#### DOCTORAL CONSORTIUM

### BETTER TOGETHER: CONDITIONS FOR SUSTAINABLE INNOVATION AIMED AT IMPROVING QUALITY OF CARE IN HEALTH DELIVERY ORGANIZATIONS

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The resilience of health care organizations over time in a changing and ever challenging socio-economic environment depends on effective innovation. Innovation is based on translating research outcomes into interventions aiming at improving quality of care which is defined as a combination of six dimensions: effectiveness, efficiency, safety, equity, accessibility and patient-centeredness of care. The majority of research papers on innovation and quality improvement deal with the conditions for dissemination and implementation (D&I) but does not address the conditions for long term valorisation of research outcomes or adopting them beyond the implementation period. Factors determining successful D&I are ordered in frameworks consisting of five domains: characteristics of the intervention, internal context, external context, adopters skills and design and management of the implementation process. In general, these frameworks provide a descriptive tool or taxonomy, but miss explanatory power which will eventually be found in a theory of good decisional practice.

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### 1 Introduction

The resilience of health care organizations in a changing and ever challenging socioeconomic environment depends on effective innovation. Innovation is based on translating research outcomes into interventions aiming at improving quality of care which is defined as a combination of six dimensions: effectiveness, efficiency, safety, equity, accessibility and patient-centeredness of care. The majority of research papers on innovation and quality improvement deal with the conditions for dissemination and implementation (D&I) but does not address the conditions for long term valorization of research outcomes or adopting them beyond the implementation period. In this proposal, the terms sustainable innovation or sustainable quality improvement will be used for the time being. Factors determining successful D&I are ordered in frameworks consisting of five domains: characteristics of the intervention, internal context, external context, adopters skills and design and management of the implementation process. In general, these frameworks omit the conditions for sustainable innovation. They provide a (limited) descriptive tool or taxonomy, but miss explanatory power which will be found in a theory of good decisional practice.

This research proposal aims at clarifying the concept of sustainability in health care innovation and at constructing and providing a tool for determining an organizations innovating capacity, based on the prevailing operative decision premises. Research will be conducted, based on the process model of Design Science Research Methodology because of the combination of methodological rigor and practical utility.

### 2 Problem definition

This proposal concentrates on health delivery organizations (aka hospitals). Healthcare organizations are under growing external and internal pressure to become more efficient in containing healthcare costs while delivering the same or better quality of care to an aging population with more complex comorbidities. This demands constant innovation aimed at quality improvement. Health care quality in this context is defined as a combination of six dimensions and their interactions: effectiveness, efficiency, safety, equity, accessibility and patient-centeredness of care (IOM 2001). Health care innovation does not include medical innovation which

focusses on patients and somatic conditions by better diagnostics, evidence based treatments and interactive revalidation supported by shared decision making between patients and professionals. Health care innovation is defined as the creation and implementation of concepts, ideas, technologies and services aimed at processes, structures and outcomes and leading to quality improvement (Donabedian 1966/2005). Both strategies depend on one-another: medical practice takes place within and by means of the health delivery organization and the organization finds her ultimate raison d'etre in care and cure for patients, but this research proposal is restricted to health care innovation among other reasons because research into medical innovation would require forms of patient related clinical research for which we are neither authorized nor qualified. Dissemination and implementation of innovation is studied by the discipline of implementation science. Implementation science develops (applied) theories and tools to plan, manage and evaluate valorization of research outcome or evidence based knowledge in (among others) health care practice (Wensing et al. 2022; Home page | Implementation Science (biomedcentral.com)).

The conditions for failure or success of dissemination and implementation (D&I) projects are listed in implementation frameworks, arranged in domains. These are: characteristics of the intervention, internal context, external context, adopters skills and quality of the implementation process. Almost all frameworks in implementation science and practice use the five domains, albeit with varying operationalization. Although the total number of such frameworks at present is about 170, only a fraction of these are more or less frequently in use (Damschroder et al. 2009; 2022) and in most cases the application is sub-optimal (Moullin 2020). Not included in most publications on innovation in health care or elsewhere are two factors which are essential when implementing evidence based interventions: sustainability of the intervention (lasting beyond the implementation phase) and the quality of the decisions made in that context which have to be both effective and acceptable.

### Sustainability

The first challenge is sustainability. Sustainable innovation depends on more than the correct application of a framework of conditions for managing D&I projects (Fleiszer et al. 2015). To begin with, "sustainable innovation" is in dire need of conceptual clarification. With an implementation science focus, sustainability has been provisionally defined as: "after a defined period of time, the program (...) and/or implementation strategies continue to be delivered and/or individual behavior change is maintained, continuing to produce benefits for individuals/systems" (Moore et al. 2017). In the present literature on innovation and implementation theory, the elements or factors conditional for or leading to sustainable quality improvement in health care or in other sectors of society are either not addressed or treated as very similar to the frameworks for D&I projects (Shelton et al. 2018; Khalil, Kynoch 2021). In a first, exploratory phase, this research proposal will contribute to clarification of the concept of sustainability in innovation, thereby contributing to its applicability and explanatory power. It will list the conditions for sustainability and present them in a framework.

### **Decision making**

The second challenge is decision making. In order to reconcile differences in and between local logics or situational rationalities in D&I projects in complex organizations, decisions have to be both effective in terms of the objective of the implementation and sufficiently acceptable to the internal and external stakeholders. In spite of a multitude of (descriptive) theories about and case-studies of decision making in medical practice and elsewhere, at present there is no broadly accepted standard for "good decisional practice" comparing to the one for "good clinical practice" (WHO 2005). In order to be reliable and effective, decisions on investments reckoning costs and benefits and the expected interacting effects on dimensions of quality will have to meet a set of guidelines, covering the way a decision making process is designed, conducted, monitored, recorded, analyzed and reported. This research proposal has as its main purpose to contribute to a concept of "good decisional practice" as one of the vital factors for successful implementation and a determining factor for the innovation capacity of any organization.

### 3 Methodology

In this proposal, research interest is limited to the conditions for sustainable innovation, or the durability of innovation and its effects beyond the actual implementation phase and to the standards and procedures for making effective and acceptable decisions in the process of dissemination and implementation. By developing design and methods, the process model of design science research methodology will be followed (Peffers, Tuunanen, Rothenberger, Chatterjee 2007; Brocke, Hevner, Maedche 2020). This model offers transparency, combi-ning the demands of methodological rigor with practical utility in first designing an artifact which improves something for stakeholders and subsequently empirically investigating the performance of that artifact in its context: "validation in context" (Wieringa 2014 p V. The DSRM process model contains six phases.

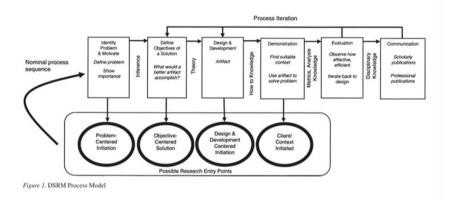


Figure 1: DSRM Process Model Source: (Peffers et al. 2007)

The six phases of the DSRM model are realized in five research projects, each answering a specific research question, including a sixth phase, presenting the outcomes to the commu-nity of health care professionals and valorization specialists. In applying this model as blueprint for the present research proposal, the coherence between the phases in the sequence becomes explicit, the phases can be evaluated in their merits and the phases can be repeated as an additional quality check. In this way, the model contributes to the objectivity, reliability and validity of the research project and its components.

# 3.1 Identifying the problem: what are the conditions for successful D&I projects and what are the conditions for sustainability in innovation?

The process of translating the outcome of (applied) research into evidence based interven-tions leading to quality improvement has been the object of research by (for instance) the discipline of implementation science for a long time (Peters 2013).

This research project will start with a literature search, leading to a survey of actual facilitators and barriers to innovation projects, comparing them with the elements of standard frame-works, based on empirical studies and reviews. Inclusion will not be restricted to papers referring to the health care sector as windfalls and setbacks or complications with dissemination and implementation are universal and not typical for care providers.

The second literature review searches for definitions of sustainability in innovation and the validated knowledge concerning the conditions for this sustainability. Given the conceptual ambiguity of sustainable implementation as a process and desired outcome and the lack of standardized frameworks in this field, the review will concentrate on available knowledge on the topic since 2015. In order to make the review up-to-date with expert opinion, a number of additional interviews with a limited number of innovation managers and specialists will be included and reported in the publication.

Both questions will be answered using grounded theory as a method for reviewing literature in qualitative research (Wolfswinkel 2011).

Outcome: The reviews will lead to an understanding of the actual use of implementation frameworks, the wide variety of operationalization of the categories and of the large number of various elements determining sustainability of quality improvement and the organizational resilience through innovation.

# 3.2 Objectives for a solution: what are the relevant aspects of a theory of decision making?

Even the best implementation framework as blueprint and management tool requires adequate decision making in preparation and management of a project or program, especially in a complex organizational context and when solid investments are required. Decisions have to be both effective and accepted in dealing with the risks and opportunities of the investments in dimensions of health care quality and their interactional effects. Not the quality of a tool like a framework but the handling of that tool determines its effectivity in the implementation process and this handling depends on adequate decision making, leading to decisions which are both acceptable to the organization and effective in the process of D&I.

In this process, different interests based on situational rationalities and local logics have to be weighed, compared and acknowledged or rejected, hence decided upon in order to implement and adopt interventions aimed at quality improvement. In order to describe and analyze the decision making process itself and its contribution to the innovation readiness of an organization, this research proposal relies on Luhmann's theory of the organization as a special kind of social system (Luhmann 1985; 2000, also Schoeneborn 2011; Blaschke 2012; Dobusch 2015).

In this theory, a social system is nothing but the totality of all communication taking place, reflecting the process of autopoiesis or development of identity in self-awareness expressed internally—defining the system's elements and their possible relationships—and externally in temporal en spatial relationships: to the system's remembered past and expected future and to the environment it perceives as "alter" or the other. In this experience of the temporal and spatial other as alter, a system experiences itself simultaneously in its identity as auto. In Luhmann's theory, the organization is denied an ontological status (or at least this status is not granted). Instead, organization are conceived of as a specific kind of social system characterized by the fact that all communication is instrumental and aimed at decision making (Luhmann 2018 p. 49; Seidl 2005; Aal 2022). Decisions are reached by exchanging and confronting arguments that derive their impact from decision premises (Luhmann 2018 p. 181 ff) which form the organization's set of genes and provide the only way an organization can define itself and reduce the limitless complexity of the possible to a form of imaginable and thereby manageable reality.

Alternative theories of decision making – presupposing the organization as ontological context of communicative interaction, resulting – or not resulting – in a decision, lead to the problem that the framework of conditions for innovation presented in the classification of objects in a domain of interest in the shape of a taxonomy (Nickerson 2017; Michie 2013) does in no way determine the communicative performance or the quality of decision making and its outcome, nor the other way around. Taxonomies provide a descriptive model, what is needed, is an explanatory one. Based on Luhmann's theory, we will propose that the referral to decision premises to add impact to argument reveals the organizations propensity to or capacity for innovation or conservation by the share nature of the premises as a set of organizational genes.

### 3.3 Design and development: the artifact or an instrument to determine a system's innovation readiness.

How can we measure an organizations willingness and capacity to innovate? The challenge in this phase of research is the selection of a communicative situation (or discourse) and constructing an artifact in combination with an appropriate methodology to analyze innovation capacity or innovation readiness (Allen 2017 p. xxxvi/56 ff). In order to construct the artifact, a number of decision premises will be selected and presented. They will be derived from the three areas where complexity reduction and risk management are vital and which are crucial in any form of innovation or changing current practice: power of decision making, costs and benefits and identity. The premises as the genes of an organization become manifest though DNA/RNA actualization in decisions on project planning, managing the process and reporting on the outcome. This process can be visualized and analyzed by applying means and methods of pragmatics or discourse analysis based on applied linguistics. The outcome will be presented in a coding scheme (Schreier 2012 p. 58-79) which forms the central tool for the analysis and interpretation of discourse or the exchange of arguments leading to a decision in a specific situation. With this instrument or artifact the quality of decisions made in specific D&I projects and programs can be appraised, contributing to an assessment of the probable outcome and determining the strength and restrictions of the organization's innovation capacity.

### 3.4 Demonstration: how to put the artifact to the test? Proof of concept.

In order to test the validity of the artifact, it will be applied in a sufficient number of multi-case studies (Yin 2018) to score the operative set of decision premises of a team with a well-established and confirmed reputation and track record for sustainable innovation. The hypothesis to be tested is, that there will be a positive correlation between the "decision premises profile" of the teams and their proven innovation capacity. The way to establish the correlation will be by structural equation modelling, linking latent variables in the domain of decision premises to well established variables like a team's proven innovation track record (Cook 2011; Phillips 2002; Kaplan 2000) by means of scheme analysis of one or more instances of yet to decide decision making discourse. The case studies will be executed with assistance from a group of quality specialists in the community of Dutch top clinical teaching hospitals. The number, nature and location of the teams has yet to be decided, based on a power analysis. Aim of the set of case studies is to calibrate the tools by measuring and comparing the realized surface set of decision premises with the well-established track record of the teams over a large enough set of data. It will be followed by the adjustment of the tools if necessary.

Outcome: a (presumably) valid tool to diagnose social systems – or innovation teams – in their innovation capacity as expressed in the predominant quality of decision making.

# 3.5 Evaluation : how to put the artifact to the test? Communication in action

Top clinical teaching hospitals are a worldwide category of health delivery organizations providing complex medical care, acting as centers of medical teaching and education and contributing to patient related clinical research. In the Netherlands the 27 top clinical teaching hospitals form a specific group, known as the Samenwerkende Topklinische Ziekenhuizen or STZ (Samenwerkende Topklinische Ziekenhuizen - STZ). This association will be asked to provide a number of sites to test the instrument on validity, reliability and effectiveness (Leung 2015). Sites could be either innovation projects or implementation teams. The tests will take place in the shape of action research (O'Leary 2017, p 415 ff), the researcher observing and actively participating in an Observe-Reflect-Plan-Act cycle in a limited

number of actual innovation projects aimed at sustainable implementation of quality improving interventions. Aim is to observe communication-in-action, being the decision making process where arguments are presented, exchanged and reacted upon, leading to a decision which is both effective in the project and acceptable to the team as a social system. Through this participating action research, it will be possible to scrutinize the actual decision making processes in innovation and the strategies for conferring pragmatic power to arguments, determining the quality of decision making in a particular case or a number of cases (McCarthy, Matthiessen, Slade 2010). In order to guarantee the appropriate level of research integrity and quality, this phase of the project will be monitored by a limited team of experts in action research, hospital management and decision making. In this way, the artifact and its efficacy can be tested, either validating or falsifying its claim to be able to assess an organizations innovation readiness and the quality of its decision making process.

### 3.6 Communication

Each of the five phases of this research project will lead to a publication in a peerreviewed international journal in the domain of implementation science and/or health care management. On top of that, a number of practice oriented publications and conferences will be delivered in order to introduce the concepts of sustainability in (health care) innovation and effective decision making or good decisional practice by deploying decision premises to a relevant audience from management, education and consultancy.

### 4 Preliminary/Expected results

Implementing the research proposal will lead to a number of outcomes adding to facilitating the implementation of evidence based interventions aimed at quality improvement in health care.

### 4.1 Scientific importance and added value

As yet, implementation theory has not presented a dedicated framework of conditions for planning, monitoring and evaluating sustainable innovation of interventions aimed at quality improvement in health care. The present research proposal will provide an outline of conditions for sustainable innovation, based on literature research and the expert opinion of innovation managers. The outline will be presented in the form of a framework. It is not just the framework of facilitator and barrier factors which determines the outcome of health care innovation, it is also – and predominantly – the proces of decision making and the effectiveness and acceptability of the decisions resulting from the process. Frameworks are a necessary condition but they are not a sufficient cause, they provide a taxonomy but have no explanatory power. The present research proposal will provide a theory of good decision making based on Luhmann's theory of social systems. This research will develop and test a set of decision premises meant to describe and analyze the decision process as such, dedicated to innovation and implementation of quality improvement. The set of decision premises will not just analyze the process of decision making but will also be used to assess the innovation capacity or innovation readiness of the organization as a social system thereby providing a tool for feasibility studies and team development.

### 4.2 Expected scientific output

This research proposal will extend the concept of frameworks for D&I projects into the area of sustainable innovation by providing a set of critical conditions for sustainability in health care. It will elaborate further on Luhmann's theory of the organization as a specific form of social system by operationalizing the crucial element of decision premises as organizational genes determining its innovation capacity or its innovation readiness. The output will consist of a number of research papers (at least one per phase) in international peer-reviewed journals in the field of health care, innovation and implementation sciences and of a number of professional publications in media dedicated to research valorization and the translation process from knowledge to practice. Aim is to bring the importance of sustainable innovation and the conditions for sustainability as well as the conditions for "Good Decisional Practice" as a parallel to "Good Clinical Practice" to the attention of the health care and implementation research community.

### 4.3 Practical significance

The development of a framework for sustainable implementation of health care innovation will contribute to successful planning, managing, monitoring and evaluating such projects as part of a continuous innovation PDCA-cycle. The validated set of decision premises as criteria for effective decision making will help to analyze, monitor and if necessary improve the decision making process, fulfilling one of the basic conditions for successful planned innovation, either incremental or disruptive. In focusing on the explanatory power of the decision making process to clarify barriers and facilitators for sustainable innovation, this research will contribute to the development of standardized guidelines for "good decisional practice".

### 5 Future development.

Both the implementation framework for sustainable innovation and the review framework for making decisions which are acceptable as well as effective will have positive effects on health care practice when converted into applications for everyday use in planning and implementing quality strategies, feasibility studies, project planning and management and outcome evaluation on behalf of a continuous PDCA improvement cycle.

Applying the frameworks into tools, guidelines, standardized action plans and evaluation formats will take place in close proximity to health delivery situations in mixed teams consisting of health care practitioners, managers and implementation specialists.

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