an eHealth innovation should either lead to the replacement of an existing form of care by a more cost efficient one; or, by being more effective, it should contribute to a reduced health care consumption in the near future. To convincingly show this to the health insurer, a detailed quantitative business case is often required.

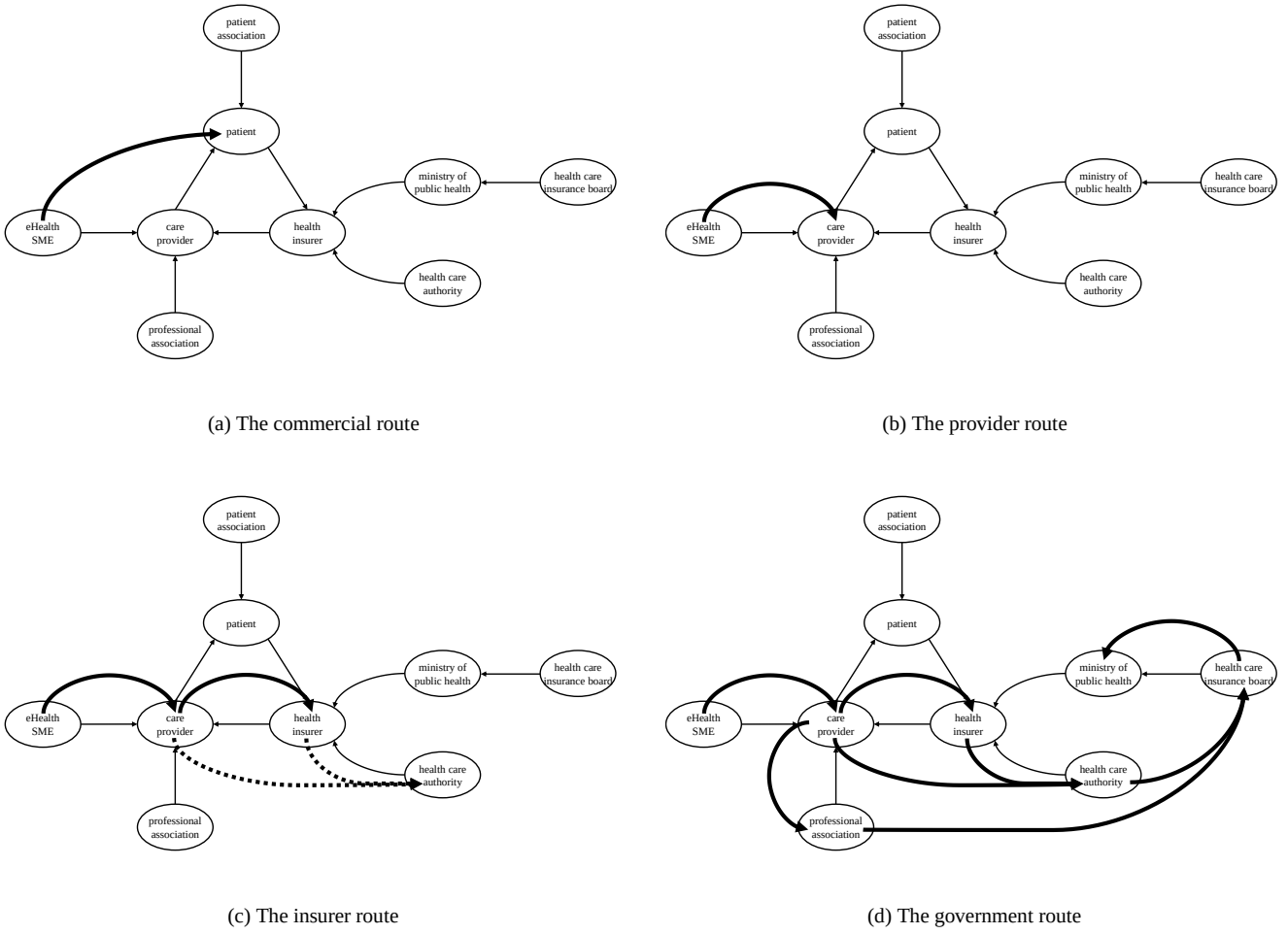
IV. FROM FINDINGS TO GUIDELINES

During the inventory and case study phases of the project it had become clear that, when evaluation plans or clinical trials are being planned, relevant stakeholders should be identified and their interests taken into account. This is especially important because, ultimately, the evidence that is collected will be constituting the foundation beneath a business case in which all relevant stakeholders and their interests are accounted for. Preferably, principal stakeholders should be involved as early as possible, and the required evidence defined and collected in a cooperative effort.

To facilitate this, eHealth SMEs required a "map": to find the most promising innovation routes within the Dutch care system, and to identify relevant stakeholders and their interests. The creation of such a map, including a set of corresponding "fact sheets" (detailed yet concise and accessible information on innovation routes, relevant stakeholders and their interests, and types of evidence required) became the project's highest priority.

A. The eHealth innovation map

The starting point when developing the innovation map was that it should provide concise yet accessible information for SMEs on (i) the Dutch health care system, (ii) the roles of the main parties within it, (iii) the interests these parties have in eHealth innovations, and (iv) examples of applicable evidence to convince them. Furthermore, the map should visualize the four innovation routes and so facilitate the identification of relevant stakeholders. The map should



(a) The commercial route

(b) The provider route

(c) The insurer route

(d) The government route

Figure 2: Thematic versions of the innovation map showing the four innovation routes. Thick arrows represent subsequent steps that should be undertaken by the SME or other involved stakeholders. Each version is accompanied by a descriptive fact sheet.

provide only an overview; detailed information with guidelines and best practices had to be provided in sets of accompanying fact sheets (of one page each): a set on the innovation routes, a set on the stakeholders involved, and a set on applicable evidence. The following paragraphs briefly discuss each of these elements.

1) The innovation map

Figure 1 shows the innovation map in its elementary version, displaying only the main parties in the Dutch health care system and the relations among them. Care has been taken to streamline the map without oversimplifying it. Three thematic versions of the innovation map (not shown here) display additional information: one shows the various stakeholders within each party, one the interests that stakeholders may have in eHealth innovations, and one the kinds of evidence (or other applicable forms of proof) that may be used to convince them. Furthermore, there are four thematic versions displaying the identified innovation routes; these versions are shown in Figure 2. Each version is accompanied by a brief description of what is shown. In this way, SMEs are provided with "at a glance" information which acts as an index to the accompanying sets of fact sheets.

2) Fact sheets on stakeholders

Each party is described in more detail in its own fact sheet. These fact sheets contain concise information on (i) the role of this party in the health care system, (ii) relevant stakeholders within this party that may play a role in decision making, (iii) their interest (or interests) in eHealth innovations, and (iv) general guidelines on how (and by what means) this party can be convinced. Table 1 shows a representative example of a stakeholder fact sheet, in this case about the insurer.

3) Fact sheets on innovation routes

The four innovation routes are also described in their own set of fact sheets. These fact sheets contain information on (i) situations where a particular route is applicable, (ii) matters to take into account when following a route, (iii) special circumstances or regulations that may apply, (iv) the main stakeholders that need to be involved, and (v) the main pitfalls. Table 2 shows a representative example of an innovation route fact sheet, i.e., the insurer route.

4) Fact sheets on evidence

The third set of fact sheets concerns the evidence that

TABLE 1: EXAMPLE OF A STAKEHOLDER FACT SHEET. THIS ONE DISCUSSES THE INSURER. OTHERS DISCUSS THE CARE PROVIDER, THE PATIENT, THE PATIENT ASSOCIATION, THE PROFESSIONAL ASSOCIATION, AND THE GOVERNMENT ORGANIZATIONS. (TRANSLATED FROM DUTCH; REFERENCES TO SOURCES IN THE ORIGINAL TEXT HAVE BEEN OMITTED FOR READABILITY.)

Fact sheet health care insurer

Role

The health care insurer is the party reimbursing the care being provided to patients with the eHealth application. Keep in mind that there will be various stakeholders within the insurer, all with particular interests with regard to the eHealth application:

- The innovation department, where potentially interesting eHealth applications are selected and evaluated.
- The investment fund, which backs the development of eHealth applications financially.
- The purchasing department, which negotiates with care providers and purchases large quantities of health care (as efficiently as possible). Therefore, the role of eHealth applications it often limited.
- The commercial department, which sets up additional insurance packages for private parties and collective insurances for organizations and which sees eHealth as a distinguishing feature.

Keep in mind that any enthusiasm in the innovation department is not necessarily shared by the other stakeholders!

Interests

As far as health care insurers are concerned, what is most important is high-quality care at low cost, which translates into the following demands being made regarding eHealth applications:

- The application needs to have sufficient support among care providers and patients (through co-creation).
- The application must deliver health care gains (better quality care or higher quality of life).
- The application has to reduce health care costs (through increased independence on the part of the patient or reduced burden on the health care provider).
- The application has to lead to substitution (no extra care but substitution of existing care).
- The application has to lead to reduced health-related absence (prevention or quicker recovery).
- The application has to be in line with national agreements and purchasing policies.

Health care insurers do business with care providers, who they see as interlocutor, which means it is important to make sure that the application is suggested to the health care insurer by an enthusiastic care provider (rather than by the entrepreneur).

Persuasion

Health care insurers have medical advisers who will assess the added value of an application on the basis of their expertise. Generally speaking, they will demand to see a business case, based on financial estimates and supported by research results (for instance a clinical trial or pilot project).

A business case can be created in stages, for instance by translating the effects that have been detected in a pilot study into financial consequences for the health care insurer. Always determine the design of a pilot study or clinical trial (what is being measured, and how) together with the care provider and health care insurer.

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will be required to convince the main stakeholders along each of the four innovation routes. The information provided in these fact sheets is necessarily generic; details on exactly which evidence to collect will depend on the specific situation (e.g., the type of eHealth application, where it is being used and to what effect, and the specific interests of relevant stakeholders). The fact sheets therefore contain (i) a concise description of the kinds of effects that need to be demonstrated for the main stakeholders, (ii) examples of the kinds of evidence that may be applicable, (iii) a few generic guidelines and best practices on how to collect evidence, and (iv) references to relevant sources of information, such as the frameworks discussed earlier in Section III.A. Table 3 shows a representative example of an evidence fact sheet, i.e., evidence for the insurer route.

B. Validation of the innovation map

Validation of the eHealth innovation map and the corresponding fact sheets has been performed along four different lines. First, experts from the participating health care providers, patient associations, and government organizations have been asked to carefully check the map and the fact sheets for correctness and completeness of the provided information. Several corrections and suggestions have been made by them, which have subsequently been incorporated into the materials.

Second, the usability and usefulness of the map and fact sheets have been evaluated with representatives from eHealth SMEs. This has been done during a series of workshops both within the project (as part of the regular project meetings) and outside of the project (e.g., at national and regional eHealth-related conferences and symposia). In these workshops the eHealth innovation map was applied to a range of different cases at hand (usually provided by workshop participants) and evaluation happened afterwards by means of questionnaires and discussions with participants. In this way, a substantial amount of valuable feedback was collected and used to improve the materials.

Third, validation of the map is currently being performed by means of "action research", where the research team is getting actively involved in a few selected cases with the aim to evaluate and extend the current insights.

Fourth, a number of successful cases are currently being

TABLE 2: EXAMPLE OF AN INNOVATION ROUTE FACT SHEET. THIS ONE DISCUSSES THE INSURER ROUTE. OTHERS DISCUSS THE COMMERCIAL ROUTE, THE PROVIDER ROUTE, AND THE GOVERNMENT ROUTE. (TRANSLATED FROM DUTCH; REFERENCES TO SOURCES IN THE ORIGINAL TEXT HAVE BEEN OMITTED FOR READABILITY.)

Fact sheet insurer route

When does this route apply?
An eHealth application is integrated into care that is already being provided or reimbursed. The application does not alter the care being provided, only the form in which it is delivered. As a result, for example, the care becomes more accessible or it can be provided more efficiently.

Examples
- An online nutrition diary that is used as part of diet advice by a dietician and promotes the patient's self-management.
- A pillbox that alerts patients when they forget to take their medication. This takes place on doctor's order and promotes patient discipline.

Points of interest
Make sure there is sufficient support! It is important for care providers, patients and patient organizations to be enthusiastic about the application, which is why it is crucial to involve them at an early stage in the development (co-creation). The specialists' professional association plays an important role in nationwide up-scaling, because they determine the guidelines for good and safe care.

If an application leads to cheaper or less labor-intensive care, while the quality of the provided care remains the same at least, this is interesting for the care provider and it may not be necessary to involve the insurer. If, on the other hand, the application makes the care being provided more expensive, it has to be demonstrated that the quality of the care has improved and a larger support base is needed. Do not approach the insurer yourself, but let the enthusiastic care provider do the negotiations.

As far as insurers are concerned, it is crucial for the application to lead to a replacement of existing care (for instance through substitution or self-management) and, ultimately, to a reduction in reimbursements. It is important to demonstrate this in a detailed business case.

Special details
If an application does not match the existing care descriptions defined by the Dutch Healthcare Authority (for example due to restrictions in the description or rate), the care provider and insurer together can submit an application at the Dutch Healthcare Authority. The Dutch Healthcare Authority can modify an existing care description or create a temporary one, giving the application time to "prove" itself.

The main stakeholders
- Care provider and professional association
- Patients and patient association
- Care insurer
- Dutch Healthcare Authority (if a care description needs to be modified or a temporary one created)

Pitfalls
Creating insufficient support (among patients, care providers, patient associations and professional associations). Approaching the insurer yourself without the backing of at least one care provider. Not paying attention to the substitution of the existing care.

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analyzed by means of desk research and interviews with parties involved, to assess the innovation routes that have been followed and the evidence that has been collected.

Overall, the consulted experts and participating SMEs had very favorable remarks. Judging from the feedback that was given, the innovation map does indeed manage to provide a concise and accessible overview of the various ways in which eHealth innovations can be embedded in routine health care. At the time of writing there is a strong interest in the map. It has, for instance, been made accessible to a large audience via the website of the Netherlands Organization for Health Research and Development [14] and a well-known website maintained by a joint initiative of four government organizations (the Dutch Healthcare Insurance Board, the Dutch Healthcare Authority, the Ministry of Health, Welfare and Sports, and the Netherlands Organization for Health Research and Development) [15].

The preliminary findings from the third and fourth lines (action research and analysis of successful cases) also provide support for the conclusion that the innovation map is a useful instrument, and that the corresponding fact sheets manage to capture all the essential information needed to guide an SME along a chosen innovation route.

C. Consolidation and tool development

The last phase of the project, consolidation and tool development, is currently nearing completion. Based on the eHealth innovation map a workshop protocol has been developed, and currently the innovation map and the fact sheets are being incorporated into an interactive, web-based tool [18]. The workshop protocol and the web-based tool both provide guidance to SMEs in finding a promising innovation route, in identifying relevant stakeholders to involve, and in determining which evidence they may require.

Last, the project's results are being documented in an accessible and illustrated booklet for SMEs. The booklet covers all the information contained within the innovation

TABLE 3: EXAMPLE OF AN EVIDENCE FACT SHEET. THIS ONE DISCUSSES EVIDENCE FOR THE INSURER ROUTE. OTHERS DISCUSS EVIDENCE FOR THE COMMERCIAL ROUTE, THE PROVIDER ROUTE, AND THE GOVERNMENT ROUTE. (TRANSLATED FROM DUTCH; REFERENCES TO SOURCES IN THE ORIGINAL TEXT HAVE BEEN OMITTED FOR READABILITY.)

Fact sheet evidence within the insurer route

What needs to be demonstrated?
A business case needs to be developed in which the interests of the care provider (see the provider route) and the health insurer are combined. Ultimately, health care insurers want to see a reduction in health care costs (through substitution or self-management), but they also focus on support among providers, scalability and compatibility with existing care processes. See the ZonMw website for a list of relevant criteria.

Which evidence is suitable?
Demonstrating a reduction in health care costs can be done in two ways:

1. By replacing expensive forms of care by less expensive ones ("substitution"). This leads to "definite", short-term cost reductions. Make clear to the insurer how the current care process will change and how this will lead to labor savings, process optimization, or lower costs. Pay attention to the aspects that will be included in the business case, and how this will be measured in a pilot or trial. Insurers will want to know how substitution is actually accomplished.
2. More effective care will lead to a reduction in care consumption in the long term, but the cost reduction is surrounded by uncertainty. Note that insurers will want to see a return on investment within three years. Reduced health care consumption will need to be demonstrated with methodologically sound research, for instance using this three-stage process: (1) a clinical trial aimed at measuring a process measure or intermediary measure, (2) translation of the effects found on the process or intermediary measure into an effect on a relevant end measure, based on the best available scientific evidence on the relation between these two, (3) calculation of the potential cost reduction based on insurer data. The Achmea Health Database is a good source of information to do this.

Some eHealth applications may be attractive for health insurer for commercial or marketing purposes (e.g., to attract or maintain subscribers). In such cases, contact the commercial department, which is responsible for additional insurances for consumers and collective insurances for organizations. In the latter case, it should be clear how the application can lead to fitter employees or reduced sick leave.

Things to keep in mind:

- In the case of improved efficiency, there has to be a clear (clinically relevant) improvement, which has to be demonstrated through scientifically sound research.
- Be careful about making assumptions, for instance in translating an intermediary measure (for instance, medication adherence) to an end measure (reduction or delay of complications). Do not add assumptions to assumptions.
- "Pick your battle": using a certain application may prove more beneficial with some syndromes compared to others. Think about this carefully.
- "Hard" data (which can be determined objectively) have more weight than "soft" data (opinions or experiences of patients and other people involved), no matter how they are collected. "Hard" data can also be obtained through routine registrations of care suppliers.

Important:

- Discuss as early as possible with the insurer and the care provider what evidence will be required.
- Involve important stakeholders, such as decision-makers, when working out the appropriate research approach.
- Consult experts when methodologically strong research is needed, but keep stakeholders involved.

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map and the fact sheets, such as the descriptions of the main parties in the Dutch health care system, the identified innovation routes, the interests of various parties in eHealth innovations, and various kinds of evidence that may be required. It is hoped that in this way, the project's results will be well consolidated and accessible for all interested eHealth SMEs in The Netherlands.

V. CONCLUDING REMARKS

The main conclusion to be drawn from the research presented here, is that evidence constitutes the foundation underneath a business case in which all relevant stakeholders and their interests are accounted for. Preferably, principal stakeholders should be involved as early as possible when planning an evaluation study or a (clinical) trial. In this way, the criteria that will play a role later on in the decision process can be clarified early on, when they can still be taken into account.

This insight has become the corner stone of the approach developed in the project "Successful Entrepreneurship in eHealth". Following this approach, the chosen innovation route, the identified stakeholders, and their interests in the eHealth innovation at hand eventually determine which kinds of evidence will be needed and how they should be collected. The developed eHealth innovation map, the workshop protocol, and the web-based tool were all developed to provide guidance to eHealth SMEs, allowing them to make better, more informed decisions. The design, implementation and analysis of clinical trials will nevertheless remain the domain of academic experts or highly trained staff members working at care providers; the level of expertise that is required makes this simply unavoidable.

With regard to the usefulness of the results in countries outside The Netherlands, the question arises how unique the Dutch situation really is. In other words, can the eHealth innovation map be generalized to other countries? When an early concept of the innovation map was presented at an international eHealth conference [4] it seemed from the responses given by the international audience that certain basic principles, such as the roles and interests of the care provider and the insurer, are certainly generalizable. Other aspects, such as the government legislation pertaining to the health care system, will vary. Nevertheless, judging by this first impression it seems that the proposed approach may be fruitful for parties in other countries as well.

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