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The influence of operative Clinical Decision Support System developers on the Dutch CDSS Innovation System

an analysis of the interplay between systemic hurdles experiences and system building activities success

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“Hiding within those mounds of data is knowledge that could change the life of a patient, or change the world.”

Atul Butte, Stanford

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Jonas Vermaas

ABSTRACT

This study analyses the difference in hurdle experience and system building activities by Dutch CDSS developers and how they influence the innovation system. By making use of a priori argument, this study addressed if public and private developers carrying out different activities, aiming for products with different socio-characteristics and therefore striving for a different institutional set-up. Theoretically, this study combined several analytical perspectives from the innovation literature to formulate a comprehensive view for researching the expected interactions. Using real-life insights of eighteen semi-structured with developers and institutional actors, this study found that both developers produce a mix of CDSS and carry out overlapping system building activities. The results showed that public developers only experience substantially less market-economic related hurdles and are better able to influence the system with successful activities. Yet, activities aimed at strengthening the guidance of the search and legitimacy creation were rather unsuccessful, explaining the formative phase of the innovation system. Given this and the aim for a mix of product types, explains the absence of the expected distinction between public and private developers strive. Overall, the findings of the study are framed within theoretical implications for similar analysis and managerial implications for the Dutch CDSS innovation system.

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LIST OF ABBREVIATIONS

CDSS = Clinical Decision Support System
EBM = Evidence Based Medicine
EHR = Electronic Health Record
EMA = European Medical Agency
MDR = Medical Devices Regulations
SBA = System Building Activity
TIS = Technological Innovation System

1. Introduction

A longstanding search in the formation of health care innovation policies is the creation of an innovative climate that result in technological development and successful breakthroughs (Herzlinger, 2006). The search for successful innovation policies feeds the discussion around the rightful balance between public and private actors (Mazzucato, 2011). Supporters of privatisation indicate that profit oriented actors in a price-based market will response quicker to specific healthcare needs then public actors, forming a good alignment between clinical demand and technological development (Herzlinger, 2006; Mcgregor, 2001). Generally private actors search for market opportunities by creating innovations that match with the market needs. Thus, their search is guided by the potency of the consumer base that requires the innovation. Criticisms of privatisation state that stimulating competition lead to a profit taking focus, that restricts Healthcare R&D investments to well-known areas (Mazzucato, 2011). Therefore, a pro-active role of public actors is required to achieve innovative breakthroughs in risky areas where private firms are unwilling to invest. Given this argument, public actors often start with performing basic-research that eventually could lead to sufficient knowledge to develop a feasible innovation. Looking at the activities performed by both type of actors indicates that they both stimulate technological development, yet the approach or strategy to reach their goal could be very different. These differences in actor strategies are conceptualised in the system building literature (Hellsmark, 2010). Focussing on the creation and modification of the broader institutional set-up of the system by entrepreneurs, in where technological development take place (Musiolik, Markard, & Hekkert, 2012).

The role of entrepreneurs in the emergence of innovations or technological developments is often analysed from a technological innovation system (TIS) perspective. This perspective is part of the wider innovation system literature that indicates that technological development is a complex process in collaboration with a much larger contextual environment. Noticeable in the innovation system are certain components, such as actors, or network of actors, institutions and the interaction between them (Markard & Truffer, 2008). Together they formulate the structure of the innovation system. An addition at this insight, is analysing the system functions that take place at the micro level or actor level within the system. System functions highlight the important processes that need to take place in an innovation system to successfully foster technology development and diffusion (Hekkert, Suurs, Negro, Kuhlmann, & Smits, 2007). Therefore, innovation systems can be analysed both in structural and functional terms (Hellsmark, 2010). Furthermore, actors within the innovation system are constantly developing new knowledge, by exchange knowledge and trying new applications what influences changes in the extent and depth of the knowledge field. This indicates that the general direction of the technological development within a TIS, is often an evolutionary process influenced by different kind of entrepreneurial activities (Hellsmark, 2010).

Activities carried out by entrepreneurs to strengthen the structure and the different system functions of an innovation system are defined as system building activities (SBAs) (Hellsmark, 2010). The ability to create and strengthen the structure as well as the functions formulates the 'transformative capacity' of the entrepreneur. The extent of the 'transformative capacity' is based on the abilities of the entrepreneur to change the institutional set-up of the TIS in a preferred way. Additionally, so called systemic hurdles can hamper activities of the developers. They are caused by exogenous factors, like for example new regulations, standardisation or new research-grants that reshape the current institutional set-up (Bergek, Jacobsson, Carlsson, Lindmark, & Rickne, 2008). Powerful actors, that have a high 'transformative capacity' can change the direction of the TIS in a preferred way and are often characterised by having access to sufficient resources or a strong network (Farla, Markard, Raven, & Coenen, 2012; Kukk, Moors, & Hekkert, 2015). They are able to formulate a strategy, based on their own strengths and needs, to overcome systemic hurdles and modify the current structure and dynamics of the system functions. Focussing on these SBAs and perceived system hurdles of present actors enables a better understanding on how developers behaviour, capabilities and resources influences the overall system performance (Farla et al., 2012).

The evolutionary study of Gittleman (2016) on medicine development identified two type of development strategies that are competing and both successful in the drug development innovation system. These so-called 'research paradigms' contrast in the way they develop and search for new medicines. From the 1950s, drug discovery was mainly done within Academic Medical hospitals by the 'clinical research paradigm' through applied research with observations of real humans. Later, from the 1970s, breakthroughs in the science of molecular biology shifted the focus to basic science R&D labs (Gittelman, 2016). This enhanced the occurrence of the 'theory-driven research paradigm' that was built upon theoretically understanding disease causality. The two

paradigms can be distinguished by their origin of the search (type of developers), either theory-driven (basis-research) or experiential from observations, and their timing and types of feedback mechanisms during development, resulting in different type of successful products (Gittelman, 2016). In the clinical research paradigms, medical innovations are developed by real-life observations providing the opportunity for direct feedback and guidance of the search right from the development phase. Contradictory, in the 'theory-driven' research paradigm feedback is only provided from intact human subjects entering the testing stages. Insights from this study indicates the occurrence of two successful 'research paradigms' or cumulative activities of actors within the medicine innovation system. Whereby, each paradigm produces a different type of product and address a different system building drive on how to set-up the complete system (Gittelman, 2016; Yaqub, 2017). Therefore, the perspective of 'research-paradigms' indicates the possibility of two competing institutional set-ups that both produce health innovation successfully, forming an addition to the current SBA literature.

A different healthcare innovation that is developed and diffused for a long time is a Clinical Decision Support System (CDSS). These software systems, are designed to provide health clinicians assistance with clinical decision-making tasks. Originated in the late 1960s, these systems were for a long time only developed and operative within a single public setting, like an academic hospital that is related to a university. This changed in the 1990s, when standardisation of the market took place by the introduction of a singular syntax (Wright & Sitting, 2008). From that moment, private firms started to enter the market as they identified new business opportunities. Nowadays, CDSS applications arise in different forms and being applied in many different medical fields both generated by private and public actors. CDSSs make use of large amount of data and link this with the real-life patient characteristics to formulate an advice in forms of alerts, predicted outcomes or recommendations. They are defined as an innovation that will play an important role in the future perspective of healthcare by stimulating personalised medicine, new treatments and improved monitoring forms (Londen Thomas & Dash, 2016). One exemplary that drew worldwide attention at the possibilities of CDSSs is the installation of the IBM Watson supercomputer at the American Cancer Society MD Anderson. This 2013 started project revolutionised the potential of artificial intelligence for healthcare by providing clinicians with accurate, evidence-based, treatment recommendations in a difficult field like oncology.

However, it turns out that despite all development activities and promising signs, overall CDSS clinical performance is still lacking. Many effectiveness studies made attempts in better understanding the current missteps of CDSSs (Garg et al., 2005; Hunt, Haynes, Hanna, & Smith, 1998; Jaspers, Smeulers, Vermeulen, & Peute, 2011). So far, these studies only focussed on the type of CDSS and implementation barriers without taken the activities of the developers and the broader innovation system into account. Therefore, this research will investigate the experienced systemic hurdles and SBAs of different CDSS developers. To eventually determine, the presence of conflicting projects or 'research paradigms', requiring or aiming for a different product type with a different need for institutional alignment (Hellsmark, 2010). Outcome of this study is likely to provide insights in the overall functioning of the system functions within the CDSS innovation system and will either confirms or weakens the a priori distinction between public and private developers by identifying how they are acting. This result in the follow research question

How do the experienced hurdles and carried out system building activities differ between operative CDSS developers and to what extent does this influences the CDSS innovation system?

A qualitative research is performed within the Netherlands to answer the research question, whereby multiple actors within the CDSS innovation system are being interviewed. The Netherlands is chosen as the geographical research area because of the innovation stimulating environment of the health system and due the limit time-span of this research and the travel constraints of the researcher. The Netherlands is the global seventh place in health expenditures percentage of GDP (OECD.Stat, 2016), indicating the high availability of financial resources. Also, the Netherlands remained on the first place of the Euro Health Consumer Index for the last three consecutive years that is based on health system outcomes. Together, this indicates the innovative environment by overall high quality of care and the high expenditures to flourish. Additionally, the presence of eight academic

universities - hospital collaborations and the availability of public research funds for health innovations[i], promotes the possibilities for different type of CDSS developers.

1.1 Relevance

This paper contributes directly to stream of literature that concerning with the development of medical innovations (Consoli & Mina, 2009; Yaqub, 2017). Also, it is part of the literature that aims for providing new valuable lessons in better understanding the concept of SBAs carried out by different type of developers (Kukk, Moors, & Hekkert, 2015). This studies specifically research how innovators carried out SBAs and system hurdles are related to the type of products that are created, the strengthening of the system functions and the 'transformative capacity' of innovators (Farla et al., 2012; Hellsmark, 2010). Researching the role of an or group of actors on a micro level in the functionality and institutional set-up of a TIS adds to the work of Kukk et al., (2016). Overall, from a macro perspective, is researched how possible misalignment of all SBAs influence the system functions of the TIS and therefore this study contributes to the TIS literature (Markard & Truffer, 2008).

Practically this studies adds a perspective on the search for successful CDSS development and dissemination (Garg et al., 2005; Hunt et al., 1998; Jaspers et al., 2011). So far, these studies mainly focus on the effectiveness of multiple single CDSSs without looking at the different type of developers, their activities and the broader contextual environment. This research provides new insights by researching the SBAs of active developers within the Dutch CDSS innovation system. Outcome of this research could provide beneficial insights for innovation policies to stimulate and coordinate specific forms of institutional set-ups to stimulate possible present 'research-paradigms'. Also, if found, it could encourage the breakdown of misaligned 'SBAs' that hamper the overall development and diffusion of CDSS in the Netherlands. Furthermore, the comprehensive framework that is formulated could be used at analysing other national CDSSs innovation systems or TIS's that focus on technologies in highly institutional and complex environments, to identify overlapping or competing 'research paradigms'.

The next section will provide a broad description on CDSSs, their development history, certain characteristics and possible classifications. Section 3 will discuss the relevant theories that are addressed by this study to form the comprehensive view and propositions on predicted hurdle experiences and SBAs. The methodological choices are described in Section 4, followed by the results of this study in Section 5. Section 6 provides a discussion with the implications, limitations, thoughts on future research and a conclusion. Finally, section 7 defines the conclusion of this research.

[iv] ZonMw is part of the Ministry of VWS (Health, Welfare and Sport) "Our aim is to promote quality and innovation of health research in order to make healthcare better and to keep it affordable" - https://www.zonmw.nl/en/about-zonmw/about-zonmw/

2. Clinical Decision Support System

Although there are many different CDSSs that have been developed for different healthcare purposes, overall a CDSS can be defined as a software program that is designed to be a direct aid to clinical decision making (Miller, Waitman, Chen, & Rosenbloom, 2007). For this purpose, individual patient characteristics are matched to a computerized clinical knowledge base, that incorporates a large amount of up-to-date evidence like systemic research combining RCTs, literature research, treatment guidelines and diseases databases. Based upon the match between patient characteristics and the available knowledge, CDSSs provide outcomes such as specific warnings, assessments or recommendations when clinicians facing a decision. By this method, CDSSs could be qualified as adapted systems that practice evidence based medicine (EBM) if the knowledge base continually reflects on the most up-to-date evidence from research literature and practice-based sources (Jaspers et al., 2011; Sim et al., 2001). By having access to much more up-to-date and diversified external evidence, clinicians that use a CDSS are capable to combine their individual clinical experience with a heavily richer source, than clinicians that only rely on their own individual experience. Preliminary testing confirms that using a CDSS enables general practitioners to reach higher (diagnostic) accuracy (Bates, Sheridan, & Overhage, 2001). Therefore, CDSS can be displayed as highly potential in contributing to substantially lowering medical errors and having a key role a future with more 'personalized medicine' characterized by individual precision diagnosis (Belard et al., 2017). Figure 1 displays an overview of a CDSS.

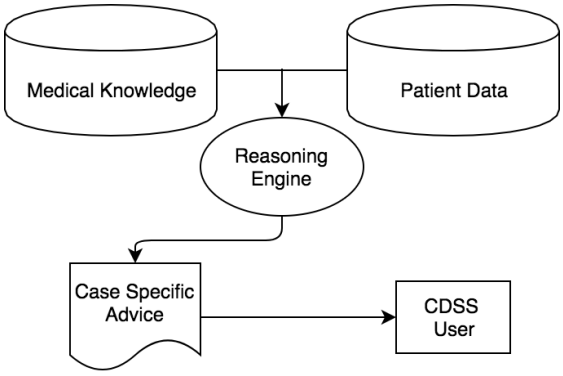

Figure 1. CDSS Figure

Although CDSSs are often indicated as a highly potential innovation in improving the healthcare quality, systemic review studies that have researched implemented CDDSs indicate that actual clinical practitioner performance and patient outcome is still quite diversified (Garg et al., 2005; Hunt et al., 1998; Jaspers et al., 2011). These studies provided multiple explanations for the variation in preliminary testing and actual clinical performance. First, CDSS performance seems to be higher if clinicians are prompted to use the CDSS, compared to clinicians that where initiated to use the system (Garg et al., 2005; Hunt et al., 1998) Second, if clinicians where involved in developing the CDSS, clinical performance is likely to be higher (Hunt et al., 1998). Third, technological specifications of the CDSS itself also influences clinical performance. For example data entry, communication style and delivery time of the advice by the system influence clinical performance (Jaspers et al., 2011). Also, different types of CDSS score differently in their clinical performance. Computerized Physician Order Entry (CPOE) systems for medicine ordering and alerting systems for abnormal patient's values or exceedance of practical guidelines systems contribute more to improving clinical care compared to more complex diagnostic systems. Clinical Diagnostic Decision Supporting Systems (CDDSS) formulate the best suitable treatments based on patient symptoms and characteristics. These kind of systems are often more advanced and provide more direct help in complex decision making (Belard et al., 2017). This means that potentially their contribution to improve healthcare could be much higher, when more often used or broader implemented.

2.1 Historical Overview

When tasks that could be executed by computers became more developed, health professionals started to anticipate and look for ways how they could be assisted by computers. The first concrete plans for real computer

assistance for general practitioners appeared during the late 1950's (Musen, Middleton, & Shortliffe, 2014). A few years later, the first CDSS prototypes were developed. From that moment, the development of CDSSs, followed trends from computer science into developing more intelligent and applicable CDSSs. This started with architectural development, from standalone decision DSSs in 1959, later on in more integrated systems from 1967, standards-based systems from 1989 and service models from the beginning of 2005 (Wright & Sitting, 2008). Despite the architectural distinction of systems, development for clinical intent, mechanisms of intervention and method for reasoning also spread out over time. Other fruitful axes in dividing these systems are reasoning method (rule-based, pattern-recognition, neural-networks etc.), clinical intent (diagnosis, therapy, prevention, public health managing etc.) and mechanisms of intervention (alerts, reminders, recommendations and information based). The most prominent influence was the introduction of artificial intelligence during the 1970's, created promising CDSSs that could provide accurate advice with a smaller evidence base by becoming self-learning systems (Patel et al., 2009). Over time, four different categorical steps can be defined based on the architectural structure of the systems which are displayed in Table 1. Nowadays, step 1 stand-alone systems are even still being developed (Wright & Sitting, 2008).

Classification		Description
1.	Standalone DSS	Limited to a single area of medicine that would run separately from any other system. In this case, the GP must enter data manually about the case and then read and interpret the results.
2.	Decision Support integrated into Clinical Systems	Integration with other clinical information systems operating in the hospital settings and dealing with a wide variety of clinical areas. Advantage is that GP's do not have to re-enter available information and can operate without user seeking assistance.
3.	Standards for Sharing Decision Support Content	Standards to represent, encode, store and share knowledge. This created the opportunity to overcome disadvantages of the natively integrated DSS (phase 2). Created the opportunity to share information between different, CDSS to enlarge the evidence base. Limitation is that there are different standards to choose from.
4.	Service Models	Improved version of CDSS that follow standardized interface in front of the CDSS like API, SAGE or SEBASTIAN. These systems recombine clinical information system (e.g. EHR systems) and CDSS into an integrated decision support system.

Table 1. CDSS Historical Classification

2.2 Evidence Based Medicine

A major influence in lowering medical errors has been the introduction of EBM that stands for providing a base for decisions and actions made by clinicians in the healthcare. The major principle of EBM is that these decisions and actions should be based on the best available evidence, intergraded from individual clinical expertise and the latest available external evidence to ensure optimal clinical care (Sackett & Rosenberg, 1995). Internal expertise is based on the proficiency and the judgement that individual practitioners have acquired over time. External clinical evidence is based on systemic research by combining multiple randomized controlled trials (RCTs), (historical) patient data and laboratory-based evidence (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996). By making sure that clinical decisions are based on internal and best available external evidence, EBM has the ability to improve the quality care system by providing a base for picking the best treatments and therefore reducing medical errors (Grol & Grimshaw, 2003; Sackett & Rosenberg, 1995). Consequently, lowering medical errors means recovering cost that are made by ineffective practice what should contribute in lowering overall healthcare costs (Pagoto, Spring, Coups, & Mulvaney, 2007; Rosenberg & Donald, 1995). However, a recently deployed report from the Netherlands indicate that still 18.4% off al medical errors that have been discovered in 2008 and 2012 could be prevented (Langelaan et al., 2013). In 77% of these cases, medical errors are partial caused by incorrect use or application of available knowledge by general practitioners, indicating that proper integration of EBM is still deficient (Pagoto et al., 2007).

3. Theoretical Framework

This chapter addresses the public and private distinction, the relevant literatures and combines them to formulate a comprehensive framework to research the Dutch CDSS innovation system. Subsequently, propositions are defined for the private and public CDSS developers. Propositions are formed for the expected experienced hurdles, carried out SBAs and their success in the evolvement of the entire system.

Public and Private developers

As initiated in the introduction this studies used the a priori argument, for the distinction between public and private CDSS developers. This distinction is based on the presence of a profit-mined focus of the CDSS developer. The Dutch Healthcare system is a public-private healthcare system where actors are present with either a profit or non-profit focus. Together they compete in providing health-care activities and developing medical innovations. Non-profit actors are for example foundations, universities or health-care providers (e.g. general practitioners or medical specialists) that develop medical innovations. Private actors are organisations (e.g. start-ups, Small-Medium Based firms or multinationals) that develop medical innovations. Hospitals and other non-private healthcare providing organisations in the Netherlands are privately run but non-profit foundations and therefore indicated as public developers within this research.

This distinction will be used to define propositions for both type of groups related to the expected experience of the system hurdles and the carried-out SBAs. Important to keep in mind is that this distinction is chosen because of the literature polarised discussion and therefore expected that these different types of actors strive for a different type of product and institutional set-up.

3.1 Relevant Literature

Innovation Systems

Innovation system scientists look at technological development from a broad perspective and state that the development is embedded within a systemic process. Freeman (1987) and Lundvall (1992) initiated the analytical concept of innovation systems thinking, by defining the National Innovation System. Lundvall (1992) defined this system as "… constituted by elements and relationships which interacts in the product, diffusion and use of new, and economically useful, knowledge and that a national system encompasses elements and relationships, either located within or rooted inside the borders of a nation state." So, the innovation system thinking acknowledge the role and the interplay between present system components: actors, institutions and network. Innovation, or technological development, in this sense, is a result of complex interactions between the system components. When alignment between the components is reached, the system can foster technological development. On the other side when there is misalignment between the system components, the system can form hurdles for further innovations (Freeman, 1997). As national innovation systems, focus on the interplay between components to promote technological development and economic growth within national borders, technological innovation systems (TIS) place their imaginary boundaries around the jointly interaction in a specific technological field. Markard & Truffer (2008) define a TIS as following "… a set of network of actors and institutions that jointly interact in a specific technological field and contribute to the generation, diffusion and utilization of variants of a new technology and/or new product". Therefore, a TIS framework can be used to analyse the dynamics that are involved in the creation of a new technology by analysing the interaction between the present components (e.g. innovators, firms, universities, institutes etc.).

System Processes

To understand the causal mechanisms that occur within an innovation system, certain key processes that are related to innovation development and diffusion are defined by the studies of Hekkert et al., (2007) and Bergek et al., (2008). These so-called system function help identifying how an innovation system functions, by finding activities that foster or hamper the generation and diffusion of innovations. Identifying these functions make it possible to assess the positive or negative influence of each function on the performance of the entire system. Table 2 provide an overview of the different functions and a brief explanation based on the work of Hekkert et al., (2007)

Key Functions		Explanation
F1.	Entrepreneurial Activities	New entrants or diversified business strategy of already existing components that translate knowledge into business opportunities and eventually innovations
F2.	Knowledge development	Learning activities that stimulate the creation of new knowledge e.g. R&D Projects, patents and investments in R&D
F3.	Knowledge exchange	Diffusion of new knowledge among actors via networks, meetings, conferences on a specific technology topic
F4.	Guidance of the Search	Relates to the activities that positively affect the needs, requirements and expectations with respect to support the direction of the emerging technology
F5.	Market Formation	Nice markets, tax regimes and new standards to create a competitive advantage for novel technologies
F6.	Resource mobilisation	Allocation of financial, human capital and complementary assets to make knowledge production possible for a specific technology
F7.	Creation of Legitimacy	Relates to the activities that counter incumbent resistance to the emerging technology by urging authorities and important system actors to reorganise the institutional configuration of the system

Table 2. System Functions

System building activities

Hellsmark (2010) state that actors in form of individuals, institutes, policymakers, alliances of actors and even network of actors within a TIS can execute SBAs. System Building Activities are intended at building or strengthen the system structure, as well as the several system functions in an emerging innovation system (Hellsmark, 2010; Kukk et al., 2016). These activities aim at changing the institutional set up of an innovation system by strategically spot uncertainties or address weaknesses of the current system. Successful SBAs are often associated with a strong muscle to shape the system in a preferred way (Kukk et al., 2016). This is done by either changing the current set-up of institutions or by creating new preferable institutional rules of the game. Success of these SBA approaches by different actors is mainly based on the available resources for the specific actors that perform the building activities (Farla et al., 2012). Degree of success is formulated by the concept of 'transformative capacity' as means of the extent and limits of the system builders in creating and strengthening the structure and various functions of an innovation system (Hellsmark, 2010).

Important for this research is that these type of activities can occur on different conflicting projects or present 'research paradigms', requiring or aiming for a different type innovation or product with an different need for institutional alignment (Hellsmark, 2010). In the case of CDSSs, this indicates that different type of actors or system builders can aim for different goals and different aligned institutional set-ups to achieve those goals. Therefore, the aim of this research is to identify the SBAs of private and public actors and if they align, partly overlap or differ. Either by individual approaches or within a kind of alliance or network structured form. When these two type of system builders are aiming for different goals and both be successful in a different way, the presence of multiple CDSS 'research paradigms' can become acknowledged.

System Hurdles

In the way that SBAs of developers aim for influencing the broader institutional system towards a preferred way of product development and diffusion, endogenous changes that occur in the system or exogenous accidents from outside the system can influence the speed and direction of technological development. These (institutional) changes can influence the structure and functions of the innovation system. Indicated by Freeman (1997), alignment between the institutions and the technology is necessary to foster technological development. Therefore, given this statement, occurrence of misalignment due institutional changes can formulate a hurdle for further development (Bergek, Jacobsson, et al., 2008). Thus, when developers are hindered by these changes their contributions to the technological development can be limited. Consequently, institutional changes or systemic hurdles can practically provide a hindrance for developer A and simultaneously provide business opportunities for developer B. In other words, hurdles can have different 'heights' for each actor or group of actors and therefore limiting actors differently in their SBAs towards their desirable institutional set up. Knowable for this research is that the expected 'heights' of the systemic hurdles can be different for public or private developers as they reach for different products and aligned institutional set-ups. For example, a

restriction in governmental grants for medical IT applications can formulate a higher hurdle for public actors, as they are might be more financially dependent compared to the private actors with more consistent financial resources. This creates opportunities for private organisations to increase their market share and consequently influence the evolvement of the CDSS innovation System.

So, researching mutually the systemic hurdles and carried out SBAs of both public and private CDSS developers and link these to the systemic functions will provide insights in the evolvement of the entire innovation system. The systemic functions are influenced by both type of interactions (SBAs → System Functions & Systemic Hurdles → System Functions) and height of the system hurdles and 'transformative capacity' of the developers.

Analytical Choices

Two analytical choices are made to categorise the different hurdles and carried out SBA with the aim to keep a clear overview of the two type of interactions.

Consoli & Mina (2009) have created the Health Delivery Innovation System based on the work of Freeman. This analytical framework defines the presence of spheres where the system actors are active in. They define a technological/scientific sphere were knowledge is developed, exchanged and product development take place and the clinical sphere were where the patient-practitioner relationship takes places. These two spheres are guided by an outer institutional sphere that defines the regulations and institutional pressures (Consoli & Mina, 2009). Market-mechanisms or competition is incorporated in the institutional sphere of the Health Delivery Innovation System. However, competition or the creation of market-opportunities form a stimulating factor in carrying out a SBA, as developers with a lot of resources are better able to influence the structure of the system (Hellsmark, 2010). Therefore, this study makes use of an adjusted analytical tool to research the CDSS innovation system, where the market-economic mechanisms are defined by an own sphere. Adding this component, provides the possibility to identify relevant differences in how public and private developers experience systemic hurdles and carry out SBAs to influence the systemic functions present in the innovation system. Figure 2 displays the adjusted analytical framework with the tree different separate spheres and the institutional outer sphere that is being used in this study to categorise the hurdles and carried out SBAs.

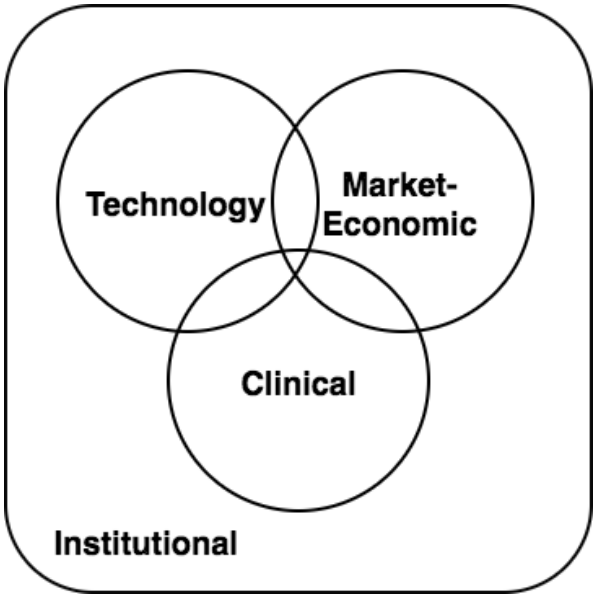

Figure 2. Analytical Spheres

Regarding the different system functions that system builders can address, Hellsmark (2010) indicate that system builders are able to address or strengthen three categorical set of the system functions besides by aiming at them directly. Hellsmark (2010) divides the system functions that deal with knowledge creation in two epistemologically distinct categories: "know - about" and "know - how" based on the literature of Grant (1996). The first category, knowing about, indicates the relative easily codified knowledge that is transferable between humans as information across time and space. In this category, the ease of communication is a fundamental

property (Grant, 1996). More tacit knowledge, that is hard and costly to transfer is categorised by the "know-how" set of activities. So, the "know-how" set formulates the science and technology infrastructure of the TIS and is strengthen by basic research [F2 & F3], experimenting and testing new ideas [F1]. Demonstration of the opportunities of the technology, influencing the perceived expectations [F7] and further alignment of the structure of the technology development [F4] is facilitated by the "know-about" set of functions. At last, the set of "enablers" has the purpose to facilitate the other two set of functions and the system by mobilising resources [F6] for the general structure as well as including the entry of new firms and by identifying new market opportunities [F5] (Hellsmark, 2010). The tree different sets are displayed in Table 3.

Categorical Set	System Functions
"Know-how"	Entrepreneurial experimentation [F1], Knowledge development [F2], Knowledge Exchange [F3]
"Know-about"	Guidance of the search [F4], Creation of Legitimacy [F7]
"Enablers"	Market formation [F5], Resources Mobilisation [F6]

Table 3. Categorisation of System Functions

3.3 Comprehensive View

Combining the relative literature and analytical frameworks, creates insights at a micro level on developer specific interactions with the system functions of and overall how this influence the entire system on a macro level (Mina, Ramlogan, & Metcalfe, 2007). Criticism on the innovation system literature is that analysing from a macro perspective results in overlooking the micro agency-sensitive activities of key actors that form the functionality of the system (Hellsmark, 2010). Therefore, analysing from an actor level provides better understanding in how different strategies, capabilities and resources of different actors influence the overall system performance (Farla et al., 2012). These two types of interactions form the basis for the comprehensive framework that is being used to analyse the performance of the CDSS innovation system.

3.3.1 Comprehensive Framework

This two-way influential interaction is displayed in Figure 3. The arrows of the public [PU] and private [PR] SBAs indicate the direction of the preferred institutional set-up that can (partly) overlap each other and/or (partly) contradict each other. The dotted arrows indicate the systemic pressures that are caused by exogenous pressures. Overall, these interactions influence the entire system (the cloud) and its evolvement (dotted pathway of the cloud). The evolvement of the system is not researched within this study. The subsequent sections will further estimate the overlap and difference in the systemic hurdles and building activities for the two type of actors.

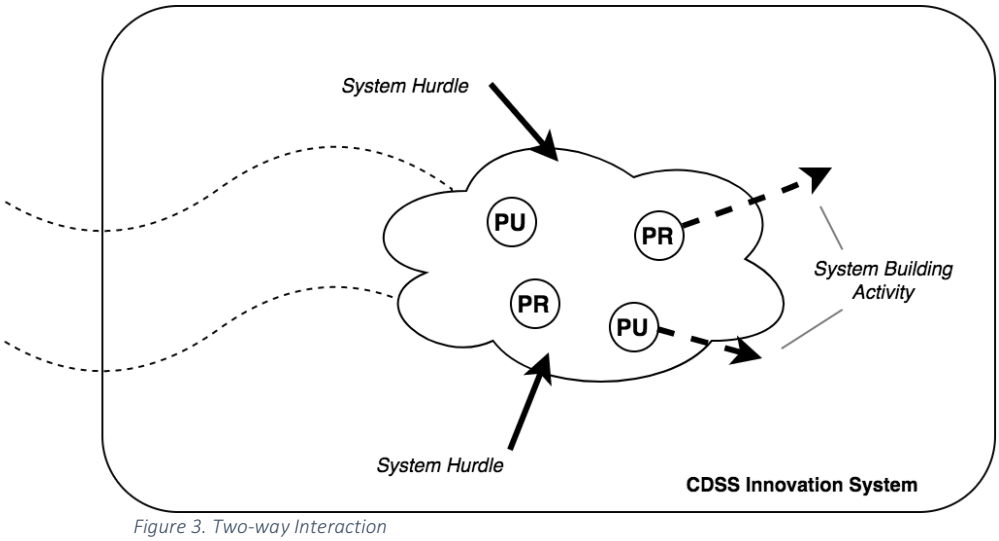

Figure 3. Two-way Interaction

3.3 Expected hurdle experience and carried out System Building Activities

The next sections frame the systemic hurdles and SBAs founded within each sphere for the two type of actors. Although SBAs are described below for a certain sphere, the initial idea for carrying it out can be aimed at one or multiple spheres. For example, redesigning or further developing the CDSS (know-how) can focus on enhancing technological performance (technological sphere) and solving users stated problems (clinical sphere). For this reason, the SBAs propositions are not linked to a specific sphere.

First the expected hurdles and SBAs are described for each sphere resulting in two sets of propositions. Second the expected success of the SBAs is defined, ensuing the third proposition. At last, different propositions will be combined and displayed in Table 4.

3.3.1 Technological sphere

The first stage of product development starts with having access to a certain amount of technology knowledge to develop a working decision supporting device. Since 1950, in where the first articles where published that address health professionals being assisted by machines, experimental prototypes where developed (Musen et al., 2014). The development of these systems, followed trends from computer science for developing more intelligent CDSSs, starting with standalone decision DSS in 1959, later on in more integrated systems from 1967, standards-based systems from 1989 together with the entry of private firms and service models from the beginning of 2005 (Wright & Sitting, 2008). Nowadays, different types of CDSS systems are produced which indicates that technological knowledge to create a CDSS is easily be gathered by both type of CDSS.

An expected difference is found in the number of users that either public or private developers try to address with their CDSS. For example, many large private electronic health records (EHR) suppliers develop clinical decision support instruments that become add-on's in their information systems. In the Netherlands 89% of the general practitioners have some form of clinical decision support available in their EHR (Medlock, Eslami, Askari, & Brouwer, 2013), indicating the focus of private developers to create CDSSs that can be operative in many different health-settings (Wright et al., 2009). On the other hand, public settings are often indicated as the early-movers in developing a new technologies (Mazzucato, 2011). In the case of CDSS this means new reasoning method or medical task executed by the CDSS application, by developing a home-grown systems within a single-healthcare setting (Roshanov et al., 2013). These systems are often not commercialised and specified to the specific wishes of the healthcare setting it is developed for. A famous example in the Netherlands is the development of Gaston, a CDSS that is designed in the Catharina Hospital Eindhoven in collaboration with the Technological University Eindhoven. Gaston was designed because clinicians requested a tool that could provide support in medicine prescribing by taking the current patient status into account (De Clercq, Blom, & Hasman, 2000). Nowadays, the initial idea of Gaston is formed into an architecture that contains a set of reusable software components for the application of guidelines that is being used in nation-wide CDSS. This difference in producing generic or more specific new forms of CDSS indicates that public CDSS developers more often carry out "know-about" SBAs by addressing new forms of CDSS, new medical fields or reasoning methods. Contradictory, private actors are more likely to prove the technological functioning of new type of CDSS, by implementing the system on a larger scale. This strengthen technological guidance of the search and legitimacy creation, so initiating "know-about" type of activities within the technological sphere.

A major concern relates to incorporating access to real-life patient data within the CDSS. Possible forms of doing this are creating a data-extraction bridge between the CDSS and the EHR system whereby the CDSS can function as an independent instrument. Another form is by integrating the CDSS into the user-interface of the EHR, which let it run unnoticed at the background during a consult. Having at least incorporated one of these two forms is often labelled as an important feature of a successful CDSS (Belard et al., 2017; Jaspers et al., 2011). Yet, this seems more difficult as expected and therefore many CDSS still run as a stand-alone software program that requires double entry of the clinician to function. Besides private EHR suppliers that develop CDSSs add-ons that are not hindered by this hurdle, all other CDSS that are developed by both type of developers need to overcome this technological hurdle.

Thus, building activities of public actors are more often aimed at broaden the scope of clinical fields supported by a CDSS application and integration with other medical software programs, like EHR. On the other hand, private developers strengthening the current possibilities by aiming for generic products. This result in the following proposition:

Proposition 1a: Public and private developers are likely to experience similar hurdles within the technological sphere

Proposition 2a: Public developers are more likely to perform "know-how" system building activities compared to private developers within the technological sphere

Proposition 2b: Private developers are more likely to perform "know-about" system building activities compared to public developers within the technological sphere

3.3.2 Market- Economic Sphere

Gathering financial, material, human capital and complementary assets belongs to resources mobilisation system function and is considered as an important function that supports the other system-functions (Hekkert et al., 2007). Gathering financial resources seems to be a problem for public developers, during mobilisation before development but also generating revenue streams after implementation. In 2005, the CDSS review study of Garg (2005), including more than 100 CDSS systems, indicated that most CDSSs used research funding to facilitate their development and implementation. This indicates that public developers deal with difficulties to commercialise their system and that the financial revenues created by a pubic CDSS are limited. Furthermore, the effectiveness study of Roshanov et al., (2013) that researched 162 CDSSs in the United States indicated that commercial systems present only 21% of the supply market, however covering almost the entire demanding market. Concluded from these facts is that the creation of a feasible business model to mobilise financial resources is rather difficult for public developers (Subramanian et al., 2007; Wright & Sitting, 2008). Reasons for this could be the dependency on grants among public developers and the larger (research) budget, market experience from their product-portfolio and more financial risk-taking mind-set private actors. This indicate that public developers experience more difficulties in gathering financial resources. Furthermore, the large coverage of the market and the production of generic CDSS types by private developers indicates market formation activities showing the practical possibilities to the public. Eventually, this growth stimulation by private developers lead to a higher availability of financial resources in the CDSS market that can strengthen the other type of system functions (Bergek, Hekkert, & Jacobsson, 2008).

Contradictory, creating a fully operative CDSS requires access to complementary assets like medical knowledge or patient data. Enough (historical) patient data is required for machine-learning reasoning based CDSS to train and test the accuracy of the decision system. On the other hand, rule-based CDSS require expert-opinions or medical guidelines to full their knowledge-base. All public healthcare providing CDSS developers e.g. medical specialist or general practitioners, generate this type of knowledge during their daily work routines. This creates permanent access to medical knowledge for their developed CDSSs to either test, validate or refine it. Besides, sharing medical data is subjected to very strict privacy regulations and therefore limited available by those firms that are not able to acquire this within their organisation.

Taken the importance of having access to financial resources and complementary assets, it can be indicated that both type of developer's experience benefits and struggles. Besides, the market stimulation activities of private actors resulting in the follow propositions:

Proposition 1b: Public developers are more likely to experience a financial capital mobilisation hurdle compared to private developers within the market-economic sphere.

Proposition 1c: Private developers are more likely to experience a complementary assets mobilisation hurdle compared to public developers within the market-economic sphere.

Proposition 2c: Private developers are more likely to perform "enablers" system building activities compared to public developers within the market-economic sphere

3.3.3 Clinical Sphere

Successful implementation of CDSSs and achieving a high level of adoption by end-users within a clinical settings still seems to be one of the largest hurdles to overcome, as many systemic reviews indicate this as a crucial problem (Belard et al., 2016; Jaspers et al., 2011). The diffusion of CDSS often result in resistance by clinicians, that is caused by contextual challenges like dissemination among different clinical settings (departments) and ease of implementation (Haynes & Wilczynski, 2010). Especially, if the clinicians are prompted to use the CDSS, compared to clinicians that where initiated to use the system (Garg et al., 2005; Hunt et al., 1998). So, a certain involvement of individuals in the innovation development process should enhance the implementation success

and will increase user acceptance. Therefore, CDSS that are already developed in a public health setting are more likely to be developed with larger involvement of clinicians and accordingly resulting in higher general acceptance. Thus, CDSS developed by public actors like medical specialist or general practitioners or by actors in close relation to end-users are likely to experience a lower systemic hurdle in the clinical sphere. In this sense, demands by clinicians are better expressed towards public developers as they are in closer relation with the clinicians. This closer relation by public developers enhances the mutual understanding of clinical needs and CDSSs capabilities within the CDSS innovation system, representing "know-how" type of activities. The implementation hurdle and user-producer interaction component building activities within the system are expressed in the following propositions:

Proposition 1d: Private developers are more likely to experience hurdles compared to public developers within the clinical sphere

Proposition 2d: Public developers are more likely to perform "know-how" system building activities compared to private developers within the clinical sphere

3.3.4 Institutional Environment

Considered important institutional forces that can pressure system components are legitimacy, interest groups, and regulations (Mendel, Meredith, Schoenbaum, Sherbourne, & Wells, 2008). In the creation of legitimacy, CDSSs often follow the principles of evidence-based medicine (Jaspers et al., 2011). This institutional pressure, demands CDSSs knowledge base to be derived from and continually reflects on the most up-to-date evidence from actual patient-data or research literature. Although EBM is widely accepted and seems a fairly common sense solution, prove of successful implementation of CDSSs that use EBM is still weak and seen as a key aspect for future CDSS research (Jaspers et al., 2011). In this sense, both type of actors deal with this lack of legitimation as an institutional hurdle. However, private developed CDSS often address a larger consumer-base and that is unknown on beforehand. This indicates that private developers need to perform more legitimacy strengthen activities to persuade potential consumers to use the system, leading to a higher requirement of "know-how" activities by private developers.

Looking at institutional pressures caused by interest groups, it appears that the demand for CDSS clinical care performance has changed over the years. Aiming for (higher) diagnostic accuracy is been the foremost focus over the years. Yet, recent tested CDSSs, developed after 2000, seemed not any more effective than those tested earlier (Bates et al., 2001). This could indicate that either performance limitations are reached or other clinical demands became important, for example better accessible by mobile devices or smoother integrated within current workflow (Roshanov et al., 2013). This is often privileged by private EHR developers, that are adding more standardised decision support in their EHR systems and therefore in the daily work-routine of the clinician. Adding these components that often work on the background in the EHR, also strengthen the idea of "know-how" activities of private-actors by responding to new important values.

Hurdles caused by regulations address every CDSS developer, for example data protection authorities that ensure privacy laws. A new law that will be settled in 2018, obliges firms that work with electronic patient-data to even more stricter regulations and ask for prove that data is handled responsibly (Europese Unie, 2016). Also, certain certifications, like the European CE marking, are required and related to the liability of the product. At last, the European Medical Agency (EMA) have just released that CDSSs in 2020 will fall under the newer stricter regulations MDR (European Union, 2017). When these regulations will be introduced, CDSSs needed to be handled similarly as other medical devices and require for example randomized controlled trials to prove a certain diagnostic accuracy. Together this ends in the following propositions.

Proposition 1e: Public and private developers are likely to experience similar hurdles within the institutional sphere

Proposition 2e: Private developers are more likely to perform "know-about" system building activities compared to public developers within the institutional sphere

3.3.6 System Building Activities Success

Although all SBAs have some purpose to strengthen the innovation system in a preferred way, actually transforming the system requires a certain amount of 'transformative capacity' of the system builder (Hellsmark, 2010; Kukk et al., 2015). This muscle or capacity to transform the established institutional setting can be created by heaving enough access to resources, knowledge or by forming alliances with other system actors (Farla et al., 2012). This caused the opportunity to strengthen individually or collectively certain elements of the innovation system. Contradictory, accomplishing actual change can be limited by resistance of opposing interest of deliberate actors or by the current technologies developers that strengthen the current set-up (Hellsmark, 2010). Therefore, transformative capacity is not only based on network activities and having access to a certain amount of resources, but also the possibilities to identify weakness and uncertainties in the current institutional set-up that can be addressed to stimulate change of the innovation system.

A previous case study by Kukk et al., (2016) researched the SBAs of a drug developing company in a highly-institutional and complex environment. The results indicated that the pharmaceutical firm acted as a powerful institutional entrepreneur to create a market for their drug by influencing the health-care system in England. An important addition to the concept of SBA is that they demonstrated that sometimes SBAs are not directly intended to realise institutional change but are required for institutional change to take place. In this sense, these activities can be seen as necessary preparatory steps to achieve critical mass and gaining momentum that proved to be critical in realising institutional change (Kukk et al., 2016).

Like described by the study of Garg et al., (2005), several private developers are able to cover roughly the entire CDSS market. Besides organisations that have CDSS as their core business, also other firms that have other core-product lines like Health Innovation System or decision support software entranced the market. Especially, those developing organisations that have access to financial sources and manage or collect medical data experience less limitations or resistance to design the entire CDSS to their preferred way. In this sense, confirmed by higher estimated "know-about" and "enablers" activities, private developer seems to have a higher 'transformative capacity' to transform the Dutch CDSS innovation system. This result in the last proposition.

Proposition 3: Private developers are more likely to carry out successful system building activities compared to public developers

3.4 Propositions Overview

Combining the different propositions that are formulated in the previous sections result in three main propositions that will be tested within the data-analysis, Table 4 displays the main propositions.

Spheres	*Hurdles*		*System Building Activity*		*System Influence*
	System → Developer		Developer → System		Developer → TIS
	First set of propositions		Second set of propositions		Proposition 3
Technological	P1a	Public: (±) Private: (±)	P2a P2b	Public: Know-How (+) Private: Know About (+)	Private: Success (+)
Market-Economic	P1b P1c	Public: Financial Capital (+) Private: Comp. Assets (+)	P2c	Private: Enablers (+)	
Clinical	P1d	Private (+)	P2d	Public: Know-How (+)	
Institutional	P1e	Public: (±) Private (±)	P2e	Private: Know-About (+)	

Table 4. Propositions Overview

4. Methodology

4.1 Study Design

The Aim of this research was to get insight in the different hurdles that CDSS developers experience, the SBAs they carry out and how this influences the entire CDSS innovation system. The geographical delineation was set to the Netherlands Healthcare System, which was chosen for three reasons. The first reason is the health innovative climate (eight academic-hospitals, top-10 ranking in the health expenditures percentage of GDP). Second, the over-all positive attitude of Dutch clinicians towards CDSSs (Medlock et al., 2013). Third, because of distance constraint to complete the research within given limited time-span. To obtain these insights, a comparative case study design was set-up in where private and public CDSS developers were being examined. A comparative study design was chosen as this is most suitable in understanding social phenomena when they are compared in relation to contrasting cases, in this situation CDSS developers (Bryman, 2012). The study was performed on a sample set of these actors, to represent the whole spectra of involved developers and system actors. Likewise, the unit of observations were single developers and actors that function as a system actor with the CDSS innovation system. The unit of analyses were the system hurdles and SBAs of Dutch CDSS developers. The study has been performed in a qualitative manner by a deductive focus, in where the formulated theories were tested on the Dutch CDSS innovation system. Data was collected through semi-structured interviewees with employees of organisations that were selected as a case. Additional information about the socio-technological characteristics of the cases, when necessary, was gathered trough 'grey literature'.

4.2 Data Collection

Interviews were executed with both a priori type of CDSS developers and with important system actors e.g. experts, researchers, regulatory agencies and interest groups within the CDSS innovation system (Consoli & Mina, 2009; Mendel et al., 2008). System actors were interviewed to validate the responses of the developers and to certify theoretical saturation. Stated by literature, theoretical saturation is reached at a point in research where no new codes emerge during data collection (Bryman, 2012). This means that over time, during the data collection, all possible patterns at the phenomena that are being researched are saturated with data. In this research, the broader perspective from the system actors and the market perception of active developers provided insights in the different a priori type of developers, system actors and CDSSs that are operating in the Dutch CDSS innovation system. These insights eventually ensured that no developers, system actors or operative CDSS with certain aspects were left unexploited. By this, a construction of triangulation was formulated to reach theoretical saturation within the two a priori sub-groups that were researched in this study (Rijnsoever, 2017). To ensure theoretical saturation two respondents were (PR4 and PR6). They belong to a type of developers that were not present in the sample beforehand. This type of developer generates CDSSs as an add-on of the EHR systems that form their core-business and were mentioned in earlier interviews as substantial representative within the Dutch CDSS innovation system.

Data was gathered trough eighteen semi-structured interviews with different actors within the CDSS Health Innovation system. All the respondents were reached by email, LinkedIn or phone, and collected through a snowball sampling approach. The data started with contacting different possible actors present in the CDSS. Their contact details were gathered from the websites of the different innovation offices of all academic hospitals, the largest public research-fund for health innovations in the Netherlands ZonMw[ii], summaries of free- available European CDSS market reports[iii] and an elaborative search on the internet for developers and system actors. Search combinations like 'Clinical Decision Support System AND Netherlands' and Dutch translations were used. Respondents were only contacted if they or their organisation has experience with a CDSS that is operative or designed to be operative in the Dutch Health System. This first wave of data collection resulted in eight interviews that were arranged directly and five indirectly by receiving contact details of a possible respondent. Two of the eight innovation offices and one health business angel that were contacted indicated that they do not had any experience with CDSSs. After each interview, respondents were asked for contact-details of other developers

[ii] *https://www.zonmw.nl/en/*

[iii] *For example; https://www.medgadget.com/2017/01/europe-clinical-decision-support-system-market-2017-latest-report-available-online-at-orbisresearch-com.html*

and system actors within their contact-list. This resulted in five more interviews and one possible interviewee that did not respond. At the end of the data collection, respondents often introduced already interviewed respondents.

Reason given for respondents to not to participate were: limited time or not wanting to participate in non-medical studies. The latter was often mentioned by interest groups that automatically responded that they only participate in medical studies because of the many applications they receive. Some (n = 7) contacts did not respond to the invitation email. Eventually, 49 respondents were contacted of which 18 were interviewed, resulting in a response-rate of 37%. As outlined earlier, the no-response did not lead to any missing aspects of CDSSs or developers mentioned by other developers or system actors. A flow-chart of the data-collection process is displayed in Figure 4.

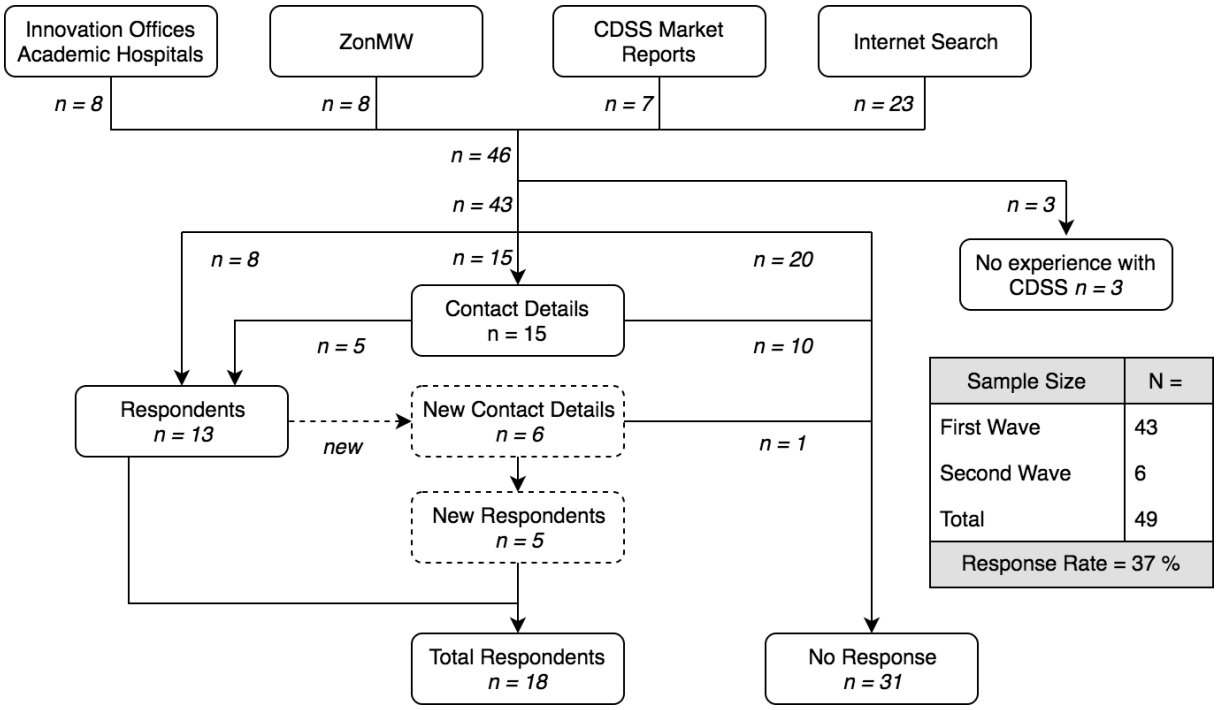

Figure 4. Data Collection Flowchart

Interviewees were classified as 'developer' if they were actively and directly involved in the development or diffusion of a CDSS at their organisation. They were classified as 'system actor' if they have comprehension of two or more CDSSs trough work experience at their organisation. If requested by an interviewee or found necessary by the researcher, interviewees were pre-informed about the definition of CDSS that is being applied in this research and the four spheres in where hurdles and building activities were categorized. The interviews were semi-structured based on an interview-guide to ensure that relevant subjects were discussed, while leaving enough room for elaboration. First, open questions about the general development of CDSSs and innovation system aspects were asked. Later more direct questions about the experienced hurdles and related activities. A Dutch and English topic list was created to meet the difference in native tongue of the interviewees. The Dutch interview guide is attached in the Appendix.

The interviews were preferably executed face-to-face and otherwise by telephone. One interview (PR6) was completed through a skype call because the actual development and the management of the diffusion of the CDSS was performed outside the Netherlands. In total thirteen interviews were executed with CDSS developers, of which six are defined as public CDSS developers and seven as private CDSS developers. Also, five CDSS system actors were interviewed, resulting in eighteen participants which are displayed in Table 5. All the interviews were recorded after asking for permission and were transcribed, to enable possible future examination of the responses and enhance the replicability of the research (Bryman, 2012). One interview is partially recorded due to technical issues. The interview length varied between 30 and 75 minutes (average 40) mainly because of the difference in experienced hurdles. To respect the anonymity of the participants and their organisations, no explicit details about the name of the CDSS and the specific operative medical field is provided.

ID	*Type of Actor*	*Function*	*Type of Org.*
PU1	Public Developer	Researcher	Healthcare Setting
PU2	Public Developer	Chief Innovation Officer	Foundation
PU3	Public Developer	Researcher & Clinician	Healthcare Setting
PU4	Public Developer	Researcher	University
PU5	Public Developer	Researcher	Healthcare Setting
PU6	Public Developer	Chief Innovation Officer	Foundation
PR1	Private Developer	Founder & CEO	Start-Up
PR2	Private Developer	Founder & CEO	SMB
PR3	Private Developer	Manager	Multinational
PR4	Private Developer	Manager	Multinational
PR5	Private Developer	Manager	Multinational
PR6	Private Developer	Manager	Multinational
PR7	Private Developer	CEO	SMB
SA1	System Actor	CEO	Foundation
SA2	System Actor	Researcher	University
SA3	System Actor	CEO & Founder	Open-Source Platform
SA4	System Actor	Researcher	Foundation
SA5	System Actor	Manager	Interest Group

Table 5. Participants

4.3 Operationalization

The conceptualisation and associated indicators of the two a priori developers are defined in Table 8. The indicators for the different spheres are conceptualised in Table 7. In this research, the unit of analyses were the experienced system hurdles and related SBAs of the developers. The conceptualisation and associated indicators for the unit of analysis are defined in Table 8 (Hurdles) and Table 9 (SBAs).

Concept	*Indicator*
CDSS Developer	An actor that is actively involved in the development and/or diffusion of a CDSS
Public	The organisation of the developer is a non-profit oriented organisation
Private	The organisation of the developer is a profit oriented organisation
CDSS System Actor	An actor that indirectly involved with the general development and/or diffusion of at least two CDSSs

Table 6. Developer and System Actor Conceptualisation

Concept	*Indicator*
Technological Sphere	Subjects that are related to technological specs/performance, programming and (EHR) software integration
Market-Economic Sphere	Subjects that are related to market share/profit, resources mobilisation and creating a feasible business plan
Clinical Sphere	Subjects that are related to CDSS usage and implementation within the clinical setting
Institutional Sphere	Subjects that are related to regulations, interest-groups and legitimation

Table 7. Sphere Conceptualisation

Concept	*Indicator*
Systemic Hurdle	Any form of hindrance experienced by a developer that influence the development and/or diffusion of their CDSS
Hurdle Present	When the developer experience hindrance by a hurdle within a sphere
Hurdle Absent	When the developer experiences no hindrance by a hurdle within a sphere

Table 8. Hurdle Conceptualisation

Concept	*Indicator*
System Building Activity	Activities that have been carried out by a developer with the aim to strengthen the system functions or lower the hindrance of present hurdles
Activity Successfully	System Building Activities that have been carried out by a developer and resulted in strengthening the system functions or lowering the hindrance of present hurdles
Activity Unsuccessfully	System Building Activities that have been carried out by a developer and not resulted in strengthening the system functions or lowering the hindrance present hurdles
Activity Absent	When the developer indicates that no activities have been carried out to strengthen the system functions or lower the hindrance of a present hurdle

Table 9. System Building Activity Conceptualisation

4.4 Data Preparation

Records collected from the interviews were transcribed and coded using NVivo, a familiar software tool to code data for analysis. Pre-established codes, related to the operationalized concepts and their indicators, were used to code the transcripts into categories. This form of coding resulted in a clear overview of useful statements per interviewee regarding the concepts, which formed the input for the data analysis.

4.5 Data Analysis

The data was analysed trough consecutive steps. The steps specified if the developers differ from each other based on the products they created (step 1), the hurdles they experienced (step 2), the SBAs they carried out (step 3) and the influence of the SBAs (step 4).

Step 1) Innovation System analysis and Socio-Technological CDSS characteristics

A broad description of the Dutch CDSS innovation system has been the key starting point of this analysis as this provided contextual background of the two type of developers. The analysis started with a description of the CDSSs that are present in the Dutch CDSS innovation system. Then, corresponding to the theoretical section, the three components, that form the structure of an innovation system: actors, institutions and networks were defined. To illustrate a broader picture of the innovation system, 'grey' literature was used to provide information about costs, financial outcomes, competition and the amount of developers and users. Furthermore, the socio-technological characteristics of the participants CDSSs were described based on data retrieved from the interviews and if needed supplemented by desk research. This provided evidence to discusses the a priori discrepancy of the public and private developers based on the type of CDSSs that are developed.

Step 2) Hurdle Experience

The second step outlined the presence or absence of the different hurdles for each developer, supplemented by the perceived hurdle experience of the system actors for private and public developers. A table was created to provide a clear overview of all the mentioned hurdles in each sphere. This table incudes a count of the present and absent hurdles and a percentage of the hurdle present experience (present hurdle count divided by present + absent hurdle count). These percentages were presented by the following notations (PU XX%|PR XX%). Another aspect is the overlap between the hurdles by calculating the average difference in hurdle experience. For example, if the following hurdles were experienced A (PU 60%|PR 70%), B (PU 100%| PR80%) and C (PU 75%|75%) within the sphere Z. Then the differences were respectively 10%, 20% and 0%, which resulted in an average difference based on all the hurdles of 10% between public and private developers for sphere Z. The overall outcome of this step provided insight in how the different developers experience hurdles and if possible, a distinction on hurdle experience was made.

Step 3) System Building Activity

The third step of the analysis focused on the SBAs that were addressed to strengthen the system functions and to lower specific hurdles. Only the experience of the developers was useful as the system actors were not able to provide clear statements about executed or absent SBAs for different types of developers. Although caused obstruction by a present hurdle urged the need for a SBA, sometimes developers mentioned that they were not able to carry out these activities.

Sometimes, SBAs were aimed at multiple hurdles in different spheres or the SBA was necessary for general development of the CDSS (e.g. SBA by [F1] entrepreneurial activities) and thus difficult to link to one specific sphere. This resulted in complications for the second set of propositions. The SBAs were therefore linked to the different categorical sets of system functions to identify the variance in carried out SBAs by all developers. Tables were created to provide an overview of the present hurdles and the absent hurdles for the "know-how", "know-about" and enablers set of activities. Present activities were noted by a "S" (= successful activity, see step 4) or by an "U" (unsuccessful activity, see step 4) and absent activities with an "A". Missing data was mentioned by n/a, when data was not applicable or not available due to the current state of development of the CDSS, or by lack of insights of the developer on this specific area. Subjects that were noted as (n/m) are not addressed by that specific developer in the open-questions. An activities percentage indicated the average presence of a specific SBA for all public and private developers. Furthermore, an overlap indication was formulated by calculating the average activities percentage difference between private and public developers over all the SBAs.

In the second analysis, the SBAs were linked to the specific spheres to support or reject propositions from the second set. The absence of SBAs provided insights in why certain developers were not able to carry out a specific SBAs. All in all, this created the necessary insight in how the different developers aimed to influence the innovation system and if a distinction between public and private developers was visible.

Step 4) Success of System Building Activity

The last step of the analyses revealed the major mechanisms that limit or accelerate the influence on the Dutch CDSS innovation system. Therefore, the 'transformative capacity' of all developers is researched by specifying the successful SBAs that strengthen the system. At the end, it was possible to clarify if the 'transformative capacity' and their influence on the system differs and if a distinction between the two groups is notable. Also, the unsuccessful SBAs were reviewed to identify if certain developers are less influential, and if this could be explained by the presence of hurdles.

4.6 Research Quality Indicators

To ensure the quality of research, multiple indicators are considered and further described below.

Construct Validity

Construct validity can be a problem when the measurements for the different concepts are not reflecting the concept that it is supposed to denoting (Bryman, 2012). In this study, due to the dynamic aspect of experiencing hurdles and carrying out SBAs, certain expression of a pressure can differ over time what limits the construct validity. To counter this, multiple well-cited literature sources are used to construct the used definitions within this study. Besides, many previous studies have used similar concepts and proven their measurements.

Internal Validity

Internal validity deals with the quality of the match between the observations and the theoretical ideas they develop (Bryman, 2012). To strengthen this, an elaborate examination on the background of CDSS and their developers by identifying the socio-technological characteristics. Furthermore, this researched considered both way interactions between the innovation system and the active developers to limit the possibility for something else to interfere in the examined relationships.

External Validity

Generalisation of this research is only feasible for the Netherlands as the geographical delineation is set to the national border. Within this area, researching a variance of developers and system actors increases the generalisation of the sample outcome to the entire innovation system. The national borders also indicate that further research is needed to enlarge the geographic scope to provide more generalizable results. Therefore, the second aim of this study is to define a more comprehensive perspective for reviewing the occurrence of 'research

paradigms' that can used in future research. Outcomes of this goal can be used in similar high-complex TIS analysis whereby a variance of developers is presence within the innovation system.

Reliability

Due to the qualitative approach, replicability of this research seems rather limited (Bryman, 2012). To strengthen the reliability, a clear description of the different steps, definitions that are used and the uses indicators within this study are provided. Furthermore, the interview guide is attached in the appendix, all to ease the possibility for another researcher to execute a similar study and strengthen the replicability.

5. Results

The following sections will provide the findings from the data analysis and the results on the defined proposition in the theoretical chapter. Section 5.1 elaborates the Dutch CDSS innovation system. Section 5.2 provides a description of the participants of this study, their CDSS and how they overall fit in the innovation system. Section 5.3 continues with the experienced hurdles, followed by section 5.4 that describe the carried-out SBAs. Finally, section 5.5 deals with the success of the developers to influence the entire CDSS innovation system.

5.1 Dutch CDSS Innovation System

Technology

Several types of CDSS are present within the Dutch CDSS innovation system and they can be categorized on different type of axes, e.g. function of CDSS, type of users, medical field, type of input and reasoning method (Sim & Berlin, 2003). Tree main categories are identified within the Dutch CDSS innovation system.

1) Medical Information System Add-ons.

These variants of CDSSs are mainly add-ons in operational EHR systems that function in general practices or hospitals. Often they are part of the 'standard' software that is sold by the EHR suppliers, or can they be bought as separate packages. The general goal behind these CDSSs is to manage the patient safety. International or national medical guidelines form the knowledge-data base resulting in alerts or simple recommendations when clinicians are not following the protocol. Input of these CDSSs is provided by incoming lab-values or medical standard codes that are filled in the EHR by the clinician during a consult. The alerts themselves are generated by an if-then rule-based reasoning method and send directly to the clinician computer or mobile device. When medical guidelines are changed, the developer of these system updates the if-then rules to guarantee that generated alerts are always based on the latest guidelines.

2) Medicine and Treatment Recommendations

The second category of CDSSs looks quite similar as the first group, however these are not available as adds-on of the EHR. Yet, these CDSSs are reliant on a data-extraction with a EHR or operate as a stand-alone system when the data-extraction is not possible. These CDSSs often use one or multiple parameters of the patient in combination with guidelines or expert opinions to function. Outcome can be specific advice for a certain treatment or alerts, for example when a prescribed medicine can harm the patient.

3) Evidence Based & Artificial Intelligence

A relative newer variant of representative CDSSs are those that are based on the principle of EBM. These CDSSs produce their recommendations and predicted outcomes on patient's symptoms and parameters by a machine learning reasoning mechanism. Therefore, data extraction or integration with a medical software is necessary. Complicated mathematical calculations that include a lot of parameters are transformed into algorithms. Some of these are developed in a 'self-learning' way in where the system constantly try to improve the algorithms. Enough historical patient data is necessary to build and test these CDSS and a broad range of sets are required for validation. The outcome of these CDSSs are often predictions, for example to what extent treatment A, B or C will result in a certain event. Maintenance or adjustment of the algorithm is required by the CDSS developer.

Actors

Several institutes, foundations, universities and private firms form the developing actors in the Dutch CDSS innovation system. The private firms that are operative as developer vary from start-ups, small-medium based organisations and multinationals. These multinationals often develop and manage the diffusion of their CDSS at a single R&D location in the world and by doing so, exchange knowledge across the national borders off the Dutch CDSS Innovation system with other similar 'national' CDSS innovation systems.

Further research is stimulated by different research institutes like universities, academic hospitals, research-institutes and private R&D. Education is provided by professional training session of developing firms to stimulate the implementation and usage of their CDSS and by Universities. For example, the University of Amsterdam in combination with the Amsterdam Medical Centre started the first MSc Medical Informatics in the Netherlands. Supplying actors within the innovation system are ICT firms that provide decision support platforms or frameworks and human capital for IT problems during development, clinical data suppliers that provide the

CDSS with patient data or guidelines. Actors on the demand side vary from patients, individual clinicians and healthcare settings.

Support within the system is generated by several organisations. Two important ones are the largest public research fund for medical innovations (ZonMW) and all health insurance companies that control the financial flows. Insurance companies can stimulate health providers to use a CDSS by financial rewards or incentives. Several network organisations are located, that manage clinical data or represent the interests of specific groups like patients, clinicians or health insurance branch organisations.

A mapped overview of the different actors is displayed in Figure 5.

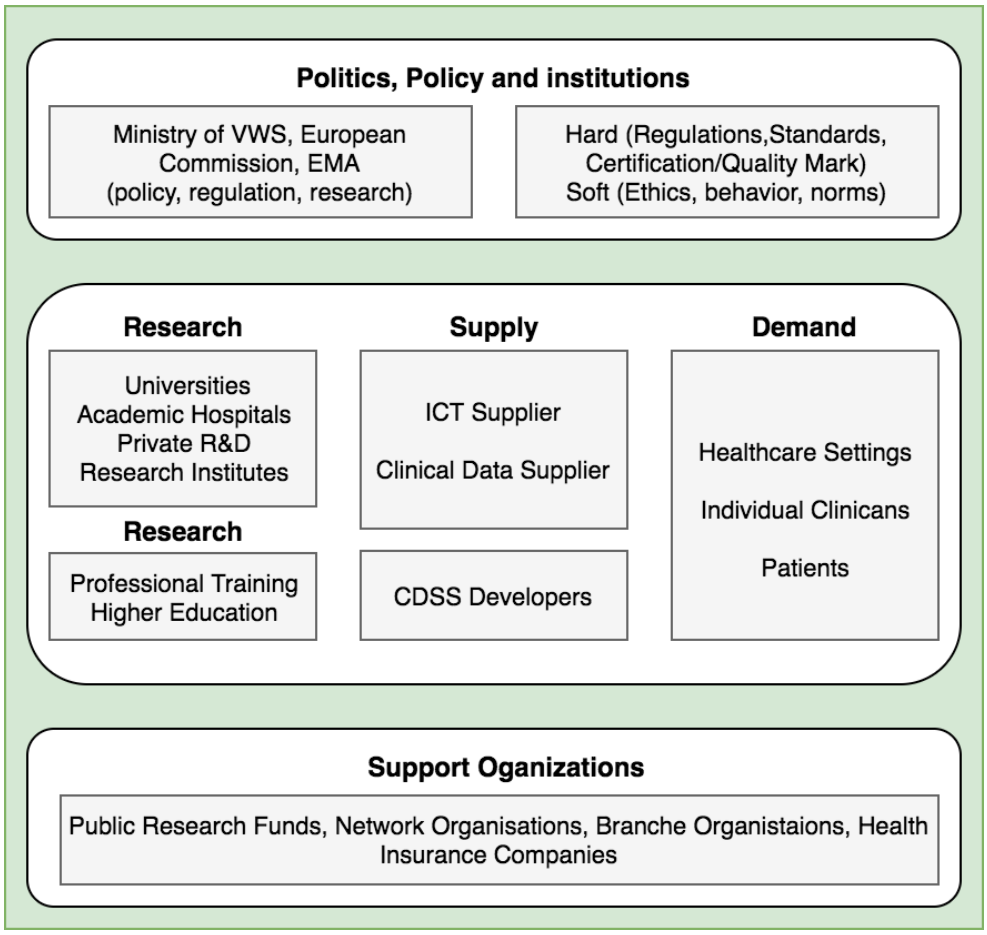

Figure 5. Dutch CDSS innovation system

Institutions

Two 'hard' forms of institutions are the CE marking that is declared by the European Commission and the Medical Devices Regulations (MDR) that is controlled by the EMA. Proper usage and exploitation of CDSSs are controlled by the 'The Healthcare Inspectorate' of the Dutch ministry Health, Welfare and Sport. Furthermore, there are standardisations provided by medical guidelines that need to be followed and quality certifications that are declared by a foundation to ensure validation of the CDSS and the quality of the outcome given by the CDSS in a certain medical field. Soft institutions are the ethical and behaviour related discussions among autonomy of medical decision making and the norms of how clinicians code properly and use free-text in EHR systems.

Networks

There are a lot of formal and informal links between different actors and groups inside the CDSS innovation system, created through attendance at conferences or by partnerships and networks. One network that is set up by the government is the 'Health Deal' on decision support in the oncology where several research, supply, demand and support organisation actors exchange relevant information. For clarification, Figure 6 provide an

overview of informal exchange of knowledge and formal partnerships/networks links that were mentioned between participants of this study[iv]. Also, several informal and formal networks present actors exceed the geographical border of the Dutch CDSS innovation system by exchanging information's with actors that are operative in other 'national' CDSS innovation systems or TISs like decision support systems in other expert fields.

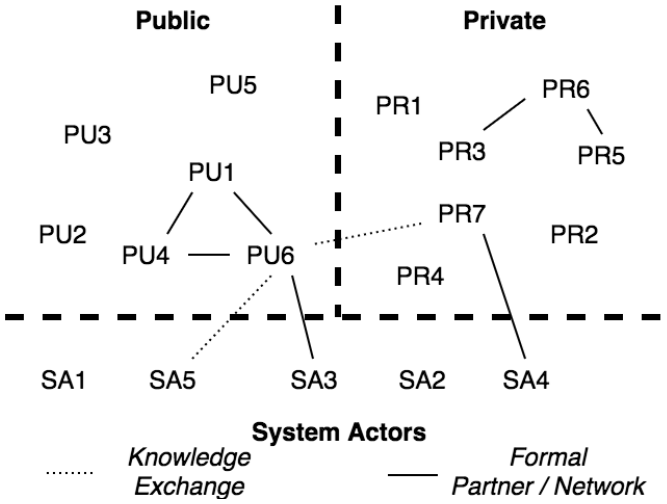

Figure 6. Network links participants

Background Information

Researching 'grey' literature forms the idea that general information about the CDSS market is very limitedly available, especially for developers with less financial resources. There are certain market rapports for sale that elaborate geographical deployment for a distinction of social and technological CDSS components. Yet, prices for these consultancy rapports start at 5000 US dollars.

Forecasts of the CDSS market indicate a further grow regarding the shift in healthcare systems towards electronic health. Financially, this means a global value of ±800 million US dollars in 2016 to a projected 1.5 billion US dollars in 2021[v]. Several summaries of available rapports indicate multiple global key-players, of who two are Netherlands based (Philips and Elsevier Bv.) and five others are also active within the Netherlands[V] (Siemens, Cerner Corporation, Epic Systems Corporation Inc., Wolters Kluwer Health and IBM Corporation).

A closer look at usage of CDSS in the Netherlands indicate that almost general practitioners have access to any form of CDSS (Medlock et al., 2013). SA5 (interest group) confirms that this is quite similar for all medical clinicians that work in hospitals. Based on the data-collection process and insights of the system actors, a rough estimation would state the presence of 30 till 65 CDSS developers in the Netherlands. Nevertheless, considering that some CDSS are still undeveloped or only used for personal usage and therefore difficult to search, the actual amount could be higher.

5.2 Description of developers and their CDSSs

Described below are the social characteristics of the interviewed developers and the technological specifications of their developed CDSSs. The important specifications are based on the classification framework of Sim & Berlin (2003).

Social Characteristics

The public developers consist of healthcare settings, universities and foundation which mainly focus on the Dutch market expect PU5 who has a global focus. Two of the public developers are foundations that have developed a CDSS to improve treatment planning and one of them (PU6) also aims for stimulate CDSS possibilities in the

[iv] *Note: Figure 6 only show links between the participants of this study – Participants can have multiple possible other knowledge exchange or formal network links with actors in the innovation system.*
[v] *Sources: micromarketsnmonitor.com, marketsandmarkets.com & psmarketresearch.com*

medical field they are active. Four of the seven private developers are multinationals that develop CDSSs that are active in multiple countries in Europe or even worldwide. The other private developing organisations focus on the Dutch market, two of them be considered as small and medium-sized businesses and one is an active start-up (PR1) that focusses on the Dutch market.

Private and public developers are both creating CDSS for different users like general practitioners, medical specialist and pharmacists, what overlaps with the different type of health care focus areas like primary care, secondary care, tertiary care and pharmacy. Only PU4 developed a CDSS where patients are the end-users two private organisations (PR4 and PR7) developed CDSSs that is used by nurses. However, the clinical disease activity and intensity that the different developing organisations address with their CDSS differs in size and necessity. For example, PU3 is focussing on a small field and states: "*… it's just about specific patients whereby knowledge is lacking. While their need for support is much higher, but it's less interesting to develop tools for these fields*." This results in the fact that private firms are more likely to focus on general or multiple diseases and treatments within the health focus area due to their profit orientation.

Defining the collaborations between the private and public developers indicate that user-producer interaction is a collective way of defining the specific medical request that the CDSS tries to address. The developers have linkages with any health clinicians either by contact with active clinicians that are operative in their organisations or by hiring them and incorporate their practical experience in their business. Public-private partnerships are also often mentioned as a common network link in other to exchange complementary assets, financial capital or even intellectual property. Table 10 provides an overview with the social characteristics of the developers and the developed CDSSs.

Technological Characteristics

Categorizing the different CDSSs on their clinical tasks outlines the picture that public developers are more likely to develop a CDSS that fulfil only a diagnostics or treatment planning task in comparison to a private developer that seems to generate more often multiple CDSSs where diagnostics and drug-describing/dosing tasks can be a part of. A bigger difference is noticeable in the type of clinical knowledge sources and reasoning methods that are being used. Five public developing organisations use (historical) patient data as their clinical data source for their machine learning reasoning methods in contrast to private developing organisations that focus more on preventing and screening clinical tasks by making use of guidelines. So far, private developed CDSSs are more integrated within the EMR considered that two of them are developed by EMR Software organisations. The CDSS developed by PU4 is still in the development phase and not diffused so fare. Both public and private developers design their CDSS to be workable as a web-based, application or plug-in/add-on form. Only PR3 recently switched to a cloud-based accessible CDSS. Table 11 specifies the technological characteristics of the developed CDSS.

Socio-Technological Distinction

Comparing the social and technological characteristics of the two a priori type of CDSS developers indicates that is hard to name specific characteristics that are either more private or public based. Indicators for slight preferences are that public developers appear to use machine-learning reasoning engines more frequently for their CDSS and that private developed CDSS are more likely to be integrated in other software programs that are used in the daily work routine of the clinician. These slight differences are confirmed by several system actors, who state that proper machine learned based CDSS still require a lot of efforts to make them market feasible. Therefore, they are more developed by public researchers and or private start-ups. Opposite, private developers prefer the more used and developed rule-based systems, as these have proven to be functional. Yet, the general large overlap indicates that both type of developers address similar CDSS, medical fields and other socio-technological characteristics.

Table 10. Social Characteristics

Respondents ID's	Social				
	Type of Org.	*Users of CDSS*	*Health Focus Area*	*Geo. Focus Area*	*Collaboration(s)*
PU1 [xi]	Healthcare Setting	General Practitioners	Primary Care	Netherlands	Health Clinicians Private Org.
PU2	Foundation	General Practitioners	Primary Care Tertiary Care	Netherlands	Health Clinicians Public Org.
PU3	Healthcare Setting	Medical Specialist	Secondary Care	Netherlands	Health Clinicians
PU4	University	Patients	Primary Care Secondary Care	Netherlands	Health Clinicians Public Org.
PU5	Healthcare Setting	Medical Specialist	Secondary Care	Globally	Health Clinicians Public Org. Private Org.
PU6[vi]	Foundation	Medical Specialist	Secondary Care	Netherlands	Health Clinicians Public Org. Private Org.
PR1	Start-Up	General Practitioners Medical Specialist	Primary Care Secondary Care	Netherlands	Health Clinicians Public Org.
PR2	SMB	General Practitioners Pharmacist	Primary Care Tertiary Care Pharmacy Care	Netherlands	Health Clinicians Public Org.
PR3	Multinational	Medical Specialists	Secondary Care	Globally	Health Clinicians Private Org.
PR4[xi, vii]	Multinational	Medical Specialist Nurses Pharmacist	Secondary Care Pharmacy Care	Europe	Health Clinicians
PR5	Multinational	Medical Specialist	Secondary Care	Globally	Health Clinicians Private Org.
PR6[xi, xii]	Multinational	Medical Specialist Nurses Pharmacist	Secondary Care Pharmacy Care	Globally	Health Clinicians
PR7 [xi]	SMB	General Practitioners Medical Specialist	Primary Care Secondary	Netherlands	Health Clinicians Public Org.

[vi] Develops multiple CDSSs
[vii] Functions also as a System Actor (HIS supplier)

Table 11. Technological Characteristics

Respondents ID	Technological					
	Clinical Task	*Clinical Knowledge Source*	*Reasoning Method*	*Integration*	*Communication*	*Form*
PU1	Prev./Screening	Expert Opinions Patient Data	Machine Learning	Integrated	Alerts/Reminders	Add-On
PU2	Treatment	Guidelines Expert Opinions	Rule Based	Stand Alone	Recommendation	Web based
PU3	Diagnostic	Patient Data	Machine Learning	Stand Alone	Recommendation	Web based
PU4	Treatment	Patient Data	Machine Learning	*Not implemented*	Recommendation	*Not implemented*
PU5	Diagnostic	Patient Data	Machine Learning	Stand Alone	Outcome Predictions	*Unknown*
PU6	Diagnostic	Guidelines Patient Data	Rule Based Machine Learning	Stand-Alone	Alerts/Reminders Outcome Predictions	Application
PR1	Diagnostic Treatment	Patient Data	Machine Learning	Stand-Alone	Outcome Predictions Recommendation	Web based
PR2	Drug describing	Guidelines	Rule Based	Integrated	Alerts/Reminders	Web based
PR3	Test Ordering	Guidelines	Rule Based	Integrated	Recommendation	Cloud-based
PR4[i]	Prev./Screening Drug describing	Guidelines	Rule Based	Integrated	Alerts	Add-On
PR5	Diagnostic	Expert Opinions	Search-Based	Stand-Alone	Recommendation	Application
PR6	Prev./Screening Drug describing Diagnostic	Guidelines Patient Data	Machine Learning Rule Based	Integrated	Alerts Recommendation	Add-On
PR7	Prev./Screening Drug describing	Guidelines Pub. Random. Trials	Rule Based	Integrated	Alerts	Add-On

5.3 Experienced hurdles

The next section outline the experienced hurdles within each sphere. Almost all developers experience multiple hurdles in each sphere. Yet, hindrance is not always caused by similar problems, as some hurdles are more mentioned than others. The most remarkable ones are described for each sphere in the following sections. An overview of all the present and absent hurdles for each developer is displayed in Table 12. This overview provides evidence to either reject or support the propositions of the first set for each sphere.

5.3.1 Technological Sphere

All developers indicate that the first step of programming the CDSS is one of the simpler parts of the whole development and diffusion process. Developers often get started by experiencing medical failures in their daily routine, job-responsibilities for executing research or a request from a demanding actor. Depending on the type of CDSS that is aimed for, important indicators or parameters are being researched by pattern recognition, found in literature or provided by guidelines to eventually build the reasoning engine of the CDSS. Software frameworks that are provided by ICT suppling actors have helped certain actors in building their rule-based tools. On the other hand, machine learning based CDSSs require more human due to the complexity of the algorithms. PU4: *"… I am a computer scientist, well that makes it a lot easier. I also have colleagues that don't have the computer programming capabilities, so they have to wait for others to finish programming before they can continue.*"

From the moment that developers start with diffusing their CDSS technological, struggles seem to occur more often. Issues are typically related to the technological performance of the CDSS. The time that is required for calculating and providing the desired outcome can become substantially longer when many clinicians simultaneously make a request or the CDSS need to receive data from many different other ICT sources. Further, CDSS that are based on a rule-based reasoning method can malfunction when the necessary input is not correctly delivered. PR2: *"Content wise, there always were problems with one of the important underlying layers of our system, the reason for medical describing, the diagnosis, the complaints or the symptoms from the patient. These were not always coded by clinicians. Yes, they have written down them somewhere, but this will not work for a CDSS. In order for a CDSS to work, they need to receive a code."* Reasons mentioned for this problem are the former way of working by clinicians, in where they could write down the findings, perceived symptoms, diagnosis and prescribed medicines in a single free-text. Also, dealing with different type of coding-scheme that are used by different ICT systems worldwide, due to the lack of standardization, forms hindrance for almost all the developers PR1: "*What remains a challenge is the integration with all the different ICT systems. These systems are not really designed for making any links on the internet or with other devices, while the rest of the electronic innovations that we use on a daily basis are designed for creating those linkages*."

Becoming fully integrated within the EHR systems is mentioned by many effective studies as one of the factors that is crucial for a CDSS to function properly (Belard et al., 2017; Jaspers et al., 2011). However, as agreed by nine developers and all system actors, this proves to be a very difficult and sometimes impossible task. Success often dependents on the willingness of EHR system suppliers to cooperate. This also explains why the EHR system supplying firms PR4 and PR6, that build their CDSS as add-ons, are the only one that mention other technical performance issues like making changes in the users' dashboard when necessary (PR6) and parallel requesting difficult calculations (PR4).

Solely one public developer (PU4) state that they have not experienced any form of technological hindrance so far. Explanation for this is given by the current state of still developing the CDSS. Though, the expectations of the developer are that technological issues will arise during the implementation phase. In conclusion, it can be stated that hurdles are experienced by both a priori type of developers within the technological sphere and particularly arise from the implementation phase when integration is needed. Looking at Table 12 indicates that overall the hurdle experience largely overlap for programming (PU 11%|PR 10%), software integration (PU 88%|PR 64%), problems with the amount of different ICT systems (PU 83%|PR 100%) and Data Quality (PU 88%|PR 82%). Only substantial differences are experienced for technological performance issues (PU 0%|PR 50%). Furthermore, reviewing the differences between the public and private hurdle experiences indicates an average difference of 23%. Thus, it can be concluded that both type of developers experiencing similar hurdles in the technological sphere, resulting in the support of proposition 1a.

Table 12. Hurdle Experience Overview

Respondent ID			T- Programming	T- Tech Performance	T- Software Integration	T - Many ICT Systems	T - Data Quality	**Technical Hurdle**	ME - Financial Capital	ME - Users not want to Pay	ME - Market Share	ME - Comp. Assets	**Market Economic I Hurdle**	C - Soc. Accept. - Autonomy	C - Soc. Accept. - Time	C - Implementation Issues	**Clinical Hurdle**	I - Certification	I - Regulations (Privacy)	I - Consensus Lack	I - Interest Groups	**Institutional Hurdle**	**EXPERIENCED HURDLES**
PUBLIC	Developer	PU1	A	A	P	A	P		P	A	P	P		A	P	P		A	P	*n/m*	A		
		PU2	A	A	P	P	A		P	P	P	A		A	P	P		P	P	P	P		
		PU3	A	A	P	P	P		P	*n/a*	P	A		P	P	P		P	P	P	A		
		PU4	A	A	*n/a*	*n/a*	*n/a*		P	*n/a*	*n/a*	P		*n/a*	*n/a*	*n/a*		*n/m*	A	P	A		
		PU5	A	A	A	P	P		A	*n/a*	*n/a*	P		P	*n/m*	*n/a*		P	P	P	*n/a*		
		PU6	A	n/m	P	P	P		A	A	P	A		P	P	P		P	P	P	A		
	System Actor	SA1	A	A	n/a	n/a	n/a		P	P	P	*n/m*		*n/m*	P	*n/a*		P	P	P	A		
		SA2	*n/m*	*n/m*	P	P	P		P	P	P	*n/m*		P	*n/m*	A		A	P	P	*n/m*		
		SA3	P	*n/m*	P	n/m	P		P	P	P	P		A	A	*n/m*		P	P	P	*n/m*		
		SA4	A	*n/a*	n/a	n/a	n/a		*n/a*	*n/a*	*n/a*	*n/a*		P	P	*n/m*		*n/m*	P	n/m	*n/m*		
		SA5	n/m	A	P	*n/m*	P		A	P	P	*n/m*		P	P	P		P	P	P	A		
PRIVATE	Developer	PR1	A	A	P	*n/m*	A		A	P	*n/a*	A		A	P	*n/a*		P	P	P	A		
		PR2	A	A	P	P	P		P	P	P	A		P	P	A		*n/m*	*n/m*	P	A		
		PR3	A	*n/m*	P	P	A		A	P	P	P		A	A	A		A	A	P	A		
		PR4	A	P	A	*n/a*	P		A	A	A	P		P	A	P		A	A	P	A		
		PR5	A	A	P	P	P		A	P	A	A		*n/m*	P	P		*n/a*	A	P	*n/a*		
		PR6	P	P	A	*n/m*	P		A	P	A	A		*n/m*	P	P		*n/a*	*n/a*	*n/a*	*n/a*		
		PR7	A	A	P	P	P		P	P	P	A		P	P	*n/m*		P	P	P	A		
	System Actor	SA1	A	A	n/a	n/a	n/a		P	P	A	A		*n/m*	P	*n/a*		P	P	P	A		
		SA2	*n/m*	P	A	P	P		A	A	A	A		P	*n/m*	P		P	P	P	*n/m*		
		SA3	A	*n/m*	A	*n/m*	P		A	A	A	A		P	P	*n/m*		P	P	P	*n/m*		
		SA4	A	P	P	P	P		P	P	P	A		P	P	P		*n/m*	P	*n/m*	A		
		SA5	*n/m*	P	P	*n/m*	P		P	P	P	*n/m*		P	P	P		P	P	P	A		**Total/Average**
Present Hurdles Public			2	0	7	11	7	27	12	14	13	6	45	13	16	11	40	7	10	9	1	27	***136***
Present Hurdles Private			1	5	7	6	9	28	5	9	5	2	21	7	9	6	22	6	7	10	0	23	***90***
Present Public (%)			11%	0%	88%	83%	88%	53%	70%	71%	100%	57%	75%	67%	88%	83%	78%	78%	91%	100%	14%	75%	***61%***
Present Private (%)			10%	50%	64%	100%	82%	58%	42%	75%	45%	18%	46%	78%	82%	75%	79%	75%	70%	100%	0%	64%	***52%***
Total			3	5	14	17	16	55	17	23	18	8	66	20	25	17	62	13	17	19	1	50	

P = Hurdle Experience is Present A = Hurdle Experience is Absent

n/a = case not appliciable/data unavailable due to current state of development, lack of insights or type of developer

n/m = not mentioned by participants

5.3.2 Market-Economic Sphere

Receiving enough financial capital and complementary assets to develop, grow and maintain successfully are mentioned as a serious market-economic hurdle by almost all developers. A difference is made in financial capital (*proposition 1b*) and receiving enough medical data as complementary assets (*proposition 1*c).

Since available contact details on the largest national public resource fund for medical innovations were used to find a part of the public developers it is obvious that these developers require grants. However, different system actors (SA2, SA3) and public actors not retrieved via the research fund state that public-grants is a very common and often only way to receive financial support for developing a CDSS. PU4 *"… the financial structure for academic research does not guarantees support for integration and implementation. Then you are talking about different numbers, as academic research grants often only consist a few tons… that amount is just not factual".* Therefore, this type of public financial structures often result in a protected developing area for public developers whereby target customers are triggered by financial incentives to corporate in temporary test-setting. SA2: *"… however, the moment that the subsidy dries out, the project automatically stops when a developer doesn't prepare themselves properly. I think that this counts for many systems that are being developed in this way, because it's very difficult to commercialise the system at that moment …"* Only two public developers (PU5, PU6) state that their organisation receives enough money by other core activities and are therefore is not fully dependent on public-funds.

Most private developers are not only depended on the income of their CDSS and therefore have access to enough financial capital. Some of them experience the same commercialisation difficulties as public developers, because market-demand is limited. Especially, diffusing a CDSS that is used by general practitioners causes hindrance as the budgets of these users is often more restricted to invest in upcoming innovations like CDSS. Secondary care focused CDSS developers often indicate that the current cost-structure of the Netherlands forms a problem for quality care improving innovations. PR3: *"I'm not sure if it's really true, but from my perspective I recognize a correlation between the number of clinicians that work in private clinics and the resistance for incorporate a CDSS for treatment planning. Of course, that has to do with the fact that if these people will do less consultants they will also receive less, right."* This misalignment between providing better care and receiving financial benefits, supports the hindrance for further market growth.

Forms of complementary assets are the different medical knowledge sources that are used as input for the reasoning method of a CDSS. Two possible forms are medical guidelines and protocols that are developed and updated by the different branch organisation to ensure medication safety and standardization of healthcare. Access to this knowledge is easy and insightful for CDSS developers that are rule-based. Only PR3 and PR4 experience sometimes hindrance by interpreting the protocols and translate them in suitable rule-based language. Access to historical medical patient datasets to test and validate machine-learned instruments is a complementary asset that is sometimes hard to reach for developers and resulting in building constrains. PU5: "*all the misery is that it takes ages before you get your data and then the clinician argument is … our techniques, our methodologies are already changed on how we consult our patients, so your model is not relevant any longer, it's based on old data. "*

Another public machine-learning developer (PU1) state. "*Yes, I think so, we don't have any privileged access to knowledge as researchers …"* This indicates the absence of a complementary assets hurdle when the developers have enough money or network linkages to gather access to new data-sets.

Comparing the private and public developers, by the percentages from
Table 12 indicate that mobilisation of financial capital (PU 70%|PR 42%) forms a bigger hurdle for pubic developers and therefore proposition 1b is accepted. However, complementary assets mobilisation also indicates a higher hurdle for public developers (PU 57%|PR 18%), resulting in the rejection of proposition 1c. Additionally, both type of actors deal with users that are unwillingly to pay for CDSS usage (PU 71%|PU 75%) and public actors experience more struggles with increasing their market-share (PU 100%|PR 45%). Comprehensive, the average hurdle experience for public developers in the market-economic sphere is 75% and 46% for private developers, with an average difference based on all hurdles of 32%.

5.3.3 Clinical Sphere

Another well mentioned hurdle in the literature is the lack of social acceptance for CDSS by its end-users (Bright et al., 2012; Garg et al., 2005). This is also the first subject that mentioned by the different developers and system actors when asking about a clinical hurdle. While different underlying mechanisms are mentioned, overall social

acceptance can be considered as low and therefore causes the presence of a clinical hurdle by almost all developers.

Firstly, the limited or even insufficient time that is available for a single consult is named by many developers when follow-up questions were asked about social acceptance. Most of these are stand-alone CDSS developers that require more time because the clinician must double entry the founded parameters in the EHR and the CDSS. SA1: *"… because you receive very limited money for filing in a CDSS, that always have been one of the biggest concerns. It cost clinician too much to spend 20 or 30 minutes at filling in the CDSS."* Also, PR7 experience time as an issue, even they have created an integrated CDSS: "*earlier you could just click, today you only have to hold your cursor at a button that enlightens to receive information about the alert. Even the time it takes for just two clicks irritates clinicians because together all those small things counts. A general practitioner has only seven minutes and they want to experience minimal irritating stuff ...".* This specific case, whereby using the CDSS requires still require minimal extra time, emphasizes the time-pressure clinicians already experience during a consult.

The second underlying mechanism that is often mentioned is the behaviour of clinicians. Changing the behaviour or routine of these medical experts seems to be a very difficult task. PR2: "*It sounds weird that we all have to make investments, but at the end it only depends on changing the behaviour. This will benefit us all, however for now, clinicians need to make an extra investment."* Often developers have the idea that clinicians experience or get the idea that the CDSS is taking over the whole decision making process, even when they present their CDSS only as a supporting tool. This discussion about professional autonomy is well explained by SA3: *"… that a system knows it better than a clinician. Yes, I think it isn't very straightforward that clinicians are willing to accept advice because clinicians are the most well-educated employees in their organisations, maybe even in the society. If you look at the educational pathway of a medical specialist, that can take approximately 12 till 15 years. So, they expect themselves, and deserved from my view, as those that are best in understanding and knowing what to do in their organisation. And so, if a (CDS-) system just tells them what to do, it's improbable that they will just … ."*

Only one developer (PR3) experience no clinical or specific social acceptance hurdle. Reason for this mentioned by the developer is the complicated field in where the CDSS is active and providing treatment planning advice. Therefore, the CDSS not interference with actual decision making of the clinician and is more focussed on patient management. Nevertheless, almost all CDSS developers deal with the social acceptance hurdle either caused by time struggles (PU 67%|PR 78%) or by autonomy difficulties (PU 88%|PR 82%). The lack of social acceptance of often results in implementation related difficulties by both type of developers (PU 83% | PR 75%). The average experience of present clinical hurdles for public developers are 78% and 79% for private developers. A large overlap is indicated by the low difference (8%) between the public and private developers average experience, leading to the rejection of proposition 1d.

5.3.4 Institutional Sphere

Several institutional hurdles are present, especially during the implementation and diffusion of the CDSS. Receiving the necessary classifications by regulating authorities and lack of consensus between different system actors are two frequently mentioned specifications. Likewise, almost all actors perceive struggles within the institutional sphere as a present hurdle.

One important certification for creating a CDSS that can be operative in different health-care settings is the European CE-mark. Authorization can be provided by a representative of the European Commission and requires multiple reports about the assurance and verifications of the CDSS. Although there is no consensus under the participants in this study if a CE mark is necessary, eventually receiving one is indicated as very cost-and time consuming PR1: "*Certificating is still a challenging subject, I've understand that certifications for algorithms is rather impossible because they are continuously changing over time.*" All the developers comply to strict patient-privacy regulations that are controlled by the government. PR1 "*Regulations are quite strict when it comes to privacy and data-usage, however we think that is deservedly. We see privacy as a good thing and we experience that mistakes are made on this subject. … of course that requires a lot of actions, you spend a lot of money on it and that irritates you*." Those public developers that have created CDSSs for a fixed amount of secondary healthcare settings 'often have to deal with even more strict regulations obtained by medical ethic committees. Also, private developers experience these strict privacy regulations when they fill in a request for medical data at certain institutions.

Another institutional issue is the lack of consensus between the different system actors within the innovation system. Different system actors like supportive organisations (interest groups, insurance companies) and political/regulation organisations (Ministry of VWS, EMA etc.) have different opinions about the importance and added value that is created by CDSS usage and therefore a clear long-term agenda is missing. As defined by the financial hurdle, most health insurance organisations so far not acknowledge the need for these systems. Also, clinicians are only persuaded when financial motivated by reimbursement pay-outs to either code correctly or use a CDSS. PR7: "*eventually it will be beneficial for the health system but realise that we are not there yet. It's a journey that we have started together to ensure that later the right knowledge is available and applied rightfully*". Although the government is stimulating CDSS by the availability of research grants and setting up the health-deal, further clear statements are missing. PU6 "*I think we still have a very passive government. Currently, there are some large issues, like the market position of the largest EHR developer, lack of further investments, the freedom for hospitals to use different coding schemes. Just ensure that CDSS are mandatory in 5 years, like in other countries."*

In one occasions the developer mentioning struggles initiated by an interest group that state that they are not supporting the CDSS. However, good relations or even formed partnerships also showed that interest groups can promote CDSS legitimacy. Ultimately, it can be stated that overall institutional struggles are similarly present for (CE) certification related issues (PU 78%|PR75%), privacy regulations (PU 91%|PR 70%), lack of consensus (PU 100% | PR 100%) and absent for interest groups related hurdles (PU 14%|PR 0%). This results in overall similar hurdle experience within the institutional hurdle during development and diffusion of a CDSS, and therefore supporting proposition 1e.

5.3.5 Average hurdle Experience

When the different spheres are being compared, it can be concluded that most hurdles are experienced simultaneously by public and private developers in each sphere. Especially, the different technological, clinical and institutional hurdles are tangible by both a priori type of developers. When taking the overall result, the average difference between the groups in the absence or presence of a hurdle is only 18 %, based on all the different individual hurdles. This indicates that the average overlap of either experiencing or not experiencing similar hurdles is in general quite high. Therefore, a stimulus for a private and public 'research paradigm' based on hurdle experience is almost negligible.

5.4 System Building Activities

As indicated, public and private CDSS developers were barely separable by the hurdles they experienced. The following section will focus on the building activities that are carried out by each developer, as these are able to change the institutional set-up of the entire system in a desired direction (Kukk et al., 2016). Based on the categorisation of Hellsmark (2010), the follow section will describe the different type of SBAs that are carried out by each developer. A table is provided at the end of each categorical set with an overview of the different SBAs. Furthermore, linkages between SBAs that are directly aimed at lowering a specific hurdle in a specific sphere are described for the public and private developers. Finally, a conclusion can be drawn with respect to the SBAs that are carried out by each a priori type of CDSS developers and if this indicates a clear distinction in how they both try to set-up the innovation system.

5.4.1 Know – How System Building Activities

F1. Entrepreneurial Activities

Entrepreneurs that carry out experimental activities are often mentioned as crucial for an innovation system to function well and to stimulate further development of the technology (Hekkert et al., 2007). Two main type of activities could be identified when the developers are talking about entrepreneurial SBAs. Often the developers started with a medical request and tried to develop a prototype of a CDSS that functions accordingly or by identifying any form of business opportunity that occurred within the CDSS field. By doing so, developers often make use of new technologies, are addressing new medical fields or combining different already used aspects. Like defined in Table 13, both private and public developers indicate that they are carrying out some form of experimenting SBAs (PU 100%|PR 100%). The following step for the proto-type is dealing with the specific wishes of the target-group or the presence of specific hurdles, during the redesigning phase and maintaining phase. PR1: *"Additionally, we tried to develop the software in a very generic way to ensure that data-extraction links are*

possible with different HIS suppliers. We also redesigned, to let the software run on the internet, that's all protected with encryption but in this sense, we only need data access through a backdoor, without being fully integrated into the HIS. This counteracts that we have to customise our codes every time." The purpose of redesigning was mainly focus on improving the relative advantage of the CDSS. Only one public developer indicated that this type of activity was absent, largely because the financial limitations they experience to invest in further development. Consequently, almost all developers carry out activities related to redesigning or improving their CDSS (PU 75%|PR 100%) as visible Table 13

F2. Knowledge Development

Even though most CDSS technologies are already operative for a long time, sometimes over two decades, and many academic studies on CDSS are executed, all public developers are publishing results of their CDSS projects. The logical reasons for this are the job-responsibilities of the public developers, namely researchers or Chief Innovation Officer and the fact some are financially supported by a public research fund. Also, private developers value the purpose of doing academic research as five of the seven execute or participate in academic research to investigate possible point for improvements. Besides developing knowledge by research, all the developers also carry out R&D related activities like pilot, effectiveness and validity studies, adjusting and searching for improvements. Table 13 indicates the low difference between carried out knowledge development related SBAs for academic research (PU 100%|PR 71%) and R&D activities (PU 100%|PR 100%).

F3. Knowledge Exchange/Diffusion

A common way to exchange knowledge is by user-producer relationships between the developers and their targeted users. All developers maintain certain relationships with their users. Information is exchanged about the usage preferences, PU4: *"… we have consciously involved the end-users in the process, to ensure that we are not producing a system that doesn't match with the practical medical request"* or to exchange information about the latest development and production capabilities, PR1 "… *we call on a weekly basis with multiple academic experts to talk about our latest progress. We also organise sessions with clinicians …* ". Reason behind this information exchanges is often related to improve the usability, adoptability or acceptability of the CDSS.

Another form of information exchange is provided by formal and informal network linkages. Multiple developers are active in one or more formal partnerships that are valuable when they must overcome present hurdles. For example, partnerships with organisations that acquiring high-quality medial data or potential other CDSS developers to stimulate market-creation. Besides, several yearly congresses are attended and mentioned by multiple developers. For example, the Dutch Universalis GP congress[viii], organised by the largest GP interest group or the international Health Information and Management Systems Society[ix] (HIMMS) conference for worldwide health informatics.

Know-How System Building Activities

Looking at Table 13, specifies that the activity percentages of both public (97%) and private developers (95%) is quite high. Besides, when considering the average difference of 9% between present activities of both developers it can be concluded that they both carry out similar SBAs that are aimed to strengthen "know-about" related functions. Related to the "know-about" set of activities, this indicates that it is important for all developers to acquire tacit-knowledge and strengthen the science/technology infrastructure of the innovation system (Hellsmark, 2010). Furthermore, the low absence of activities is interesting as this indicates that each developer found it important to apply forms of basic-research, experimenting and testing new ideas.

[viii] http://www.nhgcongres.nl/

[ix] http://www.himssconference.org/

Respondent ID		F1 - Experimenting with new technologies/fields/systems	F1 - Improve design of CDSS (Relative Advantage)	**F1- Entrepreneurial Activities**	F1 - Academic Research	F2 - R&D Activities	**F2 - Knowledge Development**	F3 - User-Producer Interaction	F3 - Knowlede Exchange Partners/System Actors	**F3 - Knowledge Diffusion**	**"KNOW - HOW"**
PUBLIC DEVELOPERS	PU1	S	S		S	S		S	S		
	PU2	U	A		S	S		U	S		
	PU3	S	U		S	S		S	S		
	PU4	S	*n/a*		S	S		S	S		
	PU5	S	*n/a*		S	S		U	S		
	PU6	S	*S*		S	S		S	S		
PRIVATE DEVELOPERS	PR1	S	S		S	S		S	S		
	PR2	S	S		A	S		S	S		
	PR3	S	S		S	S		S	S		
	PR4	S	S		A	S		S	S		
	PR5	S	S		S	S		S	S		
	PR6	S	S		S	S		S	S		
	PR7	S	U		U	U		U	S		
Public Activities Count		6	3	9	6	6	12	6	6	12	***33***
Private Activities Count		7	7	14	5	7	12	7	7	14	***40***
Public Absent Activities		0	1	1	0	0	0	0	0	0	***1***
Private Absent Activities		0	0	0	2	0	2	0	0	0	***2***
Public Activities Percentage		100%	75%	90%	100%	100%	100%	100%	100%	100%	***97%***
Private Activities Percentage		100%	100%	100%	71%	100%	86%	100%	100%	100%	***95%***
Public Succes Activities		5	2	7	6	6	12	4	6	10	***29***
Private Succes Activities		7	6	13	4	6	10	6	7	13	***36***
Public Unuccesfull Activities		1	1	2	0	0	0	2	0	2	***4***
Private Unuccesfull Activities		0	1	1	1	1	2	1	0	1	***4***
Succesfull Activities Public (%)		83%	67%	78%	100%	100%	100%	67%	100%	83%	***88%***
Succesfull Activities Private (%)		100%	86%	93%	80%	86%	83%	86%	100%	93%	***90%***

Table 13. Know-How System Building Activities

5.4.2 Know – About System Building Activities

F4. Guidance of the Search

As most "know-how" activities are focussed on widening the current CDSS knowledge base by doing research, R&D activities or pilot studies, guidance of the search diminishes the possibilities by filtering out the unfeasible ideas or technologies (Hekkert et al., 2007). This can be done by positively influencing the expectations of CDSS users towards a certain desired type or design. Another executed way is by exchanging information with regulations actors, interest groups, supplying actors, competitors and promulgate a long-term concept version of the future desired CDSS, that can lead to R&D priority setting. For example, PR5: "*… that will provide recommendations in a new way. Today it is a stand-alone system that is embedded in the workflow, and we're not working with real-life patient that is being send to the system. Now the clinician use search terms, that's more the future where we going, with the deeper embedding of real-life patient data."* or PR7: "*The spot on the horizon for our CDSS is, or CDSS in generally, that we realise that the CDSS becomes fully interwoven with the EHR systems on different modules. The EHR system that achieves this the best will be the dominant EHR system, and then our CDSS will be invisible for the clinician expect that somewhere is noted: CDSS is powered by organisation X.*"

Regarding Table 14, both developers carry out activities that aim for influencing the perception of their consumer base (PU 100%|PR 100%). Interesting is that activities related to the futuristic possibilities seems less important or achievable for public developers as two-third indicates that they are not influencing the prospective of next-gen CDSSs (PU 33%|PR 100%).

F7. Legitimacy Creation

Achieving legitimacy for CDSSs can be considered as an important task because of the high presence of clinical (PU 78%| PR 79%) and institutional hurdles (PU 75% |PR 67%). An important bottleneck that is mentioned is the muscle of the HIS supplying organisations, as they provide the necessary real-life patient data extraction that is required for a well-functioning CDSS (Garg et al., 2005; Kilsdonk, Peute, & Jaspers, 2011). The necessity for these firms to provide those types of extractions can be considered as very low. PR4 (as EHR supplier): "*We are getting requests, however we preferable see solutions created by our own tools. We already have the tool-box, so it's just a matter of establishing. Thus, the need for us to do this with software of other firms is very limited for us."* Several activities are carried out to deal with this legitimacy lack at the HIS suppliers. A collective way, carried out by all developers, is to speak directly with the HIS suppliers and discuss the possibilities (PU 100%|PR 100%), indicated in Table 14. Some developers indicate that they approach certain partner organisation or target-users to fill in a request at the HIS supplier for providing a data-extraction with the CDSS. Although this way is mentioned by more developers as a possibility, it is achieved by only one of the three public developers and two of the four private developers (PU 33% | 50%).

Being linked by a partnership with an interest group or ensuring public approval of an interest group are SBAs that are carried out to strengthen the legitimacy of overall CDSS. This activity is carried out by four of the five public developers and four private developers that mentioning this activity (PU 80%|PR 100%). Several of the developers indicated that these interest groups can be influential in the adoption of your CDSS and can form a harm when not handled with care. One developer mentioned the absence of interest group related SBAs, PU2: "*for example the interest group, they were in an uproar over our CDSS because they were not involved in the development process and they had the idea that our CDSS was formed out of a strong partnership between us and health-insurance organisation X. That resulted in a hassle, and they started to block our progress."*

An activity that is carried out by only one of the four public developers that mentioned the activity, is influencing the regulations of CDSS in any form. The self-judged impact force of private developers can be considered as high as three quarters were carrying out this type of regulations influencing activities. PR3: "*We try to do this on a national level, to achieve more regulations that compulsory the use of such a CDSS in further treatment planning of a patient, however this is very difficult and will take a long time*." This resulted in a relative large difference in the percentage of SBA related to changing the regulations (PU 25%|PR 75%) in Table 14.

Know-About System Building Activities

Table 14 indicate an average higher percentage of 22% for private developers in comparison with the public developers. This indicates that overall, know-about SBAs are marked as more importantly by private developers, whereby the largest difference in SBAs is seen in influencing the future perspective of CDSS and pressuring the current regulations. Another interesting result is the difference between directly and indirectly influencing the EHR agenda, whereby indirect pressures are generally absent of all the different "know-about" related SBAs.

5.4.3 Enablers SBAs

F5. Market Formation

To create a playing field where the new technology can compete with embedded technologies, it is necessary to stimulate forms of market formation by SBAs (Hekkert et al., 2007). Both types of developers are involved (PU 100%|PR 100%), regarding Table 15, in the market formation by carrying out activities that focus on achieving a protected space or niche-market. Arrangement for financial incentives to use the CDSS were made with stimulus of health-insurance company reimbursement or by asking reduced rates for a limited time.

Other examples of market formation are reducing the market-scope towards a smaller group, to first prove the functioning of the CDSS on a smaller scale before upgrading it towards a larger setting (PU 100%|PR 100%). At last, eight developers mentioning convergence of standardisation as an important activity to simulate the CDSS market. Three out of three public developers and four of the five private developers from this group, are carrying out such an activity (PU 100% | PR 80%), displayed in Table 15. For example, PU6: "*The reason that we started with this in our organisation, is the fact that we place ourselves in a position that can manage the quality of the medical data sources, that forms the basis for a CDSS. In the past we barely did something with this position, to fulfil certain standardisation in the way medical data is being guaranteed*" and later *"That is the reason we have certain partnerships or participate in different projects, we try as far as possible to achieve this, by sharing all the knowledge that we have achieved, open-source our software, publications of standardisations and collaboration with other parties like the national institute for ICT".*

Respondent ID		F4 - Influence expectations of CDSS users	F4 - Influence future perspective of CDSS	**F4 - Guidance of the Search**	F7 - Pressure HIS Agenda (Directly)	F7 - Pressure HIS Agenda (Indirectly by partners)	F7 - Creating legitimacy by Interest Groups	F7 - Change Regulations	**F7 - Creating Legitimacy**	**"KNOW - ABOUT"**
PUBLIC DEVELOPERS	PU1	S	*n/m*		U	A	U	A		
	PU2	U	A		U	U	A	A		
	PU3	U	*n/m*		U	A	S	*n/m*		
	PU4	U	A		*n/a*	*n/a*	S	A		
	PU5	U	*n/m*		*n/a*	*n/a*	*n/a*	*n/m*		
	PU6	S	S		U	*n/m*	U	U		
PRIVATE DEVELOPERS	PR1	S	*n/m*		U	U	S	*n/m*		
	PR2	U	S		*n/m*	U	U	*n/m*		
	PR3	U	S		U	*n/m*	*n/a*	U		
	PR4	S	S		*n/a*	*n/a*	U	U		
	PR5	S	S		S	A	*n/m*	U		
	PR6	S	S		*n/a*	*n/a*	*n/a*	*n/a*		
	PR7	U	S		U	A	S	A		
Public Activities Count		6	1	7	4	1	4	1	10	***17***
Private Activities Count		7	6	13	4	2	4	3	13	***26***
Public Absent Activities		0	2	2	0	2	1	3	6	***8***
Private Absent Activities		0	0	0	0	2	0	1	3	***3***
Public Activities Percentage		100%	33%	78%	100%	33%	80%	25%	60%	***68%***
Private Activities Percentage		100%	100%	100%	100%	50%	100%	75%	81%	***90%***
Public Succes Activities		2	1	3	0	0	2	0	2	***5***
Private Succes Activities		4	6	10	1	0	2	0	3	***13***
Public Unuccesfull Activities		4	0	4	4	1	2	1	8	***12***
Private Unuccesfull Activities		3	0	3	3	2	2	3	10	***13***
Succesfull Activities Public (%)		33%	100%	43%	0%	0%	50%	0%	20%	***29%***
Succesfull Activities Private (%)		57%	100%	77%	25%	0%	50%	0%	23%	***50%***

Table 14. Know-About System Building Activities

F6. Resource Mobilisation

Struggles with gathering all necessary resources for successfully developing a CDSS is overall indicated as the sphere with the lowest present hurdles, especially by private developers (46%). This indicates, together with the high necessity for knowledge development, why almost all type of CDSS developers carry out these types of SBAs. Addressing research grants is done by all six public developers and 2 of the 2 private developers that mentioned this form of financial injection as a possibility to strengthen the resource mobilisation system function (PU 100%|PR 100%), displayed in … Furthermore, other financial capital mobilisation activities are focussed on stimulating sales, receiving back-up by the sales of other product-lines or by intellectual property sales through a network-search. Table 15 shows that these forms of SBAs are also carried out by all type of developers (PU 100%|PR 100%).

Those CDSS developing organisations that also provide care, like hospitals, can provide the developers with complementary assets like historical medical data and the outcome of certain treatments. Other firms, that have CDSS as their core-business, carry out activities to mobilise these complementary assets by their network, to train, build test or validate their CDSS. Both activities are carried out by all developers (PU 100%|PR 100%) that mention one or both activities.

Only one form of resources mobilisation was absent by one of the three public developers that initiated influencing the current cost structure as a possible and important SBA for the future of CDSSs (PU 67%|PR 100%

see Table 15). As indicated in the presence of market-economic hurdles, the current cost-structure of insurance reimbursements is blocking the financial benefits of implementing a CDSS. Four out of four private developers carried out these type of activities, for example PR1: "*We believe in the future of value based healthcare, where doctors are being payed based on the quality of care they provide divided by the costs they have made. This type of systematics provides a reasonable stimulus for doctors to provide better care and besides, the earning models will become much more understandable.*"

Respondent ID		F5 - Creation Protected Space	F5 - Specification of Target Group (to increase ussage)	F5 - Influence Standardistations	**F5 - Market Formation**	F6 - Financial Resources by Research Grants	F6 - Financial Resources by Sales/Organisation/Network	F6 - Complementery Assets trough own Organisation	F6 - Complementery Assets trough Network	F6 - Influence Cost Structure	**F6 - Resources Mobilisation**	**"ENABLERS"**
PUBLIC DEVELOPERS	PU1	*n/m*	*n/m*	*n/m*		U	U	U	*n/a*	*n/m*		
	PU2	S	U	U		U	S	*n/m*	S	U		
	PU3	U	*n/m*	n/m		U	U	S	U	*n/m*		
	PU4	U	*n/m*	U		S	*n/a*	*n/a*	S	*n/m*		
	PU5	*n/a*	S	n/m		S	S	U	S	A		
	PU6	*n/m*	*n/m*	S		S	U	S	*n/a*	U		
PRIVATE DEVELOPERS	PR1	U	S	*n/m*		U	*n/a*	*n/m*	S	U		
	PR2	*n/m*	*n/m*	A		*n/m*	S	S	U	S		
	PR3	S	*n/m*	U		*n/m*	S	S	*n/m*	*U*		
	PR4	S	S	S		*n/m*	S	S	*n/a*	*n/m*		
	PR5	*n/m*	S	S		*n/m*	S	*n/m*	S	*n/m*		
	PR6	S	S	S		*n/m*	S	S	*n/a*	*n/m*		
	PR7	*n/m*	*n/m*	*n/m*		S	U	S	*n/a*	U		
Public Activities Count		3	2	3	8	6	5	4	4	2	21	***29***
Private Activities Count		4	4	4	12	2	6	5	3	4	20	***32***
Public Absent Activities		0	0	0	0	0	0	0	0	1	1	***1***
Private Absent Activities		0	0	1	1	0	0	0	0	0	0	***1***
Public Activities Percentage		100%	100%	100%	100%	100%	100%	100%	100%	67%	93%	***97%***
Private Activities Percentage		100%	100%	80%	93%	100%	100%	100%	100%	100%	100%	***97%***
Public Succes Activities		1	1	1	3	3	2	2	3	0	10	***13***
Private Succes Activities		3	4	3	10	1	5	5	2	1	14	***24***
Public Unuccesfull Activities		2	1	2	5	3	3	2	1	2	11	***16***
Private Unuccesfull Activities		1	0	1	2	1	1	0	1	3	6	***8***
Succesfull Activities Public (%)		33%	50%	33%	38%	50%	40%	50%	75%	0%	48%	***45%***
Succesfull Activities Private (%)		75%	100%	75%	83%	50%	83%	100%	67%	25%	70%	***75%***

Table 15. Enablers System Building Activities

Enablers System Building Activities

Comparing the public and private percentages of carried out activities in Table 15 indicate a high percentage for both type of developers (97%), as only two SBAs were indicated as absent. This resulted in a slightly higher percentage for public actors in carrying out market formation activities and a higher percentage in resource mobilisation activities by private developers. Overall can be concluded, based on the function strengthening, that both a priori type of developer's address "enablers" functions.

System Function Strengthening

Analysing the differences in carried out SBAs, in percentages, for each activity indicate an average difference of 13% between the two type of developers, based on Table 13, 14 and 15. Although major differences are found on influencing the future perspective of CDSS (PU 33% | PR 67%) and changing current regulations (PU 25% / PR 75%) the large overlap indicates limited signals for a preferred difference in institutional set-up by focussing on different functions. Therefore, the limited distinction between a priori type of developers based on the carried-out system function strengthening SBAs, agrees with the limited distinction given the hurdle experience.

5.4.4 System Building Activities in relation to the Spheres

The next section briefly address the linkages between SBAs and specific hurdles within each sphere and addresses the second set of functions. This section also indicates that specific SBAs are executed to address multiple hurdles or spheres.

Technological Sphere

Programming and performance are two specific technological hurdles that are experienced by only a few developers. If experienced, both developers seem to improve or redesign their CDSS by carrying out entrepreneurial related [F1] SBAs (PU 90%|100% PR). Assembling the necessary knowledge that is required to build or redesign is created by knowledge development [F2] SBAs (PU 100%|PR 86%) or exchanged through network or user-producer interactions [F3] SBAs (PU 100%|PR 100). The software integration hurdles with HIS suppliers were often tackled by carrying out legitimacy creation building activities [F7]. Although this is not applicable for PR4 and PR6 by being a HIS supplier themselves, all other developers carried tried to pressure the EHR agenda directly and some developers also indirectly through partner organisations. Dealing with the amount of ICT systems and poor data quality that are perceived as a present hurdle by many developers and are often linked to the lack of consensus and standardisations. PR5: "*One of the biggest problems is that everyone use different ICT systems and different coding schemes which hindrances you when you want to achieve actual deeper integration because first, you have to deal with languages barriers and second with coding problems. For example, they use different coding-sets in the US than they use over here."* Therefore, resolving this problem requires the convergence of active standards (PU 100%| PR 80%) that are being used, PR5: "*We try to embed open-source coding schemes and it will helpful if this becomes the only one that will be used*."

The theory section indicated that different type set of activities would be likely to performed differently by public and private developers. However, both type of actors able and interested to carry out a similar amount of "know-how" related activities within the technological sphere, resulting in the rejection of proposition 2a. Furthermore, it was initiated that know-about related SBAs are more likely to be performed by private developers. Regarding the "know-about" SBAs in the technological sphere, indicated is that all developers address the integration problem by legitimacy creation. Thus, the expected higher amount of private SBA's addressing these problems is not found, resulting in the rejection of proposition 2b.

Market-Economic Sphere

Acquiring financial resources, to develop and maintain the CDSS, is mainly achieved by resource mobilisation [F6] related SBAs by both type of developers. This is similar for acquiring complementary assets, as both type of developers carry out resource mobilisation related SBAs. Another struggle is the resistance of users to pay for making use of the CDSS and therefore effectuate market-share growth. SBAs to tackle this hurdle are focussed on influencing the expectation of CDSS users [F4], for example by executing studies that measure the financial or healthcare impact of the CDSS [F2]. PR5: *"A study in England showed that our CDSS is refunding itself within 90 days, so we developed an Internal Rate of Return calculator that we fill in together with our potential users to indicate which point they want to improve and see how much it cost and what the impact of our CDSS could be*." A specific action to increase the market-share [F5] is by creating a protected space or niche market (PU 100%|PR 100%) or by focussing on a specific group of end-users (PU 100%|PR 100%), PU2: *"… start to question yourself it is a valuable tool for al clinicians and then you are narrow down your target group and take it for granted that your tool doesn't work for all clinicians.*"

Taken together the market formation and resource mobilisation carried out SBAs, indicate that both public and private developers execute "enablers" set of SBAs. Expected was that private developers were more likely to perform these activities within the market-economic sphere, and therefore proposition 2c is rejected.

Clinical Sphere

Enduring the lack of social acceptance is the most influential hurdle to overcome within the clinical sphere, either caused by professional autonomy complications or perceived time restrictions of the clinician to use the CDSS. Response to the first hurdle is provided by lobbying for stricter regulations [F5] to use the CDSS. Activities to deal with the time-restrictions are often linked to the lack of data-integration as described in the technological sphere. Developers also choose to improve the relative advantage of their CDSS by user-producer integrations [F3] and redesigning their CDSS [F1] to eventually improve overall acceptance. These types of activities are similar for dealing with implementation issues. PR1: *"Speaking with clinicians, or observing their usage, for example at the intensive care to see and research which factors are important in the diagnostic process and decision making,*

which information do you want to receive at which time. These are all activities that we carry out to improve the implementation of our CDSS."

Estimated was that public developers are more likely to perform "know-how" SBAs to deal with hurdles in the clinical sphere. The provided reason for this was the close relation of public actors with end-users in public settings and their research responsibilities. Yet, specified by Table 13 it seems that private actors are also executing user-producer-interaction and generally executing a similar amount of "know-how" SBAs as public developers (PU 97%|PR 95%). Therefore, proposition 2d is rejected.

Institutional Sphere

Complying to certifications requirements and privacy regulations is indicated as a present hurdle by many developers. Both public and private developers attended this hurdle by redesigning the CDSS [F1], influence or adapt the current regulations [F7] and standardisations [F5], or by receiving help from experts [F3]. PU6: "*Eventually we requested an advisory organisation to help us with researching the European Privacy laws … so far it cost a lot of man-hours and so it's a costly aspect"* and PR1: "*At the moment we are in consultation with a few lawyers to deal invest possible challenges around certification, we have heard that there are some hard challenges to overcome".* Another struggle is the dissension among users and system actors about the usage of CDSS and the value it creates. Working together with interest groups [F3], influencing regulations [F7] or stimulating the convergence of standardisations [F5] are carried out SBAs, to deal with this struggle. Another executed SBA to address this hurdle is the guidance of the future perspective of next-gen CDSSs, to eventually build CDSSs that will be supported by all system actors. So far, influencing this seems far more done by private developers (PU 33%|PR 100%). This difference is caused by the fact that some pubic developers are mainly occupied by their own CDSS development and perform minimal activities of scanning the market for possible competing CDSSs.

In general, it was argued that private developers are more likely to perform "know-about" related SBAs within the institutional sphere. Specified in Table 13 it appears that private developers indeed carry out these activities slightly more in comparison then public developers and therefore proposition 2e is partly supported.

5.5 Influence on Innovation CDSS

The following sections focus on the success of the SBAs and the possible interaction between the different spheres

5.5.1 Success of System Building Activities

Success of SBA is defined as the muscle or capacity to influence the institutional set-up within the innovation system to a more preferred way. This study researched the success of SBAs by the capabilities of developers to lower the experienced hurdles, and therefore restructure the institutional set-up of the system. Described in the previous sections is that all developers carry out a broad range of SBAs whereby a large overlap is identified. Yet, reaching success with the SBA and lowering the experienced hurdle is indicated by the developers as a more difficult assignment.

Within the "know-how" set of activities, most developers successfully carry out their SBA resulting in fruitful new experiments with new technologies, sufficient R&D activities and exchange of knowledge with partners or system actors. A few developers experience difficulties in successfully redesigning their CDSS through financial restrictions (PU2, PU3) or setting-up successful knowledge exchange relation with their end-users (PU2, PU5). In general, the success between public and private developers barely differs (PU 88%|PR 90%) within the "know-how" set of activities (see Table 13), indicating that both their actions successfully strengthening the technological and scientific infrastructure of the CDSS innovation system.

A more difficult task relates to successfully executing "know-about" related SBAs. These activities aiming at further aligning the technological development structure by demonstrating possibilities and influencing the expectations of CDSS users. However, as specified in Table 14, overall success of these activities is rather low (< 50%). Especially, pressure the EHR suppliers Agenda successfully to achieve a form of data-extraction is a SBA that is relatively impossible. Therefore, the strong resistance of EHR suppliers remains a hurdle that influences the dissemination of CDSSs. This finding is in line with many effectiveness studies of CDSS innovation systems (Belard et al., 2017; Jaspers et al., 2011), that indicate social acceptance as an important bottleneck that needs to be overcome. Explanation for the low success of private developers is the conflict of interest between EHR and the CDSS developing organisation, as they both are profit oriented. Reason for public developer

ineffectiveness is the EHR supplier low urgency to incorporate the CDSS when the CDSS is based on local expertise or guidelines. For example, PR4: *"… so then you get local parameters, that are not used and operable for other EHR users as they register different parameters. So, if a developer builds a CDSS upon local knowledge with local parameters, then we must deal with data from different sources all the time. So, we prefer national initiatives with singular parameters, because local initiatives can be very time consuming*". Another hurdle that hard to adjust is the lack of social acceptance, as unsuccessfully addressed by influencing the current expectations (PU 33% | PR 57%) or by changing the current regulations on CDSS usage (PU 0%|PR 0%). The main reason for this is the consensus lack among all present actors in the innovation system, as the added value that is provided by a CDSS is not recognizes by health-insurance companies and only partly acknowledged by the government. However, the latter can be strengthened by positive outcomes of the health-deal that is set-up by the government. Additionally, both type of developers carry out SBAs aimed at changing the future perspective of CDSS and do this successfully (PU 100%|PR 100%). Nevertheless, both a priori developers experience a lot of struggles in carrying out "know-about" related SBAs successfully (PU 29%|PR 50%).

Like the "know-how" related SBAs, public developers experience relatively more difficulties in carrying out market formation and resource mobilisation strengthening SBAs. Table 15, indicate large difference for the "enablers" success in the average of market formation activities [F5] (PU 38|PR 83%), the mobilisation of financial resources by sales (PU 40%|PR 83%) and complementary assets through own network (PU 50%|PR 100%). Remarkable is the lower success of public organisation in gathering complementary assets successfully through their own organisations, as these organisations also produce this knowledge more often. An explanation for this is the assembling of a data-sets that can be used for validation of the CDSS, since these sets needs to be acquired outside the developing organisation and this is experienced as more difficult. Overall, public developers experience more struggles in carrying out successful "enablers" SBAs in comparison to private developers.

Reviewing the success of carried out SBAs shows an overall higher success for private developers (75%) compared to public developers (45%). The differences are especially visible in the "know-about" set of activities (PU 29%|PR 50%) and the "enablers" set of activities (PU 45%|PR 75%). Similar results are found in the know-how set of activities (PU 88% | PR 90%). All in all, it can be concluded that private developers are better able to successful influence and adapt the innovation system institutional structure. Therefore, based on different tables, it can be concluded that proposition 3 is supported.

Remarkable System Builders

Based on the amount of successful and unsuccessful SBAs it is possible to identify developers influence the system and developers could only follow the system. Influential developers are PU6, PR4, PR5 and PR6 based on the success of their SBAs, as these developers all carrying out at least eleven successful SBAs. Developers that have the lowest influence on the system are PU2 and PR7 both carrying out respectively 9 and 8 unsuccessful SBAs. Adding the hurdle experience to this way of reasoning, indicate that only two developers (PR3, PR4) experience slightly more absent then present hurdles, where all other developers experience a balanced or higher number of present hurdles. The most hurdles are experienced by PU2, PU3 and PR7, all indicating the experience of at least 11 hurdles. Taken together, it can be concluded that PR4 is the most influential developer and PU2 and PR7 have the lowest capabilities to influence the system.

5.5.2 Interaction among Spheres

During the analysis, it became clear that most carried out SBAs were aimed at strengthening multiple system functions or lowering several hurdles. This resulted in two analysis of the SBAs. First, the SBAs were analysed based on strengthening specific system functions. The second analysis coupled the SBA to the hurdles they were addressing. Combining the two analysis provides insights in possible interaction among the system functions in the different spheres. Accordingly, Figure 7 provides an overview of all the different goals or aims of the SBAs and how they are related to other system functions and hurdles. The aim or goals are indicated by the black arrows.

Besides, statements of the developers indicate that several hurdles are linked or influencing other hurdles. Most of these linkages occur within a singular sphere and sometimes they occur between different hurdles of spheres. The most common example of this is the link between software integration hurdle (tech. sphere) leading to double entry necessity and the social acceptance hurdle (clinical sphere) by time restriction. Several other of these linkages are found and indicated by the dotted lines in Figure 7. This showed the complex interaction between the SBAs carried out by both developers, hurdles and system functions within the entire CDSS innovation system.

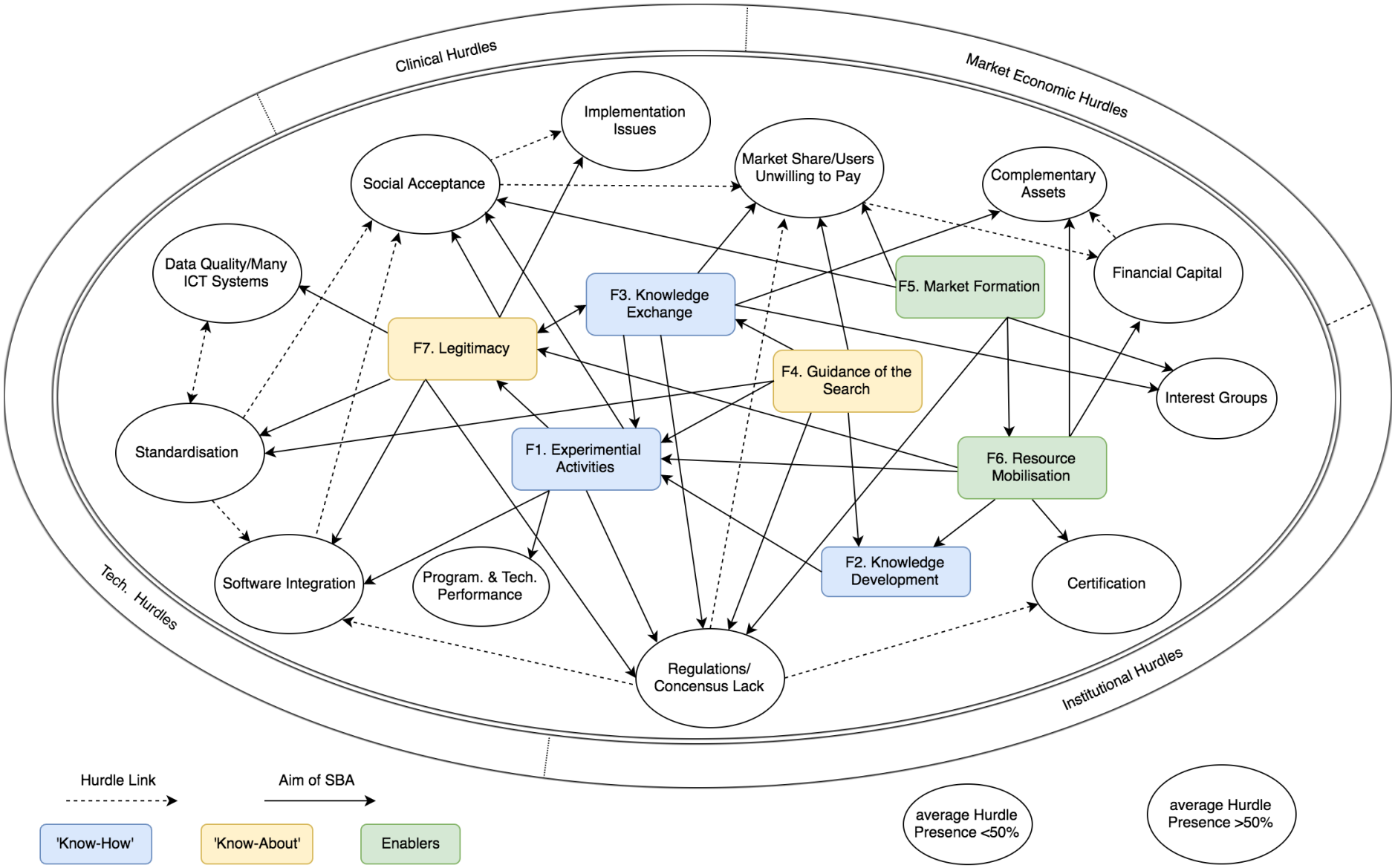

Figure 7. Interactions Overview

5.6 Overview of the Results

Multiple propositions were researched within this study. Table 16 illustrates the main results of this study. Five of the eleven propositions were supported and six were rejected.

Interaction	*Expected Situation*		*Sphere*	*Result*
Hurdle Experience	P1a	Similar (±)	T	Supported
	P1b	Public: Financial Capital (+)	M/E	Supported
	P1c	Private: Comp. Assets (+)	M/E	Rejected
	P1d	Private (+)	C	Rejected
	P1e	Similar (±)	I	Supported
System Building Activities	P2a	Public: Know-How (+)	T	Rejected
	P2b	Private: Know-About (+)	T	Rejected
	P2c	Private: Enablers (+)	M/E	Rejected
	P2d	Public: Know-How (+)	C	Rejected
	P2e	Private: Know-About (+)	I	Supported
System Influence	P3	Public (+)	∀	Supported

Table 16. Propositions Results

5.7 Additional Insights

Several additional insights were founded by the semi-structured interviews as multiple interviewees mentioned similar phenomenon. The most remarkable ones are discussed below.

Public vs private distinction by developers

During the interviews with the system actors it was important to get a description of the Dutch CDSS market, as this image is related to reach theoretical saturation. Also, developers were asked about the other developers in the CDSS market and if it was possible to make a distinction between the developers. In the follow-up question respondents were asked if distinction between private and public developers is feasible, based on their goals, vision or type of CDSS. Answers on this question provide two interesting outcomes. Most public developers made statements that the goal of private developers often is related to implementing what we know building and building a feasible product in relation to their own goal of generating new knowledge. *They state that private organisations are less interested in supporting the medical request or task of reducing medical errors and feel a limited need to a further research the content of CDSS knowledge*. Yet, results of the data-analysis indicate that both a priori developers execute academic research and R&D activities. On the other hand, most private developers had little to non-awareness of public initiatives. At last, some developers and system actors indicated that it is very difficult to make a clear distinction, and that both type of developers are quite similar in their behaviour, aim and type of products. This standpoint is in line with the results of the data-analysis.

Absent System Building Activities by being patient

A common answer provided by the developers was; 'just be patient', when questions were asked about executed activities to lower the hindrance of a hurdle. The provided explanation for this, is the complex and difficult conversion towards fully adapting and make properly use of EHR systems. Most Dutch clinicians were used to manuscript all important remarks during a consult and store these within paper database, until 2008, when the first EHR were introduced in the Netherlands. Being completely aware of the EHR possibilities and adapt this in your daily routine is still seen as an ongoing transformation that requires time. A consequence is the current lag of certain clinicians to code properly, as they still prefer to write down all their remarks in the available free-text boxes in the EHR template.

Several developers indicate that especially older clinicians experience problems with accepting EHR systems and find it hard to see what benefits the EHR or CDSSs brings. These findings are in line with the general barriers for adopting eHealth solutions as previous literature indicate that especially older clinicians lag in adopting eHealth solutions (Decker, Jamoom, & Sisk, 2012).

‘U’- shaped CDSS functioning curve

An interesting and recurring remark by some developers is the functioning area of the CDSS. These developers sketch the impression of certain ‘U’ shaped regression or relationship between the effectiveness of a CDSS and the complexity of the healthcare task that it is addressing. This means that especially simpler and high complex tasks can be covered by a CDSS effectively. Lower complex tasks need to be checked by a CDSS as simpler tasks often consist of daily-routine work that are executed on the ‘autopilot’ modus of clinicians. Executing tasks on this modus result in a higher rate of mistakes. On the other hand, far complex tasks along many parameters require the calculation and pattern recognition capacities of machine-learned CDSS. Clinicians accept that providing accurate advice on these complex tasks surpasses the capabilities of the human brain. Thus, the perception of CDSS developers is that struggle caused by professional autonomy seem to occur more often on complex tasks that are in the scope of the clinician reasoning limits. Regarding the search for effective CDSSs, future research should extinguish the presence of a u-shaped correlation between the medical task complexity and the CDSS performance.

6. Discussion

This chapter will discuss the main outcomes of tries to provide insights in why certain expected results are not found, therefore it will focus on the propositions that lack support and were rejected. Furthermore, it will provide the main practical and theoretical implications and define limitations and suggestions for further research.

6.1 Discussion of the Results

6.1.1 Socio-technological Characteristics

This research made use of the a priori distinction between public and private developers by expecting a difference in product focus, hurdles experience and institutional set-up enhancement by carried out SBAs. This reasoning was initiated by study of Gittleman (2016) on the existence of two successful operative 'research paradigms' in medicine development. Gittleman state that these research paradigms can be distinguished by the origin of the search (type of developer) and type of products that characterise each paradigm. By identifying public and private developers within the Dutch CDSS system, the distinction in the origin of the search in this study was based on the profit or non-profit focus of the respondents. However, signifying the socio-technological characteristics of the CDSS indicates that the both type of developers produce a diverse mix of CDSS systems. This lack of a clear distinction could explain the huge overlap in experienced hurdles and carried out SBAs. So, if public and private innovators develop a CDSS with similar socio-technological characteristics it could be the case that they enhance the same institutional setting and experience similar systemic hurdles (Hellsmark, 2010).

Reviewing the socio-technological characteristics of the CDSSs in relation to hurdle experience reveals some worth mentioning associations. For example, a clear distinction in relation to hurdle experience can be drawn on the type of reason method in the CDSS. First, rule-based CDSS developers often indicate that experience missing or wrong coding in the EHR by the clinician. Second, the reasoning engine of a CDSS forms a difference in how easily complementary knowledge sources can be reached in the market-economic sphere. For example, rule-based CDSS require guidelines in their knowledge base and these are much easier to assemble in comparison to privacy-sensitive patient-data. Furthermore, gathering financial capital seems more difficult for CDSSs that focus on a GP consumer base, due to the limited budgets and the higher dependency of health insurance reimbursements. A hurdle that is experienced by almost all developers is the lack of social acceptance. Though, observing the underlying mechanisms shows problems related to the amount of time (integrated vs stand-alone) or professional autonomy (providing recommendations or less strict advice). Clear distinctions between socio-characteristics and hurdle experience are harder to draw within the institutional sphere as these hurdles address all CDSS. For example, strict privacy regulations are experienced by different type of developers. Approval by the medical ethic committee is necessary for those developers where CDSS diffusion starts to outgrow the origin-hospital and those CDSS developers that reach for inner admission to a hospital patient data-set.

Concluding, a clear a priori distinction in product-type and hurdle experience is missing as many differences in the hurdle experience can be explained by one or multiple socio-characteristics of the developers. The a priori distinction is only clearly observable in experienced struggles related to mobilisation of financial capital and market-share growth within the market-economic sphere. Yet, this is a logical consequence of the non-profit or profit a priori distinction. Altogether, this indicates that explaining an existing or absent hurdle should be done by evaluating the different socio-characteristics of the CDSS. In this sense, the origin of the search (public vs private) is surpassed by the product type in explaining the actual difference and overlap among developers. Therefore, the occurrence of multiple research paradigms could be stimulated by overlapping socio-technological product types.

6.1.2 Experienced Hurdles

The results of this study revealed a large overlap in the hurdle experience between private and public developers. A high overlap, or similarity in hurdle experience, was expected for the technological sphere and the institutional sphere. The outcome of the data-analysis confirmed these expected situations. Similarities between the two developers were also found in the clinical sphere, although a higher hurdle experience was expected for private CDSS developers. A logical reason for this is the unexpected presence of intensive user-producer interactions maintained by the private developers. All private developers mention that having insight in the daily challenges that clinicians experience results in a product that is better aligned with the actual medical request. Therefore,

all private developers uphold user-producer relations or hire clinicians to incorporate this knowledge in their organisation.

A different unexpected situation was the absence of the complementary assets mobilisation hurdle by private developers. Three reasons for this are provided by different statements of developers. First, those public developers that are operative in a health-providing organisation require other data-sets to validate or further improve their CDSS. Therefore, they need to assemble data-sets provided by other health-care settings or data-managing organisations. Second, private developers more often choose to buy high-quality data compared to public developers. Third, also addressed in section 6.1.1 socio-characteristics, the private developers within this study are more rule-based and therefore require easier accessible medical guidelines as their complementary assets.

When questions were asked about the hurdles for each sphere it became clear that three hurdles causing the biggest struggles for the Dutch CDSS innovation system. These are the software integration difficulties, lack of social acceptance and lack of consensus about the added value of CDSS among all actors. Illustrated in Figure 7, it appears that many of the SBAs are aimed at those three and that these hurdles stand in relation with many other hurdles. The finding of these specifc hurdles is in line with results of many systemic studies that exposed barriers for the functioning of a CDSS (Belard et al., 2017; Garg et al., 2005; Kilsdonk et al., 2011).

6.1.3 System Building Activities

Specified by the overviewing SBAs Tables 14, 15, 16, indicates that all developers carry out a high diversity of SBAs and therefore strengthening different system functions. Expected was that public actors were carrying out more “know-how” related SBAs within the technological and clinical sphere. However, the data analysis indicated that both type of developers carry out similar SBAs. The main reason for the high overlap, and low absence of SBAs could be the way how the interview questions were asked or interpreted. A problem could be that the questions were wrongly framed, leaving out the opportunity or space to discuss absent SBAs. Reframing of adding extra follow-up questions could address possible absent SBAs and reduce the number of not-mentioned subjects. A different explanation could be that it is easier to talk about carried-out activities instead of addressing situations in where the developer did not know what to do as these situations were not experienced yet. This possible limitation should be considered in similar analyses or following-up studies.

An interesting difference in the presence of SBAs is found the influence of the future perspective of CDSS. The analysis showed, in Table 14, that only one of the three public developers is addressing this issue, compared to six private developers. Although, a large overlap is found between the SBAs, this dissimilarity indicate that public developers are less interesting or incapable to guide the future direction of the whole innovation system. This means that R&D priority setting is substantially more influenced by the stronger vision of private developers. Therefore, these developers are setting the long-term agenda goals within the Dutch CDSS innovation system and thus influencing the direction of the technological change (Hekkert et al., 2007).

Something else that stood out is the low knowledge attendance of system actors about the carried-out SBAs of developers. Expected was that the outcome of these interviews could also provide statements in addressing the difference in carried out specific SBAs, however only limited statements could be formulated. A clarification could be the attendance of only one interest group system actor as well as no governmental system actor or one that is related to the public-research fund. These actors could maybe be more interested in the broad activities carried out by developers to stand up for the issues of clinicians, GPs, patients etc. or to identify possible violations. This study has approached multiple system actors, however most of these requests resulted in a no-response.

6.1.4. Influence on CDSS innovation system

Regarding identifying important and influential developers, it stood out that only a few developers were able to achieve influential results. Specifically, it became clear that strengthening the “know-about” system functions by both developers is rather unsuccessful.

Explanations for the low success of “know-about” SBAs could be provided by two reasons. First, the Dutch CDSS innovation system is undergoing the formative phase of innovation system development. This phase is highlighted by constituent elements that put in place, the entry of some firms and other organisations, the beginning of institutional alignment and the structural components (Bergek, Hekkert, et al., 2008). On the system level, this phase is characterised by large uncertainties regarding technologies, markets and applications and the absence of powerful reinforcing features. The high uncertainties (consensus/standardisation lack and users unwilling to pay) present within the Dutch CDSS innovation system justify the low success of these activities.

Another explanation is provided by the capacities lack of the developers. The study of Kukk et al., (2016) identified that institutional entrepreneurs strategically dedicate their resources and not always target the institutions directly. This means that those developers that have the power to change the institutional set-up strategically aim for this by strengthen other system functions and avoid "know-about" related SBAs. Overall, the relatively unsuccessful "know-about" SBAs, especially by public developers, has consequences for lowering many of the mentioned hurdles. Reason for this is that the aim of these SBA's address many of the present hurdles. Figure 8, located in the appendix, highlights the number of hurdles that are addressed by carried out "know-about" SBAs, and is illustrating the possible consequences.

The success or 'transformative capacity' can be explained by having access to enough resources or can created by a strong network (Farla et al., 2012). Although specific background information about the resources and network of the linkages was missing, it is possible to identify certain linkages between hurdle experience and the SBA success. Several possible influential developers could be identified, based on the number of successful activities, namely PU6, PR4, PR5 and PR6. Interesting to see is that all the private developers are multinationals that not experience a financial capabilities mobilisation hurdle. Additionally, PU6 is experiencing financial mobilisation struggles, however is indicated by many knowledge-exchange and formal linkages illustrated by Figure 6, forming a solid network. These developer characteristics could indicate the high 'transformative capacity' leading to the high SBA success of the influential developers.

6.2 Implications

Theoretical Implications

This study addressed different literature streams to focus on the success and influence of SBAs in relation with the Dutch CDSS innovation system. Therefore, this study researched three main interactions between the developers and the innovation system; systemic hurdles, the carried-out SBAs and the success of these activities. Specifically, the analysis researched if these interactions varied among operative developers within the Dutch CDSS innovation system. This study indicated several relations between the socio-characteristics of CDSS and the hurdle experience of the developers. Furthermore, the success of SBAs to influence the system could be commonly explained by the presence or absence of certain systemic hurdles.

A different goal of this study was to research the presence of multiple 'research paradigms' within the Dutch CDSS innovation system, by reviewing two forms of interaction between the developers and the system structure. A comprehensive view to identify these 'research paradigms' was created by combining analytical perspectives from the innovation system literature. This created the possibility to identify type of activities that can occur on different and conflicting projects or 'research paradigms', demanding or aiming for a different innovation type or product and institutional alignment. Although indicators for multiple 'research paradigms' were missing in the Dutch CDSS innovation system, the comprehensive view appeared to be valuable in identifying them within an innovation system.

Two analytical choices were made to ensure a clear overview of the data-analysis, by using four different spheres and categorical system function sets. This study used an adjusted version of the Health Delivery Innovation system created by Consoli & Mina (2009) by added an extra market-economic sphere. The model created by Consoli & Mina (2009) incorporate market-economic related interactions within the institutional sphere. Outcome of this study indicates that the adjusted model only slightly improves the usefulness of the original tool, as only small differences were found between market-economic and institutional sphere. A different analytical choice was made in using the system functions set initiated by Hellsmark (2010) for the formation of the propositions. Reviewing this choice provide mixed evidence for the practicality of using these categorisations, as only small differences were found between the system functions in the "know-how" and "enablers" function sets. However, guidance of the system [F4] and legitimacy creation [F7] provide clear differences in the "know-about" set, as specified in Table 13. This means that adding them together in one 'categorical set' could result in the loss of valuable information, when the functions are not researched individually.

Practical Implications

The starting point of this study was the polarized discussion about the balance of public and private developers in dealing with the productivity lack of medical innovations and technological development. Contradicting arguments addressed a certain growth of either public or private developers to solve this problem. Results of this study indicates that in certain innovation systems, like the Dutch CDSS, public or private differences were far

more less observable when researching them from a micro and macro level perspective. Although overall private developers scored higher in the success of carrying out SBAs within this study, both type of actors are dealing with similar hurdles and carry out similar SBAs. This indicate that a mix of these type of developers is not causing contradictory type of products and aligned institutional set-ups that can be harmful for overall technological development within an innovation system.

This study also contributed to the enhanced search for a better understanding of the current difficulties and barriers for developing and carrying out a CDSS successfully. Although the outcome is based on insights within the Netherlands, certain aspects can be helpful for either developers, system actors or policy developers in stimulating further progress. First, dealing with the dominance of a few HIS suppliers in the Netherlands can become a major problem for realizing data-extractions or integration possibilities. So far, switching towards another HIS is experienced as a very time-consuming and costly process by many developers. Therefore, the technological development of the Dutch CDSS Innovation System is also depending on the willingness of the HIS suppliers. If they stay sceptical about the added value of other developed CDSS, and other actors lack the power to influence this, then there is a chance that overall development and diffusion may stagnate.

Another aspect is the current cost-structure that can form a problem for the practical effectiveness of implementing a CDSS. Reducing unnecessary care by a CDSS will remain financially unattractive, as long as healthcare remains funded by a quantitative basis. The initiative for changing this within the Netherlands, lies with the insurance companies that can stimulate CDSS usage by forms of financial compensation. So far, this is only realised when the costs for a single medical treatment are high enough, like proton beam therapy in the oncology field. A different role is provided for the Dutch government as they able to proactively stimulate CDSS usage or even make it mandatory. The Norwegian governmental regulated healthcare system obligated the storage and sharing of patient date and therefore created a highly feasible situation for further CDSS implementations (Ringard, Sagan, Sperre Saunes, & Lindahl, 2013). Their totally public regulated health system forms a structure were the costs of a national CDSS blank out by the financial and health quality benefits it causes (PR5).

At last, the recent approval of the new regulations by the European Union can bring along major problems for less financially robust developers, as they will also apply for CDSSs. These new MDR request an enormous financial and administrational efforts besides several validation and effectiveness studies to get a e-health license for a medical device. PR7: *"… eventually we need to get along, and it takes a lot of time and energy that you won't immediately get returned in form of a successfully product. So, the question remain, are you going to spend enormous efforts in complying to these new regulations instead of real innovation?"* Concerning these changes, it looks that the requested efforts will upset several developers, especially those that are already experience a lot of hurdles. Therefore, a financial reimbursement of the government could necessary for the less robust developers.

6.3 Limitations and recommendations for Future Research

Although the theoretical framework is embedded in the literature, and methodological choices are supported by arguments, several limitations can be marked throughout the research. The following section will address the limitations and provide recommendations for future research.

In search for answering the research question, this study made use of a comparative case study design. This design was chosen as this is characterised as most suitable in understanding social phenomena when comparing contrasting cases (Bryman, 2012). This resulted in a broad image of the present specific hurdles that play a role in the Dutch CDSS innovation system. Additionally, making use of semi-structured interviews created the opportunity to notice specific contextual hurdles, that otherwise could be left unsearched. Also, clinicians can provide much broader explanations, leading to insight that hurdle were caused or influences by other hurdles. Yet, the results of this study indicated that difference in systemic hurdles, carried out SBAs and their success is quite limited along the a priori distinction researched in the sample set of CDSS developers. A limitation of using a qualitative study is that the results or percentages displayed within this study were sometimes defined on a sub-set of the sample. Specifically, if multiple developers did not mention the subject indicated by the n/m within the overview tables. Therefore, a follow-up study with a quantitative study design is required to provide more evidence to see if the founded relations hold within a larger sample set. Furthermore, with a quantitative study design, it is possible to add 'weights' on the hurdles by making use of a Likert scale to express the

experienced struggle. Similar, the success of lowering hurdles can be measured more precisely. Researching the founded relation by a quantitative study design is therefore likely to strengthen the generalisability of this study.

An interesting thought that could provide stimulation for further research is the possible ‘u’ shaped regression between the complexity of the medical tasks and the effectiveness of the CDSS. Researching the existence of this regression could help better understanding the social acceptance lack, caused by professional autonomy issues. Although different developers supported this thought, conformation of this relation is required by future research.

At last, following-up studies should leave more room for addressing absent SBAs, to create a better insight in the influence of the systemic hurdles on the diversity of carried-out SBAs. This could either be done by addressing them directly, or by asking questions related to failed or desired but not accomplished SBAs.

7. Conclusion

The purpose of this study was to provide insights in the hurdle experience and SBAs of Dutch CDSS developers. Identifying these interactions together helps understanding to what extent operative developers can influence the CDSS innovation system in a desired way. Expected was, from the theoretical observations in medicine development, that the deduction of public and private developers result in an empirical distinction of systemic hurdle experience and carried out SBAs. Corresponding to Gittleman (2016), who identified two successful 'research paradigms', was argued that public and private CDSS developers are likely to produce different forms of CDSS and therefore strive for different aligned institutional set-ups. Identifying if the system building activities of private and public actors align, partly overlap or differ, will eventually acknowledges the presence of multiple CDSS 'research paradigms'.

Propositions were categorised by four different sphere and based on theoretical insights and previous studies that researched the effectiveness of CDSS. To add new insights in the missteps of current CDSSs, a combination of different analytical perspectives, suggested by the innovation literature, was used to create a comprehensive view. This view combined a micro level on the actor's actions with a macro level on the influence on the broader innovation system, and was used to analyse the interaction. All in all, this resulted in the follow research question:

How do the experienced hurdles and carried out system building activities differ between operative CDSS developers and to what extent does this influences the innovation system?

This study uncovered that carried out activities and hurdle experiences of Dutch public and private CDSS developers largely overlaps. A reason for this is the mix of CDSSs that both type of developers aim for, resulting in overlapping socio-technological product characteristics. This indicates that the preferred institutional set-up of both developers also overlaps, and contradicts based on the different product aims. Additionally, three major hurdles addressing all the developers; lack of social acceptance, lack of standards/consensus and software integration possibilities. The other experienced hurdles could often by linked to one of the socio-technological characteristics of the aimed CDSS, causing difference in the hurdle experience of all the developers. All in all, the extent to what developers could influence the system is better explained by the different products aimed for than their profit or non-profit background and their carried-out system building activities.

Yet, identifying the actual influence of the system building activities indicate that the private developers were better able to influence the system. Especially, the indicated strength of private developers to influence the future perspective of the CDSS indicates will influence R&D priority setting and the direction of the technological development.

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9. Appendix

A. Interview Guide
B. Know-About SBAs Overview (Figure 8)

A. Interview Guide

Date:	- -
Name:	
Organisation:	
Function:	o CDSS Developer (**ONT**) o Innovation System Actor (**ISA**) - Financier - Innovation Office - General Practitioner - Authority/Ministry - Researcher/Expert - Anders _____
Portfolio	o Only CDSS o Only Medical Devices o Broader portfolio
Focus Markt:	o Nederland o European o Global

Vraag interviewee om toestemming voor het opnemen van het gesprek die zal gebruikt zal worden voor verdere analyse (opname-materiaal zal anoniem gebruikt worden en niet worden gedeeld met derden).

Definities:

CDSS:
Actieve software kennissystemen die directe ondersteuning leveren bij het maken van klinische-beslissingen, waarbij karakteristieken (parameters) van een individuele patiënt worden vergeleken met een digitale medische kennisbasis (richtlijnen/uitkomsten) om zo tot patiënt-specifiek advies/aanbeveling te komen ten tijde van de klinische beslissing.

CDSS-Ontwikkelaar:
Actoren die direct betrokken zijn bij het ontwerpen en of verspreiden van een CDSS.

I. Introducerende vragen:

icb. Hoe ervaart u vanuit uw rol als [functie binnen Innovatie systeem] de algemene ontwikkeling van Clinical Decision Support Systems (CDSS) in de afgelopen 5 jaar?

II. Type Actoren

Ik zou graag willen beginnen met algemene vragen over CDSS-ontwikkelaars

a. Is het mogelijk om een onderscheid te maken tussen de verschillende type CDSS-ontwikkelaars en hoe zou je de verschillende type ontwikkelaars kunnen omschrijven?
- Achtergrond: Universiteit/Ziekenhuis/Organisatie/Samenwerking (publiek/privaat)

-> Waarin merkt u dat er [wel/geen] scheiding waarneembaar is?

Indien niet genoemd:

b. Is er volgens u een onderscheid waarneembaar tussen private en publieke CDSS-ontwikkelaars?
b. Do you do that a distinction is perceptible between private and public CDSS developers?
- Doel: Winst/Geen Winst
- Visie: Specialisatie/Generaliseerbaarheid/Uitbreiding medische gebieden
- Type CDSS: Architectuur CDSS/Tech. Specificaties/Integratie/Medisch Gebied

-> Waarin merkt u dat er [wel/geen] scheiding waarneembaar is?

Aantonen wat het onderscheid is tussen a priori CDSS ontwikkelaars

III. Systeem activiteiten

De volgende vragen gaan over activiteiten van CDSS-ontwikkelaars die als doel hebben om in het algemeen CDSS succesvoller te laten functioneren

c. Wat voor activiteiten voert u uit die focussen op het verbreden en verdiepen van de kennis over CDSS?
- Basis Research
- Experimenteren
- Testen van nieuwe ideeën/medische gebieden

d. Wat voor activiteiten voert u uit die focussen op het bewijzen van de klinische werking van CDSS?
- Demonstreren van mogelijkheden
- Versterken legitimiteit

e. Wat voor activiteiten voert u uit die focussen op het aantonen van de praktische uitvoerbaarheid van CDSS aan te tonen?
- Bewerkstelligen van middelen
- Stimuleren marktcreatie
- Versterken infrastructuur

f. Denkt u dat er een onderscheid waarneembaar is in de mate waarin deze activiteiten worden uitgevoerd tussen private en publieke CDSS-ontwikkelaars?
- verbreden (algemene) CDSS-kennis
- klinische werking
- praktische uitvoerbaarheid

g. Denkt u dat er een verschil waarneembaar is in het succes waarin deze activiteiten worden uitgevoerd tussen private en publieke CDSS-ontwikkelaars?
- verbreden (algemene) CDSS-kennis
- klinische werking
- praktische uitvoerbaarheid

h. Ervaart u dat private en publieke CDSS-ontwikkelaars een verschillend visie nastreven in het uitvoeren van deze activiteiten?
- verbreden (algemene) CDSS-kennis
- klinische werking
- praktische uitvoerbaarheid

IV. Systeem Belemmeringen

De volgende vragen gaan over belemmeringen die CDSS-ontwikkelaars ondervinden in de ontwikkeling en/of verspreiding van CDSS.
---

i. Zou u twee voorbeelden kunnen geven van technologische belemmeringen en/of hindernissen waar u mee te maken heeft (gehad) tijdens het ontwerpen en of verspreiden van een CDSS?

- Ontwerpen & Programmeren
- Technologische specificaties CDSS
- Integratie met HER

i1. Wat voor actie heeft u ondernomen om deze belemmeringen en/of hindernissen te ondervangen?

i2. In hoeverre denkt u [publieke/private] ontwikkelaars deze belemmeringen anders ervaren en/of op een andere manier proberen te ondervangen?
---

j. Zou u twee voorbeelden kunnen geven van markteconomische hindernissen waar u mee te maken heeft (gehad) tijdens het ontwerpen en of verspreiden van een CDSS?
- Bewerkstelligen middelen (financieel & medische)
- Opstellen businessplan

j1. Wat voor actie heeft u ondernomen om deze belemmeringen en/of hindernissen te ondervangen?

j2. In hoeverre denkt u dat deze hindernis(sen) verschillend wordt/worden ondervonden door [publieke/private] CDSS-ontwikkelaars?
---

k. Zou u twee voorbeelden kunnen geven van klinische hindernissen waar u mee te maken heeft (gehad) tijdens het ontwerpen en of verspreiden van een CDSS?
- Gebruik arts (acceptatie)
- Implementatie/integratie in dagelijkse routine.
- Vormgeving/Berichtgeving etc

k1. Wat voor actie heeft u ondernomen om deze belemmeringen en/of hindernissen te ondervangen?

k2. In hoeverre denkt u [publieke/private] ontwikkelaars deze belemmeringen anders ervaren en/of op een andere manier proberen te ondervangen?
---

l. Zou u twee hindernissen en/of belemmeringen kunnen beschrijven met betrekking tot regelgeving of belangengroepen waar u mee te maken heeft (gehad) tijdens het ontwerpen en of verspreiden van een CDSS?

- legitimiteit bij artsen/verzekeraars
- aanpassen aan wetgeving/regelgeving

l1. Wat voor actie heeft u ondernomen om deze belemmeringen en/of hindernissen te ondervangen?

l2. In hoeverre denkt u [publieke/private] ontwikkelaars deze belemmeringen anders ervaren en/of op een andere manier proberen te ondervangen?

B. Know-About SBAs Overview

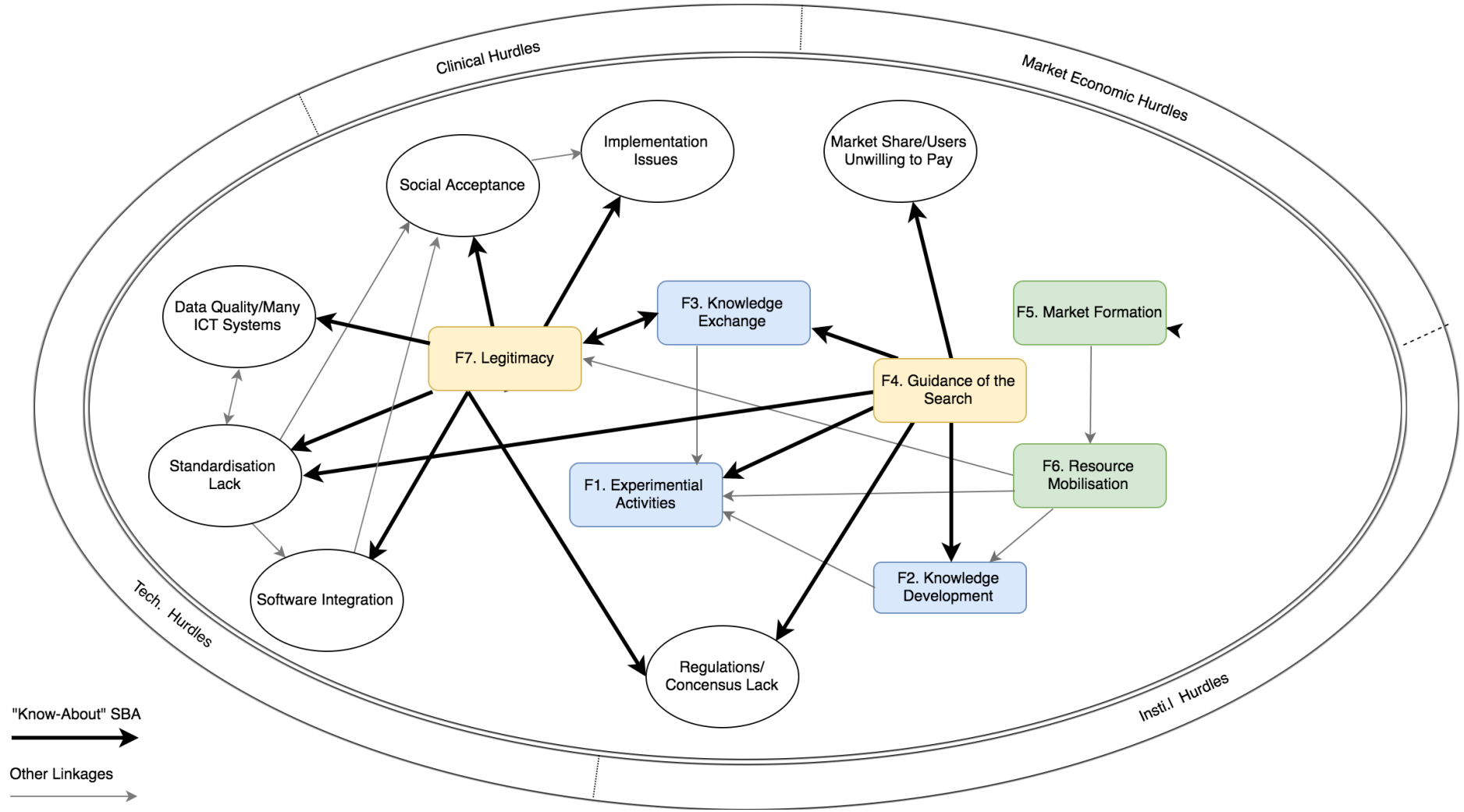

Figure 8. Know-About SBA Overview