Innovation Routes and 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 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 the project *Successful Entrepreneurship in eHealth*. The project is a cooperation between 28 parties in The Netherlands: health care providers, patient organizations, health insurance companies, national health care authorities, and 15 eHealth SMEs. 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 the main results and lessons learned are discussed. The evaluation of eHealth innovations was found to be highly context-driven, with parties involved each employing their own criteria. Among the project's main results is an *eHealth innovation map*, 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 innovation route and for determining what evidence to collect for relevant stakeholders.**

Keywords - eHealth; 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. 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 [2]. 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 small and medium-sized enterprises (SMEs) in overcoming them. For instance, the research group recently published the eHealth Innovation Matrix [3]; an online assessment and library that offers eHealth SMEs [1] guidance in developing and evaluating a business model for their eHealth innovations.

A. Problems collecting evidence for eHealth innovations

In 2011 the research group organized a series of workshops for eHealth SMEs and organizations in health care. During these workshops 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 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. 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 health care system [4].

Other researchers have also identified this barrier to eHealth implementation, albeit not specifically for SMEs. For instance, Mair et al. [5, 6] conclude in a meta-review of eHealth implementation studies that lack of validation and

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[1] 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 eHealth SMEs participating in the project had less than 10 employees.

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."* [5, p. 23].

B. Towards feasible yet convincing evidence

The project described here, *Successful Entrepreneurship in eHealth* [1], 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. Hence, the project's motto: *towards feasible yet convincing evidence*.

To achieve its aim, the project set out to 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?
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 aims to 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.

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, Sections III to VI will discuss the main results for each of the project's phases (inventory, case studies, guidelines & best practices, and consolidation & tool development). Finally, Section VII 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.

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, consultation of online documentation, an expert session with representatives of Dutch health care providers, insurers, patient organizations, and national health care authorities, and a series of follow-up interviews with these experts. 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?

The expert session was recorded and transcribed, and of each follow-up interview a report was made and sent to the participant for verification. The results of the expert session and the follow-up interviews were then summarized in a joint interpretation session by the research team, using so-called affinity diagramming [7]. Thus, the main results of this phase were:

- An overview of (scientifically founded) frameworks for the evaluation of eHealth innovations;
- A detailed list of outcome indicators and methods, clustered into three identified themes (effectiveness, cost efficiency, and labor savings);
- A comprehensive description of the Dutch health care system, including the roles of the parties involved and their interests in eHealth innovation;
- An outline of four main strategies ("innovation routes") to get eHealth innovation embedded into routine health care;

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. To this end, 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?

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. Of each interview a report was made and sent to the participant for verification. Here as well, the

results were summarized in a follow-up interpretation session using the affinity diagramming technique [7]. The main results included:

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

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: the "eHealth innovation map". This was done in a series of joint interpretation sessions by the research team. At several moments during this process, intermediate results were presented to and discussed with experts and project partners to collect feedback and suggestions for improvements.

To validate the newly developed approach it is currently being applied and evaluated in a second series of case studies. Validation has also been performed 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 approach 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. Thus, the results of this phase included:

- A systematic approach, consisting of an "eHealth innovation map" showing which parties to involve, their roles and mutual relations, their interests in eHealth innovation, and the kinds of evidence that may convince them;
- A set of corresponding fact sheets providing concise yet detailed information for choosing an innovation route and for determining what evidence to collect for relevant stakeholders;
- Validation of the approach, including an inventory of practical issues and points for improvement (partly this is still work in progress).

D. Phase 4: Consolidation and tool development

In this final project phase, the systematic approach described above is being consolidated in a workshop protocol and a web-based tool, and documented in a booklet:

- The workshop protocol and web-based tool both provide guidance in choosing the most promising innovation route, identifying relevant stakeholders, and determining which kinds of evidence they may require.

- The booklet documents the systematic approach in a concise and accessible way, and aims to disseminate the project's results to the wider audience of eHealth SMEs in The Netherlands.

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 (such as the eHealth innovation map and fact sheets), typically by applying these tools to cases at hand.

This approach resulted in several collaborations among the project's participants. For instance, during one of the meetings a representative of a health insurance company called upon the participating SMEs to enroll their innovations at the company's health innovation desk. Three SMEs did, and the progress of the three enrollments was then monitored closely by the research team to learn about the procedure and the criteria being used by this health insurance company to evaluate the three innovations. During this process both sides (SMEs and insurance company) were regularly heard by means of structured telephone interviews or brief questionnaires sent and answered by email. Furthermore, and as part of this process, the insurance company provided a list of the indicators used by its innovation desk to select promising eHealth innovations.

III. RESULTS: INVENTORY

This section highlights the results and lessons learned from the first phase, the inventory.

A. Frameworks for evaluating eHealth

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, or descriptions of methods and instruments to collect data. We will describe four representative examples here. The extent to which these frameworks are actually being adopted and used, could not be established from the literature.

1) NTOIP

The Canadian *National Telehealth Outcome Indicators Project* [8] is a comprehensive framework covering four dimensions of evaluating eHealth: quality, access, acceptability, and cost. It is based on a hierarchy consisting of categories (for instance, "health status"), themes ("quality"), indicators ("quality of life"), measures ("morbidity"), and tools ("SF-12"). In total, 12 outcome indicators have been defined for the dimension quality, 6 for access, 15 for acceptability, and 11 for cost. For each dimension a top-3 of most important indicators has also been

selected. Per outcome indicator, detailed information is provided on 16 elements, including purpose, characteristics, definition, rationale, potential uses, outcome measures and tools. NTOIP was designed to improve the scientific quality of evaluations of eHealth applications by providing guidance on specific outcome indicators. It is based on the results of an extensive literature review followed by a national experts workshop, and is aimed primarily at academic researchers.

2) MAST

In the European Union, *Model for the Assessment of Telemedicine Applications* [9] follows a similar approach. The model contains three elements: preceding considerations (to determine whether it is relevant to carry out an assessment), a multidisciplinary assessment (to describe and assess different outcomes of an eHealth application), and a transferability assessment (to assess the transferability of study results from one setting to another). In the multidisciplinary assessment, eHealth applications are evaluated in terms of seven domains, ranging from safety, clinical effectiveness, and patient perspective to economic, organizational, and socio-cultural aspects. Each domain is defined, and issues to consider within each domain are listed. No detailed guidelines are given with regard to study designs, methods, and outcome measures, although a manual is provided with examples of outcome measures for each domain, and methods for data collection. The development of MAST was initiated by the European Commission and carried out by a consortium of academic institutions using consensus building workshops with experts and decision makers. Its aim is to provide guidelines for a consistent assessment of eHealth outcomes, primarily for academic researchers performing evaluation studies to inform decision makers in health care.

3) CADTH Economic Guidelines

Economic evaluation (i.e., "value for money" analyses) of eHealth applications is an important area and specific frameworks have been developed for this purpose. An example of a rigorous framework is *Guidelines for the Economic Evaluation of Health Technologies* [10] by the Canadian Agency for Drugs and Technologies in Health. The third edition of the Economic Guidelines contains 61 guideline statements (do's and don'ts) on 14 topics: study questions, types of evaluations, target population, comparators (i.e., alternatives likely to be replaced), perspective (e.g., society), effectiveness, time horizon, modeling, valuing outcomes (e.g., in terms of QALYs: quality-adjusted life-years), resource use and costs, discounting ("translating" future costs and outcomes to present-day values), variability and uncertainty, equity ("fairness"), generalizability, and reporting. Five types of economic evaluation are discussed (cost-utility analysis, cost-effectiveness analysis, cost-minimization analysis, cost-benefit analysis, and cost-consequence analysis), selection of which depends on the research question, the health condition of interest, and the availability of data on outcomes. The framework is primarily aimed at experts performing economic evaluations to inform decision makers in health care.

4) Health IT Evaluation Toolkit

In contrast to the above frameworks, the *Health Information Technology Evaluation Toolkit* [11] by the U.S. Agency for Healthcare Research and Quality is primarily aimed at the non-expert. The toolkit provides step-by-step guidance for project teams who are developing evaluation plans for health IT projects. It does so by means of a comprehensive template guiding the team through the process of determining the goals of a project, what is important to its stakeholders, what needs to be measured to satisfy stakeholders, what items are realistic and feasible to measure, and how to measure these items. To this end, each step is accompanied by explanations and checklists. Furthermore, examples are provided of eHealth evaluation projects with suggested evaluation methodologies, as well as a detailed list of evaluation measures (with suggested data sources, cost considerations, potential risks, general notes, and references to the literature). These measures include clinical outcome measures, clinical process measures, provider adoption and attitudes measures, patient adoption, knowledge, and attitudes measures, workflow impact measures, and financial impact measures.

The Health IT Evaluation Toolkit was developed as part of a remote mentorship initiative by the AHRQ, to address common challenges experienced by health IT project teams at nonacademic institutions [12]. These challenges include: leaving evaluation as something to be determined "later", overscoped and unrealistic evaluation plans, a mismatch between the health IT being implemented and the evaluation measures chosen, searching for relatively rare events without the required statistical power, incorrect initial assumptions about data quality and feasibility of data collection, using an improper comparison group, insufficient attention to the details on data collection and analysis, and a lack of consideration of qualitative methods. It is very likely that the same or similar challenges are also faced by eHealth SMEs when they set out to collect evidence.

B. No generally accepted evaluation practice

Other frameworks were found in the literature as well. Like the examples discussed above, most are comprehensive and detailed. With a few exceptions, they are developed for academic researchers or experts informing decision makers in health care. They offer guidance – at least, once the aim of evaluating an eHealth innovation has become relatively clear – and a collection of outcome indicators, measures, methods and tools with clarifications to make informed choices. However, none of the frameworks found provide the same detailed and comprehensive guidance with regard to identifying the various stakeholders involved in embedding an eHealth innovation into routine care, their interests in the innovation, and subsequently the aim of an evaluation and the kinds of evidence that may be required. Possibly, these choices are too simply dependent on the specific case at hand to establish generic guidelines.

Furthermore, there seems to be a general consensus in the literature that there are currently no commonly accepted standards for collecting evidence for eHealth applications [e.g., 13, 14]. Some researchers have argued that 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 that alternative approaches that view evaluation as social practice rather than scientific testing need to be considered [15]. Others argue that the tendency to focus on "hard" evidence as provided by randomized controlled trials may result in a disregard for the interests and experiences of the individual patient [16]. The Council for Public Health and Health Care in the Netherlands, which advises the Dutch government on health care policy, concurs [17]: *"The advance of evidence-based medicine has brought about a lot of good things. [...] However, there are disadvantages as well. The emphasis on scientific evidence may lead to a diminished appreciation for types of care where acquiring such evidence is impracticable, and to a neglect of elements such as personal attention, trust and 'presence'. The ethical question of what constitutes good (and reimbursable) care is being reduced to the question of what has been proven effective. [...] We must ask ourselves the question: what kind of evidence fits what kind of care? Hard evidence where it is attainable, but for other types of care where it is not realistic, different requirements need to be imposed. In short, we need to look for suitable evidence."*

Some researchers 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 [18, 19]. These findings were confirmed later on during workshops and interviews with representatives of the participating organizations; they have become a cornerstone in the approach that has been developed.

C. Three main themes for evidence

During the 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?"). 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 [4].

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, or when applications directed at self-management stimulate or allow patients and their informal caretakers to assume an active role in a treatment.

Various outcome indicators and methods relating to the above themes of evidence have been identified during the session and also from the literature. They have been compiled into three detailed overviews, i.e., one for each theme. The results of this are reported elsewhere [20].

D. Putting evidence into perspective

During the same expert session with representatives of health care organizations 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, 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 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.

E. "Innovation routes" for eHealth innovations

One topic which arose very prominently during the 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., [21-25]), 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.

More details about the innovation routes are presented in Section V of this paper, and elsewhere [20].

IV. RESULTS: CASE STUDIES

This section highlights the results and lessons learned from the second phase, the case studies. During this phase, eight cases submitted by seven SMEs were selected for in-depth, semi-structured interviews. Table I lists relevant details per case.

The selected cases represented a variety of eHealth applications, including telemonitoring services, electronic health records, telemedicine, and electronic consultation. Although the SMEs would usually mention a combination of intended impacts, the primary intended impact was most frequently on effectiveness or cost efficiency; in one case it was on labor savings. Nearly all applications were designed to be used within the cure or care domains; one was aimed at prevention. None of the cases concerned applications that would lead to new treatments; instead, all were intended to impact the way in which care is being organized or existing treatments are being provided. With one exception, all were in the latest stages of development: pilot and roll-out.

In the following sections we discuss the main findings; detailed results per case are reported elsewhere [26].

A. The paths followed

The interviewed SMEs followed paths which can, in terms of the above innovation routes, be classified as either "provider routes" (where an application is offered to and paid by the care provider) or "insurer routes" (where an application becomes part of a treatment already offered by care providers and reimbursed by insurers). In the first case, the SMEs had indeed identified and involved the care provider as the main stakeholder (i.e., the party using the application and paying for it), in the second case the main stakeholders identified and involved were the care provider (the party using the application) and the health insurance company (the party reimbursing it). Sometimes other stakeholders were identified as well, for instance a patient organization (for endorsement or financial support) or a professional association (for approval).

In two cases the provider route had been followed, and in both cases with success. However, these cases had more in common than just the route followed: both innovations concerned electronic health records and were intended to organize the provision of care in a more efficient or client-centered way, the involved entrepreneurs had themselves a background in health care, they had developed their

TABLE I: RELEVANT DETAILS PER CASE.

Case	Type	Phase	Domain	Route	Stakeholders	Impact	Evidence
1	telemonitoring	roll-out	care	insurer route	care provider, insurer	cost efficiency	trial, business case
2	electr. health record	roll-out	care	provider route	care provider	cost efficiency	
3	electr. consultation	pilot	cure	insurer route	care provider, insurer, professional association	effectiveness	
4	telemonitoring	pilot	care	insurer route	care provider, insurer, patient association	effectiveness	trials (ongoing)
5	electr. health record	roll-out	cure, care	provider route	care provider	effectiveness	
6	telemedicine	roll-out	cure	insurer route	care provider, insurer	labor savings	trial, business case
7	telemonitoring	inventory	prevention	insurer route	care provider, insurer	cost efficiency	
8	telemonitoring	roll-out	cure	insurer route	care provider	effectiveness	trial

applications to address trends and challenges readily recognized by care providers, and they had done so in close cooperation with health care professionals. Hence, they needed little or no evidence to convince care providers: an appealing vision on trends in health care or challenges faced by the care provider, or a concise business case identifying the main costs and benefits, combined with the option to let professionals gain hands-on experience with the application (using a demonstrator setup, or by means of trial licenses) sufficed.

Compared to the paths classified as "provider routes", the paths classified as "insurer routes" tended to be less clear and more challenging. The key issues encountered by SMEs following this route are:

- 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 the SMEs.
- SMEs tended to involve health insurance companies too early, when strong support among care providers, endorsements from patient organizations, 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 this route, clinical trials were often essential to build up evidence for an innovation's effectiveness. Generally, 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.

At the moment the interviews took place, none of the six SMEs following the insurer route had yet achieved success. In three cases this was because plans for pilots were still being made or trials were still ongoing. However, in three cases evidence had been collected in trials – yet in all three cases it failed to convince important stakeholders.

B. The evidence collected

In all three cases where evidence had been collected in trials, this had been done using randomized controlled trials – the "golden standard" for clinical trials [27]. Two of these cases concerned the application of real-time medication monitoring (RTMM) to improve medication adherence, albeit for different patient groups and in different contexts: in one case (no. 1) for patients with diabetes type 2 [28] and in the other (no. 8) for patients with refractory epilepsy [29]. The third case (no. 6) concerned the application of a computer-assisted therapy for patients with knee or hip replacements [30]. This application had been developed by a large German firm, and the clinical trial had already been performed in Germany; the participating SME was now trying to convince care providers and health insurers in The Netherlands of its added value. Table II provides more details about the designs, methods and outcome indicators used in each of these cases.

In all three cases, the trials were designed and performed by (or in close cooperation with) experts from scientific institutes. These experts assumed responsibility for deciding which evidence was to be collected and how this should be done. As said, in all cases (including case no. 4, where evidence was still being collected) they opted for randomized controlled trials in which a combination of objective measures and subjective judgments were being used. However, with the exception of case 1 (where the innovation department of a health insurance company was closely involved) it remained unclear to which extent external stakeholders – such as decision makers in care providers or insurance companies – had been consulted before these choices were made.

In cases 1 and 6 the results from the trial were further developed by the SME into a business case for stakeholders; in case 1 this was again done in close cooperation with a health insurance company. Table II includes information on how trial results were translated into a business case for stakeholders. The approach followed in case 1 is illustrative: the effect that was found on the intermediary outcome measure used in the trial (an increase in medication adherence) 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. The reduction in health related costs that was calculated, was then translated into a reduction in insurance claims for the health insurance company using the results of an internal study performed by the health insurance company. In this way, the clinical trial could focus on an intermediary outcome measure where effects could be measured on a much shorter time scale.

In none of the cases were the obtained results sufficient to convince the main identified stakeholders. The reasons for this varied. In the case 1 the trial had shown satisfactory results; however, the health insurer's purchasing department required that an additional economic analysis be carried out before it could support a nationwide adoption and reimbursement of the innovation. Unfortunately, the parties involved were unable to reach a consensus about this. In case 8 the care provider was convinced of the benefits for the treatment of its patients, yet the insurance company (having been requested to reimburse the use of the innovation) was unconvinced by the effects found during the trial. In case 6, the implementation model proposed by the SME (which entailed the establishment of new clinics where care provision would be centered on computer assisted therapy) did not satisfy the insurer's purchasing policy and so the lack of success had little to do with the evidence collected.

Case	Patient group	Design	Outcome indicators	Conclusions	Business case
1	161 diabetes type-2 patients, randomly divided over a control group (no RTMM) and two intervention groups (RTMM with SMS-reminders; RTMM without SMS-reminders)	1. pre-measurement 2. intervention 3. post-measurement 4. follow-up duration of the intervention: 6 months	*medication adherence:* • refill adherence (determined from pharmacists' delivery registrations); • days without dosing, percentage missed doses, and percentage of doses taken within standardized time intervals (determined by real-time registration of medication intake) *experiences of patients:* • judgments on medication adherence (determined using surveys) • judgments on satisfaction (determined using surveys)	*medication adherence:* • significantly higher refill adherence (+26,5% for RTMM with SMS-reminders, +15,3% for RTMM without SMS-reminders, +10,5% for control group); • patients receiving SMS-reminders took significantly more doses within predefined time windows than patients receiving no reminders *experiences of patients:* • positive experiences of patients with the use of RTMM and with SMS-reminders	translation into financial consequences for a health insurance company, in two steps: 1. increased medication adherence (in %) was translated into a reduction in health related costs (in %), based on a published systematic literature review into this relation; 2. the reduction in health related costs (in %) was translated into a reduction of insurance claims (in €), using an internal study performed by the insurer into the costs of hospitalizations of diabetes patients
6	274 rehabilitating patients with hip or knee replacements, randomly divided over a control group (conventional therapy) and an intervention group (computer assisted therapy)	1. pre-measurement 2. post-measurement duration of the intervention: 6 months	*effectiveness:* • judgments determined using standardized surveys (Harris Hip Score, Hospital for Special Surgery Score, FIM instrument, and Hanover Functional Ability Questionnaire) *acceptance by patients:* • determined using surveys	*effectiveness:* • no statistically significant difference in effectiveness between conventional therapy and computer assisted therapy *acceptance by patients:* • positive acceptance by patients of computer assisted therapy	translation into labor savings for care providers: the intensity of the therapy can be increased by 20% with the same number of hours worked by therapists (further details are unknown)
8	28 epilepsy patients, randomly divided over two intervention groups (RTMM with SMS-reminders; RTMM first without and then with SMS-reminders)	1. pre-measurement 2. intervention 3. post-measurement duration of the intervention: ranging from 2 months to 2 years	*medication adherence:* • percentage missed doses and percentage of doses taken within standardized time intervals (determined by real-time registration of medication intake) *experiences of patients:* • judgments on medication adherence, seizure frequency and intensity (determined using surveys); • judgments on quality of life (determined using the QOLIE-31 survey); • seizure frequency (determined using diaries)	*medication adherence:* • significantly higher medication adherence for RTMM with SMS-reminders compared to RTMM without SMS-reminders: +14,4% correct intakes, and -10,8% missed doses *experiences of patients:* • positive experiences of patients (higher medication adherence, reduced seizure frequency or intensity; • no significant effect on quality of life except for higher overall health; • diaries showed no clear reduction of seizure frequency	translation into benefit for the care provider: increased effectiveness of the treatments offered to patients (no detailed business case had been developed yet)

The few cases described above are clearly insufficient to draw any firm conclusions. Yet, judging from these cases, it does seem necessary that decision makers (for instance in health insurance companies, but also in other stakeholders) are 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.

C. The criteria used by the insurance company

As mentioned before in Section II.E, three participating SMEs (i.e., cases 3, 4 and 6) accepted the open invitation to enroll their innovations at the health innovation desk of one of the participating health insurers. These three SMEs had all been following the insurer route.

Over the course of the ensuing procedures 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 (for instance, systems in use by general practitioners), and (vi) is the potential for a nationwide adoption clear. Evidence for an innovation's effectiveness was among the criteria listed by the insurer, yet in these three cases it did not seem to have played a central role. However, a detailed business case supported by relevant figures was a clear requirement used within all three cases.

Of the three enrollments, one (i.e., case 4) ultimately led to a follow-up in which the involved SME, a care provider, and the insurer are currently planning a joint evaluation study of the innovation. In this particular case:

- The SME had gained clear support from a care provider, who eventually took over the negotiations with the insurance company;

- The application was fully developed and interoperable, and had already been used on a small scale in several pilots;
- The SME and the care provider were able to come up with a detailed business case showing how the innovation would be implemented in existing care processes, and where it would lead to substitution of existing care.

Summarizing, most of 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 will be required.

V.   RESULTS: GUIDELINES AND BEST PRACTICES

This section highlights the results and lessons learned from the third phase, guidelines and best practices. In the preceding phases of the project it had become clear that, when evaluation plans or clinical trials are being planned, relevant stakeholders should be identified and there 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,
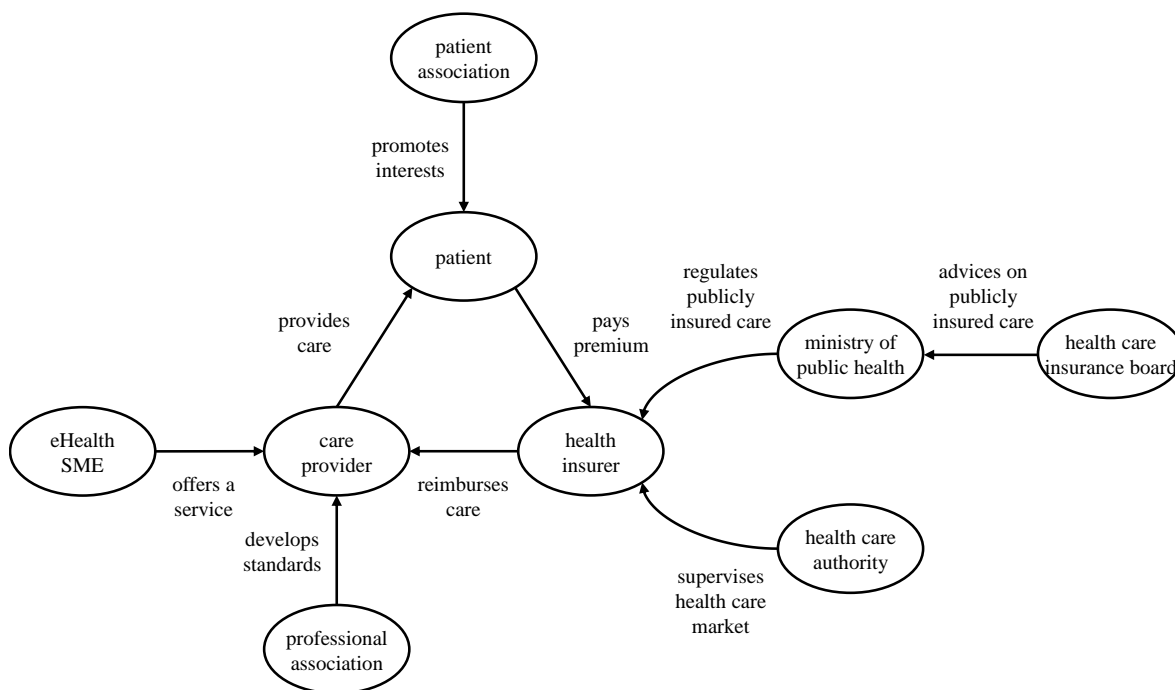

Figure 1: Elementary version of the eHealth innovation map, showing the main parties in the Dutch health care system.
Each of these parties and their interests in eHealth innovations are further described in accompanying fact sheets.

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. Creating such a map, and complementing the map with "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 provide only an overview; detailed information with guidelines and best practices was 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 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. For practical reasons these three thematic versions are not shown here; instead the information has been summarized in Table III. Last, 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. For instance, the fact sheet on the insurer mentions that the insurer will reimburse care that has been provided to patients and not the use of eHealth applications as such. It mentions the roles and interests of its innovation, investment, purchasing and commercial departments, for instance, the partly conflicting interests of innovation department (interested in the potential of new developments) and the purchasing department (interested in the efficiency of concluding large contracts). It also mentions the main criteria by which these parties will evaluate an eHealth application, listing critical success factors such as clear support among care providers, and a detailed business case showing the potential for substitution or cost reduction. Table IV shows a representative example of a stakeholder fact sheet.

3) *Fact sheets on innovation routes*

The four innovation routes are also described in their own 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 play a role, (iv) the main stakeholders that need to be involved, and (v) the main anticipated risks (pitfalls). The fact sheet on the insurer route, for example, mentions that this route is appropriate when an eHealth application leads to a new way of organizing care, or a when it will be used for providing a treatment that is already being offered by care providers and reimbursed by insurers. It mentions the importance of first

TABLE III: SUMMARY OF THE INFORMATION DISPLAYED IN THE THREE THEMATIC VERSIONS OF THE INNOVATION MAP.

Party	Stakeholders within party	Interests in eHealth innovations	Evidence or other applicable forms of proof
care provider	nurses, specialists, ict, board	"will it improve the quality or efficiency of my work?"	a strong vision, a sound business case, experiences of care professionals
patient	partner, parents, children, informal carers	"will it aid in my recovery or improve my well-being?"	advice of care professionals, experiences of other patients
health insurer	innovation, purchasing, commerce, investment	"is it effective care for a reasonable price?"	a business case supported by the results of a clinical trial
professional association	medical specialists	"is it safe and well-founded?"	results of clinical trials, experiences of care professionals
patient association	patients, advisors	"will it improve the quality of care for our patient group?"	results of clinical trials, experiences of the patient group
health care authority	advisors	"is there support for it among care providers and insurers?"	joint innovation requests from care providers and insurers
health care insurance board	advisors	"has it been proven effective?"	viewpoints of professional associations, scientific research results of the highest possible quality
ministry of public health	policy makers	"does it contribute to affordable care?"	positive advice by the health care insurance board

gathering sufficient support among care providers, professional associations and patient associations before turning to the insurer, and it mentions the special circumstance where a care provider and an insurer should jointly file an innovation request to the Dutch health care authority before a pilot can be started. Table V shows a representative example of an innovation route fact sheet.

4) Fact sheets on evidence

The third set of fact sheets concerns the evidence that 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. For instance, in the insurer route cost savings are mentioned as a principal effect to be established for the insurer. To this end, it should be shown how the eHealth innovation leads to the replacement of an existing form of care by a more cost efficient one, or how the application contributes to reduced health care consumption in the near future. Methods to establish these effects are mentioned such as, in the first case, a process analysis comparing care processes before and after introduction of the application or, in the second case, a clinical trial followed an elaboration of the effects found in a detailed, quantitative business case. Given the lessons learned during the project, the main best practice mentioned in this particular example is to closely involve key decision makers in the care provider and the insurer in order to clarify the criteria that will play a role in the decision process. Table VI shows a representative example of an evidence fact sheet.

B. Validation of the innovation map

Validation of the eHealth innovation map and the corresponding fact sheets has been (and is currently being)

(a) The consumer route

(b) The provider route

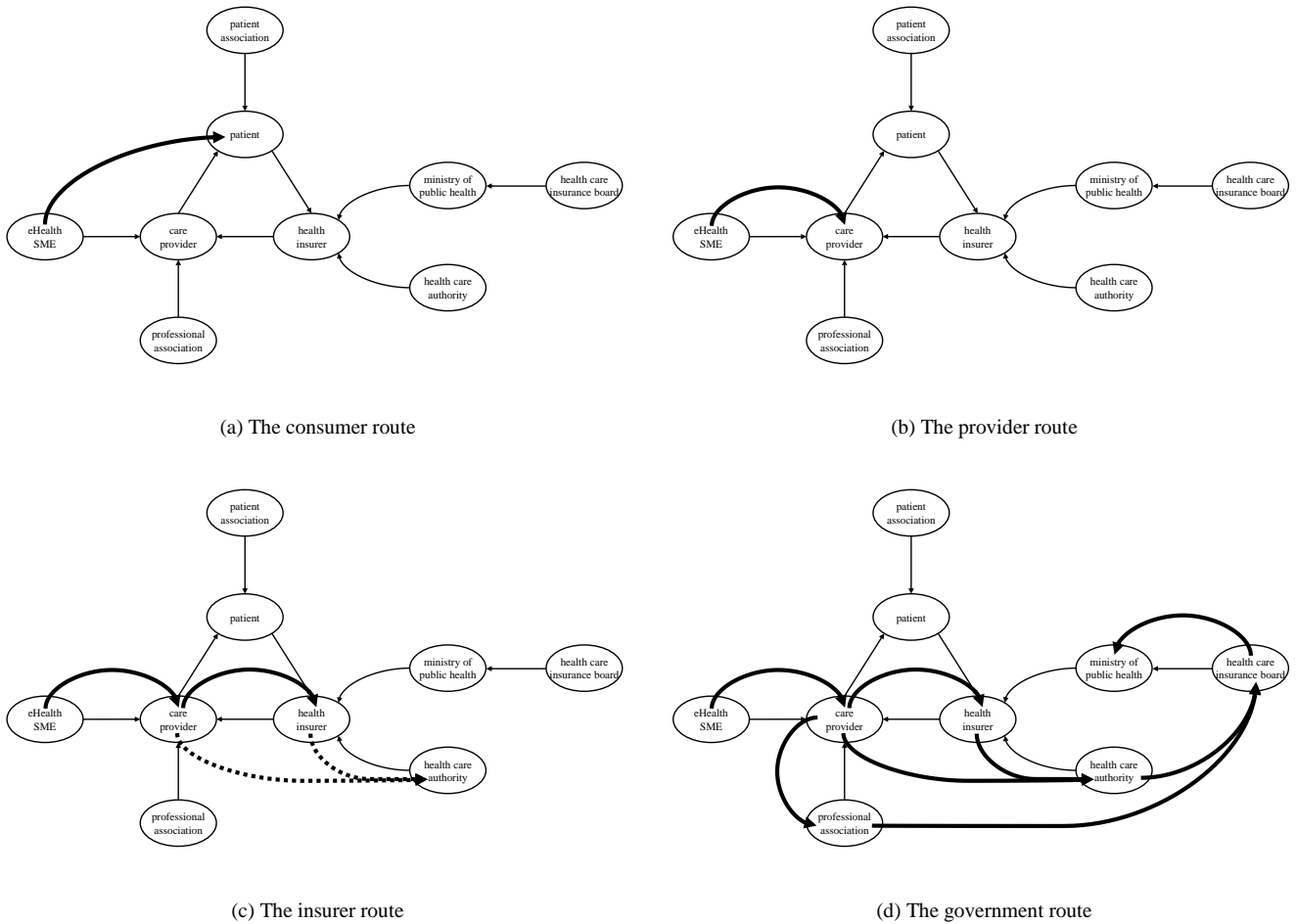(c) The insurer route

(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.

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 during a series of workshops where the eHealth innovation map was applied to a range of different cases at hand. 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 (i.e., cases 4 and 8 from Table I, and one additional case contributed by a medical research center) with the aim to evaluate and extend the current insights. At the time of writing this research is still ongoing.
- Fourth, a number of successful cases are currently being 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. This, too, is at the time of writing still ongoing.

Due to the "mixed methods" approach followed during the project, with ample involvement of both experts and SMEs, a substantial amount of feedback and support has been collected for the innovation map. Overall, the responses given by these parties have been very favorable. 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. The innovation route and stakeholder fact sheets are no "recipes for success", instead they are considered by both parties as highly useful scenarios

TABLE IV: 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. (ORIGINAL VERSION IN DUTCH. REFERENCES TO SOURCES HAVE BEEN OMITTED.)

Fact sheet healthcare insurer

Role
The healthcare insurer is the party paying for 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 potential 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 healthcare (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 healthcare 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 healthcare gains (better quality care or higher quality of life).
- The application has to reduce healthcare costs (through increased independence on the part of the patient or reduced burden on the healthcare 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.

Healthcare 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 healthcare insurer by an enthusiastic care provider (rather than by the entrepreneur).

Persuasion
Healthcare 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 healthcare insurer. Always determine the design of a pilot study or clinical trial (what is being measured, and how) together with the care provider and healthcare insurer.

to be explored by an SME and used as a means to create a stakeholder inventory. The evidence fact sheets are highly useful to start the discussion with stakeholders and experts when drafting plans for an evaluation.

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 [23] 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) [24].

VI. RESULTS: CONSOLIDATION AND TOOL DEVELOPMENT

The fourth and 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 the innovation map and the fact sheets have been incorporated into an interactive, web-based tool [31]. The workshop protocol and the web-based tool

both aim to 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 have been documented in an accessible and illustrated booklet for SMEs [32]. The booklet summarizes all the information contained within the innovation 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.

VII. 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

TABLE V: EXAMPLE OF AN INNOVATION ROUTE FACT SHEET. THIS ONE DISCUSSES THE INSURER ROUTE.
OTHERS DISCUSS THE CONSUMER ROUTE, THE PROVIDER ROUTE, AND THE GOVERNMENT ROUTE.
(ORIGINAL VERSION IN DUTCH. REFERENCES TO SOURCES HAVE BEEN OMITTED.)

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. Paying insufficient attention to the substitution of the existing care.

TABLE VI: EXAMPLE OF AN EVIDENCE FACT SHEET. THIS ONE DISCUSSES EVIDENCE FOR THE INSURER ROUTE.
OTHERS DISCUSS EVIDENCE FOR THE CONSUMER ROUTE, THE PROVIDER ROUTE, AND THE GOVERNMENT ROUTE.
(ORIGINAL VERSION IN DUTCH. REFERENCES TO SOURCES HAVE BEEN OMITTED.)

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, healthcare insurers want to see a reduction in healthcare 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 healthcare 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 healthcare 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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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.

The implications of this research are threefold. First, further research is needed to deepen and validate the insights gained so far, preferably by consistently applying the developed approach along the full development cycles of a number of eHealth services, and by evaluating the results. Since this is a process that can take several years to complete, this could not be done within the current project. Furthermore, academic experts involved in the development of frameworks to evaluate eHealth should place more emphasis an stakeholders' varying roles and interests, and incorporate these factors into their designs. Second, policy makers in both government and health organizations could use the identified innovation routes to identify any unwanted obstacles (for instance, conflicting requirements imposed by parties involved), take measures to alleviate barriers along a route, and initiate any required coordination between stakeholders, thus streamlining each route. Third, eHealth SMEs would do well to study the workings of the health care

system, for instance by using the proposed innovation map as a scenario building instrument and by applying it early on for stakeholder inventory and analysis.

Now that the project is nearing completion, the question arises how unique the Dutch situation really is. 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 [1] 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.

REFERENCES

[1] R. Janssen, M. Hettinga, H. Prins, S. Visser, R. Menko, I. Krediet, T. Haaker, and L. Bodenstaff, "Developing evidence guidelines for eHealth small and medium-sized enterprises," Proc. eTELEMED 2013, Feb. 2013, pp. 92-95.

[2] J.E. van Gemert-Pijnen, N. Nijland, M. van Limburg, H.C. Ossebaard, S.M. Kelders, G. Eysenbach, and E.R. Seydel, "A holistic framework to improve the uptake and impact of eHealth technologies," J. Med. Internet Res., 2011, 13(4):e111.

[3] R.A. Menko, S. Visser, R. Janssen, M. Hettinga, and T. Haaker, "Applying the STOF business model framework in eHealth innovations," Proc. eTELEMED 2013, Feb. 2013, pp. 108-113.

[4] Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst, Nederlandse Patiënten Consumenten Federatie, and Zorgverzekeraars Nederland, "Nationale Implementatie Agenda (NIA) eHealth," Utrecht: Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst, 2012. ["National eHealth implementation agenda". In Dutch.]

[5] F. Mair, C. May, E. Murray, T. Finch, G. Anderson, C. O'Donnell, P. Wallace, and F. Sullivan, "Understanding the implementation and integration of e-health services," London: NHS Service and Delivery R and D Organisation (NCCSDO), 2009.

[6] F. Mair, C. May, C. O'Donnell, T. Finch, F. Sullivan, and E. Murray, "Factors that promote or inhibit the implementation of e-health systems: an explanatory systematic review," Bull. World Health Organ., 2012, 90:357-364.

[7] J. Hackos and J. Redish, "User and task analysis for interface design," New York: Wiley, 1998.

[8] R.E. Scott, F.G. McCarthy, P.A. Jennett, T. Perverseff, D. Lorenzetti, A. Saeed, B. Rush, and M. Yeo, "Telehealth outcomes: a synthesis of the literature and recommendations for outcome indicators," J. Telemed. Telecare, 2007, 13 Suppl 2:1-38.

[9] K. Kidholm, A.G. Ekeland, L.K. Jensen, J. Rasmussen, C.D. Pedersen, A. Bowes, S.A. Flottorp, and M. Bech, "A model for assessment of telemedicine applications: MAST", Int. J. Technol. Assess. Health Care, 2012, 28(1):44-51.

[10] Canadian Agency for Drugs and Technologies in Health, "Guidelines for the economic evaluation of health technologies: Canada [3rd edition]," Ottawa: Canadian Agency for Drugs and Technologies in Health, 2006.

[11] C.M. Cusack, C. Byrne, J.M. Hook, J. McGowan, E.G. Poon, and A. Zafar, "Health information technology evaluation toolkit: 2009 update," Rockville, MD: Agency for Healthcare Research and Quality, 2009.

[12] E.G. Poon, C.M. Cusack, and J.J. McGowan, "Evaluating healthcare information technology outside of academia: observations from the National Resource Center for Healthcare Information Technology at the Agency for Healthcare Research and Quality," J. Am. Med. Inform. Assoc., 2009, 16(5):631-6.

[13] A.G. Ekeland, A. Bowes, and S. Flottorp, "Methodologies for assessing telemedicine: a systematic review of reviews," Int. J. Med. Inform., 2012, 81(1):1-11.

[14] A.D. Black, J. Car, C. Pagliari, C. Anandan, K. Cresswell, T. Bokun, B. McKinstry, R. Procter, A. Majeed, and A. Sheikh, "The impact of eHealth on the quality and safety of health care: a systematic overview," PLoS Med., 2011, 8(1):e1000387.

[15] T. Greenhalgh and J. Rusell, "Why do evaluations of eHealth programs fail? An alternative set of guiding principles," PLoS Med., 2010, 7(11):e1000360.

[16] E. Cummings and P. Turner, "Patients at the centre: methodological considerations for evaluating evidence from health interventions involving patients use of web-based information systems," Open Med. Inform. J., 2010, 4:188-94.

[17] D.W. Willems, R. Vos, G. Palmboom, and R. Lips, "Passend bewijs. Ethische vragen bij het gebruik van evidence in het zorgbeleid," Den Haag: Raad voor de Volksgezondheid en Zorg, 2007. ["Suitable evidence. Ethical questions regarding the use of evidence in health care policy." In Dutch.]

[18] M.P. Gagnon and R.E. Scott, "Striving for evidence in e-health evaluation: lessons from health technology assessment," J. Telemed. Telecare, 2005, 11, Suppl 2:S34-6.

[19] H. Hyppönen, E. Ammenwerth, and N. de Keizer, "Exploring a methodology for eHealth indicator development," Stud. Health Technol. Inform., 2012, 180:338-42.

[20] T. Haaker, L. Bodenstaff, R. Menko, S. Visser, H. Prins, I. Krediet, M. Hettinga, and R. Janssen, "Inventarisatie eHealth innovatieroutes en evidence," Zwolle: Hogeschool Windesheim, 2013. ["Inventory of eHealth innovation routes and evidence." In Dutch.]

[21] Website Nederlandse Zorgautoriteit, www.nza.nl. [Website of the Dutch Healthcare Authority. In Dutch.] Last accessed: December 6, 2013.

[22] Website College voor Zorgverzekeringen, www.cvz.nl. [Website of the Dutch Healthcare Insurance Board. In Dutch.] Last accessed: December 6, 2013.

[23] Website ZonMw, www.zonmw.nl. [Website of the Netherlands Organization for Health Research and Development. In Dutch.] Last accessed: December 6, 2013.

[24] Website Zorg voor Innoveren, www.zorgvoorinnoveren.nl. [Website 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. In Dutch.] Last accessed: December 6, 2013.

[25] Website Nictiz, www.nictiz.nl. [Website of the National IT Institute for Healthcare in the Netherlands. In Dutch.] Last accessed: December 6, 2013.

[26] R. Janssen, W. de Haan, T. Haaker, L. Bodenstaff, S. Visser, R. Menko, H. Prins, I. Krediet, and M. Hettinga, "Rapportage casestudies," Zwolle: Hogeschool Windesheim, 2013. ["Report about the case studies." In Dutch.]

[27] P.M. Ho, P.N. Peterson, and F.A. Masoudi, "Evaluating the evidence. Is there a rigid hierarchy?" Circulation, 2008, 118(16):1675-84.

[28] M. Vervloet, L. van Dijk, J. Santen-Reestman, B. van Vlijmen, P. van Wingerden, M.L. Bouvy, and D.H. de Bakker, "SMS reminders improve adherence to oral medication in type 2 diabetes patients who are real time electronically monitored," Int. J. Med. Inform., 2012, 81(9):594-604.

[29] M. Hettinga, T. Gutter, and J.T. te Gussinklo, "Real time medication monitoring with customized SMS reminders for people with refractory epilepsy," Proc. eTELEMED 2013, Feb. 2013, pp. 162-167.

[30] U. Eisermann, I. Haase, and B. Kladny, "Computer-aided multimedia training in orthopedic rehabilitation," Am. J. Phys. Med. Rehabil., 2004, 83(9):670-80.

[31] Website Innovatieroutes in de Zorg, www.innovatieroutesindezorg.nl. [A website and interactive assessment about four eHealth innovation routes, maintained by the Research group ICT Innovations in Health Care, Windesheim University of Applied Sciences. In Dutch.] Last accessed: December 6, 2013.

[32] R. Janssen, L. Bodenstaff, E. Gyaltsen-Lohuis, T. haaker, W. de Haan, I. Krediet, R. Menko, H. Prins, S. Visser, and M. Hettinga, "Succesvol ondernemen met eHealth: Innovatieroutes in de zorg," Zwolle: Hogeschool Windesheim, 2013. ["Succesful entrepreneurship in eHealth: innovation routes in health care." In Dutch.]