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Abstract

Innovations in health care are often characterized by complexity and fuzzy boundaries, involving both the elements of the innovation and the organizational structure required for a full implementation. Evaluation in health care is traditionally based on the collection and dissemination of evidence-based knowledge stating the randomized controlled trial, and the quasi-experimental study design as the most rigorous and ideal approaches. These evaluation approaches capture neither the complexity of innovations in health care, nor the characteristics of the organizational structure of the innovation. As a result, the reasons for innovations in health care not being disseminated are not fully explained. The aim of the paper is to present a design-evaluation framework for complex innovations in health care in order to understand what works for whom under what circumstances combining design theory and realist evaluation. The framework is based on research findings of a case study of a complex innovation, a health care quality register, in order to understand underlying assumptions behind the design of the innovation, as well as the characteristics of the implementation process. The design-evaluation cycle is hypothesized to improve the design and implementation of complex innovation by using program/kernel theories to develop design principles, which are evaluated by realistic evaluation, resulting in further refinement of program/kernel theories. The goal of the design-evaluation cycle is to provide support to implementers and practitioners designing and implementing complex innovations in health care, for improving dissemination of complex innovations.

Keywords: Innovation, Design Theory, Realist Evaluation, Health Care

INTRODUCTION

Complex innovations in health care organizations are characterized by fuzzy boundaries, having a "hard core", represented by the irreducible elements of the innovation itself, and a "soft periphery", represented by the organizational structures and systems required for a full implementation of the innovation (Greenhalgh et al., 2004). The readiness of this "soft periphery" to adapt to innovations - what works for whom in what circumstances- is a key issue (Pawson & Tilley, 1997; Greenhalgh et al., 2004; Denis et al., 2002). Individuals are not passive receivers of innovations. Innovations could be rejected, and subjects of reinventions and reconfigurations of users as well as resistance to change (Rogers, 1995; Slappendel, 1996). Greenhalgh et al. (2004) presents a conceptual model for considering the determinants of diffusion, dissemination and implementation of innovations in health service organizations, based on a systematic review of research studies. The foundation of the conceptual model is that innovation takes place in interplay between the resource system, knowledge purveyors and change agency on one hand, and the user system on the other hand. The user system is, during the design and implementation stages of the innovation, linked to the resource system and the change agency by e.g. shared meanings and mission, effective knowledge transfer, user involvement in specification, communication and information, user orientation, product augmentation and project management support.

The additional elements of the conceptual model include:
- characteristics of the innovation itself (relative advantage, compatibility, complexity, etc.)
- communication and influence, which means how the innovation is diffused and disseminated
- the adoption/assimilation process (needs, motivations, values etc. of the adopter and characteristics of the assimilation process)
- system antecedents for innovations, which includes structure or the organization, absorptive capacity for new knowledge and receptive context for change,
- system readiness for innovation, e.g. tension for change, innovation-system fit, power balances, and dedicated time and resources,
- characteristics of the implementation process, such as decision-making, internal communication and external collaboration
- the outer context of the innovation consisting of sociopolitical climate, incentives and mandates, interorganizational norm-setting and networks and the degree of environmental stability.

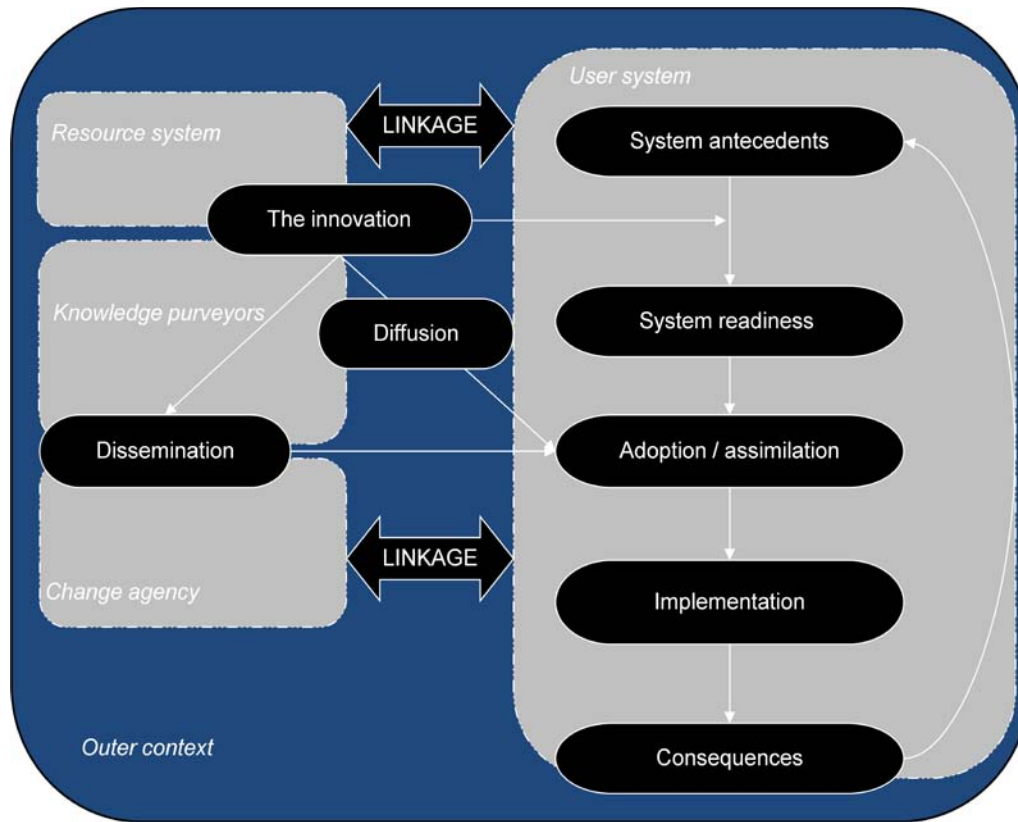The conceptual model is depicted in figures 1 and 2.

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Figure 1. Overview of the relationships between the resource system, user system, knowledge purveyors and change agency in health care innovations (Greenhalgh et al., 2004).
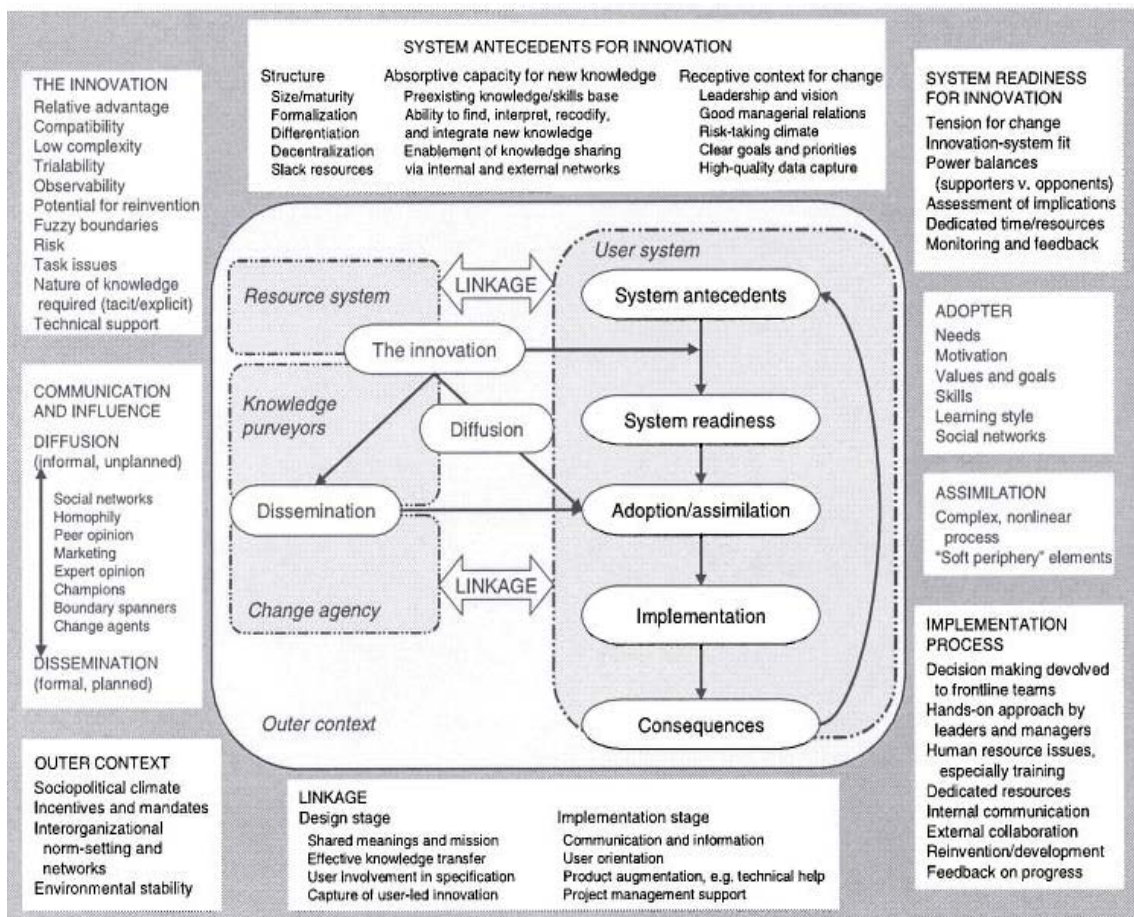
Figure 2. Conceptual model for considering the determinants of diffusion, dissemination, and implementation of innovations in health service delivery and organization, based on a systematic review of empirical research studies (Greenhalgh et al., 2004).

Although ba sed on a s ystematic r eview, t he m odel c aptures t he f ull c omplexity o f th e diffusion, di ssemination a nd i mplementation of innovations i n he alth c are (Greenhalgh et al., 2004). On the other hand, knowledge creation in healthcare organizations does not in general aim at p erforming t hese kinds of c omplex e valuations. Instead, know ledge c reation pr edominantly aims at the collection of evidence-based knowledge to e valuate treatment outcomes in order to further develop treatment and health status of the patients (Martin, 2003). The medical research tradition r anks di fferent types of s tudies, r eviews a nd e valuations i n a h ierarchy o f e vidence, where the most scientifically rigorous study is considered to be the randomized controlled trial, with co ncealed al location o f t he m edical i ntervention an d ab solute c ontrol of t he c ontextual factors, and the least rigorous the opinion of users (Pawson, 2006). This hierarchy of evidence is further described in table 1.

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Level 1	Randomized controlled trials (with concealed allocation)
Level 2	Quasi-experimental studies (using matching)
Level 3	Before-and-after comparisons
Level 4	Cross-sectional, random sample studies
Level 5	Process evaluation, formative studies and action research
Level 6	Qualitative case study and ethnographic research
Level 7	Descriptive guides and examples of good practice
Level 8	Professional and expert opinion
Level 9	User profession

Table 1. Typical structure of a hierarchy of evidence in meta-analysis (Pawson, 2006).

Innovations that could be evaluated by e.g. randomized control trials, such as new treatment, could be characterized as "simple innovations", in contrast to the complex innovations described by Greenhalgh et al. (2004). Thus, health care organizations primarily look for evidence that an innovation "work" in randomized controlled trials or quasi-experimental studies. There are relatively few experimental studies of complex innovations, such as quality improvement, and existent studies show weak or moderate effects (Walsh, 2007). The argument from health care professionals states that: *"After all… we should not embark on using a new clinical intervention such as a drug or a surgical procedure without solid experimental evidence of its effectiveness, so why should we have a lower threshold for the adoption of organizational interventions…?"* (Walsh, 2007, p. 57). Randomized controlled trials and quasi-experimental studies are adequate when the intervention studied has a low variance in content and context and there is a single, clearly measurable outcome. Innovations, like quality improvement or introduction of new information systems are complex social innovations, with a high degree of variance in context, content and outcome. The more heterogeneous the innovation, the more the experimental methods become less helpful in understanding of its effects (Walsh, 2007). Conceptual models like the one developed by Greenhalgh et al. (2004) comprises a multitude of elements and linkages between elements influencing the innovation. In this case, experimental designs are clearly inadequate. Instead, the question to evaluate what works for whom, why and in what circumstances is crucial (Carlsson, 2003; Pawson, 2006).

We argue that the application of design theory in development of innovations combined with the use of realist evaluation, as opposed to systematic evaluation, would provide a realistic and holistic view of the use and implementations of complex innovations in health care organizations.

The aim of the paper is to present a design – evaluation framework for complex innovations in health care in order to understand what works for whom under what circumstances combining design theory and realist evaluation. The framework is based on research findings of a case study of a complex innovation: a health care quality register, in order to understand underlying assumptions behind the design of innovation, as well as the characteristics of the implementation process. Based on the findings of the study, a design theory for health care quality registers is put forward. Subsequently, the perspective of realist evaluation is presented. Finally, design theory and realist evaluation are integrated into a design – evaluation cycle for complex innovations in health care organizations.

A CASE STUDY OF DESIGN AND EVALUATION OF A COMPLEX INNOVATION IN HEALTH CARE

In this section of the paper, findings from a case study of a complex innovation in health care – a health care quality register – are presented. First, the concept of health care quality registers is described. Second, findings from the case study of the Swedish Rheumatology Quality Register are presented.

Health Care Quality Registers

The general purpose of health care quality registers is to provide data for research and quality improvement in health care (SALAR, 2007). Although patient work is the core of health service, corresponding information systems have not been developed for working with patients. The traditional patient record systems have not facilitated compilation and analysis of data required for quality improvement, as they are essentially are treated like not pads supporting the treatment of individual patients by individual physicians: *"The National Quality Registries have been developed to fill the gap left by the lack of primary monitoring systems. The quality registries collect information on individual patient's problems, interventions, and outcomes of interventions in a way that allows the data to be compiled for all patients and analyzed at the unit level."* (SALAR, 2007, p. 10). Although most quality registers are of recent date, national registers have existed in Sweden since the 1970s, the first register being the Register for Knee Arthroplasty, which began as a research project in 1975 (Garpenby & Carlsson, 1994). The development of national quality registers have been decentralized in its nature, mainly accomplished by professional communities themselves. Practitioners having the greatest use of the data also have been responsible for the development of the registers and their content, and the databases are spread among clinical departments nationally (SALAR, 2007).

The effects of treatment on individual patient could be monitored, and data could be aggregated to show treatment outcomes based on groups of patients. The treatment outcomes could be compared with the national average or with treatment outcomes of other clinics, thus providing benchmarking data. Furthermore, the design of guidelines for medical treatment on a national level could be based on information obtained by means of quality register data. In 2007, 64 quality registers were established in Sweden, comprising e.g. respiratory diseases, diseases of childhood and adolescence, circulatory diseases, endocrine diseases, gastrointestinal disorders, musculoskeletal disorders and diseases of the nervous system (SALAR, 2007).

The primary goal of quality registers is to improve knowledge about different medical interventions and thus improve quality of treatment in health care. A register may be either disease-oriented or method-oriented. A disease-oriented register focus on the diagnosis of the patient and records all relevant treatment, while method-oriented registers is based on the recording of procedures, such as certain kinds of surgery. Different registers have different objectives, depending on e.g. medical specialty, but some objectives are common, such as to describe variations in the utilization of different methods, to describe differences in treatment outcomes among different departments, to monitor and assess the effectiveness of different methods over time, and to include the patient's experience of health changes and quality of life over the course of time (Garpenby & Carlsson, 1994).

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Design of the Swedish Rheumatology Quality Register

The Swedish Rheumatology Quality Register was originally designed in 1995, after two years of negotiations among the Swedish professional community of rheumatologist (Keller et al., 2009). The register aims to improve health of Swedish rheumatoid arthritis patients through continuous feedback of treatment results to patients and physicians directly during the medical consultation. The register covers rheumatology departments in county councils, as well as private practitioners in rheumatology nationally (SALAR, 2007). In 2009, 33 000 rheumatoid arthritis patients from 52 clinics were registered.

The patient data entered into the register includes treatment, findings of laboratory tests, self-assessed patient evaluations of general pain and tiredness, as well as swelling and tenderness of 28 index joints. The data is compiled to create a patient health status index, labeled as DAS28 (Disease Activity Score). The DAS28 index serves as a point of reference from which treatment outcomes are evaluated (Keller et al., 2009). Biologic drugs and their side effects are given particular attention. Since 2001, internet services can be used by the patient and the physician as a means of shared decision-making during the medical consultation. In addition to the immediate feedback during the consultation, all users have access to an internet service that makes the data available directly after entry. Diagrams are updated every night, showing information about patient groups and diagrams comparing treatment data of counties and regions as well as nationally (Keller et al., 2009; SALAR, 2007).

The main basic assumption underpinning the design and implementation of the register is that the quality improvement process is most effective in the interaction between the patient and the physician. The interaction is facilitated by using the register online at increasingly more medical consultations. The ongoing follow-up of the disease activity by the patient health status index has lead to better results of treatment every year since the registry started. The register has also played an important role in the dissemination of biologic therapies, enabling them to be used efficiently and equitably throughout the country (Keller et al., 2009; SALAR, 2007). To enhance the implementation and adoption, training session in the use of the register are offered to health care staff by the implementers.

Evaluation of the design

In our case study, we did not choose to perform a quantitative systematic evaluation. Instead, our aim was to capture qualitative aspects of the design and implementation of the register. Semi-structured interviews were performed with rheumatologists and the main implementer of the quality register aiming as well as document analysis to explore the driving factors and barriers to the implementation, as well as the influence of the register on the patient-physician relationship. The data collected from the interviews were analyzed thematically. We identified different data and put them into different sub-themes of classified patterns, with the ambition to reach distinct points of origination (Taylor & Bogdan, 1984). Documents were listed in summary forms and categorised into themes by the use of content analysis (Miles & Huberman, 1994; Krippendorff, 2004).

The factors driving the innovation fell into three main categories: the characteristics of change agents, quality improvement, and budget control. The change agents, the champion implementers of the register, were respected physicians among the Swedish professional community of rheumatologists. As a result, the implementation of the quality register was perceived as originating from the profession more than from hospital or county council management, which is hypothesized to have improved the rate of adoption. The change agents

took on the role of both administrative leaders of the implementation process and knowledge management leaders with great effort, actively discussing what kind of knowledge should be embedded in the register. Quality improvement and budget control were found to be closely interrelated. Quality improvement was interpreted as efficiency of treatment by the rheumatologists. As the newly developed biologic drugs used in treatment of rheumatoid arthritis are very expensive, the knowledge of treatment outcomes has become an indispensable means of argument towards politicians of the county councils in proving that the treatment is needed and that the increase in costs brings an improved health status of patients : *"By means of the register we can tell politicians that a certain number of patients need the biologic drugs... without the register we wouldn't had stand a chance."* (rheumatologist). *"We have to use the quality register. It's our only means of quality improvement."* (clinical manager).

The barriers to adoption of the innovation were observed to relate to four different areas: resistance from clinical management, lack of motivation to share knowledge, lack of time and perceived flaws in the interface and compilation of data in the quality register. Lack of interest or resistance from clinical management to implement the innovation was stated as a significant barrier, not only to use of the register but to quality improvement in general. As illustrated by a physician in following terms: *"Management is very important. If management does not take responsibility to lead change, the inertia will be enormous."* (rheumatologist). From the interviews, it is evident that most health care professionals were willing and motivated to share knowledge in the register, but not all: *"Perhaps they don't want their patients to be judged by others... Some colleagues do not simply find it very interesting to share knowledge."* (rheumatologist). A number of rheumatologists also experience lack of time as a barrier to use of the quality register, as consultations are tightly scheduled, and the examination of the patient must be given priority before registration of data in the register. Perceived flaws in the interface of the register and the compilation of data were also identified as barriers to adoption. Not being able to comment on data entered in the register is one identified flaw*: "It is possible to make extra comments about the health status of the patient in the patient journal system, but not in the quality register..."* (clinical manager). Also the compilation of data from the register is sometimes perceived as being unclear and insufficient: *"When it comes to aggregated statistics from the register, some things really remains to be done..."* (rheumatologist). *"There are no data from the quality register that I couldn't find in the patient journal system. Preferably, the two information systems should interact."* (clinical manager).

The quality register is adopted to be a part of the practice of medicine at the rheumatologic clinic. The practice of medicine is characterized by a combination a body of scientific knowledge and a collection of well-practiced skills. Clinical judgment is defined as the practical reasoning that enables physicians to fit their knowledge and experience to the circumstances of each patient (Montgomery, 2006). From the interviews, there is evidence that the characteristics of the physician-patient dialogue are changed by proactive use of the quality register. The physician and the patient sits together in front of the computer and study and talk about the results from laboratory tests, x-ray examinations and the disease activity index (DAS28) i.e. As one rheumatologist describes it: *"It is like having a third person in the room... But it feels secure and comfortable, as the computer presents facts and not guesses or beliefs."* There is thus evidence of the register making explicit knowledge more clear and discernible. There are also evidence of tacit knowledge of patients and physicians being confirmed or made explicit by the register (Nonaka, 1994) as e.g. a vague perception of decreasing health status of the patient could be confirmed as an increase of disease activity measured and compiled by the

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system: *"The patient tells me that he or she don't feel very well. Then I take a look at the results from the laboratory tests or the (DAS28) index, and I can confirm that the patient's health status has decreased. It is a fact and not just a vague perception or whimpering."* (rheumatologist).

Furthermore, interviews were conducted with the main change agent acting as implementer of the register. From these interviews, it was obvious that there were a number of assumptions underpinning the design of the register, e.g.:

- The patient-physician relationships are improved by the use of the quality register as a decision support system during the medical consultation.
- The registration and evaluation of treatment and patients health status made available by the quality register leads to more efficient and equal treatment of the disease, and
- The use of the quality register is a significant vehicle of quality improvement in rheumatology care.

These assumptions frame the program theory of the innovation. In table 2, the validity of the assumptions is evaluated according the findings of the interviews with rheumatologists.

When exploring the empirical findings, it is evident that the question of what works in respect of the quality register is not? A simple "yes", "no" or "to a certain degree". Instead, the validity of the underlying assumptions is dependent on adoption of user – the quality register must be used to provide any gains at all. The validity of the assumptions is also dependent on the characteristics of users, of the innovation in itself and contextual factors inherent in the organization where the innovation is implemented. It is a question of what works for whom and under what circumstances. Furthermore, the assumptions underlying the design of the register are not always obvious to potential users. To fulfill the purpose behind the design of the register they need to be clarified in a more explicit way. We propose that the use of design theory would improve the design of the quality register by theoretically clarifying and defining the characteristics, scope and purpose of register design and implementation. This is done by making the underlying assumptions into explicit design propositions, upon which the design and implementation of the register is based. Furthermore, the design propositions could be evaluated and thus refined to make the design of the register even better.

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Assumptions underpinning the design of the quality register	Expected findings from a systematic, quantitative evaluation	Empirical findings verifying or disproving the assumption
The patient-physician relationships are improved by the use of the quality register as a decision support system during the medical consultation.	Yes, no or to a certain degree.	The patient-physician relationship *is changed* in the sense that tacit knowledge is confirmed or made explicit during the medical consultation by the proactive use of the register.
The registration and evaluation of treatment and patient's health status made available by the quality register leads to more efficient and equal treatment of the disease.	Yes, no or to a certain degree.	The assumption is verified when it comes to physicians who use the register on a regular basis. *On the other hand, not all physicians use the register due to the barriers of adoption, such as resistance from clinical management, lack of motivation to share knowledge, lack of time and perceived flaws in the interface and compilation of data in the quality register.*
The use of the quality register is a significant vehicle of quality improvement in rheumatology care.	Yes, no or to a certain degree.	The assumption is verified when it comes to motivating the use of expensive biologic drugs in treatment, and budget control *for the physicians and clinics which register data regularly*.

Table 2. Examples of assumptions underpinning the design of the quality register compared to findings of the case study.

TOWARDS A DESIGN THEORY OF HEALTH CARE QUALITY REGISTERS

Design research includes the building – or design – of an artifact as well as the evaluation of its use and performance (Baskerville et al., 2007). According to Simon (1988), "*Everyone designs who devises courses of action aimed at changing existing situations into preferred ones.*" (p. 129). Thus, the rationale of developing design theory for use of information systems is that such theory can support practitioners to understand which mechanisms that may lead to desired outcomes. This is accomplished by the use of so called *design propositions* or *technological rules.* Prescriptive design knowledge follows the logic of the technological rule (Bunge, 1967; Van Aken, 2005; Venable, 2006): "if you want to achieve Y in situation Z, and then do (something like) X." A technological rule could be seen as a design proposition. As the quality register could be defined as an information system, we suggest that the design theory should fulfill Gregor and Jones' (2007) eight components of information systems design theory (see table 3). The design theory of Gregor and Jones has been chosen as it not only comprises the design of the artifact but also of the implementation process.

According to Gregor and Jones (2007), the first six components of the design theory are sufficient to give an idea of an artifact that could be constructed: (1) purpose and scope, (2) the constructs, (3) the principles of form and function, (4) the artifact mutability, (5) testable propositions, and (6) justificatory knowledge. The first five components have direct parallels to components proposed as mandatory for natural sciences theories (Van Aken, 2005; Venable 2006). The sixth component has been added to provide an explanation of *why* the design works or not works. The two additional components are (7) principles of implementation and (8) expository instantiation. Principles of implementation concerns the means and processes by which the design is brought into being, including agents and actions. Expository instantiation is a physical implementation of the artifact that can assist in representing the design theory in the form of a construct, model, method or instantiation.

Component	Description
Core components	
Purpose and scope (the *causa finalis*)	"What the system is for," the set of meta-requirements or goals that specifies the type of artifact to which the theory applies and in conjunction also defines the scope, or boundaries, of the theory.
Constructs (the *causa materialis*)	Representations of the entities of interest in the theory.
Principle of form and function (the *causa formalis*)	The abstract "blueprint" or architecture that describes an IS artifact, either product or method/intervention.
Artifact mutability	The changes in state of the artifact anticipated in the theory, that is, what degree of artifact change is encompassed by the theory.
Testable propositions	Truth statements about the design theory.
Justificatory knowledge	The underlying knowledge or theory from the natural or social or design sciences that gives a basis and explanation for the design (kernel theories).
Additional components	
Principles of implementation (the *causa efficiens*)	A description of processes for implementing the theory (either product or method) in specific contexts.
Expository instantiation	A physical implementation of the artifact that can assist in representing the theory both as an expository device and for purposes of testing.

Table 3. Eight components of an Information Systems Design Theory (Gregor & Jones. 2007).

The application of the design theory of Gregor and Jones (2007) on design of quality registers is presented in table 4. The *purpose and scope* of the design is to develop a quality register for storing, retrieving and compilation of evidence-based data in order to enable quality improvement in treatment and improvement of the physician-patient relationship. The purpose and scope of the quality register is twofold, and the aim of improving the physician-patient relationship could only be fulfilled if the aim of storing, retrieving and compiling data is fulfilled. The *constructs* of the register is represented by evidence-based data by measures of patient and treatment data. The *principle of form and function* is health care quality registers used in clinical practice and research. When it comes to *artifact mutability*, there has been a

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continuous dialogue during the design of the register with stakeholders such as the professional rheumatology community and patient organizations. *Testable propositions* are represented by the underlying assumptions acting as design propositions guiding the design of the artifact. *Justificatory knowledge* (kernel theories) supporting the design are the program theories of the innovation including evidence-based knowledge of rheumatology care, models of physician-patient relationship, knowledge management theories and theories of organizational learning and implementation of innovations. *Principles of implementation* consist of design propositions derived from the kernel/program theories guiding the design of the implementation of the artifact. Finally, *expository instantiations* of the artifact are provided by training session, offered to health care staff by the implementers.

The evaluation of the design and implementation of the quality health care register showed that the purposes (underlying assumptions) were not clear to all users. Furthermore, the process of implementation was not wholly successful when it came to adopters and contexts of certain characteristics. This emphasizes the importance of using and articulating program/kernel theories clearly as design propositions in active use in design and implementation of the register.

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Component	Description (reference from what part of the case study the component is derived)
Core components	
Purpose and scope (the *causa finalis*)	The aim is to develop a quality register for storing; retrieving and c ompilation of e vidence-based da ta i n or der t o e nable quality i mprovement i n t reatment a nd i mprovement of t he physician-patient relationship.
Constructs (the *causa materialis*)	Evidence-based k nowledge r epresented b y m easures o f patient and treatment data.
Principle of form and function (the *causa formalis*)	Health ca re quality r egisters u sed i n cl inical p ractice and research (se section.
Artifact mutability	Suggestions for improvement of the design are continuously given by the professional community of rheumatologists and patient associations.
Testable propositions: design propositions guiding the design of the register	A number of assumptions underlying the design, e.g.: • The patient-physician relationships are improved by the use of the quality register as a decision support system during the medical consultation. • The registration and evaluation of treatment and patients health status made available by the quality register leads to more efficient and equal treatment of the disease, and • The use of the quality register is a significant vehicle of quality improvement in rheumatology care.
Justificatory knowledge	Theory underpinning the design includes evidence-based knowledge of rheumatology care, models of physician-patient relationship, knowledge management theories and theories of organizational learning and implementation of innovations.
Additional components	
Principles of implementation (the *causa efficiens*): design propositions guiding the implementation of the register	Examples of design propositions: • If you want to achieve a wide range of use of the register, then make sure that the members of the medical community agree on what knowledge is stored in the register. • If you want the register to be a vehicle of quality improvement, then make sure that knowledge sharing of treatment outcomes and patient data is motivated and accepted among users. • If you want physicians to use the register proactively in the medical consultation, then make sure that enough time is scheduled for the consultation.
Expository instantiation	Examples of the quality register in action are provided by training sessions offered to health care staff.

Table 4. Components of a design theory for health care quality registers.

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REALIST EVALUATION

Seminal works in design science research in information systems emphasize the importance of evaluation, which could be performed prior to artifact construction (ex ante) as well as after artifact construction (ex post) (Pries-Heje et al., 2007). When defining components of design theories, the design process could be regarded as consisting of design method, kernel theories and testable design process hypotheses. Design methods are descriptions of procedures of artifact construction and kernel theories are theories from natural or social sciences governing the design process itself. Finally, testable design process hypotheses are used to verify whether the design method results in an artifact which is consistent with the meta-requirements, i.e. goals, of the design (Walls et al., 1992).

The use of realist evaluation in information systems (IS) has been proposed as a way of overcoming problems of traditional information evaluations research: *"…it attends to how and why and in what circumstances (contexts) an IS initiative works through the study of contextual conditioning."* (Carlsson, 2003, p. 11).

The main goal of realist evaluation is to identify explanations of outcome patterns in order to refine and improve the program/kernel theory(-ies) of the innovation. This could be accomplished by use of the realist effectiveness cycle (Pawson & Tilley 1997; Carlsson, 2003; Kazi 2003). The stages of the cycle are described in figure 3. The starting point of the cycle is the program/kernel theory of the innovation, which includes propositions on how the innovation can generate outcome patterns in certain contexts. The second step is to generate hypotheses on what reactions or changes will be brought about by the innovation, what the influence of contextual factors will be, and what mechanisms (e.g. individual, organizational, cultural) will enable the reactions or changes. The third step is the selection of data collection method(s). Based on the result of the data collection, the innovation could be adapted or fine-tuned to the practices of adopters. Then we return to the program/kernel theories, which may be further developed.
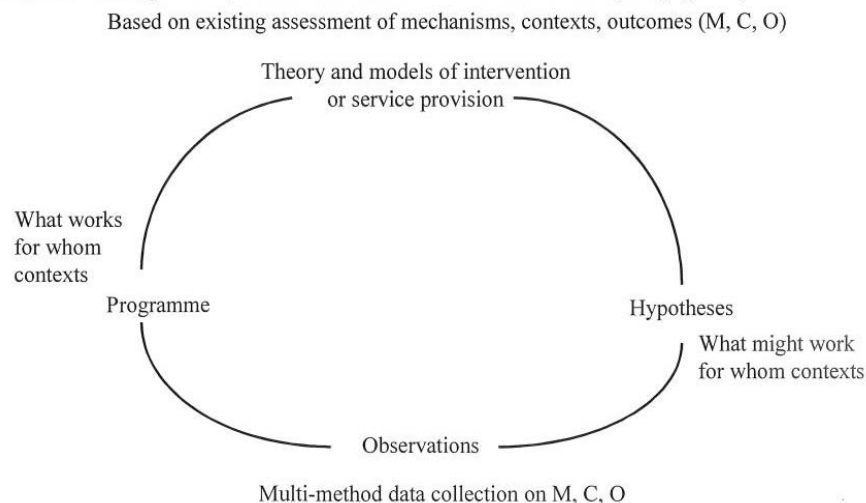

Figure 3. The realistic effectiveness cycle (Pawson & Tilley, 1997; Carlsson, 2003; Kazi, 2003).

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Realistic evaluation does not aim at providing simple causal explanations whether an innovation works or not, instead the aim is to understand outcome patterns rather than outcome regularities. Realist evaluators of innovations seek to understand why an innovation works, for whom and in what circumstances (in what context) (Pawson, 2006). The basic components of realist casual explanation is mechanisms (M), outcome patterns (O) and context (C). The relationships between the components of the model are depicted in figure 4.
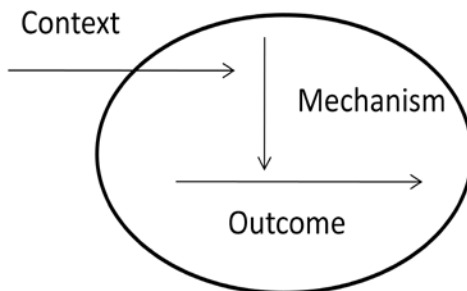
Figure 4. Basic components of realist causal explanation (Pawson, 2006).

Mechanisms explain causal relations by describing the "powers" inherent in the system (Pawson, 2006). The mechanism explains what it is about the system that makes things happen. The realist casual explanation begins with the identification of generative mechanisms and its characteristics, which produces the outcome patterns. Outcome patterns are also dependent on the contextual factors. The question "what works for whom in what circumstances could not be answered unless the evaluations are performed both in terms of context and outcome patterns. Applied on the example of innovations in health care, the realistic evaluation would explore the mechanisms triggered by the innovation (M), which are taken up selectively according to contextual factors (C), resulting in varied outcome patterns, e.g. different ways of adopting or using the innovation.

DESIGN THEORY AND REALIST EVALUATION COMBINED

By realist evaluation, the different mechanisms and contextual factors producing different outcome patterns of quality register use and implementation would have been captured, such as the variance in adopter characteristics (e.g. willingness of knowledge sharing or not), perceived characteristics of the register (e.g. perception of flaws in user interface or not) and contextual factors (e.g. a management resisting organizational change or not). These outcome patterns and contextual factors would not have been captured by an evaluation based on randomized controlled trials or quasi-experimental designs. The findings from the realist evaluation could subsequently be fed back to the design theory in order to adapt and refine the program/kernel theory(-ies) and the design principles guiding the design and the implementation of the register.

The rationale of developing a combined framework of design theory and realist evaluation to the design and implementation of complex innovations in health care is that such a framework can support implementers and practitioners to understand which mechanisms that may lead to desired outcome patterns. In figure 5, the elements of the basic components of realist causal explanation (Pawson, 2006) has been complemented with "design proposition" to

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emphasize the likelihood that mechanisms leading to beneficial outcome patterns could be increased if implementers and practitioners are given guidance based on program/kernel theories (Carlsson et al., 2008). By evaluating the outcomes of the innovation by realist evaluation, the design propositions could be adjusted and further refined to create even more beneficial outcomes.
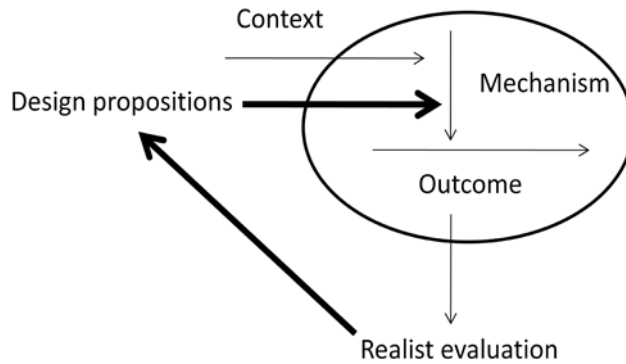

Figure 5. Basic components of realist causal explanation with design propositions guiding beneficial outcomes (adapted by the authors) (Pawson 2006).

Our framework combining design theory and realist evaluation: the design – evaluation cycle for complex innovations in health care organizations is depicted in figure 6. The cycle starts with formulation of program/kernel theories making up the theoretical foundation of the innovation. From the program/kernel theories design principles regarding the design and implementation of the innovation are derive. After the innovation is designed and implemented, realistic evaluation is applied to provide casual explanation of outcome patterns, depending on identified mechanisms and contextual constraints. The findings of the realist evaluation are then fed back to the program/kernel theories to refine them to bring about even more beneficial outcomes from the use of the innovation from the perspectives of implementers and practitioners. Refined program/kernel theories are elicited on what it is about the innovation that works for whom in what circumstances. And so the design – evaluation cycle goes on to produce design propositions based on the new theories.

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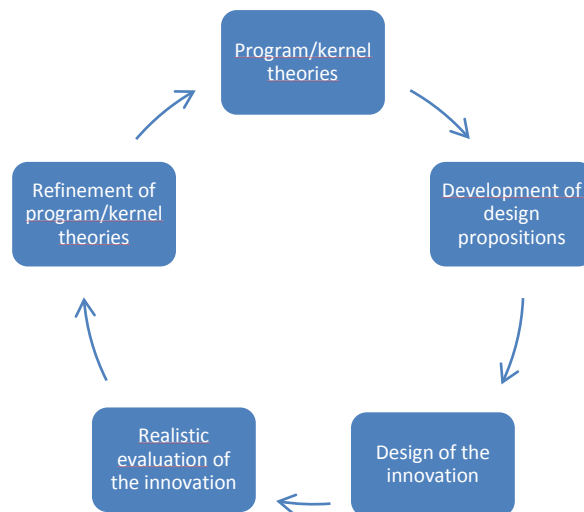
Figure 6. The design – evaluation cycle for complex innovations in health care organizations.

In this paper, we have explored the complexity of innovations in health care by examining the design and implementation of a health care quality register in order to understand underlying assumptions behind the innovation, as well as the characteristics of the design and implementation of the innovation. Based on the findings from the study, a design theory for health care registers were proposed in order to theoretically clarify and define the characteristics, scope and purpose of register design and implementation. Furthermore, realist evaluation was put forward as a vehicle of refinement of program/kernel theories and subsequently formulation of design propositions to guide the practitioners in the design and implementation of health care quality registers. The rationale behind the choice of realist evaluation is that it captures the full complexity of innovations by studying mechanisms, contextual constraints and outcome patterns. This complexity is not captured by the traditional evaluative methods used in health care, the randomized controlled trial and the quasi-experimental design. Realist evaluation *"is real and deals with a stratified reality"* (Carlsson, 2003, p. 17). Finally, design theory and realist evaluation were combined to a design – evaluation cycle for complex innovations in health care. We argue that our proposed design – evaluation cycle will be able to capture several of the elements and linkages which are parts of Greenhalgh et al.'s (2004) conceptual model of diffusion, dissemination and implementation of innovation in health service organizations (Rogers, 1995), e.g. the implementation process and the linkages between change agents and users created in the design stage and implementation stages.

As stated earlier, the goal of the design – evaluation cycle is to provide support to implementers and practitioners in designing and implementing complex innovations in health care. If the underlying assumptions of the program/kernel theory can be developed to design propositions for design of the quality register, the purpose and scope of the innovation would be clarified and explicit to implementers and users. Furthermore, the theories underlying principles of implementation could secure that implementers take the full complexity of the innovation process in consideration when planning for implementation. Concurrently with the realist evaluation and the subsequent refinement of program/kernel theories and derived design propositions, we argue that the design – evaluation cycle could provide opportunities of

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improving dissemination of complex innovations in health care. Our contribution has been to develop a model for design and evaluation of innovations that captures the full complexity of health care services with quality registers as an illustrative case. To our knowledge, this has not been accomplished before.

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