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Markus Grillitsch and Josephine V. Rekers

Abstract
Co-location alone is not sufficient to ensure efficient and effective interaction between economic agents. Also, institutions at multiple scales shape the behaviour of organizations and provide incentives for interaction. However, institutions as well as the impact of institutions on economic agents are not static, but rather change over time. In this paper we investigate this dynamic process: How does institutional change at different geographical scales affect localized learning processes? Using an intensive case study of the medical technology sector in Southern Sweden, we trace in detail how institutions at the supra-national, national and regional scale have changed over the past 15 years and how these have affected the opportunities for localized learning between firms and hospitals. Our case makes three contributions. First, it provides a detailed empirical example of the interdependencies between institutions at the supra-national, national and regional scales. Second, as institutions shape the behaviour of organizations, we demonstrate that institutional change introduced at the extra-regional scale can have profound consequences for the establishment of local innovation linkages – and thereby for the opportunities for localized learning. Third, this leads us to reconsider the ambitions of regional policies that aim to enhance localized learning.

JEL codes: Institutions; institutional change; multi-scalar interdependencies; social capital; knowledge networks; innovation; regional development

Keywords: B52; D83; I18; L50; O30; O31; O33; O38

1. Introduction

This paper is about innovation and localized learning involving hospitals and firms in the medical technology sector. Innovation, considered an interactive and systemic process, often requires the bringing together of resources that are distributed amongst a variety of organizations, rather than relying solely on internal resources (for example, Kline and Rosenberg 1986; Lundvall 1988; Chesbrough 2003). Of longstanding theoretical and empirical interest are therefore questions that concern how these organizations establish innovation linkages in an efficient and effective manner, why this process happens more smoothly in some places than in others, and why and how the ease of establishing effective innovation linkages may change over time.

Geographical proximity can make it easier to organize such interactive relationships. Innovation linkages can be highly localized due to the nature of knowledge that is exchanged (Asheim and Coenen 2006; Asheim and Gertler 2005; Martin and Moodysson 2013), the mode of innovation (Jensen et al. 2007) and the role of social networks in establishing durable trust-based relationships (Granovetter 1973). Localized learning processes, frequently held up as the foundations for continued geographical 'stickiness' of innovation activities (Maskell and Malmberg 1999), are thereby a key component of the competitiveness of regional innovation systems. However, the quality of these interactions depends not only on the co-location of capable partners, but is also shaped by institutions. Longstanding bodies of work on industrial districts (Amin 2000), knowledge-based clusters (Malmberg and Maskell 2006), innovation milieus (Crevoisier 2004) and regional innovation systems (Asheim and Isaksen 2002, Cooke 2001) recognize the role of formal and informal institutions in shaping interactions between a wide variety of actors. Moreover, there is a general consensus in the literature that

institutions operate at various scales, including regional, national and supra-national scales (Hassink 2010), but a significant gap remains as we know little about the interplay between them (Gertler 2010).

Putting these two strands – the processes of localized learning, and the role of institutions in economic geography – together, we pose the question: As innovation systems are increasingly open and influenced by institutions at scales other than the region, how does institutional change at regional, national and supra-national scales affect localized learning processes?

In this paper, we investigate this issue using an intensive qualitative case study of the medical technology (med-tech) sector in southern Sweden. The med-tech sector includes firms producing low and high-tech products ranging from plasters and adjustable beds to diagnostic kits and stents, that aim to contribute to improving and extending people's lives, and thereby improving the efficacy and sustainability of healthcare systems (Eucomed 2013). This sector is part of what is known as the Health Innovation System (Gelijns and Rosenberg 1994, Consoli and Mina 2009), in which innovation is driven by the interaction and mutual dependence between a large number of organizations, including firms, universities and medical schools, hospitals and other care facilities, professional associations, patient groups, authorities and regulators, and payers in health care systems. In order for new products to be developed, tested, approved and utilized, these organizations must increasingly work together to ensure timely and equal access to new treatment options. Medical innovation is therefore considered as "an emergent, nondeterministic process generated from complex interactions across heterogeneous knowledge bases" (Consoli and Mina 2009).

The single case study approach employed in this paper allows us to investigate in detail how institutional change at regional, national and supra-national scales affect localized learning involving firms and hospitals. This 'how' question deals with contemporary events and examines what Yin (2003) calls operational links, rather than describing the incidence or prevalence of a phenomenon. A case study approach allows us to collect concrete, context-dependent knowledge of what we consider an atypical or "extreme" case (Flyvbjerg 2006, Yin 2003). In the med-tech industry, collaboration between firms and hospitals is crucial for the development and launch of new products, yet the context of the health system is highly regulated, professionalized and dynamic and involves a wide range of stakeholders at regional, national and global scales. In other words, the need for localized learning is especially great, but the range of institutions pressing on this relationship is diverse and in flux – probably more so than in other industries. This, as described by Flyvbjerg, allows us to reveal more information, because the case "activates more actors and more basic mechanisms in the situation studied" (Flyvbjerg 2006, p.229). Our case is therefore a result of "theoretical sampling", chosen for the theoretical insights it can offer, rather than its generalizability (Eisenhardt 1989; Eisenhardt and Graebner 2007).

Our empirical case leads us to make three contributions to the literature on localized learning and the role of institutions in economic geography. First, the paper provides a detailed empirical example of the interdependencies between institutions at different geographical scales. Second, as we assume that institutions shape the behaviour of organizations, we demonstrate that institutional change introduced at the extra-regional scale can have profound consequences for the establishment of innovation linkages – and thereby for the opportunities for localized learning. Third, this leads us to reconsider the ambitions of regional policies that aim to enhance localized learning.

The paper proceeds as follows: In section 2 we present the conceptual framework, building on the literature on localized learning and the role of institutions at different scales. Following a description of our case-study research design in section 3, we trace in detail how institutions at the supra-national, national and regional scale shape the hospital-firm relationship in section 4. Here we illustrate how institutional changes over the past 10-15 years have changed the opportunities for localized learning and changed the strategies used by hospitals and firms as they seek to form innovation linkages. We conclude the paper with implications for regional policy in section 5.

2. Social and institutional embeddedness of localized learning

Localized learning processes have been identified as fundamental source of competitiveness of firms and regions (Malmberg and Maskell, 2006; Maskell and Malmberg, 1999). The importance of geographical proximity has been related to the nature of knowledge. Not all knowledge is codified or codifiable, and the transfer of non-codified, tacit knowledge is particularly difficult (Polany 1958). This usually requires face-to-face interaction and interactive learning (Lam 2000), which is more easily achieved when actors are located in close geographical proximity. Furthermore, tacit knowledge is embedded in social, cultural and institutional contexts (Gertler 2003). In a region, these different contexts tend to intersect, thus generating favourable conditions for interactive learning and the transfer of tacit knowledge (Boschma 2005; Hassink & Klaerding 2012).

The importance of localized learning processes depends on the mode of innovation. Jensen et al. (2007) have distinguished between innovation driven by science and technology (STI) and innovation generated by doing, using and interacting (DUI). The STI mode of innovation depends to a large extent on research and on knowledge generated by applying scientific

methods, often in collaboration with universities and R&D facilities. Codified knowledge as available in patents or scientific publications tends to play an important role. The DUI mode of innovation depends more on experience-based, tacit knowledge at the interface between users and producers. User-producer interactions are especially important for specialized goods such as machine tools or software packages, which "often can only be adopted in a process of cooperation between the user and the producer" (Lundvall 1985, p. 10; also Gertler 1993). Far from being mere passive receivers of innovation, users are seen to embody experience-knowledge which is valuable for producers to tap into (Rothwell 1986; von Hippel 1976; 1988; Lundvall 1988; 1992).

The literature in economic geography on localized learning resonates well with the notion of social capital (Putnam, 1995). Social capital is associated with shared norms and trust facilitating the exchange of information and knowledge, as well as individual relationships through which social interaction takes place (Westlund 2006; Rutten et al. 2010; Fromhold-Eisebith 2007). Granovetter (1973) emphasises the importance of social networks to support interactive learning processes. Social networks help to identify actors that might possess relevant knowledge and to establish successful knowledge links with these actors. Social capital, therefore, is fundamental for localized learning to take place.

In contrast to localized learning, social capital is not limited to a particular spatial scale. The spatiality of social capital largely depends on the geography of social networks (Rutten et al. 2010). Geographical proximity increases the likelihood that social ties are established due to the opportunities for people to meet and network embeddedness that is often associated with belonging to the same region. Knowledge exchange and networks are facilitated on the regional level due to labour mobility (Breschi and Lissoni 2009; Grillitsch et al. 2013).

Individuals are not perfectly mobile and will find it easier to identify relevant job opportunities in close geographical proximity due to a better knowledge of the regional job market and social networks. “[T]he fact that human beings are spatially sticky and the fact that geographical proximity greatly enhances both the frequency and the depth of social interaction make that the norms and values aspect of social capital are spatially sticky as well.” (Rutten et al. 2010, p. 869).

Localized learning processes are also embedded in institutions that are erected at different geographical scales (Gertler 2010; Hassink 2010). Institutions, according to North (1990, p. 3) “are the rules of the game in a society or, more formally, are the humanly devised constraints that shape human interaction”. Bathelt and Glückler (2014, p. 346) emphasise a behavioural and relational perspective and define institutions as “forms of ongoing and relatively stable patterns of social practice”. Hodgson (2006) argues that institutions can be observed through patterns of behaviour, but that behaviour per se does not constitute an institution. He defines institutions as “systems of established and embedded social rules that structure social interactions. Rules in this context are understood as socially transmitted and customary normative injunctions or immanently normative dispositions, that in circumstances X do Y” (Hodgson 2006, p. 18). Following this view, institutions enable or constrain but do not predetermine certain patterns of behaviour and interaction. A distinction is often made between institutions that are formal or informal. Formal institutions are codified in, for instance, the form of laws, regulations and standards. Informal institutions are not codified and relate to norms, attitudes or values (Gertler 2010). This implies a certain overlap between institutions and social capital. According to the latter, shared norms and values are important for the creation of trust and thereby interactive learning.

Furthermore, institutions have been analysed at particular spatial scales. The literature on regional innovation systems (Asheim and Coenen 2006; Cooke, Uranga, and Etxebarria 1997; Cooke 2001; Asheim and Isaksen 2002) argues convincingly that *regional* institutions play an important role. These contributions highlight the importance of informal institutions, the role of sharing a regional culture and identity as well as the trust that comes with it. The literature on national innovation systems (Lundvall 1992; Nelson 1993; Edquist 2005; Freeman 1995) and varieties of capitalism (Hall and Soskice 2001; Lam 2002; Vitols 2001; Asheim and Coenen 2006) shows that the emergence and evolution of certain industries in space depend on the configuration of the *national* institutional framework. Besides the regional and national scales, it has been argued that innovation systems have become increasingly international and that institutions erected at the *international* scale need to be considered as well (Carlsson 2006; Fromhold-Eisebith 2007). Recent work suggests that institutions influence the interplay between local and regional development as well as global production and innovation networks (Elola, Valdaliso & López 2013; Parrilli, Nadvi & Yeung 2013)

How institutions at various scales interact, however, is still not well understood. At the national scale, the concept of institutional complementarities has helped to understand how different types of national institutions interact (Amable, Ernst & Palombarini 2005; Aoki 1994; Hall & Gingerich 2009; Vitols 2001). An institution is "complementary to another when its presence raises the returns available from the other." (Hall & Gingerich 2009, p. 450). The discussion about complementarities at the national scale has been criticised for its static nature (Gertler 2010; Streeck and Thelen 2005; Thelen 2009). The static nature is inherent in the complementarity argument, which claims that change in any specific institutional domain is constrained by complementarities with other institutional domains. Also, it can be argued that the literature on complementarities has focussed on downward causation, i.e. the effects

of the national institutional framework on economic actions. However, as Martin and Sunley (2012) point out, there is a dynamic interplay between downward and upward causation. Institutions shape and constrain individual behaviour but individual behaviour also has an effect on institutions. Furthermore, the literature remains largely silent as regards the interdependencies between institutions erected at different scales.

Hassink (2010) studies lock-in processes of two shipbuilding and two textile clusters, one of each located in Germany and South Korea respectively, and finds that the differences in the evolution of these clusters cannot be explained by looking only at institutions at any particular scale and concludes that "it is of key importance when analysing regional lock-ins in old industrial areas to take the institutional context at all spatial levels, that is local, regional, national, and supra-national into account" (Hassink 2010, p. 465). Relatedly, Fromhold-Eisebith (2007) argues that although the national level is crucial for the strategic setting of policies and institutions, the region plays a central role for collaboration and learning processes. The national and regional systems are further embedded in an international regulative framework for collaborative science and education. In the case of medical technologies, safety and health regulations that are harmonized at the European level play an important role.

If one accepts that a variety of institutions erected at different spatial scales are relevant for shaping innovation linkages and localized learning, the question arises how concretely these institutions come together. Actors in an innovation system may be subject to substantially different institutional environments such as firms, universities or hospitals. The extent to which interactions across institutional boundaries take place will depend, however, on the respective institutions (Grillitsch 2015). For instance, Fritsch (2003) finds big regional

differences as regards firms-university collaborations. The probability that university professors engage with the private sector will differ depending on whether peers value such an engagement, are neutral, sceptical or even against it (Etzkowitz, 2012). In other words, the integration of university and business sectors will depend on whether institutions in the respective fields are complementary or colliding.

The take-away from this body of work is therefore that while the importance of studying the interdependencies between institutions layered at different spatial scales is well recognised, we still know relatively little about these interdependencies. As phrased elegantly by Gertler (2010, p. 6), it is important to investigate "the processes by which institutions are produced and reproduced at a number of spatial scales, from the local to the national to the global, as well as promoting one's understanding of how these institutions shape and constrain (but not determine) economic action"

In this paper we focus on the latter question, i.e. on how institutional change at different spatial scales affects local innovation linkages and thereby localized learning processes. Due to the multi-scalar embeddedness of actors in the health innovation system, we expect to find that i) institutional change at one scale triggers institutional change at other scales, and that ii) these changes affect the incentive structures for med-tech firms and hospitals to collaborate and engage in localized learning processes. Furthermore, we expect that this effect will depend on whether med-tech firms and hospitals are subject to complementary or colliding institutions.

3. Case Study: Hospital-firm interaction in Southern Sweden

This paper builds on an empirical case study of the medical technology (med-tech) industry in the region of Scania, Southern Sweden. Med-tech is part of the life science industries together with the pharmaceutical and biotechnology sectors and commonly grouped in unison by industry associations and policy-makers despite significant differences in industrial structure, firm resources and mode of innovation. As stated in the introduction, med-tech products aim to contribute to improving and extending people's lives, and thereby improving the efficacy and sustainability of healthcare systems (Eucomed 2013). Med-tech is a rather heterogeneous sector in terms of product technologies, including low-tech products such as plasters, assistive devices such as lifts and adjustable beds, as well as high-tech diagnostic kits, operating room ventilation systems and medical devices such as dialysis equipment and stent implants. The med-tech sector is dominated by small and medium sized companies (this in contrast to the pharmaceutical industry which is dominated by large and often multinational companies): The European industry association for med-tech estimates that 95% of the companies are SMEs, the majority of which are small and micro-sized companies (Eucomed, 2013). In the southern region of Sweden, Scania, we observe a similar industrial structure. Here the group of approximately 135 med-tech firms includes some larger firms, but consists primarily of small companies. Industry data on what we consider to be 'core' med-tech activities, indicates that in 2008, 62% of the firms employed fewer than 10 people, and 15% employed more than 50.

Although the med-tech sector is diverse in terms of technologies and products, firms share a dependence on skilled labour and supporting infrastructure in the region, such as the (university) hospitals, technical schools and universities, science park incubators, investors

and industry organizations. This industry sector is, and has been since the 1970s, used as a prime example in research on user-led innovations and user-producer interaction (Von Hippel 1976, Shaw 1985, Lettl et al 2006, Chatterji and Fabrizio 2013) where the interaction between firms and physicians, patients and hospitals are of critical importance to innovation. Major contributions that stem from this body of work highlight innovation activities that benefit from user-involvement, ranging from identifying need, building and testing prototypes, to serving as a reference for future sales. Firms, in other words, are advised to invest in developing collaborative relations with physicians, patients and hospitals.

A few words on this innovation partner in the context of our case study: Hospitals, in Sweden, fall under the authority of county councils. Sweden has a decentralized system of health care which means that while the central government's Ministry of Health and Social Affairs establishes guidelines for health care, it is the county councils that are responsible for financing and providing health care, which includes the structure and management of public hospitals (Anell et al 2012). This has also resulted in regional variation in health care. Municipalities are responsible for delivering elderly care and care for people with physical disabilities or psychological disorders. Public sector costs for health care in Sweden equal to 9% of GDP, and the bulk of this (approximately 80%) is paid for by county council and municipal taxes (Anell et al 2012). Sweden has 20 county councils and Scania is one of the largest with 1,26 million residents. Furthermore, in Scania the county council is also responsible for regional development.

The empirical discussion that follows investigates innovation linkages between hospitals and med-tech firms. Following a case study approach, we focus on understanding the dynamics present within a single setting, combining data collection methods including desktop

research, interviews and observations. As stated in the introduction, we emphasize that our case is chosen for the theoretical insights it offers ("theoretical sampling"), not for its generalizability (Eisenhardt and Graebner 2007). The specifics of the case (and in particular its highly regulated nature) make this an extreme exemplar (Flyvbjerg 2006), which makes the process of interest "transparently observable" (Eisenhardt 1989) and offers opportunities to explore institutional change under extreme circumstances.

In our case study, the patterns of relationships under investigation are i) between institutions at various scales (institutional change at one scale triggers institutional change at other scales), and ii) between institutions and localized learning processes (institutional changes affect the incentive structures for med-tech firms and hospitals to collaborate and engage in localized learning processes). Furthermore, this effect will depend on whether med-tech firms and hospitals are subject to complementary or colliding institutions.

The findings below are based on desktop research and original data collected using 18 semi-structured interviews with senior managers in firms (10), leaders of supporting organizations such as industry associations and regional authorities (5), and leaders in hospital administration (3). The material collected during desktop research included industry reports and statements by regional, national and European industry organizations as well as by consultancy firms; firm-level data on the number and size of establishments, employment levels and patents. Our sample of firms was selected from industry mappings carried out by regional authorities and industry associations, with the aim to cover a diversity of technological areas. The interview guide included questions about changes in the environment in which the firm carried out its innovation and business activities. Unless the respondent commented unprovoked, we probed for their thoughts on the innovation linkages

between firms and hospitals, as well as other drivers of change such as technological development, regulatory changes, changes in the market, globalization of the industry, and regional factors that may have played a role in the development of the firm and industry. Three follow-up interviews with respondents that had ten or more years of experience in the industry allowed us to corroborate and reflect on our interpretations of the findings, and to consider how widespread individual firms' experiences were. All but one interview took place in-person at the respondent's office; all were conducted, digitally recorded and transcribed in English; and they had an average duration of around one hour, the shortest being 21 minutes and the longest 93 minutes.

4. Findings

4.1. Localized learning through hospital-firm interactions

Echoing findings from the longstanding body of research on user-producer interaction in the field of medical technologies we find that clinical research sites such as hospitals are important to the med-tech companies in our sample. Hospitals are valuable partners at multiple stages of the innovation process; from the idea or problem that prompts the development of a new solution, to product development, testing, and ultimately to implementation or purchase: "Companies need to test their product in clinical settings to get validation. Also, they need to be able to say that hospitals in their home market (at least) are using their product if they are to sell them in other countries" (11). In many cases, these relationships are highly localized, where firms seek to collaborate with the local hospital. Respondents offered two explanations, presenting what we consider a 'textbook' case in economic geography: low transaction costs and the development of trust-based relationships.

First and most importantly, geographical proximity allows for frequent interaction and low transaction costs: "they [the hospital] were the site of the original request and are still an active partner on product development, testing and demonstration…We are in contact a few times a month" (4). For some firms in our sample, this was an important factor influencing their location decision: "Another thing that's really important [when deciding where to locate the company] is that you're close to someone where you can get your samples. So we have a hospital, so you can get clinical samples. And there are also other smaller hospitals around the area" (10). Secondly, building social networks and "trust-based relationships" is facilitated, though not guaranteed, by geographical proximity (9) where partners share sufficient local understandings to ease collaboration between technological and clinical development partners: "A local [hospital partner] makes it easier because you speak the same language, it's easier communication" (6). Some firms pointed to the value of social networks built up over time to justify continued investment in firm activities in this region, even after a firm has been acquired by a foreign actor: "So, the reason to keep people here [after acquisition by a foreign firm] is that we have something to offer, that could be competence academia but it could also be a very open minded healthcare system. They are well organized. Now we're going to get access to healthcare to test the products. That could be a reason to keep the unit" (12).

The interactive and trust-based nature of relationships between hospitals and med-tech firms is in stark contrast to the relationship between hospitals and pharmaceutical companies. It is important to highlight this because, as familiar as the story above might sound to economic geographers, hospitals are faced with an alternative model of interaction when dealing with pharmaceutical firms (which, in the case of the largest hospital in our case study, comprises 9 out of every 10 firm collaboration projects they are involved in). In contrast to the DUI mode

of innovation that characterizes med-tech, pharmaceutical drug development follows an STI mode of innovation, where companies develop new compounds and perform early testing on animals largely in-house, after which they design and carry out clinical tests on humans in hospitals according to guidelines set out by European regulators and implemented by national governmental agencies. This is a rather standardized procedure, also in the practical sense, where the hospital can have a unit with a dozen beds where patients are given a pill or injected a solution according to the clinical trial protocol: "developing new drugs is extremely well regulated by the authorities and there is a clear pathway and what you need to do and what you need to collect and how you should collect it" (18) "You know the regulation, pharmaceutical trials, are so strict and it's standardized, so easy. But for [med-tech] inventions, there's no standardization at all. It's very, very different depending if it's a new bed for patients for instance, or if it's a new syringe… [med-tech is] very heterogeneous. For every testing, you have to make a separate setup." (17).

There is another major difference between med-tech and pharmaceutical companies: they do not have the same resources to bring to the 'hospital-industry relationship'. Pharmaceutical companies provide financial compensation to hospitals for each patient that completes a trial which can amount to several thousand euros per patient, a practice that is not commonly available to much smaller med-tech firms: "The university hospitals have been spoiled by large pharma companies paying them with 1,000 Euros a patient or 2,000 or 3,000 even, where they get paid for everything" (7). The situation is different for med-tech: "If a [med-tech] company comes to us [the hospital] and say, "We have this new type of machine, we want to have it tested in 'X' number of patients, can you help us with that?" Yes, we can, but we cannot do it for free, they have to pay and that's the problem because biotech

companies don't have that money as pharmaceutical companies have. So they are often not very good at paying. They don't have that money" (17).

In other words, firms' motivation and resources for interaction with hospitals are very different for these two sectors. This contrast highlights that med-tech firms seek to have much more interactive relationships with hospitals and engage in localized learning because i) med-tech products are heterogeneous and are not able to share a standardized physical set-up such as 12 beds in a room, ii) the mode of innovation in the case of med-tech is based on intense user-producer interactions, which necessitate the active involvement of and communication between the clinician and the product developer, and iii) the industrial structure of med-tech is dominated by small firms that do not have financial resources comparable to large pharmaceutical companies, nor do they have the in-house expertise to navigate the administrative path to carrying out clinical tests.

4.2. Institutions shaping hospital-firm relationships

Now that we have established the importance of hospital-firm relationships to innovation in the med-tech sector, we turn to the institutions that shape such relationships. As stated in the theoretical section, co-location alone is not sufficient for actors to interact. Rather, they need to also have incentives to develop relationships with other actors in this locality. Clearly, hospitals and firms are different types of organizations that have very different mandates, goals and incentive structures, which may not naturally align. For the hospital, participating in innovation activities is only a small part of its day to day operations. Although the hospital system in Southern Sweden is in part funded by the regional authority, which has a mandate to contribute to economic development, the primary mission and financing of hospitals is dedicated to treating patients.

Hospitals, therefore, only have limited resources, time and incentives to engage in firms' innovation projects. This is particularly the case for med-tech products, many of which do not have clearly demonstrated benefits yet: "the hospitals… they are so busy and then they are doing interviews, having workshops as well. You need to really be very precise, having something that is attractive for them that they could feel, 'Okay, if I participate in here, I could benefit from it'" (13). For med-tech firms, on the other hand, collaboration with hospitals is often essential for the development of new products. This suggests that hospitals and firms do not have the same objectives, perceptions of value and risk and motivation to engage in such collaboration and firms need to convince hospitals to enter into a relationship. Hospital-firm interaction is, in other words, inherently challenged by the specific institutions which are relevant for these two types of organizations.

Moreover, institutional challenges to hospital-firm interactions can increase over time in response to for instance changes in hospital routines, changes in policies and regulations of regional authorities or the national ministry of health, as well as changes in regulatory requirements by the European Commission. As the following quote from a veteran in the life science industry illustrates, access to hospitals in the region of Scania has become more challenging:

> *"I worked in 11 companies in Malmö, Lund, Copenhagen in diagnostics, medical technology, biotech, pharma and I was one of them, knocking on doors, five, ten years ago, 20 years ago; getting access to the healthcare system, getting the machine in there being tested, developing together with the healthcare system, finalizing a product, releasing a product, getting the product sold locally in Copenhagen or Lund, or Malmö or Helsingborg or somewhere, first reference. With*

that reference and development we would roll out the product in Europe and the world. The last few years, [the hospital system] has been extremely focused on producing healthcare, cutting off all the others as we have seen with decreasing numbers of clinical trials and small-medium companies not getting access to the healthcare system." (12).

In addition, technological developments internal to the industry have resulted in firms being increasingly dependent on hospitals, which makes the need to overcome challenges to interaction even greater. With technological advancements, an increasing number of med-tech products can be used closer to the patient and therefore need to meet regulatory requirement to ensure safety.

In other words, despite the presence of well-functioning hospital-industry interactions in the past, the institutional challenges to establish and maintain hospital-firm relationships are not static but dynamic and continually re-shaped. Moreover, all of our respondents commented on the decreased opportunity to engage in innovation projects with local hospitals over the last 10-15 years. In the next section, we will trace these dynamics to changes in institutions at different spatial scales.

4.3. Institutional changes affecting hospital-firm relationships

Institutional change at various scales shape the relationship between hospitals and industry, including institutions at a European scale (in particular with respect to the certification of med-tech products), national scale (the funding of the health care system), and regional scale (regional economic development policies). Below we illustrate how these institutional environments have changed over the past two decades and how these changes affect the

routines for hospitals to collaborate with med-tech firms and engage in localized learning processes. The identified relationships are further summarized in figure 1.

Firms' demand for interaction with hospitals is increasing due to changes in *European* regulatory requirements that demand clinical evidence of safety and efficacy for an increasing number of med-tech products. Many med-tech products are used in, on, or close to the patient, and their availability on the market is controlled by a regulating body (in this case The European Commission's Medical Device Directive) to ensure safety and efficacy, a process similar to the what is used for pharmaceutical drugs. More than 500,000 types of medical devices are classified according to their risk profile, where responsibilities and evidence requirements are more strict for manufacturers of high risk devices (such as pacemakers) than they are for manufacturers of low risk devices (such as sticking plasters) (EC 2012). However, in the fallout of public scandals such as when the French company Poly Implant Prothèse's (PIP) was discovered of using non-medical grade silicon in breast implants in 2011, the evidentiary requirements for safety and efficacy are becoming more strict, which implies that the innovation process becomes longer, more costly and risky (Coombes 2012; EC 2012): "the regulation is changing, so I think we will see more of that [clinical trials for med-tech products] in the future, and also there is a higher amount from the industry and players that they would like to see clinical evidence of it before they buy it"(18). These regulations are adopted at the national level and thus directly affect firms in Scania.

At the same time however, hospitals are embedded in a health care system that is under pressure from *national* authorities to provide care for a growing number of patients in a lean and efficient manner: "[national] governmental pressure is leaving less time for doctors to do studies or research" (11). This directly affects the time that clinicians have available to spend

on uncertain med-tech innovation activities: "the amount of funding or time that the doctors have to adopt new technologies and new products is getting less and less. So, when they go to a hospital, previously they could have like one day a week where they were fiddling around with interesting things. And now, they don't have the time. They have patients all the time. …That's how they would have started new things previously: 'Well, we just went down to the hospital and we had it tested on Thursday and then we went back to the lab and fixed some things and then we went to the hospital again'" (7). Changes in institutions at the national health care system may be triggered by global trends such as the financial crises, aging populations as well as the increasing use of evidence based medicine and health economics in guiding decision-making processes in health care settings. The consequence of these trends is an increase in cost pressures and a focus on efficiency in the delivery of health care, which trickles down from the state to the regional budgets and to the hospitals that, as a result, change their routines for collaborations with firms.

This pressure on 'lean' health care from the national government is in contrast to an increasing interest (but no matching resources) at the *regional* level to utilize hospitals to spur regional economic development: This relates to the fourth mandate of hospitals (after providing care, training and medical research), which is to work with firms and participate in innovation activities such as product development and testing: "[The regional authority] has also the mandate to collaborate with the industry, for the sake of Scania, to make Scania grow, …. and since we [the hospital] are part of [the regional authority], we have the responsibility for regional development, and of course, collaboration with industry" (17). This mandate is receiving increasing attention, also in Sweden: A recent official report from the Swedish government for example (SOU 2013), calls on hospitals to be more open and supportive of clinical testing activities, in an effort to increase the number of clinical trials

conducted in the country so that patients have early access to promising new treatments. However, “the distance from the floor to the upper management is too long… I mean the activity is at the floor and I think people have to realize how the floor is working” (18). While this policy-discourse and mandate for collaboration with industry has grown in recent years, there is almost no increase in actual resources (“on the floor” (18)) to carry out such activities.

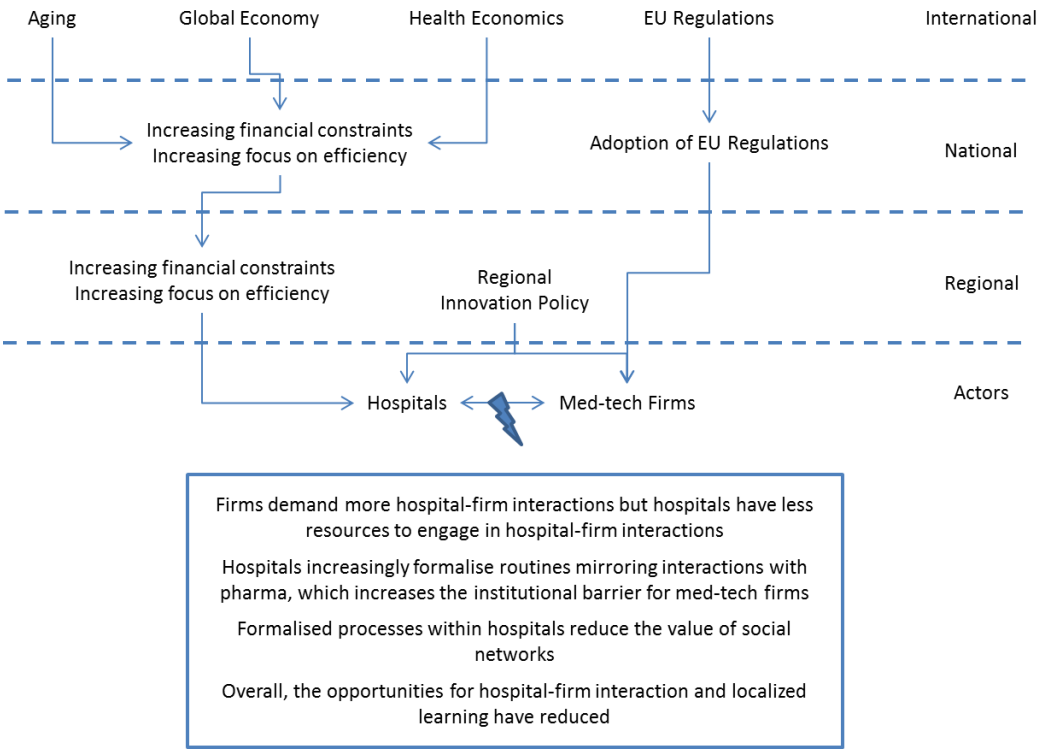
These institutional changes affect the incentive structures and routines for hospitals to collaborate with firms. For hospitals, this pressure from the national health care system to be efficient has prompted organizational restructuring and the introduction of new routines for engaging in interactions with firms, both of which have increased challenges to engage in localized learning processes. Hospitals get approached by more innovation projects while having fewer resources to dedicate to this activity, they have adopted more formal administrative procedures leading up to collaborations with firms: “we talk with the doctors and they say, ‘We want this’ and they have to try and persuade the administration to go for [purchase] it” (7). Or in the words of a hospital representative: “people think historically we have only done this in this way and it has worked fine. but it’s a new environment…There is less and less time and that means that we also have to be professional when it comes to how are we going to help out with development. That means we have to create that space and also that we have to have a process in place how we attract new companies and a process where it’s transparent so for a community to see there’s nothing odd going on, there’s money transferred…we have to be very transparent and also accountability I think is important” (18). This shows that hospitals are under pressure to enhance efficiency and accountability and therefore increasingly introduce formal procedures channeled through the central

administration for engaging in hospital-firm interactions. This increasing formalization renders the social networks available to small med-tech firms less valuable.

However, while all regional hospitals are subject to the same institutional changes at the regional, national and supra-national scales, there are some indications that the response to these changes varies between individual hospitals: “When I started development on [this new product], we were going to do a clinical study. So I called the University Hospital and they told me the first opportunity for me to [present our product] was in two months. Then I called [a smaller] hospital and they said, ‘That sounds really interesting’. So, these are two completely different worlds” (7). Hospitals vary in their size, organizational structure and routines, which results in considerable variation in how they allocate resources and how they incorporate innovation activities in their operations.

The effect of these institutional changes at different spatial scales is that med-tech firms perceive it to be increasingly difficult to establish innovation linkages and engage in localized learning. While social networks were at one time important and successful in overcoming the institutional barriers inherent in hospital-industry interactions, they have become much less valuable over the last decade. The increasingly formalized processes are difficult to navigate and require resources that the typical small med-tech firms often do not have. The organization of firm-hospital interactions following the model established for pharmaceutical firms is less suitable for med-tech firms because the mode of innovation usually differs. Pharmaceutical firms innovate according to the STI model whereas med-tech firms rely to a much larger extent on interactive learning processes between users and producers. Overall, therefore, the observed institutional change has deteriorated the conditions for localized learning in the med-tech sector.

Figure 1: Summary of main changes to multi-scalar institutions and effects on localized learning



4.4 Coping with institutional change

Although this paper focuses on the effects of changes in institutions erected at multiple scales on localized learning processes, firms are not merely passive victims of institutional changes. At the European level, the med-tech industry is represented by Eucomed, an industry association that actively negotiates the conditions of new regulatory requirements (Eucomed 2013). At the national and regional level, industry associations and innovation agencies promote the importance of hospitals engaging in innovation activities not only for the benefit of firms' product development and future growth, but also to ensure patient access to new technologies in an efficient and equal manner (SOU 2013). At the level of individual firms, we also observe strategic coping behavior. As hospitals in the region and in the country vary in their adoption of lean health care practices, firms can choose to approach different (smaller) hospitals, for example. Firms also display strategic coping behavior in response to institutional

change at the European level: In an effort to by-pass increasingly costly and lengthy clinical testing procedures to qualify for access to the European human health market, one firm in our sample has opted to fine-tune their product for the veterinary market instead. Firms, in other words, are not mere passive victims of institutional change, but they are also active participants in their development.

5. Discussion and Conclusion

The starting point for the paper was the claim that we need to learn more about the interplay between institutions erected at different geographical scales and how this affects localized learning processes. Two main propositions guided the empirical study, namely that i) institutional change at one scale triggers institutional change at other scales, and that ii) these changes affect the incentive structures for med-tech firms and hospitals to collaborate and engage in localized learning processes. Furthermore, we expected that this effect will depend on whether firms and hospitals are subject to complementary or colliding institutions.

The interdependencies between different types of national institutions have been analyzed using the concept of institutional complementarities (Amable, Ernst & Palombarini 2005; Aoki 1994; Hall & Gingerich 2009; Vitols 2001). Here we consider to what extent the concept of institutional complementarities could help to explain the interplay between institutions of different spatial scales. What we can conclude from our study is that institutional complementarity was absent from the observed changes in regional, national and supra-national institutions. Rather, the institutions relevant for med-tech firms increasingly collide with those to which hospitals are subject. These two types of actors do not share the goal to develop and test new med-tech products, and for hospitals to engage in this activity means

that it leaves fewer resources for other – more closely associated with their core mission – activities such as treating patients, educating doctors or carrying out medical research.

The problem of colliding institutions has become especially apparent over the last decade as i) European regulations became more selective and ii) hospitals and doctors are under increasing pressure from national governments to deliver efficient and lean care to an aging population. The former implies that firms request more opportunities to interact with hospitals in order to meet evidentiary requirements while the later constrains interaction opportunities. Also, the increasing focus on lean hospital management and efficiency goes against the regional policy objective according to which hospitals should engage with firms to spur innovation and economic growth. Colliding institutions have always been a challenge in hospital-industry interaction, but this weakness is exposed more clearly now with pressures placed on the health system at the national and European scale.

Our interpretation for why the observed institutional changes lead to increasingly colliding and not complementary institutions is that this relates to the actor constellation and the actors' possibility to influence the respective institutions. Med-tech firms are not directly subject to the institutions governing the health care system, and other stakeholders are key in developing the institutional response to the increasing cost pressures on the health care system. European regulators for med-tech products are more concerned with patient safety than they are with localized learning processes and resulting innovations. In the regional innovation system, efforts are made to bring med-tech firms and hospital together. However, this has to be seen in the context of increasingly colliding national and supra-national institutions, which challenge the stability of innovation linkages. Furthermore, institutional

change may lead to a disembedding of local relationships and foster global production and innovation networks (Elola, Valdaliso & López 2013; Parrilli, Nadvi & Yeung 2013).

The findings from our "extreme" case (Yin 2003, Flyvbjerg 2006) therefore suggest that the conditions for localized learning are not static, but change over time and we argue that the shifts in behavior of economic actors can be traced back to institutional changes at multiple scales. In other words, frequent opportunities for face-to-face interaction and the development of long-term trust-based relationships are not automatically available to firms that are located in close geographical proximity to competent partners. These localized assets are only assets when they are supported by the multi-scalar institutional environment in which organizations operate. Here we highlight the role of formal regulations at national and supra-national levels, and suggest that policy initiatives at the regional level have to be considered in this context.

This leaves us to conclude with a few words on policy implications that arise from our findings, when we consider the role of hospitals in the health innovation system of Southern Sweden and in particular for the innovation activities of med-tech firms. In a time of increasingly 'open' innovation strategies, sources of knowledge external to the firm are considered of great innovation potential. These ideas on open innovation also empower policymakers: if innovation potential resides not solely inside firms, but also in other organizations such as public universities and the public health system (especially in the Nordic countries), then the public sector has a role to play. The state provides funding for medical research carried out in universities and hospitals, national regulatory agencies must approve clinical trials and access to the market, and regional authorities are responsible for delivering health care in hospitals, care facilities and doctor's offices where new med-tech products are

bought and utilized. Scholars and policy-makers in welfare-states such as the Nordic countries consider their large public sector therefore well-suited to actively shape innovation activities and regional economic development, for example by investing in initiatives such as pre-commercial procurement within the context of demand-driven or mission-oriented innovation policies (Edler and Georghiou 2007; Edquist and Zabala-Iturriagagoittia 2012). As our findings indicate however, the hospitals' ability to participate in these innovation activities is shaped in response to forces acting on the hospital system from multiple scales, including but not limited to the national scale. Any policy initiatives in this context must therefore take into account that the hospital-firm innovation linkage is embedded in institutional environments that involve stakeholders at the regional, national and European scales.

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