MAJOR REGULATORY SHIFTS AS A DRIVER OF ORGANIZATIONAL CHANGE IN HEALTH CARE: A MACRO AND A MICRO PERSPECTIVE

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PREFACE

Slightly bored of studying differential calculus back in 2014 (not to be confused with differential equations, which, I am afraid, I have never completely understood), I decided to leave the economist bubble by taking a position as a student assistant at the Chair of Marketing and Innovation of the University of Bayreuth. What was meant to be nothing but a fling into the field of management and organization studies—and, in broader terms, into the academic community—turned out to be the first step of my academic career. Thanks to Professor Daniel Baier, Alexander Sänn, his doctoral student from that time, and the rest of the Chair's team, I discovered teaching and research—two sides of the academic world perfectly unknown to me until that point.

After completing my master's degree, I decided to gather some experience outside the university, finding a "real" job as some parents would say (not mine, of course). I moved back to Berlin, where I started a position as a data analyst at an IT consulting firm led by Hermann Krallmann, Emeritus Professor of Systems Analysis and Data Processing, and his family. Not that I did not enjoy creating vast amounts of PowerPoint slides and becoming part of a fast growing community of quirky blockchain enthusiasts, but after about a year the second derivative of my steep learning curve became negative (for people not familiar with differential calculus: this event predicts that your saturation point will soon follow). I eventually realized that I needed to leave the IT world when I started to run out of new buzz words to learn. My journey as a doctoral student of health services research was about to begin.

I was really glad to find a position at the University of Bern, also because living in a city whose name starts with the letter "B" has been one of the few constants in my life so far. It was a privilege for me to be part of the constituting teams of both the Swiss Institute for Translational and

Entrepreneurial Medicine and Rudolf Blankart's Professorship of Regulatory Affairs at the KPM Center for Public Management. One of the very first things I learned soon after starting the job was that next time I change my employer I should first make sure that they have their own building. You probably already know that but having your own building is a big plus. The start-up spirit that has been shaping my workplace ever since has been a great advantage, too. After moving to a new office and reinstalling my computer a few more times than I would have wished, I finally ended up writing my dissertation in my home. Even though I missed the good times with my colleagues, the days at the improvised office space of my dining room of yore proved to be the most productive phase of my doctoral thesis.

My time as a doctoral student was, in a way, a miniature of my life so far: I changed places, made new acquaintances, took up new challenges, and have been working on many projects—losing heart before eventually finding my way out of difficult situations. After obtaining my bachelor's degree, I was not completely sure that I should continue to study (you know, economists are trained to look at the margin). Now, I am grateful that I did a master's degree and am about to complete a doctoral studies program. After four years, I am still not sure that the second derivative of my learning curve is negative yet. Among the most important things I learned so far was to appreciate research methods other than quantitative research (those were not part of my undergraduate education). I think that many of the most important questions in life start not with "how much" but with "why" and it is now my deep conviction that in this regard qualitative methods may often have comparative advantage over quantitative research, especially in the absence of an appropriate panel dataset

ABSTRACT

In this dissertation, I explore how major shifts in the regulatory environment of actors involved in the delivery of health service trigger and shape organizational change. To do so, I conceptualize different types of policy intervention as exogenous shocks and use a range of qualitative and quantitative research methods. Chapter 1 portrays the general framework of this dissertation. Adopting a macro and a micro perspective respectively, I explore two distinct types of regulatory shift: First, in Chapters 2 and 3, I focus on regulation of market entry, whereas, in Chapter 4, I focus on reimbursement regulation by analyzing how the introduction of a system based on diagnosis-related groups (DRG) affects health care provision. To do so, I analyze how two acute care hospitals that had implemented kaizen—a management technique that aims to improve business processes—in a preparatory attempt to deliver their services in a more cost-efficient way. Chapter 5 concludes and suggests an agenda for future research.

The medical device industry in regulatory turmoil

In Chapter 2, I analyze how the regulatory shift induced by the new European Union Medical Device Regulation (MDR) affects the main stakeholders of the medical device industry. The theoretical framework of this review draws on the main objectives that the MDR asserts to pursue in its preamble: to facilitate free trade and enhance public health. Taking a descriptive approach based on both theoretical considerations and empirical evidence, I assess whether the new regulation is likely to achieve these two objectives. To my knowledge, this analysis represents the most comprehensive scholarly review of the MDR so far.

Discussing a range of specific regulatory issues that arguably leave some room for improvement, I provide policy makers with a set of specific coping strategies that aim to further

improve the future regulation of medical devices. My analysis indicates that the MDR is highly likely to strengthen the European internal market because it harmonizes regulations across the borders of its member states. The definitive impact of the new regulation on patient safety, however, remains unclear because there are no longitudinal studies on this topic.

Highlights

- I review the most extensive regulation of medical devices since the 1990s.
- The regulation aims to strengthen the internal market and increase patient safety.
- The initial reactions of scholars, physicians, and industry representatives diverge strongly.
- The regulation introduces multiple regulatory instruments that are likely to enhance trade.
- The effect of the regulation on patient safety, however, remains unclear.

The link between organizational capacity for change and financial performance

In Chapter 3, I conceptualize the new European Union Medical Device Regulation (MDR) as an exogenous shock that elicits a major shift in the regulatory environment of the medical device industry. To make sense of this new environment, firms are forced to reorient and recreate their working practices. Using Switzerland as ground for the subject of this study, I aim to determine the preliminary economic impact of the MDR on the European medical device industry.

By focusing on the relationship between organizational capacity for change and performance, I examine whether firms capable of change show higher levels of financial performance than their rivals. In this study, top executives and business leaders of medical device firms based in

Switzerland completed an online survey with a Likert-scale-design. I used structural equation modeling (1) to determine whether some firms are more capable of change than others when faced with a major shift in their regulatory environment, and, (2) to outline ways in which firms may seek to improve their capacity to react to such a shift.

My results suggest that higher levels of organizational capacity for change (OCC) are generally positively associated with financial performance ($p < 0.01$) but that small and medium-sized firms show higher levels of OCC ($p < 0.01$) and lower levels of performance than their larger competitors ($p < 0.01$). Furthermore, start-ups showed lower levels of financial performance than established firms ($p < 0.05$). Finally, I outlined (1) strategies business leaders may wish to consider if they were to make their organizations more capable of change, and (2) measures policy makers could take to ensure that medical devices with no close substitutes are withdrawn from the market, especially in times of a global pandemic.

Highlights

- The new European Union Medical Device Regulation has substantially changed the way products enter the market, conceivably inducing a period of major organizational change.
- This cross-sectional study sheds light on which organizational characteristics enable firms to adapt better to change and secure a competitive advantage in the marketplace.
- I measured organizational change capacity by using a multi-dimensional instrument in an online survey of top managers.
- I used structural equation modelling to examine how organizational change capacity interrelates with financial performance.

- Although change-capable firms generally show higher levels of performance, this relationship may be qualified by specific organizational characteristics such as firm size and age.

Improving health care from the bottom up

In Chapter 4, I examine how providers of inpatient care respond to shifts in the reimbursement regulation of their services. I move forward towards an analysis from a micro perspective by examining organizational change on the example of individual providers. Additionally, I contrast examples of positive and negative implementation of kaizen—an approach thus far missing in the literature on health management research. By examining how two acute care hospitals had recently implemented the continuous improvement technique, I aim to (1) explore and understand the experiences of nurses, and (2) identify factors affecting the implementation of the technique. Based on my findings, I derive influencing factors for the successful implementation of kaizen management in hospital care.

By means of purposeful sampling, I selected 30 nurses from different units in two private acute care hospitals in Switzerland in May 2018. I used the Organizational Transformation Model developed by Lukas, et al. (2007) to conduct semi-structured interviews and perform qualitative content analysis. Lastly, originating from the two-factor motivation theory (Herzberg et al., 1959), I suggested two types of factor influencing the implementation of kaizen—hygiene factors that may prevent nurses from getting demotivated, and motivational factors that may boost their motivation.

Overall, nurses experienced kaizen as a positive practice that enabled them to discuss work-related activities in a more comprehensive manner. In some cases, however, a lack of visible improvement in the workplace lowered nurses' motivation to make suggestions. Nurses' attitudes towards kaizen differed across both hospitals depending on the available managerial support, resources such as infrastructure and staffing levels. From my findings, I derived several coping strategies to help health practitioners implement kaizen for the benefit of their organization and employees: Strong managerial support, appropriate use of kaizen tools, and a greater sense of team cohesion, among other factors, can influence how effectively hospital teams implement kaizen. To reap the benefits of kaizen, hospital managers should promote the exchange of opinions across hierarchy levels, allocate the necessary resources in terms of personnel and infrastructure, and show nurses how the technique can help them improve their workplace.

Highlights

- A managerial technique that aims to improve an organization continuously, kaizen is increasingly employed in health care.
- Semi-structured interviews were conducted with nurses working at two Swiss acute care hospitals in May 2018.
- I used the Organizational Transformation Model to perform qualitative content analysis and the two-factor motivation theory to synthesize the findings.
- Nurses' attitudes towards kaizen differed across the hospitals depending on the available resources, managerial support, and staffing levels.

- From these and further findings described in this dissertation, I derived several coping strategies to help health practitioners implement kaizen for the benefit of their organization and employees.

ABSTRACT (GERMAN)

In dieser Dissertation untersuche ich, wie drastische regulatorische Veränderungen im Gesundheitswesen Organisationswandel auslösen und gestalten. Dazu betrachte ich unterschiedliche Arten von Regulierungen als exogene Schocks und wende dabei eine Reihe von qualitativen und quantitativen Forschungsmethoden an.

Kapitel 1 beschreibt den konzeptionellen Rahmen der Dissertation. Zunächst aus einer Makro- und darauf aus einer Mikro-Perspektive untersuche ich zwei verschiedene Arten von regulatorischen Veränderungen: In den Kapiteln 2 und 3 konzentriere ich mich auf Marktzugangsregulierung am Beispiel der Medizinprodukteindustrie, während ich in Kapitel 4 die Rückerstattungsregulierung als Forschungshintergrund nehme und analysiere, wie die bevorstehende Einführung eines auf diagnosebezogenen Fallgruppen basierenden Abrechnungssystems die stationäre Gesundheitsversorgung beeinflusst. Kapitel 5 hält die wichtigsten Schlussfolgerungen sowie Handlungsempfehlungen für Politik, Praxis und Wissenschaft fest und schliesst mit Vorschlägen für künftige Forschung.

Die Medizinprodukteindustrie im regulatorischen Umbruch

In Kapitel 2 untersuche ich, wie sich der regulatorische Wandel, der durch die neue Verordnung der Europäischen Union über Medizinprodukte (MDR) ausgelöst wurde, auf die zentralen Akteure der Medizinprodukteindustrie auswirkt. Meines Wissens stellt diese Studie die bisher umfassendste wissenschaftliche Analyse der MDR dar. Zusammenfassend zeigt meine Analyse, dass die MDR höchstwahrscheinlich den europäischen Binnenmarkt stärken wird, da sie regulatorische Vorgaben über die Grenzen der Mitgliedsstaaten hinweg weiter spezifiziert und

harmonisiert. Die endgültigen Auswirkungen der Verordnung auf die Patientensicherheit bleiben jedoch unklar, da bis dato keine belastbaren Längsschnittstudien zu diesem Thema vorhanden sind.

Der Zusammenhang zwischen Anpassungsfähigkeit der eigenen Organisation und Geschäftsergebnissen

In Kapitel 3 stelle ich die neue MDR als einen exogenen Schock dar, der die regulatorischen Rahmenbedingungen der Medizinprodukteindustrie erheblich verändert. Um sich in diesem neuen Umfeld zurechtzufinden, sind Unternehmen gezwungen, ihre bestehenden Geschäftspraktiken anzupassen und neue einzuführen. Das Ziel dieser Studie ist, am Beispiel der Schweiz die vorläufigen wirtschaftlichen Folgen der MDR auf die europäische Medizinprodukteindustrie zu untersuchen. Abschliessend skizziere ich (1) Strategien, die Führungskräfte in Betracht ziehen könnten, um die OCC ihres Unternehmens zu erhöhen, und zeige (2) Massnahmen auf, die politische Entscheidungsträgerinnen und -träger ergreifen könnten, um sicherzustellen, dass Unternehmen in finanzieller Notlage Medizinprodukte nicht vom Markt nehmen, für die es keine Substitute gibt und deren Rückzug die gesundheitliche Versorgung von Patientinnen und Patienten beeinträchtigen kann.

Wie Pflegefachkräfte die stationäre Gesundheitsversorgung durch Kaizen verbessern können

In Kapitel 4 untersuche ich, wie die Anpassung der Rückerstattungsregulierung stationärer Behandlungen Organisationswandel auslösen kann. Vor diesem Hintergrund betrachte ich, wie zwei private Akutspitäler Kaizen-Management im Hinblick auf die zum damaligen Zeitpunkt bevorstehende Einführung eines Fallpauschalensystems für die Abrechnung von gesundheitlichen

Leistungen im stationären Bereich (DRG-System) implementiert haben. Kaizen stellt eine niederschwellige Managementtechnik dar, die die kontinuierliche Verbesserung einer Organisation durch kleine aber ständige Anpassungen von Unternehmensstrukturen und -prozessen bezweckt.

In dieser Studie stelle ich Beispiele positiver und negativer Implementierung von Kaizen gegenüber – ein Ansatz, der in der Fachliteratur bislang fehlt. Mein Ziel ist, (1) die Erfahrungen der Pflegefachkräfte zu untersuchen und (2) Faktoren zu identifizieren, die die Implementierung der Managementtechnik beeinflussen können. Aus meinen Erkenntnissen leite ich mehrere Bewältigungsstrategien ab, die Führungskräften helfen sollen, Kaizen zum Nutzen ihrer Organisation und ihrer Angestellten zu implementieren: Um die Vorteile des Managementansatzes zu nutzen, sollten Führungskräfte den Meinungsaustausch über Hierarchieebenen hinweg fördern, die notwendigen Ressourcen in Form von Personal und Infrastruktur bereitstellen und den Pflegefachkräften zeigen, wie die Technik ihnen helfen kann, ihren Arbeitsplatz zu verbessern.

ABBREVIATIONS

AIMDD	Active Implantable Medical Devices Directive
BIC	Bayesian information criterion
CFI	Comparative fit index
DRG	Diagnosis-related groups
Eudamed	European database on medical devices
FDA	Food and drug administration
MDD	Medical Device Directive
MDR	Medical Device Regulation
OCC	Organizational capacity for change
OTM	Organizational Transformation Model
RMSEA	Root mean square error of approximation
SEM	Structural equation modeling
SMEs	Small and medium-sized enterprises
SMSR	Standardized mean square residual
TLI	Tucker-Lewis index
UDI	Unique device identifier

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CHAPTER 1
THE INTERPLAY OF REGULATION AND ORGANIZATIONAL CHANGE ON THE EXAMPLE OF DIFFERENT STAKEHOLDERS INVOLVED IN HEALTH CARE DELIVERY

Health care provision is an intricate and ever changing field. Accordingly, decision makers and academic scholars devote considerable effort to finding ways to improve the delivery of health services. To do so, they consider a whole host of objectives that include enhancing public health, achieving cost-efficiency, increasing patient satisfaction, and improving the work conditions of health professionals (see, for example, Bernabeo and Holmboe, 2013; Bodenheimer and Sinsky, 2014; Kaplan and Porter, 2011; Sikka et al., 2015).

Change, in its many facets, can represent both the impetus for and the result of the efforts of researchers and decision makers to better design the basket of health services delivered to patients. Indeed, the literature shows that health systems are in a constant state of flux for a wide range of reasons. Major among these are technological advance (Gamm et al., 2007; Grover and Niecko-Najjum, 2013; Varabyova et al., 2017), complex patient needs (Figueroa et al., 2021; Papanicolas et al., 2021), the schemes used to reimburse health services and technologies (Clemens and Gottlieb, 2014; Dafny, 2005; Jürges and Köberlein, 2015; Schreyögg et al., 2009), and the large number of stakeholders pursuing closely intertwined yet often diverging interests (Busse et al., 2017; Saltman and Busse, 2002).

In this dissertation, I explore the questions of whether and to what extent a shifting regulatory environment acts as another factor that can change the work practices of the organizations involved—directly or indirectly—in health care delivery. Conceptualizing different types of policy intervention as exogenous shocks that interrupt one state of market equilibrium and eventually establish a new equilibrium, I use qualitative and quantitative research methods to examine how shifting regulatory environments may drive and shape organizational change. Within this setting, I assume a shock to be exogenous if it is not directly provoked by the actors it eventually affects. An exogenous shock is therefore an external event outside the control of the subjects of my analysis

(see, for example, Geels and Penna, 2015; Kilian, 2008). In this line of thinking, representatives of medical device firms, for instance, can participate in a consultation process of a future law and make suggestions about its scope and content, but those representatives do not determine the final wording of the law. This view is in line with Geels (2014) who describes rules, standards, and regulations as externally imposed by policy makers.

Adopting a macro and a micro perspective respectively, I explore two distinct types of regulatory intervention: First, in Chapters 2 and 3, I focus on regulation of market entry by examining the impact of the new European Union Medical Device Regulation (MDR) on the medical device industry. Second, in Chapter 4, I use the context of reimbursement regulation and analyze how the introduction of a system for the classification of hospital cases based on diagnosis-related groups (DRG) has affected health care provision. Here, I aim to determine how reimbursement regulation makes health providers reorient their work practices. To do so, I analyze how two acute care hospitals that had implemented kaizen—a management technique increasingly employed in health care—in a preparatory attempt to deliver their services in a more cost-efficient way within a DRG-based system. Summarizing the approach depicted above, Fig. 1 illustrates the conceptual and methodological framework of this dissertation. By outlining the objectives and the methods of the research conducted in each of the following chapters, the remainder of this chapter provides background information that motivates my exploration of how regulation and organizational change interact with each other in the context of health care.

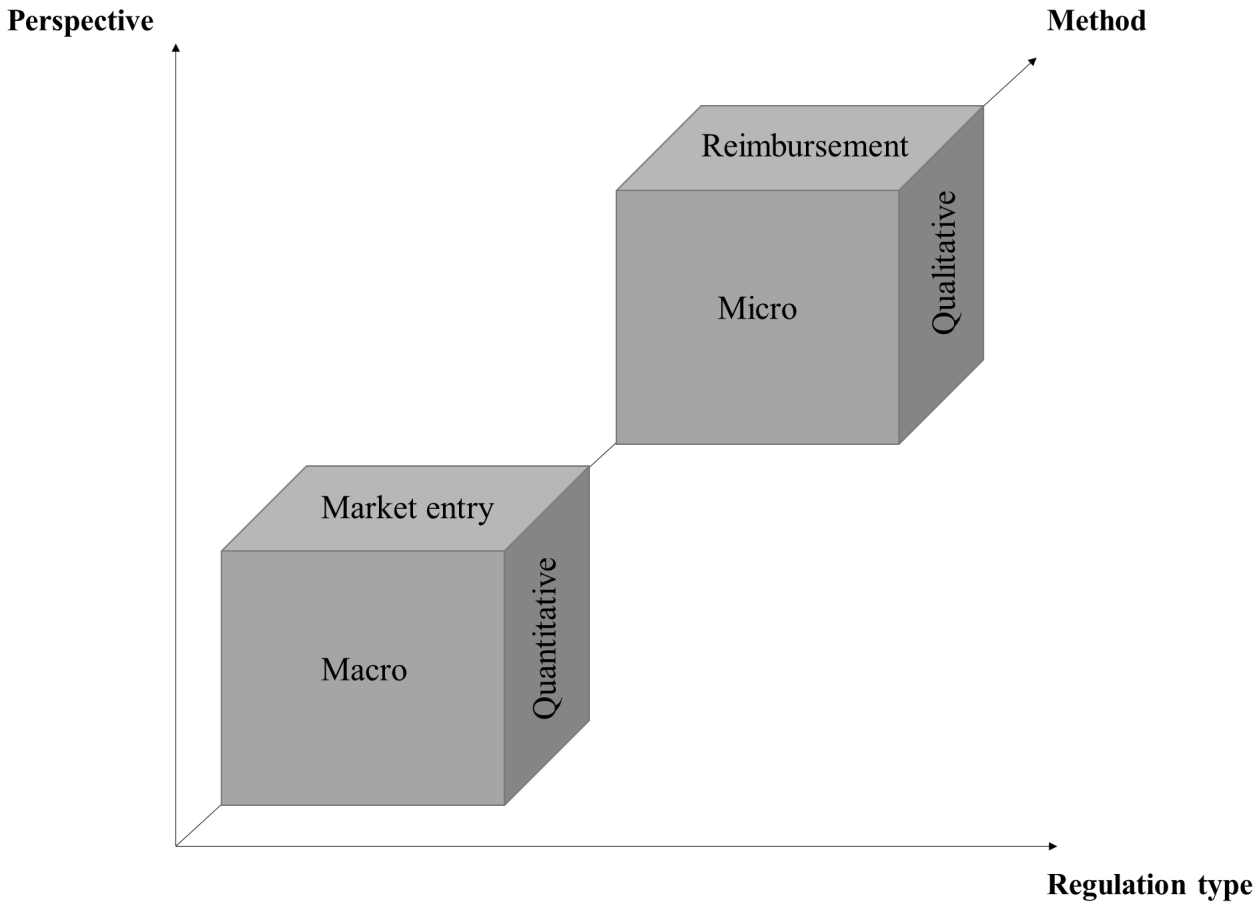

Fig. 1. Conceptual and methodological embedment of this dissertation.

The medical device industry in regulatory turmoil

By using the context of the newly enacted MDR, Chapter 2 explores the interrelation between regulation of market entry and organizational change from a macro perspective. Health professionals use medical devices throughout the entire care pathway for making diagnoses and treating diseases. In general, a medical device achieves its intended purpose by acting in a physical way—unlike pharmaceuticals that elicit metabolic, immunological, or pharmacological effects on the human body. Constantly subject to technological change, the industry's regulatory environment

often lags behind the high pace of innovation typical of medical devices (Altenstetter, 2003; Campillo-Artero, 2013; Fraser et al., 2011). The resulting gap between regulation and technological advance is unfortunate because it may pose challenges to public health, firms' research and development activities, or both. Thus, reacting to a series of scandals and adverse events involving medical devices over the past decade (Greco, 2015; Heneghan et al., 2012; Heneghan et al., 2017), the European Union has recently overhauled the way medical devices enter its internal market. As a result, the medical device industry has been undergoing the most extensive regulatory change since the early 1990s with the implementation of the MDR of 2017 (Official Journal of the European Union, 2017a).

After a transition period of four years, the MDR has become fully applicable on May 26, 2021. Although the medium- and long-term effects of the new regulation are still unclear, many scholars, health care professionals, and industry representatives have begun to publish early evidence and publicize their views on how the new regulation may impact free trade and patient safety (Allan et al., 2018; Fraser et al., 2018; Tarricone et al., 2020; Thienpont et al., 2020). Even a cursory view of their output reveals hypotheses and opinions that could hardly be more divergent. The reasons for these substantial differences of opinion are unclear and may extend beyond the different interests of the various stakeholder groups. To find out why this might be the case and to advance scholarly understanding of the new regulation, I examine the new regulatory regime set out in the MDR.

Comparing and contrasting the new and the former regulation of medical devices, Chapter 2 provides policy makers with a set of specific coping strategies aiming to further improve the future regulation of medical devices by maximizing economic and social welfare. To my knowledge, this analysis represents the most comprehensive scholarly review of the MDR so far. The theoretical

framework of this review draws on the key objectives the MDR asserts to pursue in its preamble: to facilitate free trade and enhance public health. Taking a descriptive approach based on both theoretical considerations and empirical evidence, I assess whether the new regulation is likely to achieve these two objectives.

The link between organizational capacity for change and financial performance

Remaining within the macro perspective of the industry yet moving on from theoretical to empirical research, I continue exploring market entry regulation of medical devices in Chapter 3. Using the context of the MDR, I conceptualize a major shift in the industry's regulatory environment as a double-edged sword for medical device firms: On the one hand, complying with the heightened safety and performance requirements set out in the MDR is supposed to foster free trade and help firms enhance product safety over the long term; on the other hand, seeking to meet the new requirements by adjusting business processes can increase the costs of placing a device on the market and potentially impede the access of firms in financial distress to the European internal market. Indeed, a growing body of literature suggests that the administrative overhead associated with implementing the new regulation poses a financial burden on firms, in particular those of small and medium-size (Miclăuş et al., 2019; Migliore, 2017; Tarricone et al., 2020).

In this chapter, I conceptualize the new European regulation of medical devices as an exogenous shock that triggers organizational change, inducing firms to reorient their work practices. From this perspective, I aim to determine the early economic impact of the MDR on the European medical device industry. By focusing on the link between organizational capacity for change (OCC) and performance, I examine whether firms capable of change outperform their rivals

financially. In this cross-sectional study, top executives and business leaders of medical device firms based in Switzerland completed an online survey with a Likert-scale-design. I used structural equation modeling (1) to determine whether some firms are more capable of change than others when faced with a substantial shift in their regulatory environment, and, (2) to outline ways in which firms may seek to improve their ability to react to such a shift.

Improving health care from the bottom up

After shedding light on market entry regulation in the previous chapters, I examine another type of regulatory punctuation in Chapter 4: a reform related to the reimbursement of health care services. Switzerland introduced a reimbursement system based on DRGs in 2012, pursuing a wide set of objectives. These included increasing transparency related to the billing of health services and reducing health expenditure while, ideally, maintaining a high quality of care delivery. As a result, decision makers placed pressure on inpatient care providers—especially on those who showed low levels of cost-efficiency—to adjust their work practices by taking the "average hospital" as a benchmark.

In this chapter, I move forward towards an analysis from a micro perspective by examining organizational change on the example of individual health providers. Additionally, I contrast examples of positive and negative implementation of kaizen—an approach thus far missing in the literature on health care management research. Based on my findings, I describe influencing factors for the successful implementation of kaizen management in hospital care.

Kaizen enables employees, regardless of their hierarchy level, to contribute to the improvement of their organization. This managerial technique puts special emphasis on frontline employees, because it represents one of their major opportunities to participate directly in decision

making. Additionally, kaizen helps health professionals to find easily applicable yet effective ways to reorganize health provision for the benefit of patients and the organization.

By examining how two hospitals had recently implemented the continuous improvement technique, I aim to (1) explore and understand the experiences of nurses, and (2) identify factors affecting the implementation of the technique. By means of purposeful sampling, I selected 30 nurses from different units in two private acute care hospitals in Switzerland in May 2018. I used the Organizational Transformation Model developed by Lukas, et al. (2007) to conduct semi-structured interviews and perform qualitative content analysis. Lastly, originating from Herzberg's motivation theory (Herzberg et al., 1959), I synthesized the findings of the study and derived two types of factor influencing the implementation of kaizen—hygiene factors that may prevent nurses from getting demotivated, and motivational factors that may boost their motivation.

CHAPTER 2
THE EUROPEAN MEDICAL DEVICE INDUSTRY IN REGULATORY TURMOIL: STILL FAR AWAY FROM PATIENT SAFETY AND FREE COMPETITION?[1]

[1] By the authors Kosta Shatrov and Carl Rudolf Blankart. Submitted to Health Policy in May 2021. Under review.

Purpose of the new policy

After a quarter of a century of relative standstill in reforms, regulation of the European medical device industry, worth EUR 110 billion and accounting for more than 675,000 jobs (European Commission's Official Website, 2020), is undergoing the most extensive change in its history: Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017, otherwise known as the European Union Medical Device Regulation (MDR). The chief impetus behind the MDR was a series of scandals related to the safety of medical devices, such as urogynecological (Medicines and Healthcare products Regulatory Agency), orthopedic (Heneghan et al., 2012), and breast implants (Greco, 2015). Although adverse events associated with medical devices can have multiple causes unrelated to the devices themselves (Amoore, 2014; Nobel, 1991), these safety issues nevertheless raised serious doubts about the rigor of existing regulation (Bowers and Cohen, 2018). Indeed, scholars demonstrated a range of safety deficiencies associated with the previous regulatory framework, providing impetus to policy makers to update the way medical devices gained entry to the European market (Campillo-Artero, 2013; Fraser et al., 2011; Jha et al., 2010; Ronquillo and Zuckerman, 2017; Ward and Clarkson, 2004).

The new regulation has evoked mixed reactions among the various stakeholder groups: whereas some firms fear that they will be unable to comply with its more stringent safety and performance requirements (Cohen, 2013a; Miclăuş et al., 2019), a number of scholars assert that the MDR will simplify administrative procedures and increase legal certainty (Tarricone et al., 2020), may improve patient safety (Melvin and Torre, 2019; Zippel and Bohnet-Joschko, 2017), and will not interfere with innovation capacity (Thienpont et al., 2020). Other scholars, as well many physicians and medical experts – some of whom have suggested that clinical evidence on medical devices should be as readily available to health professionals as is the clinical evidence on

drugs (Fraser et al., 2018) – are disappointed in what they see as a missed opportunity to enhance the safety of medical devices (Allan et al., 2018; Bowers and Cohen, 2018; Cohen, 2013b; Eikermann et al., 2013; Fraser et al., 2018; Godlee, 2018).

The reasons why these assessments of the MDR diverge so strongly are unclear and unlikely to be due solely to the different interests of the various stakeholder groups. To explore this question further, we first describe in detail which regulatory measures have been introduced with the MDR to achieve the two major objectives enshrined in its preamble: (1) "to ensure the smooth functioning of the internal market" and (2) to set "high standards of quality and safety for medical devices in order to meet common safety concerns" (Official Journal of the European Union, 2017a). Subsequently, we discuss whether the MDR is likely to achieve these objectives. We conclude by offering policy makers suggestions to help improve future regulation.

Political background

The beginnings of the reform of the MDD from 1993 date back to 2008, when the European Commission made initial proposals for amending the regulation. After several of the stricter amendment options were rejected in response to pressure from the industry, particularly from MedTech Europe, the industry's largest trade association, a revised proposal was put forward in 2012 (Bowers and Cohen, 2018). The phase of public deliberation that lasted from 2008 to 2013 was marked by industry representatives continuously exerting their influence (Bowers and Cohen, 2018; Fraser et al., 2011), leading some members of the European Parliament to assert that they had never experienced such intense lobbying pressure in the previous 20 years (Cohen, 2013a). Whereas industry representatives suggested at the time that stricter regulation would hamper innovation, possibly leading to a shortage of medical products and thereby jeopardizing patient

safety, a number of health insurance companies took the opposite position (German National Associations of Statutory Health Insurance Funds, 2013).

The MDR was passed on 5 April 2017 and entered into force on 25 May 2017, replacing both the Active Implantable Medical Devices Directive from 1990 (AIMDD; 90/385/EEC) (Official Journal of the European Union, 1990) and the Medical Device Directive from 1993 (MDD; 93/42/EEC) (Official Journal of the European Union, 1993). The new regulation was due to become fully applicable on 26 May 2020 after a three-year transition period (Official Journal of the European Union, 2017a). Due to the coronavirus pandemic, however, the European Commission postponed this day by a year (European Commission, 2020).

Fig. 2 places the MDR in the context of major events related to the regulation of medical devices from the early 1990s to 2027, including dates related to the implementation of earlier European regulations, adverse events that triggered reforms, and important milestones in the ongoing implementation of the MDR. Ultimately, by leaving out, among other reform suggestions, an independent regulatory agency and a requirement for premarket clinical testing, the European authorities adopted a less stringent regulatory framework than initially envisaged (Cohen, 2013b), resulting – according to at least some researchers and medical experts – in a regulation that is neither centralized, nor transparent, nor evidence-based (Eikermann et al., 2013).

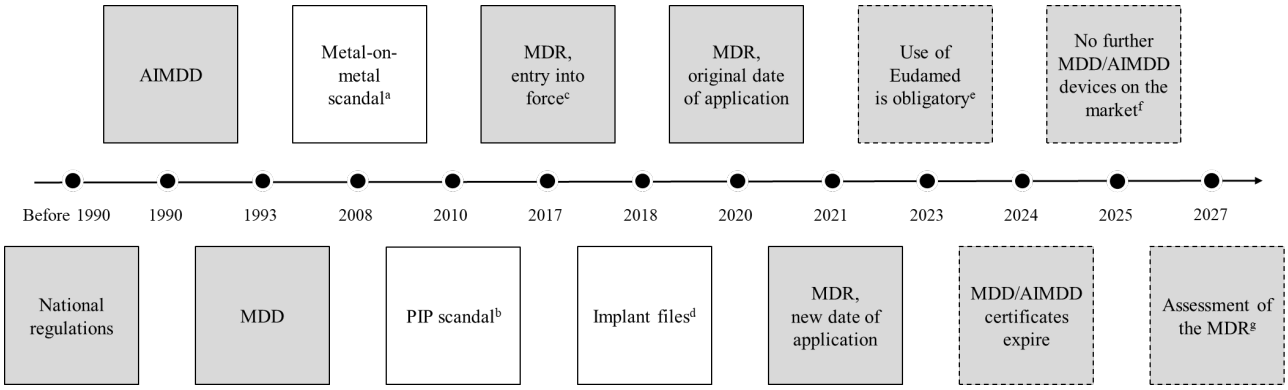

Fig. 2. The regulatory context of the MDR, including implementation milestones and some major adverse events leading to its adoption.

Notes:

[a] It is difficult to assign a single date to what can now be referred to as the metal-on-metal hip replacement scandal. Two major events in this context are the voluntary recalls of the Zimmer Durom acetubular component, and of the ASR hip prostheses by DePuy – both due to much higher failure rates than expected (Heneghan et al., 2012) and the failure of the companies and authorities to follow-up on these.

[b] In the course of the Poly Implant Prothèse (PIP) breast implant scandal, it became clear that the manufacturer had used non-medical grade silicone, causing adverse events ranging from back pain to death (Greco, 2015). After a subsequent series of similar incidents, the need for a comprehensive overhaul of the regulation of medical devices became evident.

[c] The adoption of the MDR represents a shift of legislative power away from member states towards the EU: While *EU directives* must be incorporated into national law to become applicable, *EU regulations* prevail over national law and thus enter into force 20 days after they have been published in the Official Journal of the EU (Official Website of the European Union, 2019).

[d] *The Implant Files* was a global investigation into the medical device industry by the Associated Press, BBC, the BMJ and others that unveiled more than 120,000 safety issues with medical devices, demonstrating that on many occasions, these had reached the market after insufficient or no testing and had caused substantial harm to millions of patients (Godlee, 2018; International Consortium of Investigative Journalists, 2018; Lenzer, 2018).

[e] To ensure a smooth transition from the old to the new regulation, the obligation to use the European database on medical devices (Eudamed), which stores information about the safety and performance of medical devices, will come into effect 18 months after the date of application of the MDR itself.

[f] As certificates issued under the MDD/AIMDD will become void at the latest by 27 May 2024, medical devices certified under the MDD/AIMDD cannot be put into service or made available on the market after 26 May 2025 (Official Journal of the European Union, 2017a).

[g] The MDR introduces a provision that foresees the European Commission assessing by 27 May 2027 how the MDR has been applied. The assessment will give special attention to the traceability of medical devices (Art. 121).

Content of the reform

In this section, we draw upon the chapters and annexes of the MDR to summarize the regulatory requirements that have been introduced or tightened by the new regulation. In doing so, we take an approach structured around the main stakeholders and processes involved in placing a medical device on the European internal market, as shown in Fig. 3.

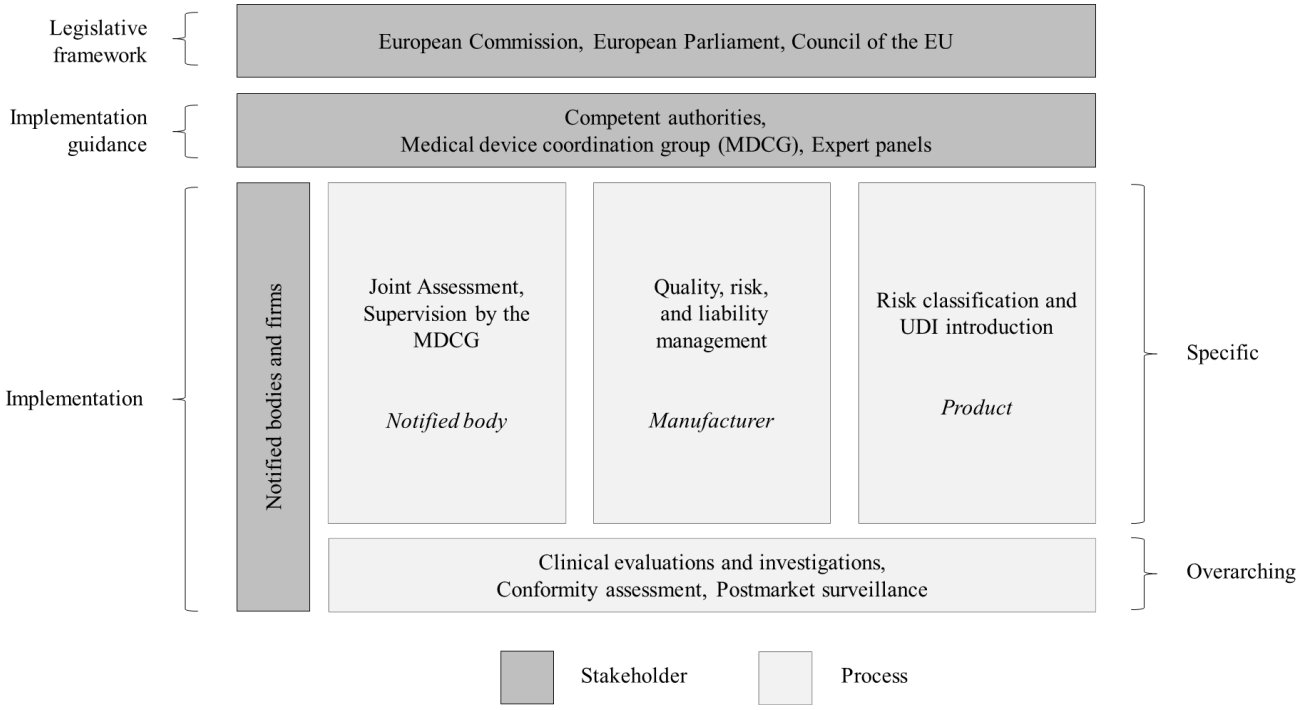

Fig. 3. Main stakeholders and processes involved in placing a medical device on the market.

Definitions and scope

Compared to the previous regulation, the MDR contains an expanded introductory list of definitions, namely 71 compared to seven in the AIMDD and 14 in the MDD. Additionally, the

MDR has a wider scope than the previous regulations: software and products that were classified previously as consumer goods, such as contact lenses, are now classified as medical devices (Art. 2 & Annex XVI).

To demonstrate conformity with the MDR, manufacturers must comply with a range of harmonized European standards (Art. 8) and common specifications (Art. 9). To ensure an equivalent level of safety and performance across devices, manufacturers must provide a justification if their product diverges from these standards and specifications (see Table 1).

Table 1. Definitions and detailed explanations of regulatory terms related to the implementation of the MDR.

Regulatory term[a]	**Detailed explanation**
Common specifications	*'Common specifications'* represent a set of requirements that manufacturers may use to demonstrate compliance with legal obligations. If harmonized standards do not exist or are insufficient, or if there is a need to address public health concerns, the European Commission will adopt common specifications (Art. 9) by means of implementing acts (Art. 91) after consulting medical experts and relevant stakeholders, and by considering international standards.
Economic operators	The MDR introduces the collective term *'economic operators'* to describe the following stakeholders: legal manufacturers, authorized representatives, importers, distributors or natural and legal persons who combine or sterilize system or procedure packs.
Risk classes of medical devices	Medical devices are divided into four major *risk classes* – I, IIa, IIb, and III – according to the risk they constitute to the health of patients and consumers, class I representing devices posing the lowest risk. The risk class of a device is determined by a set of 22 rules, which are divided into four groups: rules for non-invasive, invasive, or active devices, as well as special rules (Annex VIII).

Regulatory term[a]	**Detailed explanation**
Notified bodies and competent authorities	*Notified bodies* are mostly private organizations that charge fees to manufacturers for assessing the conformity of a medical device with the requirements of the MDR. Upon assessment, manufacturers are allowed to place their devices on the European internal market. Notified bodies are designated and supervised by the statutory *competent authorities* of the EU member states or, if agreed upon, by non-member states. To review the quality system of manufacturers of devices of class IIa or higher, notified bodies must perform unannounced, on-site audits at least once every five years to assess the conformity of manufacturers with the provisions set out in the MDR, as well as that of their suppliers and subcontractors by testing an adequate sample of devices (Art 52 & Annex IX).
The Medical Device Coordination Group (MDCG)	The MDCG consists of up to two members (and two alternates) per member state who have expertise in different types of medical devices. The MDCG is a self-governing, executive body that supports the European Commission and the competent authorities in performing a broad spectrum of tasks such as defining common specifications for complying with the requirements of the MDR (Art. 9); undertaking the initial assessment (Art. 39 & 42), re-assessment and monitoring of notified bodies (Art. 44); developing guidance documents and programs for the surveillance of medical devices in the internal market (Art. 93); setting the general and performance requirements set out in Annex I to the MDR; contributing to harmonizing administrative practice in the EU and providing advice to the European Commission related to the implementation of the MDR (Art. 103 & 105).
Clinical evaluation and clinical investigations	A *'clinical evaluation'* is the systematic process of continuously collecting and assessing the clinical data related to a device with the aim of verifying the safety and performance of the device (Art. 2). A *'clinical investigation'* is a systematic investigation involving at least one person with the aim of assessing the safety or performance of a device (Art. 2); it is required for the assessment of high-risk devices, i.e., of classes IIb and III, unless specific exemption criteria are met. A clinical investigation may be a clinical trial, and it constitutes one of many ways to perform a clinical evaluation. While clinical evaluations can be conducted, for example, in the form of a literature review, a clinical investigation necessarily involves the study of human subjects.

Note: [a] in order of appearance in the text.

Stakeholders and the supply chain for medical devices

Overall, the MDR aims to make medical devices safer by obliging each economic operator (see Table 1) along the supply chain to verify the compliance of the previous economic operators. Thus, importers (Art. 13) and distributors (Art. 14) have a broad range of duties ranging from verifying the conformity of medical devices with the MDR to keeping a register of and informing other economic operators about complaints, recalls, and withdrawals.

The regulation also requires that manufacturers establish a quality management system corresponding to the risk class (see Table 1) of the underlying device and to improve this system continuously (Art. 10). Manufacturers from non-EU countries need to appoint an authorized representative who is located within the EU and is fully legally liable for defective devices (Art. 10-11). Additionally, economic operators are obliged to have sufficient financial funds or insurance to cover possible damages. Moreover, manufacturers must designate at least one person who is responsible for ensuring regulatory compliance of their devices (Art. 15). This person must meet pre-defined criteria related to education and professional experience in a relevant field.

Strengthened procedure for designating notified bodies

The new procedure for designating notified bodies (see Table 1**Fehler! Verweisquelle konnte nicht gefunden werden.**) is shown in Fig. 4. The procedure is carried out by a joint assessment team consisting of three experts – one from the European Commission and two from member states other than the state in which the applying conformity assessment body is located. Towards the end of the procedure, a newly established body called the Medical Device Coordination Group (see Table 1) issues a recommendation, which the competent authority duly considers (Art. 39).

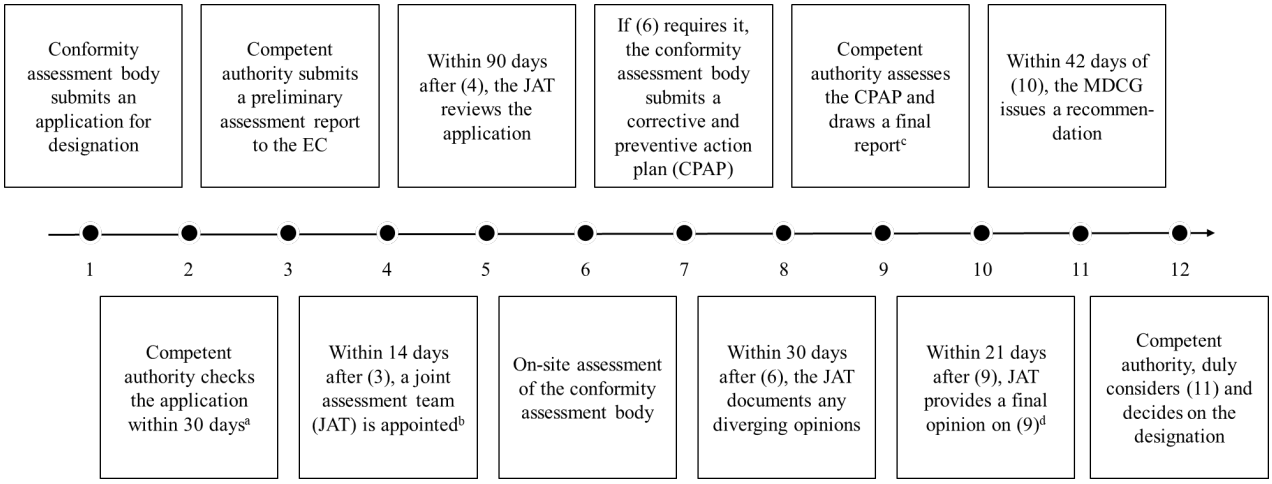

Fig. 4. Overview of the new designation procedure of conformity assessment bodies under joint assessment.

Notes:

[a] Competent authority may ask the conformity assessment body to provide any missing information. The complete application is sent to the European Commission.

[b] The European Commission appoints an expert team consisting of persons – coming from member states other than the one of the notified body to be assessed – who are in charge of a so-called joint assessment procedure.

[c] The report includes a recommendation on the scope of designation, e.g., the range of risk classes that the notified body will be able to certify.

[d] This opinion is submitted to the European Commission and the Medical Device Coordination Group (MDCG).

In addition to regular inspections, the competent authority may conduct unannounced reviews to verify the regulatory compliance of the notified body (Art. 44). Lastly, notified bodies may delegate a range of activities related to assessing the conformity of medical devices with the requirements of the MDR to subcontractors (Art. 37 & Annex VII).

Prior to market entry: Classification and conformity assessment

Devices are divided into four risk classes according to their inherent risk (Art 51) based on 22 classification rules. The new set of rules is more specific compared to the earlier directives,

resulting in some medical devices being assigned to a higher risk class. For example, most software products are class IIa devices under the MDR.

To reinforce the conformity assessment of certain class IIb and III devices, the MDR has introduced a special mechanism that involves an expert panel comprising clinical and technical experts (Art. 54-55, Art. 106 & Annex IX). The expert panel is a newly created advisory body appointed by the European Commission and can modify the requirements related to the assessment of medical devices – for example, by developing common specifications or providing manufacturers with advice on their clinical development strategy (Art. 106). The expert panel may also provide its opinion on the certification of high-risk devices. The notified body must justify its decision if it decides to disagree with the opinion provided by the panel.

To place a new device on the market, manufacturers must conduct a clinical evaluation (see Table 1) of the available clinical evidence by (i) critically evaluating relevant scientific literature, (ii) critically evaluating the results of all available clinical investigations, and (iii) considering currently available alternative treatments (Art. 61 & Annex XIV). Alternatively, it is possible for a manufacturer to conduct a clinical evaluation by demonstrating the equivalence of the technical, biological, and clinical characteristics of a device to those of a predicate one (i.e., a product that has already been placed on the market). To do so, however, manufacturers need to access the proprietary technical documentation of other devices already on the market.

A critical review of the scientific literature is sufficient for placing most devices on the market. For implantable class IIb and class III devices, device-specific clinical data are generally required (Art. 61), although multiple exceptions may apply. In addition, manufacturers must submit a clinical investigation report that includes a critical evaluation of both the positive and negative

findings they have generated in a clinical investigation (Annex XV), and they must conduct and document clinical evaluations, for example, by establishing and updating a clinical evaluation plan (Annex XIV).

After market entry: Enhanced traceability and surveillance

Mechanisms to ensure the identifiability and traceability of medical devices are the core components of the postmarket surveillance rules introduced by the MDR. These mechanisms comprise an expansion of the European database on medical devices (Eudamed) and the introduction of unique device identifiers (UDI). Eudamed, a database of key information about medical devices, has been expanded to include information about the certification procedure, as well as vigilance and (post-)market surveillance data (Art. 33). The medical device or its packaging is labelled with a UDI (Art. 27 & Annex VI), which allows the device to be identified unequivocally and linked to relevant technical documentation, declarations of conformity, as well as any relevant certificates, serial and lot numbers, and place of manufacturing.

The MDR also reinforces the postmarket surveillance of medical devices by introducing detailed rules for executing a series of reports and monitoring plans. The aim of postmarket surveillance is to identify any need for taking additional preventive actions and to promote collaboration between economic operators after devices have been placed on the market. Manufacturers must create postmarket surveillance plans to inform competent authorities and notified bodies about events such as (non-)serious incidents and undesirable side-effects, as well as feedback and complaints provided by users and economic operators (Art. 83-84 & Annex III). To summarize the results and conclusions derived from their postmarket surveillance data, manufacturers of class I devices must produce a postmarket surveillance report (Art. 85), whereas for all other classes of devices, manufacturers must produce periodic safety update reports

(Art. 86). Consequently, manufacturers may need to update the technical documentation of the device and, if necessary, recall the device or inform users, authorities, notified bodies, and economic operators about any incongruities. Manufacturers must also report any statistically significant increase in non-serious incidents or expected side-effects that may affect the balance between the benefits and risks of a device (Art. 88). In turn, notified bodies are required to verify that postmarket surveillance is an integral part of a manufacture's quality management system (Annex VII). Lastly, the MDR urges manufacturers to conduct postmarket surveillance in a proactive way, for example by reinforcing the postmarket clinical follow-up process with the aim of identifying unknown side-effects or the systematic misuse of medical devices (Annex XIV).

Expected outcomes

Through the measures described in the preceding chapters, the MDR has facilitated two major changes: (1) the ongoing exchange of information between economic operators, notified bodies, and competent authorities, and (2) an increase in the depth and breadth of regulations pertaining to the entire life-cycle of devices (Studer, 2016). By discussing these and further aspects of the MDR in the following chapter, we aim to examine whether the MDR is likely to achieve its major goals of (i) strengthening the European internal market and (ii) increasing patient safety.

Strengthening the European internal market

Competition and firm size

Small and medium-sized enterprises (SMEs) traditionally form the backbone of the European medical device industry (MedTech Europe, 2019b). The majority of the SMEs, however, lack the financial capacity to enter new device markets (Stern, 2017), or to independently conduct large clinical studies (Sorenson and Drummond, 2014). Presumably for this reason, the MDR makes

some concessions towards SMEs, such as exempting them from the obligation to directly employ a person responsible for regulatory compliance (Art. 15). Preliminary analysis, however, suggests that complying with the MDR may still be challenging for SMEs (Miclăuş et al., 2019; Migliore, 2017; Studer, 2016; Tarricone et al., 2020; Werner et al., 2018). Additionally, we expect to witness me-too products and own-brand labels (i.e., brand products that are sold under different names) being withdrawn from the market. Manufacturers of such products must access the technical documentation of a predicate device. Thus, firms may have to conduct clinical investigations even if their device is identical to another one that is already on the market. Although requiring access to the technical documentation of other devices and thus making the certification of new ones more difficult could conceivably improve patient safety, there is little question that this measure will inhibit the market entry of some firms and thus hinder competition.

Recertification of devices

All devices must be recertified under the MDR by 26 May 2024, which is the date that certificates issued under the former directives expire. This transition period may not be of sufficient length for all of the roughly 500,000 medical devices available on the internal market to be recertified (MedTech Europe, 2019b). Recertification usually takes at least six months (MedTech Europe, 2019a), and notified bodies are scarce and difficult to access, especially for SMEs. The more stringent safety and performance requirements of the MDR are likely to increase the costs of certification, leading to shortages (Werner et al., 2018) and temporarily reducing the availability of some devices (Martelli et al., 2019).

Recertification of notified bodies

Under the MDR, notified bodies must fulfil new, stricter requirements to stay on the market (Art. 36 & Annex VII). It is probably because of these that five of the notified bodies that had been

designated under the former directives had withdrawn from the market by April 2021 (Oriel STAT A MATRIX Blog, 2020). As of today, only 20 of the 56 existing notified bodies have been designated under the MDR (European Commission's Official Website; European Commission's Official Website), decelerating the certification of medical devices and posing an additional challenge to manufacturers, at least during the transition period ending 27 May 2024.

Increasing patient safety

Eudamed

Eudamed, which will eventually include UDIs and thus centralize and facilitate the monitoring of devices, is likely to improve patient safety over the long run. By pooling postmarket data on adverse events, these can be detected much faster in the future. However, there are some obstacles to adopting the database, including the tight implementation deadlines and stakeholders' insufficient familiarity with the database itself (Camus et al., 2019).

Notified bodies

Notified bodies tend to establish strong relationships with manufacturers (Cohen, 2012a; Srinivasan, 2019), some of whose business may constitute a large share of their turnover (Cohen, 2012b). This interdependence is unlikely to disappear under the MDR because medical devices are placed on the market largely in the same way as under the former directives, albeit subject to a reinforced designation procedure.

Pre- and postmarket clinical evidence

Providing evidence of safety and performance through clinical investigations has not become mandatory under the MDR, even for high-risk devices. Manufacturers may still show that a new device is not significantly different from a predicate one without performing clinical testing, even

though a series of incremental changes may, in fact, lead to a new device that is substantially different from the original one. Devices placed on the market based on equivalence, however, have failed to protect public health on many occasions in the past (Allan et al., 2018). Some scholars even regard the equivalence procedure as providing the wrong incentives by deterring manufacturers from gathering new clinical evidence (Sorenson and Drummond, 2014).

Even though *premarket* data do not provide information about the long-term effects of medical devices (Maisel, 2004), and premarket clinical testing is not necessary in a range of cases (Annex XIV), the MDR could nevertheless lead to greater improvements in patient safety compared to the former regulation by virtue of its expansion of *postmarket* scrutiny. Whether this hypothesis will hold true over the long term is unclear, however. On the one hand, while manufacturers have not managed to reap the benefits of the learning gained through postmarket surveillance so far (Zippel and Bohnet-Joschko, 2017), the stricter requirements of the new regulation may encourage them to make more efforts in this regard. On the other hand, learning from postmarket surveillance is limited, at least for some medical devices, because the data are observational and cannot be used to establish causality (Grennan and Town, 2020). In addition, long-term postmarket evidence is mostly irrelevant for assessing the safety and effectiveness of medical devices currently on the market because many of these are continuously modified and replaced, making the data collected on the parent device less valuable (Fox and Zuckerman, 2014). Moreover, many health professionals regard adverse events as natural and reporting these as unnecessary, unfeasible, or even futile, and, often, industry does not respond to safety issues (Gagliardi et al., 2018). Many users also do not have sufficient knowledge of adverse event reporting systems, even in large hospitals (Galgon, 2016). Under the MDR, even when problems are reported and registered, the

way these are interpreted is the responsibility of the competent authorities of the member states (Art. 94-97) and will thus vary across countries.

Nevertheless, the MDR introduces measures that aim at improving the safety of medical devices within the European internal market. For example, the series of postmarket reports which force manufacturers to collect and assess postmarket data in a systematic way, has the potential to improve patient safety over the long run. Additionally, the European Commission and the member states must facilitate the creation of databases for collecting comparable information on, and enhancing the independent evaluation of, the traceability, safety, and performance of devices (Art. 108).

Ambiguous terms

While the MDR generally adds precision to the regulation of medical devices, the text of the regulation uses many ambiguous terms, such as "sufficient clinical evidence" (e.g., regarding the safety, performance, and benefit-risk ratio of devices; Art. 61), "substantial modifications" (e.g., concerning the design of clinical investigations; Art. 75), and "reasonable period" (e.g., concerning the withdrawal of defective devices from the market; Art. 95). These terms are not specified in Article 2, thus leaving scope for various interpretations with an uncertain effect on patient safety and the harmonization of standards. Guidance documents produced by the competent authorities, expert panels, and Medical Device Coordination Group, however, are expected to bring more clarity to such issues.

Policy recommendations

Although the impact of the MDR on patient safety and the medical device industry is disputed among researchers and industry representatives, we expect that the new regulation is likely to

achieve its main goals, albeit to different extents. First, the MDR harmonizes the regulatory framework at the EU level and will thus facilitate trade with medical devices. Second, the MDR introduces a range of mechanisms that will probably improve patient safety over time if rigorously implemented by the parties involved. The next decade will bring more clarity to the question of whether EU authorities need to amend the MDR – for example, if it turns out to be detrimental for SMEs or fails to make medical devices safer. The European Commission should remain vigilant and react if it has evidence that small adjustments to the law might help solve the challenges caused by the recertification of notified bodies, medical devices, or both. However, larger adjustments, particularly during the transition period, should be avoided because these might cause firms to shift resources from operational units to administrative activities, thus reducing the capacity of firms to invest in research and development.

In the following sections, we outline ways in which the future regulation of medical devices might be improved further. Policy makers may wish to consider these when working on legal frameworks seeking to enhance free trade and patient safety.

Conflicts of interest

As suppliers of manufacturers, notified bodies have obvious conflicts of interest, and these must be observed closely by the competent authorities, who should not refrain from taking corrective measures if necessary. If the number of notified bodies withdrawing from the market continues to grow, competition will decrease overall, potentially leading not only to an increase in the price of certification procedures, but also to stronger interdependence of notified bodies and manufacturers.

Transparency

Although Eudamed remains a reactive tool that cannot prevent incidents from happening, its expansion will make medical devices easier to trace, thus enabling the discovery of adverse events at a much earlier stage than previously. To reap the benefits of the new data collected in Eudamed and help manufacturers and physicians make informed choices, competent authorities, together with medical experts and researchers, could develop quality indicators that capture the performance of notified bodies and medical devices. For example, metrics illustrating the rates of market withdrawals and adverse events may improve the safety of medical devices in the long run. While competent authorities and the European Commission have full access to the clinical assessment data stored in Eudamed, other stakeholders have restricted access only. Following the example of the United States, safety and approval data can be made public under consideration of proprietary rights (Maak and Wylie, 2016).

Mutual learning

Improved access to data will help (i) manufacturers to make their products safer and more performant, (ii) notified bodies to improve assessment procedures by learning from empirical evidence, (iii) physicians to make informed choices, and (iv) scholars to advance research on, among other topics, the cost-effectiveness of medical devices. All of these stakeholders will benefit from closer cooperation in collecting and evaluating clinical data. For example, by having early dialogues with one another, stakeholders can generate the empirical evidence needed to foster innovation, adopt new technologies, and make more informed assessment and reimbursement decisions. Indeed, if notified bodies, manufacturers, and payers were to engage in early dialogues more intensively, the certification of medical devices might be accelerated (Blankart et al., 2021).

Comprehensibility

Future regulation will be more accessible if it is written in simpler language and with fewer cross-references among articles and annexes. Additionally, it may be useful to expand the list of definitions set out in Article 2 to make it easier for stakeholders to understand the regulation. Increasing the breadth and depth of consultation procedures, both in terms of content and the parties invited to participate, may increase planning security and lead to regulations that are easier to understand and more acceptable for stakeholders. Lastly, implementing the MDR may have been better facilitated if guidelines and a beta-version of Eudamed had been provided in a more timely fashion.

Conclusion

While many analysts of the MDR argue that stricter regulation impedes innovation (Bowers and Cohen, 2018; German National Associations of Statutory Health Insurance Funds, 2013), others see a range of advantages and do not expect the burdens imposed by the new regulation to have a substantially negative impact in this regard (Thienpont et al., 2020). More generally, the often-assumed negative association between regulation and innovation has yet to be demonstrated convincingly in empirical studies. Indeed, more stringent regulation may even stimulate firms to develop more efficient and sustainable services and technologies, and thus internalize negative external effects (Dewick and Miozzo, 2002). More extensive regulations – especially if accompanied with patent protection – could conceivably increase the overall profitability of firms (McCulloch, 2012). Because clear and comprehensible regulatory guidelines are crucial to decrease the time needed to certify new devices (Stern, 2017), EU regulation needs to become more transparent and easier to understand, and not necessarily less stringent. To ensure that innovative

and safe products enter the market, regulation must find the right balance between accepting existing evidence uncritically and requesting new evidence unnecessarily or prematurely (Garber Alan M., 2010).

Devices certified under the MDR take years to be placed on the market, and devices certified under the former directives will continue to be used for years, if not decades. It is therefore too early to assess the impact of the MDR in a conclusive and evidence-based way. What is clear, however, is that the MDR is not a revolution, but rather an incremental change – a development that can be explained by its genesis as a compromise between the competing interests of different stakeholders, but also the complexities of the market. Indeed, the makers of the MDR appear to have sought to strike a balance between facilitating trade within the European internal market and improving patient safety. For the reasons outlined in this paper, we expect that the MDR will be effective in terms of its goal of strengthening the internal market because it centralizes competences at the EU level, thus harmonizing regulation. In terms of its other goal, to improve patient safety, a final assessment must wait until enough data have been gathered on medical devices certified under the MDR. Although many scholars and physicians have criticized the MDR as being too lax, it has introduced mechanisms that – if implemented properly – have a real chance at improving the safety of medical devices. The enhanced traceability of devices, in particular, has the potential to improve patient safety by allowing incidents to be detected more rapidly.

There is no doubt that the new regulation is not as transparent and rigorous as it could be, but it does appear to constitute a pragmatic step in the right direction. The next decades will show whether amendments are needed to prevent harmful devices from entering the market. Here, investigative journalism and rigorous research will be of paramount importance to discover potential problems and protect the public health. Lastly, as long as they do not undermine

intellectual property rights or remove incentives to develop new medical technologies, enhanced transparency and data access are needed to push the boundaries of evidence-based research and help manufacturers produce devices that are highly safe and effective.

CHAPTER 3
TOO BIG TO CHANGE? THE LINK BETWEEN ORGANIZATIONAL CAPACITY FOR CHANGE AND FINANCIAL PERFORMANCE IN THE SHIFTING REGULATORY ENVIRONMENT OF THE EUROPEAN MEDICAL DEVICE INDUSTRY[2]

[2] Single authorship. To be submitted to Research Policy in Q4 2021.

Introduction

Aiming to better understand the forces shaping organizational change, researchers and practitioners have devoted considerable effort to studying its causes and effects since at least the 1960s, when, for instance, Cyert and March (1963) pondered whether it is necessity or slack resources that makes firms implement new ideas. Inspired by the field of paleontology (Gould and Eldredge, 1977) and informed by a fruitful debate between the adaptation and selection camps in organizational science and entrepreneurship research (Barnett and Carroll, 1995), academic scholars have adopted and developed a range of tools to describe how organizations faced with shifting environments reorient and recreate their work practices. Prominent among these is the punctuated equilibrium theory (Gersick, 1991; Romanelli and Tushman, 1994; Tushman and Romanelli, 1985), according to which radical organizational change takes place during short periods of disequilibrium that punctuate a status quo, or steady state, in which firms make rather small, if any, modifications to their structure and operations. Generally, whereas new firms use disequilibria as opportunities to enter the market, incumbent ones seek to respond to new circumstances by reorganizing their business practices (Gersick, 1991). The punctuated equilibrium theory has been used as a means to explore the ontogenesis of major organizational and policy change across a diverse range of fields, including health care (Haveman et al., 2001), financial services (Haveman et al., 2001), tobacco policymaking and regulation (Givel, 2006), and strategic research and development management (Mudambi and Swift, 2011).

Occasionally interrupting the general state of stability, exogenous shocks—such as significant changes in the legal environment of organizations—are a major trigger of organizational change (Haveman et al., 2001). A host of exogenous factors, including external pressures from policy makers, civil society, and consumers, may affect an industry's legal environment, thus driving

firms to reorient their mode of operation strategically by allocating more resources towards innovation (Geels, 2014) and implementing changes in technology, system beliefs, and mission (Geels and Penna, 2015; Penna and Geels, 2015). An organization's legal environment is, in fact, among the most important factors influencing structure and agenda setting, as well as the way organizations pursue their strategic goals (Edelman and Suchman, 1997). Yet, while scholars who look empirically at the genesis of organizational change have traditionally focused on exploring the relationship between organizations and their natural, business, and knowledge environments (Judge and Elenkov, 2005; Makkonen et al., 2014; van den Bosch et al., 1999, respectively), the legal and regulatory environments have received less attention to date. Indeed, we know little about what enables firms to adapt to a shifting legal or regulatory environment or prevents them from doing so, especially when it comes to industries characterized by a high rate of technological advance. This lack of understanding is unfortunate for several reasons. To begin with, the literature shows that such environments may affect the innovative capability of the economy as a whole (van Waarden, 2001). What is more, firms capable of adapting to changing situations are, in general, also able to improve their performance (Zajac et al., 2000) and secure a competitive advantage in the marketplace (Douglas and Judge, 2001; Siggelkow and Levinthal, 2003). Additionally, previous studies have focused primarily on large companies, thus failing to further our understanding of the extent to which small and medium-sized enterprises are capable of change (Heckmann et al., 2016, p. 782). More generally, scholars and practitioners would benefit if more attention were devoted to exploring empirically the factors that enable firms to respond to major exogenous shocks.

To help address the gaps described above, I examine in this paper how firms react to challenges posed by regulations and conceptualize this by interpreting a shifting regulatory environment as an

exogenous shock that punctuates the general equilibrium and potentially initiates a phase of organizational change. In this study, I refer to the regulatory environment of the medical device industry as the subset of its legal environment that pertains to meeting the safety and performance requirements of the MDR and therefore to obtaining the right to place a device on the market. With this idea in mind, I focus on the Swiss medical device industry and the enactment of Regulation 2017/745 of the European Parliament and the Council of 5 April 2017, otherwise known as the European Union Medical Device Regulation (MDR) (Official Journal of the European Union) as the research context for this study. The reasons for this choice are as follows: First, the medical device industry is characterized by a high pace of innovation, which means that firms eventually reach the limits of their sphere of action as defined by the industry's regulatory environment. Indeed, this is a major reason why the MDR was enacted in 2017, representing the most extensive overhaul of the regulatory environment of the European medical device industry since the early 1990s. According to some observers, the industry has now entered a period of turbulence that will probably have a large impact on competition and patient safety, the full extent of which, however, has yet to be established (Shatrov and Blankart, 2021). Second, Switzerland is affected by the provisions of the MDR because the country needed to align its national legislation to the new regulation in order to maintain the access of its medical device industry to the European internal market. Third, in proportion to the size of its population and economic output Switzerland has a large medical devices industry. Lastly, the majority of companies in the medical device industry are small or medium-sized and are especially vulnerable to regulatory changes (Migliore, 2017; Stern, 2017).

Within this setting, I pursue two objectives: (1) to determine whether certain firms are more capable of change than others in response to shifts in the regulatory environment; and, (2) to outline

ways in which organizations may seek to improve their ability to react to changes in their regulatory environment. By providing novel empirical evidence and formulating policy implications for scholars and practitioners, I aim to contribute to the literature on organizational change, innovation management, and organizational capacity for change.

Conceptual framework

This study focuses on specific characteristics of firms, including firm size, age, and cluster affiliation, to examine how organizations respond to changes in their regulatory environment. I chose to measure this set of variables because they can be measured and interpreted in a transparent manner. Importantly, these variables can serve as proxies for more complex influencing factors, including experience, creditworthiness, market power, commercial viability, and economic interconnectedness. The notion of organizational capacity for change completes the theoretical framework used in the empirical analysis. Fig. 5 depicts the causal relationships hypothesized in this paper, and the remainder of this section sets out their theoretical foundation.

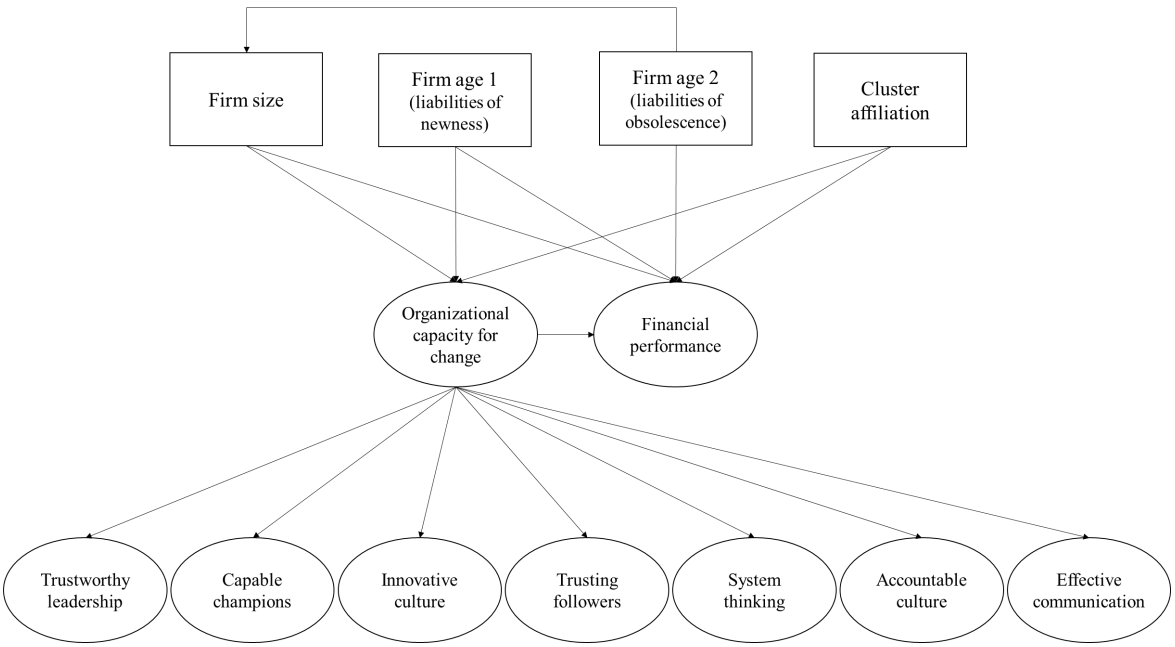

Fig. 5. Hypothesized model.

Organizational capacity for change

Many managers agree that initiating change management is a skill essential for organizational success (McCauley, 2008). Implementing change in such a way that it persists over time, however, is a challenging task that is often marked by poor success rates (Balogun et al., 2016). Possible explanations range from the lack of a solid theoretical background on the nature of organizational change to researchers and organizations tending to rely on anecdotal evidence and historical patterns of behavior (By, 2005; Stouten et al., 2018). Seeking to answer the call of these authors for empirical research to be more clearly driven by theory, I examine in this paper the concept of an organization's capacity for change, which is defined by Judge and Douglas (2009) as the set of managerial and organizational capabilities that enable a firm to adjust to changes in its environment. Drawing on the dynamic capabilities notion within the resource-based view of the firm, this multidimensional construct can be used to assess an organization's capability to adapt to new circumstances and to identify the specific organizational features that need to be addressed to make change initiatives more efficient and predictable (Judge, 2011). While closely related to the concept of readiness for organizational change (Armenakis et al., 1993; Weiner, 2009), organizational capacity for change is more comprehensive: in addition to employee attitudes towards change, it comprises the perspective of senior executives, as well as a broader set of organizational characteristics including questions about how change-friendly an organization's culture is, and how effectively information flows throughout the organization (Judge and Douglas, 2009).

The assessment tool developed by Judge and Douglas to measure organizational capacity for change is well suited to the purposes of this study because (1) its development was informed by a

special emphasis on manufacturing companies, and (2) it was validated in an industry confronted with a changing environment and comprised mainly of small firms.

Performance

A growing body of literature suggests that the ways in which organizations respond to punctual regulatory change may determine their financial performance (Haveman et al., 2001; Perez-Batres and Eden, 2008). Scholars of the organizational sciences have demonstrated the interdependency between performance and capacity to change, and have argued for the central importance of this link on multiple occasions (Barnett et al., 1994; Carroll, 1993; Heckmann et al., 2016; Siggelkow and Levinthal, 2003), especially when a firm's task environment is characterized by high levels of uncertainty (Judge et al., 2009). I therefore propose:

Hypothesis 1: Organizational capacity for change and financial performance are positively associated.

Firm size

The role of firm size has been the subject of intense discussions in the literature, especially when it comes to examining the link between change capacity and performance. The distinct effect of firm size on performance has been shown to depend on a variety of factors, including the strategy of the firm and the industry or industries in which it operates (Barnett et al., 1994; Judge and Douglas, 2009). One stream of the literature suggests that smaller firms initiate change when their financial performance is high, whereas larger firms tend to do so in times of low financial performance (Bloodgood, 2006). From this, I argue that:

Hypothesis 2: Large firms are associated with lower levels of organizational capacity for change than small and medium-sized enterprises.

Hypothesis 3: Large firms are associated with higher levels of financial performance than small and medium-sized enterprises.

Firm age

Organizational age is another factor whose negative and positive effects on organizational capacity for change finds wide support in the literature (for a discussion see Barnett et al., 1994; Barnett and Carroll, 1995). The majority of firms, however, produce major innovations—measured in terms of patents or other technologically important contributions—only once in their life cycle and are unable to sustain their innovative activities over anything but short periods (Geroski et al., 1997). Acknowledging that failure is prevalent among firms of all ages, Thornhill and Amit (2003) show that factors like poor leadership and lack of financial knowledge are among the main reasons for younger firms to enter bankruptcy, whereas they attribute the failure of established firms to their incapability to adapt to shifting environments. Based on this line of thinking and the notion that firms generally tend to become less adaptive and more inert with age (see Coad, 2018; Le Mens et al., 2015), I propose that an organization's capacity for change diminishes over time. While evidence for an industry-independent age threshold that leads growth rates to drop and firms to become more routine-driven (and inert) is lacking, Coad (2018) demonstrated that the most interesting effects associated with organizational age occur within the first five to seven years. My next hypothesis therefore reads as follows:

Hypothesis 4: Start-ups (age $\leq$ 5 years) are associated with higher levels of organizational capacity for change than incumbent firms.

While organizational aging may take place at different levels, including those of the firm, unit and employees, this study focuses on the firm level. In general, firms undergo different phases of

organizational development while aging, each of which is characterized by a different set of challenges. For example, firms are first associated with below-average productivity rates during the initial period after they enter the market, and gradually approach the industry's average productivity rates over time (Hyytinen and Maliranta, 2013). The literature suggests different ways to decompose the phases of organizational aging, which can be summarized into the overarching categories "liabilities of newness" and "liabilities of aging" (see, for example Coad, 2018). According to the liability of newness argument, young firms are associated with higher rates of growth and market exits, and lower levels of performance. Liabilities of aging, and liabilities of obsolescence in particular, occur when inert organizations fail to adapt to an environmental drift (Le Mens et al., 2015). Le Mens and colleagues (2015) showed that financial performance is (1) negative in the early (liability of newness) and the late (liability of obsolescence) stages of organizational development and (2) positive in the stages in between (liability of adolescence). Building upon these results, I propose a negative U-shaped relationship between firm age and financial performance, which I define as follows:

Hypothesis 5a: Start-ups (age $\leq$ 5 years) are associated with lower levels of financial performance than their older competitors.

Hypothesis 5b: Incumbent firms (age > 20 years) are associated with lower levels of financial performance than their younger competitors.

Lastly, Coad (2018) has demonstrated that the question of whether researchers should control for variables that mediate the relationship between age and performance depends on whether the research interest lies in decomposing the effect of age into its constituent parts. I follow this notion and include the effect of age on size by proposing a mediating path that goes from age to size (as shown in Fig. 5).

Additionally, I perform a sensitivity test by examining whether omitting the mediation path hypothesized above affects the relationship between age and performance.

Cluster affiliation

A major research topic in the fields of knowledge economics and entrepreneurship research, knowledge spillovers refer to the exchange of knowledge bounded in space. The effects of knowledge spillovers on innovation are well-studied, with previous research suggesting that a major reason for firms to form industry clusters is to accelerate the rate of innovation (Saxenian, 1996). Spatial proximity can substantially facilitate cross-organizational knowledge sharing, enabling firms to learn faster and obtain advantages against their rivals located elsewhere and not in clusters of their own (Breschi and Lissoni, 2001). Small firms benefit disproportionately from locating their economic activities in industrial clusters because they often lack financial and human resources to exchange knowledge in other ways (Torre, 2008). In particular, when it comes to creating complex knowledge in European regions, innovative economic activities are shown to have the tendency to form spatial clusters, fostering regional economic growth (Pintar and Scherngell, 2021). Lastly, studies of the medical device industry show that public funding of research institutions can reinforce innovation and knowledge production effectively at the regional level (Vadia and Blankart, 2021). Expressed formally:

Hypothesis 6: Spatial proximity is associated with higher levels of organizational capacity for change.

Hypothesis 7: Spatial proximity is associated with higher levels of financial performance.

Material and methods

To explore the early impact of the European Union Medical Device Regulation (MDR) on the change capacity and financial performance of medical device firms, I sent a survey questionnaire to the executives of those firms via e-mail two years after the new regulation entered into force on 25 May 2017. In doing so, I asked one representative per firm to complete the questionnaire. Applying the conceptual framework described in the previous section, I used a cross-sectional study design and employed two multi-item scales, one to measure the construct of change capacity and another to measure the construct of performance. The design of these scales and the mediating variables are explained below. This section concludes by describing how the data were collected and analyzed.

Study design

Answering Bartunek's call for nurturing the relationship and mutual understanding between academics and practitioners by conducting joint forums (2007, 2008), I participated in five researcher/practitioner gatherings whose purpose was to bring together representatives from academia, industry, and regulatory agencies, as well as health care professionals. At these gatherings, domain experts held a lecture series seeking to establish the effects of the MDR on the industry, and to elaborate strategies for coping with the challenges posed by the new requirements set out in this regulation. The gatherings took place between 16 April 2018 and 6 March 2019 at the University of Bern, and were visited by 68 people on average (standard deviation = 17.8). During the direct and regular exchange with practitioners, I had the opportunity to gain a detailed overview of how the MDR had been affecting the industry since it came into force in 2017. In the course of the gatherings, I aimed to explore the candid insights of informed practitioners in order

to elicit information on issues of both scholarly and practical relevance. Based on these insights and by following the advice of a group of domain experts from academia and practice who I invited to pretest the preliminary version of the survey questionnaire, I revisited the theoretical construct for organizational capacity for change originally derived by Judge and Douglas (2009) and aligned it to the idiosyncrasies of the medical device industry by leaving out one, and slightly adapting two, of its dimensions. Table 2 presents both the initial and adapted dimensions of the instrument for measuring organizational capacity for change.

Table 2. Dimensions and items of the organizational capacity for change instrument (L2)[a].

Dimension	Item[b]
Trustworthy leadership (L1)	Do business leader(s) ... ... protect the core values while encouraging change? ... consistently articulate an inspiring vision of the future? ... show courage in their support of change initiatives? ... demonstrate humility while fiercely pursuing the vision?
Capable champions[c] (L1)	Do we have a person/people responsible for RA[d] who ... ... command the respect of the rest of the company? ... possess good interpersonal skills? ... are willing and able to question well-established processes? ... have the will and perseverance to implement new regulatory requirements?
Innovative culture (L1)	Do we have an organizational culture that ... ... values innovation and change? ... attracts and retains creative people? ... provides resources to experiment with new ideas? ... allows people to take risks and occasionally fail?
Trusting followers (L1)	Do employees ... ... open themselves to consider change proposals? ... have opportunities to voice their concerns about change? ... generally know how change will help the company[e]? ... generally view top management as trustworthy?
Systems thinking[c] (L1)	Does the person/the people responsible for RA recognize the ... ... consequences of the RA requirements for the business model? ... importance of the sustainable implementation of the RA requirements in the company? ... need to realign incentives that encourage the implementation of RA requirements in the company? ... need to significantly change processes to ensure RA conformity?
Accountable culture (L1)	Do employees throughout the company ... ... experience consequences for outcomes of their actions? ... meet deadlines and honor resource commitments? ... accept responsibility for getting their work done? ... have clear roles for who has to do what?
Effective communi-cation (L1)	Does information flow effectively ... ... from executives to workers? ... in a timely fashion? ... across organizational units/teams? ... from customers to the organizational unit?

Notes:

[a] The dimension *Involved mid-management* was left out because of the relatively small size of medical device firms in Switzerland; L1 = first-level latent variable, L2 = second-level latent variable.

[b] All items were measured with a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree).

[c] Adapted to the context of Switzerland and the purposes of the study by changing 'capable champions' to 'person/people responsible for regulatory affairs'

[d] RA = regulatory affairs.

[e] 'Business unit' was replaced by 'company' because of the relatively small average size of the firms in the Swiss medical device industry.

The literature on organizational performance offers numerous ways to define and measure the concept of financial performance. I measured performance subjectively by using a multi-item scale suggested by Powell (1995) with a 5-point disagree-agree design. Respondents rated whether, over the past three years, their firms':

(1) financial performance had been outstanding,

(2) financial performance had exceeded that of their competitors,

(3) revenue (sales) growth had been outstanding,

(4) profits had been higher than those of its competitors, and,

(5) revenue growth rate had exceeded that of their competitors'.

Subjective measures are a common way to evaluate performance in the field of management and organization studies. My analysis relied on such a tool because the target group consisted of many (small) firms that had no legal obligation to disclose financial statements publicly and probably would not have revealed confidential financial data upon request.

To achieve a deeper understanding of the relationship between change capacity and performance, I sought to exploit the strengths of exploratory and formulaic research based on mainstream theorizing (Jarzabkowski et al., 2021). To do so, I proposed that the two constructs are mutually dependent on three mediating factors and included these as dummy variables in the analysis. First, the measure of firm size I used in the study originated in the definition of small and medium-sized enterprises suggested in European Union recommendation 2003/361 (Official Journal of the European Union). Second, for the age variable capturing liabilities of newness and the age variable capturing liabilities of obsolescence I defined start-ups and established firms as the reference categories, respectively. As described in Section 2.4, I defined the former as firms founded no longer than five years before the survey was administered. Lastly, to examine the

effects of knowledge spillovers conceptualized as spatial proximity, I created a dummy variable that defines cluster affiliation as follows. I defined cantons, which are the largest administrative subdivision of the Swiss federal state, as constituting a knowledge cluster within the medical device industry if they had above average values for both of the following selection criteria: (1) relative size as measured by the share of the cantonal workforce working in the medical device industry; and (2) firm density, defined as the number of medical device firms per resident. The following seven cantons were therefore assumed to constitute knowledge clusters: Bern, Neuchâtel, Obwalden, Schaffhausen, Solothurn, Vaud, and Zug. Table A1 provides the numerical values for the selection criteria described above, including some reading examples.

To translate the scales measuring organizational capacity for change and performance into German and French in such a way that the new versions were conceptually the same as the English original, I used an instrument adaptation framework suggested by the World Health Organization (World Health Organization). The approach encompassed the following steps: (1) I translated the instruments; (2) within a series of iterations, an advisory panel consisting of four scholars, native speakers, and domain experts verified the translations; and (3) I pretested the translated instruments on seven respondents working in the medical device industry who I considered to be representative of the target group of the study. As a result, participants were able to complete the survey in any of the three most commonly used languages in Switzerland (German, French, and English).

Data collection

To create and distribute the survey questionnaire, I used the survey management tool Qualtrics and a 5-point Likert-scale design to measure the instruments for change capacity and performance. I administered the survey to 1,416 partner organizations of Swiss Medtech—the country's largest trade association comprising medical device firms across the country. The target group of the

survey comprised top executives who (1) were working in manufacturing, supplying, or distributing companies, and (2) were knowledgeable of recent firm activities related to the domain of regulatory affairs. The initial request was sent on 5 June 2019, and two reminders were sent within four weeks after this date. To incentivize people to participate in the study, I committed to donate 10 Swiss Francs per completed survey (approximately 10 USD) to non-government organizations supporting students interested in sciences.

To help ensure that the data would be valid and reliable, I adopted a standardized process for data collection. This comprised promising respondents anonymity, informing them about the purposes of the study, and explaining potentially ambiguous terms in more detail.

Data analysis

This cross-sectional study used structural equation modelling to test the hypothesized model proposed in Fig. 5 (shown in Section 2). The main interest of the analysis was to determine whether the constructs of organizational capacity for change and financial performance were positively associated with each other. Additionally, the statistical model tested the effects of firm size, age, and cluster affiliation on both constructs.

Employing the ‘lavaan’ package (Rosseel, 2012) of R (Version 4.0.2), I conducted structural equation modelling. The estimation method I used was maximum likelihood with robust (Huber-White) standard errors and a scaled test statistic asymptotically equivalent to the Yuan-Bentler test statistic. To help researchers evaluate the model fit, I first describe an initial model and then use theoretical and empirical considerations to better fit the initially hypothesized model to the data (see, for example, Wong et al., 2010). In doing so, I present the following fit indices (for a discussion see, for example, Fan et al., 2016): comparative fit index (CFI), Tucker-Lewis index

(TLI), root mean square error of approximation (RMSEA) with its associated confidence interval (CI_{90}), standardized mean square residual (SMSR), chi-square (χ^2), and degrees of freedom (df). Additionally, to compare the goodness-of-fit of competing models, I (1) computed the Bayesian information criterion, and (2) used a scaled difference chi-square test statistic (cf. Satorra and Bentler, 2001).

Armstrong and Overton (1977) argued that the variation observed between early and late responses is similar to the non-observed variation between respondents and non-respondents. Therefore, to estimate the magnitude of a potential non-response bias, I conducted a Levene's test to assess the homogeneity of the variances between early and late respondents. For this purpose, I divided the observations into terciles and compared the variation of the first to that of the last one. Furthermore, I examined whether the variances of the responses across firm type were homogeneous.

Although self-report surveys are a standard technique for collecting data, item validity and reliability may be affected in surveys that use a single method for measuring dependent and independent variables at the same time (Podsakoff et al., 2012). To test for a common method bias, I performed a constrained Harman's single factor test using no rotation (Podsakoff et al., 2003). The internal consistency of all multi-item constructs was tested by calculating Cronbach's alpha.

Ethics approval

All study procedures, including the data collection and management concept, were approved by the Ethics Committee of the Faculty of Business, Economics and Social Sciences of the University of Bern (date of approval: 21 November 2018). After being informed about the study

objectives and procedures, all respondents gave their written informed consent before completing the survey.

Results

Descriptive statistics

To explain the objectives of the study and provide information on how to complete the survey questionnaire, I sent 1,416 solicitation emails to CEOs, top executives, and business leaders in the medical device industry who were working in or familiar with the domain of regulatory affairs. Of the 226 recipients who opened the email, 204 participated in the survey. Four of the 204 responses were unusable because the answers did not come from representatives working in the medical device industry. As a result, 200 observations were included in the analysis. This yielded a raw response rate of 16.0% (using as the denominator the number of solicitation emails sent) and a refined response rate of 88.5% (using as the denominator the number of survey questionnaires opened). Although relatively low, a raw response rate of this magnitude is not atypical of studies involving top executives (Heckmann et al., 2016; Judge and Douglas, 2009) or in health services research more generally (Choung et al., 2013; Ebert et al., 2018; Hikmet and Chen, 2003). In this study, about 61% of the respondents worked at the highest level of hierarchy (C level) and a further 28% at the second highest level of hierarchy in their organization. The majority of the remaining 11% were working either two levels below the C level at larger firms or preferred not to indicate their position in the hierarchy, but revealed that they were experts in at least one of the following domains: regulatory affairs, quality assurance, research and development, and legal and compliance.

By and large, the sample characteristics were comparable to large-scale sector studies of the Swiss medical industry (Murer Mecatta et al., 2018; Rütter et al., 2010). In terms of firm profile, suppliers were slightly underrepresented, whereas manufacturers were slightly overrepresented. With regard to geographical location, some cantons were slightly underrepresented (e.g., Bern comprised 11% instead of 14% of all Swiss medical device firms, and 16% instead of 19% of all medical device firms situated in Zurich), whereas others were somewhat overrepresented (e.g., Aargau comprised 9% of the medical device firms that participated in this study compared to 6% in the large-scale sector studies, and Solothurn comprised 10% of medical device firms compared to the expected value of 4%). Fig. A1 shows the geographic distribution of the respondents. In terms of firm size, large firms comprised 22.6% of the sample (compared to the national average of about 7% of large firms among all medical device firms), meaning that small and medium-sized enterprises were somewhat underrepresented. Overall, 10.7% of the firms were start-ups, and 32% of the firms were assigned to a knowledge cluster. Lastly, most respondents completed the study in German (74.5%), followed by French (14%) and English (11.5%).

Robustness analysis

To examine the quality of the sample, I performed a series of robustness checks. First, Table ***3*** reports the coefficients of internal consistency (Cronbach's alpha), all of which were acceptable, ranging between 0.81 and 0.93 (Nunnally and Bernstein, 1994). To improve the internal consistency of the scales, three items were deleted whenever the "alpha if item removed" was higher than the overall scale alpha (*innovative culture 4, trusting followers 1*, and *effective communication 4*). The table also shows the response ranges, anchors, number of items, and descriptive statistics for the two instruments measuring organizational capacity for change and financial performance.

Table 3. Descriptive statistics and reliability analysis for the scales of the two instruments.

First- (L1) and second-level (L2) latent variables	Range[b]	Items	Mean	SD	Alpha (95% CI)	Factor loading
Organizational capacity for change (L2)	1-5	28	4.1	0.54	0.93 (0.92-0.95)	NA
Trustworthy leadership (L1) [a]	1-5	4	4.1	0.84	0.90 (0.88-0.93)	1.000**
Capable champions (L1) [a]	1-5	4	4.4	0.56	0.81 (0.76-0.86)	0.276*
Innovative culture (L1) [a]	1-5	4	4.0	0.79	0.84 (0.80-0.88)	0.867**
Trusting followers (L1) [a]	1-5	4	4.0	0.69	0.81 (0.76-0.86)	0.899**
Systems thinking (L1) [a]	1-5	4	4.2	0.72	0.84 (0.79-0.88)	0.190
Accountable culture (L1) [a]	1-5	4	3.9	0.74	0.82 (0.78-0.87)	0.610**
Effective communication (L1) [a]	1-5	4	4.0	0.81	0.89 (0.86-0.92)	0.776**
Financial performance (L1)	1-5	5	3.2	0.99	0.89 (0.86-0.92)	NA

Notes:

SD = standard deviation, CI = confidence interval; NA = not available (available only for items); ** $p < 0.01$, * $p < 0.05$.

[a] Table 1 presents the constituting items of the organizational capacity for change instrument (L2).

[b] The anchor was "strongly disagree to strongly agree" in all cases.

Next, the results of Levene's test suggested that there were no significant differences ($p < 0.05$) in variance between types of medical device firms participating in the survey (i.e., manufacturers, suppliers, and distributors). With regard to the difference between early and late respondents, the variances of all but one item (*trusting followers 1*) were homogeneous between the first and last tercile. This item was therefore not used in the regression analysis. Lastly, Harman's single factor test showed that the proportion of explained variance was 0.31, which was below the critical value of 0.5. Consequently, neither a non-response nor a common method bias appeared to pose a serious restriction to the validity of the study results.

Regression analysis

Because the indicators of the latent variable capturing the construct of organizational capacity for change were latent variables themselves, I verified whether the first-level latent variables were sufficiently correlated with each other. Two of these—*capable champions* ($p > 0.01$ on two occasions, and $p > 0.05$ on another) and *system thinking* ($p > 0.1$ on all occasions)—were insufficiently correlated with the other constituent variables of the instrument for measuring organizational capacity for change. These two variables also had low standardized factor loadings (above 0.4 in only one of 10 cases), so I did not consider them while estimating the higher-order model proposed in Fig. 5 because I still had a sufficient number of items for identification after doing so. This decision made sense from theoretical point of view, as well, because these were the two dimensions of the instrument measuring organizational capacity for change that were adjusted for the purposes of this study based on both the researcher/practitioner gatherings and the pretest with the domain experts. To assign the second-level latent variable *organizational capacity for change* to a scale and proceed with the model estimation, the factor loading of the first-level latent variable *trustworthy leadership* was constrained to one. Table 4 presents the correlations between the first-level latent variables.

Table 4. Correlations between the first-level latent variables constituting the organizational capacity for change latent variable.

Latent variable	(1)	(2)	(3)	(4)	(5)	(6)	(7)
(1) Trustworthy leadership	1						
(2) Capable champions	0.48**	1					
(3) Innovative culture	0.89**	0.33**	1				
(4) Trusting followers	0.79**	0.28*	0.79**	1			
(5) System thinking	0.24	0.74**	0.14	0.15	1		
(6) Accountable culture	0.69**	0.37*	0.65**	0.75**	0.23	1	
(7) Effective communication	0.62**	0.28·	0.55**	0.68**	0.02	0.75**	1

Note: ** $p < 0.01$, * $p < 0.05$, · $p < 0.1$.

Running the initial regression model with all seven dimensions of the organizational capacity for change construct did not result in acceptable fit indices: CFI = 0.89, TLI = 0.88, RMSEA = 0.062 with CI_{90}: (0.053, 0.072), SMSR = 0.066, $\chi^2 = 575.51$, df = 364.

To assess whether parameters should be added to the model, I used modification indices and added these to the model if they (1) resulted in a substantive improvement in the fit of the model (I chose > 10 as a threshold because of the relatively small sample size), and (2) were theoretically justified. Four indices met those conditions. Three of these indices were covariances: (1) between *trustworthy leadership* and *innovative culture*, as well as the these between the following two pairs of items measuring the financial performance construct: (2) *"our financial performance has exceeded that of our competitors"* and *"we have been more profitable than our competitors"*, and (3) *"our revenue (sales) growth has been outstanding"* and *"our revenue growth rate has exceeded that of our competitors"*. The fourth modification index added was originally unexpected yet intuitive: The path between the item *accountable culture 4* (regarding the question whether employees generally view top management as trustworthy) and the *effective communication* dimension of the organizational capacity for change construct. Finally, the scaled difference chi-

square test statistic suggested that the final model had a significantly better goodness-of-fit. The result of the scaled difference chi-square test statistic suggested that the final model had a better goodness-of-fit ($p < 0.01$) and a lower value of the BIC (5792.5 vs. 6708.4). Fig. 6 illustrates the final model.

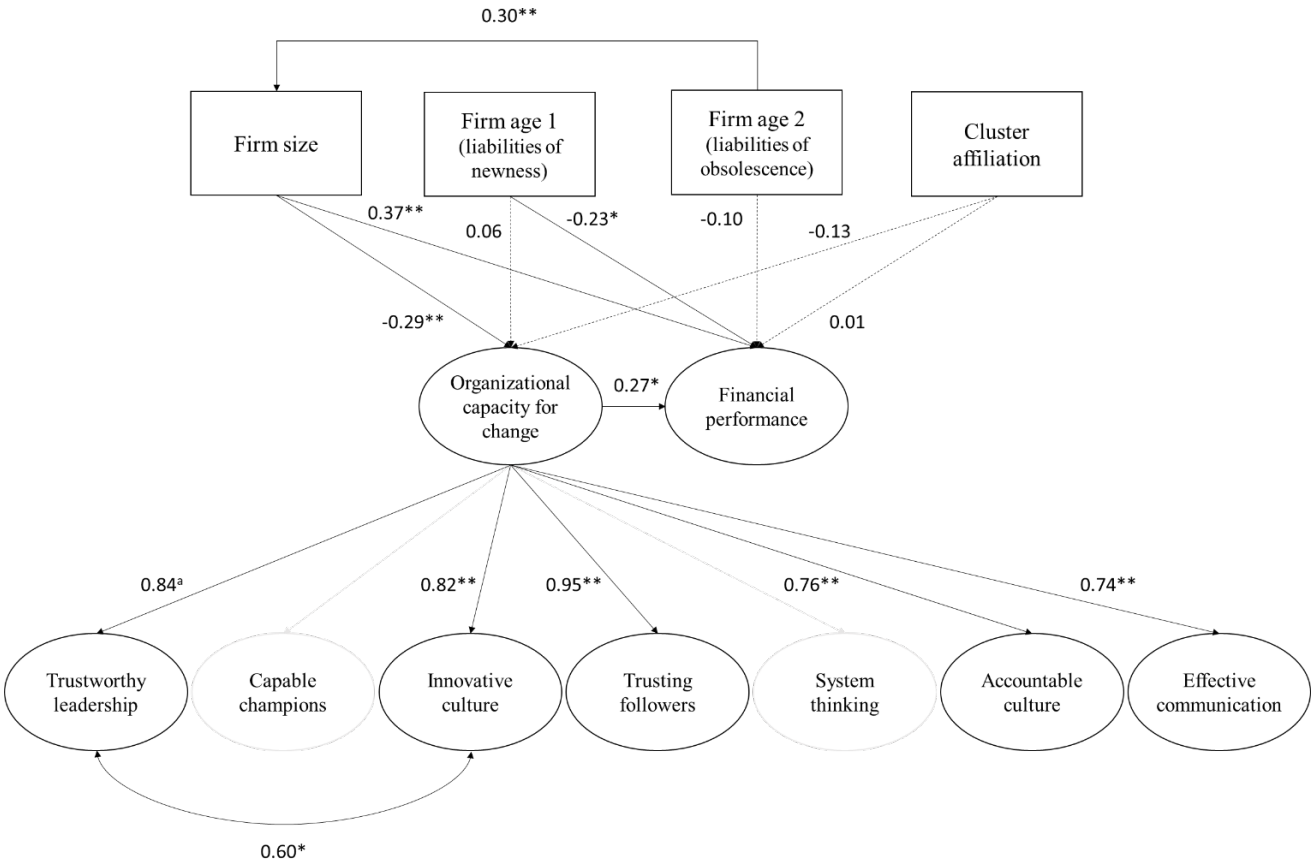

Fig. 6. Final model paths with standardized parameter estimates.

Notes:

Solid lines represent significant paths, whereas * $p < 0.05$ and ** $p < 0.01$; dashed paths represent non-significant relationships ($p > 0.05$); grey paths were dropped from the model.

[a] Reference category.

Because 51 observations were deleted due to missing values in exogenous variables (e.g., *Firm size*), a total of 149 observations were used to estimate the final model. This number of observations is sufficient for conducting SEM (Kline, 2015). The following statistics suggested a satisfactory model fit (see Fan et al., 2016; Hu and Bentler, 1999): CFI = 0.95, TLI = 0.94, RMSEA = 0.047 with CI_{90}: (0.033, 0.059), SMSR = 0.056, $\chi^2 = 374.00$, df = 282. Table 5 presents the results of the regression analysis.

Table 5. Standardized regression estimates for the structural and measurement equations.

Model path	Standardized estimate	SE	p
Organizational capacity for change (L2) → Trustworthy leadership (L1)	0.840**	reference	reference
Organizational capacity for change (L2) → Innovative culture (L1)	0.817**	0.096	0.000
Organizational capacity for change (L2) → Trusting followers (L1)	0.945**	0.146	0.000
Organizational capacity for change (L2) → Accountable culture (L1)	0.759**	0.194	0.000
Organizational capacity for change (L2) → Effective communication (L1)	0.741**	0.172	0.000
Organizational capacity for change (L2) → Financial performance (L1)	0.267*	0.156	0.017
Firm size (O) → Organizational capacity for change (L2)	-0.286**	0.168	0.004
Firm size (O) → Financial performance (L1)	0.372**	0.206	0.000
Firm age 1 (liability of newness) (O) → Organizational capacity for change (L2)	0.062	0.246	0.570
Firm age 1 (liability of newness) (O) → Financial performance (L1)	-0.234*	0.299	0.014
Firm age 2 (liability of obsolescence) (O) → Financial performance (L1)	-0.098	0.210	0.364
Firm age 2 (liability of obsolescence) (O) → Firm size	0.296**	0.064	0.000
Cluster affiliation (O) → Organizational capacity for change (L2)	-0.125	0.141	0.214
Cluster affiliation (O) → Financial performance (L1)	0.008	0.182	0.935

Notes: SE = standard error; L1 = first-level latent variable, L2 = second-level latent variable, O = observed variable; ** $p < 0.01$, * $p < 0.05$.

The regression estimates suggest that organizational capacity for change and financial performance were positively associated ($p < 0.01$). Second, compared to large firms, small and medium-sized enterprises had higher organizational capacity for change ($p < 0.05$) and lower

performance levels ($p < 0.01$). Next, while established firms did not differ in terms of change capacity from start-ups, the latter showed lower levels of performance ($p < 0.05$). Finally, cluster affiliation did not have a statistically significant effect on either change capacity or performance. Table 6 summarizes the hypotheses tested and the results of the study.

Table 6. Overview of hypotheses and empirical conclusions.

Hypothesis	Proposed sign	Result
Hypothesis 1: Organizational capacity for change and financial performance are positively associated.	+	+
Hypothesis 2: Large firms are associated with lower levels of organizational capacity for change than SMEs.	-	-
Hypothesis 3: Large firms are associated with higher levels of financial performance than SMEs.	+	+
Hypothesis 4: Start-ups (≤ 5 years) are associated with higher levels of organizational capacity for change than incumbent firms.	+	NS
Hypothesis 5a: Start-ups (≤ 5 years) are associated with lower levels of financial performance than their older competitors.	-	-
Hypothesis 5b: Incumbent firms (> 20 years) are associated with lower levels of financial performance than their younger competitors.	-	NS
Hypothesis 6: Firms grow in size while aging.	+	+
Hypothesis 7: Spatial proximity is associated with higher levels of organizational capacity for change.	+	NS
Hypothesis 8: Spatial proximity is associated with higher levels of financial performance.	+	NS

Note: NS = Non-significant

Sensitivity testing

I performed a series of sensitivity tests to examine whether key model assumptions might be challenged. To do so, I took the following steps: (1) dropping the mediation (indirect) effect of liabilities of obsolescence (*Firm age 2*) on performance and change capacity; (2) testing whether

the results of the analysis differed across the different language regions of Switzerland; and (3) changing the definition of the age and cluster mediating variables.

First, dropping the path from *Firm age 2* to *Firm size* (see Fig. 6) did not affect the goodness-of-fit of the model, nor the significance of the regression estimates. However, the BIC and the χ^2 test statistics of the model with firm size as mediating variable were somewhat better ($p < 0.1$).

Second, I introduced a dummy variable to test whether the German-speaking cantons of Switzerland differed from the remaining cantons (the number of responses was insufficient to define an additional variable that distinguished between the French- and Italian-speaking cantons). The regression estimates did not reveal a significant difference between these two groups of cantons.

Third and last, because the literature on liabilities of age does not provide unequivocal age thresholds for the shift between the different stages of the lifecycle of a firm, I tested whether changing the range used to define the age variables would affect the regression estimates. Analogously, I tested alternative definitions of the cluster variable. The regression results were robust to alternative definitions of both firm age and cluster mediating variables.

Discussion

This paper examined the initial response of the European medical device industry to the European Union Medical Device Regulation (MDR), which was enacted in 2017 and became fully applicable in 2021. By conceptualizing the MDR as an exogenous shock that created an environment of legal transition and uncertainty, this study attempted to determine whether change-capable firms are able to enhance their financial performance in such an environment. With this aim in mind, Switzerland constituted a particularly interesting research context because of the

disproportionate importance of the medical device industry for the country's economy compared to most European countries. The remainder of this section discusses the study results in detail by (1) looking more closely at the distinct dimensions of the organizational capacity for change framework, and (2) focusing on influencing factors such as age, size, and cluster affiliation that may moderate the relationship between change capacity and performance.

First, I was able to identify strong evidence of a positive relationship between organizational capacity for change and financial performance. From this, I conclude that managers need to enhance the change capacity of their organization if they wish to be better prepared to respond to situations like the introduction of a new regulatory framework and, in so doing, enhance profitability. Based on my findings, some dimensions of the organizational capacity for change framework seem to be somewhat more important than others. The three dimensions that appeared to have the highest impact on an organization's capacity for change are the ones related to strong leadership, empowering organizational culture, and having capable frontline workers. Business leaders can help their teams cope with challenges efficiently by supporting them with the implementation of change initiatives and by articulating an inspiring image of the firm's future and core values. Additionally, an innovative organizational culture should be able to attract creative people and provide them with adequate resources to contribute and test new ideas. A further example of what distinguished firms with high organizational capacity for change was employees who were willing to change their working practices and voice their concern about change initiatives if needed.

Second, my findings suggest that in times of regulatory change, small firms show lower levels of financial performance than their larger rivals. Depending on how pervasive this relationship turns out to be in the long run, it may be detrimental to the medical device industry, which consists

almost entirely (ca. 95%) of small and medium-sized enterprises. This result is in line with recent literature suggesting that the MDR is likely to affect small and medium-sized enterprises disproportionately (Miclăuş et al., 2019; Migliore, 2017). Moreover, in the related pharmaceutical industry, small firms have suffered dramatic reductions in research productivity because of heightened FDA regulations, whereas large firms have managed to increase profitability and market value (Thomas, 1990). Nevertheless, small firms seem to be able to reduce this performance gap somewhat thanks to their greater capacity for change.

Third, I found that young firms were more capable of change. Somewhat surprisingly, this ability was not associated with higher financial performance. This might be due to the fact that in periods of organizational change, firms transfer resources from operations into restructuring, which can have a negative impact on performance (Barnett and Carroll, 1995). To comply with the MDR, firms need to shift resources to the business units responsible for regulatory affairs, necessitating the reorganization of production and sales processes throughout the company. Not all firms, however, are equally successful in allocating resources in this way. Firms of different ages usually face different challenges and have different capacities to cope with shifts in the regulatory environment. Nonetheless, younger have been shown to be more likely to generate employment growth (see Coad et al., 2016). At the same time, young firms, especially the small ones among them, are more vulnerable to challenges—typically because they suffer from liabilities of newness—and might therefore benefit from receiving special (non-pecuniary) support (Coad, 2018). In line with this research, my results reinforce the observation that young and small firms are associated with lower levels of financial performance.

Fourth and last, my findings do not provide evidence in support of the notion that firms situated in knowledge clusters differ from their rivals, whether in terms of change capacity or performance.

This result may be attributable to a myriad of factors preventing geographic knowledge clusters from emerging in Switzerland, such as high individual mobility of people in this industry and the many opportunities for business people to meet at corporate events (see Torre, 2008). Additionally, the topography and the small size of the country (and its administrative units) may be further factors preventing knowledge clusters from emerging.

Conclusions

Adopting the adaptionist view that organizations are able to change once challenged by external factors, this study explored how the equilibrium-breaking exogenous shock of a major shift in the regulatory environment is affecting the European medical device industry. Following on from the dynamic capabilities literature, the analysis examined the link between an organization's capacity for change and financial performance, as mediated by a specific set of organizational characteristics. In doing so, this study sheds light on which firms are more likely to change the way they do business, and whether change capacity and financial performance are positively associated in the context of a shifting regulatory environment. I found that, first, change-capable firms tend to outperform their rivals financially. Second, while small firms generally have higher organizational capacity for change, they nevertheless show lower levels of financial performance than their larger competitors. Finally, young firms may experience difficulties achieving above-average financial results in times of regulatory change.

In summary, this paper contributes to the study of organizational change by helping bridge the translational gap between theory-driven scholarly interest and practical relevance through conducting empirical research—a need that has been continuously highlighted during past decades (Bartunek, 2008; By, 2005; Geels, 2014). With this study, I add to the literature on organizational

capacity for change (Heckmann et al., 2016; Judge, 2011; Judge and Douglas, 2009) by advancing its measurement framework and applying it to the European medical device industry, which is characterized by a high share of small and medium-sized enterprises and short product development phases. At the same time, this study explored a specific set of influencing factors mediating the link between change capacity and performance, and did so within the perspective of legal transition and uncertainty.

Strengths and weaknesses

This is the first empirical study to use the organizational capacity for change framework to explore the extent to which the new European Union Medical Device Regulation (MDR) has affected the European medical device industry during the transitional period of the regulation (2017-2021). A strength of this study is that the data were collected by interviewing top executives and business leaders. Using both scholarly and practitioner knowledge to validate and enrich the survey questions further strengthened the methodological approach.

Nevertheless, the study has some important limitations. The first of these is its cross-sectional design, which makes it impossible to establish causal relationships in the absence of further analysis. Second, the analysis relied on self-reported data, partially measured in a subjective way, and the results may therefore be distorted by self-esteem or social desirability bias. A third drawback is that the analysis was not able to distinguish between the different types of medical device firm that participated in the survey (i.e., manufacturers, suppliers, and distributors). This was because 27.5% of the firms indicated that they belonged to more than one of these categories; moreover, introducing firm type as additional mediating variable would have resulted in splitting the data into subsamples too small to conduct structural equation modeling while keeping all hypothesized model paths. A fourth, and more general, drawback is that I measured performance

by focusing only on financial aspects of organizational success. Expanding the measurement of performance to include further determinants of organizational success at the firm (e.g., failure), product (e.g., portfolio management and streamlining), staff (e.g., employee commitment and retention), or customer (e.g., patient safety and satisfaction) levels might help scholars further the study of organizational change capacity beyond the prevalent logic of looking solely at indicators that capture economic growth and profitability.

Future research

This study offers a number of avenues for future research on factors that help or hinder firms as they respond to changes in their regulatory environment. To this aim, special attention must be paid to cultural differences, because these may affect important outcomes, such as performance (Rosenbusch et al., 2011) and its determinants, including change capacity (Judge and Douglas, 2009) and innovative activities (Jones and Davis, 2000). Because the bulk of studies on the topic of organizational capacity have focused thus far on industrialized countries, and the United States in particular, directing more of our attention to emerging economies would enrich the field. Additionally, both scholars and practitioners would benefit from knowing more about how the global pandemic of coronavirus disease 2019 (COVID-19) affects an organization's capacity for change, and whether change-capable firms will manage to overcome the challenges of the pandemic in a more efficient manner. In their attempt to address these research gaps, future researchers should ideally strive to conduct longitudinal studies in order to observe the effects of a shifting regulatory environment on change capacity over time. Moreover, future researchers may wish to expand the scope of this study by including frontline employees, or comparing the medical device industry to other life science industries such as pharmaceuticals.

Policy implications

The MDR became fully applicable on 26th May 2021 after a transitional period of four years, overhauling the safety and performance requirements medical devices must fulfil in order to enter and remain on the internal European market. The considerable time lag between the realization that the regulatory regime needed to be revised and the passing of the law (Shatrov and Blankart, 2021) demonstrates how the pace of innovation in high-tech industries like that for medical devices—and presumably in the life science industries in general—can exceed that of regulatory regimes and policy making more generally. Depending on the stock of knowledge and entrepreneurial boldness of a firm, this gap between legislation and innovation capacity may cause harm, either by impeding technological advance or compromising product and patient safety. When it comes to the medical device industry, the findings of various researchers suggest that a regulatory framework that is not fit for purpose has oscillated between seriously jeopardizing public health in the past (Heneghan et al., 2012; Heneghan et al., 2017) and hampering research and development activities in the present (Miclăuş et al., 2019; Tarricone et al., 2020).

Challenged by the new MDR, medical devices firms must now paving the way for organizational change while, ideally, striking the right balance between exploiting their field of activity and exploring new business opportunities. The results of the present study suggest that it might be worthwhile for policy makers to target support towards small and young firms because these may have difficulties coping with the challenges of a regulatory environment marked by transition and uncertainty. One solution might be to consider temporarily extending the validity of medical devices certified under the regulatory framework preceding the MDR, albeit only if there is sound empirical evidence that the products in question have no (close) substitutes *and* have been shown to be safe and effective in the past may otherwise be withdrawn from the market. This is

especially important to consider if such products are used to treat rare diseases or might help ameliorate the COVID-19 pandemic. In case the help of legislators or regulatory authorities comes late or does not come at all, managers may still be able to respond aptly to shifts in their regulatory environment by enhancing the change capacity of their organizations.

CHAPTER 4
IMPROVING HEALTH CARE FROM THE BOTTOM UP: FACTORS FOR THE SUCCESSFUL IMPLEMENTATION OF KAIZEN IN ACUTE CARE HOSPITALS[3]

[3] By the authors Kosta Shatrov, Camilla Pessina, Kaspar Huber, Bernhard Thomet, Andreas Gutzeit, and Carl Rudolf Blankart. Published with the same title in PLOS ONE (2021).

Introduction

Kaizen is a management approach that aims for the continuous, incremental improvement of an organization. If implemented successfully, it empowers employees, regardless of their hierarchy level, to address problems and take actions to solve them (Imai, 1986). The concept promotes organizational change and a culture of continuous improvement with the ultimate goals of avoiding waste and increasing quality throughout the organization (Bhuiyan and Baghel, 2005). In this context, improvement is regarded as a recurring process and not a project with a predefined timeframe. Kaizen encompasses the real-time assessment and quick implementation of ideas from the bottom up, ultimately resulting in small but substantial improvements (Knechtges and Decker, 2014). Employees are able to make suggestions and decide which ones to implement (Mazzocato et al., 2016), which typically requires infrastructure that reduces barriers to reporting problems, and facilitates the adoption of ideas. Examples include suggestion boxes, discussion rounds, and interactive dashboards tracking how ideas are implemented.

Increased health spending in recent decades has led many health care providers to take measures to contain costs. This trend is especially true for countries that refund inpatient care treatments through diagnosis-related groups, a reimbursement system that induces hospitals to focus on cost-efficiency by providing financial incentives to deliver health care at below-average costs. When faced with the objective of reducing costs and improving quality, hospitals that organize their activities around core business processes in a structured way obtain higher levels of efficiency (Vera and Kuntz, 2007). Kaizen offers managers the opportunity to provide high-quality care and increase organizational performance while maintaining cost efficiency. Promoting employee engagement affects performance at the organizational, team, and individual levels (Bailey et al., 2017), and also boosts job satisfaction and commitment to the workplace (Glew et

al., 1995). By expanding the role of less senior employees, whether formally or informally, managers can reinforce employee participation in decision making (Glew et al., 1995). More generally, continuous improvement techniques result in a series of tangible outcomes, such as reductions in errors or costs, and intangible outcomes, such as increased autonomy and employee motivation (Comtois et al., 2013; Radnor and Boaden, 2008). Given that continuous improvement techniques like kaizen can benefit both the organization (e.g., by reducing costs), and the individual (e.g., by increasing job satisfaction) (Comtois et al., 2013; Iannettoni et al., 2011; Knechtges and Decker, 2014), it is hardly surprising that they, as well as the broader concept of lean methodology, have been applied widely by health care organizations in recent decades (D'Andreamatteo et al., 2015; Filser et al., 2017; Jacobson et al., 2009; New et al., 2016). Encouraging employees to contribute to decision making has thus become a widespread management practice, which, however, varies widely in terms of its implementation and outcomes.

While research on continuous improvement techniques in health care is plentiful, it has given short shrift to cases of less successful implementation (D'Andreamatteo et al., 2015), and to the interrelationship between implementation and staff (Filser et al., 2017). This gap in the literature is unfortunate considering that (1) much can be learned from failures of implementation (D'Andreamatteo et al., 2015; Edmondson, 2004) and (2) integrating frontline employees is crucial to the success of continuous improvement techniques (Jørgensen et al., 2003; Young et al., 2004). We aimed to address this gap by exploring the implementation of kaizen in two private acute care hospitals in Switzerland. In doing so, we capitalized on three aspects of our study design to advance scholarly and practitioner knowledge of continuous improvement management techniques: First, we exploited the variation between two distinct approaches to implementing kaizen, e.g., in terms of how managers set goals aiming to measure the implementation of the technique. Second, we

sought to understand the experiences of nursing staff with the implementation of kaizen. We chose to focus on this professional group because both sites had implemented kaizen specifically to provide nurses with the opportunity to improve their workplace. Additionally, nurses—unlike physicians—had few other opportunities to contribute to decision making related to the organization of the hospitals of interest. Lastly, by offering evidence from outside the widely studied cases of the United States and the United Kingdom (D'Andreamatteo et al., 2015; Filser et al., 2017), we aimed to support mutual learning among countries with different health systems and traditions of nursing education and practice.

A general comparison of public and private hospitals in Switzerland

Inpatient care in Switzerland is reimbursed by health insurers at a flat rate based on diagnosis related groups (World Health Organization. Regional Office for Europe, European Observatory on Health Systems and Policies et al., 2015). This system was introduced in Switzerland in 2012 and applies to all hospitals regardless of their ownership status or profit-orientation. In 2013, about 30% of all acute care hospitals in Switzerland were privately owned, and provided mostly standard surgical and elective treatments (World Health Organization. Regional Office for Europe, European Observatory on Health Systems and Policies et al., 2015). Farsi and Filippini have shown that there are generally no significant differences in cost-efficiency between Swiss hospitals of different ownership status; rather, the cost-driving factors are higher levels of teaching activities in some hospitals and a broader range of specialization in others, and both are associated with lower cost-efficiency (Farsi and Filippini, 2008).

Although the two hospitals that participated in our study were private and profit-oriented, they were comparable to public and non-profit hospitals in terms of a wide range of indicators, including the number of outpatient consultations, number of days in inpatient care, staffing (measured in full-

time equivalents), and the overall complexity of treatments provided (measured by a case mix index) (Hauser et al., 2020). However, there are some important differences between the hospitals examined in this study and the average Swiss hospital, public ones in particular. The most important difference is that the majority of specialist physicians in the two participating hospitals were not employed by the hospitals but affiliated with them and hired as locums. These physicians provided treatment to patients by renting the infrastructure of the hospital and a team of supporting physicians (anesthetists, emergency and intensive care physicians). Some of the specialists were nevertheless directly employed by the hospitals or had post-doctoral degrees and a range of teaching tasks, something that would be more typical of a university hospital. Second, compared to the Swiss median, the two hospitals treated a larger proportion of patients who had a private insurance plan. Such plans enable the patients to choose their treating physician and to stay in a single-bed room. Lastly, although both public and private hospitals have the same range of tasks and obligations in Switzerland, private hospitals are not eligible for public funding in certain domains, such as investments in building infrastructure.

Importantly, the two hospitals are not exclusive private clinics, but an integral part of the Swiss health system in their provision of general acute care. In Switzerland, private hospitals are reimbursed in the same manner as public ones, resulting in financial incentives that are independent of ownership status and profit orientation. The Swiss hospital sector comprises a spectrum ranging from non-profit university hospitals funded by public funds that usually treat the most complex cases to niche private hospitals working almost exclusively with privately insured patients and focusing on selective treatments. Overall, the two hospitals we examined are—irrespective of the important features discussed above—fairly similar to what can be described as the average Swiss hospital.

Methodology

Ethics approval

The study design, the interview guide, and our data management concept were approved by the ethics committee of the Faculty of Business, Economics and Social Sciences of the University of Bern (Date: 2018-05-08; Process number: 180503_1).

Study design

The main purposes of our study design were to (1) explore nurses' perceptions of kaizen, and (2) derive factors that affect the implementation of the technique from a direct comparison of two acute care hospitals. Based on the Organizational Transformation Model (OTM) developed by Lukas, et al. (2007), we created a semi-structured interview guide (the full version of which can be found in the S1 Table). Table 7 provides an overview of the content and structure of the interview guide.

Table 7. Sample interview questions.

Organizational transformation via kaizen	
Impetus to transform	• In your opinion, why were you given the opportunity to make suggestions for improvement with the kaizen technique? • How important do you think is it to your supervisor that you work independently?
Leadership	• How would you describe the general support of hospital management in your daily job? • What was the reaction of your supervisor to a kaizen suggestion you made?
Staff engagement	• Have you already made any suggestions? • Could you give an example of a suggestion you have made for solving a specific problem? • Would your participation behavior change if you had no access to the kaizen tools?

Organizational transformation via kaizen	
Alignment	• What was the impact of your suggestions? How were they implemented? • Do you have specific responsibilities within the kaizen technique and how do you exercise them?
Integration	• The staff in your ward is encouraged to report problems and make suggestions for improvement, is that correct? Can you please describe what this looks like in practice? • What is the impact of kaizen on the way your ward operates? • How important is the opinion of the nursing staff at the hospital?
Commitment	• Does performing kaizen affect your attitude towards the hospital as employer? • Does the opportunity to express your opinion have any influence on your willingness to continue to work at the hospital?

We would expect that OTM is a suitable framework for our study design because it was developed during a series of case studies in private sector health care organizations. The OTM describes five drivers that are crucial to transforming patient care successfully: (1) impetus to transform; (2) leadership commitment to quality and change; (3) staff engagement in improvement initiatives; (4) alignment of an organization's goals with resource allocation; and (5) overcoming of boundaries between the constituent parts of the organization so that it operates as a fully interconnected system, pursuing the overarching goals of the organization.

In order to gain insights that would be valuable to both scholars and practitioners (Corley and Gioia, 2011) and to extend the scope of qualitative research in this area (Bansal and Corley, 2011), we added an additional driver to the OTM framework—employee commitment—to describe employees' attachment to the organization or to parts of it, such as their supervisors (Becker et al., 1996). Organizational change initiatives may affect employee commitment to the change itself or to the whole organization (Fedor et al., 2006). Given the positive general association between commitment and participation (Bailey et al., 2017; Meyer and Allen, 1991; Scott-Ladd et al., 2006),

the opportunity to contribute to the improvement of the workplace may increase nurses' willingness to stay at a hospital.

Data collection

Following the guidelines of Gill, et al. (2008), we conducted semi-structured interviews with 30 nurses in May 2018. The two hospitals (hereinafter referred to as Hospital A and Hospital B) had recently implemented kaizen and were open to the idea of exploring nurses' experiences with the implementation of the technique. We selected these two hospitals because medical experts and representatives of their management teams (AG, KH, BT) had indicated that the sites were fairly similar in terms of size and specialization, but differed in the way kaizen had been applied. Both hospitals were medium in size, profit-oriented, located in Switzerland, and belonged to the same corporation. The hospitals were comparable in terms of the average length of stay (5.0 vs. 5.6 days), bed occupancy rate (84.8% vs. 84.2%), number of newborns (827 vs. 860), and number of emergency admissions (4,316 vs. 4,212) in the fiscal year 2017/2018. In the same fiscal year, the first hospital (Hospital A) was smaller than the second one (Hospital B) in terms of the number of beds (196 vs. 333), patients (12,198 vs. 18,389), and employees (1,377 vs. 2,128) (Hirslanden, 2018).

In Hospital A, an implementation working group, whose main objective was to set out the conditions for the nursing teams to be able to start contributing ideas, was appointed by the management team of the hospital at the beginning of the implementation phase. To communicate the concept of kaizen to the staff in all units, the working groups defined a set of general and specific aims. While the general aims involved encouraging nurses to seek to identify problems in the workplace and subsequently solve them, the specific ones defined concrete measures intending to facilitate collaboration. Such specific measures included the advice that kaizen meetings should

be held on a regular basis and that nurses should aspire to be role models to their colleagues from other units by working with and for each other. Lastly, the process of implementing kaizen was represented graphically in the recreation rooms of Hospital A and defined in five steps as follows: (1) identify waste; (2) make an improvement suggestion; (3) prioritize the suggestion and define action to implement it; (4) take the defined actions; (5) measure the success of the actions.

The initial phase of implementing kaizen was defined in a similar way in Hospital B. Together, the quality management team and the nursing team of the hospital elaborated a strategy to design the way in which kaizen would be implemented in all inpatient care units. The strategy of Hospital B sought to encourage employees to question existing working procedures, inform their colleagues in case action is required, and eventually make a collective effort to improve their workplace. In addition, responsible persons received special training and subsequently served as an important reference point to the rest of team.

By means of purposeful sampling (Patton, 2015), we selected 15 nurses from each hospital to obtain an information-rich sample that was balanced in terms of age, gender, tenure, and specialization. Our sample included nurses from several units, including orthopedics, gynecology, and thyroid diseases treatment. The nurses comprised 28 women and two men, of whom 11 were in training—some of whom had recently started working for the hospital—and 19 had professional qualifications. Five of the latter occupied senior positions, such as head nurse. We informed all nurses in advance that they would receive a small thank you gift after completing the study. After being introduced to the study purpose and design, all participants gave their written informed consent to be interviewed and recorded. Interviews lasted an average of 26 minutes [range: 15-38 min].

Analysis

The interviewer (CP) used the recordings to (1) transcribe the interviews, including pauses, filler words (e.g., "hmm"), and important non-verbal reactions (e.g., laughing), and, (2) to conduct a qualitative content analysis of the transcribed interviews in MAXQDA (Version 18.0.8). First, we identified patterns in the text and grouped these into overarching themes to develop an in-depth understanding of the interviews. The full list of themes, categories, and marker words we used to conduct the content analysis of the transcribed interviews can be found in S2 Table. The next step was to summarize the interviews by exporting quotes into a structured matrix organized by site, interviewee, and question (see S3 Table). Then, we applied the OTM framework revising the influencing factors suggested by Sullivan, et al. (2018), who recently validated the framework by assessing the implementation of a pilot health care services program in long-term care facilities. In the next step, to enhance the credibility of analysis (Lincoln and Guba, 1985), two researchers (KS and RB) used the OTM framework to analyze the interviews. The two analysts independently assigned each of the quotes to one of the six influencing factors and their sub-categories: (1) nurses' perspectives, (2) job commitment and satisfaction, (3) team dynamics and processes, (4) infrastructure availability and adoption, (5) human resources and staffing, and (6) resource allocation and culture. Auxiliary evidence from the interview notes was considered if needed. After an initial agreement of 68% between the two analysts, we refined some sub-categories and developed categorization rules to avoid ambiguity (see S1 Fig. for illustration and S4 Table for an overview of the categorization rules). In a second iteration, applying the categorization rules

increased overall agreement between authors to 90%. In the final iteration, the two analysts resolved any disagreements in their categorization by reaching consensus through discussion.

After analyzing the interviews using the OTM framework, we interpreted our findings within the scope of the two-factor motivation theory, which posits that certain factors influence employee motivation at the workplace (Herzberg et al., 1959). The theory distinguishes between hygiene factors that lead to dissatisfaction and motivational factors that boost employee satisfaction. The core of the theory is that both types of factor do not build a continuum – that is, hygiene factors cannot yield satisfaction, and motivational factors are not associated with dissatisfaction. More specifically, hygiene factors comprise the working conditions that managers need to provide to prevent their employees from losing motivation and becoming unhappy with their workplace (e.g., due to unsafe work practices or conditions), whereas motivational factors comprise the working conditions that should increase employees' job satisfaction and keep their motivation high (e.g., work practices promoting employees' sense of achievement). Even though the validity of Herzberg's theory has been called into question because working conditions have changed significantly since the theory was initially proposed in the late 1950s, Bassett-Jones and Lloyd have demonstrated that the underlying idea of the two-factor theory still has utility in a contemporary organizational context (2005). By interpreting our findings within the scope of the two-factor motivation theory, we aim to provide health care practitioners with insights into factors—at the individual and organizational levels—that may either increase or decrease the motivation of nurses to participate in kaizen.

Results

Based on our examination of how hospital nurses used kaizen, we identified a range of specific individual and organizational factors that affected the implementation of the management approach. Overall, nurses experienced kaizen as a positive practice that promoted teamwork and provided them with an opportunity to participate in decision making and contribute to the continuous improvement of the hospital. Most nurses in both hospitals participated in kaizen by attending regular meetings, reporting problems, and making suggestions regarding the availability of resources and patient well-being. Table 8 presents some illustrative quotes assigned to the respective influencing factor derived from the modified OTM framework. Additional illustrative quotes—originating from nurses of different age, gender, tenure, and specialty—that support our findings have been included in the results section.

Table 8. Illustrative quotes assigned to corresponding influencing factors.

Influencing factor	**Sub-category**	**Illustrative quote**
Nurses' perspectives	• Nurses participate in kaizen by making suggestions and/or implementing ideas • Nurses support the use of kaizen at the hospital • Other perceptions of kaizen and its importance	"It's hard to say... [what the importance of kaizen is.] Well, it is important, but yes, of course, I also have more important tasks." (Hospital A/08) "Our ideas mostly refer to improvements in terms of quality and time management. For example, how we can organize rooms to save space, which additional equipment we need or don't use so often." (Hospital B/20)
Job commitment and satisfaction	• Kaizen increases commitment to the hospital • Kaizen increases overall job satisfaction	"I enjoy sharing my opinion and making suggestions, but… I'd still work here even if there were no kaizen." (Hospital A/14) "No. No [link between kaizen willingness to stay]. We are free people, we can quit and go or we can stay." (Hospital B/29)

Influencing factor	Sub-category	Illustrative quote
Team dynamics and processes	• How well staff fit with kaizen either through commitment to the program vision and/or experience and skills needed for successful implementation • Teamwork, coordination, and cohesion in terms of how well hospital staff work together, support each other, and create a collaborative work environment • There is a clearly pre-defined process/structured way in which kaizen works	"The head nurse collects the opinions of everyone, and we discuss our ideas. She considers our suggestions and draws conclusions from our opinions. It works out very well." (Hospital A/03) "If many of my colleagues come up with good suggestions, then that motivates me to think more about what can be improved." (Hospital B/18) "The team meeting gives us structure […] At the same time, it's hard to make a meaningful contribution if you desperately need to do something or you're quite busy." (Hospital B/21)
Infrastructure availability and adoption	• Infrastructure needed for the sustainable implementation of kaizen is available and accessible, e.g. dashboards, regular meetings • Nurses make use of the kaizen infrastructure provided	"I like the circle [a pie chart illustrating the progress of implementing suggestions; a part of the kaizen dashboard] […] it's like a reminder." (Hospital A/06) "We have a kaizen training, in which the system is explained and applied. I think this is good for employees who are new and have no previous experience with the system." (Hospital A/07)
Human resources and staffing	• Constraints with existing staff, e.g. short-staffed, not enough time to include kaizen in the work routine • High staff turnover/extensive use of agency staff	"What I find very often a pity, quite a pity, is that the nursing staff in general has far too little time for nursing." (Hospital A/09) "We are understaffed and rely on agency staff. These employees don't belong to us. […] They don't have the same responsibilities as we do. And if there's something they don't know, we have to spend extra time to help them." (Hospital B/29)
Resource allocation and culture	• The adequacy of resources dedicated to kaizen implementation and/or achieving sustainable results • Management shows general support and/or is persistent in encouraging the implementation of kaizen • Management has established a culture that promotes open dialog and/or tolerates failure	"No, that's no problem [if colleagues don't agree with me]. It's really a platform where everybody can express their own opinion." (Hospital A/04) "Sometimes we work with very dominant physicians, and you can feel the hierarchy. In some situations, I thought 'I'd better not say anything' [...] I lacked the courage to speak up, because of the hierarchy." (Hospital A/14) "It's difficult, when you address a problem, and your opinion is kind of accepted, but it's always accompanied by an excuse that defends the underlying problem. That makes it a bit difficult to discuss in the first place." (Hospital B/27)

The remainder of this section is organized around the six influencing factors derived from the OTM, starting with the individual factors and then moving on to the organizational ones.

Individual factors

Nurses' perspectives

Experience and seniority seemed to affect the willingness of nurses to share their opinion in front of colleagues, especially in Hospital A:

> *'Four and a half years ago, when I was still a trainee, I had the impression that we weren't allowed to say very much, and I was a bit more cautious about what I was allowed to say and what not; and now, as a full-time employee, I've noticed that every opinion counts' (Hospital A/07)*

Less experienced nurses were indeed often reluctant to speak their mind. Nonetheless, they appreciated that kaizen gave them an equal chance to contribute ideas. In Hospital B, however, two nurses stated that they had had no experience with kaizen in their hospital so far, and three others suggested that they had not used kaizen in their unit (although they went on to describe having used structures typical of kaizen, such as dashboards, regular team meetings, and goal setting).

Job satisfaction and commitment

At both hospitals, kaizen seemed to evoke positive feelings among many nurses, who reported feeling valued, understood, and confident. The majority of our interviewees appreciated having had the chance to contribute their ideas, and some nurses noted that working as a team towards the goal of improving working conditions had increased their job satisfaction somewhat. In addition, many nurses—mostly in Hospital A—agreed that kaizen promoted individual decisional power. Although not decisive in itself, the kaizen-related policy that every person's opinion counts

increased nurses' willingness to work for the hospital, albeit only marginally and only in Hospital A. Especially in that hospital, the feeling that one's ideas were being considered appeared to boost overall motivation. In contrast, some nurses in Hospital B felt that the new management practice was not being implemented properly—partially because of the profit-orientation of the hospital—generating a negative emotional response and, to a certain extent, decreasing employee motivation:

> *'I would like to be able to provide my patients with high-quality, evidence-based care, and that's only possible if certain preconditions are met. If […] you are constantly short on staff because of the profit situation here in a private hospital […] then you get demotivated' (Hospital B/27)*

Organizational factors

Team dynamics and processes

Nurses in both hospitals generally agreed that team meetings promoted collaboration:

> *'Once a month, the kaizen [meeting] takes place and the employees meet in the office. […] The problems are then discussed within the team, and we see what can be improved, what the options are, and which person or people are responsible for implementing it' (Hospital A/12)*

Moreover, discussing work-related problems made nurses feel part of the team and the hospital. Many nurses said that they appreciated the contributions of new employees because they felt their perspectives were innovative and unconventional. The cross-hierarchy exchange, moreover, was generally regarded as meaningful and constructive. However, nurses also indicated that there was still a need for better coordination of working routines, including agenda-setting:

'Well, sometimes there are too many [kaizen] targets, and you don't even look at them anymore. I think that's a bit of a shame' (Hospital B/30)

Both hospitals implemented kaizen in a similar way. Regular discussion rounds were introduced—up to once in a fortnight in Hospital A and on a weekly basis in Hospital B—and kaizen dashboards were installed in all units. The dashboards represented whiteboards, so nurses were able to make improvement suggestions and track their status by documenting their ideas using markers and post-it notes. The dashboards had been placed in easily accessible places such as break rooms and kitchens. Nevertheless, there were also some differences. Hospital A started implementing kaizen in 2010; Hospital B did so in 2011—first in all inpatient departments, and two years later in the intensive care unit. Although the dashboards in both hospitals were divided into sections that were devoted to the tasks of contributing ideas and defining a set of actions for their implementation, Hospital B did not use a pie diagram to visualize the implementation status of ideas. Hospital A offered compulsory introductory training to all nurses. In Hospital B, however, the quality management team visited units to answer any questions nurses had during the initial phase of implementation. Hospital A set the goal of implementing 20 ideas in each unit per year, whereas Hospital B aimed to have 36 meetings dedicated to kaizen during the first year of implementation. Within this year, Hospital A implemented 958 suggestions in total, whereas Hospital B implemented 321 suggestions.

In Hospital A, all nurses were encouraged to make suggestions, which were then evaluated and prioritized by an assigned person, and implemented by the entire team. Nurses in this hospital seemed aware that they had to contribute ideas to make kaizen work, and emphasized that the each-opinion-counts policy reinforced team cohesion. These perceptions were less evident in Hospital

B, where a few employees nonetheless stated that they associated kaizen with meeting colleagues and discussing current issues.

Infrastructure

The majority of nurses highlighted that the regular discussion rounds were important because they animated everyone to exchange views and contribute ideas. Nurses at Hospital A appreciated tools such as dashboards and sticky notes, because they facilitated the flow of information and implementation of change initiatives. In the same hospital, one nurse asserted that kaizen tools encouraged less motivated employees to become more active. Dashboards, for instance, enabled ideas to be submitted and prioritized, tasks to be assigned, and their implementation status to be tracked:

> *'Sometimes there are things that can be implemented immediately […] and sometimes there are things that need to be purchased first, and that takes longer. That's why we have […] something like a cake... [a pie chart]. It has four parts, and you can always fill in the part as soon as the process has been completed' (Hospital A/04)*

Monitoring tools and introductory lessons, which were highly appreciated in Hospital A, were also present—although less common—in Hospital B:

> *'No, not really [in response to the question whether an introductory training had been offered]. I cannot really tell you [how kaizen works]' (Hospital B/18)*

In Hospital B, kaizen was occasionally regarded as a tool only to address problems rather than as opportunity to trigger change in a proactive way, and some nurses even felt that kaizen could be applied only if somebody else made a suggestion. Kaizen was sometimes described as time consuming because of the many meetings and occasional discussions of the correct way to

implement the technique that were taking place. One nurse in Hospital B suggested, however, that kaizen structures and responsibilities had recently been defined more clearly.

Human resources and staffing

Most nurses agreed that nursing is a tough job and prioritizing tasks is demanding. Overall, nurses did not always manage to engage in kaizen because they assigned higher priority to patient care. Nevertheless, nurses—mostly those in Hospital A—were aware that kaizen was an integral part of their work and even a way to reduce workload over the long term. Stress, however, was a recurring topic at both sites. Describing their daily routines, nurses often suggested that they felt under pressure. In Hospital B, stress levels seemed to be higher due to job fluctuation, the use of agency staff, and a lack of manpower:

> *'I think time management is a huge problem, because creativity […] takes time, and employees simply do not have time for that' (Hospital B/17)*

Many nurses who had regular contracts at Hospital B did not regard agency nurses as equal team members, nor did they support the policy of hiring agency staff, who they felt put in less effort and were less familiar with the working methods. Additionally, the nurses in this hospital occasionally attributed difficulties in implementing kaizen to the agency staff:

> *'Well, we are currently using it [kaizen] a bit less because there is an extreme shortage of staff, and so many agency staff are coming in; and the agency staff don't participate in kaizen—they take care of their patients and that's it' (Hospital B/19)*

Resource allocation and culture

Organizational culture was another key factor that affected participation. In Hospital A, one nurse suggested that individual units probably interpreted kaizen differently according to their own culture:

'And, naturally, depending on the culture [of the hospital department or individual stations], kaizen is implemented differently; because to keep it going with a high level of commitment you need a certain culture of openness on the team, so that you can sometimes also suggest an idea that might sound a little bit crazy—maybe something will come out of it' (Hospital A/10)

Nurses in Hospital A seemed to be generally satisfied with the support they had received from hospital management and also cited the role of the head nurse as a leading figure. They also agreed more often than nurses in Hospital B that management was open to new ideas. Though more pronounced in Hospital B, hierarchy was present in both hospitals:

'They [the physicians] don't say "hello", they don't look you in the eye... you often have the feeling they are something much better […] Well, not all the doctors, but many are like that' (Hospital B/25)

Nevertheless, nurses in both hospitals admitted that they needed more supervision and that they expected a person to be in charge of implementation (e.g., head nurse) and guide them in practicing kaizen.

Some nurses in Hospital B attributed lukewarm participation levels to a lack of sustainable results in their units:

'At the beginning it [kaizen] has an effect – I would say for about […] 4 weeks, or even only for 10 days, and then a lot, not everything, but a lot is forgotten' (Hospital B/28)

In addition, the long time span between contributing an idea to improve the workplace and adopting it reinforced the view that kaizen was a rather laborious approach. This being said, many Hospital B nurses agreed that they needed to invest more time in kaizen to improve their work environment over the long run.

Positive and negative cases in direct comparison

Noting that the study of kaizen has focused so far on success stories, D'Andreamatteo, et al. (D'Andreamatteo et al., 2015) and Filser, et al. (Filser et al., 2017) advocate learning from examples of less effective implementation. With this in mind, we gained insights from comparing both of our participating hospitals in terms of (1) nurses' attitudes towards kaizen, (2) participative behavior, and (3) the results of implementing kaizen.

First, nurses' attitudes towards how kaizen had been implemented at the workplace differed between the hospitals. Nurses in Hospital B were less fond of engaging in kaizen, although they expressed their general willingness to contribute to the improvement of the hospital and recognized that kaizen is generally a useful practice. While Hospital B nurses reacted to the implementation of kaizen with a certain skepticism, nurses in Hospital A remained motivated to contribute ideas even if they did not always have time to adopt them immediately. Moreover, many nurses in Hospital B generally experienced kaizen as an additional workload imposed by management, whereas nurses in Hospital A were more likely to understand the approach as an integral part of the hospital's culture and their work that could help them improve working routines.

Next, the degree of participation in kaizen also differed. Even though kaizen structures were available in both hospitals, participation levels varied, for example due to a lack of leadership in individual units. Nurses who contributed their own ideas constituted the majority in Hospital A,

but not in Hospital B. In the latter, it seemed that many nurses hardly ever made suggestions, though they still attended meetings and implemented kaizen projects.

Finally, the results of implementing kaizen differed between the hospitals. In Hospital A, most nurses agreed that kaizen improved their workplace. In contrast, some of the nurses in Hospital B indicated that kaizen did not lead to visible results at all times, which they often attributed to high levels of stress. Although nurses in Hospital A also agreed that nursing was stressful, they did not see a contradiction in taking part in kaizen alongside their other duties, and mentioned a sense of doing something meaningful when engaging in kaizen more often.

Discussion

In this study of kaizen, we addressed the current research gap by focusing on the experiences of nursing staff and examining two opposing cases of kaizen implementation—one of which could be described as more successful than the other. We interviewed 30 nurses in two acute care hospitals in Switzerland. To obtain an information-rich sample, we selected nurses of different age, gender, tenure, and specialization. Our findings provide insights from a setting outside of the United States or the United Kingdom, which has been the almost exclusive focus of previous research in this area. In line with the literature (Scott-Ladd et al., 2006), we found evidence that participation in decision making—through kaizen—may increase job satisfaction, albeit only to a limited extent.

Our main finding, however, is that there seem to be two types of factor that affect how kaizen is implemented in hospital care. In Table 9 we summarize our findings by assigning them to either of the two categories suggested in Herzberg's two-factor theory (1959) in an attempt to specify which implementation measures affected nurses' motivation to participate in kaizen in what way—

either by preventing them from getting demotivated, or by boosting their motivation. As in the results section, we distinguish in this summary between influencing factors at the individual and organizational levels. Building upon Herzberg's theory, we want to sensitize health care practitioners to the idea that there are certain working conditions they need to focus on in order to prevent nursing staff from losing motivation to participate in kaizen in the first place (hygiene factors), and that other working conditions may lead to nurses participating more intensively in the continuous improvement of their hospital organization (motivational factors).

Table 9. Factors affecting nurses' motivation to participate in kaizen.

	Hygiene factors	**Motivational factors**
Individual level	• Management and head nurse leadership and support • Visibility of results	• Promoting everyday interactions • Adopting employee suggestions • Communicating the impact of kaizen activities
Organizational level	• Availability and accessibility of tools, e.g., dashboards • Clearly defined processes and roles • Team stability	• Culture of continuous improvement • Team cohesion

Strategies for the successful implementation of kaizen

Additionally, we identified several factors that influenced the implementation of kaizen in hospital care. Overall, the two hospitals we examined implemented kaizen by introducing a specific target to be achieved on a yearly basis, as well as regular discussion rounds and communication tools to facilitate the adoption of ideas. Hospital A seemed, however, to have capitalized on the potential of kaizen because it managed to implement the approach in a more structured and purposeful way, focusing on outcomes more than process. For instance, Hospital A defined the

number of kaizen *ideas* to be adopted on a yearly basis as a target to be pursued by nurses, whereas Hospital B used the number of *meetings* held. Based on these and our other findings, we suggest six coping strategies for implementing the approach in hospital care. Depending on whether they relate to behavioral patterns that specific team members may need to pursue, or, instead, processes and structures that health professionals might wish to establish, the following strategies are assigned to either the individual or organizational level of acute care hospital systems:

Individual level

First, managers have to support nurses with expert assistance and advice. At both sites, nurses often expected managers not only to show them how a problem could be solved if they could not think of a solution right away, but to support them in implementing the solution. Many unexperienced nurses were reluctant to share their opinion, even though their ideas were often appreciated by their senior colleagues. Managers should therefore encourage the entire team to engage with kaizen and explain the benefits of sharing ideas. Some interviewees suggested that head nurses might also take on this role given that they are seen as important reference persons to other nurses. Indeed, support and leadership have been identified as essential preconditions for employee participation and the sustained implementation of change initiatives (D'Andreamatteo et al., 2015; Edmondson, 2004; Knechtges and Decker, 2014; Vera and Kuntz, 2007). Moreover, employees may have difficulty admitting that they have been doing things wrong for years and adjusting the way they work accordingly (Vera and Kuntz, 2007). Our findings indicate that managers also have to create an open-minded work environment that promotes collaboration, self-criticism, and an efficient flow of information to make change possible. Authentic and trustworthy leadership may indeed improve the work environment, encourage team members to voice their concerns, and increase the perceived quality of care among nurses (Wong et al., 2010). Conversely,

a poor relationship with supervisors has been shown to decrease employees' willingness to contribute ideas (Bassett-Jones and Lloyd, 2005).

Second, managers should promote everyday interactions across hierarchy levels and convincingly demonstrate to nurses that each of their opinions counts. Most nurses we interviewed enjoyed an increased sense of employee equality while participating in kaizen. Additionally, nurses widely associated kaizen with employee empowerment because it gave them a voice in decision making. This result is in line with previous research, which shows that hospital employees appreciate being able to act more autonomously by participating in continuous improvement activities (Drotz and Poksinska, 2014). Although most nurses admitted that they generally had only limited scope to make managerial decisions, they enjoyed reorganizing their workplace through kaizen. We therefore conclude that nurses should not have the impression that supervisors make all the decisions. It is indeed important to leave some leeway for self-initiative and self-coordination (Comtois et al., 2013) and to establish a corporate culture that eschews the traditional top-down approach to improvement initiatives (Collar et al., 2012; Zaheer et al., 2015). Additionally, giving employees more autonomy may boost motivation and augment the perceived value of their actions (Gagné et al., 2000). Leadership has the special task of finding the right balance between enabling the team to contribute and discuss ideas autonomously, and judiciously intervening in the prioritization and execution of suggestions.

Third, nurses need to see that their actions lead to meaningful results. In both hospitals, nurses seemed to lose patience and participate less if they had the feeling that kaizen was being implemented as an end in itself. In Hospital B, the absence of short-term results in some units was seen as proof that kaizen did not work, demotivating nurses. Therefore, managers should demonstrate to nurses that kaizen improves their workplace and the quality of care.

Edmondson (2004) as well as Mazzocato, et al. (2016) also underlined the importance of continuously sharing insights and results with staff to keep motivation high. Indeed, the perceived success of adopted ideas has been shown to influence employee motivation to participate (Gagné et al., 2000). Our findings suggest, moreover, that motivation to participate may suffer if hospital staff sees kaizen only as a means to improve the financial performance of the hospital and not as a way to increase patient well-being. Furthermore, managers should recognize that nursing may be stressful, and nurses cannot always engage in kaizen because their main obligation is to care for patients. Nevertheless, to make kaizen work, nurses need to participate regularly.

Organizational level

Fourth, managers need to create a culture of continuous improvement. Many nurses had the impression that physicians did not always accept their suggestions or take their concerns seriously. This is unfortunate given that open dialog and a change-friendly work atmosphere have been shown to be essential for successful continuous improvement (Drotz and Poksinska, 2014). With this in mind, both physicians and managers should continuously encourage nurses to report problems and propose solutions to solve them. Previous research also suggests that continuous improvement initiatives must be integrated into organizational culture to be successful (Clark et al., 2013) and are not something that can be introduced all at once because change should take place gradually and not radically (Vera and Kuntz, 2007). Imai described kaizen as a state of mind as opposed to a finite task (1986). To be implemented successfully, kaizen should not be seen as an independent activity, but rather as complementary to usual work (Simon and Canacari, 2012). We found support for the idea that managers need to dedicate sufficient resources to implementing kaizen—especially in its initial phase—if they want nurses to perceive the approach as part of their work and to participate continuously.

Fifth, policies that weld the team together are fundamental. Combining teamwork training with continuous improvement initiatives may not only enhance process measures, but also improve quality outcomes, such as patient safety (Robertson et al., 2015). Not all nurses participated in kaizen by contributing their own ideas, and in Hospital B some nurses did not participate at all. Yet we found that nurses who participated regularly tended to enjoy the approach because it facilitated teamwork and promoted team spirit. This result is consistent with the work of Knechtges and Decker (2014), who describe teamwork as critical to implementing kaizen successfully, and of Drotz and Poksinska (2014), who show that all team members should contribute to make change happen. We also observed that understaffing seemed to impede participation. Additionally, managers who relied on agency staff and units with high staff turnover experienced challenges to keep everybody involved. Managers may therefore want to avoid allowing a heavy workload to undermine the integration of continuous improvement programs in work routines. This result is in line with previous literature that has shown long-lasting groups to achieve better outcomes (Brännmark and Holden, 2013).

Finally, health care practitioners need to implement kaizen in a structured way. Providing staff members with fixed times and physical space for collaboration is important for implementing continuous improvement techniques successfully (New et al., 2016). The well-defined responsibilities and processes in Hospital A made the approach clear to the entire team and fostered participation. By holding regular meetings, Hospital A established working routines to convey the message that kaizen is a team-oriented approach that must be performed on a regular basis. In both hospitals, although not equally successful, a number of communication tools integrated kaizen efficiently into the work routine. Dashboards, for example, made change initiatives

comprehensible, helped their implementation status to be tracked, and increased compliance with new codes of conduct.

Limitations and further research

Our study has several important limitations, some of which provide opportunities for further research, which we describe and discuss below.

One limitation of this study is that it included a small number of hospitals. Future efforts should strive to incorporate as many sites as feasible bearing in mind the specific constraints of the research project and context. Another limitation is that the two of the researchers (KS and RB) did not participate in the on-site interviews with the nurses. However, these researchers had the chance to familiarize themselves with the data (Braun and Clarke, 2006) by reading the transcribed interviews, having a series of discussions with the interviewer (CP), and receiving an introduction to the concept of kaizen and its principles by a team of medical experts (AG, KH, BT). Additionally, to help establish the trustworthiness of our qualitative research methods and results (Lincoln and Guba, 1985; Nowell et al., 2017), we sought to ensure dependability by providing thorough and transparent documentation of our research interest, methodological choices, and qualitative results in the manuscript and its supporting information (Tobin and Begley, 2004).

Nevertheless, there are two additional points to bear in mind when considering the transferability of our findings. First, the two acute care hospitals we examined in this study were private and profit-orientated. Although previous research on the hospital sector in Switzerland has shown that there is no significant relationship between (1) profit orientation and hospital ownership and (2) cost-efficiency (Farsi and Filippini, 2008), scholars may nevertheless wish to examine whether these organizational characteristics influence the way hospitals engage with continuous

improvement techniques. Furthermore, the hospitals we selected had implemented kaizen with differing degrees of success, which poses the further question of which characteristics are shared by hospitals that are equally successful at implementing kaizen. In this vein, it might be worthwhile in future research to enrich our conclusions by selecting organizations that have implemented the technique in a similar way but at different points in order to explore how the participation of employees evolves over time. Future research may also wish to expand the scope of this study by verifying whether its results hold in settings other than that of inpatient acute care, such as outpatient or long-term care.

Data collection is a second factor that should be considered when interpreting the findings of this study and judging their transferability. While the purposive technique we used to select the interviewees enabled us to gain deep insight into the work environment of both hospitals, it may also have led us to place a disproportionate amount of attention to some experiences the nurses had had with kaizen. For example, there were several interviewees who had started working in their unit fewer than six months before the interview and their observations may have been influenced by limited knowledge of the work context, the kaizen approach, or both. Yet, purposive sampling helps researchers obtain an in-depth understanding of the phenomenon of interest (Patton, 2015) and is therefore suited to our exploratory approach. When revisiting our work, future researchers could consider using other or additional sampling techniques such as snowball or maximum variation (Palinkas et al., 2015), thus aiming to identify key informants who could contribute additional insights and perceptions that would otherwise remain undiscovered. Moreover, according to the social-desirability argument—a common bias occurring in many areas of social sciences that rely on self-reporting values—interviewees may provide answers that do not reflect their real opinions but rather are convenient or socially acceptable (Fisher and Katz, 2000).

However, we do not expect reporting biases to have distorted our findings substantially because most nurses were not overly shy in criticizing hospital policies or the behaviors of their supervisors. By giving us an intimate look into their working place, the nurses enabled us not only to capture and explore their perceptions of kaizen, but also to realize that this managerial technique—no matter how beneficial it can be in some situations for both employee and organization—is not necessarily a panacea for all problems and aspirations managers may have.

Conclusion

When implemented successfully, kaizen can reinforce team spirit and increase job satisfaction and commitment among nursing staff in hospitals, enabling the continuous improvement of the organization. To reap these benefits, however, health care managers need to enable nurses to implement the approach in a structured and sustained manner. Drawing upon in-depth qualitative data from diverse examples of implementation, we suggest six strategies for doing so. Health care managers need to (1) show nursing staff how to implement kaizen whenever necessary; (2) endorse each-opinion-counts policies; (3) promulgate the progress achieved in a comprehensive *and* timely manner by showing the entire team how kaizen can improve quality of care; (4) establish an organizational culture that fosters open dialogue across hierarchy levels; (5) ensure team stability and cohesion; and (6) provide employees with infrastructure and communication tools that enable the adoption of ideas.

Employees are among the most important assets of any organization. We believe that the role of employees is even more decisive in non-consumer goods industries like health care because patients depend on the work of caregivers for high-quality treatment and psychological and emotional support. In our view, nursing teams who have more say in everyday decision-making

also have greater potential to increase patient satisfaction and quality outcomes. In this regard, kaizen offers health care professionals a practical way to improve the quality of care through small and continuous changes in their workplace.

CHAPTER 5
CONCLUSIONS

The findings of this dissertation showed that legal environments may shape health care provision in several ways. Looking at both market access and reimbursement regulation from different perspectives, this dissertation sought to provide two important stakeholders with policy implications—the ones who design legal environments, and the ones who are mainly affected by the design thereof. Addressing policy makers, practitioners, and scholars, I summarize the main implications of this work below. Finally, I conclude by describing some avenues for future research.

The medical device industry in regulatory turmoil

Even a brief look at the public health and medical literatures shows that not all interest groups that were involved in the making of the MDR were equally influential. While policy makers adopted many of the concerns shared by both medical doctors and patient organizations at the beginning of the consultation process, they eventually gave more weight to the interests of industry representatives, leaving out many of the heightened safety requirements initially envisaged (Bowers and Cohen, 2018). Undoubtedly, both types of interest—improving the safety of medical technology and protecting the financial interests of the industry—are legitimate. Policy makers, however, should bear in mind that industry representatives are generally better organized and have more resources than patient organizations, and weigh the diverging requests of these different stakeholder groups accordingly.

Discussing a range of specific regulatory issues that leave some room for improvement, in the first chapter of my dissertation I provided decision makers with a wide set of policy implications that they may want to consider in order to improve future regulation. My conclusion indicated that the MDR is highly likely to foster free trade because it harmonizes and specifies further the regulation of medical devices across the member states of the European internal market. The definitive impact of the new regulation on patient safety, however, remains unclear because, at least to date, there are no studies on this topic based on empirical data.

The link between organizational capacity for change and financial performance

To bridge the gap between the diverging opinions on the MDR, which I identified in Chapter 2, I devoted the third chapter of my thesis to measuring the initial impact of the new regulation on the medical device industry. My results suggest that higher levels of organizational capacity for change (OCC) are generally positively associated with financial performance ($p < 0.01$) but that small and medium-sized firms show higher levels of OCC ($p < 0.01$) and lower levels of performance than their larger competitors ($p < 0.01$). Furthermore, start-ups showed lower levels of financial performance than established firms ($p < 0.05$). I concluded with a set of practice implications, outlining (1) strategies business leaders may wish to pursue if they want to make their organizations more change-capable, and (2) measures policy makers could take to ensure that medical devices essential to protecting public health do not disappear from the market, especially in times of a global pandemic.

To improve the financial performance of their firms, practitioners could devote more effort to establishing an organizational culture that enables organizational change, promotes the free

exchange of opinions, and unites the staff by defining common values and goals. Moreover, if policy makers were to conduct economic policy that aims to help medical device firms to comply with the regulatory requirements of the new regulation, they would need to bear in mind that organizational characteristics such as firm size and age have been argued to be unreliable indicators when it comes to the economic value a firm adds to the market (Coad, 2018). Consequently, the fact that a firm is small, young, or both, is not necessarily a sufficient reason to grant aid to this firm (in the form of subsidies, tax benefits, countervailing measures etc.). To best allocate aid to firms in financial distress, policy makers may therefore want to focus on other indicators that represent a firm's market value in a more thorough manner. Such indicators should seek to capture whether firms contribute to public health by bringing on the market medical devices that are safer or more cost-efficient than those of their competitors. At the same time, future researchers need to determine whether the MDR forces firms to withdraw from the market and—probably more importantly—whether these potential exits negatively affect competition, consumer prices, or the quality of medical devices over the long term.

Improving health care from the bottom up

In Chapter 4, I showed how health care providers may implement kaizen management to mitigate unintended negative consequences related to the introduction of a reimbursement regulation based on diagnosis-related groups. Overall, nurses experienced kaizen as a positive practice that enabled them to discuss work-related activities in a more comprehensive manner. In some cases, however, a lack of visible improvement in the workplace lowered nurses' motivation to make suggestions. Nurses' attitudes towards kaizen differed across both hospitals depending on the available managerial support, resources such as infrastructure and staffing levels.

From my findings, I derived several coping strategies to help health practitioners implement kaizen for the benefit of their organization and employees: Strong managerial support, appropriate use of kaizen tools, and a greater sense of team cohesion, among other factors, can influence how effectively hospital teams implement kaizen. To reap the benefits of kaizen, hospital managers should promote the exchange of opinions across hierarchy levels, allocate the necessary resources in terms of personnel and infrastructure, and show nurses how the technique can help them improve their workplace.

In more general terms, the pressure placed on hospitals to become more cost-effective, typical of DRG reimbursement systems, seems to be passed over, at least to some extent, to the nursing teams. Future researchers might therefore want to suggest alternative ways to reimburse health care providers that focus more explicitly on improving public health than on treating as many patients as possible. To make this paradigm shift possible, researchers would show policy makers how financial incentives can be redesigned by using indicators that draw on quality aspects of public health such as patient satisfaction and comorbidity indices. Against this background, promoting disease prevention activities (e.g., by apprising the general population about the positive effects of vaccinations) and stimulating patients to lead a healthier life (e.g., by giving up unhealthy nutrition habits) are some specific aims that policy makers and health care providers could allocate more resources to.

Strengths, weaknesses, and outlook

This dissertation sought to strike the balance between abiding to the principles of mainstream theorizing and enriching the scholarly toolkit by advancing a set of quantitative and qualitative research methods and study designs. By taking this approach of “scholarly ambidexterity”, I was

able to conduct rigorous and relevant research at the intersection of management practice and academic interest. This being said, I think it would be worthwhile to make investigations similar to those included in this dissertation by using longitudinal study designs, especially if causal effects were to be established. To achieve this, several generations of doctoral researchers could collect data over time to compile the different waves of a predefined panel dataset. Such studies would conceivably enhance the chances of researchers to disentangle the causal effects of regulatory interventions on patient safety, an industry's capacity for innovation, and the price level of medical devices as well as to observe these effects over time. A more thorough study of organizational change of that type would have exceeded the scope of this doctoral dissertation.

In a world marked by change in an increasing number of ways, it is researchers who have the particular responsibility to present evidence-based arguments to decision makers and show them how to implement change initiatives in a successful manner and for the benefit of the greatest number of stakeholders. To do so, I drew upon a solid theoretical framework to conduct the exploratory research presented in this doctoral dissertation. Furthermore, I refined the theoretical foundations of my research by enabling health professionals and researchers on several occasions to enrich an initial study design with insights specific to the context of the study in question. By engaging in such exchanges, researchers are, to my mind, far more likely to identify literature gaps and generate knowledge relevant to both current practice and scholarship.

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APPENDICES

Appendix, Chapter 3

Table A1. Selection criteria used to define cluster cantons.

Canton	Firm density[a]	Cantonal workforce share[b]
Aargau	184	0.7%
Bern*	285	1.4%
Basel Country	282	1.0%
Basel City	365	0.8%
Fribourg	163	0.8%
Geneva	206	0.3%
Jura	412	0.8%
Lucerne	226	1.4%
Neuchâtel*	393	2.4%
Obwalden*	270	2.3%
St.Gallen	240	1.1%
Schaffhausen*	376	2.5%
Solothurn*	300	2.6%
Thurgau	262	0.8%
Ticino	227	0.9%
Vaud*	259	1.1%
Zug*	901	3.1%
Zurich	266	1.0%
Rest	114	0.2%

Notes:

Reading example: In the canton of Aargau, there were 184 medical device companies per one million people, amounting to 4.7% of all people employed in the Swiss medical device industry worked in this canton, and 0.7% of the cantonal labor force worked at a medical device firm in 2008. The data sources were the Federal Statistical Office of Switzerland (Federal Statistical Office, 2017) and a report produced for FASMED, a former industry association representing medical devices companies (Rütter et al., 2010).

* – the asterisk denotes the cantons that constitute a knowledge cluster

[a] Density of medical device firms per one million people. On average, there were 251 medical device firms per million people.

[b] Share of employees working in the medical device industry of the overall cantonal workforce. The Swiss average amount to 1.1% of the overall workforce, whereas 0.7% of the cantonal workforce of the canton Aargau was employed in the medical device industry.

Figures

Fig. A1. Geographical location of the Swiss legal headquarters of the respondents.

***Note*:** This representation is based on source code provided by the Swiss Federal Office of Topography.

Appendix, Chapter 4

Tables

S1 Table: The interview guide, which we used for the semi-structured interviews.

Interview ID:	Hospital ID:	Interviewed person:	Date:
SECTION I: INTRODUCTION & CONSENT			
Consent to participate: **Yes** **No**		*The study design and interview guide were approved by the responsible ethics committee of our university. I would like to record the interview so that it can be transcribed afterwards and also for the sake of transparency. We are obliged to abide by the data protection regulations of our university. The transcribed interviews will be stored on servers of our university and will be deleted twelve months after the publication of the manuscript. Please do not hesitate to tell me if you if you do not want the interview to be recorded.*	

SECTION II. BACKGROUND INFORMATION
How old are you?
How long have you been working at this hospital?
What is your position and which tasks are your responsible for?
Please describe briefly what your usual workday at the hospital looks like by giving some examples.

SECTION III. QUESTIONS ABOUT PARTICIPATION IN THE WORK PROCESSES ASSOCIATED WITH KAIZEN, STRUCTURE & DAILY ROUTINE	
Q1*: The staff in your ward is encouraged to report problems and make suggestions for improvement. Is this correct? Can you please describe what this looks like in practice?*	
Auxiliary questions	
Main auxiliary questions	*Secondary auxiliary questions*
What kinds of suggestions have been made?	
Can you describe the conversations with your colleagues?	- *Are all employees involved? How?* - *How much are you involved in these discussions? Why?* - *Do you think that, for example, twice a month is enough? Why or why not?*
Do you have specific responsibilities within the kaizen management technique?	- *How do you exercise these responsibilities?* - *If not, why?* - *How would you judge your involvement in kaizen? Why?*
Who makes the final decisions?	- *Do you consider this fair?* - *Are there other people who would be more suited to make these decisions?*
What is the impact of kaizen on the way your ward operates?	- *What is your personal attitude towards kaizen?* - *What do you associate with the word "kaizen" when you hear it?*
Do you have any previous experience with kaizen?	- *What was your initial experience when you started to work at the hospital?* - *Were you skeptical at the beginning?* - *Did something change afterwards? Why?*

SECTION III. QUESTIONS ABOUT PARTICIPATION IN THE WORK PROCESSES ASSOCIATED WITH KAIZEN, STRUCTURE & DAILY ROUTINE	
Have you already made any suggestions?	- *Why?* - *What makes you think that a particular issue should be reported?* - *Does the number of suggestions made by your colleagues have any influence on you?*
Notes:	
Q2: ***Could you give an example of a suggestion you have made for solving a specific problem? (If not, why?)***	
Auxiliary questions	
Main auxiliary questions	*Secondary auxiliary questions*
Then what happened? Did your kaizen suggestion have any consequences?	- *How was it implemented?* - *What did you think when you noticed that your solution led to some visible improvements?* - *Has it ever been the case that your solution was perceived to be inefficient or inconvenient after it was implemented? What happened then?*
Why did you make this suggestion?	- *Do you talk regularly with your colleagues about problems? Why?* - *And with your supervisors? Why?*
Do you remember how you felt when your suggestion was considered/not considered?	- *Why did you feel that way?* - *Did that feeling affect your motivation to make further suggestions? Why?*
How was this suggestion perceived by your supervisor?	- *Is your supervisor's opinion of your suggestion more important to you than your colleagues' opinions? Why?*
Would the way and amount you participate change if you had no access to the kaizen tools?	- *How?* - *Why?*
Notes:	

SECTION III. QUESTIONS ABOUT PARTICIPATION IN THE WORK PROCESSES ASSOCIATED WITH KAIZEN, STRUCTURE & DAILY ROUTINE	
Q3*: Does participating in kaizen affect your attitude towards the hospital (as an employer)?*	
Auxiliary questions	
Main auxiliary questions	*Secondary auxiliary questions*
Why?	- *Could you be more specific about your feelings?* - *How do these feelings affect your work?*
Do your suggestions address job-related issues? What about patient satisfaction?	- *Why?* - *How important is patient satisfaction to you? What about the satisfaction of employees? Why?*
Does the opportunity to express your opinion have any influence on your willingness to continue to work for the hospital?	- *In what way? What role does kaizen play compared to other factors when considering whether or not to stay at the hospital?* - *What about job satisfaction? Why?*
In what way could kaizen improve the relationship with your colleagues?	- *And with your supervisor?*
Notes:	

SECTION IV. QUESTIONS ABOUT DESIRED PARTICIPATION IN THE WORK PROCESS	
Q4: *How important is it for you to express your own opinion?*	
Auxiliary questions	
Main auxiliary questions	*Secondary auxiliary questions*
Why is it important?	
How do you feel when you share your opinion about a specific issue in front of other people?	- *Do you find this useful? Why?*

SECTION IV. QUESTIONS ABOUT DESIRED PARTICIPATION IN THE WORK PROCESS	
What factors motivate you to express your opinion?	- *Why is/are this/these factor(s) so important?* - *Do you encounter this/these factor(s) in your workplace?*
Are there any disadvantages that you associate with the possibility of expressing your opinion?	- *Which ones?* - *Could these disadvantages sometimes discourage you from expressing your opinion? Why? Has this ever happened?*
Do you think that you express your opinion differently at work than you do in private?	- *Why?*
Notes:	
Q5: *How important is the opinion of the nursing staff in your job?*	
Auxiliary questions	
Main auxiliary questions	*Secondary auxiliary questions*
In your opinion, why do you have the opportunity to make kaizen suggestions?	- *May physicians also make kaizen suggestions?* - *Do you consider this fair? Why?*
Notes:	
Q6: Compared to your participation so far, would you like to participate more, less, or the same amount in the future?	
Auxiliary questions	
Main auxiliary questions	*Secondary auxiliary questions*
If more: What do you think the reasons/factors are that prevent you from participating more?	
If more: Who do you think should have the responsibility to promote participation?	
If less: What are the reasons that make you participate as much as you do?	
If equally: What do you think about the freedom to make suggestions only if necessary?	- *Why?*

SECTION IV. QUESTIONS ABOUT DESIRED PARTICIPATION IN THE WORK PROCESS	
Are there any aspects of the approach that you would like to change?	
Notes:	

SECTION V. QUESTIONS ABOUT ORGANIZATIONAL SUPPORT	
Q7: ***How would you evaluate the general support of hospital management in your daily job?***	
Auxiliary questions	
Main auxiliary questions	*Secondary auxiliary questions*
Can you describe the support you receive?	- *How do you feel when you receive this support?* - *Has it ever happened that you needed support for a specific problem, but nobody from the management team was willing to help you?*
Do you feel part of the hospital?	- *Why?*
How do you contribute to the success of the hospital?	- *What is your personal contribution? Could you do even more?*
How important do you think is it to your supervisor that you work independently?	- *Why?* - *Can you work independently?*
Notes:	

SECTION VI. END OF THE INTERVIEW
Is there anything else you would like to add?
Word of thanks.

S2 Table. Overview of primarily and secondary categories, as wells as text markers we used in the content analysis of the interviews. Organized by interviewee and hospital (XSLX). Available online at https://doi.org/10.1371/journal.pone.0257412.

S3 Table. A minimal underlying data set, which contains illustrative quotes we used to summarize the interviews by site, interviewee, and question (XSLX).

Available online at https://doi.org/10.1371/journal.pone.0257412.

S4 Table. Overview of the decision rules we developed to specify the scope of the categories we applied to perform the qualitative content analysis of the interviews.

Category	**Sub-category**	**Decision rule (if feasible)**
Nurses' perspectives	Nurses participate in kaizen by making suggestions and/or implementing ideas	If possible, always choose a category more specific than "Nurses' perspectives".
	Nurses support the use of kaizen at the hospital	N/A
	Other general or specific perceptions of kaizen and its importance	N/A
Job commitment and satisfaction	Kaizen increases commitment to the hospital	If a quote can be assigned to both a specific category (i.e., "HR", "Infrastructure", "Team dynamics and processes") and to one of the other more abstract categories (i.e., "Resources allocation & culture", "Quality outcome"), then also choose the specific one.
	Kaizen increases overall job satisfaction	N/A

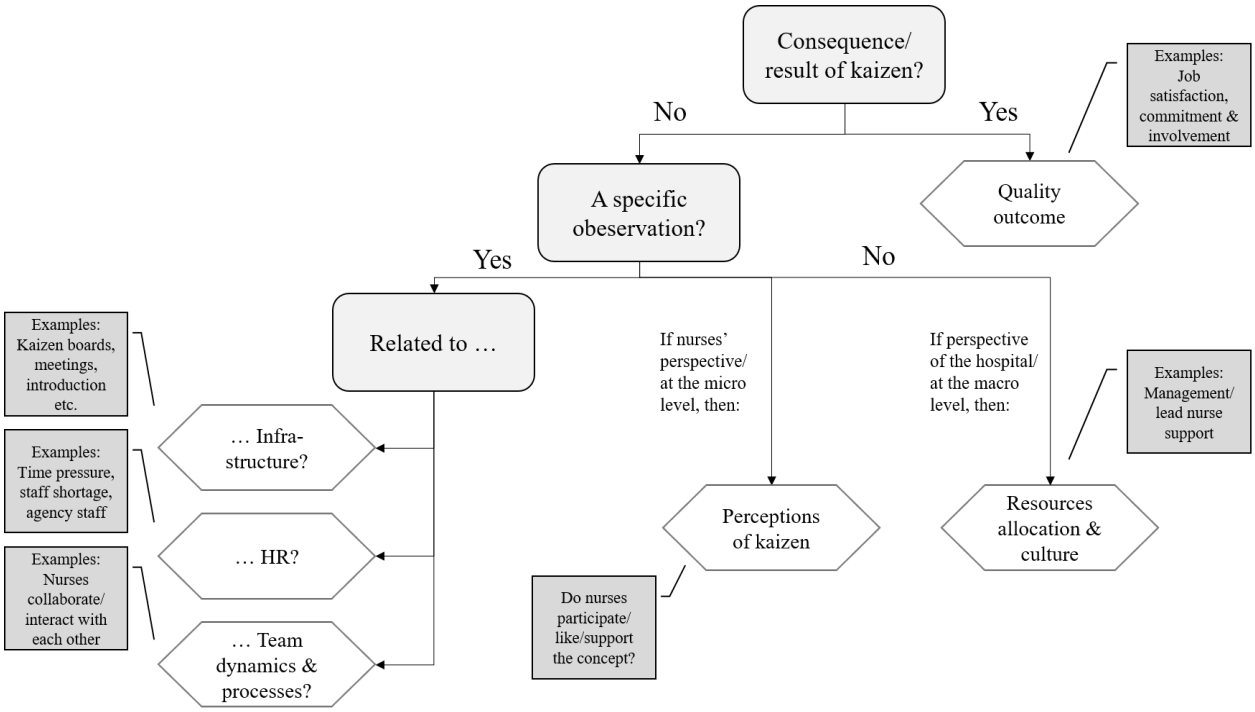
Category	**Sub-category**	**Decision rule (if feasible)**
Team dynamics and processes	Staff fit with the program either through commitment to the program vision and/or experience and skills needed for successful implementation	"Team dynamics and processes" category is not about the relation between nurses and physicians/the management of the hospital. For that reason, choose "Resources allocation & culture" if the topic of the quote is related to physicians/the management of the hospital.
	Team work, coordination, and cohesion in terms of how well hospital staff work together, support each other, and create a collaborative work environment	N/A
	There is a clear pre-defined process/structured way, in which kaizen works	Select if a (detailed) process is described.
Infrastructure availability and adoption	Infrastructure needed for the sustainable implementation of kaizen is available and accessible, e.g. introductory course, dashboards, and regular meetings	N/A
	Nurses make use of the kaizen infrastructure provided	N/A
Human resources and staffing	Constrains with existing staff, e.g. short-staffed and/or there is not enough time to include kaizen in their work routine	N/A
	High staff turnover and/or extended use of external staff	N/A

Category	**Sub-category**	**Decision rule (if feasible)**
Resource allocation and culture	The adequacy of resources dedicated to program implementation and/or achieving sustainable results	If a quote can be assigned to both a specific category (i.e., “HR”, “Infrastructure”, “Team dynamics and processes”) and to one of the other more abstract categories (i.e., “Resources allocation & culture”, “Quality outcome”), then also choose the specific one.
	Management shows general support and/or encourages adoption of kaizen with persistence	Management = Managers AND/OR (Chief) Physicians
	The management has established a culture, which promotes an open dialog and/or tolerates failure	Management = Managers AND/OR (Chief) Physicians

Note: N/A denotes that applying a decision rule was not feasible.

Figures

S1 Fig. A graphical illustration of the decision rules we developed to specify the scope of the categories we used in the qualitative content analysis of the summarized interviews.



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PUBLICATIONS

Blankart, C.R., Dams, F., Penton, H., Kaló, Z., Zemplényi, A., **Shatrov, K.**, Iskandar, R., Federici, C., 2021. Regulatory and HTA early dialogues in medical devices. Health policy (Amsterdam, Netherlands). doi:10.1016/j.healthpol.2021.07.010.

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STATEMENT OF AUTHORSHIP

Ich erkläre hiermit, dass ich diese Arbeit selbständig verfasst und keine anderen als die angegebenen Quellen benutzt habe. Alle Koautorenschaften sowie alle Stellen, die wörtlich oder sinngemäss aus Quellen entnommen wurden, habe ich als solche gekennzeichnet. Mir ist bekannt, dass andernfalls der Senat gemäss Artikel 36 Absatz 1 Buchstabe o des Gesetzes vom 5. September 1996 über die Universität zum Entzug des aufgrund dieser Arbeit verliehenen Titels berechtigt ist.

Bern, 25.10.2021 Kosta Shatrov