Quality improvement: understanding the adoption and diffusion of digital technologies related to surgical performance

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Quality improvement: understanding the adoption and diffusion of digital technologies related to surgical performance

Digital technologies in surgical operations

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Abstract

Purpose – Quantifying the performance level of surgeons with digital virtual reality (VR) simulators can help ensure that quality requirements in healthcare are met. In order to better understand integration amongst quality principles, practices and technologies in the adoption and diffusion of VR simulators, the authors applied a technological innovation system (TIS) framework. The purpose of this study is to understand how the adoption and diffusion of VR surgical simulators in a Swedish healthcare context is influenced by various system factors.
Design/methodology/approach – In this study, single-case holistic design based on innovation system theory was used to analyse the adoption of digital quality technologies related to surgical performance in Swedish hospitals. The case employs a mixed methods approach triangulating data longitudinally from published documents and expert interviews.
Findings – Adoption of digital technologies regarding surgical performance is restricted by system factors relating to inconsistent normative and regulatory requirements for quantified performance criteria to judge surgical expertise. Addressing these systems' weaknesses with evidence-based training programmes can have a significant impact on the further development of the innovation system and can ultimately affect healthcare reliability and quality.
Originality/value – This paper explores quality management (QM) challenges in the context of digital transformation in healthcare. The paper attempts to fill the gap for TIS studies in a healthcare context and highlight the role of innovation function strength along the value chain and in relation to technology cycles to increase the understanding of adoption of digital technologies relating to surgical performance.

Keywords Digital quality improvement, Technological innovation system (TIS), Simulation-based training, Virtual reality (VR)

Paper type Research paper

1. Introduction

Since reports on medical errors have been highlighted (Kohn *et al.*, 2000), healthcare organisations have become increasingly aware of the need to understand the system factors

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that relate to patient safety and quality. One study showed that 12% of the hospital admissions resulted in adverse events, 70% of which were preventable (Soop *et al.*, 2009). As a result of these findings, efforts to improve patient safety, quality and reliability have spread through healthcare organisations (Wachter, 2004; Leape and Berwick, 2005; Bergman *et al.*, 2015; Smith *et al.*, 2019). However, the overall impact of these efforts is hard to see and recently published data declared medical error as the third-leading cause of death in the USA (Daniel and Makary, 2016). Evidence-based medicine is a well-established approach in healthcare, where treatment guidelines are based on clear scientific evidence. During recent decades, there has been a similar movement towards a systematic approach for how healthcare is delivered in order to continue providing high-quality and reliable healthcare to patients. One theory claims that a focus on the skills of individuals at the "sharp end" (situations where healthcare professionals interact with patients) may lead to better performance and clinical outcomes (Woods *et al.*, 2017). Further, the European Union (EU) Directive 2005/08 on the free movement of healthcare professionals triggered a debate concerning competency levels across member states; to address this issue, many professional medical societies developed harmonised European training curricula.

Surgery plays a crucial part of healthcare, given that 234 million surgical operations are performed annually throughout the world (Weiser *et al.*, 2008), but it is also associated with a high risk for complications. Between 50 and 66% of medical errors in hospitals are attributable to surgery and surgical care (Daniel and Makary, 2016) and almost half of the medical errors are performance related (Leape *et al.*, 1991). In surgery, complex judgements and technical skills are required at a level that is unmatched in most other fields; hence, skills training has a significant role in medical outcomes (Gallagher and O'Sullivan, 2011). The growing number of technically challenging surgical procedures has resulted in the need for training in environments where patients are not put at risk (Atesok *et al.*, 2016). A recent report shows that a high number of patients die every year in Sweden due to medical errors caused by insufficient technical skills (SOU 2015:98). An alternative to the traditional master–apprenticeship training method, where skills are acquired primarily in the operating theatre, is training with digital technologies that enable skills training without posing risk to patients. Simulation-based training with VR technologies can meet these demands and potentially lead to more efficient, reliable and safe healthcare (Felländer-Tsai *et al.*, 2004; Gallagher *et al.*, 2005; Woods *et al.*, 2017). For example, studies on laparoscopic surgery have shown that simulation-based training improved the technical abilities and reduced complication rates (Vanderbilt *et al.*, 2015); vascular surgery trainees undertaking simulation-based training performed better in real-life interventions compared to standard trained surgeons (Chaer *et al.*, 2006). However, despite improvements in surgical performance, simulation-based training with VR technologies is still not being used to its fullest potential within healthcare organisations (Aggarwal, 2017).

Digitalisation is lower in the healthcare sector than in other fields and innovations have not been adopted by healthcare organisations as quickly as technology has advanced (Laurenza *et al.*, 2018; Lennon *et al.*, 2017). Thus, there is a need to better identify and understand the system factors related to the adoption of digital technologies in complex socio-technical healthcare systems (Effken, 2002; Greenhalgh *et al.*, 2004). Judging surgical expertise with digital technologies can potentially enhance quality and reliability of complex healthcare systems.

The innovation system approach may be useful for studying the contextual factors that influence the adoption and diffusion of innovations (Carlsson and Stankiewicz, 1991; Malerba, 2002). Therefore, the present paper applies an innovation system approach to analyse and capture processes related to surgical simulation-based training with VR technologies and to provide knowledge on the digital transformation in the field of healthcare quality. The socio-technical framework of TIS has emerged as a prominent approach with which to understand the dynamic interplay between institutional structures and the various groups of actors that enable the adoption of emerging technology fields (Bergek *et al.*, 2008; Hekkert *et al.*, 2007; Markard and Truffer, 2008). The innovation system approach has been used in many fields, such as off-shore wind power (Wieczorek and Hekkert, 2012) and bio-refinery (Hellsmark *et al.*, 2016), to understand the adoption of innovation and technological transformation processes. In this paper, we argue that it can also be used to understand conditions for the introduction of digital technology innovations related to healthcare quality. Therefore, the purpose of this paper is to study how the adoption of VR surgical simulators in a Swedish context is influenced by surrounding system factors. This study addresses two related research questions as follows: (1) Which structures and key processes influence the adoption of digital VR technology innovations relating to healthcare quality and safety? (2) Can system blocking mechanisms for surgical simulation-based training with VR technologies be identified? By answering these research questions, we intend to contribute to further knowledge on digital transformation in the context of healthcare.

2. Theoretical framework

This article represents an attempt to show how the quality and reliability of surgery can be enhanced through the use of digital innovations in general and VR simulations specifically. Previous research has shown that digital innovations are important for organisational excellence (Carvalho *et al.*, 2019). Moreover, Carvalho *et al.* (2020) noted the potential of using and integrating (QM and quality improvement (QI) into digital transformation processes. The present article applies some key principles of quality and reliability thinking (such as systems thinking, improvement and innovation) to explore how surgery and the innovation system of surgical simulation can be improved as part of the healthcare system.

2.1 Simulation-based medical training with VR technologies

The essence of simulation training is to replace dangerous activities with non-dangerous ones in simulated environments. In surgery where complex judgements and technical skills are required, simulation training means that the difficulties of learning new surgical techniques can be trained in risk-free environments without posing risk to patients.

Since the introduction of simulators for medical skills training in anaesthesiology (Gaba, 1992) and surgery (Satava, 1993), simulators have continued to grow in sophistication, scope and usage and are now considered to have great potential for training everyone from novices to experts in different medical disciplines (Dawe *et al.*, 2014; Gallagher and O'Sullivan, 2011; Harrison and Gosai, 2017; Issenberg *et al.*, 2005; Kneebone, 2003; Motola *et al.*, 2013; Seymour *et al.*, 2002). One recent medical training methodology is the proficiency-based progression (PBP) methodology, where validated performance criteria are used to objectively assess surgical skills of practitioners on VR simulators (Gallagher and O'Sullivan, 2011). For example, a group of surgeons trained with a PBP curriculum made 56% fewer performance errors than the traditionally trained group (Angelo *et al.*, 2015). Similar results were seen for knot-tying skills, where PBP-trained surgical residents improved performance compared with the standard trained group (Pedowitz *et al.*, 2015). Hence, healthcare quality and reliability may be improved with PBP training programmes where surgical skills are objectively assessed with quantified performance criteria integrated in the VR simulators (Angelo *et al.*, 2015).

The rapid development of digital technologies has resulted in various commercially available VR simulators. As described in Table 1, task-trainer simulators can be used for individual technical skills training for particular tasks, such as venepuncture or measuring blood pressure. Procedural skills simulators are used for training of full procedures. Human patient simulators are used for training of entire clinical teams, where a complex suite of non-technical skills is required to bring together individual competencies in the service of a common goal of treating the patient.

2.2 Technological innovation systems (TIS)

TIS incorporate analysis of structures and system functions that influence innovation activities (Bergek *et al.*, 2008; Hekkert *et al.*, 2007; Markard and Truffer, 2008). These functions influence and interact with each other and the strength of each function affects the overall functioning of the innovation system. A suggested TIS analysis scheme starts with an analysis of structural components, followed by identification and assessment of system functions (Bergek *et al.*, 2008). System functions and structures are analytical constructs that reflect important factors identified in prior innovation research. Functions listed in Table 2 include knowledge, resources, actors and various types of institutional structures and synergistic effects that influence innovation. The function knowledge development and diffusion (F1) function relates to the depth and breadth of scientific, technological and market

Table 1.
Examples of commercially available VR simulators for medical skills training

Simulator type	Example of applications
Task-trainer	Individual skills training for particular tasks, such as SimPad blood pressure trainer (Laerdahl AS, Norway) or venepuncture pads (Limbs & Things Ltd, UK)
Procedural	Procedural skills training, such as the VIST endovascular simulator (Mentice AB, Sweden) or LapSim laparoscopic simulator (Surgical Science AB, Sweden)
Human patient	Team skills training, such as emergency care and trauma scenarios with the SimMan simulator (Laerdal AS, Norway) or the HPS (CAE Healthcare Inc., Canada)

Table 2.
Functions of innovation systems and their indicators of strength

System function		Function description	Indicators of function strength
F1	Knowledge development and diffusion	Refers to the breadth and depth of the scientific, technological and market knowledge base	Qualitative assessments of function by managers and others
F2	Legitimation	Relates to the social acceptance and compliance of the technology with relevant normative institutions	Normative institution: how legitimacy influences demands and behaviours
F3	Resource mobilisation	Mobilisation of infrastructure and human and financial resources	Volumes of available capital
F4	Guidance of search	Influence on the direction of development within the innovation system	Cognitive institution: articulation of needs for technological innovations by end-users and the demand-side as well as expectations about growth potential
F5	Entrepreneurial experimentation	Refers to the probing into new technologies and applications	Number of new entrants and actors and different types of applications (supply side)
F6	Market formation	When innovations are widely available on the market	Size and type of markets and customers. Actor's strategy to enhance market access
F7	System-wide synergies	Reinforcing system where all functions are fulfilled and spread positive effects	Economic effects due to cognitive-regulative institutions (demand-side): establishment of standards and formal networks between actors

Source(s): Bergek *et al.* (2008), Hekkert *et al.* (2007), Rickne (2000) knowledge. The function's strength and dynamics can be assessed with various types of indicators; for example, qualitative assessments by managers and others and the number of publications relating to the technology (Bergek *et al.*, 2008; Hekkert *et al.*, 2007). The function, legitimation (F2), relates to the existence of normative institutions in favour of a technology and the social acceptance of the technology. As an example, the time it takes from development of new applications to customer installations may serve as an indicator (Hekkert *et al.*, 2007). Furthermore, the function strength of legitimation (F2) can be assessed with qualitative data on how legitimacy influences other functions and demands, behaviours and legislations (Bergek *et al.*, 2008). In the present study, the function was assessed based on the availability of a curriculum including surgical simulation-based training from national professional medical societies. Resource mobilisation (F3) concerns the extent to which actors on the demand and the supply side are able to mobilise infrastructure, financial capital and human resources (Bergek *et al.*, 2008). Function strength may be assessed by changes in volumes of physical, human and financial resources relating to the innovation system (Bergek *et al.*, 2008). Guidance of search (F4) is primarily a cognitive institution that guides innovators, both in general by incentives for actors to engage in the innovation system and the expectations of growth potential by key stakeholders. However, it also includes more detailed information about end-users' needs relating to the technology and thus constitutes an important demand-side factor of an innovation system. Function strength can be assessed with qualitative analysis of end-users' articulation of their needs relating to the technology innovation (Bergek *et al.*, 2008). Hence, the authors assessed the function strength based on published data concerning the potential use and value of VR technologies for surgical training. Entrepreneurial experimentation (F5) refers to the probing into new technologies and applications, and in the present study, it constitutes an important supply-side factor of the innovation system. Function strength can be assessed with the number of applications, new entrants and actors (Bergek *et al.*, 2008). Market formation (F6) relates to when supply meets customer demand and when innovations are made widely available on markets. Function strength can be assessed by analysing the factors that drive market development, such as the existence of public tenders and reimbursement for the technology and the stage of market maturity (Rickne, 2000). A mutually reinforcing and synergistic system can function and spread positive effects within the innovation system and to other regions and sectors when all functions are fulfilled (Bergek *et al.*, 2008). This process is sometimes referred to as positive externalities or system-wide synergies (F7) (Bergek *et al.*, 2008; Larisch *et al.*, 2016) and can be assessed with the adoption of international standards that enhance technology acceptance and interoperability within its use context (Bergek *et al.*, 2008; Hekkert *et al.*, 2007). System-wide synergies capture effects as well as collective cognitive and regulative institutional conditions that, in turn, create synergies. For simulation-based training, this could, for example, be related to broadly accepted regulations concerning accreditation of medical specialities formulated by national and international authorities.

3. Material and methods

The nature of the research problem requires an in-depth exploration of experts' views to understand the processes of surgical performance relating to simulation-based training with VR technologies. A case study is a suitable research technique in this context, as this approach is used to explore and understand a phenomenon within its context (Eisenhardt, 1989). The present study applies an innovation system approach to analyse surgical simulation-based training with VR technologies in a healthcare context. There is no consensus regarding preferred data collection methods for innovation systems studies (Jacobsson and Bergek, 2011), and we have applied a mixed methods approach that triangulates quantitative and qualitative data over time to provide an in-depth understanding of the research topic (Creswell and Clark, 2017).

3.1 Research setting

The study was conducted in Sweden based on the researchers' access to data and because Sweden achieved the number-three ranking on the Global Innovation Index 2018 rankings (Dutta *et al.*, 2018). Bergek *et al.* (2015) recommended putting TIS in a broader context when the dynamics of a given innovation system are intertwined with the structure and dynamics of the sector of which it is a part. Therefore, due to the intertwined institutional structures between Sweden and the European Union concerning law-making in general and medical training and education specifically, the authors decided to include European professional medical societies and unions of medical specialists in this analysis (EAHC, 2013; Wahlstedt, 2019). Furthermore, medical device companies play an active role in providing professional education and training to clinicians through established training institutions throughout Europe; therefore, medical device companies were included in the analysis.

The structural components of the innovation system in this study refer to actors, networks and institutions related to surgical simulation-based training with VR technologies in a healthcare context. Hence, the study analyses medical speciality training related to surgical procedures, which means that other medical specialities, such as interventional cardiology and interventional radiology, that perform surgical interventions are included. However, simulation-based training related to basic medical training is not included in this study.

3.2 Data collection

Qualitative expert interviews were conducted in two steps to (1) explore experiences of experts and (2) to validate findings and collect empirical evidence from clinical skills centre managers. In addition to expert interviews, secondary data were collected from official and publicly available sources. The interview protocol used for both experts and clinical skills training experts can be found in Appendix 1.

3.2.1 Step 1 – expert interviews. Expert interviews were conducted to gather more information on structural components and perceived weaknesses and strengths over time. An expert was defined as an individual who had technical, process-oriented or interpretive knowledge of surgical simulation-based training gained from simulator development, business development, clinical and technical skills training, curriculum development or accreditation. The initial selection of experts was based on the authors' established network in the field; to avoid biased data collection, eight of the experts were selected based on the snowballing technique, whereby initially sampled experts referred to other participants who had characteristics of interest (Flick, 2014). An interview guide based on the theoretical framework and the researchers' previous knowledge in the field was developed with open-ended questions to avoid priming answers and to allow for further exploration of the phenomena through the natural language used by experts (Flick, 2014). As described in Table 3, 24 expert interviews, 16 face-to-face interviews and 8 phone interviews were conducted in 2017 and 2018. Each interview lasted approximately 30–60 min.

3.2.2 Step 2 – interviews with clinical skills training experts. To gather information on specific functions related to clinical skills training and to validate findings from Step 1, phone interviews with clinical skills training experts at Swedish university centres were conducted. All seven clinical skills centres were contacted. Experts were selected based on availability during the time of data collection; two clinical skills centres were not available and were therefore excluded from the study. Each expert interview lasted 20–30 min. Secondary data, including infrastructure, training courses and staff, were collected on public websites published by each clinical skills centre.

3.2.3 Definition of qualitative and quantitative assessment criteria. Qualitative data from primary sources were triangulated with secondary quantitative data and used as assessment criteria for functional strength. For example, and as descried in Table 4, knowledge

Type of organisation	Simulator development	Field of expertise Business development	Clinical/technical skills training	Curriculum and accreditation
Professional medical societies	–	–	a (1), b (2)	a (1), b (1)
University hospital clinics	–	–	c (2), d (2), e (1)	c (1), d (1)
Regulatory authorities	–	–	–	f (1), g (1)
VR companies	h (1), i (1)	h (1), i (1), j (1)	j (1)	–
Medical device companies	–	k (1), l (1)	k (1), l (1)	–

Note(s): The number in parentheses indicates the number of experts in the specific organisation

Table 3. Categorisation of experts from Organisations a, b, c, d, e, f, g, h, i, j, k and l

development and diffusion (F1) was qualitatively assessed by expert opinions and quantitatively assessed with bibliometric analysis of the number of publications in scientific journals using the keywords as follows: ("medical education" OR "medical training" OR "surgical education" OR "surgical training" OR "medical skills" OR "surgical skills") AND (surgery OR laparoscope* OR endoscope* OR cardio* OR vascular OR endovascular) AND (VR OR virtual reality OR simulation* OR "medical simulation" OR simulator OR "medical simulator" OR "VR simulator" OR "VR simulation"). Further, the legitimation function (F2) was assessed by analysing the social acceptance for the technology in articles published by professional medical societies and Swedish daily newspapers.

3.3 Data analysis

Qualitative data were transcribed and coded according to themes that corresponded to the research questions. Interviews were analysed with an abductive reasoning approach, where field notes and transcripts were revisited, resulting in renewed rounds of coding in light of emerging theoretical insights (Timmermans and Tavory, 2012). The two authors of the present paper had personal experience (seven and three years, respectively) with the innovation system and they analysed and reflected upon the findings in this study.

4. Results and analysis

RQ1. Which structures and key processes influence the adoption of digital VR technology innovations relating to healthcare quality and safety? – is highlighted in Sections 4.1 and 4.2.

RQ2. Can system blocking mechanisms for surgical simulation-based training with VR technologies be identified? – is answered in Sections 4.3 and 4.4.

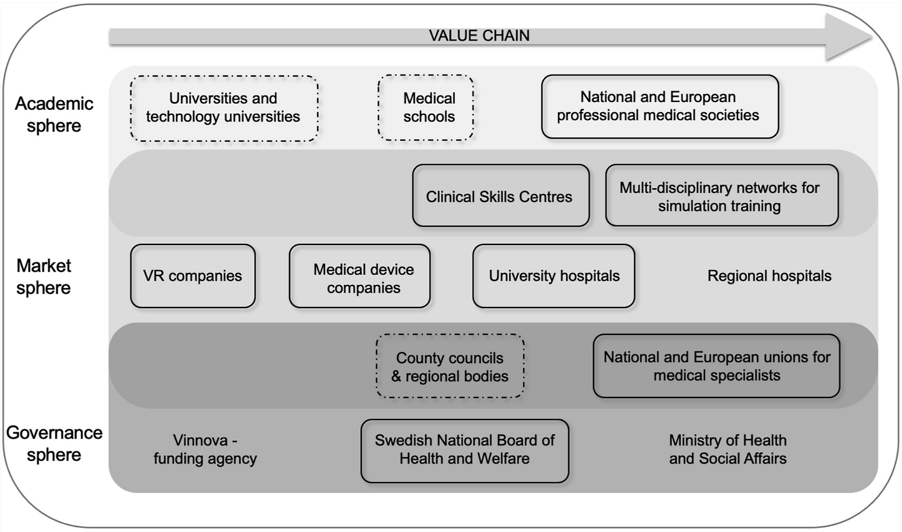
4.1 Actors, networks and institutions

The structural components were analysed according to a sectoral innovation system map, including key actors classified into academic, market and governance spheres along the value chain, as illustrated in Figure 1. The market sphere included VR companies, medical device companies and hospitals. Swedish VR companies include Mentice AB, Orzone AB, Sensegraphics AB and Surgical Science AB. Examples of medical device companies

System function		Assessment criteria for function strength
F1	Knowledge development and diffusion	Market and technological knowledge (supply side) were assessed by expert opinions of the technological level and market position for the Swedish VR companies Scientific knowledge was assessed with bibliometric analysis of the temporal development of the number of publications in scientific journals and in comparison with other European nations
F2	Legitimation	Requirements for surgical simulation training (demand side). No requirements by any professional medical society reflected function weakness, whilst requirements by all societies indicated function strength Social acceptance for the technology was assessed with qualitative expert opinions and bibliometric analysis of the temporal development of the number of articles in daily Swedish newspapers
F3	Resource mobilisation	Training capabilities and infrastructure were assessed by the numbers of clinical skills centres at university hospitals (demand side). Function weakness was indicated if no centres were established, and function strength was indicated by the establishment of centres at all university hospitals Training capacities were assessed with available staff and budgets for surgical training in clinical skills centres at university hospitals (demand side). Function weakness indicated by lack of targeted staff and budgets for surgical simulation training. Function strength was indicated by targeted budgets and staff at all centres
F4	Guidance of search	Qualitative assessment for simulation training expressed and demonstrated by clinical experts (demand side) Quantitative assessment of the temporal development of the number of editorials published in scientific journals (demand side)
F5	Entrepreneurial experimentation	Quantitative assessment of the number of Swedish VR companies in relation to European VR companies (supply side) Qualitative assessment of the temporal development of variety of training modules provided by the supply side Swedish VR companies
F6	Market formation	Quantitative assessment of the temporal development of annual revenues to reflect the number of installations and type of simulators. Function weakness is indicated by no installations; function strength is indicated by installations for all surgical specialities at all university hospitals and an exponential growth of annual revenues The temporal development of the number of procurements was analysed to assess the ratio of simulators acquired through public tenders in comparison to simulators acquired for research purposes. Function weakness is indicated by a majority of installations related to research
F7	System-wide synergies	Regulatory requirement for simulation-based training for accreditation purposes (demand side). Function weakness indicated by no regulatory requirement. Function strength indicated by regulatory requirements for all surgical specialists Accreditation of clinical skills centres based on widely agreed standards in regard to simulation training. Function strength indicated by accreditation of clinical skills centres at all university hospitals

Table 4.
Assessment criteria used in this study to assess function strengths based on indicators related to surgical simulation training in a Swedish context

include Boston Scientific, Johnson & Johnson and Medtronic. There are 7 university hospitals and 70 regional hospitals in Sweden and 50 clinical skills centres in total (www.klinsim.se). The academic sphere included universities and professional medical societies, such as the Swedish Surgical Society (http://www.svenskkirurgi.se) and the Swedish Society of Cardiology (https://www.sls.se/SVKF/). The national societies are associated with



Note(s): Boxes indicate study participants and dotted boxes indicate actors who were addressed, but not selected for interviews
Source(s): Larisch *et al.*, 2016

Figure 1. Selection of key actors, networks and institutions related to surgical simulation training

equivalent European societies, such as the European Surgical Association and the European Society of Cardiology (www.escardio.org). The regulatory sphere included governmental funding agencies, such as Vinnova and the Swedish National Board of Health and Welfare issuing accreditations to medical doctors. The medical profession was organised in unions (www.slf.se), which are associated with the European Union for Medical Specialists (www.uems.net). Multi-disciplinary networks, such as the Society for Simulation in Europe and the Network of Accredited Clinical Skills Centres of Europe (www.nascenet.org), provided accreditation services for clinical skills centres.

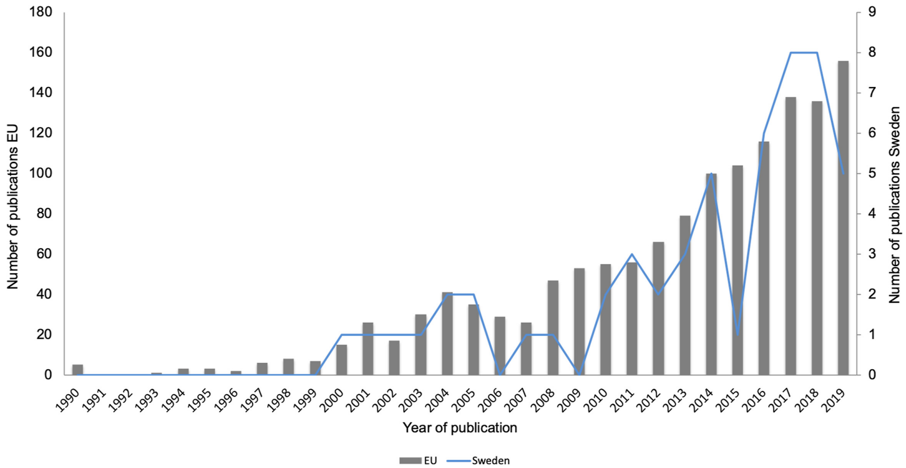
4.2 Functional assessment

The system functions are described in this section. Function weaknesses, marked with *(W)*, and function strengths, marked with *(S)*, indicate function strength as described in the assessment criteria in the methods and materials section.

4.2.1 Knowledge development and diffusion (F1). Market and technological knowledge were assessed by expert opinions. Three-quarters of the VR companies have grown steadily since their establishment in the 1990s (www.allabolag.se). According to experts in this study, *many Swedish VR companies were market leaders and internationally recognised by experts for their technology innovations (S1)*. In addition, many high-profile experts were engaged in the application development, which indicated trust and commitment for the VR companies' technologies.

> Compared to other medical simulators, the Swedish VR simulator may not look like a Ferrari on the outside, but it is definitely a Ferrari on the inside. Senior simulation expert, Organisation c.

Bibliometric analysis of the temporal development of the number of publications in scientific journals was performed in order to assess the level of scientific knowledge for the demand side. As illustrated in Figure 2, *the number of publications in scientific journals related to*



Source(s): Web of Science (2019)

Figure 2.
The number of publications in scientific journals related to surgical simulation-based training with VR technologies in a European and a Swedish context

surgical simulation-based training has increased exponentially (S2). The increasing trend pattern is similar for research related to Sweden and Europe, indicating a dynamic temporal function development on the demand side. Although the absolute number of publications (53) for Sweden is low, it is twice what would have been expected in relation to Europe and for a country of its size (10 million inhabitants). By comparison, the main providers of scientific publications in Europe were Denmark, Ireland and the United Kingdom, which published approximately six, four and three times more than what would have been expected for countries of their size.

4.2.2 Legitimation (F2). Requirements for simulation training by national and European professional medical societies were used to assess function strength. Societies set training requirements through a national curriculum with learning objectives and competency levels. The national curriculum may be based on a European curriculum, such as the curriculum by the European Society of Cardiology (Gillebert *et al.*, 2013). Except for a few national curricula, a majority of the curricula across most surgical specialities recommended, however in many cases not required, simulation-based training (www.svenskkirurgi.se). Hence, there were *inconsistent normative requirements for simulation-based training stipulated by professional medical societies (W1).*

> As a society, we cannot formally recommend simulation-based training as most hospitals do not have the resources nor capacities to run training courses. Board member, professional medical society, Organisation a.

Social acceptance for the technology was assessed with bibliometric analysis of the temporal development of number of articles in daily Swedish newspapers. As illustrated in Figure 3, the number of articles increased in two separate innovation cycles, indicating a dynamic temporal function development on the demand side. The first phase was primarily related to hype around the VR company, Prosolvia AB, whose VR technologies continued to thrive in new VR companies after its bankruptcy in the late 1990s. The second *increase of publications in Swedish daily newspapers was primarily related to the establishment of regional clinical skills centres (S3).* The increase may have been triggered by strong recommendations by well-established surgeons and clinicians to establish regional clinical skills centres to fulfil the needs for medical trainees to get acquainted with new devices, techniques or procedures (Ihse *et al.*, 2006).

4.2.3 Resource mobilisation (F3). The function was assessed by analysing training capacities, including availability of staff and budgets. Interviews revealed that utilisation often depended on local requirements and engagement by senior experts. In some centres, such as Karolinska University Hospital, all surgical trainees went through simulation training programmes, whereas in other centres training was provided on a case-by-case basis. Clinical skills centre staff often resided within the fields of pedagogy, nursing or anaesthesiology, although *surgical training required educators with surgical skills on expert levels and the availability of such resources was scarce in most centres (W2)*. Consequently, experienced surgeons had to be withdrawn from daily clinical practice, which was considered challenging due to the pressure from hospital management to increase clinical output. Staffing is often the largest portion of a budget, comprising around 70% of operating costs; hence, increased access to pre-defined training programmes would release human and financial resources (Palaganas *et al.*, 2015). Approximately, one-quarter (26%) of all clinical skills centres receive budgets from universities, nearly half (45%) from healthcare providers, and one-third (29%) from both universities and healthcare providers (Masiello and Mattsson, 2015). In comparison, clinical skills centres in Europe and North America are often centrally organised and receive financial resources from authorities (Masiello and Mattsson, 2015). In the present study, *few clinical skills centres had budgets targeted for postgraduate training and continued professional development for surgical specialities (W3).*

> It is challenging to take senior surgeons from the operating room to train novice surgeons. We do not have the budgets. Head of clinical skills centre.

Further, interviews revealed that *all Swedish university clinics had established clinical skills centres (S4)*. However, the number and type of simulators varied, and although all centres were equipped with basic skills and team training simulators, the installations for surgical simulators varied; for example, one centre only had one task trainer, whereas another centre had various simulators to provide comprehensive surgical training.

4.2.4 Guidance of search (F4). User needs were assessed by qualitative interviews, where the technology potential was demonstrated as a guide for further innovation. *Many experts embraced VR technologies and were actively involved in influencing the direction of development (S5)*, such as developing and validating performance criteria. Various actors organised unique events demonstrating the potential for VR technologies to solve critical problems. For example, medical congresses such as the Cardiovascular Interventional Radiology Society of

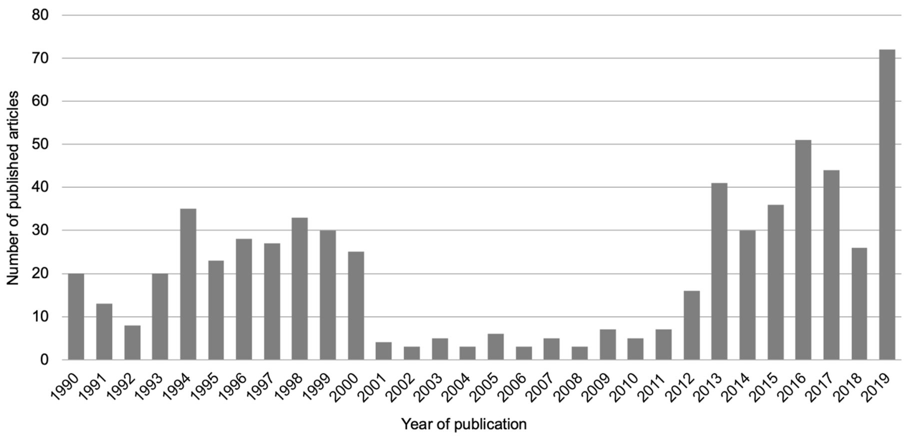


Figure 3. The number of published articles in Swedish daily newspapers during 1990–2019 related to surgical simulation training (www.tidningar.kb.se)

Europe (CIRSE) provided workshops at which delegates received hands-on technical experiences on VR simulators (www.cirse.org).

> Performing the procedure in advance on a simulator helped me to choose the optimal catheters. Senior surgeon, Organisation e.

The number of editorials published in scientific journals was analysed in order to assess the demand side, and as illustrated in Figure 4, the *number of editorials related to surgical simulation training have grown steadily during the last decade (S6)*. Although the number of editorials was relatively small, a temporal development of the function strength was seen. European experts expressed the need to provide training without jeopardising patient safety, where training with digital technologies such as VR simulations could be utilised (Ahmed *et al.*, 2010; Gould and Reekers, 2008). Many experts articulated the need for further work on design, fidelity, reliability and validity of simulators to ensure accurate transfer of skills from simulator to patient (Ahmed *et al.*, 2010; Gould *et al.*, 2007). Many experts expressed a need for evidence-based training programmes in order to improve patient safety and reduce medical errors (Felländer-Tsai *et al.*, 2010; Jensen *et al.*, 2014). One approach to address this issue is the PBP method, where surgical skills are trained and objectively assessed with quantified performance criteria integrated in the VR simulators (Ahlberg *et al.*, 2007; Gallagher and O'Sullivan, 2011; Stefanidis *et al.*, 2010). Furthermore, many clinical skills experts emphasised that compliance with technology would increase if practical instructions for how to integrate simulation-based training into daily practice were developed. The need for such guidelines was also addressed in the literature (Nayahangan *et al.*, 2019); to overcome this, the PBP training method was perceived suitable as a next-generation training method (Atesok *et al.*, 2016; Hedman and Felländer-Tsai, 2020; Khamis *et al.*, 2016).

4.2.5 Entrepreneurial experimentation (F5). Entrepreneurial experimentation was assessed (supply side) by analysing the number of Swedish VR companies in relation to European VR companies. Nearly, half of the VR companies in Europe relating to surgical simulation-based training are Swedish (Levine *et al.*, 2013), indicating that *Sweden is well established in surgical simulation-based training* (S7).

> Sweden has great potential to develop the eco-system for simulation-based training. We are the world leader in VR technologies used for surgical applications. Senior developer, Organisation i.

Assessment of the variety of training modules (supply-side) showed *continuous temporal development of new and enhanced applications for surgery related procedures (S8)*. For example, endovascular techniques and procedures can be trained on the vascular intervention simulator (VIST, Mentice AB), such as cardiac rhythm management, percutaneous coronary interventions and acute ischaemic stroke. Laparoscopic techniques

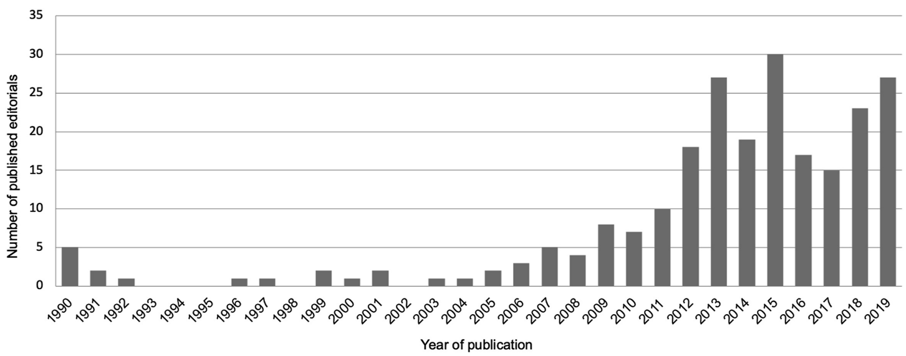


Figure 4.
The number of published editorials addressing simulation training in scientific journals during 1990–2019 related to European researchers (Web of Science)

can be trained with the minimally invasive surgical trainer (MIST, Mentice AB), which is considered the most validated VR simulator and is now available as LapSim provided by another Swedish VR company (Surgical Science AB). Flexible endoscopy procedures can be practiced in scenarios whilst experiencing complications (EndoSim, Surgical Science AB). Sensegraphics AB has developed various simulators, such as a model that allows surgeons to train on the real console for robotic-assisted surgery (da Vinci skills simulator). Finally, Orzone AB provides digital tools for medical speciality examinations (Ortrac) and a simulator environment or multi-disciplinary team training (Orcamp).

> The number of applications has increased steadily. However, integration in daily practice takes a long time." Business developer, Organisation j.

4.2.6 Market formation (F6). The temporal development of annual revenues for VR simulator companies were used to reflect the number of installations in order to assess market formation on the supply side (www.allabolag.se). As described in Figure 5, *the annual revenues for the VR companies have grown steadily (S9)*, experiencing a steeper growth since 2017. The accumulated number of installations for one of the companies doubled during the last five years; the exact number of installations in Sweden was not disclosed by the company. On the demand side, expert interviews revealed a low number of surgical skills training activities as also confirmed in the literature; one-third of the clinical skills centres provided surgical skills training (Masiello and Mattsson, 2015).

> It is up to each department to offer training for their staff. Today, it is mainly Emergency and Intensive Care that provide training in our centres. Head of clinical skills centre.

Market formation on the demand side was further analysed by the temporal development of the number of simulators acquired through public tenders in comparison to simulators acquired for research purposes. The only publicly available data source for public procurement in Sweden is *Tenders Electronic Daily*, which reports large value tenders regulated by the EU's Public Procurement Directives. Given that the main interest in this study has potentially lower contract values, we also collected data from a private data provider (Mercell). In total, there were 14 unique tenders in the database during 1999–2019; approximately, two-thirds belonged to university hospitals and one-third to regional hospitals as illustrated in Figure 6. *A majority of the simulators purchased through public tenders were acquired for research purposes (W4).*

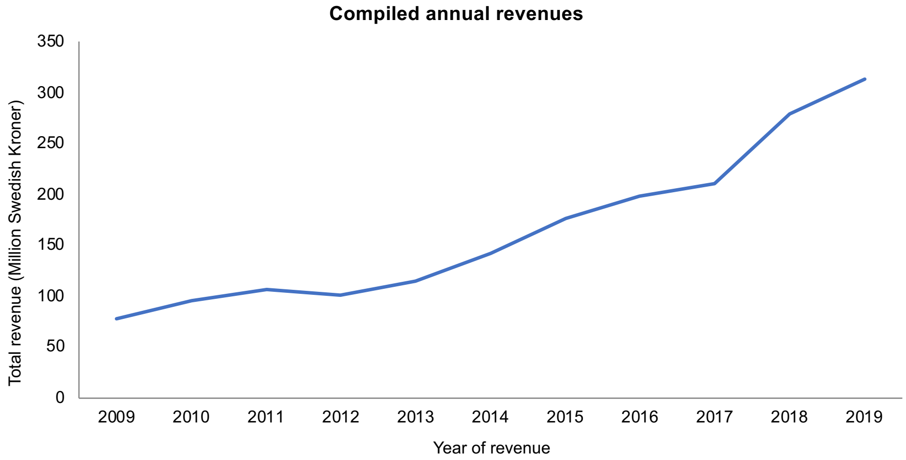


Figure 5. Compiled annual revenues (Million Swedish Kroner) for VR companies during 2009–2019 (www.allabolag.se)

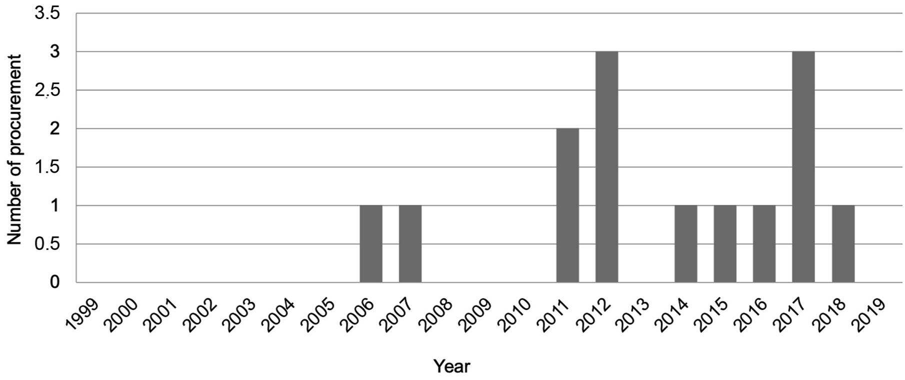


Figure 6.
The number of procurement for surgical VR simulators during 1999–2019

4.2.7 System-wide synergies (F7). Regulatory requirements for simulation-based training for accreditation purposes were used to assess function strength. Each trainee keeps a logbook, which is used as the basis for accreditation by the authority Swedish National Board of Health and Welfare (Socialstyrelsen). Although the authorities concluded that simulation-based training was as good as, but also safer than, the master–apprenticeship training method (Masiello and Mattsson, 2015; SBU, 2016_03, 2016), there were *no regulatory requirements for surgical simulation-based training for accreditation purposes (W5)* (SOSFS, 2015:8). On a European level, the European Union of Medical Specialists (UEMS) declared that the traditional master–apprenticeship training method was the key training method and that VR simulators could play an important role of gaining competence in practical procedures when technology had advanced further (UEMS, 2013). Further, expert interviews revealed that the national authority stipulated the regulatory requirements based on the training requirements stipulated by professional medical societies.

> We have approximately 60 specialty groups in Sweden and it is up to each society to decide whether to integrate simulation-based training in their curriculum. There are no general requirements from authorities. Manager at national authority, Organisation e.

Accreditation of clinical skills centres based on widely agreed standards regarding simulation training was used to further assess the function strength on the demand side. Although there were no requirements for accreditation of clinical skills centres by Swedish regulatory authorities, approximately one-third of the clinical skills centres were accredited by international non-governmental organisations, such as the case of Lund University Hospital which is accredited by the European organisation Network of Accredited Skills Centres in Europe (NASCE) and the American College of Surgeons (https://vardgivare.skane.se/kompetens-utveckling/practicum/).

4.2.8 Summary of functional assessments. A summary of the functional assessments, including identified system weaknesses and strengths, is described in Table 5. The authors used the number of weaknesses and strengths as an indication of function strength. In the event that a function experienced system weakness only, it was deemed weak. A strong function was indicated by system strengths only, whereas a function with system weaknesses and strengths was deemed intermediate.

Based on the analysis, the knowledge development and diffusion (F1), guidance of search (F4) and entrepreneurial experimentation (F5) functions were assessed as strong functions. Three functions were of intermediate strength and system-wide synergies were deemed weak.

4.3 Functional pattern

Our analysis shows that knowledge development and diffusion (F1), guidance of search (F4) and entrepreneurial experimentation (F5) were strong, which may indicate functional interdependencies. Further, the analysis shows that university hospitals follow requirements from the national authorities, who based the regulatory requirements from training curricula stipulated by professional medical societies. Hence, if societies did not include simulation-based training in training curricula, regulatory requirements were not put forward by the accrediting authorities. Further, the willingness of university hospitals to invest in the innovation system was influenced. Authorities were generally supportive of simulation training and claimed to be willing to include simulation training as part of the accreditation process, if it was required and legitimised by the national professional medical societies. Further, developing evidence-based practice guidelines would increase legitimacy and create a need for regulatory requirements and standards amongst users (demand side) and producers of surgical simulators (supplier side). Hence, lack of or insufficient legitimation (F2) has a negative influence on system-wide synergies (F7) as illustrated in Figure 7. Further, regulatory standards would require increasing financial resources for surgical simulation training at university hospitals; hence, we conclude that insufficient system-wide synergies (F7) has a direct negative influence on resource mobilisation (F3) and market formation (F6).

Furthermore, the analysis shows that the willingness of professional medical societies to integrate VR in training curricula was restricted by the low availability of evidence-based training programmes.

4.4 System blocking mechanisms

The innovation system analysis shows that surgical simulation-based training is primarily restricted by the system blocking mechanisms, or function weaknesses, for legitimation (S2) and system-wide synergies (F7). As described in Figure 8, the weakness, the *inconsistent normative requirements for simulation-based training stipulated by professional medical societies (W1)*, has a direct influence on legitimation (F2), which affects system-wide synergies (F7). Further, the identified system weakness *no regulatory requirement for surgical simulation-based training for accreditation purposes (W5)* has a direct effect on system-wide synergies (F7) and indirectly affects legitimation (F2).

To summarise, our analysis shows that some blocking mechanisms are more important to address than others, due to their functional pattern as well as direct and indirect effects on other functions. Consequently, we conclude that addressing the demand-side function weaknesses of legitimation (F2) and system-wide synergies (F7) can have a significant impact on the further adoption and diffusion of VR simulation in healthcare systems.

5. Discussion and conclusions

The purpose of this paper was to study how adoption and diffusion of VR simulators relating to surgical performance in a Swedish healthcare context is influenced by various system factors of the surrounding innovation system, applying a TIS framework. The data analysis shows that the innovation system is primarily restricted by the system factors inconsistent normative and regulatory requirements regarding quantified performance criteria for judgement of surgical expertise. Further, the analysis identified a need for further development of such evidence-based training programmes for more surgical procedures. For the purposes of comparison, in the aviation industry there is more regulation, and standards for training curricula and VR flight simulators are legally binding (such as the Commission Regulation EU No, 1178). Further, it can be expected that the establishment of standards for the VR simulators themselves can enhance subsequent technology acceptance.

Assessment	System function		Identified strengths	Identified weaknesses
Strong	F1	Knowledge development and diffusion	Many Swedish VR companies were market leaders and internationally recognised by experts for their technology innovations (S1) The number of publications in scientific journals related to surgical simulation-based training has increased exponentially (S2)	
	F4	Guidance of search	Many experts embraced VR technologies and were actively involved in influencing the direction of development (S5) Numbers of editorials related to surgical simulation training have grown steadily during the last decade (S6)	
	F5	Entrepreneurial experimentation	Sweden is well established in surgical simulation-based training (S7) Continuous temporal development of new and enhanced applications for surgery-related procedures (S8)	
Intermediate	F2	Legitimation	Increase of publications in Swedish daily newspapers was primarily related to the establishment of regional clinical skills centres (S3)	Inconsistent requirements for simulation-based training stipulated by professional medical societies (W1)
	F3	Resource mobilisation	All Swedish university clinics had established clinical skills centres (S4)	Surgical training required educators with surgical skills on expert levels and the availability of such resources was scarce in most centres (W2) Few clinical skills centres had budgets targeted for postgraduate training and continued professional development for surgical specialities (W3)
	F6	Market formation	The total number of VR simulator installations has grown steadily (S9)	A majority of the simulators purchased through public tenders were acquired for research purposes (W4)
Weak	F7	System-wide synergies		No regulatory requirement for surgical simulation-based training for accreditation purposes (W5)

Table 5.
Assessment of functions based on identified strengths and weaknesses for simulation-based training with VR technologies in a healthcare context

In order to increase the adoption of digital quality technologies relating to surgical performance, the establishment of quantified performance criteria to judge surgical expertise is most likely critical. This study is an attempt to describe how the ongoing digital

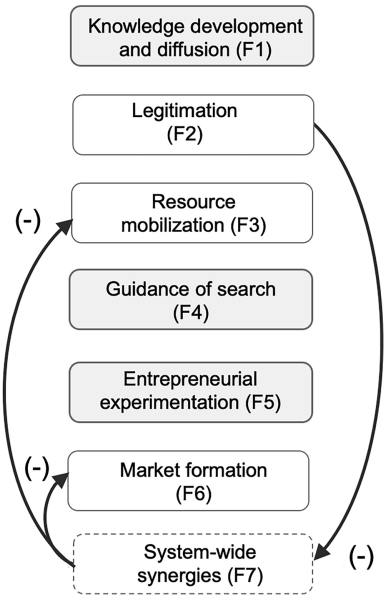


Figure 7.
Interaction between system functions for simulation-based training with VR technologies in a healthcare context

transformation (Carvalho *et al.*, 2019) can be studied using QM and system innovation principles.

5.1 Theoretical contributions

The results of this study contribute to the development and understanding of functional dynamics of the innovation system approach in healthcare (Larisch *et al.*, 2016). In other analyses of innovation systems, knowledge development and diffusion (F1), legitimation (F2) and resource mobilisation (F3) have been shown to be related and provide initial conditions for guidance of search (F4) and entrepreneurial experimentation (F5) (Hekkert and Negro, 2009; Larisch *et al.*, 2016). However, our analysis shows that the functional pattern of an innovation system may change over time. For example, legitimation (F2) initially played a key role in drawing resources into simulation but did not fulfil the same role in supporting further technology cycles to support the development of regulatory requirements for surgical simulation-based training for accreditation purposes (system-wide synergies, F7). Similarly, guidance of search (F4) seems to have played an important role in guiding the initial development of the supply side (entrepreneurial experimentation, F5) and has since remained strong. Based on this insight that TIS undergo innovation cycles, we can see that a transformation into a new stage requires interactions across the supply and demand side. In our case, the supply side is strong; but due to demand side deficiencies, the next cycle to further develop the TIS has not materialised. Based on this case study, we think there is a need in the field of TIS research to further explore the importance of where system function strengths and weaknesses are located along the value chain from supply to demand side to initiate user–producer interaction (Lundvall, 2016) and how the strength of the functions varies over time. It is our hope that these findings can guide other researchers on how to study digital transformation and dynamics of TIS over time.

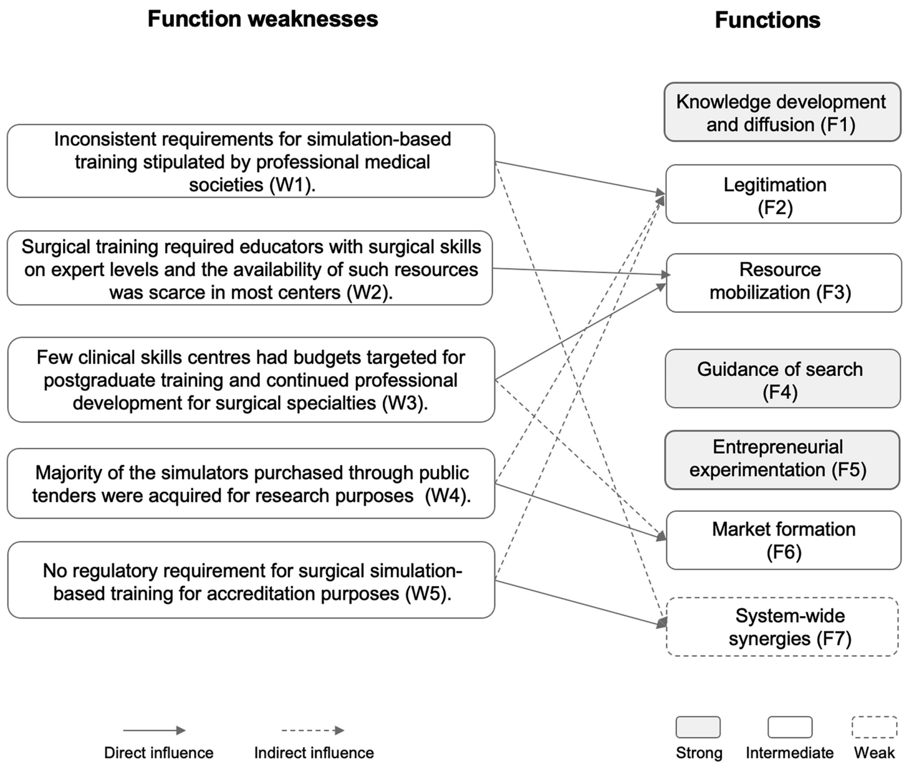


Figure 8.
Function weaknesses, or system blocking mechanisms, for simulation-based training with VR technologies

5.2 Research limitations

The researchers acknowledge the limitations of analysing and drawing conclusions based on a case study. This case study is based on triangulation of data from published documents, qualitative interviews with 24 experts and phone interviews with five clinical skills centre representatives, and thus, it may not be indicative outside the primary Swedish setting. Therefore, the findings of this study should be viewed within the study's limitations, and generalisations based on these findings should be considered with caution.

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Appendix 1. Interview guide for experts

My name is [...] and I understand that you are an expert/authority on (any of the following):

(1) Medical/professional education and training;

(2) Technical/clinical skills training;

(3) Certification/accreditation of medical doctors/specialities;

(4) Simulator development with VR technologies and

(5) Business development.

Your expertise is of great interest for me and thank you for taking the time to share your experiences. The purpose is to increase knowledge and understanding of the structures and processes relating to simulation-based training with VR technologies.

(1) Could you please share a bit about your background and experiences where you have worked in this field?

(2) What is your general view about medical/surgical skills training with VR technologies? Are there any specific challenges?

(3) Who are the main players/organizations/institutions/companies? Why are they important? Role and how do they interact?

(4) Can you please describe how training/certification/accreditation is organized/managed where you work?

(5) Which VR technologies are you familiar with? Greatest value? Strengths and weaknesses?

(6) What do you consider the major hurdles and obstacles for the use of medical/surgical skills training with VR technologies? Are there any specific technology/regulatory/people aspects?

(7) Is there anything else you would like to share with me, anything I did not ask that I should have?

Thank you very much for your valuable input. Finally, are there any other experts that you would recommend me to speak with?

Appendix 2. Interview guide for clinical skills training experts

My name is [...] and I understand that you are a manager at the clinical skills centre at your university hospital. Your expertise is of great interest for me and thank you for taking the time to share your experiences. The purpose is to increase knowledge and understanding of the structures and processes relating to simulation-based training with VR technologies.

(1) What are the main training courses in your clinical skills centre?

(2) Can you please describe how your training courses are organized/managed?

(3) What is your general view about medical/surgical skills training with VR technologies?

(4) How do you develop curriculum and practical guidelines for the training courses? Support/guidance/recommendations from professional societies? Which?

(5) Do you have a targeted budget for purchasing new training equipment? For daily operations? From the university/hospital/other?

(6) Do you have a targeted budget for running/managing courses related to continued professional training and education? Any particular medical speciality?

(7) How many full- or part-time employees do you have? Specific staff for surgical training in particular? Affiliated researchers?

(8) Is your clinical skills centre accredited? If so, by which organization/authority?

Thank you very much for your valuable input.

About the authors

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