HHL LEIPZIG GRADUATE SCHOOL OF MANAGEMENT

Dissertation

Innovation Management in Healthcare

A Multi-Level Perspective in Three Essays

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Innovation in healthcare is a central way of coping with the changes affecting the healthcare system through the megatrends of demographic change, digitalization as well as the opportunities in the life-sciences sector and the "-omics" subjects. Due to the multiple facets of the topic, research on innovation in healthcare is diverse and draws insights from systems theory, management theory, human resources, innovation and change management. While the literature on innovation in healthcare has grown steadily in the last 20 years and publications on pharmaceutical and medical device innovation, health technology assessment strategies, or digital innovations have increased significantly, other areas such as sectoral health innovation systems, the creation and implementation of innovation in hospitals still remain fairly uncharted. Applying established concepts such as systems of innovation theory, mass customization theory or management of employee involvement in innovation activities to the healthcare sector provides new insights into a field that is often considered a "blackbox". This thesis adds to the topic in three essays, each focusing on a different aspect and depth level ranging from a macro perspective on healthcare innovation on a global scale to a meso level perspective on the implementation of personalized medicine in one country and putting a micro lens on innovation activities of hospital staff. The aim of this thesis is to provide an overview for researchers, policy makers and healthcare stakeholders about current developments, propose tools for measuring innovation and allow for benchmarking the current status quo in healthcare in order to foster new and innovative developments.

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List of abbreviations

Abbreviation	Explanation
EU	European Union
GDP	Gross Domestic Product
HIS	Health Innovation System
NHIS	National Health Innovation System
NIS	National Innovation System
OECD	Organization for Economic Co-operation and Development
RQ	Research question
UK	United Kingdom

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1. Introduction

The healthcare system in the western world is a complex sector with a strong impact on social welfare (Held, 2016; Porter & Teisberg, 2006). It is multifaceted and encompasses a multitude of stakeholders, a rapidly changing technological environment and the need to balance excellent health outcomes with reasonable cost of care. The demographics of society are changing: the global population is growing, society is aging within the western world and developed countries face a net positive immigration. Digital transformation is set to change the world through smart devices and infrastructures, machine learning, artificial intelligence, automation and connectivity, impacting all industry sectors and the life of patients, practitioners, healthcare stakeholder and everyday people alike. Through the improved access to (medical) knowledge within the global knowledge society, citizens are able to learn about prevention of diseases. Patients are becoming better informed about their illnesses and treatment options. As a consequence they often demand the use of the best available technology and the provision of higher service levels. Advancements in life sciences and the "-omics" subjects have the potential to allow for more targeted treatments with fewer side effects and better health outcomes. The combination of all these effects leads to an increased need for innovation within the healthcare sector that required the attention of all stakeholders alike (Roncarolo, Boivin, Denis, Hébert, & Lehoux, 2017). This development poses a very relevant and interesting topic for researchers and thus, the research on innovation in healthcare has gained importance in the last decades (Conger, 2016; Djellal & Gallouj, 2007; Dzau, Asch, Hannaford, Aggarwal, & Pugh, 2017; Kelly & Young, 2017; Porter & Guth, 2012; Ramlogan & Consoli, 2007; Thune & Mina, 2016).

Due to the multiple facets of the topic, research on innovation in healthcare is diverse and draws insights from systems theory, management theory, human resources, innovation and change management. In general, research on innovation in healthcare can be clustered along the following streams:

1. General literature reviews (Boaz, Baeza, & Fraser, 2011; Djellal & Gallouj, 2007; Länsisalmi, Kivimäki, Aalto, & Ruoranen, 2006; Thune & Mina, 2016)
2. Healthcare systems (e.g. (Braithwaite et al., 2017; Porter, 2009; Starfield & Shi, 2002)
    a. Single country studies (developed and emerging countries, e.g. (Caliari & Ruiz, 2011; Myllyoja et al., 2016; OECD, 2011; Porter & Guth, 2012; Simou & Koutsogeorgou, 2014)
    b. Country comparisons (e.g. Calltorp, 1999)
    c. System transformation and innovation policy (e.g. (Eiff, 2016; Mazzucato & Roy, 2017; Porter, 2010; Sobrio & Keller, 2007)
3. Health Innovation Systems (Buttigieg & Gauci, 2015; Donaldson & Mohr, 2001; Iyawa, Herselman, & Botha, 2016; Martin, 2013)
    a. Regional health innovation systems (Jonsson, 2009; Larisch, Amer-Wåhlin, & Hidefjäll, 2016)
    b. Single technology / sectoral innovation (Consoli & Ramlogan, 2012; Metcalfe, James, & Mina, 2005; Ramlogan & Consoli, 2007)
    c. Public health innovation (Béland, 2010; Conger, 2016; Lander, 2016; Marmor, Freeman, & Okma, 2005; Marmor & Wendt, 2012)
4. Objects of innovation in healthcare (e.g. Amshoff, 2010)
    a. Service innovation (e.g. (Bessant & Maher, 2009; Ciasullo & Cosimato, 2017; Fox, Gardner, & Osborne, 2015; Keller, Edenius, & Lindblad, 2013; Pfannstiel & Rasche, 2017)
    b. (Medical) Device innovation (e.g. (Callea, Cavallo, Tarricone, & Torbica, 2017);(Galbrun & Kijima, 2010; Gelijns et al., 2013; Hermelin, Dahlström, & Smas, 2014; Skinner & Staiger, 2015)
    c. Innovation for pharmaceuticals (e.g. (Bianchi, Cavaliere, Chiaroni, Frattini, & Chiesa, 2011; Chiaroni, Chiesa, & Frattini, 2009; Hippel, DeMonaco, & de Jong, Jeroen P. J., 2016; Hughes & Wareham, 2010; Schuhmacher, Germann, Trill, & Gassmann, 2013)

d. Hospital and hospital management innovation (e.g.(Albach, Meffert, Pinkwart, Reichwald, & Eiff, 2016), (Bose, 2003; Braithwaite, Vining, & Lazarus, 1994; Debatin, Goyen, & Schmitz, 2006; Goes & Park, 1997; Salge & Vera, 2009)
e. Digital health innovation (e.g. (AlMarshedi, Wills, & Ranchhod, 2016; Ramtohul, 2016)
    i. eHealth (incl. telemedicine, e.g. (Black et al., 2011; Chen, Wen, & Yang, 2014; Eysenbach, 2001; Hordern, Georgiou, Whetton, & Prgomet, 2011; Peters, Blohm, & Leimeister, 2015; Valerie, Giesen, Jansen, & Klokgieters, 2010)
    ii. mHealth (e.g. (Dale, Dobson, Whittaker, & Maddison, 2016; Hamine, Gerth-Guyette, Faulx, Green, & Ginsburg, 2015; Head, Noar, Iannarino, & Grant Harrington, 2013; Lazakidou, 2016; Ventola, 2014)
    iii. Electronic health records (e.g. Hillestad et al., 2005)

5. Sources of innovation in healthcare (e.g. (Herzlinger, 2006; Leydesdorff, Rotolo, & Rafols, 2012; Nelson, Buterbaugh, Perl, & Gelijns, 2011)
    a. Open innovation and collaboration (e.g. (Bullinger, Rass, Adamczyk, Moeslein, & Sohn, 2012; Gelijns, Annetine, Thier, SO, 2002; Hartweg, Kaestner, Lohmann, Proff, & Wessels, 2015b; Nembhard, 2009; Reinhardt, Bullinger, & Gurtner, 2015; van den Broek, Boselie, & Paauwe, 2017)
    b. User-led innovation (e.g. (Oliveira & Canhho, 2014)
        i. Patients (e.g. (Fidelis, Zejnilovic, & Oliveira, 2014; habicht, Oliveira, & Shcherbatiuk, 2012; McColl-Kennedy et al., 2017; Svensson & Hartmann, 2018; Swan, 2009; Trigo, 2016)
        ii. Practitioners and management (e.g. (Amo, 2006; Birken, Lee, & Weiner, 2012; Chen, Lee, Parboteeah, Lai, & Chung, 2014; Kajamaa, 2015; Schultz, Schreyoegg, & Reitzenstein, 2013; Valentine, Nembhard, & Edmondson, 2015)

iii. Employees (e.g. (Fottler, Blair, Whitehead, Laus, & Savage, 1989; Kokkinen & Konu, 2012; Lahtinen, Aaltonen, Järvinen, Teittinen, & Pirttimäki, 2017; O'Donoghue, Stanton, & Bartram, 2011; Thune & Gulbrandsen, 2016)

c. Technological trajectories (Lehoux, Miller, Daudelin, & Denis, 2017; Mina, Ramlogan, Tampubolon, & Metcalfe, 2007; Ramlogan, Mina, Tampubolon, & Metcalfe, 2007; Thrane, Blaabjerg, & Møller, 2010)

6. Assessment of innovation in healthcare (Burgess, 2012; Cucciniello & Nasi, 2013; Jacobs et al., 2017; Klazinga, Fischer, & Asbroek, 2011)
    a. Cost and quality (Chandra & Skinner, 2011; DiMasi, Hansen, & Grabowski, 2003; Goyen & Debatin, 2009; Kairy, Lehoux, Vincent, & Visintin, 2009; Wahlster, Goetghebeur, Kriza, Niederlander, & Kolominsky-Rabas, 2015; Wang et al., 2003)
    b. Diffusion (Cain & Mittman, 2002; Chaudoir, Dugan, & Barr, 2013; Ciani et al., 2016; Fitzgerald, Ferlie, Wood, & Hawkins, 2002)
    c. Health technology assessment and management (Brower, 2003; Hartz & John, 2009; Lebioda, Gasche, Dippel, Theobald, & Plantör, 2014; Schreyögg, Bäumler, & Busse, 2009)
7. Healthcare innovation management processes (Granig, Gabriel, Stadtschreiber, & Pertl, 2011; Minvielle, Waelli, Sicotte, & Kimberly, 2014)
    a. Within hospitals (Chiocchio & Richer, 2015; Djellal & Gallouj, 2005; Ivan Su, Gammelgaard, & Yang, 2011; Labitzke, Svoboda, & Schultz, 2014; Nilsson & Sandoff, 2016; Salge, 2012; Schultz, Zippel-Schultz, & Salomo, 2012)
    b. Within the pharmaceutical industry (e.g. (Gassmann & Reepmeyer, 2005; Rosenberg-Yunger, Daar, Singer, & Martin, 2008)

While the literature on innovation in healthcare has grown steadily in the last 20 years and publications on pharmaceutical and medical device innovation, health technology assessment strategies, or digital innovations have increased significantly, other areas such as health innovation systems as sectoral innovation systems, the creation and

implementation of innovation in hospitals still remain fairly uncharted. Calls have been placed to e.g. analyze the link between health policy and innovation policy, the "boundaryless hospital" (Albach et al., 2016; Braithwaite et al., 1994) and the relationship between hospital resources, clinical practice and innovation or micro-level analyses of innovation and hospital practitioners.

2. The purpose of a multi-level analysis in the field of healthcare innovation

Innovation in healthcare can be viewed through a multitude of lenses at different depth levels. In order to tackle the aforementioned challenges that the healthcare systems in the (western) world face, policy makers, healthcare managers and other stakeholders within the healthcare system need to be informed about the current status of innovation production and commercialization in their specific jurisdiction and how it compares at the regional, national and global level in order to learn and benefit from winning formulas and mistakes made before by other participants. Further, they need to know how innovation in the sector occurs, how to define whether an innovation is beneficial as well as how to implement and measure the results of successful innovation in their surroundings.

This thesis uses well-established concepts such as the theory behind national and sectoral innovation systems, mass customization and employee involvement and applies these concepts to the healthcare system. In order to provide comprehensive insights into the research topic, this thesis analyzes the topic of innovation in healthcare in three essays. These essays provide a macro, a meso and a micro perspective, each targeting a specific field.

Overall, this thesis adds to the understanding of the "blackbox" innovation in healthcare in the following respects:

(1) Measurement of healthcare innovation and global benchmarking

By applying a multi-indicator approach to measure innovation in healthcare we divert from the conventional way of only considering patents or scientific publications as innovation metrics and provide a more comprehensive way of benchmarking innovative capacity, not only for the sectoral case healthcare, but also for the national innovation system.

(2) Transfer of the NIS concept to sub-national entity NHIS

By transferring the established concepts of NIS and NIC to the sectoral case "healthcare", this thesis contributes to a better understanding of sub-national entities, such as specific industrial sectors, which "are becoming, or have already become, more important than the nation-state" (Freeman, 1998, p. 3; Lundvall, 2007)

(3) Guidance on the creation and implementation of complex innovations in the healthcare system

By applying the established concepts of mass-customization and employee involvement in innovation processes to the healthcare sector and thus diving deeply into the implementation of innovation in the healthcare sector, this dissertation showcases new insights into how public entities such as hospitals can learn from industry in order to improve their service delivery, provide a more targeted customer experience and improve employee satisfaction and retention in a highly competitive market for talent.

The results of this thesis target the following stakeholders:

The multi-indicator approach provides a new and improved way of measuring innovation in healthcare for researchers and thus sheds light into healthcare innovation. The clear distinction between NIS and NHIS provides significant opportunities for further research.

Health policy makers benefit from the global benchmarking of healthcare systems and the deeper understanding of innovation dynamics in the healthcare sector, which are needed for more targeted health innovation policy initiatives.

Finally, hospital management gains insights into factors that foster innovative activities amongst employees and can use those to improve patient care and hospital efficiency. Further, the derived readiness assessment model allows for targeted measures to improve innovation implementation success rates.

3. The scientific contribution of this doctoral thesis

This dissertation consists of three studies on innovation management in healthcare, each approaching the topic on a different level. An overview of the papers, their authorship, contribution and status of publication is provided in Table 1.

The first article transfers the methodology of national innovative capacity to the healthcare sector and provides a macro-level view on the innovative output of the OECD healthcare systems. The second paper takes a meso perspective on one innovation system and provides an overview of success and readiness assessment factors for adopting the new concept of personalized medicine within the German healthcare system. The third paper focuses on the hospital and the involvement of employees in the innovation process. Overall, this thesis aims to provide insights into the interplay of different success factors in the change process that is underway within the healthcare sector.

	Article 1 – Macro level	Article 2 – Meso level	Article 3 – Micro level
Title	National Health Innovation Systems: Clustering the OECD countries by innovative output in healthcare using a multi-indicator approach	Adopting a Mass Customization Approach to Implement Personalized Medicine in German Hospitals	Employee involvement in innovation activities in hospitals: how perception matters
Joint work with	Dorian Proksch Marcus Max Haberstroh Andreas Pinkwart	-	Simone Haubner Andreas Pinkwart
Contribution	Co-authorship with Dorian Proksch, Marcus Max Haberstroh and Andreas Pinkwart • Main responsibility for literature review on health innovation and outcome and national health innovation systems, data gathering on health variables and responding in detail to the health innovation related questions within the review process • Shared responsibility for research design, data collection, description, writing and interpretation of results	Single authorship	Co-authorship with Simone Haubner and Andreas Pinkwart • Main responsibility for literature review on employee innovation and innovation in healthcare, research design and initial coding framework. • Shared responsibility for questionnaire development, data collection, coding, writing and interpretation of results
Presentation and double blinded peer review	ISPIM Innovation Forum Conference 2017; Toronto, Canada	R&D Management Conference 2016; Cambridge,UK	R&D Management Conference 2017; Leuven, Belgium
Awards	Nominated for the Knut Holt Best Paper Award (ISPIM Innovation Forum)	2nd Prize PhD student poster competition (R&D Management Conference)	
Publication status	Published in *Research Policy* in 2019 (JOURQUAL ranking according to VHB: A) DOI: https://doi.org/10.1016/j.respol.2018.08.004	Published in the proceedings of the R&D Management Conference 2016	Submitted for publication in *Health Services Management Research* (JOURQUAL ranking according to VHB: C), currently in 2nd review round

Table 1 – Summary of contributions, publications and co-authors of the three publications

3.1 National Health Innovation Systems: Clustering the OECD countries by innovative output in healthcare using a multi-indicator approach

- *Study significance:* Innovation systems research distinguishes national, regional, technological and sectoral innovation systems. The healthcare innovation system can be classified as a sectoral innovation system. Despite the high importance of innovation for the provision of high-quality and cost-effective care and its prominent role for global competitiveness, HISs have rarely been analyzed from a systems perspective. Moreover, there are only a few papers that have studied HISs in general and the determinants of innovative output in this field in particular in the last decades. This paper allows for a first comparison of innovative output in healthcare between countries and reveals a strong difference between the innovation output of a nation as a whole and healthcare as a specific sector. It answers the following research questions: (1) Can countries be grouped by their innovation output in healthcare and do those groups differ in factors describing the healthcare system? and (2) Do countries with strong national innovation systems also have strong national health innovation systems and vice versa? Moreover, it provides a measurement approach for the output of sectoral innovation systems through a multi-indicator approach and thus enables a more comprehensive view on sectoral innovation systems compared to previously used metrics. Finally, it sheds light on a sectoral innovation system that has not yet been subject of an in-depth analysis.
- *Methodological approach:* There is little empirical literature that provides comparisons of sectoral innovation systems amongst different countries, especially focusing on healthcare. We therefore performed a cluster analysis of the OECD countries (excluding Estonia, Iceland, Latvia, Luxembourg and Slovenia due to a lack of data in one or more of the output variables) in order to group countries by their innovative output in healthcare. We measured innovative output through a multi-indicator approach distinguishing knowledge production and knowledge commercialization variables. We further provide insight into the health system through a set of variables commonly used to

describe the health system of a country. The analysis is based on a data set of 14 variables for each country for the years 1995-2014, whereby the cluster analysis uses data of 2012 (the most current year for which data was available for the majority of the countries included in the study). Though cluster analysis is a common method within national innovation systems and health system research, we are one of the first to apply the methodology to NHIS.

- *Main findings:* The results show a two-to-nine cluster salutation with the four-cluster solution producing the most interpretable results. The clusters strongly differ in their innovation output in healthcare. An overview of the cluster affiliation is provided in Table 2.

Cluster A	**Cluster B**	**Cluster C**	**Cluster D**
Czech Republic	Japan	Australia	Switzerland
Portugal	South Korea	New Zealand	Denmark
Germany	Hungary	Israel	Norway
France	Poland	United States	The Netherlands
Italy	Slovak Republic	Canada	Sweden
Greece	Turkey	Austria	
Spain	Chile	United Kingdom	
	Mexico	Ireland	
		Belgium	
		Finland	

Table 2 – Four cluster solution (Proksch, Busch-Casler, Haberstroh, & Pinkwart, 2019)

Cluster D ranks first in all variables other than patent output and is thus classified as the most innovative cluster. *Cluster C* ranks first in patent output and second in the remaining variables. *Cluster B* ranks second in patent output and ranks last in all other variables. *Cluster A* has the weakest patent output and ranks third in all other variables. We further performed a cluster analysis using the same output variables but including all industries. The results show that NHIS differ from NIS. Having a strong national innovation system does not indicate a strong national health innovation system or vice versa.

- *Scientific / practical value:* This research adds to the literature on innovation in healthcare, on national and sectoral innovation systems. We demonstrate that innovative output in healthcare differs among countries and that it allows for clustering. We use a multi-indicator approach to provide a more comprehensive

picture of healthcare innovation. Further, the resulting NHIS clusters differ from the NIS clusters when using the same indicators for the whole industry. We provide valuable insights for policy makers and policy researchers as sectoral innovation systems and specifically healthcare innovation systems are an important issue in political discussions. Our work provides a basis for assessing a country's inputs and measures to boost innovation and facilitate cost-effective care. It shows that innovation in healthcare needs to be assessed more comprehensively, e.g. through considering specific factors such as the level of digitalization.

- *Areas of improvement:* Measuring the innovative output in healthcare along the previously described four variables may not encompass all innovations. Process innovation in particular is hard to measure. Additionally, some healthcare innovations may not be patentable and may thus be partially excluded from our analysis. The descriptive variables serve as a first indicator for characterizing the NHIS clusters. However, they may not encompass all relevant variables, as healthcare with its related regulations and financing is a complex system with diverse indicators and systems definitions.

3.2 Adopting a mass customization approach to implement personalized medicine in German hospitals

- *Study significance:* Patient demand for individually adjusted treatment and medical service experience has increased over the last years (Hartweg, Kaestner, Lohmann, Proff, & Wessels, 2015a) and hospitals have to customize their offerings accordingly. Personalized Medicine (PM) is an emerging concept which allows even more tailored treatments for patients based on extensive pre-treatment diagnostics and developments in the "-omics" subjects. Implementing PM in hospitals, however, poses a challenge. Using learnings from the established concept of mass customization (MC) may be a beneficial for implementing PM in hospitals. This paper is one of the first to examine the feasibility and potential success and readiness factors for using MC as a method

for implementing PM in hospitals. It answers the following research questions: (1) Is it beneficial to apply the concept of MC to hospitals in the context of PM?; (2) What are potential success factors?; (3) What is the status of PM implementation in Germany?; and (4) What are the implications for PM in German hospitals? It further provides insights into the current status of PM implementation within the German HIS.

- *Methodological approach:* RQ 1 and RQ 2 are answered by applying the MC framework of (Broekhuizen & Alsem, 2000) to PM through a comprehensive literature review in order to assess whether the model is applicable to PM. The literature search was conducted through EBSCO and Google Scholar with "Personalized medicine" and "concept" as keywords. Overall, 70 papers published between 1999 and 2016 were reviewed in the literature analysis and statements matched to the categories proposed by (Broekhuizen & Alsem, 2000). In order to provide insights for RQ 3 and 4, ten semi-structured expert interviews were conducted to get an initial overview and create a basis for further analysis. Interviews were conducted with experts from the main stakeholder groups: physician, hospital management, special PM center, the medical technology industry, pharmaceutical industry, medical IT industry, health insurance sector and academia. The interviews were conducted in German, taped, transcribed and coded through qualitative content analysis. Quotes presented in the findings were translated into English.
- *Main findings:* Both, the results of the literature analysis and the interviews, indicate that the success and readiness factors proposed by Broekhuizen & Alsem (2002) may be beneficial for the implementation of PM in hospital. However, some adaptions may be required due to the specific nature of the healthcare sector and hospital setting. The adjusted model is presented in Figure 1:

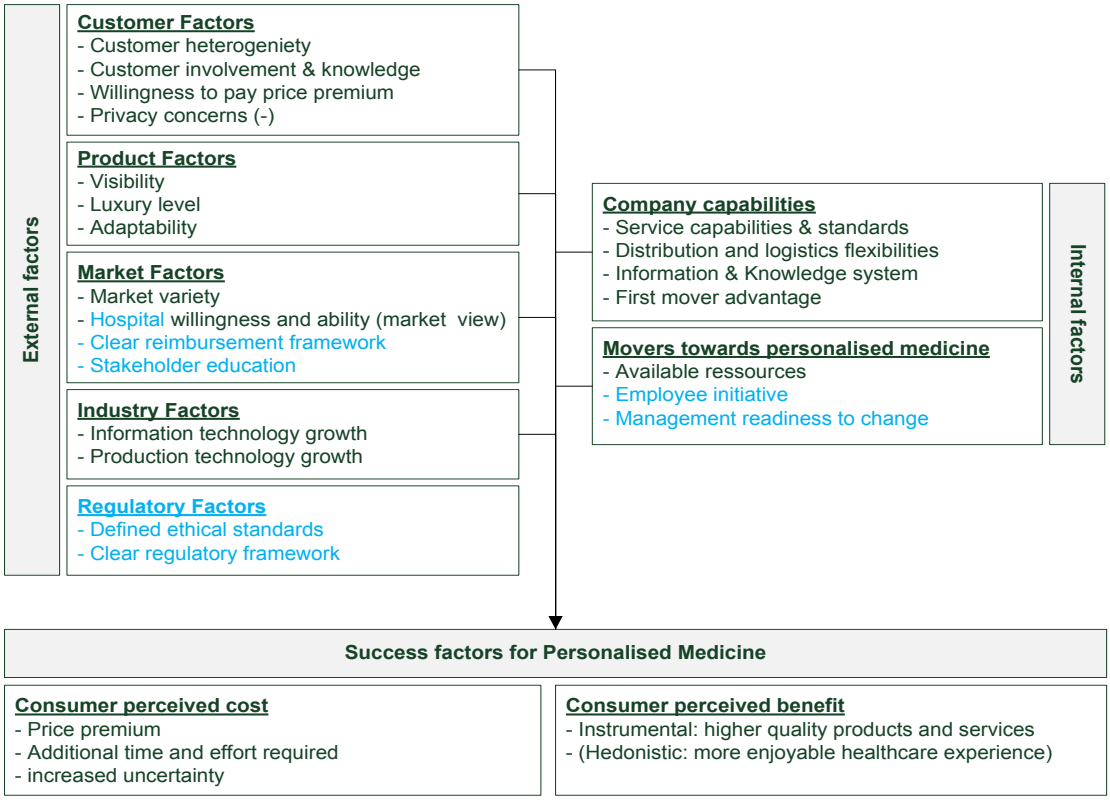

Figure 1 – Model of success factor PM readiness assessment (taken from Busch, 2016)

- *Scientific / practical value:* This research adds to the literature on innovation in hospitals and the German sectoral innovation system. It demonstrates that the proposed success and readiness factors for MC can be transferred to PM implementation in hospitals with minor adaptions of the model due to the specific nature of the HIS. It further provides practitioners a tool for assessing their hospitals' PM readiness and allows them to take measures to tackle the upcoming challenge of PM and its implementation. Finally, it provides practitioners with insights into the status of PM and its implementation in the German HIS.
- *Areas of improvement*: Within the literature review, research results may have been neglected due to the vast amount of PM literature. The interview sampling was purposive. It represents only a small fraction of the relevant stakeholders and can only provide a contemporary snapshot of stakeholder opinions. As with qualitative research, the results of this paper cannot be generalized. Thus, additional quantitative research, e.g. an empirical study of the different stakeholder groups, may add to the knowledge base and provide relevant

insights. Additionally, the derived model of PM success factors has not been tested in a quantitative study, which may be an interesting future research opportunity.

3.3 Employee involvement in innovation activities in hospitals: how perception matters

- *Study significance:* Innovation has become ever more important for hospitals (Porter & Teisberg, 2006) with continuous calls for research into the subject of innovation creation, implementation and dissemination (Thune & Mina, 2016). Employees are a very important source of innovation, especially within a service (co-creation) environment (Bessant & Moeslein, 2011; Schweisfurth & Herstatt, 2016). (Perceived) high employee involvement has been shown to be beneficial along all steps of the innovation process (Abu El-Ella, Stoetzel, Bessant, & Pinkwart, 2013; Bessant, 2003). Perceived involvement, however, has not been studied extensively within the healthcare sector. This study aims to answer the following research questions: (1) "How do different employee groups perceive their involvement in the innovation process and their interaction with other employee groups?" and (2) "How does this perception influence the innovation output?"

  This paper adds to the literature in the following respects: (a) showcasing perceived involvement in innovation activities and perceived between-group interactions within a hospital department, (b) deriving propositions for hospital management on how to foster innovative behavior among employees and (c) create a base case for management comparison.
- *Methodological approach:* We use a qualitative single case study approach with theoretical and purposive sampling of a university-linked hospital with a baseline of innovation activities. We introduced the project to the head of the department, who facilitated introductions to some participants, but was unavailable for an interview. We performed 11 episodic interviews in German with different department stakeholders (e.g. physicians, nurses, IT

administration, medical technology management, laboratory staff, pharmacologists, and administrative staff). We further used publicly available data such as press coverage and annual reports to triangulate the results. All data was coded. We used a qualitative content analysis procedure with deductive category application.

- *Main findings:* We found that all stakeholder groups are involved in innovation activities; however, the perceived involvement differs immensely among different groups, hierarchy levels and between phases along the innovation process. Hierarchy, physician-centricity and high workload limit the participation in innovation activities of certain groups. Further, there is a gap between perceived and actual involvement levels. An overview of the perceived involvement levels is presented in Figure 2.

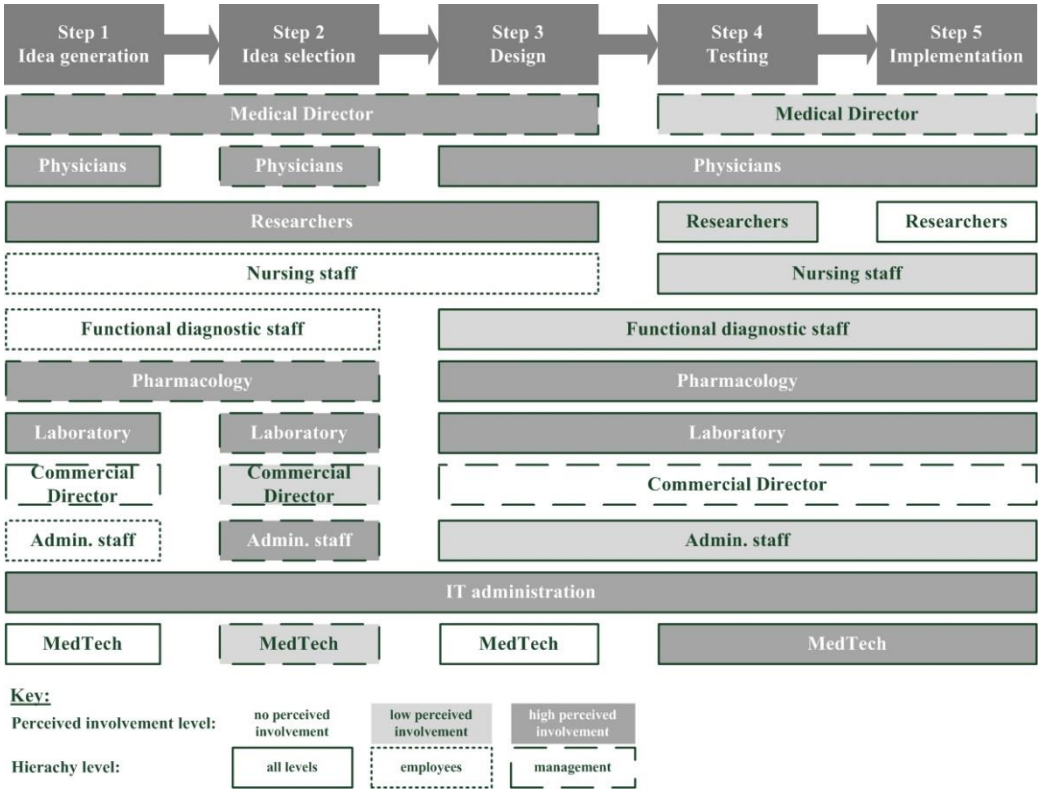

Figure 2 – Perceived involvement levels

Interaction levels also differ immensely. Respondents in management positions report higher interaction levels compared to regular employees, who attribute their low interaction to their standing in the hierarchy. There is little perceived

interaction at the ideation stage and only nursing staff mentioned co-creation efforts with patients. The between-group interaction increases during the idea selection stage when it comes to more radical innovation, while incremental innovation, often process improvements, are mainly discussed within the respective group. The highest levels of interaction are perceived in the testing and implementation phase, particularly through involvement in clinical trials and training on the use of innovative technology.

Employees with high perceived levels of involvement and interaction within networks appear more likely to take initiative, push and communicate projects and actively engage with new ideas, while staff groups with low perceived involvement appear reluctant to share suggestions and to communicate their ideas. Thus, following a hierarchy-independent open innovation approach may increase hospital innovation output.

- *Scientific / practical value:* This research adds to the literature on innovation management in hospitals and employee involvement in innovation activities by providing a model of perceived involvement and showcasing the interaction of stakeholder groups in the innovation management process of a hospital. With this, we provide a base case for further comparative research. We discuss measures that allow management to foster innovative behavior in the specific setting of a hospital.
- *Areas of improvement:* The results are based on a single qualitative case study and cover a limited circle of stakeholders with in-depth insights. Thus, they provide only a snap-shot of subjective opinions. Shadowing the employees would have led to a more objective assessment of their actual involvement. Additional qualitative research in form of a multiple case study or additional quantitative research based on a larger population may add to the knowledge base and provide relevant insights.

4. Future research opportunities

The field of innovation in healthcare provides a myriad of opportunities for further research on the macro, meso and micro level. At a macro level, it would be interesting to see how the innovation clusters develop in a longitudinal study and to assess which policy measures impact the clustering in particular. Further, a detailed case study of the health innovation systems of the top performing countries and the measures they have taken to foster innovativeness in their healthcare sector while containing cost and improving or maintaining patient welfare may be very insightful for policy makers and researchers alike. Here, it would also be interesting to analyze how the willingness to implement change and digitalization in the healthcare sector, as for example already underway in Estonia, impact the innovation output, both in the short and the long term. On the meso level and considering the apparent need of digitalization in the healthcare sector, it would be interesting to portrait cases of successful implementation of (digital) innovation with a large positive impact on social welfare in order to provide best practices for hospital management and healthcare payers. Further, it would be interesting to see how policy initiatives such as the "*Gesetz für eine bessere Versorgung durch Digitalisierung und Innovation*" (bill for improving care through digitalization and innovation), which was passed in July, 2019 by the German Bundestag, impact the implementation of health innovation. Likewise, given the importance of staff involvement in innovation for incremental process improvements as well as radical process changes, best practice cases and comparative case studies on the implementation of a (digital) hospital innovation management and the continuous improvement of innovation processes may be very insightful for managers. Finally, given the patient centricity of healthcare, involving the patient (user) in the innovation process and providing best practice cases will add to the literature.

5. References

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Appendix

Article 1: *National Health Innovation Systems: Clustering the OECD countries by innovative output in healthcare using a multi-indicator approach*

Article 2: *Adopting a Mass Customization Approach to Implement Personalized Medicine in German Hospitals*

Article 3: *Employee involvement in innovation activities in hospitals: how perception matters*

Article 1:

National Health Innovation Systems: Clustering the OECD countries by innovative output in healthcare using a multi-indicator approach

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Abstract:

The importance of innovation in healthcare has increased within the last decades as challenges, like rising costs and an aging demographic, have to be solved. The degree of innovativeness in healthcare is strongly influenced by the National Health Innovation System, which as a sectoral innovation system encompasses a wide variety of actors and related knowledge. Despite the highly practical relevance of the topic, there are only a few studies that analyze innovation in healthcare on a national level. Thus, this study is a starting point and, building on the theoretical framework of national innovation systems, answers the following questions: "Can countries be grouped by their innovation output in healthcare and do those groups differ in factors describing the healthcare system? Do countries with strong national innovation systems also have strong national health innovation systems and vice versa?" We compare the healthcare innovation output of 30 OECD countries using a multiindicator approach and categorize them into four distinct groups using cluster analysis. The cluster consisting of the Scandinavian countries, the Netherlands and Switzerland shows the highest innovation output measured in knowledge production and knowledge commercialization. Surprisingly, these countries, with the exception of Switzerland, only rank in the medium group when considering the entire national innovation system. Policymakers and researchers might be particularly interested in studying the healthcare systems of these countries.

Article 2:

Adopting a Mass Customization Approach to Implement Personalized Medicine in German Hospitals

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Adopting a Mass Customisation Approach to Implement Personalised Medicine in German Hospitals

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Personalised Medicine (PM) is an emerging concept which allows tailored treatments through extensive pre-treatment diagnostics. Implementing this approach in hospitals poses a challenge. Using mass customisation (MC) may be a beneficial method of implementing PM in hospitals. This paper examines the feasibility and potential success factors for using MC as a method for implementing PM in hospitals, the status of its implementation of PM in Germany and potential implications for hospital management. Therefore, a comprehensive literature review and interviews with German practitioners were conducted. The results show that MC may be one way of attaining a successful PM implementation. Success factors for MC can be transferred to PM implementation in hospitals as there is an overlap between both concepts. However, factors such as a regulatory framework, ethical standards and reimbursement have to be added to the construct. Overall, PM and its implementation into hospital structures do not seem to be a top priority of German hospitals, speciality centres excluded. However, practitioners expect this to change in the upcoming years, partially due to Government incentive. Future research opportunities include case studies of successful PM implementation in different countries or quantitative surveys to allow cross-country comparisons.

Keywords: Personalised Medicine, Mass Customisation, Healthcare, Implementation of Innovation, Germany

1. Introduction

The German healthcare system has undergone several changes since the millennium. Two examples are technological advancements in surgery techniques and the introduction of Diagnosis Related Groups (DRG) as a new reimbursement scheme. The latter imposed significant financial pressure on hospitals leading to increased efforts to improve efficiency and productivity (Korff, 2012). This pressure has been compounded by increasingly informed and engaged patients demanding higher levels of service and the use of the best technology available. "Personalised Medicine" (PM) has become a new technology through advancements in the field of genomics. It promises to improve the well-being of patients through the specific administration and dosage of drugs, thus personalising treatment and minimising potential side effects. Patients demand treatments that are adjusted to their individual needs, not only in terms of medicine, but also as a service experience at the hospital (Hartweg et al., 2014). Thus, hospitals must shape their service offerings to better compete on a regional and international level (Hartweg et al., 2014). Due to these developments, the Federal government of Germany has recognised PM as one of six action fields (BMBF, 2010).

Other industries have successfully adopted strategies for personalising their product and service offerings. Such personalisation has been subject of intensive research, primarily focusing on mass customisation (MC). Companies can fulfil clients' needs through integrating economies of scope with powerful IT solutions and forming a flexible approach in manufacturing. This paper aims to apply the concept of MC to the hospital sector, to assess its applicability to the implementation of PM and to identify potential success factors. Following a short literature overview of mass customisation and its success factors, this paper will focus on applying the recent literature on personalised medicine to the developed factors in order to assess the applicability of this concept. The remainder of the paper is structured as follows: Section 2 provides an overview of the relevant literature.

The research design and methodology is described in section 3. Section 4 presents the results of both literature analysis and interviews. The discussion of the results, their implications, and their limitations are presented in section 5 and conclusions in Section 6.

2. Literature Overview

2.1. Personalised medicine

PM has been in the focus of medical research since the 1990s (Marshall, 1997). Both the German Federal Government (BMBF, 2010) and US President Barack Obama (National Institutes of Health, 2016) have emphasised its importance. However, PM has no widely agreed definition. Ruaño (2004) states that "medicine has attempted to be rather personal" (p. 1), indicating that personalising medicine is not a new topic. Swan (2009) suggests "A systemic approach may incorporate a combination of an individual's genetic, blood and other biomarker, environmental, lifestyle and other data" (p. 503) as a comprehensive definition. Schleidgen et al. (2013, p.14) state that PM "seeks to improve stratification and timing of healthcare by utilizing biological information and biomarkers on the level of molecular disease pathways, genetics, proteomics as well as metabolomics". For this paper, the broader definition of Swan (2009) is applied.

The notion that PM may lead to better health has mainly been analysed from a biological standpoint. It is mostly based on biomarkers and clinical studies (among others Ross et al., 2009). Additional research was conducted from a pharmaceutical perspective (Amir-Aslani & Mangematin, 2010, Haruya & Kano, 2015). Despite the clear value proposition of more targeted treatments and the reduction of potential side effects and ineffective treatments (among others Collins & Varmus, 2015), the implementation of PM in hospitals has been characterised as sporadic and slow (Simmons et al., 2012, Teng, 2015). This may be due to a lack of evidence as studies on efficacy, safety, clinical utility, and cost-effectiveness progress slowly for smaller, harder to assemble patient cohorts (Sorich & McKinnon, 2012, Frueh , 2013, Manolio et al., 2015). Ways to foster implementation have only been the subject of a few studies (e.g. PWC, 2011, Fenstermacher et al., 2011). Current research is mainly based on case studies of hospitals and comprehensive cancer centres. It describes the implementation of the relevant IT-systems and changes in their internal processes as well as their status of implementation (PWC, 2011, Roden et al., 2008, Manolio et al. 2015, Bonter et al., 2011, Kron et al., 2016). However, current research lacks widely applicable implications for hospital managers in other sectors and other regulatory environments.

2.2. Mass customisation

Research on mass customisation (MC) mainly discusses the demand-side dynamics of more fragmented markets and increasingly educated customers (Gilmore & Pine, 2000). The goal of MC is to provide superior customer value by generating goods and services that meet individual customer needs with a close to mass production efficiency (Tseng and Jiao, 2001). The benefits of MC for companies include:

- Better match to the customer needs (Gilmore & Pine, 1997)
- Increased interaction with customers through co-creation and better customer understanding (Prahalad & Ramaswamy, 2004, Piller, 2004)
- Increased willingness to pay by the customer (Cavusoglu et al., 2007)
- Improved customer loyalty (Piller, 2004)
- Differentiation from competition (Broekhuizen & Alsem, 2002)

MC strategies (Lampel & Mintzberg, 1996, Kumar, 2004) are aided by the advances in manufacturing and information technology as well as just-in-time processes (Cavusoglu et al., 2007). It has been implemented, for example, in the bike, apparel or electronics industry (Kumar, 2004, Hvam, 2006). However, especially in established markets, the customisation of any product may be challenging and costly for the manufacturer (Cavusoglu et al., 2007). It may also be confusing and overwhelming for the consumer (Miceli et al., 2007). Thus, Cavusoglu et al. (2007) propose "targeted mass customisation" as a hybrid strategy. A company offers multiple customization scopes, that each represent a range of customised products instead of continuous customised varieties. With this approach, there is also the option of customising targeted segments. This leaves other segments to be served by a standard product variety. In this context, Cavusoglu et al. (2007) conclude that nowadays customisation is not a technological problem, but rather a strategic issue. Firms facing competition

have to carefully consider whether to customise at all. If they do, they have to assess which company segment will profit most from an added USP at the lowest possible cost of technology and most profit from gathering customer insights. Success factors of MC have been the focus of research papers for some time (Hart, 1994, Broekhuizen & Alsem, 2002, Piller, 2004). Among those, Broekhuizen & Alsem (2002) have proposed a model of success factors that influence a fruitful adoption of mass customisation by an organisation. External factors include: customer factors, product factors, market factors, industry factors. Internal factors are classified as company capabilities and movers towards mass customisation (cf. Figure 1).

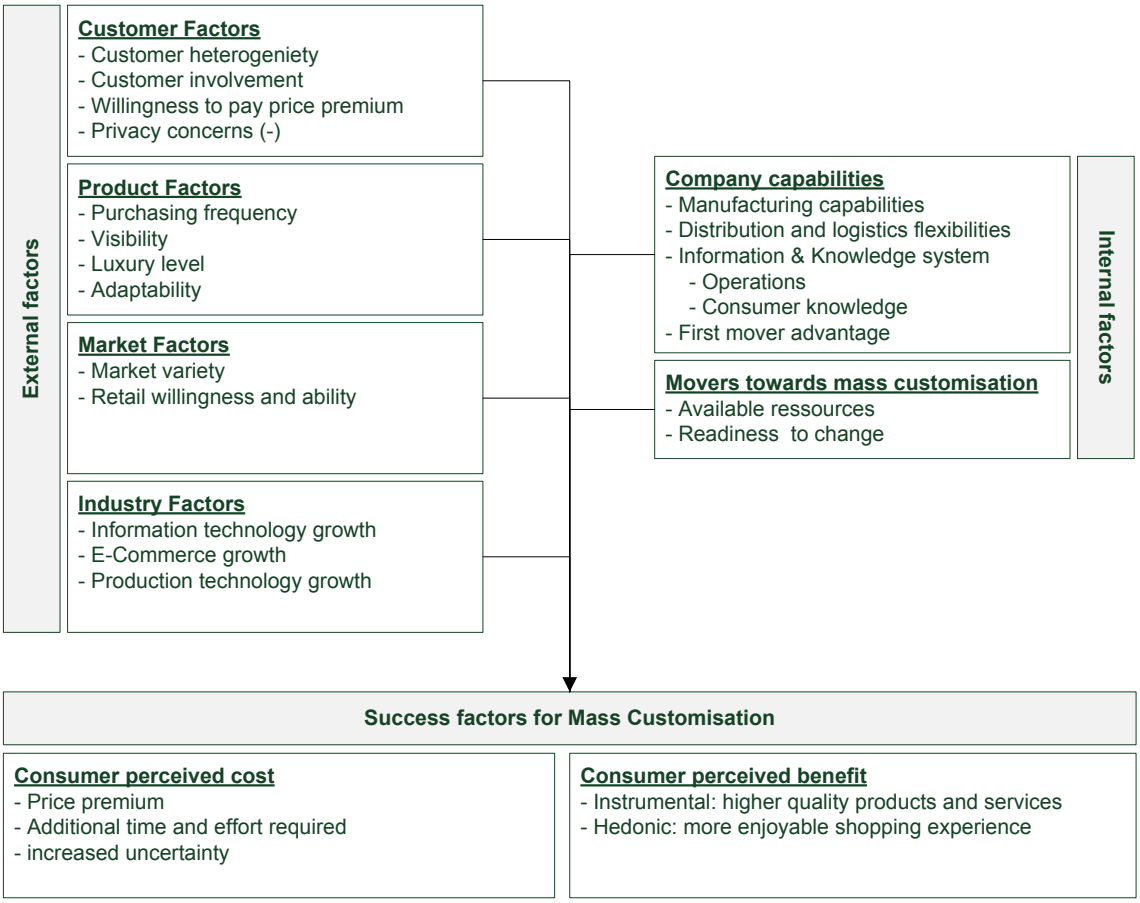

Figure 1 – Success factors for MC, adapted from Broekhhuizen & Alsem, 2002

This model shows an approach for assessing whether MC is useful and practical for a business, as it not only encompasses market factors but also evaluates the internal capabilities of a company. The defined success factors have been confirmed in further studies (Merle et al., 2007).

2.3. Mass customisation for personalised medicine

The literature on MC in healthcare is rather limited. Healthcare as a service is by nature tailored to the symptoms of a specific patient. Lampel & Mintzberg (1996) proposed a tailored customisation, presenting the customer with a standard which is then adapted to customer needs. Current research is looking at a systemic solution, thus tailoring the patient pathway across all respective providers (White & Chao, 2014). While this value-based, patient-centred approach should ultimately be the goal of an efficient healthcare system (Porter, 2006); it seems far from being realised in practice (Porter, 2009). Thus, enabling hospitals as major drivers in the healthcare system to successfully adopt PM appears to be a step towards a more patient-centred, value-based healthcare. Chaudhuri & Lillrank (2013) provide a first insight into customisation in healthcare and the trade-off between resources and flow efficiency in the Indian healthcare sector. The authors identify several research gaps including competencies and advances needed for MC implementation and the dimensions of the competitive advantages for hospitals and how both factors can be combined. Minvielle et al. (2014) have suggested a first approach on how to manage customisation in the healthcare sector by deriving a framework from the services

sector literature. They develop six relevant factors for implementing care customisation: categorisation, IT use, developing service skills, patient self-management, patient's experiences and economic impact. They also introduce the term "care customisation", meaning the "uniqueness of each care process" (Minvielle et al., 2014) in contrast to patient-centred care referring to large-scale actions such as IT implementation and comprehensive care standards. The model is of theoretical nature and has not yet been supported by data. Pourabdollahian & Copani (2015) propose four different business models for customisation in healthcare based on a product service system and evaluate them based upon a qualitative analysis of benefits and challenges. Their approach is theoretical and does not provide the reader with case studies or data on the implementation of such business models. Thus, research is currently based on theoretical concepts, which have not yet been evaluated by practitioners. The majority of studies focuses on the US market, with research on other health-regulatory environments being rather underrepresented in the reviewed literature (Manolio et al. 2015 provide comprehensive insights into global developments in PM). Currently, there seems to be no research that provides data for insights into the possible implementation of MC in healthcare in general or in a country-specific setting. Those factors pose relevant research gaps, which will be addressed in this paper.

3. Research design

The increased scientific interest in PM and its translation into clinical practice pose a very interesting research opportunity. In accordance with Minvielle et al. (2014) this paper postulates that MC may be beneficial for implementing PM in the hospital sector. Since there is only limited research on country-specific implementation, this paper aims to provide insights from a German perspective. Therefore, the objective of this research project is to investigate the following questions:

1. Is it beneficial to apply the concept of MC to hospitals in the context of PM?
2. What are potential success factors?
3. What is the status of PM implementation in Germany?
4. What are the implications for PM in German hospitals?

The MC framework of Broekhuizen & Alsem (2002, cf. Figure 1) is applied to PM through a comprehensive literature review in order to answer questions one and two. Each factor of the framework is analysed for its fit to PM to determine whether the model is beneficial in the application context.
First, a Google Scholar search for "personalised medicine" in conjunction with "concept" was conducted to get an initial overview of the relevant literature. For this purpose, the first 20 result pages were screened which resulted in 31 relevant research articles. Further, an EBSCO search using the terms "personalised medicine" in combination with "concept" was conducted. The literature was then screened for papers focusing on the PM concept.
In a next step, citations of the chosen papers were scanned for further relevant research. Overall, 70 studies were reviewed for the literature analysis section. The selected papers were published between 1999 and 2016. Of these, 71% have been published since 2009. Statements matching the categories defined according to Broekhuizen & Alsem (2002) and some additional factors were compiled in a database.

For questions three and four, ten semi-structured interviews with German practitioners were conducted. Their aim was to get an overview of the status of PM across Germany as well as of the practicability and applicability of the model. The sampling of the participants was done conveniently. The interview goal was to get responses from relevant stakeholders: physicians (1 participant), hospital management (3), special PM centres (1), the medical technology industry (1), pharmaceutical industry (1), medical IT industry (1), health insurance sector (1) and academia (1). Overall, all interviews were conducted between January and April 2016. Each interview lasted between 25 and 45 minutes. The survey questions were derived based upon the model of Broekhuizen & Alsem (2002). The questions were clustered into four parts: (A) general questions, (B) the concept of PM, (C) implementation of PM and (D) future of PM in Germany. Both (A) and (B) focused on external factors defined in the model. Part (C) concentrated on respective internal factors. The questions were slightly adapted to the professional background of the interview participants. For convenience purposes of the partners, the interviews were conducted in German and taped. Afterwards, they were respectively transcribed, coded and evaluated.

4. Results

4.1. Literature analysis

The results gathered from the literature review indicate that the success factors for mass customisation can be applied to personalised medicine. Figure 2 shows an overview of how many papers presented statements that match the categories of the model by Broekhuizen & Alsem (2002).

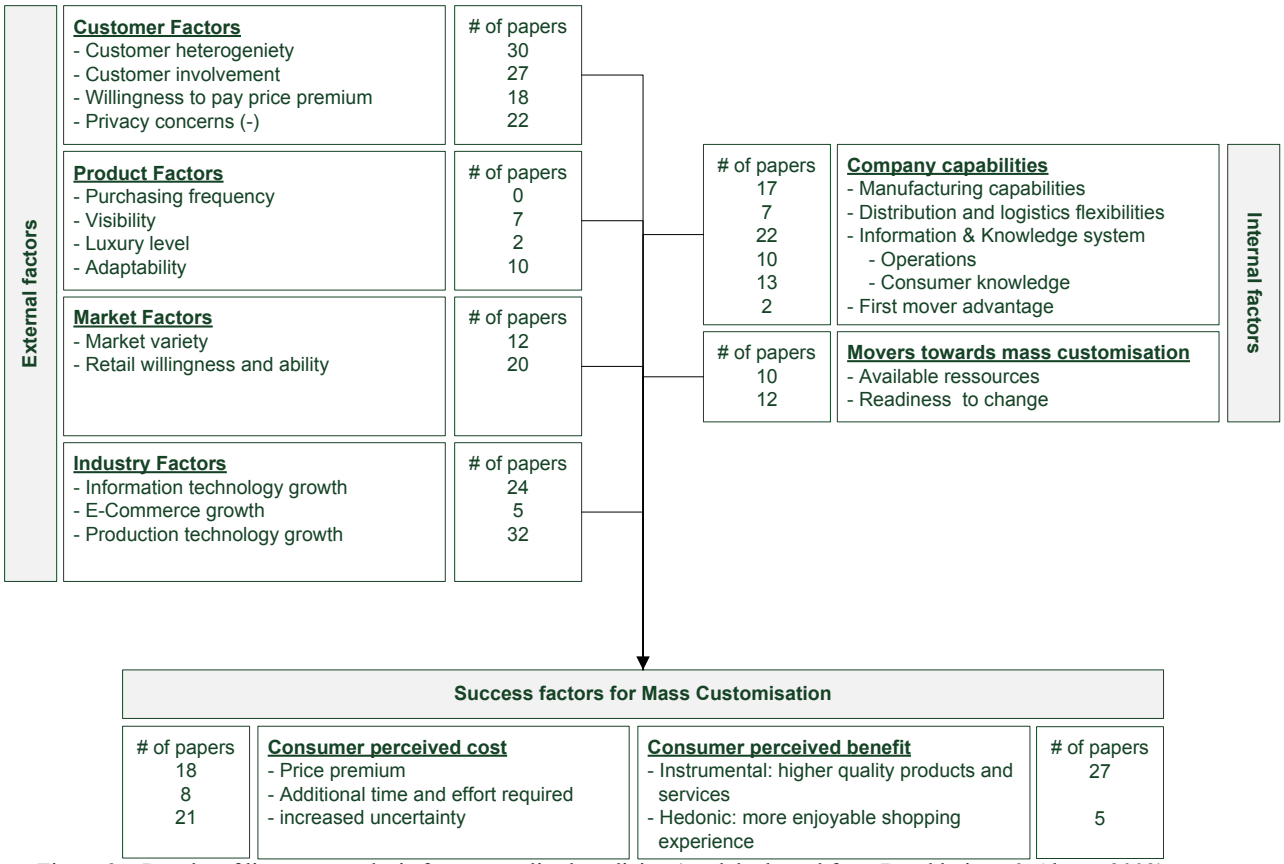

Figure 2 – Results of literature analysis for personalised medicine (model adapted from Broekhuizen & Alsem, 2002)

External influence factors include: (i) customer factors, (ii) product factors, (iii) market factors, and (iv) industry factors. Customer factors comprise of customer heterogeneity, customer involvement, willingness to pay price premium, and privacy concerns (having a negative impact on the success of MC). Reviewing the papers indicated that customer heterogeneity is widely accepted, with papers stating "Humans are individual, so medicine must be" (Fierz, 2004, p. 119) or "Recognition of interindividual differences in drug response is an essential step towards optimizing therapy" (Mancinelli et al., 2000, p.1). Statements relating to customer involvement were found in approx. 40% of the reviewed papers. Evidence for an increased willingness to pay additional costs could be revealed in several papers. However, some of the articles state that there may not be an increased willingness to pay (by the health insurances) due to a persisting lack of clinical evidence (Ginsburg & Willard, 2009, Horgan et al., 2014). Further, some suggest that PM may lead to an overall cost reduction through e.g. disease prevention (Aspinall & Hamermersh, 2007). The negative impact of privacy concerns of data security was found in 30% of the papers. Relating to the data security, fears of discrimination due to leaked genomic information were raised (Savard, 2013, Swan, 2009, Yang et al., 2011).

Product factors include purchasing frequency, visibility, luxury, and adaptability, the latter referring to the ease of adapting the product to target more segments. Interestingly, there were no statements found to match the category purchasing frequency. This indicates that returning patients (e.g. chronically ill) are not relevant for the implementation of MC in healthcare. Statements referring to the visibility in a sense of using health as a factor of self-expression (Swan, 2009) could be found in a few papers. Luxury was only rarely mentioned. Adaptability was mentioned more frequently mostly referring to adaptability of treatment to heterogeneous customers

(Mancinelli et al., 2000).

Market variety and retailer's willingness and ability are combined to form market factors. Several papers mention market variety – mostly concerning available biomarkers and genomic tests (Conti et al., 2010, Hamburg & Collins, 2010). Some also mention the different stages of PM implementations (Horgan et al., 2014). The retailers' ability and willingness is evaluated differently, since PM is a service that is aided by several products. Rather, PM is consumed at the time of creation (Hartweg & Lindgren, 1993) or possibly with a slight delay due to lab results. There is no need for a retailer from a hospital point of view. Thus, the retailer's willingness is interpreted here as the "healthcare providers' willingness and ability" from a market perspective. This ability was mentioned frequently in the literature. However, it was mostly referring to reluctant adaptation of the concept. For example, Davis (2009) states that only "few personalised medicine tests have been widely adopted in the clinic so far" (p. 279). Horgan et al. (2014) postulate "The complex process to translate PM into the member states and European health systems has delayed its uptake." (p. 278) Several papers identify institutional and systemic barriers to a widespread adoption of PM, which include, among others, knowledge, regulation, education, or ethical concern (Lundshof et al. 2006, Horgan et al., 2014).

Industry factors comprise of IT growth, E-commerce growth, and production technology growth. IT-growth is widely mentioned, specifically referring to the possibilities of Electronic Health Records (Bonter et al., 2011), Big Data (Harvey et al., 2012, Swan, 2012), Quantified-Self (Swan, 2012), shared data (Luciano et al., 2011, PWC, 2011), and predictive algorithms (Kohane, 2009, Swan, 2009). E-commerce is rarely mentioned, only referring to direct-to-customer genetic testing as pioneered by companies such as *23 and me* (Swan, 2012). Approximately 45% of the analysed literature refers to production technology growth in genomic research, biomarkers, and related second generation sequencing technologies. However, Harvey et al. (2012) state that "new technologies for detailed biological profiling of individuals at the molecular level have been crucial in initiating the move to personalised medicine; further novel technologies will be necessary if the vision is to become a reality." (p. 625). It is another indicator for the slow implementation of PM. Challenges such as standards to ensure interoperability and harmonisation of different therapies pertain (Ginsburg & McCathy, 2001, Horgan et al., 2014).

Internal factors include company capabilities and movers towards MC. Company capabilities comprise of manufacturing flexibility, distribution and logistics flexibility, information and knowledge system as well as first-mover advantage. Manufacturing flexibility is interpreted as "service flexibility" since PM as a service is consumed at the time of creation (Bowen, 1990). A few papers refer to the service-delivering process. Bonter et al. (2011) state that "Canadian and US studies have demonstrated that current physician knowledge, real-world data and guidelines relating to PM have often been insufficient for appropriate adoption […]" (p. 6). A need for education of current and future service providers was mentioned frequently (Cornetta & Brown, 2014, Hall et al, 2015, Keller, 2010). However, distribution and logistics flexibility was only rarely mentioned. Relating papers only suggested integrating PM processes (testing, genetic counselling, etc.) into comprehensive patient care (Fierz, 2004, Merci-Bernstam et al., 2013). The information and knowledge system was frequently mentioned. Most of the statements in this field referred to the need for solutions that deal with the generated data and related issues such as storage, interoperability of systems, computer-assisted decision-making etc. (Horgan et al, 2014, Swan, 2009 and 2012, Stelzer et al., 2015). Interestingly, there were almost no statements referring to a first mover advantage. Movers to MC include available resources and readiness to change. Statements about resources mostly referred to the lack thereof (Yang et al., 2011, PWC, 2011, Meric-Bernstam et al., 2013). Readiness to change, or more precisely, the lack thereof, was also mentioned in several papers. PM "may not be seen as a priority" (Swan, 2012, p.112) or there may be "a timing issue" (Swan, 2012, p. 112), as the technologies still undergo extensive R&D and may not be in the full focus of healthcare providers yet.

Finally, the success factors seen from the customer's perspective are divided into customer perceived costs and customer perceived benefits. Customer perceived costs include price premium, additional time and effort required and increased uncertainty. There are two polarized opinions regarding the price premium: overall cost reduction (Faulkner et al., 2012, Flores et al, 2013) and overall cost increase (Sorich & McKinnon, 2012). Teng (2015) states that PM "is not usually synonymous with low costs" (p. 232). He adds, however, that it will lead to more elaborate prevention and care, thus reducing overall healthcare costs through early detection and treatment. The need for adequate reimbursement is yet another frequently mentioned factor (Davis, 2009, Ginsburg & Willard, 2009, Hitz & Katsanis, 2014). Additional time and effort required is rarely mentioned. Statements refer to an increased effort for longitudinal data collection (Chang & Ginsburg, 2011) for healthcare providers. However, increased effort is also mentioned for patients as they seek to be active about their health, their relating data and its potential implications (Gonzales-Angulo et al., 2010). Increased uncertainty is mentioned very frequently. It relates to all stakeholders – healthcare providers, physicians, patients and payers. It manifests itself

in: physicians' and patients' uncertainty about "the right treatment" (Chan & Ginsburg, 2011, Cornetta & Brown, 2014, Horgan et al., 2014), patients' uncertainty about data collection, storage, privacy, and handling (Burke et al., 2010), payers', physicians' and patients' uncertainty about efficacy of methods (Conti et al., 2010, Hamburg & Collins, 2010, Hitz & Katsanis, 2014), and healthcare providers' and industries' uncertainties about reimbursement (Faulkner et al, 2012). Consumer perceived benefits consist of instrumental benefits (better quality products and services) and hedonistic benefits (more enjoyable "shopping experience"). The latter is translated into a "more enjoyable healthcare experience" for the purpose of this paper. Better quality, mostly defined as higher efficiency and efficacy of treatment, is explicitly mentioned in almost 40% of the analysed articles. This factor is viewed as the main goal of PM (Horgan et al., 2014). Hedonistic benefits were only rarely mentioned. As PM involves undergoing intensive tests, patients may not experience hedonistic benefits in the service co-creation.

In addition to the factors found by Broekhuizen & Alsem (2002), several others were identified for a successful implementation of PM in hospitals:

1. Definition and uphold of guiding ethical principles as well as "the right not to know" (Burke et al, 2010, Cornetta & Brown, 2014, Hall et al., 2014)
2. Effective regulatory policies and set standards for PM (Chan & Ginsburg, 2011, Davis, 2009)
3. Clear reimbursement standards (Faulkner et al., 2012)
4. Education of all stakeholder groups on the meaning of PM (Keller, 2010, PWC, 2011).

4.2. Interviews

The interviews confirmed that there is no clear, overarching understanding and definition of PM. Every interviewee had a different understanding when asked for a definition. One partner had not previously come across the term at all, despite working with hospitals. Statements like "PM is observing and acting on the current needs and concerns of the patient in an individualised fashion" or "using the technical possibilities and processes of teams for individualising standard-based [treatments]" occurred. Standardised processes were frequently mentioned as a basic need for PM. Some participants mentioned that personalisation may not be feasible for single patients, but rather for cohorts or sub-cohorts. The lack of common understanding may result in a delayed adoption.

The results of the interviews further indicate that the model of MC success factors is applicable to the German healthcare sector; however, minor adaptions have to be made. External factors of the framework were mentioned by all partners during the interviews. All customer factors were frequently referred to. Customer involvement was almost always linked with statements like "customers are increasingly informed", partially due to available information in online resources. Customers and their demand were perceived as heterogeneous. Interviewees proposed a distinction of customer demands depending on the severity of their illness. Participants from non-specialised centres did not experience patient demand yet. Specialised centres, however, reported an increase. There was no consensus whether patients are willing to pay for PM services. However, the challenges of adequate reimbursement were frequently mentioned. All interview partners stated concerns about privacy and data protection, even though some agreed that some patients are already sharing their data for research purposes. As in the literature review, product factors were rarely mentioned by the interviewees. Only adaptability of the service occurred, often with the notion that standardisation of processes enables individualisation. This seems to be an important point for German stakeholders. Market factors were rarely stated in the interviews. Variety was not stated, possibly due to the lack of awareness of PM projects among the interviewees. Most said that they are not able to state beacon projects of PM in Germany. Only the partners most closely linked to PM research and reimbursement revealed two to three current German initiatives. All of those are carried out by specialised university hospitals. Interestingly, the company *23 and me* was mentioned several times in the context of beacon projects. Statements about healthcare providers' willingness and ability lead to differing viewpoints: when considering the payers, most stated reimbursement issues that prolong implementation. Considering the hospitals, almost all interviewees highlight that PM "will come and must come" to the German market. However, adoption may only be useful and feasible for specialised centres or university clinics. Industry factors, meaning IT growth and production technology growth, were stated very frequently. There were no statements concerning E-Commerce, which is in line with the literature analysis. Finally, regulatory issues were derived as a further success factor, which is in accordance with the literature analysis. Participants stated that there may be too much regulation, which may hinder the implementation of PM in German hospitals. It was suggested that a clear regulatory framework for reimbursement is required. Almost all participants raised ethical concerns about genomics and data security.

Internal factors were also frequently mentioned. Participants highlighted the need for employee involvement and initiative as a main factor for implementing PM service capabilities in a hospital. It may be aided through internal systems, specific rewards and internal education as enablers. The statements are consistent with the literature review results. Interviewees rarely mentioned distribution and logistics flexibility, however, they emphasised the need for new organisational standards, breaking up existing hierarchies, and team work. This relates to all hospital staff and cooperation with stakeholders. All partners identified IT-systems as one of the most relevant factors for PM and changes in healthcare in general. However, the status in Germany was assessed with statements such as "not enough IT, not enough hardware, outdated hardware", "IT departments can barely handle the amount of data generated" but also "we had to cancel [the implementation of Electronic Health Records] due to financial reasons". They indicate that outdated, not interoperable IT systems and a lack of resources to replace them pose a strong barrier for PM implementation. Further, (anonymised) data sharing was perceived as impossible by many partners due to very strict German data security regulations. A first-mover advantage was stated by a few participants. Resources and readiness to change were pointed out by almost all participants as movers (or the lack thereof as barriers) for PM. Available resources were referred to as being critical to success. Sources of additional financial resources may be obtained through external grants, which may also serve as a motivating factor for staff. Readiness to change was perceived as a "management issue" by the participants. Successful implementation is accompanied by a strategic decision towards PM.

Better quality of service was mentioned as the most important goal of PM and thus a major success factor. However, better service was often attributed to non-medical service experiences such as better rooms, reduced waiting times or friendly staff as a way to "personalise" medicine. This adds more to the hedonistic "more enjoyable service experience". With regard to better quality, risk prediction and non-genomic, preventive measures were also stated. Some subjects attributed this to be a responsibility of payers. All agreed that a high level of uncertainty pertains – about the definition of PM, the efficacy of new treatments, data security, potentially predictive qualities of tests, efficacy and "false positives". Additional time and effort for the patient was stated by several partners. However, there was consensus that patients incur this additional time already in order to gather information about their illness. Finally, the overall notion was that PM comes at a price premium. There was no agreement on whether PM will reduce the overall healthcare cost.

5. Discussion and Implications

The results of the literature analysis and the interviews indicate that MC may be beneficial for hospital implementation of PM. However, adaptions may be required. In both, the literature and the interviews, no clear definition of the concept of personalised medicine could be revealed. Therefore, a diverse understanding of the term and concept resulted among the stakeholders. Thus, PM is often used as a "buzz word" with no clear understanding of its implications. A common understanding between the stakeholders needs to be established to enable a fruitful discussion of the topic.

Additionally, there is a difference in perceived value of PM between the stakeholders. A core concept of German healthcare is the divide between the healthcare receiver (patient) and healthcare payer (health insurance). The results indicate that there is uncertainty about whether PM does lead to better healthcare economics for the overall healthcare system. Cost of customised testing, care plans and treatment may be higher in the short term. However, PM may also lead to reduced overall lifetime treatment costs for the patient. On the other hand, personalising every treatment may result in a cost explosion. Performing quantitative research on this question would be beneficial for all stakeholders, as it enables a more economic view on the subject.

There also seem to be specific "German phenomena" regarding the implementation of PM. Very strict rules on data security and data sharing make sharing data within overarching biobanks or similar IT systems nearly impossible. Further, current IT in German hospitals seems entirely unfit for the challenges of genomics data creation, usage and storage. This may partly be due to a lack of hospital IT infrastructure funding in relation to the DRG introduction. Additionally, the German population is very concerned about gene manipulation. This may explain comparatively low patient demand and a related delayed adoption of genomics based medicine, even within larger clinics. The current view is that PM is only a topic for a relatively small number of diseases, mostly cancer, and thus only a relevant concept for university hospitals and specialty clinics in Germany. However, the Federal Government has recently launched a research initiative, which hands out funding for

research specifically aimed at PM basic and translational research (BMBF, 2016). Additionally, there will be changes in reimbursement, such as the introduction of reimbursement for specific companion diagnostic tests (KBV, 2016). This may set incentives for a broader adoption of PM.

The model of success factors for MC seems to be a good starting point for implementing PM. This is due to a significant overlap of external, internal and final success factors. However, some factors were not seen as important, while new ones were emphasised in the results. Factors such as purchasing frequency (e.g. referring to chronic patients) or E-Commerce growth were not seen as important for PM, and hence removed from the model. The literature review and interviews revealed several other factors that are of relevance for PM implementation. These include a clear reimbursement framework, education of relevant stakeholders, ethical standards and clear regulations seem to play an important role for PM. Reimbursement of e.g. companion diagnostics incentives the use of the new technologies. Further stakeholder education appears necessary to increase awareness and increase understanding of the possibilities, challenges and implications of PM. Ethical standards and regulatory clarity provide security for hospitals wanting to implement PM. Thus, those factors were added to the framework. Moreover, two additional movers towards PM were identified in the literature review and interviews: employee initiative and management readiness to change. Hedonistic benefits were left within the model, as German partners were heavily focused on the overall hospital service experience. The suggested model for PM implementation success factors is shown in Figure 3.

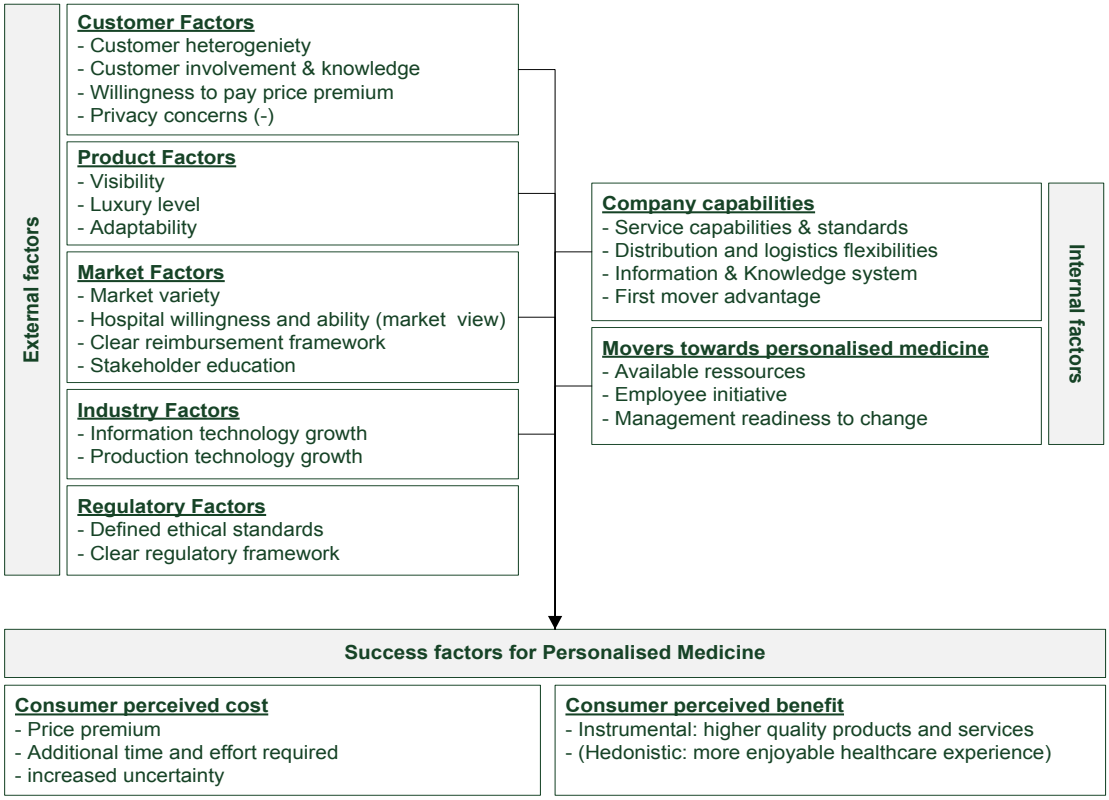

Figure 3 – New model of factors for successful PM implementation,

There are numerous implications for German hospital practitioners. First, there is a pressing need to find a common understanding of the concept of PM in order to facilitate a political, regulatory and financial discussion about the topic. A first starting point for the discussion may be the "Aktionsplan Individualisierte Medizin" by the Federal Ministry for Research & Education (BMBF, 2016), which offers research grants for basic research, but also for translation into clinical practice. Additionally, PM should not only be recognised as a better service for patients, but rather as a customised treatment plan for a (sub-) cohort of patients. Further, practitioners should familiarise themselves with the concept, the successes and failures of mass customisation and draw lessons on the implications of MC for PM and possible limitations of the concept. Hospital key performance indicators should be set, measured and analysed accordingly. Interesting input may arise from other countries, such as the United States or Asian countries. Finally, German hospital practitioners will have to accept a slowly increasing demand for PM services, as more patients educate themselves about the medical possibilities that arise in relation

to the "-omics" subjects. Thus, if a hospital wants to be prepared for the future, there is a need to find ways to finance and use new technologies in order to stay ahead in the market place. A strategic focus on PM may help in this regard. The derived success factors may provide first guidance in developing a PM strategy.

This paper has several limitations and shows opportunities for further research. First, although the literature review can be regarded as comprehensive, research results may have been neglected due to the vast amount of PM literature. Further, the model is derived based on one specific framework of MC success factors. There may be other models, which may be adapted to healthcare. In addition, the framework wording was modified to fit the healthcare industry. Thus, a more in-depth bibliometric analysis of the derived model may pose an interesting research opportunity. Second, the interview sampling was done conveniently and presents only a small fraction of the relevant stakeholders. It can thus only represent a contemporary snapshot of stakeholder opinions. Additionally, the stakeholder sample is, despite the author's efforts, not fully comprehensive, as it does not include general practitioners, patients or representatives from the Federal Government. Thus, for further research, the sample should be extended to all relevant stakeholders. As with qualitative research, the results of this paper cannot be generalised. Thus, additional quantitative research, e.g. an empirical study of the different stakeholder groups, may add to the knowledge base and provide relevant insights. Additionally, the derived model of PM success factors has not been tested in a quantitative study, which may be an interesting future research opportunity. Other research opportunities may include applying the proposed framework to a "real-life" case study of PM implementation, both in Germany and other countries. Additionally, a cross-country case-comparison may lead to more comprehensive policy implications.

6. Conclusion

This paper aimed at analysing the applicability of the concept of MC to PM in a German context. Additionally, the status of PM implementation in Germany was assessed. In order to evaluate the adaptability of MC to the specifics of PM in Germany, a comprehensive literature review was carried out. Further, semi-structured interviews with experts from the German medical sector were conducted. The results show that MC may be one way through which implementing PM is possible. The success factors for MC can be transferred to PM with minor adaptions of the model. Overall, however, PM seems to not be in the focus of German hospitals at the moment. As the technological and medical advancements progress and additional funding is provided by the Federal Government, focus will shift towards this evolving concept. However, it is necessary to first establish a common definition of the concept. Afterwards, there will be a need for developing implementation strategies and defining success factors. The results of this paper may be a starting point for further, in-depth research of PM in the German healthcare sector.

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Article 3:

Employee involvement in innovation activities in hospitals: how perception matters

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The following paper shows the initial submission to Health Services Management Research. The paper has since been revised and is undergoing a second round of reviews.

Employee involvement in innovation activities in hospitals: how perception matters

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Employees are a very important source of innovation and essential for the generation, dissemination and implementation of these ideas throughout the organization. This is especially relevant when considering innovation in services during service (co-) creation such as within the healthcare sector. However, perceived employee involvement in innovation (EII) and between stakeholder group interactions in hospitals has not yet been studied in detail. This paper addresses the following research questions: (1) "How do different employee groups perceive their involvement in the innovation process and their interaction with other employee groups?" and (2) "How does this perception influence the innovation output?" We analyzed a single typical German research hospital and conducted episodic interviews with employees representing different staff groups. We revealed that while all groups of employees are involved in innovation activities, perception of their involvement in innovation activities differs widely between stakeholder groups, hierarchy levels and along the innovation management process. Further, their interaction and co-creation with each other and external stakeholders such as industry and patients differ widely as well. Both factors influence innovation output. With our paper, we add to the understanding of perceived EII in hospitals and discuss measures for hospital management to increase EII.

1. Introduction

The German healthcare system and its hospitals have undergone diverse reforms in the last 20 years. While cost containment has been improved, hospitals still struggle to meet the demands of patients, payers, and other stakeholders. Recent developments show changing customer / patient needs and demand for a more patient-centered and value-based approach to healthcare[1]. Hospitals, as complex service organizations, engage various stakeholder groups and need to ensure their viability in a consolidating market while delivering the highest treatment quality within tight economic constraints and an institutionalized, bureaucratic environment. Thus, next to policy initiatives and reforms, innovation and the innovativeness reputation become more important for hospitals to cope with future challenges [2].

It is widely accepted that employees are a very important group for innovation and value co-creation in a multi-stakeholder service environment [3–5]. Thus, the topic of employee involvement in innovation (EII) has been extensively studied in the literature [6,7], and practices to foster innovative behavior amongst employees along the innovation process have been adopted across different organizations.

Current observations on EII in healthcare stem predominantly from medical technology and pharmaceutical companies [8]. There have been continuous calls for research on the topic at the hospital level [9]. So far, only few papers are concerned with the different stakeholder groups involved in innovation in hospitals and their interaction [10]. Their focus lies on specialized groups such as nurses [11] , physicians [12] or on specific innovation activities (IA) such as R&D [13] and the implementation of medical innovations [14]. To our knowledge, perceived involvement in innovation processes has not been studied extensively in the healthcare sector despite its importance for healthcare organizations [15,16,6]. This poses an apparent gap in current research. Thus, this paper adds to the understanding the topic by answering the following research questions: (1) "How do different employee groups perceive their involvement in the innovation process and their interaction with other employee groups?" and (2) "How does this perception influence EII and innovation output?".

We conducted an in-depth case study of a typical German research hospital on perception EII and interaction in the innovation process. We add to the literature on EII in hospitals in the following respects: (a) we showcase a gap between perceived and actual involvement and interaction for different stakeholder groups within a hospital department, (b) we derive suggestions for hospital management to foster innovative behavior among employees, and, by using a typical case environment (c) we provide a benchmark case for management comparisons.

2. Literature review

Employee involvement has been defined as "the participation of the entire firm's workforce to improve the working environment, product quality, equipment productivity, and eventually, company competitiveness"[17] and is naturally linked to innovation. An employees' perception of being involved impacts innovation success[15]. EII has received significant attention amongst researchers, which lead to a vast literature base drawing on social, behavioral as well as management sciences[18,4,19–21]. More recently, EII has gained traction in the services innovation literature with employees acting as value co-creators within the service delivery process. With close proximity to the customer, employees can provide in-depth insights on customer needs and opportunities for new services generation [22]. Thus, EII provides significant opportunities for innovation in service-intensive environments such as hospitals.

Applications of the research base on (perceived) EII to the specific case "hospital", however, are increasing, but still rare. Thune and Mina[9] argue that the hospital as a source for innovation is still under-researched and that IA are happening in a "black box". Notable examples of research on the topic include: Djellal and Gallouj[23] deriving a framework for analyzing hospital innovation output, Salge and Vera[24] focusing on the link between hospital innovation and hospital performance, Benzer et al.[25] focusing on innovation and organizational change in hospitals, or Cucciniello et al.[26] describing a health innovation implementation process. Existing literature on EII in healthcare rarely covers all employee groups, their perceived involvement in activities or their perceived interaction with one another (with the exception of [10]), but rather focuses on physicians or nurses only [11,12].

As EII occurs through interaction of various groups, especially in a multi-stakeholder setting, we argue that the innovative potential of employees in hospitals has not been fully analyzed in the literature yet. Additionally, Thune and Mina[9] suggest that the organizational capacity of hospitals and their employees to produce innovation is currently underemphasized in research. This is surprising as it is of high practical relevance of innovation for high-quality provision of medical services at reasonable cost.

3. Research Design

We conducted a qualitative single case study in order to get an in-depth understanding of the process and interactions under study [27]. The sampling was theoretical and purposive. We found a typical German university-linked research hospital, which can be contrasted with extreme cases, both positive and negative, in future research projects. After an initial literature review, we derived two research questions and a guideline for semi-structured interviews. We performed episodic interviews in order to better understand EII and interactions within the innovation process. We combined the benefits of a semi-structured approach with the depth of information of a narrative and employ a method that is specifically useful for group comparisons, while also triangulating different approaches of data collection [27].

We prepared a list of stakeholder groups necessary to construct the case. These include: physicians, nurses, functional diagnostic staff, IT administration, medical technology management, laboratory staff, pharmacologists, central services, administrative staff, the medical director of a department and the economic director of a department. We contacted the head of a clinic department to discuss the project and to obtain ethical consent. We were provided with initial points of contact for the stakeholders on the list. Afterwards, we contacted the potential partners for interview appointments.

Overall, we conducted 11 interviews, which lasted between 30 and 60 minutes. The interviews were conducted in German during a personal meeting or through a phone call. Following the interview, the researchers' perception of the interview process was documented in a research note and the interviews were transcribed. We also collected data from publicly available sources such as the annual reports, press coverage and the hospitals website.

All data was imported into MAXQDA and coded. The coding followed a qualitative content analysis procedure with deductive category application [28]. Involvement was coded based on Shadur et al.[15] Main and subcategories for involvement and interaction levels, stakeholder groups and steps of the innovation process were defined. The definitions, examples and coding rules were collected in a coding agenda and revised before final coding of the material and interpretation of the results. An excerpt of the coding agenda can be found in Appendix 1.

4. Results

4.1 (Perceived) Involvement in innovation activities

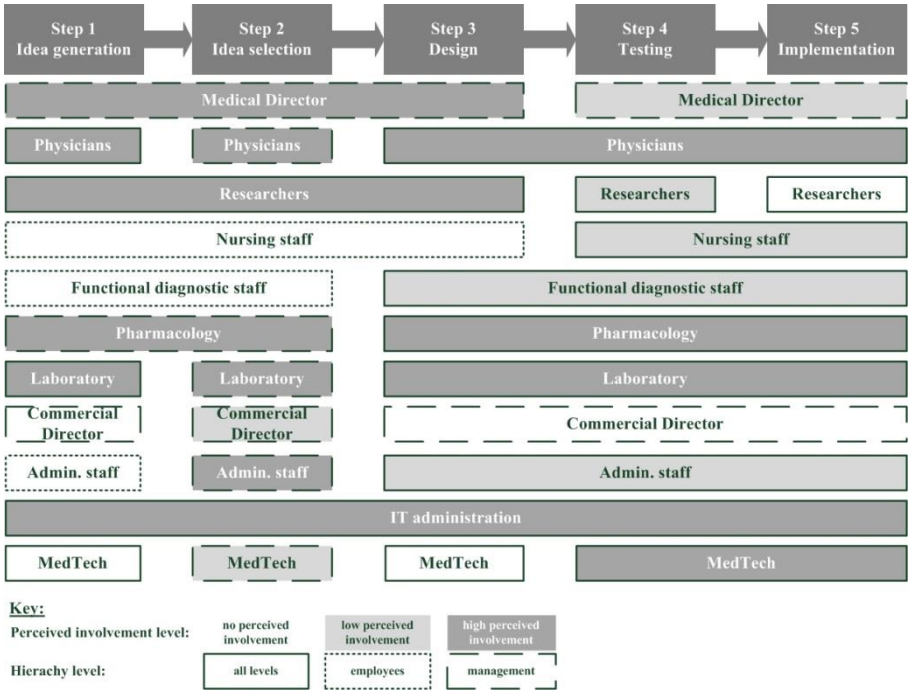

Figure 1 - *Overview of perceived involvement in innovation activities based on interview results*

All respondents agreed on the importance of innovation and stated that they were motivated to try new things. A nurse said "I am open for everything, so if someone has a new idea that provides a benefit, I am very happy to look at it. I would never say 'This does not make sense, leave it as it is' right from the start."[1] While all groups of employees are involved in the innovation process to a certain extent, the perception of their involvement in IA differs immensely between employee groups and between hierarchy levels (Figure 1).

[1] As the interviews were conducted in German, all quotes mentioned in this paper were translated into English.

Physicians reported high involvement levels, such as "as chief resident I am critically involved [in IA]", while another physician described optimizing the patient management process in an outpatient clinic and further stated multiple joint research projects that he takes part in. Other groups with a perception of high involvement include researchers, pharmacology staff, laboratory staff as well as the IT department. On the other hand, nursing staff, functional diagnostic staff, the commercial director or members of the administrative staff seem to perceive only limited or no involvement in multiple phases. A nurse stated: "Especially such small things, where a nurse would be asked: 'What would you improve?' — that is not done often enough".

High perceived EII is linked to a high position within the hierarchy. This was acknowledged by most participants, with an anesthesiologist stating: "I think this is because I am, let's say, further up in the hierarchy, so that if I have a good idea, I know who I need [to pursue it] and which network I have to create by myself to implement it." The Head of Pharmacology stated "100 percent, this is my job", while the Head of IT said that "We are always involved, because almost nothing works without IT support anymore." The Head of Laboratory stated "[My involvement] is very high, which even leads to some suffering […] as a lot of innovation [means] a lot of change. On the other hand, regular employees and even middle management, especially within the nursing and administrative departments recount no or only very little involvement without prompting. Nurses said: "I think, the lower you are in the hierarchy, the less you are involved and the less you are consulted." and "We are generally not involved in the idea process." Interestingly, when prompted about specific IA such as talking about potential process improvements with colleagues, taking part in training on innovative technology or taking part in research projects, even participants who had previously stated no involvement were able to recount an episode from their daily work that showcased at least low levels of involvement. A nurse said in this regard "Those were not really my ideas, but rather suggestions how we can transfer processes from others, that are more modern, to our department." Some even exhibited high involvement e.g. within research projects such as a nurse working directly on project to improve oral care. She stated "[A doctor] was very engaged and worked with me, because I [work with] the patient group."

Finally, as portrayed in Figure 1, perceived involvement levels also differ along phases of the innovation process. While the IT and the laboratory departments recount high perceived levels of involvement throughout the whole process, other department stakeholders perceive their involvement being tied to certain phases of the process. The department for medical technology reported to be mainly involved in testing and implementation of innovation, with the Head of the department saying "We are integrated in the process. Certainly not in the primary phase, but rather in the secondary phase" and "Yes, we are involved, but the idea does not come from us." The administrative staff perceived their involvement to mainly happen within the idea selection stage by contributing through e.g. cost-benefit analyses or market analyses, with a respondent stating "We do a cost-benefit analysis, calculate the cases, the profits, the costs." Interestingly, an upper management level anesthesiologist reported that "[Within the administrative staff] there are a lot of people, whose main goal is not to innovate, best case they tolerate it". Nurses and lower level administrative staff perceive no involvement in the early stages of the innovation process, even though they are able to recount episodes that clearly point to involvement, such as developing ideas and communicating them to their superiors.

Overall, staff perceiving high EII appears very active in their pursuit of implementation through forming networks of support or engaging with other stakeholders to push the desired project, leading to a positive influence on innovation output. Staff levels with no or very low levels of perceived EII frequently reported obstacles to innovation, often linked to the phase of idea generation and idea selection. A nurse said "We have this suggestion system. But I have never used it, because I do not know what happens to my idea." They often report a lack of motivation to participate in IA due to a high workload, a lack of time, no or negative feedback in the past or lack of management support. This in turn negatively impacts innovation output.

4.2 (Perceived) Interaction between stakeholder groups along the innovation process

All respondents highlighted the importance of interaction and collaboration between the different employee groups to create and implement innovations. The Head of Pharmacology stated in that regard: "Without physicians, nurses and pharmacology [cooperating] you cannot succeed."

Perceived interaction, however, differed widely amongst the stakeholder groups, hierarchy levels and phases of the innovation management process. The Head of Pharmacology underlined this by stating: “We are ahead when it comes to interdisciplinarity in medicine. However, this ends with the physician. If they [were to] start to take other groups more seriously, not just formally, but really seriously — but we are not there yet.” Physicians reported interactions with functional diagnostic staff and nursing staff, such as an anesthesiologist who stated “Chemists and physicians [working on the proposal], during implementation functional diagnostic staff will be involved” and when asked about another project: “Physicians and outpatient clinic staff. This is mainly nursing staff. [..] oh yes. And the IT department.” The medical technology department reported interactions with “Nursing staff for sure. The functional diagnostics staff, the pathology department and the laboratory department […] and the IT department of course.” This indicates high perceived interaction with a multitude of stakeholder groups. However, another physician stated: “Mainly with doctors […] not with nursing staff at all. Not in this aspect” and “Well, it is hard to get connected to the right people. Sometimes I feel like there is not a lot of cooperation within the university. And sometimes, there are colleagues that define themselves through dissociation. […] they just take an [idea for an] innovation opportunity from you and do it themselves, rather than cooperating.” The administrative staff reported low interaction levels with other groups, indicating that they mainly follow established feedback protocols, while the upper management of the administrative department mainly interacts with physicians, the IT department and external partners.

Respondents of the nursing staff mainly reported low levels of interactions (often one-off) and mainly with physicians. Interestingly, they attributed it to their standing in the hierarchy. A nurse stated “It is difficult, because [it is] such a hierarchically organized company with no intention of reducing hierarchies”. Another nurse recounted an episode of a task force: “I think [the medical director] was more of an autocratic decision maker. I do not know how far it could be considered an equal task force.” Interestingly, EII of nursing staff is sometimes overlooked by other stakeholders and hierarchy levels. An anesthesiologist stated: “I would not make a big fuss about it. If it comes to fine tuning and process improvement, of course we talk every day. No question. And for the recovery room […] we talked with the middle management nursing staff, because they are directly involved.” The Head of Laboratory recounted: “Well no. We have a lot of contact, but not about the topic [innovation]. Actually, we do interact with all stakeholder groups. If we talk about innovation in transporting samples, we talk with nursing staff, because they are more involved.”

Finally, perceived interaction differs along the stages of the innovation process. Idea generation often occurs within a stakeholder group rather than following a joint ideation process. A nurse said “I talked to my colleagues about [my idea] and they said ‘do it, it is a very good idea”. The Head of Medical Technology said “Firstly within my department and then, if there is friends from other departments I may talk with them.” A notable exception is the pharmacology department as the Head mentioned a joint ideation effort together with physicians, IT and the Board in order to draft a proposal for an innovation fund. Several department heads mentioned cooperation with industry in the idea stage. Interestingly, collaboration and co-creation with patients as external partners was only mentioned by nursing staff. One nurse stated: “This was not a big idea we implemented, but rather the patients and their families demanded it and we complied with the request over time.” Interaction within the idea selection and innovation design stage depends on the type of innovation. With incremental innovation, there is usually within-group communication, often with undesired outcomes. A nurse reflected: “If you try to improve something for the ward, my ideas are always nipped in the bud or my ideas were not good enough.” For more radical innovations, the idea selection stage involves high levels of management interaction as projects often need to be approved by multiple department heads and the Board, sometimes leading to long delays of the process. A physician stated “There is an idea that was communicated to the Board, to the IT department, to external partners, to the health ministry […] everybody is excited, but nothing happens.” Interestingly, he also stated “Everybody is wary of the others. If you have a good idea, someone will just come and steal it. This culture inhibits fruitful interactions.” High levels of interaction are perceived in the testing and implementation stage. Physicians, nurses and functional diagnostics staff recount being involved in clinical trials or research projects, often with external partners such as industry or other research institutions. A nurse stated: “We treat patients according to clinical trial protocols.” The implementation of innovation is often linked to training and with that interaction with other stakeholder groups, with a nurse stating “I am trained on every new technology”, indicating an interaction with the medical technology and IT department staff.
Overall, staff with a perceived high involvement in innovation also tends to report high interaction levels with other stakeholders, even though idea generation is usually done within a certain stakeholder group.

5. Discussion and implications

5.1 Strict hierarchy levels, physician centricity and high workload limit EII of certain stakeholder groups in hospitals.

EII differs amongst the different stakeholder groups of a hospital department. Employees in management positions are more likely to classify IA as innovations, while employees lower in the hierarchy, especially within nursing, functional diagnostics or administrative staff often see their activities as part of their jobs and not particularly innovative. Respondents on all hierarchy levels mentioned that they see a need for cultural change and opening up the strict hierarchies and diverge from the physician-centricity still prevailing in the hospital culture. Next to a high workload and low levels of freedom for creativity, lower level employees often mentioned a lack of management support which is in line with O'Donoghue et al.[29] This observation is in line with the hierarchical and physician-centric structure of a research hospital. Cultural change may provide a positive impact on the individual's readiness for change and innovation and foster individual engagement[25] Further, digitalization of the hospital may lead to more democratization and decentralization of the innovation process. However, the implementation must be done thoughtfully and communicated thoroughly, as indicated by the example of the digital suggestion system in our case. Since there is no transparency about the process, respondents prefer personal interaction within their network over submitting a suggestion into the system.

5.2 There is a significant gap between perceived involvement and actual involvement in innovation activities, which lowers employee motivation and inhibits innovation output.

While it seems that all employees are contributing to IA, albeit to varying degrees, and within different stages of the innovation process, not all perceive their contribution as actual involvement. This is particularly the case for nursing, functional diagnostic or administrative staff – staff that directly interacts with the patient in front-line service provision. Given the importance of (service) co-creation in service intensive environments [4] this suggests a lot of untapped potential for hospitals in their search for improving patient care and internal processes. By empowering (front-line) employees and helping them recognize that their actions are actively contributing to innovation and improvement, management could leverage this potential to provide more tailored and more efficient patient care. Concrete measures could include: training staff on the basics of idea creation and idea management[30], providing a transparent suggestion and feedback system or facilitating systematic ideation workshops or think tanks, as suggested by a participant from the nursing staff. These think tanks should include participants from all stakeholder groups and emphasize an open culture, where hierarchy is not important and all participants are able to speak and interact freely without fear of negative repercussions. These measures would increase the perceived involvement, especially in the idea creation and idea selection phase, leading to more potentially fruitful ideas entering the innovation management process. The implementation of such measures, however, demands a move towards a more innovation-friendly culture. Our results suggest that the perception of EII and the overall involvement of the peer group in the hospital have an impact on employees' willingness to partake in IA. This is in line with findings change management research and findings from Amo [11] and Shadur[15] in a healthcare setting. When employees perceive that they are not involved in IA or that their ideas are not worth to even be discussed, such as mentioned e.g. by nursing staff, they often keep ideas to themselves or even try to interfere with ideas of others as indicated by physicians.

5.3 Pursuing an open innovation approach and increasing perceived hierarchy-independent interaction with internal and external stakeholder groups may increase innovation output

Our results show that between-group interaction is limited along the innovation process – notable exemptions being the joint ideation for large research projects at management level and some interaction within the implementation phase. This is not surprising given the hierarchical nature of the hospital and perceived mistrust amongst staff members. As internal supporting networks are very important for innovation [7], this poses a clear barrier to successful IA. There is a need for organizational and cultural change. Recognizing and communicating the potential and importance of all groups regardless of their standing within the hierarchy for their contributions to the innovation process may be a first step to empowerment. Furthermore, an investment in communication training could decrease the inhibitions of lower level employees to participate in the ideation phase and

collaborate in other phases. Interestingly, while a lot of respondents report interactions with industry, other researchers or hospitals, only members of the nursing staff report interaction and co-creation with patients. However, research has shown that co-creation with users, especially within service environments, can lead to significant improvements[1]. Hence, management should consider implementing open innovation approaches such as joint ideation activities and frequently ask for ideas from front-line employees.

Overall, our data shows that there is untapped potential for innovative ideas within certain groups of hospital staff. Management may be particularly interested in the results of this study, as these ideas may have the potential to reduce costs and provide better patient care. It is important to know who perceives to be involved in the innovation process and who interacts with whom. Management should create a common understanding and awareness for all types of innovation by providing training for all staff groups on the importance of this topic and aim to increase the innovation awareness, involvement, interaction and output by the hospital staff in order to achieve the overarching goal of providing the best possible patient care.

6. Limitations and opportunities for further research

We conducted a single exploratory case study; our findings are limited to a specific setting. The gathered data is subjective to the respondent. We aim to counter this by using episodic interviews and triangulating with publicly available sources. For further research, it would be interesting to conduct a multiple case study using the present case as a base case within a national setting. Measuring and comparing the innovation output of hospitals that are implementing EII initiatives before and after implementation may also lead to informative results for management. We explored EII in a large public research hospital. Contrasting privately owned hospitals may further add to the understanding of EII. Unfortunately, we were not allowed to shadow our interview respondents, which would have allowed for a more objective assessment of real vs. perceived involvement.

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Appendix 1 – Excerpt from Coding Agenda

Category	Definition	Examples
3 Perceived Involvement		
3.1 High perceived involvement	**Subjective conviction** of being **actively involved** in innovation activities through different actions at work OR **subjective conviction** that **own innovation activity** is of **high importance**, with involvement (acc. to Shardur et al. 2016) consisting of: - Communication: generating and communicating ideas (e.g. submitting ideas to suggestion system] - Teamwork: initiating or taking part in meetings /innovation / research projects etc., facilitating testing or implementation of innovation - Decision making: evaluation activities and decision making (e.g. on purchasing new technology)	"There are a lot of different mouth care products that are supposed to help patients with stomatitis and there she was very engaged and, together with me, because I have the matching patient group [analyzed the needs], she also worked with other clinics" *(nurse 1, line 52)* "100 percent, this is my job" *(Head of Pharmacology, line 48)*
3.2 Low perceived involvement	**Subjective conviction** of being **passively involved** in innovation activities or **subjective conviction** that **own innovation activity** is of **low importance**, with involvement (acc. to Shadur et al 2016) consisting of: - Communication: receiving training in usage of innovation or using an innovation without providing feedback - Teamwork: taking part in actitivities based on order from boss - Decision making: observing innovation activities within the workplace or deciding to use an implemented innovation - incremental improvement	"With […], patents always play a role. Personally I am not very involved in that" *(Physician anaesthesia, line 39)* "the cooperation or our support for the medical faculty, however, this is limited" *(Head of IT, line 93)* "yes, all those teeny, tiny inventions, they just support daily business. You forget about them after a couple of minutes" *(Nurse 1, line 44)*

Category	Definition	Examples
3.3 NO perceived involvement	Subjective conviction of **not being involved** in innovative activities, neither actively nor passively, with involvement consiting of teamwork, communication and decision making	"I think the lower you are in the hierarchy, the less you are involved and the less you are asked" *(Nurse 2, line 18)* "Yes, within the ideation process we are generally not involved" *(Nurse 3, line 66)* "Yes, exactly, so maybe this very impersonal internet portal which I would never use, even if I had a very good idea, because it is impersonal" *(Nurse 3, line 80)*

Category	Definition	Examples
4 Involvement		
4.1 High involvement	**Active involvement** and engagement in innovation activities through different actions at work, independent of importance of innovation Involvement consists of: - Communication: generating and communicating ideas or - submitting ideas to suggestion system - Teamwork: initiating or taking an active part in meetings / projects etc. or facilitating testing or implementation of innovation - Decision making: evaluation activities and decision making (e.g. on purchasing new technology)	"Long time ago, [the medical director] realized that is was used somewhere else and that we should have it as well, even though [XX) had suggested it 20 years ago. And then he initiated a project group. But I think, well, it was not very democratic, instead he took part. But I think he was more so an autocratic decision maker" *(Nurse 3, line 54)* "Those are so-called photosensitizers, that we conincidentally do research on. So an employee of our department. And there we cooperate. And there is a lot of innovation going on, I would say" *(Physician anaesthesia, line 19)* "Yes this is the case. So we are almost always involved, because almost nothing works without IT anymore." *(Head of IT, line 24)* "It was very hectic and it was about submitting a proposal to the innovation fund and there we were approached from the Board, what could be done. Then we discusssed in a interdisciplinary group with nursing physicians and IT. Then we formulated, which steps need to be taken in the region" *(Head of Pharmacology, line 29)*

Category	Definition	Examples
4.2 Low involvement	**Passive involvement** in innovation activities, independent of importance of innovation e.g.: - Communication: receiving training in usage of innovation - Teamwork: taking part in activities based on order from boss - Decision making: observing innovation activities within the workplace or just using innovation	"There are specific standard forms that need to be used, so that [the innovation] is understood in the same manner by everyone. And those pass through all departments that are involved adn they add there opinion" *(Commercial Director, line 78)* "we are more [passively] involved, it is not generated by us in the first place. It comes more from the side of the specialists." *(Head of MedTech, line 25)* "Nothing has motivated me to do that. I was send to participate" (*Nurse 1, line 66)*
4.3 NO involvement	Not being involved in any innovative activities, neither actively nor passively, meaning no communication, no teamwork and no decision making	"and then there is this suggestion system, where you can send things. I have not send in anything, because I do not know where it is going." (Nurse 1, line 82) "Yes, but we are generally not included in the ideation process" (Nurse 3, line 66)

Category	Definition	Examples
5 Perceived interaction		
5.1 High perceived interaction	**Subjective conviction** of **continuous** interaction with people from **other stakeholder groups** about innovation topics, e.g. through: - personal communication (talks, emails, other communication tools) - active participation in workshops with different stakeholder groups - actively providing feedback to other stakeholder groups	"It was very hectic and it was about submitting a proposal to the innovation fund and there we were approached from the Board, what could be done. Then we discusssed in a interdisciplinary group with nursing physicians and IT. Then we formulated, which steps need to be taken in the region" *(Head of Pharmacology, line 29)* "Those are so-called photosensitizers, that we conincidentally do research on. So an employee of our department. And there we cooperate. And there is a lot of innovation going on, I would say" *(Physician anaesthesia, line 19)* "There is a head ambulatory care nurse. There is myself, who took responsibility from the physicians side. And there is a contact person from the IT department. Those are the main. Oh. And there is the central patient management department. With whom we interact a lot for specific clinical departments." *(Physician anaesthesia, line 35)*

Category	Definition	Examples
5.2 Low perceived interaction	Subjective conviction of **one-off** interaction with people from **other stakeholder groups** about innovation topics, e.g. through: - one-off personal communication (talks, emails, other communication tools) - passive participation in workshops with other stakeholder groups - providing feedback to other stakeholder groups when prompted to do so	"in relation to innovation? I mean, I know of course that the clinic purchases consulting services for specific projects. We had one meeting about it. That was about the acquisition of new employees. But I do not remember specifics." *(Physician, anaesthesia, line 63)* "Apparently, it [the suggestion] is evaluated in a first step. Whether it makes sense or not. If is makes sense, then the departments, that are involved, get the suggestion for evaluation. So often the IT as well, since there are often suggestions in regards to IT or IT support. We give our opinion and then it goes back to the administative department." *(Head of IT, line 63)* "yes, sometimes with the building services, since technology has to be connected, sometimes to the water or power or cooling system" *(Head of MedTech, line 31)* "the cooperation or our support for the medical faculty, however, this is limited" *(Head of IT, line 93)*

Category	Definition	Examples
5.3 NO perceived interaction	Subjective conviction of **not interacting with other stakeholder group** or **only interacting with colleagues within the same stakeholder group** about innovation topics, e.g. through: - personal communication (talks, emails, other communication tools) with colleagues of the same stakeholder group - actice participation in workshops within the stakeholder groups - providing feedback within the same stakeholder group	"No, I do not remember anything" *(Nurse 3, line 68)* "with nursing staff not at all. In this aspect." *(Physician, laboratory, line 16/17)* "I have no one that I would interact on a basis of trust" *(Physician, laboratory, line 35)* "I have talked to my colleagues and they said "do it, it is a good idea" *(Nurse 2, line 59/60)*
6 Interaction		
6.1 High interaction	**Continuous** interaction with people from **other stakeholder groups** about innovation topics, e.g. through: - personal communication (talks, emails, other communication tools) - active participation in workshops with different stakeholder groups - actively providing feedback to other stakeholder groups	"It was very hectic and it was about submitting a proposal to the innovation fund and there we were approached from the Board, what could be done. Then we discusssed in a interdisciplinary group with nursing physicians and IT. Then we formulated, which steps need to be taken in the region" *(Head of Pharmacology, line 29)* "and then work the researchers, […] radiologists, surgeons all together to someday cure cancer" *(Nurse 1, line 54)* "yes. Of course. So IT, of course. and the departments, you mean within this hospital? [yes] yes. hundreds. Well, not hundreds, but a lot. ENT, oral surgery, eye surgery, visceral surgery, [...] almost all. all that send patients to us" *(Physician, anaesthesia, line 27-31)*
Category	**Definition**	**Examples**

6.2 Low interaction	**One-off** interaction with people from **other stakeholder groups** about innovation topics, e.g. through: - one-off personal communication (talks, emails, other communication tools) - passive participation in workshops with other stakeholder groups - providing feedback to other stakeholder groups when prompted to do so	"the cooperation or our support for the medical faculty, however, this is limited" *(Head of IT, line 93)* "rarely, more with the building services, otherwise there is not so much. From my point of view they supply the possibilities we need to operate the medical technology devices. " *(Head of MedTech, line 51)*
6.3 NO interaction	**No interaction with other stakeholder group** or **only interacting with colleagues within the same stakeholder group** about innovation topics, e.g. through: - personal communication (talks, emails, other communication tools) with colleagues of the same stakeholder group - actice participation in workshops within the stakeholder groups - providing feedback within the same stakeholder group	"I have talked to my colleagues and they said "do it, it is a good idea" *(Nurse 2, line 59/60)* "No, I do not remember anything" *(Nurse 3, line 68)* "so when we identify topics, then it is mainly IT topics and then we try to get them organized ourselves, can we improve it ourselves. And this then leads to an IT change or an IT project." *(Head of IT, line 71)*

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