Understanding healthcare innovation systems: the Stockholm region case

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Abstract

Purpose – There is an increasing interest in understanding how innovation processes can address current challenges in healthcare. The purpose of this paper is to analyze the wider socio-economic context and conditions for such innovation processes in the Stockholm region, using the functional dynamics approach to innovation systems (ISs).

Design/methodology/approach – The analysis is based on triangulation using data from 16 in-depth interviews, two workshops, and additional documents. Using the functional dynamics approach, critical structural and functional components of the healthcare IS were analyzed.

Findings – The analysis revealed several mechanisms blocking innovation processes such as fragmentation, lack of clear leadership, as well as insufficient involvement of patients and healthcare professionals. Furthermore, innovation is expected to occur linearly as a result of research. Restrictive rules for collaboration with industry, reimbursement, and procurement mechanisms limit entrepreneurial experimentation, commercialization, and spread of innovations.

Research limitations/implications – In this study, the authors analyzed how certain functions of the functional dynamics approach to ISs related to each other. The authors grouped knowledge creation, resource mobilization, and legitimacy as they jointly constitute conditions for needs articulation and entrepreneurial experimentation. The economic effects of entrepreneurial experimentation and needs articulation are mainly determined by the stage of market formation and existence of positive externalities.

Social implications – Stronger user involvement; a joint innovation strategy for healthcare, academia, and industry; and institutional reform are necessary to remove blocking mechanisms that today prevent innovation from occurring.

Originality/value – This study is the first to provide an analysis of the system of innovation in healthcare using a functional dynamics approach, which has evolved as a tool for public policy making. A better understanding of ISs in general, and in healthcare in particular, may provide the basis for designing and evaluating innovation policy.

Keywords Innovation systems, Healthcare innovation, Challenges in healthcare, Stockholm

Paper type Research paper

1. Introduction

Healthcare faces a constant need to adapt, learn, and develop to meet the needs of patients, providers, and payers. To meet these needs, innovation is increasingly seen as a critical capability for healthcare organizations (Länsisalmi et al., 2006; Exton, 2010; Savory and Fortune, 2015). Understanding the dynamics of innovation in healthcare is not only of interest for social and medical scientists but also for policy makers...
interested in using innovation policy to spur efficiency and contain costs related to public healthcare services (Lehoux et al., 2008; Omachonu and Einspruch, 2010).

However, knowledge about innovation in healthcare is scarce (Ovretveit et al., 2012). Many studies on innovation in healthcare focused on single technologies (Consoli and Mina, 2009), specific policies (e.g., financing and public procurement) (Cappellaro et al., 2009, 2011; Hartz and John, 2009; Sorenson and Kanavos, 2011; Sorenson, 2008), or actors, e.g., physicians (Chatterji et al., 2008), patients (Oliveira et al., 2015), and entrepreneurs (Exton, 2008, 2010). There has also been an enduring research focus on conceptualizing the spread and implementation of innovations (May, 2013). Implementing innovations in highly regulated healthcare and social service delivery systems requires bridging social and cognitive barriers of medical professions (Ferlie et al., 2005). Innovation processes are complex and non-linear and require broader and subtle system transformations (Lehoux et al., 2009). Based on this, we argue that the wider socio-economic contexts of innovation processes and conditions for implementing, and also developing innovations in healthcare, need to be better understood.

To take all important contextual factors into account that influence innovation processes, an innovation system (IS) approach is useful (Carlsson and Stankiewicz, 1991; Bergek et al., 2008a, 2015; Malerba, 2002). Interdependent actors, networks, and institutions contributing to innovations in specific socio-technical regimes constitute an IS. In this paper, we use a functional dynamics IS approach to study a regionally limited part of the healthcare sector around Stockholm in Sweden.

There are several reasons to study the Stockholm healthcare innovation system (HCIS). Sweden is said to have one of the most sophisticated ISs in the OECD region, and the capital region Stockholm is considered a global hub for innovation (OECD, 2006). However, regional and national innovation policies have been criticized for being fragmented, unclear, and non-holistic (VINNOVA Information VI, 2013). Although Sweden’s healthcare system ranks high on cross-country comparisons of population health, healthcare outcome measures, and quality of care, it ranks low on technical efficiency (Anell et al., 2012; Tchouaket et al., 2012). Innovation is usually seen as the most powerful way to achieve quantum leaps in efficiency although it also requires some necessary “waste” due to entrepreneurial experiments that fail.

To our knowledge, no previous studies have taken a functional dynamics IS approach to study innovation in a healthcare sector with a focus on products and services rather than a specific technology. Such an approach may provide the basis for a holistic innovation policy. It further responds to the call for more research on the mechanisms of innovation (Martin, 2015; Bergek et al., 2015) in healthcare (Cappellaro et al., 2009, 2011).

The aim of this study is twofold: empirically to understand how actors, networks, and institutions in the Stockholm HCIS contribute to the functions of the IS and to identify supporting or blocking mechanisms and theoretically to explore the suitability of an adapted functional dynamics IS approach to a new empirical setting, a regional healthcare sector. The aim is not to evaluate the actual innovation performance using indicators but merely to understand how actors and institutions influence the various IS functions. In this paper, we first discuss a functional dynamics approach in a sectoral IS context. Based on previous theoretical contributions, a grouping of the functions of an IS will be suggested. The case methodology used is described as well as the results according to the defined functions. In the discussion and conclusion, we address the relevance of a functional dynamics approach for analyzing an IS in the healthcare sector.
2. A functional dynamics sectoral IS approach

ISs may be analyzed according to technology, geography (e.g. national or regional), or industry (sectoral) dimensions (Hekkert et al., 2007). Malerba (2002, pp. 250-251) defined a sectoral IS in terms of its elements: products; agents; knowledge and learning processes; basic technologies, inputs, demand, and the related links and complementarities; mechanisms of interactions both within and outside firms; processes of competition and selection; and institutions.

In the earlier literature on ISs, focus was on identifying either missing actors or system failures in terms of infrastructural, institutional, interactional, or capabilities deficiencies (Klein Woolthuis et al., 2005). This was criticized by Bergek et al. (2008a) as not being specific enough as the effects of these missing actors or system failures on innovation processes were usually not analyzed. To overcome this deficiency, Bergek et al. (2008a) presented “a framework that not only captures the structural characteristics and dynamics of an innovation system but also the dynamics of a number of key processes, here labeled ‘functions,’ that directly influence the development, diffusion, and use of new technology and, thus, the performance of the innovation system.”

In their proposed framework, they were very clear that their proposed framework could also be used to analyze a sectoral IS by focusing on products instead of a knowledge field (p. 411). However, Bergek et al. (2015) mention that most IS studies have been done with a focus “on understanding how the innovation system around a particular technology functions”; thus, technology is being defined as a knowledge field and not a product. Although the sectoral IS framework of Malerba (2002), as mentioned in footnote 13 of Bergek et al. (2008a), covers most of the functions identified in the “functional dynamics” framework, it does not categorize the system elements into structural components and functions that make the analysis of a system more straightforward.

2.1 HCISs – structure and functional dynamics

Healthcare innovations can be defined as implemented new or significantly improved products – goods or services, processes, marketing methods or business models, policies, or organizational structures (OECD/Eurostat, 2005). Healthcare innovations aim to improve measurable indicators of healthcare, including quality, health disparities, effectiveness, patient-centeredness, safety, timeliness, etc. (Agency for Healthcare Research and Quality, 2013), that lead to better health outcomes. HCISs are complex adaptive systems (Koberg et al., 2003; Essen and Lindblad, 2013) consisting of interdependent actors (networks) whose activities contribute to the overall function of developing, diffusing, and utilizing innovations (Carlsson and Stankiewicz, 1991) within the healthcare sector under the influence of institutional arrangements.

Actors in HCISs are individuals or organizations contributing directly or indirectly to healthcare innovation (Carlsson and Stankiewicz, 1991). Actors sharing similar interests can self-organize in formal or informal networks to achieve common goals such as sharing knowledge and experience or advocating for institutional change (e.g. professional or patient organizations). Institutions can be regulative (e.g. laws and regulations), normative (e.g. practice guidelines), or cultural cognitive (e.g. common belief and product codes) (Scott, 2008).

The sectoral innovation map illustrates relevant structural components of an HCIS (Figure 1). These components can be placed into three spheres (academic, market, and governance) along the vertical axis, and on the horizontal axis along the value chain with patients as the ultimate end-users. The key role of the governance sphere is to
provide resources and governance to actors; the role of academia is to critically validate knowledge claims; and within the market sphere, instrumental learning and allocation of resources take place. The map emphasizes the substantial part of actors within the healthcare sector with possible influences from other technological fields (e.g. telecommunication and banking) and sectors (e.g. fitness industry).

To analyze the performance of an IS, the functional dynamics approach suggests analyzing the composition, interaction, and activities of structural IS components and their contributions to seven-key system functions (Hekkert et al., 2007; Hekkert and Negro, 2009; Bergek et al., 2008a). Since the concept of system functions was developed, it has been revised, adapted for different levels of analysis, and empirically tested (Bergek et al., 2008a, 2015; Bleda and del Río, 2013; Radosievic and Yoruk, 2013; Hekkert et al., 2007; Hekkert and Negro, 2009). Based on previous literature, we adapted the definition of functions (Figure 2) for this first analysis of an HCIS, considering their use in a sectoral rather than a narrow technology-specific context. The functional dynamics approach has originally been developed for the analysis of IS around single technologies. However, it has also been suggested to use this approach for the analysis of sectoral systems of innovation (Bergek et al., 2015). This means that the functions must be related to all innovation activities in the system instead of only activities related to a specific technology. Instead of legitimating a technology, legitimation refers to acceptance and support of innovation broadly in the sector, guidance of search relates to activities that focus entrepreneurial experimentation toward unmet needs and critical problems across various technologies and places in the sector, and market formation must mean not the formation of a market for a specific emerging technology but for all early-stage product or service innovations in the sector.

The structural and functional dimensions of IS are highly intertwined and influence its function over time (Markard and Truffer, 2008; Hekkert and Negro, 2009) (Figure 3).
Complementary knowledge from various fields has to be developed and diffused. Includes knowledge specific to innovations and about the regulatory framework, entrepreneurship and business knowledge. Interdisciplinary networking and collaborations increase the level of knowledge development and diffusion.

Leadership and management influence the development and diffusion of innovations through the institutional framework. Important to create acceptance and support for innovation activities in the system by clearly expressed visions and expectations for innovation in the healthcare sector.

Financial and human resources as well as infrastructure for the creation and diffusion of innovation need to be available.

Functionality of the system depends on the capacity of the system to identify and direct activities to critical needs and problems.

Through experimenting and testing, knowledge is transformed into innovations, generate new knowledge by learning from trial and error and reduce uncertainties inherent to innovations.

Innovations are made widely available on markets where supply and demand meet. Markets speed up learning processes by allowing for comparisons between alternatives and fast diffusion of superior innovations. Market formation in healthcare is more restricted by regulations compared to other markets.

If functions are fulfilled, a mutually reinforcing and synergistic system can function and spread positive effects primarily within the HCIS, but also to other sectors, and also in geographic terms to other regions or countries. Standards enable reuse and inter-operability of innovations. Open innovation platforms and entry on new actors support network synergies.

Figure 2. Innovation system functions in HCISs

Figure 3. Healthcare innovation system
Problems in the system can be related to both the structural composition and functional dynamics of the system. In theory, if system functions are fulfilled, they can create reinforcing dynamics and a virtuous innovation cycle.

2.2 Functional interdependence
The seven functions described in Figure 2 are not mutually exclusive or independent of each other, or always play a similarly important role, as can be understood from previous research using the functional dynamics approach (Bergek et al., 2008a; Hekkert et al., 2007). Functional interdependence can play a key role in overall system dynamics and has been insufficiently studied compared to other aspects of the functional dynamics approach (Markard et al., 2015).

Although all functions are influencing each other in some way, they potentially play slightly different roles in the emergence and development of an IS. Hekkert et al. (2007) argue that “entrepreneurs are essential for a well-functioning innovation system,” and Carlsson and Stankiewicz (1991) explain that “the role of the entrepreneur is to provide the spark or the vision that turns a network into a development block.” However, as pointed out by Bergek et al. (2008a), entrepreneurial experimentation and search is guided and incentivized by articulation of demand from leading customers, critical problems, visions, etc., making the two functions of entrepreneurial experimentation and guidance of search mutually constitutive. This close interdependence is also pointed out by other researchers (Hekkert and Negro, 2009).

The magnitude of the entrepreneurial challenge in turn depends on its legitimacy as well as on availability of resources, knowledge, and competent co-actors. In accordance with Bergek et al. (2008b), we argue that legitimacy is a prerequisite for resources to be mobilized, and resources in turn are needed to fund research, knowledge development, and diffusion. Also, knowledge creation in a certain field is highly dependent on its legitimacy which in turn changes due to knowledge accumulation in a process of institutional change (Bush, 1987).

Resources, knowledge, and legitimation jointly influence the difficulty level of certain explorative entrepreneurial activities whereas other functions (positive externalities and market formation) primarily influence the economic “exploitation” effect of entrepreneurial activities. The degree of positive externalities and market formation influence the competitive pressure on entrepreneurial activity and also the economic effects of entrepreneurial activity (Carlsson and Stankiewicz, 1991; March, 1991). For example, by providing a highly interoperable technology platform or standard, positive externalities are created that can be captured via market formation. The close relations of these functions have also been pointed out by Bergek et al. (2008b).

In an IS where market formation and positive externalities exist, economic outcomes create opportunities for renewed resource mobilization, learning from market outcomes with resulting institutional change, and identification of new critical problems to be targeted by entrepreneurial experimentation, thus leading to a status of self-sustained innovation activity.

3. Materials and methods
3.1 Materials
This case study was part of a larger research project on the Swedish Medtech-HCIS which studied the Swedish Medtech industry’s conditions for innovation. In the present study, we focused especially on the healthcare system’s ability to implement innovations. Data from diverse sources were used following the triangulation principle. Initially, 70 actors
and networks from Stockholm’s HCIS were invited to an initial workshop. They belonged to the network of the SLL Innovation Advisory Board and were regarded as central to the HCIS. In total, 28 representatives from 16 different organizations supporting innovation activities participated. They were asked to outline actors and networks performing activities of importance for the functioning of the HCIS and to suggest possibilities for improvement. Discussions were recorded for analysis. Together with a follow-up workshop, this represented the main data source for identifying structural components of the HCIS and understanding cooperation hurdles between actors. To capture all relevant structural components, the sectoral innovation map was used as a grid. Figure 1 indicates the type of organizations participating. From the pool of actors and networks identified, we purposively selected a sample of 23 actors for in-depth interviews to analyze system functions. Inclusion criteria were experiences with healthcare innovation in the Stockholm region and positions at higher organizational level. We aimed to interview a sample representing actors covering the three spheres of the sectoral innovation map.

Of the 23 invited interviewees, 16 agreed to participate (organizations presented in the Appendix), which was satisfactory as the interviewees were not compensated, and the sample largely fulfilled the selection criteria. Most interviewees had been working with healthcare innovation in the Stockholm region or on a national level between eight months and 10 years. Underrepresented actors were risk capital providers, conference organizers, and medical journalists.

The interview guideline was developed based on the functional dynamics approach (Hekkert et al., 2007; Bergek et al., 2008a). The interviews lasted between 50 and 90 minutes and were performed by one of the authors (LML) in Swedish between May and October 2015. All interviews were recorded and transcribed (LML). The follow-up workshop was organized after the analysis of interviews to present preliminary results of blocking mechanisms. Participants were asked to collaboratively formulate goals for healthcare innovation in the region and ways to achieve those goals. In total, 35 representatives from 23 organizations participated (Appendix).

A third source of data was annual or public reports and websites of different actors in the HCIS. All respondents – workshop participants and interviewees – were asked for approval before discussions were recorded. After the analysis, respondents were asked to validate their responses.

3.2 Methods

In this qualitative in-depth investigation, the regional HCIS in the Stockholm County was studied as a case. The transcriptions from the workshop and the interviews were analyzed in a mixed approach of deductive and inductive coding (Thomas, 2006; Hsieh and Shannon, 2005). As a first step, eight randomly selected interview transcripts were analyzed by all authors independently to create samples of relevant comments. These samples were compared, and a large degree of consensus was found among the selection of comments. In the next step, the researchers jointly identified topics to group similar comments. These topics were attributed to seven IS functions primarily according to Bergek et al. (2008a). The remaining eight interview transcripts and the transcripts of the discussions during the workshop were analyzed deductively according to the identified topics in each function, but it allowed for new topics to emerge, which were discussed in the same fashion as described previously. The empirical evidence retrieved from the workshops and interviews was then expanded and cross-checked with data from additional documents found on the respective actor’s websites. Direct citations for the paper were translated from Swedish to English by the authors.
4. Results

4.1 The structure of Stockholm’s HCIS

The Stockholm region is one of the 21 counties in Sweden responsible for healthcare, transport, and culture in the region. The respective county councils (CCs) fund (by regional taxes) public and private healthcare services and manage public providers. The Swedish acronym for the Stockholm CC is SLL. Responsibility for parts of elderly care remains with the 26 municipalities in the county. CCs independently decide upon the implementation of national government recommendations (Anell et al., 2012).

The Stockholm region has one of Europe’s largest life science clusters with 611 companies and 20,852 employees. In 2012, 53 percent of the workforce belonged to the pharmaceutical subsector. Medical devices (Medtech) accounted for 24 percent and biotechnology tools and supply for 12 percent. Contract research organizations and service contributed 6 percent and diagnostics 5 percent. Other biotechnology companies constituted less than 1 percent. Overall, 65 percent of life science companies were small- and medium-sized enterprises (SME) with one to ten employees. Only 2 percent of the companies had more than 250 employees (Stockholm Uppsala Life Science, S.S.C.U.B., 2014/2015). A total of two hundred primary health clinics and six emergency hospitals with 41,168 employees in healthcare including dental care delivered healthcare to 2.2 million residents. According to prognosis, Stockholm will be the fastest growing metropolis region in Western Europe until 2030 (Stockholm Chamber of Commerce, 2013). Following legislation to promote private primary care in 2008 (Swedish National Audit Office, 2014), about 50 percent of primary healthcare centers in the region are run privately (Dahlgren et al., 2013), and a growing amount of specialized care is shifting into private as well.

The medical university Karolinska Institutet was described as central in the academic sphere. However, respondents stressed that at least ten other academic entities could potentially be more actively involved in healthcare innovation. In Sweden, the so-called teacher’s exemption gives researchers at institutes of higher education the sole right to capitalize on their research results in contrast to most other countries where the intellectual property (IP) remains with the universities (VINNOVA, 2006). Due to an increased focus on innovation and entrepreneurship, a growing number of organizations were established during the last 15 years to contribute to the translation of scientific discoveries toward commercialization and implementation. Among them are the innovation offices of certain universities, as well as public-private organizations.

SLL Innovation (founded in 2003), the Innovation Center at Karolinska University Hospital (2010), the SLL Innovation Advisory Board (2012), and the Innovation Gateway for primary healthcare (2014) were organizations created to support innovation in healthcare and part of the SLL structure. Under the guidance of the former innovation director, the SLL Innovation Advisory Board organized regular meetings and discussions about the need of a common strategy for these support organizations. However, due to unclear areas of responsibility, these organizations lacked strategic alignment and overarching leadership. In 2014, an innovation commissioner was appointed for the CC, and the responsibility for innovation was given to the SLL research and development (R&D) department. Interviewees interpreted the innovation commissioner as an important political contribution in terms of actors. Other agencies influencing the regional HCIS were the regional health technology assessment unit and the procurement unit at SLL, according to respondents. On the national level, the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) evaluate treatment or diagnostic methods primarily for reimbursement decision makers.
Three ministries were named that may influence innovation activities: the Ministry of Health and Social Affairs, the Ministry for Enterprise and Innovation, and the Ministry for Education and Research. Several public or private risk or venture capital providers, as well as incubators, were identified as being active in the field of health and life science. The Swedish Medical Products Agency and the Dental and Pharmaceutical Benefits Agency (TLV) were perceived as key to licensing and reimbursement decisions of medical products.

4.2 The functions of the Stockholm HCIS

This section presents how actors, networks, and institutions contribute to IS functions and the resulting dynamics between functions, based on the perceptions of interviewees and workshop participants. The numbers in parentheses refer to IS functions (FX) in Figure 2 or the interviewees (X) listed in the Appendix.

4.2.1 Knowledge development and diffusion, legitimation, and resource mobilization.

A central theme during both workshop discussions and interviews was the lack of clear leadership and strategy for innovation in healthcare (F2, F4). Even though public sector innovation is a common political term, respondents lacked the translation from rhetoric into action. The regional government SLL was described as not officially commissioning healthcare organizations to engage in innovation activities (F2, F4). Interviewees experienced a strong focus on treating patients within given budget constraints. One interviewee reasoned: “Full legitimacy can only be created if the county council requests innovation from the hospitals. Explicitly!” (7).

According to respondents, SLL should make resources for innovation available (F3) and should “[…] evaluate their organizations based on that [innovation outcomes]” (3) if they expect innovation in healthcare. Hospitals were given a yearly budget with incremental adaptations, making long-term investment in innovative solutions difficult. From 2016, hospitals will be given a four-year budget to increase ownership and flexibility.

Lacking the mission for innovation, healthcare organizations are restricted in making resources in the form of time, competence, or infrastructure available for healthcare professionals and patients to become involved in innovation activities (F2, F3).

Respondents described the paradox that SLL expects innovation to come from academia and industry while not investing in structures to implement scientific advances or facilitate uptake of innovations from industry or academia (F1).

“How much of their revenues do big medical technology or IT [information technology] companies spend on R&D? Well, somewhere between 7-15%. How much of the hospitals’ income is being used to develop their organizations? Less than 0.5 percent” (7) criticized one respondent. Availability of risk capital for healthcare innovation was commented by Stockholm Science City: “The Swedish state in general is not putting a lot of risk-capital to healthcare and venture capital attention goes to sectors other than life science because long-term investments with high risk are not very attractive” (4).

Four organizations were partly financed by SLL and commissioned to support innovation in healthcare, but they lack strategic alignment and overarching leadership (F2, F4), thereby impeding an efficient use of resources (F3). Outside these innovation-supporting structures, collaborations with industry are experienced as extremely limited due to the restrictive collaboration rules between industry and healthcare implemented in 2006 (Swedish Medtech, L.A.S., 2006/2013) (F2). Interviewees stressed that the healthcare sector is depending on collaborations with and knowledge-spillovers from other sectors such as medical technology, game industry, banking, and...
telecommunication, which develop rapidly. One respondent stated, “It is about the capacity of healthcare to include knowledge from other sectors. [...] Insights from other parts of the world are small in healthcare” (7).

Instead of actively involving and opening up healthcare settings for innovation projects, respondents described that decision makers seem to expect innovations to result in a linear fashion from scientific discovery followed by clinical trials as the only legitimate way of creating evidence-based innovations (F2, F1). This is reflected in large investments into research while only limited resources are available for projects to develop, test, and implement innovations (F3, F5).

One respondent reasoned: “I think the will is there, resources are there, but not really the knowledge on how to do (innovation)” (6).

Entrepreneurship, management, or business knowledge necessary to develop and introduce innovations into practice is not part of the curriculum of medical universities and is difficult to introduce (F1, F5). Management positions within healthcare organizations are often given based on a research track record, not based on management or leadership skills (F1, F3). This might contribute to a narrow medical focus on treating patients rather than on how to organize care better (F2).

In combination with the restrictive collaboration rules, occasions for knowledge development and diffusion across sectors and disciplines and between healthcare professionals, patients, and relatives are limited (F1). According to respondents, patients are not actively involved in innovation projects.

4.2.2 Guidance of search and entrepreneurial experimentation. “The ones that are going to use innovations have to be involved and articulate needs in order for innovation to be successful” (12). However, “in healthcare, it is seldom the patients who interpret their needs” (3). A patient representative described that focusing on the demand is easier in sectors with a clear focus on the customers’ perspective where customers pay directly (3). This pathway is blurred in healthcare because patients are seldom actively involved in clinical decision making (7) (F4).

Respondents agreed that “Healthcare has to be the workshop for innovation” (11). However, restrictive collaboration rules minimize possibilities for healthcare workers to reach out to the competences and resources in the industry and for companies to find the necessary clinical expertise and user-perspectives of healthcare professionals and patients. Guiding efforts and resources within healthcare and companies to critical needs and problems is therefore extremely limited (F4), as well as sharing and developing knowledge (F1). An innovation such as digitalization, widespread in many other areas of life, creates expectations among patients for digitalized solutions in healthcare, thus indicating a critical need according to respondents (F4). New technologies are available, but due to described problems, respondents reported that the translation of these advances to the healthcare sector is slow:

It is difficult to change a paradigm from within the paradigm. [...] If someone is a part of healthcare, it can be really difficult to see what the new healthcare could look like. [...] I think people are genuinely surprised over how far behind healthcare is (3).

Respondents described that healthcare professionals with their enormous creative capital and insights into patients’ needs are generally not provided opportunities to become involved in innovation processes (F5). Only enthusiasts in higher organizational positions, mostly doctors with higher social and financial capital, successfully develop innovations. One interviewee stated: “Looking back, there have
been many enthusiasts with a lot of inner drive. But if you think further, how many have gotten lost? How many said ‘no way’ even if they had loads of good ideas?” (13).

Another prominent institutional barrier to entrepreneurial experimentation is a disagreement concerning the involvement of public institutions in commercialization activities (F5, F2). This aspect is connected to the discussion about profit in welfare with the motto: “Every single krona for welfare will be used for welfare and not for making profit” (10).

Having no clear structure for the development of businesses in public healthcare, the head of the Innovation Advisory Board explained: “It can happen that people working in healthcare who want to bring their idea forward and start a company end up on the other side, and are being worked against by former colleagues and the healthcare environment. Do you understand? That is really difficult. I have met so many of those idea providers” (14).

A medical doctor owning a company emphasized that it is important to strengthen the importance of commercialization and developing innovations necessary for improving healthcare.

Reservation toward commercialization was expressed mainly from healthcare administration or actors not involved in business. The primary arguments were that the primary goal and official mission of healthcare innovation is to create better healthcare and not to create new companies, “This (new companies) can be a positive by-product” (7).

In line with the lack of a business development strategy within public healthcare, respondents mentioned that an unclear IP situation in healthcare prevents healthcare professionals from investing time and money in innovation activities (F3). As opposed to the rights in relation to research, the IP usually stays with the public organizations. One interviewee reflected upon the insecurity related to IP:

It makes it difficult for an individual employee to decide whether to invest evenings, and weekends and holidays for something and then it might be owned by the employer (13).

Furthermore, respondents described the Swedish taxation rules as disincentivizing for establishing SMEs in Sweden due to early and high tax on venture capital and R&D.

Respondents described the dilemma of a common belief that innovation comes as a result of scientific discovery. Researchers are driven by and paid for the prospect of publishing scientific articles. Research funding and evaluation criteria are usually journal impact factor and less value creation for patients. Respondents reasoned that the implementation and potential commercialization of scientific discoveries require other competences, collaborations and resources to navigate through the complexity of reimbursement, HTA, procurement, and other regulations for which there is no strategy in place at SLL today (F5).

In summary, respondents expressed that the critical needs of Stockholm’s HCIS are not systematically identified, communicated, and matched with entrepreneurial actors who can overcome uncertainties in commercializing possible solutions.

4.2.3 Market formation. Especially interviewees from the academic and market sphere working with business aspects stressed the importance of creating a home market for healthcare innovations (F6).

In their opinion, competent entrepreneurial customers in the home market are important for the establishment of companies in Sweden. SLL plays a crucial role as one of the most important and largest Swedish counties.
One interviewee (13) mentioned that the disproportional growth of healthcare markets globally bears many opportunities for countries like Sweden with its abundant know-how and innovation-oriented population:

But the system in the county has not yet flourished. We actually have the possibility to expand globally by facilitating improvement and innovation power. But if one doesn’t have access to one’s own healthcare system, and if there is no power at home, people won’t grow here. It is necessary to have a strong and willing home healthcare system (13).

The process from ideas to commercialization has to become faster, explained mostly actors from the industry or innovation-supporting organizations, to make the region attractive for businesses. Interviewees (3, 4, 5) gave concrete examples of Swedish companies that moved their clinical trials and companies abroad directly due to a slow and unresponsive home market:

He got tired of Sweden and went to California (3).

I think that it is very sad that there is a big disinterest from the county council to support and buy innovations and lead with a good example. I think this is the biggest […] I mean I have completely given up on the county council, I don’t try. We sell to the private clinics and others, but it is so difficult (5).

“I don’t know why this environment in Stockholm that should be very successful cannot compare to Silicon Valley” (2), was a reflection about market formation. He continued to provide a reason in lacking market formation of healthcare itself (F6):

“There is no demand on healthcare to earn money and to compete, that’s why it is hard to create a culture of innovation and entrepreneurship within healthcare” (2).

According to the same interviewee (2), public healthcare needs to realize that they also function on a market even though market formation might not be the primary goal. This was described as especially important as new legislation opens up for competition across borders (SFS, 2014).

Other barriers to market formation relate to HTA, reimbursement, and procurement mechanisms. Bureaucratic procurement mechanisms are perceived as a hindrance to the introduction of innovation:

Procurement mechanisms have been very rigid and focused on price only and not promoting innovation (13).

During recent years, innovation-friendly procurement was announced as a means to help SMEs overcome the bottleneck of long, expensive, and bureaucratic procurement processes but has rarely been used (8). SMEs often lack human and financial resources necessary for lengthy procurement processes and rather target the private healthcare market or foreign ones instead (F6). On the other side, respondents explained that healthcare clinics lack the resources and competence to systematically and routinely formulate clinical needs for successful innovation procurement processes (F4):

There is no tradition of procuring innovative solutions to identified problem. Instead, healthcare organizations procure predefined products. This is discouraging instead of promoting innovation (2).

Up to date, the regional government has not evaluated this innovation procurement policy (8). In addition, respondents described the reimbursement system as a hindrance for market access and formation (F6). Respondents criticized the reimbursement
mechanisms for not allowing introduction of innovations which would reduce costs, exposure to infections, environmental impact, and time.

Unclear requirements for HTA and limited possibilities for companies to develop clinical evidence were described as other obstacles to market formation. HTAs are performed on an ad hoc basis upon request from actors. The HTA unit at SLL stressed the importance of creating opportunities to develop necessary evidence in clinical test beds where clinical competence and patients’ needs and preferences can be integrated as evidence-based medicine principles (16). Conditional reimbursement to develop further evidence for promising innovations does not exist today. Procurement, reimbursement, and HTA are not connected in a formal way. According to respondents, it is problematic that principles for evaluating pharmaceuticals are generalized as the only way of generating evidence today. One respondent summarized: “There are well-intended reasons for trying to protect patients from things that may cause harm. But in my experience, people protect a bit too much. It is not possible to produce innovation if slightly unusual solutions are not allowed […]. The present system does not enable innovation to the extent we want” (3).

Traditional randomized controlled trials are appropriate for testing pharmaceuticals. But process, organizational, or communication innovations providing novel ways to design, manage, and deliver healthcare cannot be evaluated by traditional research methods. Furthermore, introducing organizational and process innovations is especially difficult because they are usually not procured:

What is needed now is a focus on service innovation, especially to make use of IT and Internet. This can best be achieved by moving from closed, expert-driven innovation environments to open ones, meaning environments where people are being invited to contribute with ideas and solutions, a bit like crowdsourcing (2).

4.2.4 Positive externalities. If other functions are fulfilled, a mutually reinforcing and synergistic system can spread positive effects primarily within the HCIS, and also to other sectors.

Respondents criticized that lack of leadership on innovation causes fragmentation which hampers efficient use of resources. Finding new ways of coordination and collaboration would support a more efficient use of resources. “During the past years, supporting actors came up here and there as individual initiatives. It is time for a comprehensive innovation strategy that enables cooperation” (14), described the director of one of the SLL supporting organizations:

“Who is responsible for innovation at SLL, including R&D, is very unclear. This organization has been and still is a lot too scraggly and fragmented” (10), described an interviewee working for SLL. “There are so many that want to encourage innovation in Stockholm that you can’t keep track of them” (3). “What do we want? […] Now we are doing a little of everything everywhere and everybody wants to do that. That’s not effective. We have to find areas we are best at” (12).

Sometimes, innovation-supporting actors do not know about each other which is quite embarrassing. And sometimes they know each other but they regard each other as competitors because very few resources for innovation are to be distributed amongst them (3), discussed one respondent.

Many stressed that the SLL supporting actors should work more synergistically and less fragmented to achieve common goals. During the first workshop, we observed that actors were unfamiliar with each other’s missions, making collaboration impossible.
During the second workshop, we observed difficulties to understand innovation in healthcare as a collective action and a tendency among organizations to prioritize their individual goals. Respondents explained the lack of inter-operability of IT systems as one of the results of fragmentation and lack of oversight and collaboration. About 2,000 different medical IT-systems are currently used in the region, requiring healthcare workers to spend time logging in to various systems in clinical everyday practice (F6):

> It is good that so many different people were thinking and trying to find different solutions. But moneywise and on a rational level this was terrible because things got so fragmented (13).

Interviewees stressed the importance of addressing barriers to healthcare innovation to realize the potential influence on the national economy, regional employment, and environmental impact. Digitalization and personalization can help optimize and reduce the use of pharmaceuticals, and telemedicine can reduce transportation costs for overcoming long distances between patients and healthcare facilities.

5. Discussion
This case study is the first to analyze the structure and functions of a HCIS by applying and adapting the functional dynamics IS approach. The structure of the HCIS is characterized by one of Europe’s largest life science clusters, numerous universities, an environment attractive for entrepreneurs, and a healthcare system labeled as world leading. However, we identified critical blocking mechanisms for the overall capacity of the HCIS to realize innovations in a clinical setting. These blocking mechanisms were central in the interviews and seem to affect several functions simultaneously. The main blocking mechanisms identified were furthermore often mutually supportive.

5.1 Blocking mechanisms
Blocking mechanisms of innovation among companies and in healthcare certainly differ along the value chain in the sector. However, many medtech innovations also require organizational innovation in healthcare for their clinical realization, thus making them highly interrelated.

An insufficient understanding of the inherent uncertainties involved in realizing innovations clinically tended to be maintained by the widespread notion of clinical innovation as merely translation or implementation of research results. This view of innovation is in accordance with a linear view of how innovation occurs. By not systematically evaluating unmet clinical needs among healthcare professionals and patients, their ability to contribute to new improved solutions was untapped. Interaction between medical device companies and clinicians is fundamental to medical device innovation as identified in numerous case studies (Lettl, 2007; Lettl et al., 2008). A lack of understanding among healthcare management and policy maker of both the uncertainties involved in innovation and the need to involve external parties with critical competences may also be a reason for the lack of a unified innovation strategy across healthcare and industry as well as between academia, healthcare, and policy makers. This was also evidenced by the many uncoordinated innovation-supporting organizations present in the HCIS. This inability to work together with parties external to healthcare was sustained by the severely restrictive agreement regarding rules of cooperation that had been signed between healthcare governance and industry representatives (Swedish Medtech, L.A.S., 2006/2013). In addition, many interviewees reported a widespread reluctance to accept profits in healthcare, profits that could be seen as remuneration to the production factor entrepreneurship in healthcare.
Other identified blocking mechanisms were related to the formation of markets for early-stage innovations such as restrictive HTA and procurement procedures, lacking reimbursement and implementation pathways for especially medical device innovations (Hartz and John, 2009). A better coordination of HTA, procurement, and reimbursement policies might help to exploit the potential of innovation for improving healthcare while balancing their risk. If creating social value is the objective of public healthcare, the decision criteria for introducing innovations have to include the public or patient perspective. If these are integrated, the idea of a reimbursement decision purely based on evidence has to be abandoned to allow for a stronger integration of public involvement (Lehoux et al., 2009). Many promising innovations fail due to the fact that evidence is considered insufficient. This occurs in parallel with innovation not getting the possibilities to develop more evidence through scientific evaluation, according to our results. Conditional reimbursement could provide opportunities for entrepreneurs to develop such evidence (Hartz and John, 2009) as research funding as well as scientific competence to perform clinical trials is often scarce in SMEs. In addition to the already mentioned organizational fragmentation of innovation-supporting structures and insufficient organizational innovation capability in healthcare, information technology (IT) causes further hurdles. Many different and often incompatible IT systems contribute to block potential positive externalities from emerging. Establishing clear strategies for innovation in healthcare should also include the development of standards to ensure inter-operability between different systems to reduce fragmentation (Continua, 2016). We observed that communities of practice related to healthcare innovation – “[…] groups of people who share a concern, a set of problems or a passion about a topic and who deepen their knowledge and expertise in this area by interacting on an ongoing basis” (Wenger et al., 2002) – were in rather initial states in the Stockholm area and could probably be spurred by providing platforms (portals) for knowledge exchange to support the emergence of positive externalities.

5.2 Functional dynamics in a HCIS
Many of the concepts of the functional dynamics IS approach are clearly developed to analyze a new technology rather than analyzing innovation more broadly in a sector. Thus, there is a need to adapt and redefine some functions to allow an analysis of the determinants of innovation in a regional sectoral healthcare context. The main change in definition of functions to a sectoral setting was the function legitimation that did not relate to the legitimation of a technology as traditionally intended but rather to the legitimation of innovation activities in the sector. In a sector context, legitimation is the result of policy making and strategies toward innovation broadly and not toward specific needs that would affect another function, that of guidance of search. A critical limitation of the functional dynamics approach was the lack of clear conceptualization of demand and needs. Lacking demand articulation could be analyzed as blocking of market formation and lacking need articulation could likewise be seen as insufficient guidance of search activities.

In line with previous research (Hekkert and Negro, 2009), we found support for the grouping of certain functions as more closely related (Figure 4). Knowledge development and diffusion, legitimation, and resource mobilization showed clear interdependencies. Innovation has entered the agenda of policy makers, and the willingness to commit resources to innovation-supporting organizations has increased in accordance with the increasing legitimacy of innovation in healthcare. However, it could be argued that this may be more of a ceremonial concession (Bush, 1987) rather than having a real impact on clinical activities. An example of this is the collaboration rules mentioned by interviewees that restrict real
interaction between industry and healthcare. This is an example of an important normative institution that determines the kind and extent of collaboration between users who can provide guidance of search to entrepreneurs and possibilities for knowledge development and diffusion. Patients and healthcare professionals as end-users of healthcare innovations are not systematically involved in public procurement or in innovation processes. The consequence is that clinical competence and articulation of patient needs is missing.

Guidance of search and entrepreneurial experimentation necessary to meet critical needs and problems in healthcare are mutually dependent critical functions for innovation (Hekkert and Negro, 2009). Today, there seems to be a strong focus on traditional research activities as the legitimate way of contributing to healthcare innovation. Clinical settings for developing and testing innovations in multidisciplinary collaboration were very limited as were in-depth needs investigations during procurement processes. Only if innovations meet critical needs or problems, and if they are given opportunities to be tested, will they have a chance to become established in the market. The regulative institutions (procurement, reimbursement, HTA, an unclear IP situation, and lack of business development strategies for public healthcare) restrict market access and market formation for innovative products and services.

If actors, networks, and institutions in the system are well coordinated, system-wide synergies can be created that reinforce all functions. The identified fragmentation prevents such synergies and reflects the lack of leadership and successful innovation management. In accordance with Figure 4, we can see several blocking mechanisms that prevent a self-sustaining innovation across the three clusters of functions to materialize. A lack of cross-sectoral mission and strategy for healthcare innovation that could legitimize resource mobilization and knowledge creation for innovation; restrictive collaboration rules that prevent interaction between users and producers of innovation; and restrictive HTA, reimbursement, and public procurement that prevent market formation of innovative products and services are mechanisms that prevent the Stockholm HCIS from entering a state of self-sustaining innovation.

5.3 Strengths and limitations
The functional dynamics approach to IS, in combination with the sectoral innovation map, were suitable tools for identifying structural and functional dynamics, as well as
blocking mechanisms in HCISs. We developed this approach by adapting the description of functions for the context of healthcare and by illustrating interdependencies between functions which further studies may confirm. We provided novel insights that may help decision makers and managers to identify, understand, and remove blocking mechanisms to improve the conditions for innovation in healthcare. The results also contribute to the development of the IS approach in general by applying it to the specific context of healthcare which have implications for further conceptualization of ISs (Bergek et al., 2015).

Our findings are based on comprehensive in-depth interviews and are limited by the aspects inherent to qualitative studies. In order to address those, various data collection and analysis methods were chosen. It is possible that involving more respondents would have added valuable data; however, the data showed a degree of saturation. Generalization or extrapolation to HCISs elsewhere is limited, but findings of this study might help to understand the functional dynamics of HCISs in general. We are just at the beginning of understanding innovation in healthcare systems, the relation between IS functions, the quality and quantity of innovations as the main output of ISs, as well as their impact on healthcare outcomes. More research on HCISs, including comparisons of HCISs in different regions, is necessary to further develop the conceptual framework for qualitative and quantitative investigation of HCISs and inform healthcare innovation policy.

An additional limitation of this study was that it did not attempt to capture IS outputs in terms of innovations and their impact on population health.

6. Conclusion
This case study suggests that the potential of Stockholm’s HCIS to create healthcare innovations is insufficiently exploited due to several mutually supporting blocking mechanisms. The development of healthcare innovation-related communities of practice is in initial stages and could be strengthened by providing easily accessible internet platforms for knowledge development and diffusion. A joint healthcare innovation strategy for academia, industry, and healthcare may strengthen the inclusion of more competence fields for the co-creation of holistic healthcare innovations. To dismantle the linear way of innovation, more resources specific for healthcare innovation and opportunities for intra- and entrepreneurship and business acumen in healthcare are necessary. The institutional framework, mainly HTA, procurement, and reimbursement processes, and IP should be adapted to create a more enabling environment for innovation. A systematic encouragement of healthcare professionals and patients’ need articulation on both the demand and supply side is necessary for value-based healthcare. These findings have implications for designing effective regional innovation policy by addressing identified blocking mechanisms. Further research on HCISs is needed to understand the connection between functional and structural dynamics and their impact on the amount, kind, and impact of innovations produced in HCISs.

References


Appendix. List of interviewed organizations

**Academic sphere**

1. Center for Technology in Medicine and Health.
2. Karolinska Institutet, Department of Learning, Informatics, Management and Ethics.
3. Patient representative and researcher at Karolinska Institutet (Comment: this interviewee is positioned twice on the map due to the fact that she is a chronic care patient and a researcher at the same time).

**Market sphere**

4. Stockholm Science City.
5. Swedish Medical Technology start-up company and doctor.
(6) Stockholm County Council (SLL) Innovation, innovation support organizations owned by the CC and located at several hospitals in the region.

(7) Innovationsplatsen (Innovation center) at the Karolinska University Hospital in collaboration with SLL.

(8) Swedish Medtech, Industry association for medical technology companies.

(9) Innovationsslussen (Innovation gateway), organization supporting innovation in eHealth in primary care.

(10) Patient’s Advisory Board at SLL.

(11) Swedish Rheumatism Association, Patient organization.

Governance sphere

(12) Vinnova, Sweden’s Innovation Agency.

(13) Lobbying organization ForskaSverige.

(14) Innovation Advisory Board at SLL.

(15) Director of Healthcare at SLL.

(16) HTA unit at SLL.