Technology Innovation Systems in Healthcare The case of Artificial intelligence (AI)

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Submitted to: Journal of Medical Internet Research
on: May 12, 2024

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The case of Artificial intelligence (AI)

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Abstract

Background: Artificial intelligence (AI) is a topic of considerable hype, with many actors sensing its high potential for healthcare applications. Despite this, the uptake has been slow, with few applications being implemented in clinical practice.

Objective: A qualitative case study with a mixed method approach was conducted at one of Sweden's largest hospitals. A literature review and mapping of CE-approved AI medical devices was conducted and primary qualitative data from 14 expert interviews were collected and cross-referenced with secondary quantitative data. The framework technological innovation systems (TIS) was used to analyze the system factors and its dynamics to identify blocking mechanisms and areas for improvement.

Methods: The present study employed a mixed methods approach that triangulated quantitative and qualitative data to provide a more comprehensive and nuanced understanding of the research topic [34].

Results: The challenges related to resource mobilization and market formation block the continued development of the innovation system. Establishing a technical infrastructure for testing and validation could strengthen subsequently contribute to reinforcing the entire system, given how functions interact and influence each other.

Conclusions: As shown by this analysis the adoption of AI healthcare technology innovations can be enhanced by establishing avenues for testing and validation to yield illustrative use cases. Interconnectedness between the guidance of search and entrepreneurial experimentation in the early development of TIS have been confirmed. Additionally, our study provided evidence that TIS undergo innovation cycles, where interactions across the supply and demand side are needed. Clinical Trial: N/A

(JMIR Preprints 12/05/2024:60458)
DOI: https://doi.org/10.2196/preprints.60458

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Abstract

Background: Ageing populations, in which many people suffer from multiple diseases and health problems, have contributed to an increased burden within the health sector. In recent years, artificial intelligence (AI) has been a topic of considerable hype, with many actors sensing its high potential for healthcare applications. Despite this, the uptake of has been slow, with few applications being implemented in clinical practice.

Objective: This study aims to investigate opportunities and challenges associated with using AI in healthcare, as well as provide suggestions for how further adoption of AI within healthcare organizations can be facilitated.

Method: Firstly, to get an idea of the external market, a mapping of CE-approved AI medical devices was conducted. With the aim of understanding the context of healthcare organizations and the prerequisites they set for the adoption of AI, a case study was conducted at one of Sweden's largest hospitals, Sahlgrenska University Hospital (SU). The application of technological innovation systems theory made it possible to analyze the innovation system factors and its dynamics and identify areas for improvement.

Results: A total of 343 products were identified, most of which were within radiology. The implications for the adoption of AI concern the generation and illustration of cases, enhanced knowledge and competence, enabling infrastructure, providing support for the development and implementation of products, and the stimulation of research and collaborations.

Conclusion: This analysis served as a foundation for drawing insights relevant to future research involving AI in healthcare, particularly from a healthcare provider point of view. Additionally, it underscores the role of innovation function strengths in enhancing comprehension regarding the adoption of digital technologies within the healthcare sector.

Keywords: artificial intelligence, healthcare, medical device, technological innovation systems (TIS).

Introduction

Emergent technologies in healthcare, such as artificial intelligence (AI), can transform healthcare [1] and AI has been recognized as a key source of economic growth and societal development by the Swedish Agency for Digital Government [2], particularly for the public sector with a potential annual savings of up to 140 billion SEK equivalent to 6 percent of total public spending. Despite technological advancements, digitalization within the healthcare sector lags behind that of other industries and the adoption of AI technologies has been slow [3]. While the industry is considered a primary driver for the digitalization of early-stage digital health startups [4] and well-established life science companies [5], most AI initiatives in the Swedish healthcare system were related to research projects [6]. Capturing the full value of AI technology involves numerous obstacles and challenges, such as ethical considerations [7,8]; and regulations [9,10] lessons learned from implementation and innovation sciences suggest that each individual factor is less important than the dynamic interactions between the factors [11,12]. The greater the complexity of an innovation or its context, the lower the likelihood of successful adoption, scaling, dissemination, and long-term sustainability [13,14]. The primary purpose of the present study is to explore the opportunities and challenges associated with the integration of AI in a healthcare context, while also providing recommendations to facilitate its further adoption.

Research Questions

The innovation system approach offers a valuable lens through which to examine the contextual elements impacting the uptake and diffusion of innovations [15,16]. Consequently, the present study employs an innovation system approach to scrutinize and capture the dynamics surrounding AI in healthcare. The socio-technical framework of technological innovation systems (TIS) has emerged as a prominent methodology for comprehending the intricate interplay among institutional frameworks and the diverse array of actors involved in facilitating the adoption of emerging technological domains [17-19]. The innovation system approach has been applied across such sectors as offshore wind power [20], bio-refinery [21], and healthcare [22,23], which shed light on the adoption of innovations and technological shifts. We contend that it can similarly shed light on the prerequisites for the integration of digital technology innovations aimed at enhancing healthcare quality.

To unravel the complexities surrounding the adoption of AI technologies, we have employed the Technological Innovation System (TIS) framework [15]. This conceptualization views technological systems as intricate networks of agents operating within an economic or industrial domain, influenced by a specific institutional infrastructure. Applying the TIS framework to evaluate the performance of AI, with particular focus on its limited adoption within a specific healthcare organization, helps to evaluate how system functions contribute to the overall dynamics of the innovation system. Understanding these functions provides a comprehensive lens for analyzing the dynamics, challenges, and opportunities within the TIS, shedding light on the intricate interplay of actors and institutions in the AI adoption landscape within healthcare systems. The analysis uses a technology innovations system framework. The following research questions were formulated:

RQ1: What are the strengths and weaknesses of AI in healthcare from a technology innovation system perspective?

RQ2: What are the patterns and relationships between the functions influencing the technology innovation AI system?

RQ3: What are the system-blocking mechanisms for AI technology?

This article aims to demonstrate the potential for healthcare improvement through the incorporation of AI- and AI-associated healthcare technology innovations. Building on prior research that has highlighted the significance of digital innovations for organizational excellence [25], the present study attempts to assess the processes relating to the adoption and diffusion of AI and AI-associated technology innovations. Grounded in key principles of innovation and systems thinking, the article delves into the improvement possibilities within healthcare systems.

A note on AI technologies

Despite the recent surge in interest, AI still lacks a universally agreed-upon definition. Tegmark [24] simplified AI as “non-biologic intelligence,” where intelligence is able to achieve complex goals. Furthermore, the widely recognized Turing test (created by Alan Turing) posits that, in order for something to be considered as artificial intelligence, it must convincingly mimic intelligent human behavior, as assessed by an observer being unable to distinguish between a computer and a human being [25]. Machine learning, a subset of AI, comprises various techniques that allow computers to learn without explicit programming. Artificial neural networks, which resemble the architecture of the human brain, are an example of machine learning technology. In the human brain, billions of interconnected neurons form complex networks, enabling the generation of intricate actions and thought patterns. Over the course of a person’s lifetime, neurons establish connections that form functional circuits.

Similarly, artificial neural networks consist of nodes or neurons that are arranged in different layers and can capture complex non-linear relationships between outcomes and data variables. Deep learning, which is a specific subset of artificial neural networks, addresses intricate problems by employing several hidden layers. In the context of healthcare, convolutional deep neural networks are often used for image analysis; for example, for interpreting structured MRI or CT data. Recurrent deep neural networks are used for the analysis of sequential data, which includes genetic sequencing. Natural language processing (NLP) is used for the analysis of unstructured data, such as information from electronic health record systems and clinical examinations. In the present study, the term AI technologies is used to include all generations and techniques of AI.

While AI holds promise in various healthcare applications, its current prominence is particularly evident in image analysis within the field of radiology facilitating the analysis of large image datasets [26]. Historically, healthcare has been designed to treat entire populations with the aim of developing solutions that can address the needs of large groups of individuals with similar symptoms [27]. However, we noted a current trend whereby AI is expected, in the near future, to lead to a significant shift toward precision medicine, also known as personalized medicine [28]. Future advancements are expected to include more sophisticated telemedicine and AI products, including self-diagnostics through medical devices, and intelligent assistance [29]. Healthcare systems could become increasingly predictive and preventive by using AI to enhance telemedicine and precision medicine. Mobile AI devices can provide personalized support to maintain healthy behavior, provide valuable insights to healthcare providers, and increase adherence to prevention programs [30]. Such an approach can enable effective self-regulation and extend the reach of primary care. A shift towards more preventive healthcare can help healthcare systems alleviate burdens and make their care more cost-effective and efficient.

Technological Innovation Systems (TIS) framework

TIS analysis involves examining structures and system functions that influence innovation activities [17–19]. The structural TIS components incorporate actors, networks, and institutions, encompassing both formal elements (such as laws) and informal elements (such as norms) that collectively shape the "rules of the game" [18]. The system functions within a TIS interact, and the strength of each function impacts the overall innovation system. The analysis scheme often begins with evaluating structural components and then identifying and assessing system functions [17].

Table I outlines the system functions in the technology system framework. The function of knowledge development and diffusion (F1) pertains to the depth and breadth of scientific, technological, and market knowledge. Indicators for this function include qualitative assessments and the number of relevant publications [17,18]. Legitimation (F2) relates to the establishment of normative institutions that support a particular technology and the overall social acceptance of that technology. Indicators may include the time from development to customer installations and qualitative data on the influence of legitimacy [17,18]. In the present study, the function was assessed based on the perception of legitimacy and how it influences demands and behaviors. Resource mobilization (F3) assesses the ability to mobilize infrastructure, financial capital, and human resources. Changes in resource volumes related to the innovation system are indicators of function strength [17]. Guidance of search (F4) is a cognitive institution that guides innovators and includes incentives and expectations of growth potential. Qualitative analysis of end-user needs of the particular technology can assess the function strength [17]. Entrepreneurial experimentation (F5) involves probing new technologies and applications, while function strength can be assessed by the number of applications, new entrants, and actors [17]. Market formation (F6) concerns the intersection of supply and demand, and its strength can be assessed by analyzing the stage of market maturity and the factors that drive market development, such as the existence of public tenders and reimbursement [31]. Positive externalities or system-wide synergies (F7) capture effects and conditions creating synergies [17,23]. Assessing function strength can include setting international standards and establishing formal networks among actors in order to enhance technology interoperability and acceptance [17,18].

Table I. Innovation systems' functions and strength indicators [17, 22, 23, 31].

System function		Function description	Indicators of function strength
F1	Knowledge diffusion and development	Breadth and depth of scientific, technological, and market knowledge base	Market and technological knowledge assessed by experts. Scientific knowledge assessed by the temporal development of the number of publications in scientific journals.
F2	Legitimation	Social acceptance and compliance of the technology with relevant normative institutions	Perception of legitimacy and social acceptance for the technology. Temporal development of the number of articles in daily Swedish newspapers.
F3	Resource mobilization	Mobilization of infrastructure. Human and financial resources.	Availability of capital and the perceptions of whether resources are sufficient.

F4	Guidance of search	Degree of influence on the development direction within the innovation system	Belief in growth potential and articulation of demands and needs for the technology by end-users. Temporal development of the number of editorials published in scientific journals.
F5	Entrepreneurial experimentation	Probing and testing of new technologies and applications	Number of new entrants and actors. Availability of AI technologies in the medical fields and the diversity of applications.
F6	Market formation	Refers to the market of available products and availability of innovations	Size/ type of markets/customers, and actors' strategies to enhance market access.
F7	System-wide synergies	Reinforcing a system in which functions are fulfilled can be seen as an indicator of the overall system dynamics	Establishing standards and formal networks between actors.

Methods

Qualitative case studies are designed to explore phenomena within a specific context [32]. Such a research technique emphasizes contextual understanding and provides in-depth insights. The choice of data collection methods in innovation systems studies can vary, and there is no consensus on a single preferred approach [33]. The present study employed a mixed methods approach that triangulated quantitative and qualitative data to provide a more comprehensive and nuanced understanding of the research topic [34].

Research setting

The case study was conducted at Sahlgrenska University Hospital (SU), one of Sweden's largest university hospitals, which engages in advanced research across various medical disciplines. The Swedish Government (2018) has emphasized the importance of harnessing the potential of AI, aiming for Sweden to lead in technological development [35]. The decision of SU as the empirical setting was driven by a combination of factors, including data accessibility and Sweden's high ranking on the Global Innovation Index [36].

The study seeks to explore and understand the innovation landscape in Sweden and draw insights that may be relevant beyond the specific geographical context. When the dynamics of a specific innovation system are closely linked to the structure and operations of its associated sector, it is advised to place the TIS in a broader context [37]. Consequently, recognizing the interwoven institutional frameworks between Sweden and the European Union concerning regulatory approval of AI technologies, the authors opted to incorporate European data into the analysis. The structural components of the innovation system in this study refer to actors, networks and institutions related to AI technologies in a healthcare context, more specifically technologies that are applied within departments that are in direct contact with patients, thus excluding AI technologies used for administration.

Data Collection

Data collection methods were conducted in two steps: (1) literature review including secondary data and (2) exploratory expert interviews. Official and publicly available documents such as reports, white papers, and government protocols were analyzed to provide context and support findings.

Step 1 –secondary data and product mapping

An initial literature review with a narrative approach made it possible to gain a comprehensive overview and a foundational understanding of the research area. As innovation systems literature about healthcare is scarce, insights from other sectors like energy were incorporated. Google Scholar and the Chalmers University of Technology Online Library, among other databases, were utilized extensively during the literature review.

To analyze the external market, we performed a product mapping of medical devices according to the EU's definition (EU 2017/745) [38]. The product mapping involved a thorough examination of previous mappings (Swedish and international) of healthcare-related AI products. Moreover, updates were regularly sourced from news outlets, supplemented by specific product category databases where applicable. We obtained information regarding the products we had identified from the website of each company. The products were organized into categories based on product purpose (as illustrated in Table II) with some overlap between categories, requiring subjective assessment based on manufacturer descriptions. Notably, some products fell into multiple categories, reflecting combinations such as telemedicine and monitoring. Furthermore, due to the absence of a standardized definition for AI, product classification as AI was based on how they were described by the supplying company (for example, references to AI, ML, DL, etc.).

Table II. Product purpose categorization

Product purpose	Description
Decision support	Advanced analysis
Diagnosis	Tools to detect correlations between symptoms and diseases
Monitoring	Aids for the monitoring and assessment of conditions
Telemedicine	Applications for remote healthcare
Workflow	Enhancement of workflow, such as triage and automation of tasks.
Other	Robotics, prosthesis, etc.

Step 2 – exploratory expert interviews

In the initial phase of the project, exploratory meetings with key stakeholders were held to define the project's scope, enhance understanding of the research area, and familiarize the researchers with the organization. In order to gather more information relating to the research topic, semi-structured interviews guided by a predefined set of questions were conducted to offer a balance between direction and flexibility and enable the exploration of diverse viewpoints [39]. To capture different perspectives, experts at various hierarchical levels were sought, aligning with the concept of triangulation, and allowing a comprehensive understanding of the subject. Purposive and snowball sampling methods were considered appropriate due to the complexity of the topic and the challenges in identifying experts. Interviewees were asked for recommendations, leading to referrals for additional interviews. A total of 14 expert interviews were carried out. The interviewees were comprised of 11 experts from Sahlgrenska University Hospital, one representative from the eHealth unit, one from the innovation platform, and one from AI Sweden. From the experts at Sahlgrenska University Hospital, three were members of the Hospital Board, one was a strategist, and seven were clinicians/researchers (two from cardiology, one from anesthesiology, dermatology, medical physics, psychiatry, radiology respectively. The interviews were conducted using Zoom and Teams. One of the authors led the questioning based on the interview guide and another author acted as note-taker. Recording ensured comprehensive data availability for subsequent analysis without subjective interpretations.

Data Analysis

The secondary data were analyzed through simple quantitative assessments. The primary data gathered from the qualitative interviews underwent computer-aided analysis of qualitative data (CAQDAS), utilizing NVivo software [39]. Prior to the analysis, all interviews were transcribed. Grounded theory [40] was employed for the analysis. Initial coding of first-order concepts was carried out from the interview transcripts, which were then aggregated into broader second-order themes. These themes were further condensed into larger aggregated dimensions. Following data collection, field notes and transcripts were revisited and analyzed with an abductive reasoning approach, which resulted in renewed coding rounds as theoretical insights emerged [41]. This methodological approach ensures a systematic and structured inductive qualitative research process, enhancing rigor in the results [40]. The derived themes and concepts underwent analysis using the TIS approach. We have built this article on our previous studies that have analyzed AI in healthcare with the use of the TIS framework [5, 22, 42].

Moreover, the primary qualitative data were cross-referenced with secondary quantitative data to serve as evaluative benchmarks for the assessment of functional strength. For instance, to assess knowledge development and diffusion (F1), we conducted a bibliometric analysis focusing on the number of publications in scientific journals concerning the TIS within both Swedish and European contexts. Additionally, to quantify legitimation (F2), the number of articles published in Swedish daily newspapers was examined to scrutinize the societal acceptance of the technology.

Results

Actors, networks, and institutions

The analysis of structural components followed a sectoral innovation system map, categorizing key actors into academic, market, and governance spheres along the value chain, as depicted in Figure 1. Sahlgrenska University Hospital (SU) is a central actor in the market sphere, which also includes life science companies, companies with AI technologies, and regional hospitals. Examples of life science companies include AstraZeneca, Mölnlycke Healthcare, and Getinge. The academic sphere included the central actors Gothenburg University and Chalmers University of Technology with its research center for AI (CHAIR). Innovation platforms, science parks, and incubators have been established to foster innovation and to actively facilitate the development of novel ideas and technologies. Research Institutes of Sweden (RISE) is an independent, state-owned research institute that serves as an innovation partner for academia, private and public sectors. Among the national actors in the governance sphere were the Ministry of Health and Social Affairs, the Medical Agency, the Agency for Innovation Systems (Vinnova), and the Swedish Government. The AI Sweden ecosystem network, which is the Swedish National Center for applied AI, is funded by the Swedish Government, as well as partners in the Swedish public and private sectors, that aims to accelerate AI usage [43].

"The regional structure has not benefited this area; quite the opposite. There is considerable competition among the regions. Everyone wants to be in the lead. There is amazingly little cooperation between the regions today."

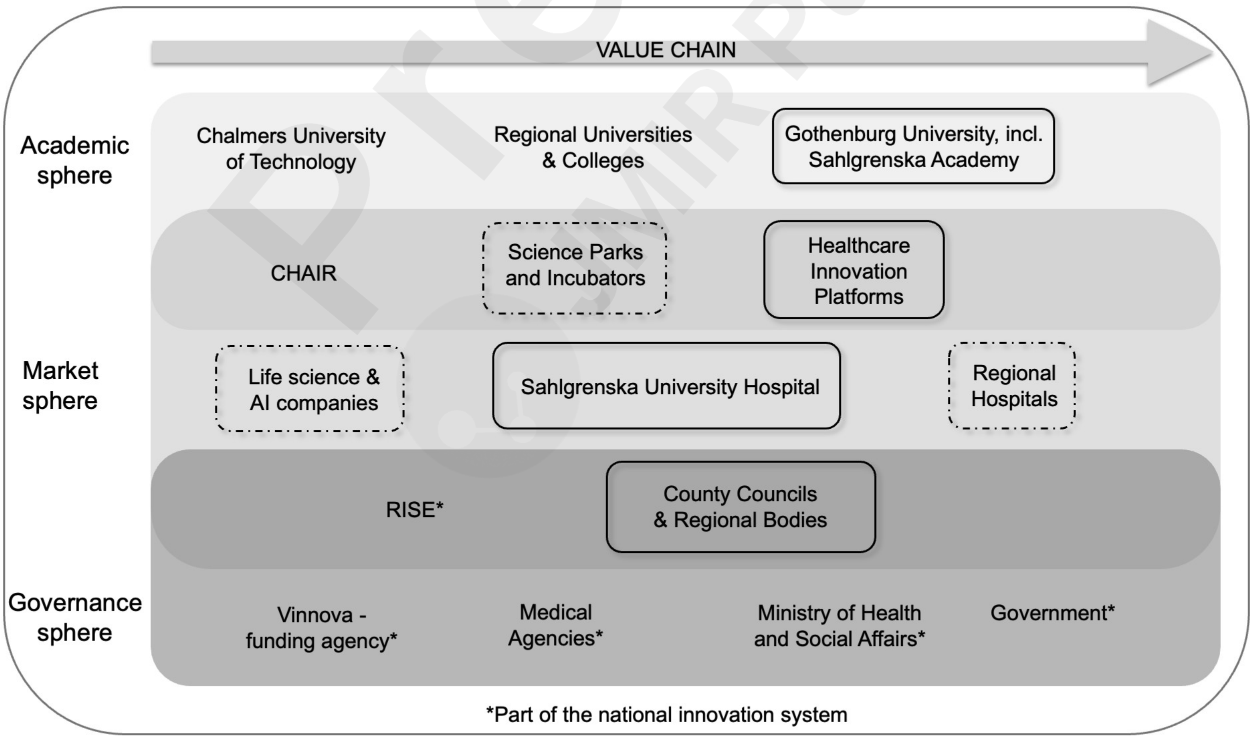

Figure 1. Selection of central actors, networks, and institutions related to AI technologies in a healthcare context. The boxes show the participants included in Phases I and II; the boxes with dotted borders show

actors that were contacted, but were not selected for further interviews.

Functional assessment

RQ1: What are the strengths and weaknesses of AI in healthcare from a technology innovation system perspective? The system functions are described in this section. Strengths, marked with *(S)*, and weaknesses, marked with *(W)*, indicate the function strength.

Knowledge development and diffusion (F1)

Rather than gaining deep technological knowledge, many respondents emphasized the importance of in-house competence to test and validate products that could potentially be deployed in clinical practice. Moreover, a recurring theme was the *knowledge gap and insufficient competence for the potential impact of AI among healthcare professionals (W1).* Individuals at various levels within the organization were perceived to lack an understanding of the technological capabilities, which hindered their ability to articulate their needs and to use and implement AI in clinical practice. Furthermore, respondents emphasized the importance of enhanced competence among decision-makers and regional purchase units to increase the understanding of the market and commercialized products in order to bridge the knowledge gap between internal and external actors.

“While we need our own technical competence, we won’t spend time writing algorithms, which should be done by those at Chalmers University of Technology, for instance.”

In addition to collaborations with external actors, *numerous research projects within the organization contributed to knowledge expansion (S1)*; for example, the Swedish cardiopulmonary bioimage study, SCAPIS, a massive and distinctive national initiative involving collaboration among six Swedish universities and university hospitals. The primary goal of the project is to predict and prevent chronic obstructive disease and cardiovascular disease by analyzing image data from 30,000 individuals. Moreover, the large number of research projects in other industrial sectors, the technological knowledge base among academia, and the electromobility sector is broad. Knowledge diffusion from other sectors and among actors generated spillovers to the healthcare sector, but only to a limited number of individuals.

“Machine learning is here to stay. Once you have opened that door, there is no going back.”

The number of publications in scientific journals has increased exponentially, which indicates a continuous expansion of the general knowledge base (S2); see Figure 2. Interestingly, the Swedish data had a similar pattern compared to European data, which means the scientific and technological knowledge had the same development.

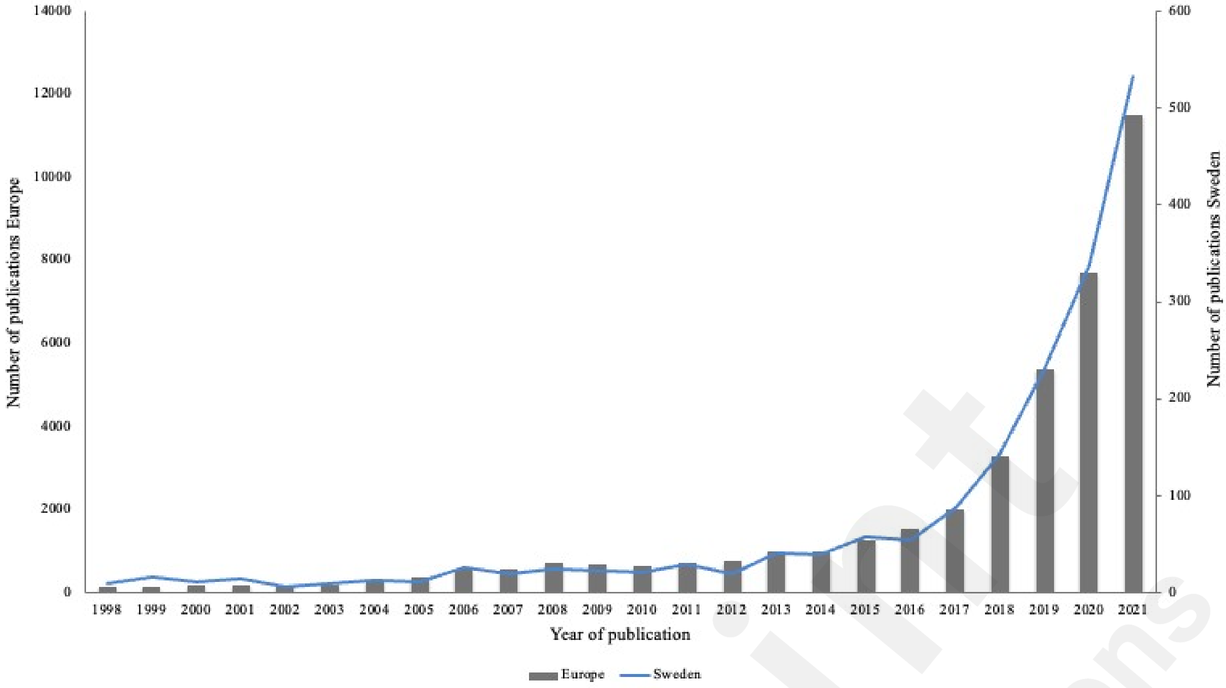

Figure 2. The number of published scientific articles addressing AI in healthcare in a Swedish and European context, 1998–2021.

Legitimation (F2)

Hospital management, clinicians, and researchers all expressed a *positive attitude toward the utilization and implementation of AI in healthcare (S3).* Many interviewees highlighted the challenges of change management in healthcare, emphasizing that while individuals may hold a positive view of AI, they may resist the necessary processes involved in reaching the end goal. The consensus-driven decision-making climate was viewed as potentially hindering transformative efforts, and some respondents called for more assertiveness and clarity in decision-making to drive necessary transformations. Moreover, the potential negative impact of AI on healthcare professionals' work contributes to the hesitancy to use the technology.

"I think we have an anxious climate when it comes to decision making. We are highly consensus-driven and that is not necessarily the best way to drive transformations. It is likely that some people will have to step forward and be clear about the fact that we have to do this, and then get people to follow".

A prevalent theme that emerged from the interviews is the substantial complexity of AI in healthcare resulting in uncertainties related to myriad interconnected factors, such as data accessibility and technical intricacies. Participants expressed frustration over the *difficulties of obtaining access to data due to the stringent compliance requirements, and data protection regulations (W2)* such as GDPR, PDL, and MDR were highlighted as major obstacles to the effective use of AI.

"I think it is important to play down the notion of AI, but at the same time avoid putting up overly large visionary prospects of something that isn't yet there. Otherwise, it can easily result in disappointment and even resistance that will ultimately slow down the development."

"There is no such thing as anonymized data; there is only a question of how much data you are provided with. If you only have enough data points, there will be a risk that you

can identify a single individual."

Social acceptance was assessed with bibliometric analysis of the temporal development of the number of articles in daily Swedish newspapers. As Figure 3 illustrates, the *number of articles increased exponentially indicating an increased social acceptance of AI innovations in a healthcare context (S4).*

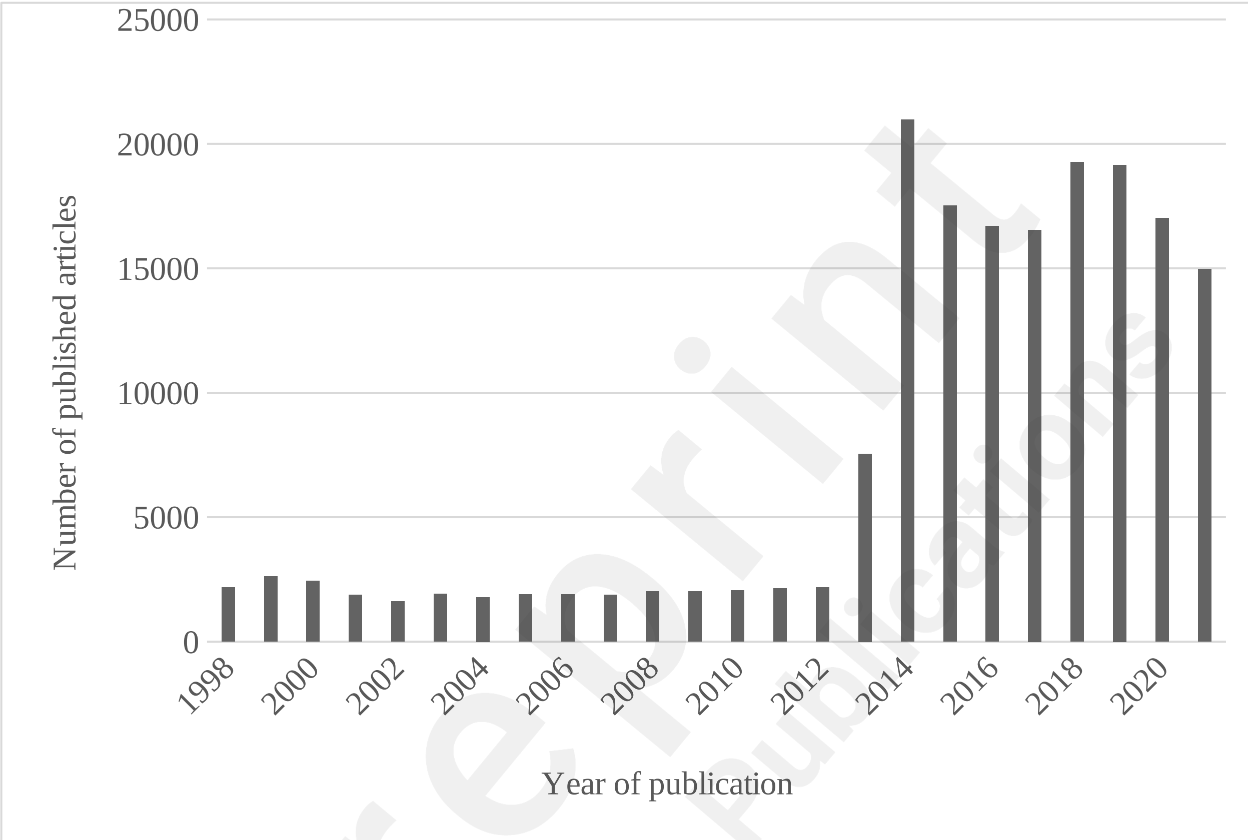

Figure 3. The number of published articles in Swedish daily newspapers (1998–2021) related to AI innovations in a healthcare context.

Resource Mobilization (F3)

Respondents highlighted *concerns related to the digital infrastructure and interoperability among existing IT systems (W3)*. Access to data, a prerequisite for AI, presents a substantial problem due to restrictions on the use of patient data. One interviewee pointed out the risk of compromising personal integrity, whereas individual patients can be identified with a sufficient number of anonymized data points. Additionally, the interviewees highlighted challenges related to data sharing, expressing frustration that healthcare data cannot be readily shared with institutions like technological universities possessing high expertise in AI. Moreover, ethical concerns were raised about the *weak transparency of data used for training the algorithms, resulting in uncertainties regarding the reliability of AI innovations (W4)*. For example, participants stressed the importance of understanding the rationale behind AI-generated suggestions and the parameters that influence these outcomes. Moreover, issues with data quality, particularly concerning unstructured free text in medical journals, were emphasized. Some expressed unease about algorithms trained on data from specific regions or populations and the ethical implications of such biases, questioning accountability when AI applications make mistakes were emphasized. One participant shared an example of a diagnosis application that overlooked a rare condition due to limited training data, leading to concerns about responsibility in the event of errors.

"If AI is the rocket, data is the fuel."

Few participants identified financial constraints as a major challenge. In fact, some argued that *obtaining funds was straightforward from internal and external organizations, like Vinnova (S5)*. However, individuals from hospital management acknowledged the difficulty of balancing strategic considerations with operational concerns, thus justifying investments in areas with high uncertainties can be challenging. Furthermore, the recurring theme of healthcare staff facing considerable time pressures results in *restricted time for contemplating AI projects (W5)*. For example, despite being purchased and demonstrating added value, an AI-based software for MR had not been fully implemented in clinical practice due to time constraints.

"The further down in the organization you are, the more occupied you are by daily problems."

Guidance of Search (F4)

In 2018, *the Swedish Government unveiled its national strategy for AI, emphasizing the need to harness the advantages and calling for active support to develop and adopt the strategy (S6)*. The Research Institutes of Sweden (RISE) has developed an agenda that aims to expedite AI advancements in Sweden, with an emphasis on the role of AI in the public sector (RISE, 2021). Moreover, international entities such as the European Union (EU), assert the critical importance of adopting the technology, especially within healthcare (COM/2020/65).

"It is a strategically important area for the hospital. We think it will be important to manage the challenges that healthcare is facing."

Interviews revealed *high expectations and strong belief in the strategic potential of AI within the hospital (S7)*. There was a desire among the hospital management to be at the forefront of development, although respondents also stressed the importance of overly visionary perspectives, and that AI should address real-world problems and provide value by improving healthcare and supporting the profession. For example, optimism was expressed about the potential to save time, automate tasks, enhance the overall quality of care, telemedicine, and provide a "second opinion" in decision-making.

"On one hand, you struggle with the strategic. On the other hand, you struggle with the operative. People in my type of position are expected to think of the strategy, but we are also occupied by operative issues, especially during a pandemic, when we must focus on solving acute problems. In such circumstances, these types of questions become overshadowed."

To quantitatively assess the function strength, the number of editorials published in scientific journals was analyzed and, as illustrated in Figure 4, *the number of editorials related to AI innovations in a healthcare context has grown steadily (S8)* over the last four years. The number of editorials in a Swedish context followed the same temporal development as in a European context.

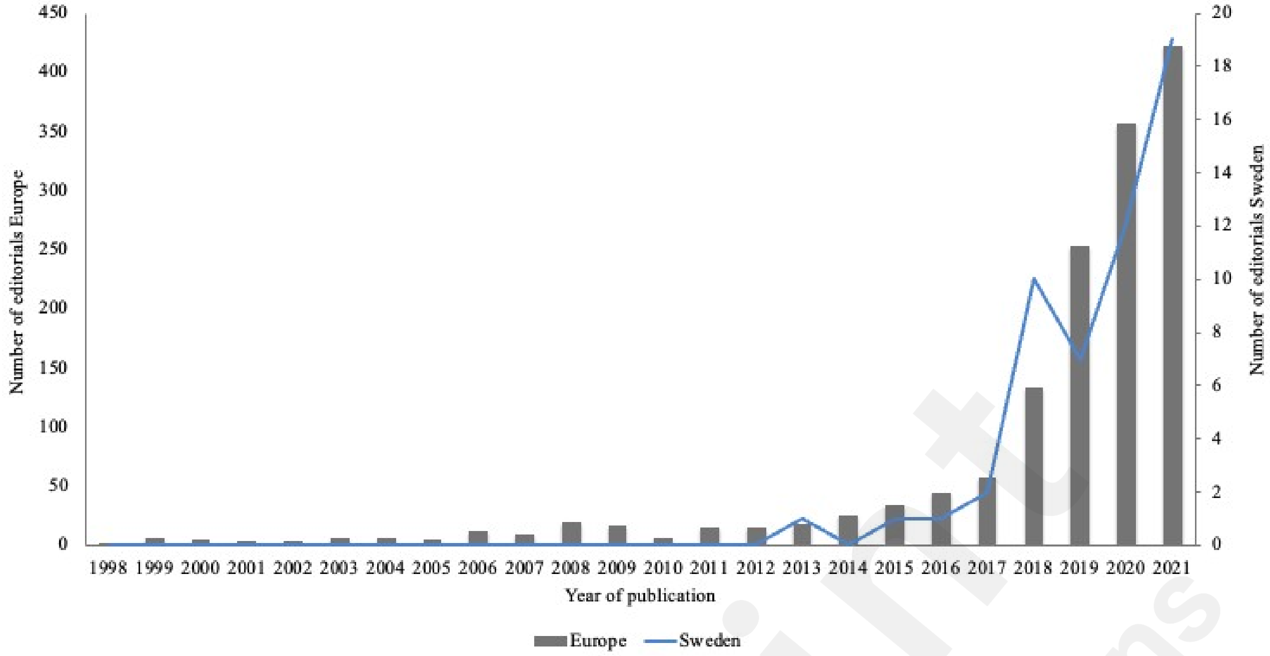

Figure 4. The number of published editorials in scientific journals related to AI in healthcare in a Swedish and a European context, 1998–2021.

Entrepreneurial Experimentation (F5)

We assessed the entrepreneurial experimentation function (F5) by analyzing the number of medical disciplines involved in AI initiatives and the diversity of end-user applications. The product mapping revealed that certain areas were more mature than others on the supply side. Examples included radiology (53 percent of the total number of products) leveraging scans from computed tomography (CT), ultrasound, magnetic resonance (MR), and X-ray for image analysis. Among the included features were the detection of abnormalities, quantification, and enhancing overall visualization serving as decision support for diagnosis, treatment, and surgical planning. Cardiology (9 percent) was often used for assessing and interpreting ECG data. Neurology (6 percent) was used for pain assessment and early detection of dementia. Other disciplines included pathology (3 percent), ophthalmology (4 percent), gastroenterology 2 percent, and oncology (2 percent). Moreover, the hospital (demand side) was actively engaged in a significant number of experiments related to AI (58 projects). The most prevalent category was decision support (41 percent); diagnosis (21 percent); telemedicine (14 percent); monitoring (11 percent); and workflow improvements (8 percent). The remaining (4 percent) encompassed "smart" prosthetics, surgical robotics, and VR glasses for rehabilitation. Hence, *AI innovations were identified across medical disciplines and for various end-user applications on the demand as well as the supply side (S9).*

> *"It is necessary to push, because you may not see the result so clearly now. But then we have to do motivational work, and you also need answers on 'what's in it for us?'"*

Many interviewees expressed the belief that instead of being developed in-house, most upcoming AI products will be procured from external commercial entities. As a key factor in support of this perspective, several interviewees noted that the process of taking a product from research to CE approval was challenging. Despite generally being positive about commercial products, many respondents also highlighted the complicating factors associated with acquiring solutions from external actors, which included the importance of rigorous testing and validation to assess safety and efficacy.

"If it works, it's actually a breakthrough since we can neatly overcome the legal barriers that are currently causing a lot of trouble."

Market Formation (F6)

An examination of the external market reveals *a growing number of available products and an increasing presence of commercial actors (S10)*. A total of 343 CE-approved products were identified and the actors involved ranged from small startups to large corporations, totaling 284 different entities. Despite the theoretical potential of purchasing products that could bring immediate value, there appears to be a lack of a systematic process for these solutions to transition into clinical practice. The number of integrated AI innovations in clinical practice was low in the light of an evidence-based culture; accordingly, *supportive mechanisms for validating AI innovations to ensure safety and efficacy were requested (W6)*.

"There are tons of apps out there and some people might wonder, why don't we just buy them? But it's not quite as simple as that."

In cases where no suitable product exists on the market, internal development may be pursued; however, the process of taking an algorithm from research to clinical practice was perceived as highly intricate. Despite a significant amount of AI research activities, the sentiment among respondents was that little, if any, of the research makes it to implementation, with a substantial percentage of pilot projects yielding no tangible outcomes. Questions were raised on how to optimize integration into existing workflows and align with current processes and there was a consensus regarding the *necessity for testing opportunities for in-house as well as externally purchased products (W7)*. Moreover, respondents argued that researchers may lack the commercial drive and might not be motivated to proceed to the next stage, particularly when faced with the challenges of commercialization, such as obtaining CE mark.

"We need to identify products and see which ones are valuable to us … we need support in the organization in terms of routines and testbeds to evaluate whether a certain product is useful or not … otherwise, we do not want to buy this tool."

System-wide synergies (F7)

While the importance of laws and regulations, such as LOU, GDPR, PDL and MDR, in safeguarding privacy and security is acknowledged, some have argued that such *legislation can be overly restrictive and emphasize the importance of alignment with technological advancements to effectively integrate AI innovations into clinical practice (W8).*

"In Sweden, we have the law of public procurement, which is not always the best method for this type of transformation. You specify your requirements and suppliers then have the opportunity to present offers. This is not particularly suitable for things that are somewhat fuzzy and difficult to define."

Founded in 2020, *the National Center AI Sweden was considered an asset to enhance collaboration across the ecosystem, fostering cluster-like dynamics (S11)*. The center is funded by the Swedish government through the Innovation Fund Vinnova and its 120 partners represent private companies, the public sector, academia, and research institutes (www.ai.se). The industry partners span sectors such as automotive (CEVT, VOLVO, and Zenseact), computer science (Embedl, Recorded Future, and Talkamatic), and the life science industry (AstraZeneca and Essity). Fostering collaborations with diverse external actors provided valuable exchange of knowledge; one participant also suggested expanding collaboration between regions to facilitate the sharing of ideas and best practices. The academic partners include Chalmers University of Technology and Gothenburg University; participants felt that collaboration with academia was valuable in order to integrate AI elements into the education of future healthcare professionals.

"I think it is very important to utilize our united forces."

Summary of the functional assessment

Table III provides an overview of the functional assessments, encompassing both identified system weaknesses and strengths. The number of weaknesses and strengths was used as an indication of function strength. If a function exhibited system strengths only, it was categorized as strong. A function showcasing more system weaknesses compared to system strengths was deemed weak. Following the analysis, the functions of Guidance of Search (F4) and Entrepreneurial Experimentation (F5) were assessed as strong functions. Three functions demonstrated intermediate strength, while Resource Mobilization (F3) and Market Formation (F6) were assessed as weak.

"It's important to avoid narrowing down, and to instead obtain a comprehensive picture of the various factors. People sometimes tend to focus on one factor … but they go hand in hand."

Table III: Summary of assessment of functions based on identified strengths and weaknesses.

Assessment	System function		Identified strengths	Identified weaknesses
Strong	F4	Guidance of search	Swedish Government unveiled its national strategy for AI, emphasizing the need to harness the advantages and calling for active support to develop and adopt the strategy (S6).	
			High expectations and strong belief in the strategic potential of AI within the hospital (S7).	
			The number of editorials related to AI innovations in a healthcare context has grown steadily (S8).	
	F5	Entrepreneurial experimentation	AI innovations were identified across medical disciplines and for various end-user applications on both the demand and supply sides (S9).	
Intermediate	F1	Knowledge development & diffusion	Numerous research projects within the organization contributed to knowledge expansion (S1).	Knowledge gap and insufficient competence for the potential impact of AI between healthcare professionals (W1).
			The number of publications in scientific journals has increased exponentially, which indicates continuous expansion of the general knowledge base (S2).	
	F2	Legitimation	Positive attitude toward the utilization and implementation of AI in healthcare (S3).	Difficulties obtaining access to data due to the stringent compliance requirements and

				data protection regulations (W2).
			The number of articles in Swedish daily newspapers increased exponentially which indicates an increased social acceptance of AI innovations in a healthcare context (S4).	
	F7	System-wide synergies	The national center AI Sweden was considered an asset to enhance collaboration across the ecosystem, fostering cluster-like dynamics (S11).	Legislation can be overly restrictive and emphasized the importance of alignment with technological advancements to effectively integrate AI innovations into clinical practice (W8).
Weak	F3	Resource mobilization	Obtaining funds for AI projects was straightforward, from the internal organization and from external sources (S5).	Concerns related to the digital infrastructure and interoperability among existing IT systems (W3). Weak transparency of data used for training the algorithms, resulting in uncertainties regarding reliability of AI innovations (W4). Time for contemplating AI projects (W5).
	F6	Market formation	A growing number of available products and an increasing presence of commercial actors (S10).	Supportive mechanisms for validating AI innovations ensuring safety and efficacy was requested (W6). Necessity for testing opportunities for in-house as well as externally purchased products (W7).

Functional pattern

RQ2: What are the patterns and relationships between the functions that influence the technology innovation AI system? It is reasonable to assert that the landscape of AI within healthcare is complex and multifaceted; this sentiment is echoed by many interviewees. Consequently, interdependencies likely exist between most functions in the system, with varying degrees of visibility and directness. The identified functional patterns in this study are depicted in Figure 6. Our analysis shows that resource mobilization (F3) and market formation (F6) were weak. The uncertainties surrounding digital infrastructure, interoperability between IT systems, and quality of data may discourage the allocation of resources to AI in healthcare. Furthermore, the lack of supportive mechanisms for validating AI innovations for safety and efficacy directly inhibits the implementation into clinical practice; hence, resource mobilization (F3) has a negative influence on market formation (F6). Moreover, there appears to be a direct link from market formation (F6) to knowledge development and diffusion (F1). This connection arises from the "evidence-driven" culture, where testing and validation in real-life environments is desired before integration into clinical practice. Tangible examples of successfully implemented AI innovations, adding value to clinical practice, can illustrate how uncertainties can be overcome and subsequently strengthen legitimacy. Moreover, despite hospital management underscoring the importance of AI and the need for resource deployment, vague directives among decision-makers within the organization (demand side) may weaken this influence. Hence, a low level of AI competence in parts of the organization (demand side) undermines the continued development of the innovation system.

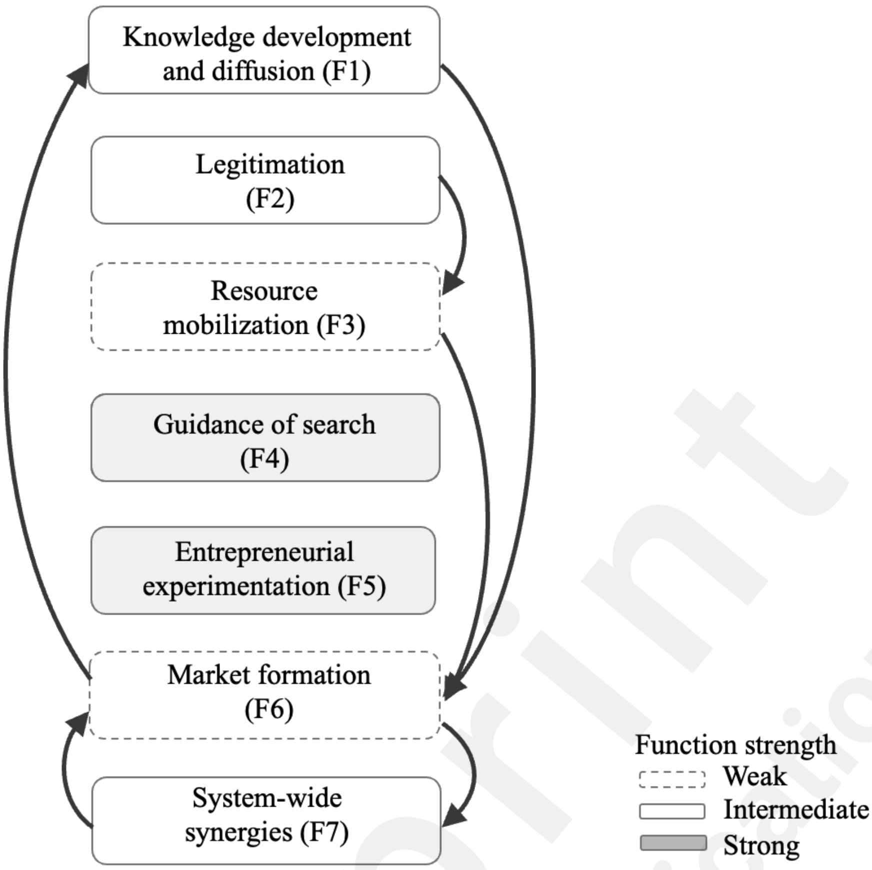

Figure 5: Illustration of the interactions and negative influences between system functions.

System blocking mechanisms

RQ3: What are the system-blocking mechanisms for AI? As we have depicted in Figure 7 and outlined in our analysis of functional patterns within the TIS, some system functions exert influence over multiple functions, making them more pivotal in addressing system challenges. It is evident that resource mobilization (F3) and market formation (F6) play central roles in the system dynamics and the continued development of the innovation system. There also exists a feedback loop involving market formation (F6) and knowledge development and diffusion (F1), as well as with system-wide synergies (F7). These functions and their interconnections may give rise to virtuous cycles, reinforcing themselves when adequately fulfilled, or vicious cycles if neglected. Importantly, strengthening legitimation (F2) could subsequently contribute to reinforcing the entire system, given how functions interact and are influenced by these interconnected cycles.

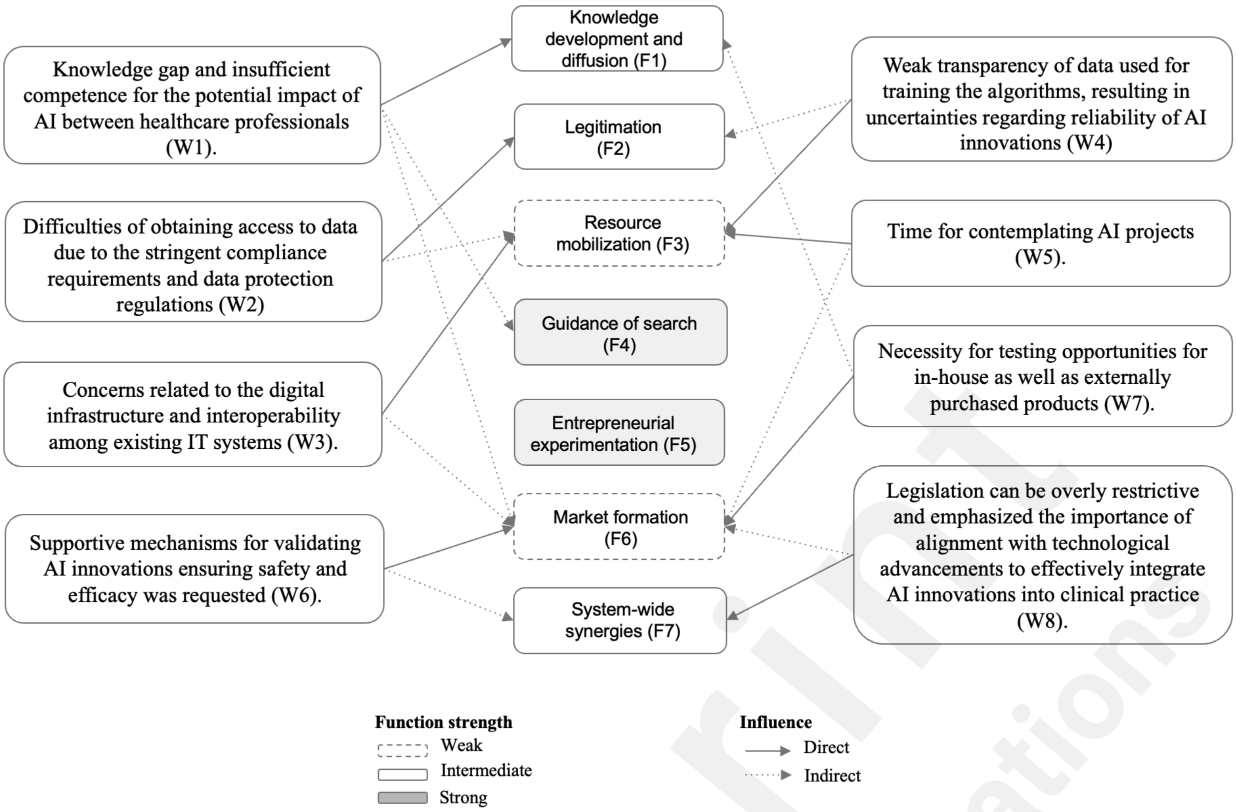

Figure 6: Function weaknesses or system blocking mechanisms for AI and AI-associated healthcare technology innovations.

Discussion and conclusions

This final part of the article discusses implications for policy and practice, together with some general conclusions.

Implications for policy interventions

Therefore, the overall system can be significantly enhanced by dealing with the weaknesses regarding its central functions. Establishing avenues for testing and validation may bolster market formation (F6). If validation yields illustrative use cases of implemented AI, this could lead to substantial improvements in both knowledge development and diffusion (F1), which could, in turn, influence legitimation (F2) and resource mobilization (F3). These functions are closely tied to institutional aspects such as laws and regulations, which may necessitate alterations. For resource mobilization (F3), the importance lies in the digital infrastructure, interoperability among existing IT systems, and increasing data quality and transparency. To reinforce knowledge development and diffusion (F1), a broader understanding of AI needs to permeate the organization, coupled with sustained collaboration efforts. The role of driven individuals throughout the operation, acting as pioneers in their respective professions, was emphasized as vital in this endeavor.

This study has highlighted that policy interventions and activities can target specific system-blocking mechanisms to enhance innovation system performance. Some interventions pertain to the overall system, such as a thorough assessment of existing legislation to streamline institutional alignment. The primary constraints identified include deficient technological infrastructure, lack of testing and validation facilities, and a low level of AI competence in parts of the organization (demand side), undermining the continued development of the innovation system.

The absence of a comprehensive database or registry containing approved AI medical devices in Sweden and Europe complicates the identification of external solutions [46]. The European Commission is currently working to develop the EUDAMED database, with the aim of enhancing transparency on medical devices available in the EU market [47].

Theoretical contribution

As highlighted above, there is limited literature applying the TIS framework within a healthcare context. This study has demonstrated the utility of the TIS in analyzing the dynamics within an innovation system specific to the healthcare sector, with a primary focus on a particular healthcare organization [5, 22, 23]. The analysis concentrated on the interactions directly involving the organization, leading to somewhat unspecified boundaries of the innovation system. Nevertheless, the TIS has proven to be a valuable tool for examining system dynamics. Previous examinations of innovation systems have shown that knowledge development and diffusion (F1), legitimation (F2), and resource mobilization (F3) are interconnected and establish initial conditions for the guidance of search (F4) and entrepreneurial experimentation (F5) [23, 48]. Moreover, it has been demonstrated that knowledge development and diffusion (F1) and entrepreneurial experimentation (F5) are independent of each other, and also provide the initial conditions for other functions (Apell and Eriksson, 2023). Our analysis confirms the interconnectedness between the guidance of search (F4) and entrepreneurial experimentation (F5) [22]. Our study also confirms that knowledge development and diffusion (F1) need to be strengthened to continue developing the overall innovation system once guidance of search (F4) and entrepreneurial experimentation (F5) are strengthened. Based on previous insights that the TIS undergoes innovation cycles [22], we confirm that interactions across the supply and demand side are needed in order for the innovation system to transform into a new stage. This insight is also provided by analyzing the long-term development of AI healthcare technology innovations by comparing our current study (demand side) with the previous study (supply side) within the same context [5]. Given that this study is a single-case analysis, further research is essential to assess and expand upon the functional dynamics within healthcare contexts. Additionally, incorporating indicators of function strengths based on both quantitative and qualitative data could enhance the depth and breadth of understanding of the assessment of TIS functions.

Limitations

A limitation of this study concerns its generalizability, given its reliance on a case study with a restricted dataset. Caution should be exercised when extrapolating the findings and drawing conclusions. Despite this, several aspects might be relevant to other contexts, particularly within different healthcare organizations. The study’s interviews were somewhat limited in number, and the participants, being individuals who are interested and knowledgeable about AI, may not offer a fully representative perspective of the entire organization. This selection was intentional, seeking to extract pertinent information efficiently from a confined interview pool. However, a broader range of interview subjects, including patients, IT professionals, and individuals with legal expertise, could have added value.

Concerning external product mapping, there is a risk of overlooking some approved products due to the absence of a comprehensive AI product database. Nevertheless, the general market conclusions likely remain valid. The subjective nature of assessing what qualifies as AI introduces an element of subjectivity. A more in-depth market analysis, delving into actors and their characteristics, could have enhanced comprehension. The study has predominantly focused on AI for clinical purposes, but exploring other AI applications for administrative and logistic functions could be insightful, as these might be more straightforward to implement. Lastly, given the rapid pace of advancements in AI and healthcare, some information may become outdated, particularly details regarding the external product market.

Conflicts of Interest

The authors report no potential conflicts of interest.

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Supplementary Files

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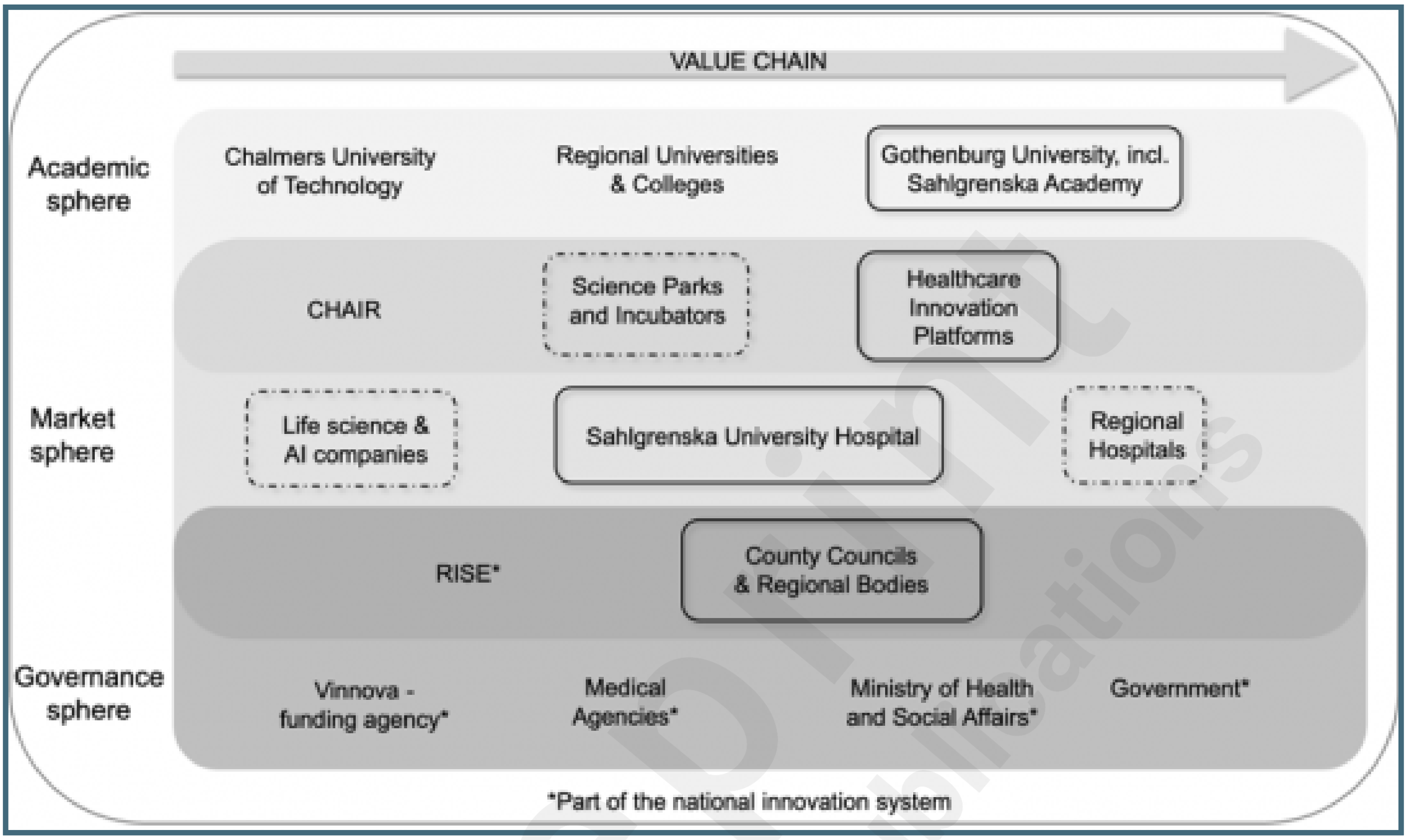
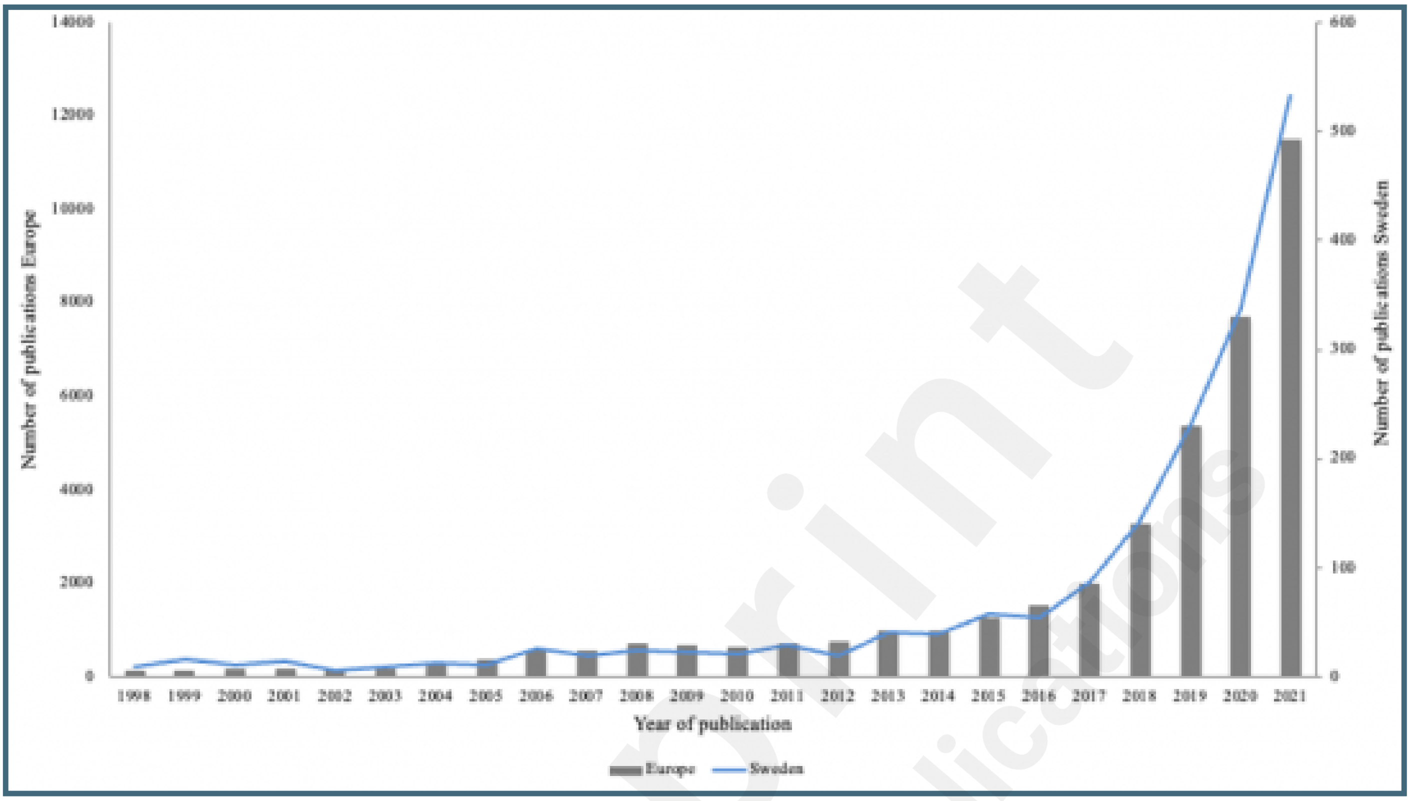
Figures

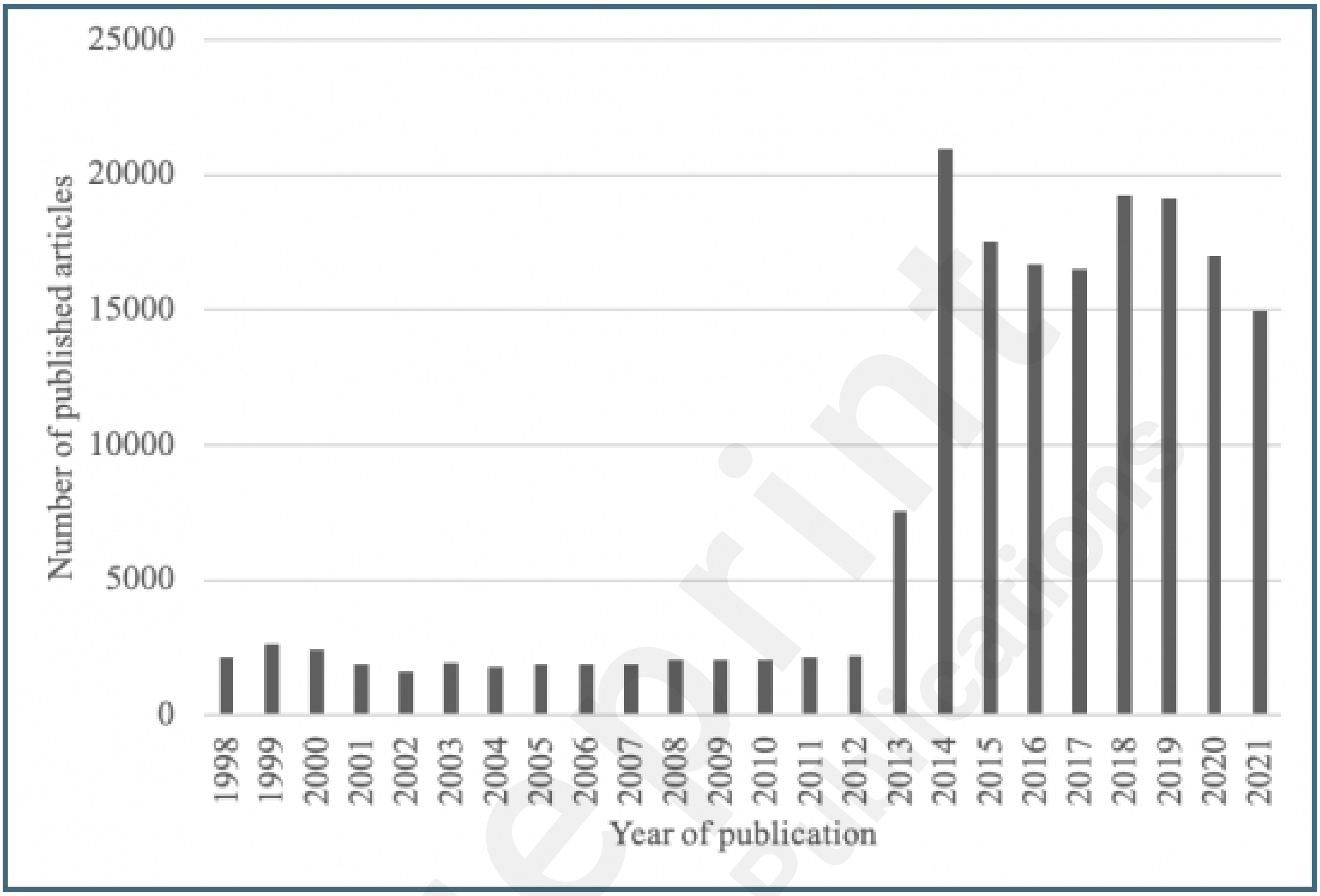
Selection of central actors, networks, and institutions related to AI technologies in a healthcare context. The boxes show the participants included in Phases I and II; the boxes with dotted borders show actors that were contacted, but were not selected for further interviews.



The number of published scientific articles addressing AI in healthcare in a Swedish and European context, 1998–2021.



The number of published articles in Swedish daily newspapers (1998–2021) related to AI innovations in a healthcare context.



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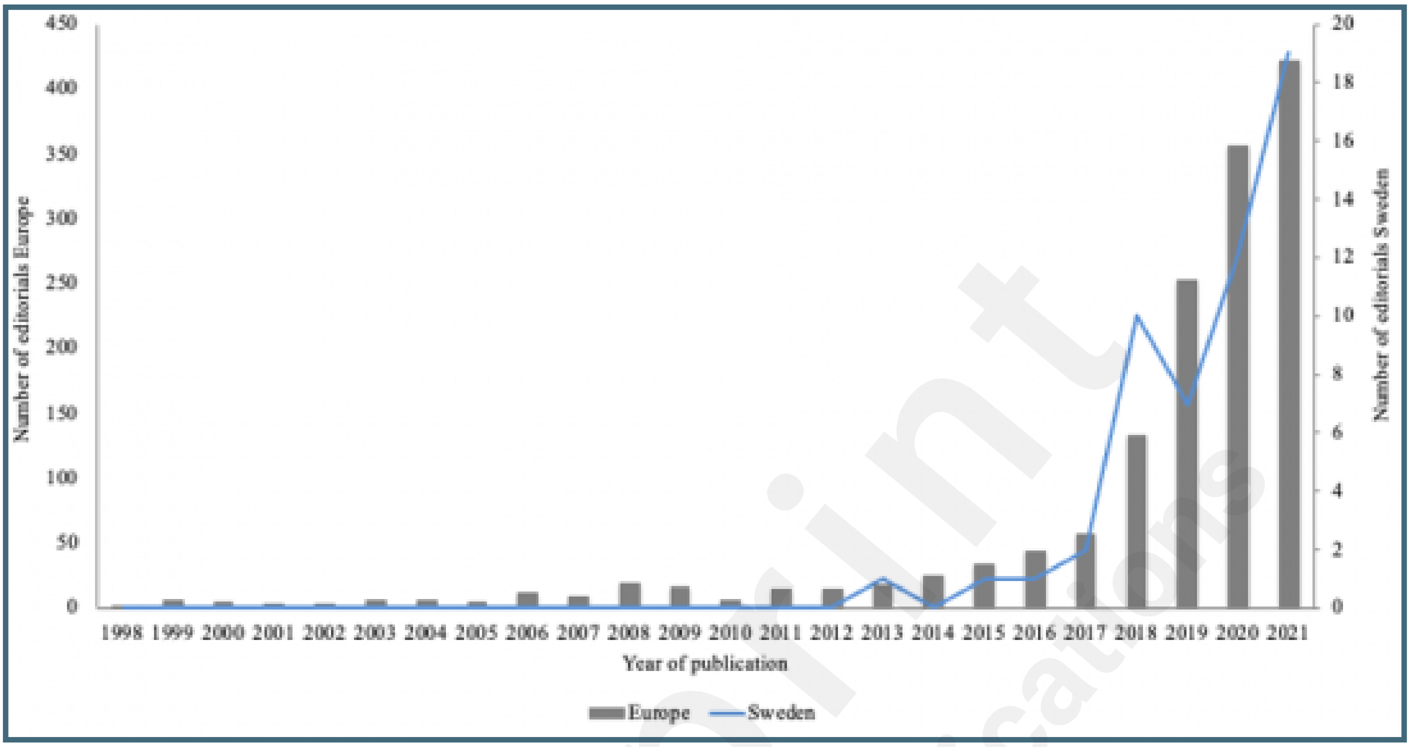
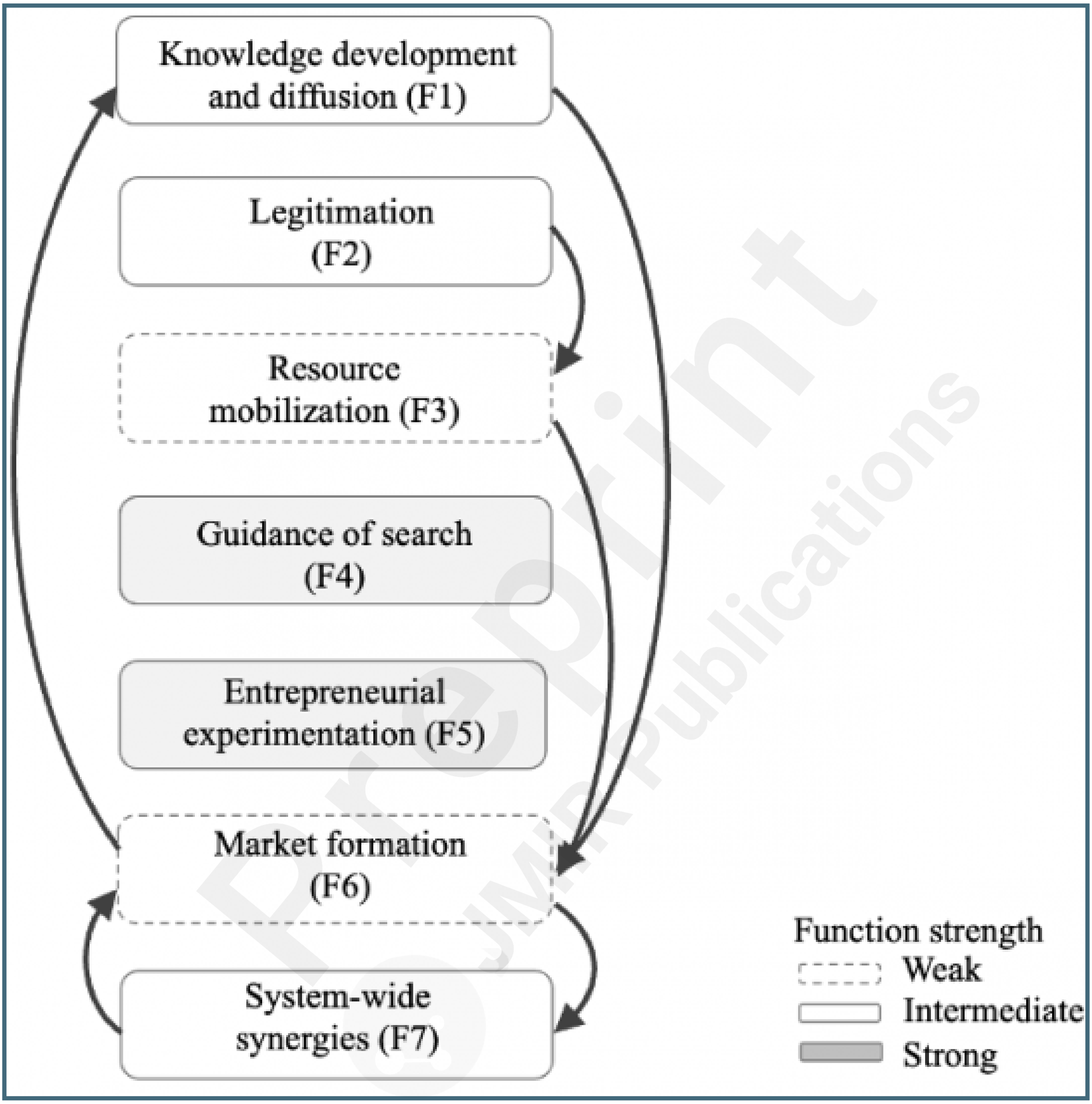


Illustration of the interactions and negative influences between system functions.



Function weaknesses or system blocking mechanisms for AI and AI-associated healthcare technology innovations.