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CONTEXT AS A RELATIONAL CONFIGURATION DURING NEW TECHNOLOGY IMPLEMENTATION IN HEALTHCARE

Abstract

This article proposes a new way of viewing the concept and significance of context during the implementation of new evidence-based medical procedures. Implementation theories and models often emphasize the importance of considering the context as a facilitator or a barrier to the sustainability of healthcare innovations. One of the drawbacks has been addressing the complex interconnections and dynamic relationships within the inner and outer contexts. The paper suggests the relational perspective as a new way of viewing this phenomenon. In the article, some principles of the relational perspective are applied to the findings of a longitudinal ethnographic study of introducing a new cardiothoracic procedure in Norway. TAVI (Transcatheter Aortic Valve Implantation) is an evidence-based, minimally invasive procedure to repair a damaged aortic valve. It has become a preferred treatment option for many patient groups suffering from aortic stenosis. The research followed the implementation of TAVI from its experimental phase to its standardization as a multiple case study. This manuscript examines the initial stages of its implementation from a relational standpoint, discussing environmental frictions and value configurations to present an alternative approach to understanding the context and multiple interactions during innovation implementation in healthcare.

Keywords: innovations in healthcare, implementation, interorganisational relations, management practice, context, ethnography, case study

1. Introduction

Work practices in healthcare are shaped by many procedures, rules, labor divisions, and many involved stakeholders and technologies. Medical innovations often break with the conventions of established medical practices, which may threaten their sustained use. A lack of stakeholder involvement at macro-levels, or their lock-ins, professional standards, institutions, organizational structures, or inadequate

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resources, can all impede the successful implementation of even the most beneficial evidence-based medical procedures (Currie et al., 2012; Fitzgerald et al., 2002; Greenhalgh et al., 2004). Thus, scholars have developed theoretical frameworks such as the Dynamic Sustainability Framework (DSF) (Chambers et al., 2013), the Practical, Robust Implementation and Sustainability Model (PRISM) (McCreight et al., 2019), or the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009; Kirk et al., 2015) to identify various factors to be considered for a successful implementation of healthcare innovations. These factors include the characteristics of the intervention, the various processes, stakeholder groups, and the inner and outer contexts. The latter factor, contexts, has been recognized as more complex, as authors object that the existing frameworks often fail to account for its richness and dynamics, mainly because of the contextual environment's interconnectedness (Grossi et al., 2021; Gusmão Louredo et al., 2024; Rincón et al., 2022).

This article suggests a step further in considering the context's interdependence as it contributes particular insights from the relational perspective to this field (Bailey et al., 2022; Emirbayer, 1997; Kyriakidou & Özbilgin, 2006). The relational perspective is becoming increasingly identified as a central perspective in management, organization, and information systems studies (Bailey et al., 2022; Hui et al., 2017). Still, it has not penetrated the studies and practice of sustainable healthcare innovation implementation. Applying the relational perspective to the idea of context leads to re-conceptualizing context from either a factor, construct, or background against or within which a healthcare innovation is implemented and is considering it as its central and defining element. The article thus aims to problematize and contribute to our understanding of this important factor by analyzing this proposition through empirical case findings, particularly on the examples of the factors of organizational fit and secure resources and funding.

The original primary research is a longitudinal multiple case study of introducing a new medical procedure in Norway. Transcatheter aortic valve implantation (hereafter TAVI) is a viable solution for a large portion of (generally) elderly patients who have earlier had no option for treatment of a deadly disease called aortic stenosis. Aortic stenosis has a prevalence of 5-8% in older adults over 75, and its incidence increases with aging (Ramos et al., 2018). During the last 15 years, this evidence-based procedure has become the preferred treatment for almost all patient groups introduced to aortic stenosis (Vahanian et al., 2012). However, the implementation of TAVI has been a complex and multifaceted process involving many people, technologies, organizations, procedures, clinical findings (etc.) in continuous attempts to reach standardization. Through a five-year ethnographic case study, the research team empirically followed the adoption of TAVI from 2011 (while it was still experimental) to 2016 (when it became a standard treatment) at a main case hospital in Norway, with

research also expanding to another 9 case hospitals in Scandinavia and to other locations and stakeholders. This article uses a retrospective approach to focus on the elements of its initial introduction that later proved critical for its sustained use¹ in terms of institutionalization, routinization, continuation, and development (Fleiszer et al., 2015; Urquhart et al., 2020). The case epitomizes the efforts and challenges of the global shift from open to minimally invasive cardiac surgeries and the typical processes these kinds of medical technologies will undergo during their implementation in practice. Notably, the study's design as a relational ethnography (Desmond, 2014) allowed for an analysis of the new practice development within deeply interconnected internal and external contexts.

2. Literature and theory

Studies of healthcare innovations that link their implementation to sustainability regularly contribute by identifying the factors that play significant roles. In general, as reviews of implementation theories have shown, context is mainly recognized in determinant theories as a construct that influences implementation outcomes within different models and frameworks (Cowie et al., 2020; Lennox et al., 2018; Nilsen, 2015; Zurynski et al., 2023). Often divided between the inner and outer organizational environments, the context factor is always prominent as a background into which the innovation or intervention must be made to fit or adapt (Chambers et al., 2013; Cowie et al., 2020; Kirk et al., 2015; Lazaretti et al., 2020; Zurynski et al., 2023). The Dynamic Sustainability Framework (DSF) (Chambers et al., 2013) describes medical interventions as being a part of two contexts: a practice setting (the characteristics of the organization) and the ecological system, which comprises external practices, policies, regulations, market forces, and so on. It takes into account these elements of the context as going through continuous change and stresses the importance of, for example, available resources, compatibility, or internal and external policies surrounding the intervention (Kirk et al., 2015; Shelton et al., 2018). The Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009; Kirk et al., 2015) and Practical, Robust Implementation and Sustainability Model (PRISM) (McCreight et al., 2019) are similar in many regards in their approach to understanding context. They differentiate between the inner and outer settings as domains, extracting and defining their constructs to make empirical measurements transferable. Context assessments are generally made by quantitative measurement instruments to identify barriers and facilitators of the case implementation (Robinson & Damschroder, 2023) most assessments using the CFIR have relied on qualitative methods. One

¹ The later years of the TAVI development in this study are discussed in other publications e.g., (Mikhailova, 2018, 2022; Mikhailova & Olsen, 2016; Mørk et al., 2018; Nicolini et al., 2017, 2018).

challenge to measurement is to translate conceptual constructs which are often described using highly abstract, technical language into lay language that is clear, concise, and meaningful. The purpose of this paper is to document methods to develop a freely available pragmatic context assessment tool (pCAT. Financial support and budgeting, persistent leadership, and adequate role establishment (Grossi et al., 2021) within the organization and the socio-political or funding environment, priorities of external communities, and changing patient needs (Aarons et al., 2011; Chambers et al., 2013; Damschroder et al., 2009; Kirk et al., 2015; Mancini & Marek, 2004; McCreight et al., 2019; Stirman et al., 2012) are all factors of the context to take into account. However, context is now seen as more complex than it has been treated, with some authors arguing that current frameworks often overlook its complexity and dynamics, especially the interconnectedness of the healthcare environments (Grossi et al., 2021; Gusmão Louredo et al., 2024; Rincón et al., 2022). The specific ideas of the relational perspective and the ethnographic, practice-based research methods used in this study may address this shortcoming.

The relational perspective (Bailey et al., 2022; Emirbayer, 1997; Kyriakidou & Özbilgin, 2006) leaves behind the consideration of different factors or variables as facilitators or barriers to the adoption and sustained use of new technologies, reorienting the lens on their relations and interactions. The main outline of the relational perspective was elaborated by Emirbayer (Emirbayer, 1997) in his “Manifesto for a Relational Sociology” (Crossley, 2010; Donati, 2010). The turn to relational thinking rests on a few core premises (Crossley, 2010; Donati, 2010; Emirbayer, 1997). It begins with the premise that all human and non-human entities should be defined by their agential capabilities in specific situations rather than by fixed categorizations. These agential capabilities are entirely formed by their relations; they emerge from a network of connections within which the entity is (temporarily) embedded. In a more simplified expression, the relational view proposes that any phenomenon or entity is meaningless outside of its connections with the world, that is, its environment or context. The context is thus the primary source of what the technology, intervention, or practice *is* at any given point in time. For example, a surgical scalpel is recognized as a surgical knife not only by design but also by being located in a room identified as a surgical suite, handled daily by the hands of (externally) legitimated surgeons during organized medical procedures or surgical training, mutually agreed upon to be these situations by many other people, groups, and institutions. Similarly, what a new medical procedure, intervention, or technology is depends not only on its material or procedural characteristics but is defined by the communities involved locally and externally, clinical research, and the assigned benefits (etc.). These, the theory asserts, co-create the entity under consideration, and the way to understand its nature is by tracing the relational configuration that sustains it, as observed in vivo and expressed

by those involved in the work. In this sense, the context is a relational configuration, a set of relation-making processes that co-creates the practice (intervention or innovation) as it is implemented and used.

In this way, the relational lens de-centers the innovation and the noticeable social actors, thus allowing more objectivity and inclusiveness of (f)actors to be considered. Importantly, it goes hand-in-hand with (post-humanist) practice-based empirical studies (Gherardi, 2016, 2022; Monteiro & Nicolini, 2015; Nicolini, 2012), many of which have studied the issues of implementing new technologies in medical work *in vivo* (e.g., 21–27). Thus, the theory has been developed into a practice-based research and analysis approach and has been used for over two decades in these areas to conduct empirical research (Bailey et al., 2022; Hui et al., 2017; Østerlund & Carlile, 2005). The following are the methods used to collect data, the analysis, and the case study's findings on the implementation of TAVI from a practice-based view. Context, taken as a relational configuration, is presented as a moving, shifting nexus of relation-making processes that comprises the innovation.

3. Methods

3.1. Case study and materials

The primary case study site was the Intervention Centre (IVC) at the Oslo University Hospital. This Research and Development Centre was established in 1996, and its primary goal is to test and develop new procedures and devices before they are released as standard treatment methods in Norway. The case study object was transcatheter aortic valve implantation (TAVI), a new medical procedure for treating aortic stenosis at that time. The TAVI project at the Intervention Centre began as a medical research study in 2009, whose purpose was to determine the clinical, hospital, and societal costs of adopting this procedure. Our part of the research team empirically followed the adoption of TAVI for five years, from 2011 (while still experimental) to 2016, when it became a standard treatment option, to describe the elements of the new practice that contribute to (or hinder) the project being successfully implemented from an organizational perspective which expands further than only its local implementation.

The participants in the research were chosen purposively according to the choice of case and phenomena of interest; that is, they were in some way working on or involved in TAVI projects (Silverman, 2005). They included cardiac surgeons and interventional cardiologists of the TAVI teams, radiographers, anesthesiologists, echocardiographers and nurses, and others involved in TAVI procedures. The other research participants included staff and department management at the IVC and its hospital

(meso-level), as well as practitioners and persons performing TAVI or involved in it in other ways at other locales, at nine different hospitals in Scandinavia, at national and international conferences and also the technology providers representatives were included.

The study approach was interpretative, meaning it relied on the information from informants who gave their in-depth, qualitative views of realities (Feldman, 1994; Walker, 1988). Because the research project was envisioned as a study of a novel medical practice as it was being created in real time, an ethnographic approach was chosen to provide the appropriate tools (Desmond, 2014; Schultze, 2001; Silverman, 2005). Moreover, the study expanded into a relational ethnography (Desmond, 2014) to trace the connections involved in local practice development. Following this research design, the research team conducted observations, interviews, field talks, and document analysis. The primary and most significant research data sources were ethnographic observations and in-field interviews. Inside and outside the primary locale, the team conducted around 1400 hours of observations, also including hundreds of pages of ethnographic fieldwork interview notes over five years. The ethnographic approach meant that the researchers were present at the locale for extended periods, observing the performance of the new procedures in operation suites (usually from control rooms), interacting with the involved staff around the procedures, and participating in the daily life of the Intervention Centre. While not being participant observers, the extended exposure and interaction with the study participants and site allowed for the development of deep understanding, openness, and truthfulness during in-field data collection and formal interviews. As a result, the research material is robust, in-depth, and respectful of the context within which the practice develops.

However, it has been observed that single-site studies of technology implementation might provide a limited lens to understanding the development of new technological practices (Nicolini, 2009; Williams & Pollock, 2012). Following the information collected at the main locale, the research team also traced the external actors and locations and studied their mutual relationships, negotiations, and temporary settlements over time. This was mainly conducted through single rounds of formal interviews at other hospitals (nine hospitals in Norway, Sweden, and Denmark), two to three rounds of formal interviews with representatives of three technology producers, and informal interviews with their representatives on-site, and through informal interviews with various professionals at national and international TAVI conferences. Altogether, next to the in-field ethnographic interviews, 60 formal interviews were held with 16 different types of professionals, such as cardiologists, cardiac surgeons, nurses, hospital managers, and technology vendor representatives. The research team also continuously analyzed procedure-relevant documents, such as procedure protocols, videos, media reports, presentations, etc., provided by the informants. We

collected and studied documents such as written instructions, contracts, clinical research, statistical information, and other relevant documents for the TAVI projects as they were being published.

3.2. Data analysis

The analysis followed an abductive approach common in ethnographic and field data analysis. It relies on warranted qualitative interpretation (Brinkmann, 2014; Locke, 2011) as it is suited to understanding high-context work practices, the multiple interpretations of realities, and changing relationships when observed over a long period. Information collected during ethnographic inquiries is usually complex and convoluted, with various meanings given to single constructs and dynamic interdependencies between their meanings. The issue of appropriate coding and categorization becomes even more troublesome when data collection is done through multiple methods, at more than one location, and collected from an extensive array of stakeholders, such as in relational ethnographies. Thus, mechanical analysis methods such as coding are often inappropriate (Clerke & Hopwood, 2014; MacLeod et al., 2019). Hence, the suggested analysis of such information is aimed at analyzing processes, instances, their different interpretations, conjectures, and interactions between them, often as narrative forms (Hopwood, 2018). Firstly, all document, observational, and interview data were transcribed into text (done by each researcher separately). At the beginning of the research, some primary information was highlighted from the various data collection sources (e.g., fieldwork, formal and informal interviews, documents, and clinical literature). It included the history of TAVI globally, the TAVI project at the hospital, its team members and composition, important events during its development, a general description of TAVI procedures, its current state worldwide, the external stakeholders involved, etc. These findings created a central thematic framework, allowing us as active researchers to methodically integrate and reiteratively question new data sets over time (Bryman, 2008; Feldman, 1994).

The findings were compared and discussed in co-researcher meetings, during which we identified the evolving situations of external actors, their own causal trajectories, missing information, and further research plans to capture their diverse inter-relationships. The notes from fieldwork were independently mined by researchers and compared in co-researcher meetings, and the relevant findings were bundled and related back to the themes of interest. The data was visually mapped on whiteboards (Langley & Ravasi, 2019) during the meetings and then copied into shared documents. Collaboratively, we engaged with the themes and conjectures, described and filled in the gaps of the actors and their parallel phases and developmental tracks, co-created valuable insights, and brought up issues unique to each individual analysis. This analysis was aided by using PowerPoint presentations, physical print-outs, and

whiteboard discussions, including drawing different types of visual maps to describe parallel and multidirectional processes, similar to the method elaborated by Langley and Ravasi (Langley & Ravasi, 2019). These were considered emergent relation-making processes to which one could assign meaning only by combining the data in this way and tracking relations. Instead of strictly adhering to pre-scripted coding and categorization, this approach allowed us to maintain systematic rigor oriented by themes while being open to emergent relevancies during ongoing research. This technique has proven especially beneficial for relational ethnographies, as described by Clerke and Hopwood (Clerke & Hopwood, 2014) and MacLeod and colleagues (MacLeod et al., 2019).

Using ethnographic data collection methods often begs the question of replicability: whether another researcher would gain the same results given an almost identical exposure, that is, whether the same data would be visible (Murchison, 2010; Schultze, 2001). However, the goal of this method is not to produce universally replicable results, but rather to achieve thick descriptions, i.e., a detailed and nuanced understanding of a particular social phenomenon (Jarzabkowski et al., 2022). As qualitative ethnographic data analysis is necessarily abductive (Brinkmann, 2014; Locke, 2011; Murchison, 2010), the judgments of the adequacy of interpretation rest on evidence and warranted inference from extensive knowledge of the phenomenon rather than on claims of general truth (Suchman, 2007). The research also faces a temporal limitation in that collecting research material began around two years after the TAVI project was launched at the research site, so a part of its history is collected through ad hoc accounts.

4. Results

The following are the results of the analysis of the research case. Two main topics were addressed within the concept of context: the existence of a 'fit' between an intervention and its micro or macro context (Chambers et al., 2013; Cowie et al., 2020; Kirk et al., 2015; Lazaretti et al., 2020; Zurynski et al., 2023) and the question of the factor of secure resources or funding (Aarons et al., 2011; Chambers et al., 2013; Damschroder et al., 2009; Grossi et al., 2021; Kirk et al., 2015; McCreight et al., 2019; Shelton et al., 2018; Stirman et al., 2012; Zurynski et al., 2023). These elements are investigated in the case study of TAVI implementation through the lens of the relational perspective. The findings show that the new procedure cannot be said to fit or not fit its context, but instead that it is profoundly defined by its context, with the defining role of technology producers as an example. The factor of secure resources or funding, often considered substantial for an innovation's sustainability, is also rediscovered to be co-created within a relational configuration of multiple stakeholders in mutually

affecting relationships, all holding different meanings of the costs and resources. The discussion translates these findings into a reconceptualization of the idea of context. It shows no real boundary between the inner and outer contexts, as the intervention and its elements are co-created by the relations between it and within its environment.

4.1. Environmental frictions

In 2009, a small group of specialists from Oslo University Hospital interested in developing a TAVI treatment option was formed, including cardiac surgeons, interventional cardiologists, and radiographers. The project's two leaders defined TAVI for this hospital as a research protocol, a clinical study whose form was largely 'copied' from a technology producer's global clinical study called the PARTNER study. Even though they initially approached another TAVI producer, they decided to purchase TAVI technologies from Edwards Lifesciences, the sponsor of the PARTNER TAVI trials, and they were flown to France for training. Upon return, a cohort of patients was chosen, and proctors (coaches) from Edwards came for intermittent visits and guided the first 20 procedures, teaching the steps and pitfalls of the procedure to the entire TAVI team, now including also nurses, anesthesiologists, echocardiographers, and others. The TAVI protocol could thus be described as designed via a corporate actor's protocol (PARTNER trial) into a specific research protocol for the IVC, and the continuous deepening of the relationship between the IVC's TAVI team through training and interaction further defined the shape of the TAVI practice at the locale. This was clearly observed in the operation rooms, not only in the technologies but also in how TAVI was performed, by whom and for which patients were directly shaped by Edwards Lifesciences' proctoring. In this sense, the external context, as in the backdrop of the implementation of TAVI at the locale, profoundly defined what TAVI was at the hospital through relation-making processes between the users, TAVI technologies, and market actors in specific configurations.

Around 2009, there were two leading technology producers of TAVI: Edwards Lifesciences and Medtronic. The selling strategies of the two companies were somewhat different as they competed in this market area. Because Edwards' other products' core market clients were *cardiac surgeons*, they designed the TAVI delivery systems to suit these users' needs (as well as cardiologists'). Medtronic, however, placed their bets that TAVI would become a *cardiological* procedure and made delivery systems of the valves somewhat unsuited for access positions of cardiac surgeons. However, due to safety concerns, both companies insisted that both types of practitioners have to be involved in the new procedures. In 2009, Medtronic even refused to train practitioners who did not arrive in teams, including representatives of both groups. Over time, the practitioners at our research site also slowly divided themselves by the

types of TAVI procedures, each aligning more with the technology (and thus provider) that was better designed for the purpose.

The TAVI procedure is an example of a novel procedure that might be a threat to the work of cardiac surgeons, who are more used to working with their hands on patients (Fosse, 2009). Minimally invasive, image-guided procedures on the heart (such as TAVI) are performed through catheters and via imaging modalities representing patient bodies on TV screens. Minimally invasive procedures such as TAVI have historically become recognized as being under the jurisdiction and, thus, the expertise of interventional *cardiologists*. Cardiac surgeons, however, have historically treated aortic stenosis; therefore, their group had jurisdiction over treating patients with aortic stenosis. If TAVI replaces the surgical treatment of aortic stenosis (SAVR), cardiac surgeons would be denied a part of their regular work. Thus, they competed on who would have jurisdiction over this type of treatment in the future, which has by many informants been referred to as “turf battles”. Indeed, as all informants reported, collaboration within the TAVI team was difficult. Numerous issues were reported, and this technological development’s threat to cardiac surgery was a persistent undercurrent. The groups were in disagreement over whether the procedure and technologies were necessary at all, the task distributions were unclear, practitioners were quarrelling over who is going to hold the catheter, “who sits on the patients, “or “who owns the equipment“. Indeed, over time, the TAVI procedures split into two types of procedures; the central access (cardiac surgery-led) and peripheral access (cardiology-led) types, splitting patients into two groups as well. Both groups, however, had to be present during all TAVI procedures.

While the literature on innovations and innovation management in healthcare recognizes the role of markets and producers in new technology implementation (Mikhailova, 2022), studies of sustainable healthcare innovations sometimes exclude their roles and relations (Chambers et al., 2013; Gusmão Louredo et al., 2024; Lazzaretti et al., 2020; Stirman et al., 2012), especially those who focus on local implementation processes (Cowie et al., 2020; Zurynski et al., 2023). In this case, the empirical data reveals that while practitioners locally aimed to develop a TAVI procedure to treat specific aortic stenosis patients, technology producers (previously considered parts of an external context) co-shaped these possibilities influenced by their dynamic interactions in the market. Their market decisions to cater predominantly to one or another type of TAVI practitioners, while at the same time insisting on both being included in TAVI teams, continuously fed into the local negotiations of control over the new procedures. At the same time, in the operation rooms, the practitioners struggled to cooperate and work together, negotiating the ownership of equipment and the boundaries of their professions. This highlights how the new technologies mediate the results of distant interactions and strategies into local practice, streamlining the local

adoption of new technological practices via their relation-making processes with local users. In the case of TAVI, the result was a diversification of types of TAVI treatments; one better suited for cardiac surgeons and the other for interventional cardiologists, and shaping patient pools.

4.2. Value configurations

As told in an interview with an informant, the TAVI research protocol at the IVC was a “clear-cut losing proposition for the hospital.” While hospital management often considers the short-term costs of a particular treatment, the public and governments might instead consider the long-term costs of not having such a treatment. The TAVI devices are comparably costly. An average price for a TAVI valve and delivery system cost was (and still is) approx. 21,000 EUR, while a standard surgical valve for SAVR, on average, costs about 130 EUR. The other equipment, room, and staff cost approximately 20,000 EUR. As an experimental procedure, the government did not reimburse it, and the costs were shared between the Thoracic Department and the Intervention Centre. However, the results were encouraging; after this minimally invasive procedure, the patients could leave the hospital in less than three days, with very short recovery times and better quality of life. The leadership of the IVC used these results to argue with the hospital management to expand their grounds, staff, and equipment so they could increase the number of procedures. Finally, to quote one of the informants, “the horse was out of the stable”; modern hospitals worldwide were already implementing TAVI in large numbers, and clinical research (funded mainly by technology producers) was showing increasingly good results.

Previous literature indicated that adequate resources from internal and external sources are consistently among the most important facilitators of an innovation’s implementation and sustainable success (Cowie et al., 2020; Lazaretti et al., 2020; Stirman et al., 2012; Zurynski et al., 2023). However, what resources represent in a relational perspective needs to be observed from multiple points of view simultaneously. Hence, the factors of cost-effectiveness and benefits to patients also become difficult to capture and are susceptible to multiple interpretations. It was a losing proposition for the hospital to do TAVI as it was comparably expensive and took resources away from other procedures. The hospital had to choose whether to continue funding TAVI or reorient their funding to other patients and treatments, i.e., the opportunity costs. Yet, if national and regional healthcare authorities allow more patients to be treated with TAVI, the costs of healthcare services will increase. The other price of not having these treatments is direct mortality for a large number of Norwegians slowly becoming aware that there is a procedure that can be done for patients who were previously denied treatment due to associated risks. For the Intervention Centre, TAVI investments were a positive resource upon which they could argue to be allocated more staff

and equipment. Resources are also patients that are available for TAVI, given by the cardiothoracic surgery department, bed vacancies, and other necessary equipment, rooms, and staff, all taken away from the other work areas. Finally, the eagerness to connect to the TAVI movement worldwide was one of the motivations for moving ahead with the costly procedure at the Oslo University Hospital. The cost of not having the procedure would mean, if only symbolically, excluding its cardiothoracic department from the worldwide community of modern university hospitals that will sooner or later offer TAVI. Viewing the factor of resources as relationally configured problematizes the idea that it is possible to indicate the actual cost and resource requirements of a new intervention, micro or macro, as it is subject to multiple interpretations and consists of more than quantitative measurements. Instead, this factor may be seen as a configuration aligning the interests and motivations of various stakeholders to achieve an optimal way forward, in the case of TAVI at the IVC as a pilot study with an open potential for growth.

5. Discussion and conclusions

The study's results problematize two elements of context: the 'fit' or 'compatibility' of the intervention with the practice setting (Chambers et al., 2013; Cowie et al., 2020; Kirk et al., 2015; Lazaretti et al., 2020; Zurynski et al., 2023) and the internal or external elements of resources or funding (Aarons et al., 2011; Chambers et al., 2013; Damschroder et al., 2009; Grossi et al., 2021; Kirk et al., 2015; McCreight et al., 2019; Shelton et al., 2018; Stirman et al., 2012; Zurynski et al., 2023). Firstly, the case shows no real boundary between an innovation or a new medical practice and its context, nor a boundary between an internal and external context. For example, related to the organizational fit of the intervention, it shows that the intervention is *co-created* by its relations within its environment. The users define the TAVI procedure by their specific organizational setting and capabilities. They might make the intervention similar to that already developed and shown promising by an external actor, such as the producer-funded global clinical study. The technology vendors continuously create new and improved TAVI valve and delivery system models responding to user needs. Their decisions on, for example, which types of practitioners should or are expected to do TAVI in the future meant that TAVI technology vendors engineered distinct technological designs necessitating varied team compositions and working methods. Their training also included tips for coordination, team organization, and division of labor during TAVI procedures, all following company protocols. They define the patient criteria and disseminate knowledge and formal and informal rules of the trade. It is their clinical research that the Intervention Centre's TAVI practitioners must follow to stay ahead of the curve and was, in this case, the model for the intervention's

design itself. Rather than simply selling valves and delivery systems, these manufacturers mandated the organization's practice setting rather than making the intervention 'fit' with the setting.

The very relevant and necessary factor of calculable funding or resources is also a part of the innovation's implementation context. The suggested relational perspective proposes to consider the different perspectives of stakeholders, akin to the PRISM (McCreight et al., 2019). However, it calls for their integration as a way forward, visible in the negotiated outcomes. As the different (local and external) actors and stakeholders comprise the TAVI practice, they bring their own interpretations of the benefits and costs of the new procedure to the scene of action. Existing in a relational configuration, they negotiate and agree upon the value of the procedure and the various costs it requires as each have their own values, and are only temporarily agreeing upon its future form. This suggests an entirely different perspective on the factor of funding or resources. Instead of being viewed as a part of the context, the relational configuration, including the various technologies, their immediate users, their clinical communities, hospital managers, departments, national governance bodies, global communities, and market players, co-creates what is called the costs and resources of the procedure.

The relational perspective insists that any phenomenon, object, or activity entirely depends on the network of connections surrounding it (Emirbayer, 1997; Hui et al., 2017), that is, its context, which may also be understood as a relational configuration. The paper invites healthcare managers to expand their focus from assessing the qualities of users, organizations, communities, resources, clinical results, and other factors to consider how their networks sustain and shape the intervention. While emergent at a locale, the new medical procedure is constituted through a dense network of relations across time and space. It is suggested that managers and researchers make "thick" descriptions of the implementation efforts within and beyond the locales. Context assessments could benefit from an alternative to assessing pre-set categorizations of factors to descriptions of situations and narratives about the environment in everyday language that is clear and meaningful to those involved in the daily practice of the intervention. Understanding the relationships within networks of human and non-human elements of a practice configuration and remaining alert and responsive to mutual relationship changes may ultimately determine an innovation's success.

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Kontekst kao relacijska konfiguracija tijekom uvođenja novih tehnologija u zdravstvu

Sažetak

Ovaj članak predlaže nov način promišljanja o konceptu i važnosti konteksta pri uvođenju novih medicinskih postupaka u zdravstvene organizacije. Teorije i modeli implementacije naglašavaju važnost konteksta koji može biti poticajan ili može biti prepreka održivosti zdravstvenih inovacija. No, kontekst uvođenja inovacija u praksu kompleksan je pojam, a dodatno je zahtjevno obuhvatiti složene, dinamične odnose između unutarnjih i vanjskih konteksta organizacija. Ovaj rad uvodi relacijsku perspektivu kao rješenje. Načela te perspektive primijenjena su u longitudinalnoj etnografskoj studiji u Norveškoj, usredotočenoj na uvođenje nove kardiorakalne metode TAVI (Transkateterska ugradnja aortnog zalisaka), minimalno invazivnog postupka za popravak oštećenih aortalnih zalisaka. Istraživanje je pratilo TAVI od eksperimentalne do faze standardizacije u višestrukoj studiji slučajeva. Promatrajući početne faze implementacije iz relacijske perspektive, članak proučava frikcije koje okružuju inovaciju u unutarnjem i vanjskom kontekstu te vrijednosne konfiguracije kako bi ponudio alternativno razumijevanje konteksta i mnogostrukih interakcija koje oblikuju inovacije u zdravstvu.

Ključne riječi: inovacije u zdravstvu, implementacija, međuorganizacijski odnosi, menadžerska praksa, kontekst, etnografija, studija slučajeva