The regulation, assessment, and management of orthopaedic medical devices in Mexico: Crucial aspects, problems, and steps to improve it.

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Prof. Dr. Martin Spiess
Dekan

Dedicated to the Mexican health system

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Summary

Introduction:

In organisational theory there is an assumption that knowledge is used effectively in healthcare systems that perform well. Actors in healthcare systems focus on managing knowledge of clinical processes like, for example, clinical decision-making to improve patient care. We know little about connecting that knowledge to administrative processes like high-risk medical device procurement or technology assessments. Well-tailored policies for health technologies such as medical devices are essential and contribute to improved quality of health care. The regulation, assessment, and management represent important functions of the Medical Device Life-Cycle (MDLC). Insufficiently developed interactions between these functions impact the quality of health care and health system's effectiveness. To date studies lack to analyse these functions in a broad way even though they are increasingly of interest to policy makers and health system experts in Mexico.

Objective:

This Ph.D. research was designed and carried out so get a better understanding on policies and practices of the MDLC areas for orthopaedic medical devices in Mexico. The research encompasses four objectives spanning from (i) defining which areas of procurement are crucial for clinical practice and outcomes of orthopaedic medical devices, (ii) assessing attitudes of stakeholders regarding outcomes of the MDLC areas and analysing knowledge-related factors that influence these areas, (iii) analysing challenges of and discussing possible ways forward in fostering the regulation, assessment, and management of orthopaedic medical devices in Mexico, and (iv) analysing interests, positions, and power of stakeholders to three alternative strategies to improve processes and practices with regard to the regulation, assessment, and management of orthopaedic medical devices in Mexico to assess

the political feasibility of these strategies.

Methods:

We used a mainly qualitative research approach through overall 166 interviews (four sub-studies) and 187 survey participants (one sub-study) as well as a literature review (one sub-study) based on an overall framework that considers the MDLC relevant areas and the different levels by which the delivery of health care is being shaped.

First, we determined and analysed themes that were relevant to the different interest groups of the MDLC by using 'procurement' as starting point. We used in-depth interviews and interviewed 58 persons representing different stakeholders from four countries to define which areas of procurement are crucial for clinical practice and outcomes of orthopaedic HRMDs.

Second, we generated initial conclusions that served to further provide more specific insights on the most relevant themes. To do so we conducted two sub-studies: (i) we conducted a study using semi-structured interviews to assess opinions from 48 stakeholders from Mexico, and (ii) we conducted a survey to assess attitudes of 187 orthopaedic specialists from Mexico.

Third, we discussed ideas for possible ways forward in fostering the MDLC. To do so we conducted two sub-studies: (i) we interviewed 42 persons representing different stakeholders from Mexico to analyse challenges of and discuss possible ways forward in fostering the regulation, assessment, and management of orthopaedic medical devices in Mexico, and (ii) we used a literature review to discuss the contribution of survival rate benchmarks as decision-making rule.

Fourth, we analysed interests, positions, and power of stakeholders to specific strategies with regard to changes of processes and practices of the MDLC relevant areas. We used a stakeholder analysis method and included 17 persons

representing multiple interest groups to analyse interests, positions, and power of stakeholders to three alternative strategies to improve processes and practices with regard to the regulation, assessment, and management of orthopaedic medical devices in Mexico to assess the political feasibility of these strategies.

Results:

The MDLC system in Mexico is not coherently outlined and set-up across the regulatory, the assessment, and the management domains of orthopaedic medical devices, and this results in a situation that the quality of services delivered to patients is sub-optimal. First, the management of data and information is a critical aspect of the performance of the MDLC. Our research provided insights into problems related to data and information, and how this might have an influence on outputs and outcomes of the MDLC.

The focus on knowledge-related factors (second sub-study) allowed us to better explain the relation of MDLC function such as 'management' and clinical procedures for orthopaedic medical devices in Mexico. Second, technovigilance receives relatively high attention by policy makers in Mexico but that stakeholders of the MDLC underestimate its contribution regarding improving MDLC outcomes. Our research showed that the information flow between the micro level (observations from clinical practice) and macro level is relatively weak.

Third, in Mexico, HTA adds little value to decision-making and HTA at the level of hospitals has not received a lot of attention yet even though it may provide important benefits to the quality of health care and to the health system's effectiveness. Fourth, stakeholders of the MDLC function 'management' in Mexico underestimate the role played by procurement regarding purchasing of orthopaedic HRMDs. Our research showed that decisions are either based on simple decision criteria or impacted by

lowest-price offers. Quality attributes such as clinical long-term performance and intra-operative handling performance is rarely influencing into decision-making.

Conclusion:

Only some of the findings that our research has produced have been discussed in the literature before. This research is novel in terms of its specific focus on key MDLC functions and on orthopaedic medical devices. Further, it was timely because some of the presented themes are currently undergoing policy discussion in Mexico. The MDLC system in Mexico is not coherently outlined and set-up across the regulatory, the assessment, and the management domains of orthopaedic medical devices.

The fragmentation of responsibilities of the MDLC areas, which is underpinned by the health system structure, has recently received more attention from different stakeholders and is subject to the current policy discussion. The suggested changes of current processes and practices of the regulation, assessment, and management can improve outputs and outcomes of these functions and positively influence the quality of health care and health system's effectiveness. We have the following recommendations to the Mexican policy makers and other stakeholders related to the MDLC: (i) A government agency is needed to broadly oversee, monitor and report on quality-related issues within the health system; (ii) Decision-makers should apply an integrative approach of selecting medical devices to better prevent an economic and health burden due to disconnected processes and practices of the MDLC functions; (iii) Specific policies and organizational practice targeting orthopaedic medical devices are necessary; (iv) Technovigilance needs to be strengthened to improve the understanding of potential health risks associated with sub-standard HRMDs; (v) Data, information, and knowledge need to be managed appropriately across the sub-systems of health care provision; (vi) Technologies should be assessed during the

purchasing process by applying strategies such as risk assessment, the adequate involvement of end-users, and basing decisions on multiple criteria including clinical impact in the short-term and long-term; (vii) The methodology applied to technology assessments for evaluating HRMDs needs to be adapted to the gold standard and HTAs at the level of hospitals should be introduced; (viii) Decision-making needs to distinguish between different risk classes of medical devices because decisions on complex medical devices are based on simple decision criteria; and (ix) 'Procurement' needs more attention so that actors involved in procurement or impacted by procurement decisions are less confronted by problems.

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List of abbreviations

ANM	Academia Nacional de Medicina (National Academy of Health)
CENETEC	Centro Nacional de Excelencia Tecnológica en Salud (National Centre for Health Technology Excellence)
CFE	Comisión Federal de Electricidad (Federal department of electricity)
COFEPRIS	Comisión Federal para la Protección contra Riesgos Sanitarios (Federal department of health and human services of Mexico)
CONACYT	Consejo Nacional de Ciencia y Tecnología (National Council of Science and Technology)
CONAMED	Comisión Nacional de Arbitraje Medico (National commission for medical arbitration)
CSG	Consejo de Salubridad General [1]
DGEC	Dirección General de Calidad y Educación (General Directorate of Quality and Education)
DRG	Diagnostic related groups
e.g.	Exempli gratia
etc.	Et cetera
HCDM	Healthcare Delivery Model
HRMD	High-risk medical device
HTA	Health Technology Assessment
IMSS	Instituto Mexicano de Seguro Social (Mexican Institute of Social Security)
IMSS-O	Programme of Ministry of Health for non-insured population living in specific states or areas: Instituto Mexicano de Seguro Social – Oportunidades (Mexican Institute of Social Security - Opportunities)
ISSSTE	Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado (Institute of Social Security and Services for State Workers)
LMIC	Low- and Middle-Income countries
MDLC	Medical Device Life-Cycle
MOH	Ministry of Health
NICE	National Institute for Health and Care Excellence
NJR	National Joint Registry
ODEP	Orthopaedic Data Evaluation Panel
OECD	Organisation for Economic Cooperation and Development
OMD	Orthopaedic Medical Devices
PAHO	Pan American Health Organization
PEMEX	Petróleos Mexicanos (Mexican Petroleums)
SEDENA	Secretaría de la Defensa Nacional (Secretariat of National Defense)
SEMAR	Marina
SESA	Servicios Estatales de Salud (State Health Services)
UK	United Kingdom
WHO	World Health Organization

1. Introduction

1.1. Quality of health care

"Health care outcomes become the ultimate measure of quality as they reflect the influence of both, structure and processes of care." [2]

There are multiple ways to define quality of health care and for the present research, the following definition is appropriate: *"The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge"* [3]. The World Health Organization (WHO) states that one goal of a health system and their actor is to ensure and improve quality of health care [4]. High quality of health care improves the chances of successful treatments and promotes better outcomes for health in general. According to the literature, quality improvement is a process that can be addressed from different dimensions of quality [5, 6] and levels within a health system [7]. These dimensions were first defined almost 50 years ago [2] and were specified in more detail by, e.g., WHO: Health care should be efficient, effective, accessible, equitable, acceptable and safe [5].

Quality is therefore one of the cornerstones of health care [5] and is of high importance to health systems [8]. The multiple actors and processes within a health system aim at specific quality goals for health care [9]. Failures determined by actors or processes influence health outcomes. For this reason, ensuring and improving quality receives high attention by, e.g., policy makers and has an evolutionary nature [10]. However, knowledge and resources of a health system do not always translate into the desired effects for quality of health care [5]. This concerns high-income

countries as well as middle- and low-income countries [5, 8, 9, 11-13]. How can policy makers and health system experts respond to this?

First, to provide important insights about specific aspects of the delivery of quality of care different perspectives can be applied [7, 14]. This allows the multiple actors focusing on the patient and the health care professional as well as on organizational aspects and health system functions [15]. For instance, applying a health system's perspective can help to uncover and explain performance gaps or inefficiencies of processes, which a health system might have across the different levels of health care delivery. These approaches might contribute to the identification and analysis of quality issues, and help improve the delivery of quality of care, and consequently, strengthen the health system [16].

Second, the health care delivery model (HCDM) emphasises four levels by which the delivery of health care is being shaped [15]. This model helps to understand the conditions under which the multiple actors and organizational groups operate so that appropriate quality of care results (Figure 1.1). The interrelations are determined by processes, which contribute to the health care delivery function. Distinguishing between the different levels of the HCDM not only allows policy makers to focus on inputs at the macro level of policies and regulations, or clinical outcomes at the micro level, it also enables the researcher to provide the multiple actors with important insights about aspects that contribute to or inhibit the delivery of high quality of health care [7].

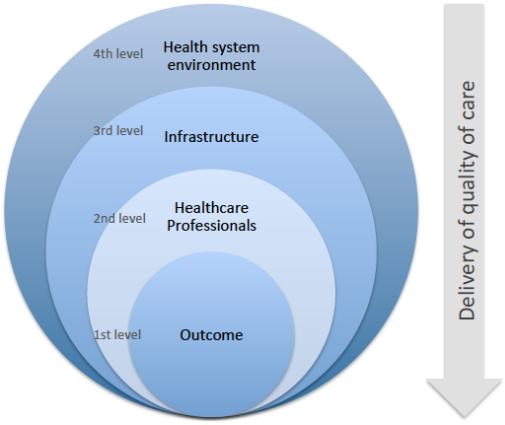

Figure 1.1. Healthcare Delivery Model (adapted from [15])

1.2. Health technologies

"Good health services deliver effective, safe, high-quality care to those who need them with a minimum waste of resources." [17]

A health system consists of multiple actors aimed at promoting, restoring or maintaining health. To better explain the relationships and interactions within a health system the WHO defined six Health System Building Blocks [9] that can be understood as sub-systems encompassing several other systems [16]. These blocks are: Leadership and governance; healthcare financing; health workforce; medical products and technologies; information and research; and service delivery. Four main groups of goals/outcomes of the system building blocks are of interest: Improved health (level and equity); responsiveness; financial risk protection; and improved efficiency.

Medical devices, together with other health technologies, laboratory items and medicines, are essential for patient care and producing good health outcomes. As such, they are considered by the WHO [18] as one of the six building blocks of health systems. They can essentially influence the quality of delivered healthcare based on the following considerations that were defined by WHO to better explain why medical

devices can fit within a national overarching health policy [19]: Regulations of medical devices minimize risk to the population; safe use and availability of medical device improve health service delivery; affordability of medical devices increases health service coverage; telemedicine enhances patient-centred care; health technology assessment provides basis for priority setting and informed decision-making; needs assessment helps in rational allocation of resources; research and innovations respond to the needs of a particular health system and population.

1.2.1. Medical devices

A health technology encompasses the application of technology-based knowledge and skills to solve a health problem and improve quality of life using devices, medicines, vaccines, procedures and systems [20]. A medical device is *„an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose.“* [19]. WHO explains the role played by medical devices as [19]: *“Medical devices save lives, improve health and quality of life, and are indispensable for the prevention diagnosis, treatment, and management of all medical conditions, diseases, illnesses and disabilities…”.* The regulatory authorities of countries have established classifications for medical devices to better distinguish between the requirements needed to evaluate their sanitary risk. The device classification depends on the intended use of the medical device and thus classification is risk based [21]. Class I includes medical devices with the lowest risk and requires general controls before granting market approval, for example enema kits and elastic bandages. Class II includes medical devices with moderate risk and requires general and specific controls, for example powered wheelchairs and some pregnancy test kits. Finally, class III includes medical

devices with high-risk and requires additionally premarket approval, for example breast implants, pacemakers or joint replacements.

1.2.2. Impact of medical devices on quality of healthcare

This research is concerned with class III medical devices, which are also described as high-risk medical devices (HRMDs) for orthopaedic speciality. HRMDs are implanted in the human body (such as a knee joint implant) and are therefore recommended subject to the highest level of pre-market and post-market [22, 21]. Their clinical indication is to replace the original joint by an artificial joint (implant) and to reconstruct the affected function of the locomotor system entirely or partially (see system building block goal ‘improved health’). They will remain in the patient’s body as long as they fulfil their mechanical function, which is to restore the joint function, and are not associated with any other complication such as an infection. Therefore a HRMD is not based on pharmacological, immunological or metabolic effects, but on a physical interaction (mode of action) in or on the patient’s body to achieve an intended effect [23].

Studies concerned with the epidemiology of hip and knee joint replacements show that the demand for primary joint replacements and revision surgery is growing [24, 25]. To meet the system building block goal ‘financial risk protection’ health systems respond by different strategies. For instance, to control the financial impact of joint replacements regarding its demand, some health systems define a maximum number of joint replacements per year (United Kingdom), a maximum budget for a period of time that can be used for joint replacements (part of the public sector in Mexico), or intervening in the entitlement of clinical decisions for joint replacements (in discussion in the United Kingdom). The financial impact of joint replacements depends as well on the implant quality. It is important to achieve good quality of delivered healthcare, which is represented by good survival rates of the used

implants (number of years that the implant remains successfully in the human body after surgery), for example. Arthroplasty register data shows that the clinical performance of hip and knee implants in the long-term demonstrate a strong variation [26]. Using poorly performing implants increases the revision risk. Studies for joint replacements in the United States show that primary joint replacements and revisions will increase. Knee-replacement revisions, for instance, are predicted to increase by 332% between 2012 and 2030 [24]. Further, the rate of primary joint replacement for patients aged 65-74 years and 75-84 years is much higher than for patients aged 85 years and older. Overall, the incidence has increased significantly between 2000 and 2006 [25].

These findings may be relevant for middle-income countries and countries with moderate life expectancy. Mexico is the second largest importer of orthopaedic medical devices in Latin America and the demand is increasing [27], even though this demand is still low in comparison to high income countries [28]. The life expectancy of the Mexican population has increased over the past 15 years in Mexico [29], which impacts among else on the incidence of osteoarthritis and thus the demand for joint replacements. Further, the demand is influenced by first, a larger population of patients over 50 years of age [30], which is affected by ostheoarthritis that increases rapidly. Second, Mexico is marked a population with high obesity rates [31, 32] who is on higher risk of early joint wear. Third, by patients who might have received a joint replacement with an implant of sub-standard quality that impacts the implant survival.

The clinical long-term performance of HRMDs is an important input parameter for the regulation, assessment, and management areas because it determines the future need for a joint replacement (revision surgery) of the artificial joint and influences the quality of delivered healthcare. *“The necessity for revision surgery has serious consequences for the patient’s quality of life and causes high health-care*

expenditure" [33]. A certain number of high-income countries have access to high-quality data of joint replacements (patient registries or arthroplasty registries), which they use to evaluate medical outcomes [34, 26, 35]. Using poorly performing medical devices is one of the reasons for high revision rates. For instance, increased incidence of post-operative problems resulting from the use of metal-on-metal hips led to higher hip revision rates [36]. But only few upper middle-income countries have a comparable access to high-quality data of joint replacements such as Romania. However, in Mexico, no arthroplasty register is established and clinical long-term performance of HRMDs is rarely included into the quality agenda of the functions of the MDLC areas. Currently, only the federal techno-vigilance department and health technology assessments may consider this data type to improve decision-making.

1.3. Regulation, assessment, and management of medical devices

Policies for health technologies such as medical devices are essential to assure equitable access to high quality and affordable devices and their appropriate use and thus, contributing to improved quality of care [37]. The WHO emphasizes the importance of developing and implementing health technology policies within the context of a national health plan. WHO indicated that 34% of 145 countries have a health technology national policy in place that is part of the national health programme [38]. Such policies are concerned with the regulation, assessment, or with the management of health technologies.

Health technology policies are aimed at outreaching safety, equity, quality, and universal coverage. They are thus closely related to important functions for medical devices. Understanding the challenges among the multiple actors involved contributes to clearly defined policy needs [39]. For instance, countries are increasingly considering integrating the evaluation and monitoring of HRMDs into

their quality agenda [35, 40]. In the United States and in many European countries the policy discussion about medical devices has encouraged policymakers to change policies and procedures that specifically govern the regulation of medical devices to improve the post-market safety of orthopaedic HRMDs [41, 39]. Less information is available from middle-income countries such as Ukraine, which started to improve regulation in 2016 [42]. Studies show that using poorly performing implants has a financial impact due to higher revision rates [43, 44]. The potential consequences in the absence of strategies to solve the evidence gap and prevent the selection of poorly performing implants are spanning from the provision of inferior healthcare provision to increased healthcare expenditures [45]. To clearly define health technology policy needs the delivery of care for using orthopaedic HRMDs must be understood in a holistic context such as the Medical Device Life-Cycle (MDLC) (Figure 1.2).

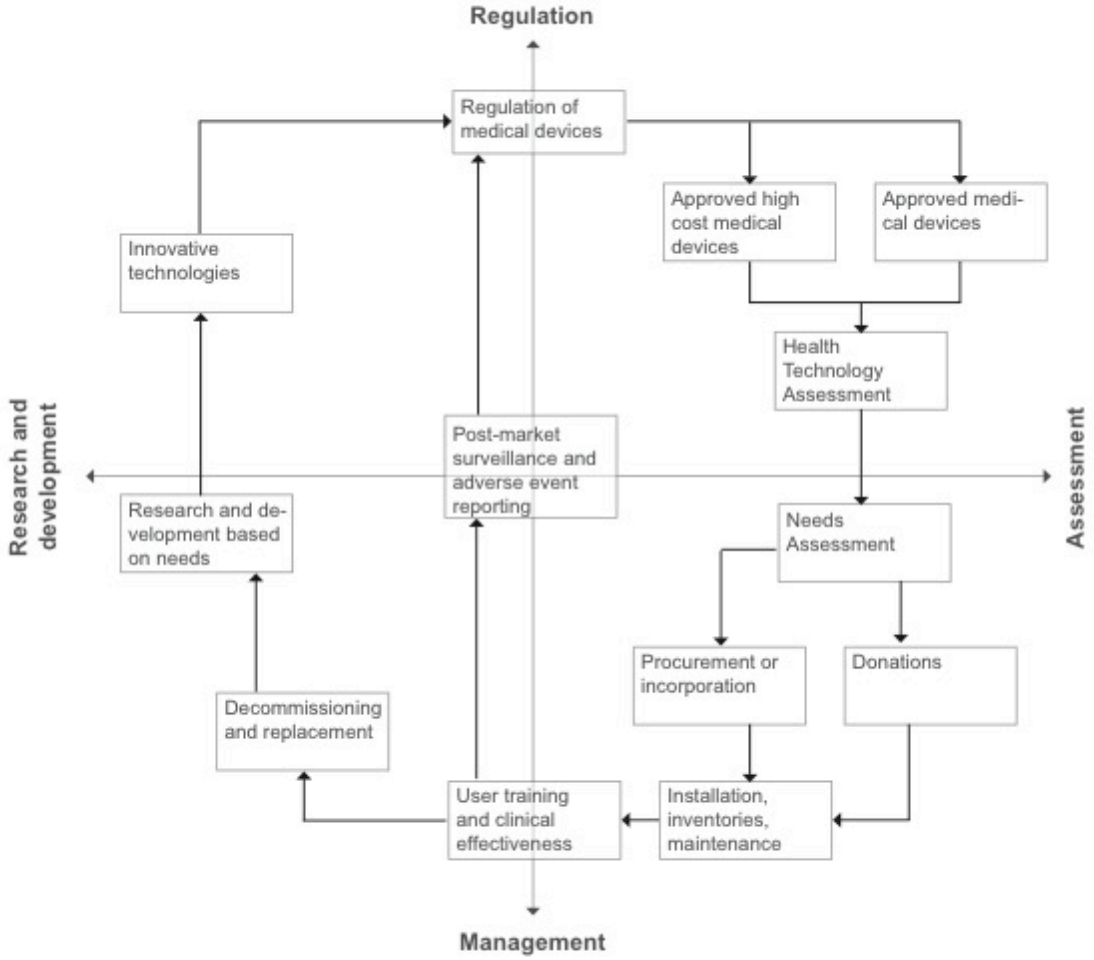

Figure 1.2. Medical Device Life-Cycle (adapted from [19])

The MDLC integrates important functions for medical devices and encompasses four areas [37]: (1) research and development; [23] medical device assessment; [23] medical device regulation; and [23] medical device management. Table 1.1 displays important inputs, outputs, and outcomes for each area. In the following subsection we outline important aspects of the regulation, assessment, and management of medical devices.

Table 1.1. Important outputs and outcomes of the MDLC areas

Areas	Description	Outputs	Outcomes
Regulation	Safety and efficacy are in the focus of this phase to aim population safety. Key elements are performing testing, safety assessment & post-market reporting using criteria of safety and quality standards.	Mandatory compliance	Assuring minimal standards of quality
Assessment	Key elements are systematic analysis and critical review using epidemiology and evidence data and assessing the cost-effectiveness.	Recommendations on highly complex technologies	Responsiveness and maximization of clinical outcomes and cost-effectiveness
Management	Health service providers are in the focus of this phase. Key element is the operational management of technology life-cycle using needs analysis and reliable device availability for clinical use.	Operational rules and guidance for all medical devices	Improved health delivery; sustainable availability of high-quality and safe devices

Source: Adapted from WHO [19, 46]

1.3.1. Regulation of medical devices

The aim of the regulation is to *"protect the public through the publication of standards, testing protocols, pre-market approval, registration, post-market surveillance, and adverse event reporting"* [19]. Various countries have a regulation for medical devices [19], and/or a regulatory agency. In addition policymakers are frequently concerned with effectively ensuring standards of clinical safety, performance, and efficacy of, e.g., orthopaedic high-risk medical devices [47, 48].

Medical device regulation is challenged with the mismatch of validity of information needed for the market approval and evidence from actual use of high-risk medical devices [49-51, 18]. One reason for this is that pre-market regulation is mainly based on conformity assessments and does not include findings from clinical long-term outcome studies [51, 52]. Therefore, post-market regulation plays an important role. For instance, post-market surveillance (e.g., supervised by techno-vigilance officers) seeks to monitor the safety and effectiveness of HRMDs once they are on the market and is aimed at detecting adverse events [53]. This is an important step of medical device regulation concerning the identification of the quality of an implant. Countries use different strategies in terms of ensuring or monitoring safety and performance of medical devices. These strategies range from strengthening the post-market regulation [54, 40], monitoring clinical treatment outcomes by introducing arthroplasty registers [34], to assessing the risk of HRMDs by post-market due diligence programmes [55], classifying the quality of implants [56], and establishing revision rate benchmarks to prevent the use of poorly performing implants [57]. These strategies are frequently integrated into the regulators' work and help bridge the gap of evidence and uncertainty [58, 59].

1.3.2. Assessment of medical devices

Health Technology Assessments (HTAs) represent one area of the MDLC. HTAs include clinical and economic analysis and they take place at the level of the regulation of high-risk medical devices. Their findings are used to define the eligibility of technologies. However, assessing the value of medical device technologies through HTA depends on the existence of relevant evidence on safety, performance and effectiveness of the technology [51]. Nevertheless, this data is often not available. Further, HTAs assess the value of a technology at a certain time based on the existing evidence data. Data that is generated afterwards is not integrated. This

limitation inhibits HTAs to integrate the survivorship of implants in actual use and should be covered by post-market regulation.

1.3.3. Management of medical devices

This area of the MDLC encompasses a wide range of functions and starts with the influence of the regulation and assessment areas and ends with outputs that determine desired clinical services [37]. The procurement process of a health system is expected to support the quality of healthcare and *"it is an essential element for service delivery"* [60]. Moreover, it has the potential to contribute to improved health system performance [61]. However, it does not always receive the recognition it deserves. This fact can be observed more frequently in countries with less developed health systems [62]. When the procurement function fails, a health system is weakened with regards to the quality of delivered healthcare.

The procurement process aims to transfer inputs into outputs to satisfy the customer's needs [63]. One crucial factor of the procurement process is the procedure that results in a decision on the purchase and use of services. This procedure can fail in terms of financial indicators but also with regards to delivering the required quality. Two important dimensions of this process are efficiency and effectiveness [64, 65]: Efficiency measures the success of transferring inputs into outputs whereas effectiveness measures the success of the system in terms of the outputs received.

Procurement processes of health systems might impact the goal of the MDLC significantly. This raises an important question that could be subject of future research: How does the impact of procurement processes translate into results for the micro level? Further, studies often focus on procurement performance in general but rarely on the meaning that procurement performance might have for other MDLC areas and in specific in the context of quality of healthcare. Procurement

performance can be evaluated, besides others, based on generic measures, among others, for which the procurement functionaries do have the control over. The focus lies on the supply link (relation between internal customer, purchasing department and supplier) and therefore, focuses mainly on efficiency and effectiveness of the procurement process [66]. The measurement areas that can be derived from it are illustrated in Figure 1.3.

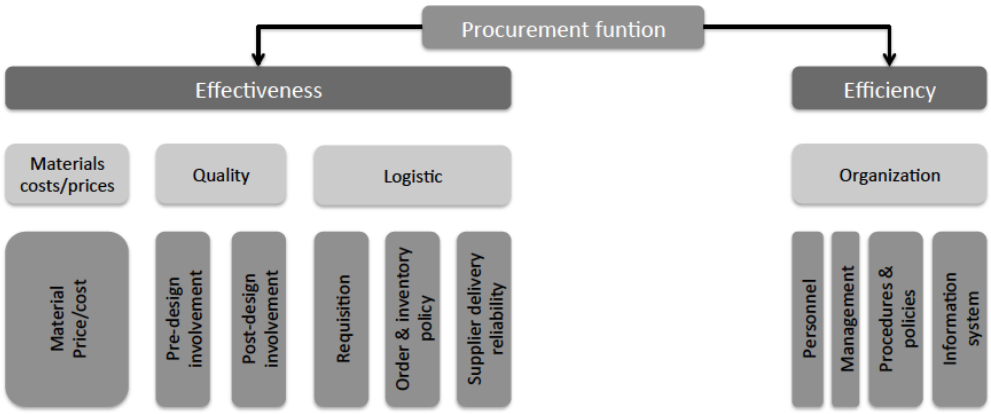

Figure 1.3. Key areas of the procurement process (adapted from [67])

Cost respectively potential savings are used by various countries as important indicators or measures of performance. Therefore, the function of the procurement is in several instances established to achieve cost minimization and efficiency maximization at the same time. But financial indicators or measures do not permit covering all relevant performance areas [68]. What possible disadvantages do health systems have when procurement is used as isolated and generic measure driven administrative function for medical devices? Non-financial measures are also very relevant. They help to better understand the effects of performance among core areas and activities of procurement. This leads to the consideration of more components that can be evaluated [66] such as environment and structure, and operating procedures within procurement (management area of MDLC) but also outside procurement (other areas of MDLC). Based on the prior theoretical

frameworks, the evaluation of the non-financial performance can also be derived from an amplified perspective (Figure 1.4).

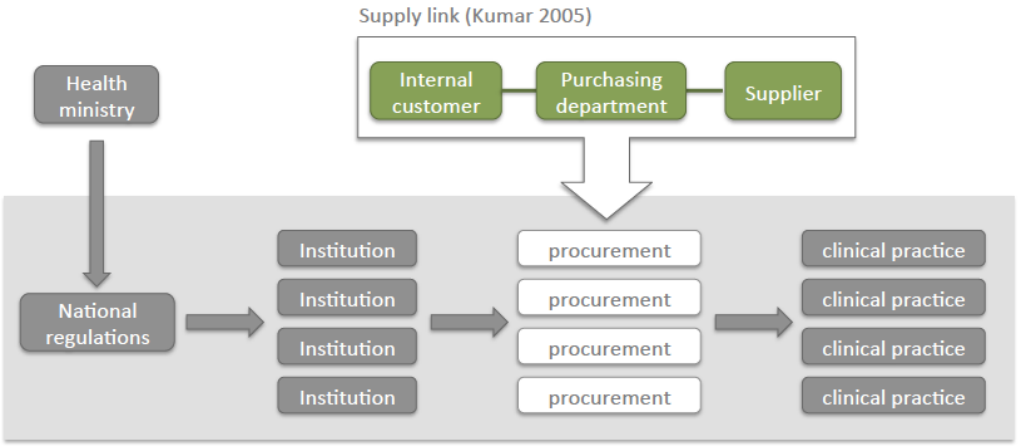

Figure 1.4. Performance of procurement process in the context of its environment

1.4. Mexico

Mexico is the second largest economy in Latin America with an estimated population of over 127 million [69]. It is a middle-income country built up along 32 states.

1.4.1. Mexican Health System

The Mexican health system is relatively segmented and fragmented, and it is characterized by a public and a private sector [70]. The latest OECD report on Mexico from 2016 [32] states that *"Mexico's health system persists as a cluster of distinct sub-systems, each offering different levels of care, to different groups, at different prices, and with different outcomes"*. Figure 1.5 provides an overview on the multiple actors providing health services.

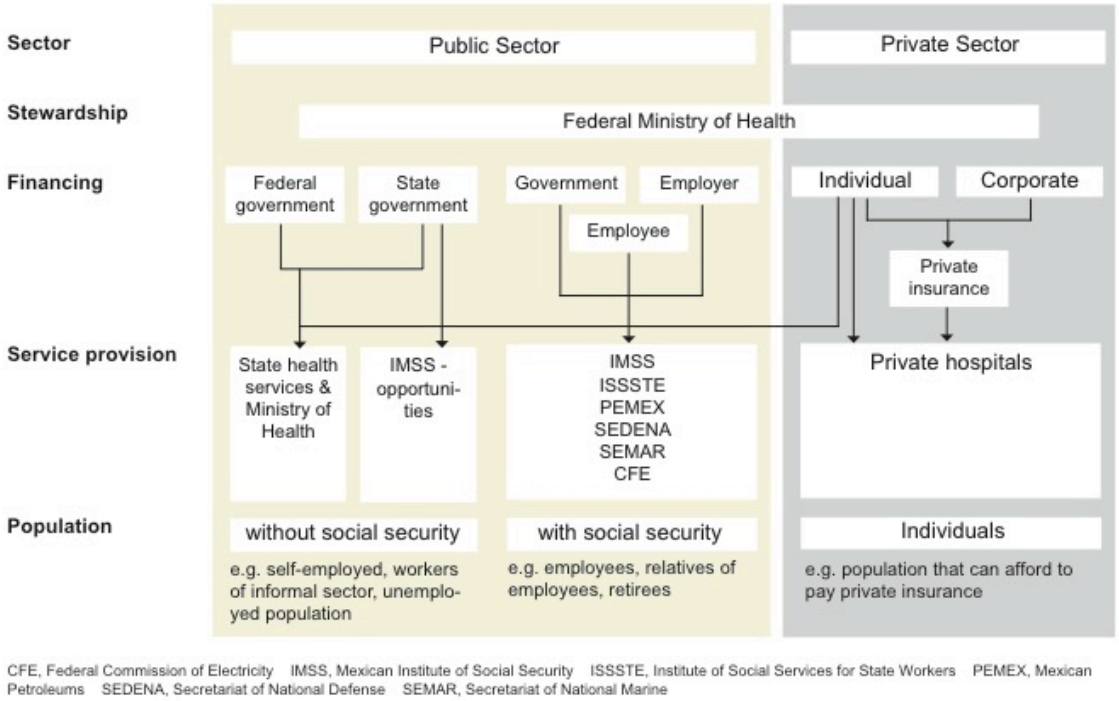

Figure 1.5. Overview over the multiple actors providing healthcare in Mexico (adapted from [70])

The public sector provides healthcare attention to the Mexican population with and without social security based on a centralized service provision scheme. The centralized service provision scheme encompasses multiple social security institutions and the state-level healthcare services (SESA). The social security institutions encompass population groups that are employed in the formal sector of the economy and are represented by: Mexican Institute of Social Security (IMSS, Instituto Mexicano de Seguro Social), Institute of Social Services for State Workers (ISSSTE, Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado), Mexican Petroleums (PEMEX, Petróleos Mexicanos), Secretariat of National Defense (SEDENA, Secretaría de la Defensa Nacional), Secretariat of National Marine (SEMAR, Secretaría de la Mariana), and Federal Commission of Electricity (CFE, Comisión Federal de Electricidad). SESA belongs to the MOH and attend the population that is not employed in the formal sector of the economy. In

addition to SESA the MOH installed a decentralized service provision scheme, which encompasses programmes that attend the population without social insurance and limited or no financial resources to pay health services such as *IMSS Oportunidades*. The private sector attends that part of the population that can afford to pay private insurance or that has access to private insurance through its employer. That way it plays a role in respect to some of the health systems functions such as service provision and financing.

The National Health Program (PRONASA) and the Sectorial Health Program (PROSESA) aim to guarantee the access to basic health services and reduce disparities. However, the fragmentation of the health system takes place as well at the level of disease treatment, which are often distinguished into three attention levels [71]: (i) first level attention encompasses the basic treatment of diseases, (ii) second level attention focuses on a variety of different diseases that require a treatment in a hospital, and (iii) third level attention encompasses specialized treatments such as a joint replacement.

The general health law specifies that the MOH is in charge of the strategic planning of the sector, the definition of priorities, the coordination within and across sectors, and the development and introduction of health policies [72]. However, the health service provision at the level of the public and private sector are not obliged to adhere to all regulations from the various MOH departments that operate at the national level [72, 73]. This causes a variety of problems ranging from the reimbursement to important aspects of information flow between the sectors and the MOH [71]. For instance, CENETEC provides purchasing guidance to procurement agents within SESA based on recommendations for expensive medical equipment such as a computer tomography scanner. If and how this might influence the quality

of provided health services regarding medical devices hasn't been investigated yet in detail.

1.4.2. Policies for health technologies in Mexico

WHO indicated that globally 35% of 174 countries for which information is available have a national health technology policy in place that is part of the National Health Program [38]. Mexico is one of these countries and its response to the call for developing and implementing health technology policies within the context of a national health plan can be described by three aspects:

- the introduction of the Inter-institutional Commission of the Standard List for Health Supplies in 1975, which is responsible for the eligibility of health technologies by assessing their cost-effectiveness [1];
- the establishment of the Federal Commission for the Protection against Sanitary Risks (COFEPRIS) in 2002, which is responsible for the regulation of health technologies;
- the creating of the National Centre for Health Technology Excellence (CENETEC) in 2004, which is a specialized agency of the MOH to support policy decisions based on e.g. and for instance health technology assessments (HTA).

Mandating government agencies and defining regulations that support policies for health technologies is essential to establish and develop important functions for medical devices that support healthcare delivery at different organizational levels within the health system as described by the MDLC. Besides the development and implementation of health technology policies, WHO emphasizes the importance of the commitment for, and realization of a continuous improvement plan within and between the areas of the MDLC (improving organizational practice) in order to strengthen the implementation of national health technology policies and to

contribute to improved health [37]. This can be achieved when necessary interactions between the areas are established, which are necessary because of the interdependence of these areas. In this context, WHO emphasises the role played by organizational structures at different levels within the country [37].

1.4.3. MDLC in Mexico

In Mexico, several governmental offices as well as several non-governmental stakeholders are involved in the MDLC (Table 1.2).

Table 1.2. Principle actors involved in the regulation, assessment, and management of medical devices in Mexico

Principal actors	Main responsibility and regulatory reference
General Council of Health (CSG, Consejo de Salubridad General)	• Sanitary authority directly accountable to the President • Council whose mission it is to strengthen the governance and the articulation of the National System of Health. Founded: 1917 Regulatory reference: Article 4 of the Political Constitution of Mexico • Publishes the standard list of Health Supplies • Holds the Inter-institutional Commission of the standard list for Health Supplies whose mission is to manage the approved technologies in the standard list for Health Supplies Regulatory reference: DOF-22-06-2011; Edition 2015 of the Standard list; Article 9, fraction XXI and XXII, 15, fraction II, and 22 of the Interior Regulation of the General Council of Health • Auditing of hospitals with regards to quality standards (certification process) Regulatory reference: Interior regulation of the commission for the certification of health provider facilities DOF-22-10-2003
Ministry of Health (MOH, Secretaria de Salud)	• Government department and member of executive cabinet in charge of all health services in Mexico. Its mission is to establish the state policies towards the realization of the right to health for all. Founded: 1943 Regulatory reference: Law of General Health, DOF-01-06-2016; Interior regulation of the Ministry of Health, DOF-10-01-2011
Sub-secretariat for Health System Integration and Development (SIDSS, Subsecretaria de Integración y Desarrollo del Sector Salud)	• Government agency whose mission is to propose to the MOH national policies that improve the quality of social health services; issues the Mexican Official Norms (NOM) Regulatory reference: Article 19 of the Organic Law of the Federal Public Administration, DOF-18-07-2016

Federal Commission for the Protection against Sanitary Risks (COFEPRIS, Comisión Federal para la Protección contra Riesgos Sanitarios)	• Decentralized organ of the MOH whose mission is to protect the population against medical risks derived from the introduction of new medical drugs, medical devices and other health inputs. Founded: 2002 Regulatory document: Regulation of the Federal Commission for the Protection against Sanitary Risks, DOF-13-04-2004; and Regulation for Health Supplies, DOF-12-03-2014 • Sanitary Authorization Commission whose mission is the market approval of medical products and technologies Regulatory reference: Medical devices class III are subject of the requirements of the articles 179 and 180 of the Regulation of Health Services; NOM-064-SSA1-1993, NOM-137-SSA1-2008, NOM-163-SSA1-2000 • Technovigilance department whose mission is to implement and realize post-market surveillance Documents: NOM-240-SSA1-2012 • Support function of “Sanitary Authorization Commission” whose mission is to provide technovigilance reports for the renovation of market approval • Regulatory reference: Article 190 Bis 3, fraction IV of the Regulation of Health Services
National Centre for Health Technology Excellence (CENETEC, Centro Nacional de Excelencia Tecnológica en Salud)	• Governmental organization and unit under the scope of the SIDSS whose mission is to contribute to the development and governance of the National Health System in Mexico based on: Health Technology Assessments, Supervision of medical equipment, Telemedicine, Clinical guidelines. Founded: 2004 Regulatory reference: Interior Regulation of the MOH, article 41, DOF-02-02-2010 • WHO collaborating centre
Ministry of the Public Function (SFP, Secretaria de la Función Publica)	• Governmental organ whose mission is to coordinate, evaluate and oversee the governmental public practice at federal level such as for example the public spending Regulatory reference: Administrative Manual for General Application in the Acquisition, Leasing and Services of the Public Sector, DOF-03-02-2016; Application of the evaluation criteria “binario” (cost benefit), article 42 of the Regulation of the law for acquisition, leasing and services of the public sector, DOF-20-08-2001; Organic Law of Federal Public Administration, articles 31, 34, and 37, DOF-18-07-2016
General directorate of health planning and development (DGPLADES, Dirección General de Planeación y Desarrollo en Salud)	• Governmental organization and unit under the authority of the SIDSS whose mission is to steer the strengthening of health services among policy makers, and giving guidance to improve health services sustainable and cultural based on populations’ needs Regulatory reference: Interior regulation of the MOH, article 25
General directorate of quality and education (DGCES, Dirección General de Calidad y Educación)	• Governmental organization and unit under the authority of the SIDSS whose mission is to ensure that the quality and safety of health services, including human resources of the health sector and the regulatory environment of social health supplies is aligned with national policies Regulatory reference: Interior Regulation of the MOH, article

	18
Public sector for healthcare delivery	Via MOH • State-level healthcare services (SESA, Servicios Estatales de Salud) • MOH facilities such as National Institutes • MOH programmes for service provision such as IMSS-Opportunities (IMSS-O, IMSS oportunidades) or financial programmes such as Social Population Insurance (SPS, Seguro Popular de Salud), initiated 1979 Social Security Institutions • Mexican Institute of Social Security (IMSS, Instituto Mexicano de Seguro Social), founded 1943 • Institute of Social Security and Services for State Workers (ISSSTE, Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado), founded 1960 • Mexican Petroleums (PEMEX, Petróleos Mexicanos) • Secretariat of National Defense (SEDENA, Secretaría de la Defensa Nacional) • Secretariat of Marine (SEMAR, Secretaría de la Marina)
Private sector for healthcare delivery	• Private insurance companies • Private healthcare facilities
General directorate of information in health for data collection (DGIS, Dirección General de Información en Salud)	• Governmental organization and unit under the authority of the SIDSS whose mission is to collect and make available health information, including the administration of the general health information Regulatory reference: NOM-035-SSA3-2012 • Oversees the implementation of the National System of Essential Information in Healthcare [74] whose mission it is to improve the collection and exchange of health information of the social security institutions and the state healthcare systems • Regulatory reference: NOM-024-SSA3-2012
National Commission for Medical Arbitration (CONAMED, Consejo Nacional de Ciencia y Tecnología)	• Contribute to guarantee the right of health protection and to improve the quality of health providers in terms of intervening in case of patient/health provider conflicts Regulatory reference: Introduction of CONAMED, DOF-03-06-1996; Regulation of procedures for the management of complaints and incidents of CONAMED, DOF-21-01-2003
General directorate of evaluation of performance (DGEP, Dirección General de Evaluación del Desempeño)	• Governmental organization and unit under the authority of the SIDSS whose mission is to evaluate the performance of the national and state health systems, and of the health programmes and services; to provide relevant information to improve policies, programmes and services Regulatory reference: Interior Regulation of the MOH, article 23
National Academy of Medicine (ANM, Academia Nacional de Medicina,)	• Professional association of doctors that promotes scientific corporation, organises congresses and continuous professional education; consultant organization of the Federal Government of Mexico that proposes and discuss among its affiliates solutions to the main health problems of the Mexican society.

However, the different sub-systems of the public sector have relatively high decision-spaces (and legal autonomy) regarding post-market regulation, assessment and management of medical products. For instance, they have their own health service providers, manage medical products (purchasing and delivering services) to their covered populations, and define and set their own priorities. The ability of policymakers to comprehensively oversee the MDLC in Mexico regarding challenges in organizational practice is limited because their responsibilities are limited by the design of the health system.

Regulation:

COFEPRIS is the main institution for the pre- and post-market regulation of medical devices. It establishes and implements policies, programmes and projects at the level of international best practice, and in coordination with the different actors of the health system to prevent health risks. This encompasses the market approval of medical products (pre-market regulation) and the post-market surveillance of medical products in clinical use (post-market regulation). In the United States and in many European countries, the policy discussion about medical devices has encouraged policymakers to change policies and procedures that govern the regulation of medical devices [41]. Studies show that using poorly performing implants has a financial impact due to higher revision rates [43, 44]. To date, no studies or grey literature (websites, reports, etc. from government offices and national or international organizations) indicate the multiple actors in Mexico have similar discussions.

Assessment:

The General Council of Health [75] is the main actor for decisions about the eligibility of medical products at national level [1]. The CSG oversees the Inter-institutional Commission of the Standard List for Health Supplies that decides the listing of health

technologies in the national standard list. It integrates information from health technology assessments into their decision-making process. However, articles 83, 179 and 180 of the current Medical Device Regulation of Mexico indicate that there are no specific regulations for HRMD differentiating them from lower risk medical devices. Medical devices of different risk classes are bundled within the same list. There is uncertainty how this influences e.g. procurement agents and their assessment of medical devices of different risk classes.

Management including procurement of medical devices

The sub-systems, which have their own facilities, are responsible for purchasing and the delivery of services to their covered populations. *"The Mexican federal public administration has strengthened its public procurement function in recent years, which contributed to a more professional handling of medical product purchase"* [60]. A better understanding of the context, in which purchasing takes place, might help to identify challenges of organizational practice and discussing possible ways to fostering the management of medical products. Procurement of healthcare providers belonging to the MOH is relatively decentralized while procurement of the public social security institutions is centralized at regional or national level.

The OECD report from 2012 on the public procurement process of IMSS, which represents one of the largest public insurance sectors [60], and the latest OECD report on the Mexican health system from 2016 provide the most complete information on current findings for procurement in Mexico. OECD noted in its report regarding IMSS that they demonstrate a lack of well documented procurement strategy and communication through the organization of IMSS and a lack of sufficient procurement data, which compromises important management activities, and monitoring of procurement performance [60]. Further, current resource management

is associated with the risk of sub-standard quality. In its report about the Mexican health system OECD concluded that Mexico should strengthen the governance of its health system aiming at a more data-driven health system (raise data availability and use among the areas regulation, assessment, and management) and that the public sub-systems need a smarter purchasing of goods and services (raise efficiency and quality of care).

1.5. Research gap

Research gaps have been identified based on the previous literature research and reviewing grey literature (websites, reports, etc. from government and national or international organizations). This contributed to the definition of the present research topic and the identification of research objectives. Talking in a first step to public health experts provided some insights and supported to the definition of the present research question:

- Studies or other public information provides information in terms of the accessibility and coverage of healthcare services of specific public institutions but rarely for the whole Mexican health sector [76].
- Few aspects are documented on other quality dimensions to improve the delivery of healthcare such as organizational or operational processes influencing the outputs and outcomes of the MDLC.
- In Mexico, little research has been done to understand challenges of the regulation, assessment, and management for orthopaedic HRMDs and how these challenges influence the outputs and outcomes of the MDLC areas, and affect the goal of national health technology policies.
- To date, some aspects regarding the structure and the performance of procurement are highlighted in the OECD reports from 2012 and 2016 [60,

32]. But evidence on the regulation and assessment of medical devices is still scarce.

- Literature research for the HCDM applied for the Mexican health system only provided results for specific institutions and for some of the four levels the HCDM is representing.
- To date, literature is lacking regarding the quality of delivered orthopaedic HRMD and effects on quality of care across the various sub-systems of the Mexican health system. There is a need to bring insight into quality dimensions, which are relevant to foster the quality of the delivered healthcare.
- There are doubts regarding different attributes of the MDLC areas of orthopaedic HRMDs in Mexico and their influence on clinical practice and thus, on the delivered quality of care. However, these perceptions were based on viewpoints of the orthopaedic society of physicians and mainly address the content of the area 'technology management', which encompasses procurement.
- Literature research for the relation of the procurement process and the delivery of quality of care did not provide specific results. Nevertheless, the OECD from 2012 presents some aspects of the relation of 'technology management' and the quality of care for the largest institution of the public sector.

Mexico is classified as a middle-income country. Compared to high-income countries, typically we observe a limited amount of research in low- and middle-income countries (LMIC) [77]. Little published evidence does exist regarding regulation, assessment, or management of medical devices in Mexico [78]. This situation

warrants detailed research for Mexico necessary to provide a better understanding of the regulation, assessment, and management of orthopaedic HRMD and their role for the quality of delivered healthcare necessary. Despite the fact, that available information from the literature is insufficient to realize the research project, it is mandatory to involve a broad range of local actors.

2. Study aim and objectives

This research was designed and carried out in the context of gaining insight on policies and practices of the MDLC areas for orthopaedic medical devices in Mexico and to discuss and analyse possible ways forward in fostering them. In specific this thesis encompasses four research objectives.

Objective 1 (Chapter 4)

- Define which areas of procurement are crucial for clinical practice and outcomes of orthopaedic HRMDs.

Objective 2 (Chapters 5 and 6)

- Analyse knowledge-related factors that influence procurement of orthopaedic HRMDs in Mexico.
- Assess the attitudes and thoughts of orthopaedic specialists regarding their role in purchasing decision-making of HRMDs, their experience with purchasing processes and impact on clinical practice as well as potential areas for improvement.

Objective 3 (Chapter 7 and 8)

- Analyse challenges of and discuss possible ways forward in fostering the regulation, assessment, and management of orthopaedic medical devices in Mexico.

- Discuss possible ways forward in fostering the regulation, assessment, and management of orthopaedic medical devices in Mexico.

Objective 4 (Chapter 9)

- Analyse interests, positions, and power of stakeholders to three alternative strategies to improve processes and practices with regard to the regulation, assessment, and management of orthopaedic medical devices in Mexico to assess the political feasibility of these strategies.

3. Research design and methods

A mainly qualitative research approach is used to support the four research objectives (Creswell 2009). This research encompasses six sub-studies. For each sub-study, we will consider different approaches and include multiple stakeholder groups. The main focus regarding interest groups representing the meso and micro levels will be on the public sector while the private sector investigation will serve rather as comparative element. The final goal is the analysis of possible strategies in fostering the MDLC areas. To assure feasibility of the objectives, the qualitative research approaches will be focused on a region of interest that is defined by 2 out of 31 states (Estado de Mexico and Cuernavaca) plus the federal district (Distrito Federal). We selected this region of interest because it represents important offices of the MOH, international organizations or experts of the health system, and it represents the highest volume for orthopaedic surgeries within the country encompassing representations of all public sub-systems and the private sector.

Our research approach is based on an overall framework (Figure 3.1) that includes two main perspectives: the MDLC areas in the context of the HCDM levels. It served us to capture important findings regarding the MDLC areas and the HCDM levels.

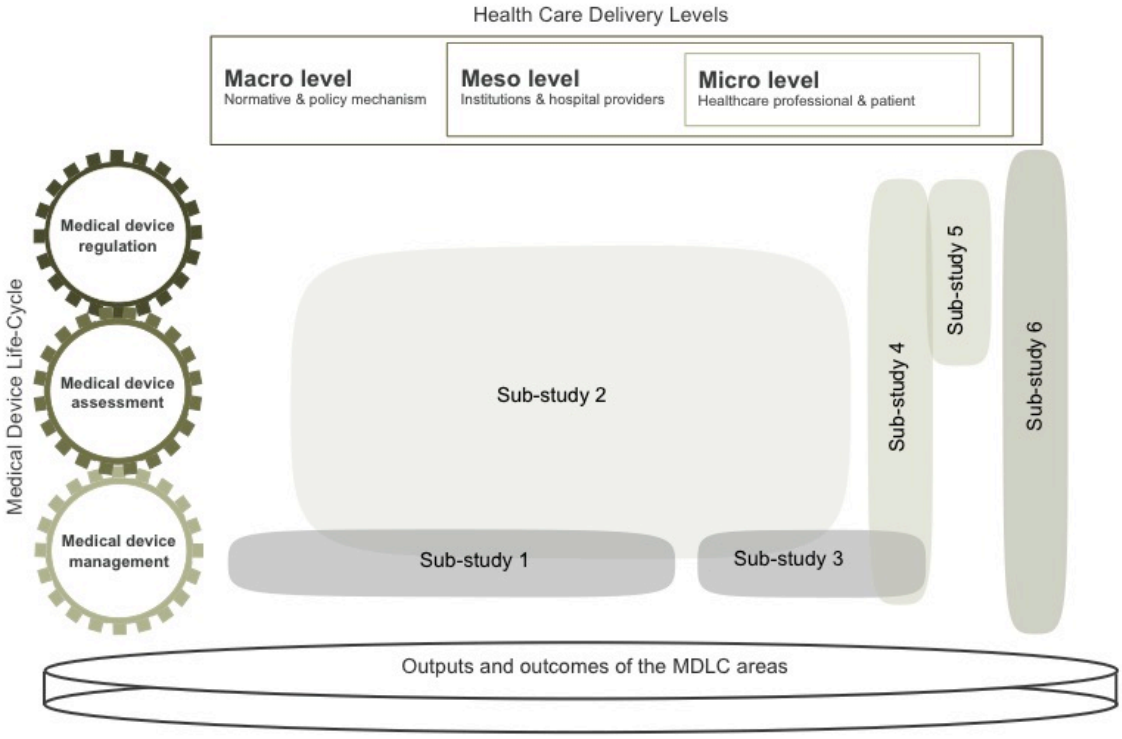

Figure 3.1. Overall framework

The framework guided our research in three ways. First, to determine and analyse themes that were relevant to the different interest groups of the MDLC for orthopaedic medical devices using 'procurement' as starting point and describing the identified themes regarding their meaning for the MDLC areas, and distinguishing between the macro, meso, and micro levels (sub-studies one to three). Second, to generate initial conclusions that serve to further provide more specific insights on the most relevant themes and to discuss possible ways forward in fostering the regulation, assessment, and management of orthopaedic medical devices in Mexico (sub-study four and five). Third, to overall conclude on the findings of the different sub-studies and to overall answer our research questions by analysing possible changes of processes and practices regarding the MDLC areas in a stakeholder context (sub-study six). For this inductive research approach we focused on mainly qualitative methods in our effort to collect first in-depth qualitative data (in-depth and

semi-structured interviews), second highlight specific aspects by quantitative data (structured survey), and third narrowing down the findings by terminal qualitative data collection (semi-structured interviews).

	Study 1	Study 2	Study 3	Study 4	Study 5	Study 6
Setting	MX, UK, DE, CH	Mexico	Mexico	Mexico	Mexico	Mexico
Objective	Define which areas of procurement are crucial for clinical practice and outcomes of orthopaedic HRMDs.	Analyse knowledge-related factors that influence procurement of orthopaedic HRMDs in Mexico	Assess the attitudes and thoughts of orthopaedic specialists regarding their role in purchasing decision-making of HRMDs, their experience with purchasing processes and impact on clinical practice as well as potential areas for improvement.	Analyse challenges of and discuss possible ways forward in fostering the regulation, assessment, and management of orthopaedic medical devices in Mexico.	Discuss possible ways forward in fostering the regulation, assessment, and management of orthopaedic medical devices in Mexico.	Analyse interests, positions, and power of stakeholders to three alternative strategies to improve processes and practices with regard to the regulation, assessment, and management of orthopaedic medical devices in Mexico to assess the political feasibility of these strategies .
Method	Qualitative study; 59 in-depth interviews	Qualitative study; 48 semi-structured interviews	Cross-sectional study; 187 participants	Qualitative study; 42 semi-structured interviews	Review of literature and grey literature	Qualitative study; 17 structured interviews
Target group	Stakeholders from macro, meso, and micro level	Stakeholders from macro, meso, and micro level	Orthopaedic specialists	Stakeholders from macro, meso, and micro level	-	Stakeholders from macro, meso, and micro level

Figure 3.2. Overview table with study and method per objective

3.1. Research methods to achieve objective 1

For sub-study one (see chapter 4), we took a healthcare delivery perspective in our effort to determine (i) how the set-up of HRMD regulations exerts influence on procurement (macro level), (ii) how procurement regulations and practices align with expectations of clinical practice (meso level) and, (iii) how procurement practices affect clinical practice and outcome (micro). We adapted the HCDM [16] and the supply link framework [13] so our research approach model captured the factors that influence procurement regulations and practices for orthopaedic HRMDs (Figure 4.1). We focused on three levels by which the delivery of healthcare is being shaped: 1) macro (regulatory, normative, managing); 2) meso (care provider facility); and, 3) micro (healthcare professional and patient). We emphasised procurement based on

the supply link framework and installed it between the meso and micro levels. Procurement has three main actors: supplier; procurement administration (purchaser); and, meso level (internal customer) and micro level (user). The interaction between the main actors is defined by (i) procurement administration and internal customer or user, and (ii) procurement administration and supplier. We also defined themes related to procurement: (i) regulations (pre- and post-market), (ii) eligibility, (iii) procurement, and (iv) clinical procedure. We compared the context and set-up of procurement for orthopaedic HRMDs across four countries: Mexico (upper-middle income country) and United Kingdom, Switzerland and Germany (high income countries) and conducted in-depth interviews with healthcare system stakeholders. We used semi-structured interviews among four interest groups: (i) healthcare system stakeholders who represented macro and meso levels, and supplier (Group 1, 2, and 4) to understand how the health system environment affects procurement (regulations for HRMDs, eligibility for HRMDs, programmes targeting quality of HRMDs, etc.), and (ii) orthopaedic specialists who represent the micro level (Group 3) to capture the interplay between procurement regulations and practices, the interests of parties involved directly or indirectly in procurement, and clinical practice and outcomes.

3.2. Research methods to achieve objective 2

Sub-study two (see chapter 5)

For sub-study two, our research approach is based on a working framework presented in Figure 5.1, which is guided by two considerations (i) procurement supports healthcare delivery and (ii) procurement decision-making is knowledge sensitive. First, we defined three healthcare delivery levels based on the healthcare delivery model [7]: 1) macro (normative and policy mechanism); 2) meso (insurance system & care provider facility); and, 3) micro (orthopaedic specialist and patient).

Differentiating between these levels is a crucial aspect of our research because public procurement in Mexico and procurement decisions take place at the meso level and not at the micro level. The user is employed by the social security institute or MOH and has little autonomy during procurement decision-making in respect to select a medical device. This differs from other healthcare systems where users are self-employed and the procurement mechanism used by healthcare providers is independent of a central purchasing function [79]. Second, we explain procurement based on the supply link framework [66] and embed it along the three healthcare delivery levels. Procurement has three main actors: supplier; procurement administration (purchaser); and, internal customers (at the meso level) and users (at the micro level). The interaction between the main actors is shown by arrows and defined by (i) procurement (administrator or agent) and internal customer or user, and (ii) procurement and supplier. Third, we implemented the four knowledge management dimensions [80] as the underlying concept of this research approach and used them as orientation to analyse factors of managing knowledge (healthcare delivery levels), to assess the role of knowledge from clinical procedures and in relation to procurement, and to identify findings having the ability to improve managing knowledge. We used semi-structured interviews among different interest groups. The study is based on: (i) semi-structured interviews with healthcare system stakeholders that represented macro and meso levels (Group 1) to analyse how knowledge of clinical procedures is managed among the knowledge management dimensions; and (ii) semi-structured interviews with orthopaedic specialists who represent the micro level (Group 2) to assess the role of knowledge from clinical procedures and in relation to procurement of orthopaedic medical devices.

Sub-study three (see chapter 6)

For sub-study three, our research approach is based on a working framework, which is guided by two considerations: (i) end-users have low purchasing decision autonomy, and (ii) purchasing fails to integrate a broader spectrum of decision criteria such as clinical long-term outcome of medical device brands. The framework influenced the data collection and analysis in three ways. First, the framework helped to describe the role of orthopaedic specialists in purchasing decision-making. Second, to assess their experience with purchasing processes and the relationship to clinical results. Third, to obtain ratings of them on areas for the improvement of outcomes of purchasing processes. The study is based on primary data collected through a survey, representing end-users of orthopaedic HRMDs, defined as orthopaedic specialists in Mexico.

3.3. Research methods to achieve objective 3

Sub-study four (see chapter 7)

For sub-study four (see chapter 7), our research approach is based on a working framework (Figure 7.1), which is guided by two considerations: (i) MDLC represents key functions for medical devices and as a whole it is a functional system contributing to improved health, and (ii) important stakeholders related to the MDLC exert their influence at the macro level (regulation and policy mechanism), meso level (public healthcare institutions and care provider facilities), and micro level (healthcare professional and patient). The framework guided the data collection and analysis. We used semi-structure interviews among different interest groups: (i) stakeholders influencing MDLC areas; (ii) stakeholders influencing between MDLC areas; and (iii) stakeholders that have potential to influence MDLC areas in the future.

Sub-study five (see chapter 8)

For sub-study five (see chapter 8), our research approach is based on a literature review, which is guided by two considerations: (i) issues concerning medical devices

(regulation, quality standards, technology policies, epidemiology of joint replacements, economic and health burden of revision surgery), and (ii) the use of survival rate benchmarks of orthopaedic implants as „do not do recommendations"-rule for decision-making in Mexico.

3.4. Research methods to achieve objective 4

For sub-study 6 (see chapter 9), our research approach is based on a stakeholder analysis used as foresight and based on four steps: demarcating the analysis, identifying stakeholders, analysing stakeholder characteristics, concluding on stakeholder's position, interest, and resources in relation to the proposed changes or improvements. This study encompasses possible ways forward in fostering the regulation, assessment, and management of orthopaedic medical devices that address the macro (federal level), meso (institutions of public and private sector), and micro (orthopaedic specialist) level of healthcare delivery. For this study we use a national level of analysis collecting data from the multiple interest groups concerned with the different healthcare delivery levels. We used structured interviews [81] and included stakeholder groups that are directly or indirectly related to the MDLC areas at the macro, meso, micro, and/or supplier level. The information obtained during qualitative data collection is used to provide important insights from stakeholders regarding if and how they can affect or be affected by the issues under consideration among different interest groups.

3.5. Ethical statement

The sub-studies were conducted in compliance with good epidemiological practice. The work proposed herein fully complied with the ethical principles stipulated in the declaration of Helsinki. The researcher ensured that generated data was anonymised and confidentiality was maintained during all the proposed work, for survey reports

and scientific publications. An informed consent was obtained of participants who participate either in the survey or in the focus groups. They were informed about the survey purposes in detail, their involvement (answering questionnaire) and benefits from participation and that the participation in the survey was entirely voluntary.

The ethical committee of the Autonomous University of Mexico [82] approved this research project (Date of approval: November 4th 2014, FMED/CI/SPLR/188/2014). The study was submitted to the ethical review committee of Northwest and Central Switzerland overseeing research activities at the University of Basel. Given the characteristics and the involved methods, the committee exempted the study by decision letter dated 24th June 2014 from an ethical review. Along the national guidelines of the Health Research Authority Decision Tool, no formal ethical approval was required for the United Kingdom. Similarly in Germany, guidelines of the ethic committees of the State Chambers of Physicians for “Nordrhein”, “Hessen”, “Baden-Württemberg”, and “Bayern” waive the present study from formal ethical approval (paragraph 15 of the medical professional code of conduct and their requirements for studies to be registered [83]). All interviewees gave written or verbal informed consent before the interview.

4. Effects of procurement practices on quality of medical device or service received: A qualitative study comparing countries

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4.1. Abstract

Background: We know little about how procurement of high-risk medical devices (HRMD) affects clinical practice and outcomes. In health systems in high-income countries, and specifically those that maintain a national arthroplasty registry, procurement decisions are frequently influenced by long-term clinical results, with the goal of ensuring at least standard quality of HRMDs. But in countries like Mexico, decision-making is often dominated by lowest acquisition price. We set out to study the impact of procurement for orthopaedic HRMDs on clinical procedures and outcomes.

Methods: We based our qualitative study on 59 in-depth interviews with stakeholders from Mexico, Switzerland, Germany, and UK: orthopaedic specialists, government officials, other experts, and social security system managers or administrators. We took a healthcare delivery approach to capturing and comparing factors that affected the regulations of HRMDs and procurement processes, and to understanding connections between procurement and clinical practice.

Results: Our findings demonstrate for procurement processes that the three European countries compared to Mexico don' t have similar concerns with regards to their procurement processes. Deficiencies of procurement regulations and practices identified from representatives in Mexico were almost absent in European countries. We identified three areas of deficiency: 1) HRMD regulations based on insufficiently robust clinical evidence (mainly noted by European countries); 2) Follow-up on Health Technology Assessments is inadequate (noted by Mexico) and methodology not always good enough (noted by European countries); and, 3) Lowest-acquisition price often guides procurement decisions and thus may not align with needs of clinical procedures (noted by Mexico and some European countries).

Conclusions: Procurement processes for orthopaedic HRMDs may have an impact

on clinical procedures and outcomes. A favourable approach is one where orthopaedic specialists are parties to the procurement process, and post-market surveillance data informs decision-making. Actors in the procurement process can improve their impact on clinical procedures and outcomes by developing specific strategies that better align the needs of both, procurement and clinical procedures.

Keywords

Medical devices, Procurement, Purchasing, Health systems, Medical technology, Orthopaedic

4.2. Background

The procurement process supports healthcare delivery [60] and includes activities related to purchasing and managing inputs, such as demand management, selection and contracting, relationship management, and operational delivery [67]. Ideally, procurement decisions should be guided by principles of transparency and money should be spent efficiently [84]. However, in some procurement systems, the pressure to contain cost is very high, and clinicians have less input into the process than administrators. We are here concerned with the procurement of high-risk medical devices (HRMDs), and that some procurement systems do not take the concerns of all parties into account, or work to resolve their competing interests. HRMDs are highly regulated medical devices (class III medical devices) implanted in patients, such as knee or hip prostheses used for arthroplasty surgery.

In health systems of high-income countries, specifically those that have a national arthroplasty registry, procurement decisions usually take long-term clinical results into account. National registries can contribute to quality assurance by tracking and monitoring the clinical performance of orthopaedic implants [26]. Clinical

performance can be measured with outcome data, like the length of time certain implants last (implant survival) [85] and used to define implant survival requirement [55]. Low- and middle-income countries may lack these quality assurance initiatives, and not give the procurement process the attention it deserves [62]. In these countries, healthcare system actors are urgently concerned with resolving larger healthcare questions, like universal access to healthcare services, before they turn their attention to optimization. For example, reorganizing Mexican procurement processes would improve outcomes but Mexico's' resources are mainly dedicated to meeting other goals, including universal coverage [86].

There is a dearth of knowledge about the processes health service providers have devised for procurement [8, 87, 88]. Papers that discuss procurement are usually concerned with evaluation measures [66], including financial measures like cost and time [88]. Extra-financial measures can also be used to flag weaknesses in the procurement process [64]. These measures can capture aspects of the procurement process that financial measures cannot [68]. A recent paper from the United Kingdom reflected on the history of procurement processes of the health sector, and offered a conceptual framework for clinicians and managers in the National Health Service (NHS) to help them better understand their role in procurement and to improve procurement practices [84]. A study on Mexico described the association between procurement practices and the risk of sub-standard medical devices or services received [8, 60], but there were no follow-up studies providing insight into this association.

Purpose

We set out to study the impact of procurement on clinical practice and outcomes for orthopaedic HRMD (highly regulated medical devices that remain in the patients' body). We took a healthcare delivery perspective in our effort to determine (i) how the

set-up of HRMD regulations exerts influence on procurement (macro level), (ii) how procurement regulations and practices align with expectations of clinical practice (meso level) and, (iii) how procurement practices affect clinical practice and outcome (micro). We adapted the healthcare delivery model (HCDM) [7] and the supply link framework [66] so our research approach model captured the factors that influence procurement regulations and practices for orthopaedic HRMDs (Figure 4.1).

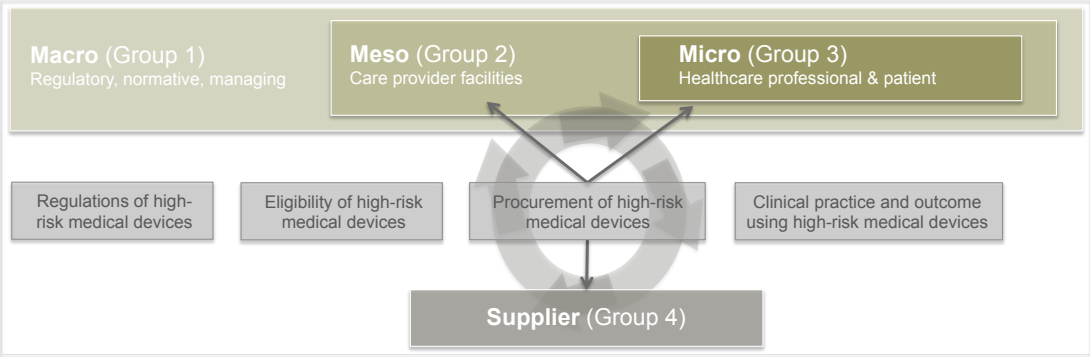

Figure 4.1. Research approach model

We focus on three healthcare delivery levels: 1) macro (regulatory, normative, managing); 2) meso (care provider facility); and, 3) micro (healthcare professional and patient). We emphasised procurement based on the supply link framework and installed it between the meso and micro levels. Procurement has three main actors: supplier; procurement administration (purchaser); and, meso level (internal customer) and micro level (user). The interaction between the main actors is defined by (i) procurement administration and internal customer or user, and (ii) procurement administration and supplier. We also defined themes related to procurement: (i) regulations for HRMDs, (ii) MD eligibility, (iii) procurement, and (iv) clinical procedures.

4.3. Methods

Setting

To better understand the impact of procurement on clinical procedures and outcomes, we compared the context and set-up of procurement for orthopaedic HRMDs across four countries: Mexico (upper-middle income country) and United Kingdom, Switzerland and Germany (high income countries) and conducted in-depth interviews with healthcare system stakeholders. We interviewed (i) healthcare system stakeholders who represented macro and meso levels, and supplier (Group 1, 2, and 4) to understand how the health system environment affects procurement (regulations for HRMDs, eligibility for HRMDs, programmes targeting quality of HRMDs, etc.), and (ii) orthopaedic specialists who represent the micro level (Group 3) to capture the interplay between procurement regulations and practices, the interests of parties involved directly or indirectly in procurement, and clinical practice and outcomes.

Rationale and validity of selected research method

We chose this approach because a quantitative approach would not have given us enough data to answer our sensitive and complex research question, and because there were so few prospective participants representing the macro level and low-to-moderate number of prospective participants representing the meso level.

To ensure validity and reliability we used the following strategies: (i) during interviews we probed deeply to uncover attitudes, open up new dimensions of a problem, and to urge the stakeholder to describe their personal stake in the process, (ii) we triangulated data by defining four groups of stakeholders per study country, and (iii) we used different interview guides (described in “data collection”) that we pre-tested with few stakeholders from the study countries.

Study country selection

We wanted to compare the context and set-up of procurement in Mexico in relation to countries that met the following inclusion criteria: (i) No centrally organized procurement process mandated for the whole healthcare system; (ii) Healthcare system had a DRG payment mechanism to reimburse for HRMD; (iii) Country had a National Arthroplasty Registry for HRMDs (established or in progress); and, (iv) Discussion about the clinical burden of high-risk HRMDs was on-going in that country. We selected The United Kingdom, Switzerland and Germany from a list of countries that met these criteria and on purposive criteria.

Study population and recruitment

We interviewed 59 people. Of these, 26 (44%) were government officials or experts who focused on health regulations, health technology assessment, reimbursement, adverse events and complaints, medical device quality, investigation, or medical training (Group 1 represented the macro level); 6 (10%) were staff of the healthcare provider facility, responsible for or expert in procurement, quality and investigation (Group 2 represented the meso level); 15 (26%) were orthopaedic specialists (Group 3 represented the micro level); and, 12 (20%) were employed by the medical device industry (Group 4 represented the supplier level). Table 4.1 shows the composition of participants by stakeholder country.

Table 4.1. Composition of participants

Stakeholder group	Mexico	Switzer-land	Germany	UK	Other	Total
Group 1 (macro level)	9 (38%)	7 (50%)	5 (50%)	4 (40%)	1 (100%)*	26 (44%)
Regulations	2 (22%)	2 (29%)	1 (20%)	-	-	7 (27%)
Eligibility	2 (22%)	2 (29%)	2 (40%)	-	-	7 (27%)
International expert	2 (22%)	-*	-*	-*	1 (100%)*	3 (11%)
Quality assurance	3 (34%)	3 (42%)	2 (40%)	-	-	9 (35%)
Group 2 (meso level)	3 (12%)	1 (8%)	1 (10%)	1 (10%)	-	6 (10%)
Group 3 (micro level)	8 (33%)	3 (21%)	2 (20%)	2 (20%)	-	15 (26%)
Group 4 (supplier)	4 (17%)	3 (21%)	2 (20%)	2 (20%)	-	12 (20%)
Total per country	24 (41%)	14 (24%)	10 (17%)	10 (17%)	1 (1%)*	59 (100%)

* As an international expert for the three European countries under review we selected one stakeholder that is listed in column "Other".

We identified and recruited participants for interviews: (i) by searching each countrys' listings from the ministry of health and industry for orthopaedic HRMDs, national academic expert, orthopaedic key opinion leaders, organisations, hospitals, and institutions; and (ii) we asked interviewees to recommend other national or international experts in our area of interest. We focused on generating sufficient and useful material to reflect a variety of opinions and experience, and achieving saturation for general themes. We based the sample we selected for each country on three criteria: (i) it should include at least one stakeholder for each group; (ii) stakeholders from each group should be distributed evenly across study countries; and, (iii) each country group provided its experience and opinions on each of the four theme (regulations for HRMDs, eligibility for HRMDs, procurement, clinical practice, and clinical outcome). We approached prospective interviewees between June and September 2014, contacting them by email or phone to introduce them to our study rationale and research. Before we invited them to an interview, the principal investigator talked or wrote to them.

Data collection

Interviews averaged 24 minutes (min=17 min, max=45 min) and were conducted in the language of the country (English, Spanish or German). We used a file naming system and anonymised interviewees by generating a list of archival numbers. The principal investigator interviewed all participants. Of the 59 interviews we conducted, 44 (74%) were face-to-face and 14 (24%) were phone interviews; only one (2%) interviewee submitted a written answer because his employer required it. We audio recorded 53 (90%) interviews and transcribed them with F5 software [89]. The transcriptions of the interviews that we did not record were based on an interview protocol. The principal investigator and one assistant transcribed the interviews, and the principal investigator reviewed them again. The interviewer used semi-structured interview guides (Table 4.2) to explore stakeholder experiences and solicit their opinions on the environment of the health system, its effect on procurement, and the role of programmes that target quality and support procurement (Group 1, 2, 4). They also asked about the influence of procurement regulations and practices on clinical procedures and outcomes (Group 3).

Table 4.2. Extraction of interview guide questions

Q1	What do you think induces healthcare professionals to claim that the clinical practice is sometimes affected adversely when the medical device (clarify that this question does not address the device technology but the brand) is selected by a purchasing or procurement department rather than by the physician itself?
Q2	What do you think are core aspects for the provision of medical device quality? The term “medical device quality” refers to a medical device that demonstrates the successful use intra-operatively (no failures of implant, instrument or surgical technique) and post-operatively (average to high implant survival rate based on clinical data). The term “provision” covers all aspects that contribute to the decision process of the purchasing or procurement department.
Q3	Evaluating the performance of a procurement process, generally generic measures (costs, time, etc.) are considered. The literature appeals that the performance of a procurement process within the health system has to be based on non financial measures too; this permits also to evaluate how the

	procurement process is embedded in its environment. Non financial measures cover i.e. information flow, failure reporting, quality monitoring, etc. What do you think are important non financial measures that contribute to the successful "provision" of "medical device quality"?
Q4	As a follow up of Q3: From the perspective of a HCP, what do you think are additional and desirable non financial measures that contribute to the successful provision of "medical device quality"?
Q5	The procurement function generally implements a quality assurance system to guarantee good practices and outcomes of a procurement process. What do you think such a system should incorporate to provide medical device quality (consultation of clinical studies, arthroplasty registers, HTAs, internal reports on implant use, etc.)?

Data analysis

We iteratively analysed the content of all interviews in MAXQDA software [90] and systematically inferred interdependencies between the experiences and opinions of stakeholders. First, we closely read each transcript (data orientation) during initial coding. Second, we selected statements that addressed frequently mentioned themes and fact-based arguments (data reduction). Third, we revised our list of themes, improved codes if necessary, and clarified ambiguous statements (data display). Fourth, we drew on the themes we identified as deficiencies in the understanding of the impact of procurement and factors influencing procurement (conclusion drawing). The main researcher analysed all data.

4.4. Results

We divided our findings into three perspectives: macro; meso; micro. Table 4.3 contains a selection of relevant quotations.

Table 4.3. Extraction of original statements

Themes	Illustrative quotations	Interviewee
Macro level: How does the set-up of medical device regulations exert influence on procurement		
Regulation for medical devices	*„[W]ho gives us the mayor quality guarantee is Cofepris...“*	Mexico (O.1._201409251747_MEX)
	“[B]ecause we had to make the experience that the regime of medical devices … in comparison to the regime of pharmaceuticals is frequently criticized due to its putative rather liberal market access requirements.”	Switzerland (O.1._201409020858_ZRH)
	„[F]or all other products especially medical devices that are classified as high-risk products there are requirements that these have to work. How this is measured is not clearly described.“	Germany (O.1._201410291400_TUT)
	„[E]ach car that is being validated hast four wheels and confirm with a specific quality norm and for medical devices it is the same”	Germany (O.1._201406260812_ZRH)
	“[I]ndeed we have a discussion that we could say that since ever there have been sometime problems also with hip implants and other implants. But this is almost not possible to avoid because for technical innovations you obtain a better understanding based on practical experiences…”	Germany (O.1._201409020858_ZRH)
Eligibility for medical devices	*“…[t]he standard list is based on evidence that is already 6 to 10 years old, obsolete, and it will be used for additional 6 years.”*	Mexico (O.1._201410031215_MEX)
	“…[b]ut what exists already which has years, our work will be to update and to classify or segment.”	Mexico (O.1._201410311530_ZRH)
	“[I]t doesn’t imply any problem, no, because the standard list contains good products.”	Mexico (O.1._201409251747_MEX)
	“[M]edical devices have relatively immature HTA methodologies that frequently fail to address the lower levels of evidence associated with medical devices…”	United Kingdom (O.1._201409181100_ZRH)
	“[C]urrently it seems that in the ministry of health there will be more focus on new responsibilities with a focus on HTA.”	Switzerland (O.1._201408211231_ZRH)
Meso level: How are procurement practices and regulations aligned with expectations of clinical practice		
Procurement regulations and practices	*“…[i]t is very economic driven and what is cheaper is what will be purchased.”*	Mexico (O.1._201409251542_MEX)
	“[T]he provider of service packages has a free ticket to select the medical device that he will provide to the hospital.”	Mexico (O.1._201409180852_MEX)
	“[T]here have been problems like always and we try to prevent this with a new tender.”	Mexico (O.1._201409251542_MEX)
	“[I]f we are lucky in procurement there are administrators that have experience and know what they are procuring. But normally this is not the case and they base their documentation on the standard list that isn’t always updated and that is very generic and in consequence we are purchasing sub-standard quality.”	Mexico (O.1._201410311530_ZRH)
	“…[i]t is not the best quality because the standard list is very obsolete and not updated and there are no specific guides to make an evaluation.”	Mexico (O.1._201409191334_MEX)

Programmes targeting quality and supporting procurement	*"…[t]he administrator now use providers for service packages … but the quality is not guaranteed because these providers don't have to provide what has been included in the standard list and they can provide what they want."*	Mexico (O.1._201409191334_MEX)
	"[S]o what I am trying to say is that it is not just the cost you need, you need have really good health economist data to support your products really well, and to also calculate the actual full treatment cost including the health benefits and the cost of the revision or failure or lack of performance …"	United Kingdom (O.1._201407211627_YRK)
	"…[w]e are under huge fiancial pressures to trying to save money and we will save on certain, any reasonable thing we can but you cannot compromise the quality on patients safety and outcomes."	United Kingdom (O.1._201407221144_BOL)
	"[T]he expectation was that hip joint should have a survival ship of 90 % at 10 years at post market."	United Kingdom (O.1._201408011100_LUZ)
	"…[a] new product and the clinical data isn't gonna be there and how do you fight against that. And that is when you need that senior engagement where you end up ... And quality is there, finance is there, they than gonna said to me "but how does it interact in the patient?"	United Kingdom (O.1._201407221144_BOL)
	"[I] think what we do is continuing to mature and it gets better each year."	United Kingdom (O.1._201408011100_LUZ)
	"[S]o HTA they are useful but they are not anything like what is a clinical outcome."	United Kingdom (O.1._201408241352_LUZ)
	"[W]ell there are hospitals where the price takes over priority so that the surgeon just has to accept what he get provided."	Germany (O.1._201408061342_DOR)
	"…[i]n Mexico we are missing something such as a department that monitors clinical practice…"	Mexico (O.1._201410070910_MEX)
	"…[w]e have different social security systems and in consequence the secretary of health doesn't have full regulatory control."	Mexico (O.1. _201410061100_MEX)
	"…[t]here is no culture of quality assurance even we have good structures … but when you go to a health centre you find disinformation, …, no continuous information, no one monitoring clinical practice…"	Mexico (O.1._201410061100_MEX)
	"…[o]r we do have two systems doing the same and in some way they are competing and this causes confusion."	Mexico (O.1._201410061100_MEX)
	"…[u]nfortunately we cannot make a patient monitoring of more that 2 to 3 years because of the system."	Mexico (O.1._201409251747_MEX)
	"…[w]e have indicator that doesn't represent quality assurance but it is somehow a constant monitoring of the quality by means of the indicator that we are using."	Mexico (O.1._201411191930_ZRH)
	"[I]n my opinion a registry is a good basis for decision-making…"	Switzerland (O.1._201408121000_BAA)
	" [P]rimarily we are interested in the outcome quality."	Switzerland (O.1._201407291401_ZRH)
	"…[t]o make sure, that surgeon use evidence based, to decide on their prosthesis."	United Kingdom (O.1._201407231054_LON)
	"…[t]he implant registry for us in joint replacements, is our key source of information with the devices.	United Kingdom

	The spontaneous reporting with incidence … gives you incomplete numerators and you don't now the nominators. If I am producing registry data … real time survival ship data, performances, mix of devices and than some decisions in terms of sizes, materials used, etc. So it is a very powerful tool for getting indicators on post market performance."	(O.1._201408011100_LUZ)
	"…[t]hey will be able to tell how long the implant has been available and what level of evidence there is to support its use …"	United Kingdom (O.1._201408072230_ZRH)
	"…[c]lass II and III devices have a safety-profile, but this does not include evidence of clinical efficacy."	United Kingdom (O.1._201409181100_ZRH)
	"[S]o the ODEP system would set up on the basis of guidance given by NICE … The expectation was that hip joint should have a survival ship of 90 percent at 10 years at post market … than they gave indications of how well the performance was of those devices well against set NICE criteria at a 10 year mark."	United Kingdom (O.1._201408011100_LUZ)
	"[W]ell, the surgeon can't use the Beyond Compliance implants unless they have been specifically trained and is agreed by the manufacturer and the champions surgeons. Beyond Compliance are being used by a limited number of people."	United Kingdom (O.1._201408072230_ZRH)
	"…[wi]mplant registries, which company devices, and that from all perspectives is a key item for gaining continuous information about the involving, safety profile…"	United Kingdom (O.1._201408011100_LUZ)
	"[J]ust think in the patient. When you are facing the problem of an artificial cardiac valve and you get informed by the health professional that they don't have information about the clinical value but that they can assure you that it doesn't cause any electric shock and doesn't oxidize…"	Germany (O.1._201408201611_KOL)
Micro level: How may procurement practices influence clinical practice and outcome		
Cost-related factors	*"[W]e are drawing attention to the economic aspects but not to what the surgeon needs…"*	Mexico (O.1._201410031215_MEX)
	"…[t]he aspect is fundamental economically; that what is cheaper is that what will be purchased."	Mexico (O.1._201409251542_MEX)
	"[U]nfortunately in our country what we do is that we don't focus on the best quality but on the best price. In consequence this impairs the delivery of quality of care, but this is only one aspect …"	Mexico (O.1._201409171712_MEX)
	"[N]ow, the person who is just buying hips is not thinking about the added value to the hospital. That is why the procurement people got to think on value and they need to understand all the elements that could make up that value. Otherwise they make own purchasing decisions."	United Kingdom (O.1._201407210956_LEE)
	"[W]ell, there are hospitals where price dominates everything…"	Germany (O.1._201408061342_DOR)
	"…[I] did experience in one healthcare facility that they switched from one cicatrice material to another because of a lower price … we observed more wound problems than before."	Germany (O.1._201408061342_DOR)
Knowledge-related factors	*"[T]he surgeons' opinion is important to determine the services he is going to have and to calculate required quantities."*	Mexico (O.1._201410081050_MEX)
	"[b]ecause the procurement staff is deciding we don't always receive what we need or what the patient requires."	Mexico (O.1._201409191220_MEX)
	"…[w]e as surgeon do not always agree with a provided product. Based on our experience and	Mexico

	knowledge we believe in other products of higher quality and superior performance…"	(O.1._201409251747_MEX) Mexico
	"[T]he surgeon is asked to work with what he has."	(O.1._201409251747_MEX) Germany
	"The decision if we use a new implant system is always done by the user and the user is the surgeon"	(O.1._201408051326_FRA) Germany
	"[I] had the impression that the surgeons weren't very satisfied when they were not involved in decision-making."	(O.1._201406260812_ZRH) Switzerland
	"…[t]he expertise of the surgeon is very crucial. He is responsible for what the patient gets implanted and therefore he needs to be convinced of what he is using during surgery."	(O.1._201408121000_BAA) Switzerland
	"[I]n Switzerland much is in the responsibility of the surgeons and the hospitals"	(O.1._201409081044_BER) Switzerland
	"… [i]n the end it is up to 90% the surgeon."	(O.1._201407101428_LUZ)
Clinical evidence related factors	*(please consult quotations for programmes targeting quality and supporting procurement)*	
Procurement framework related factors	*"[I]n some situations what we have seen is that they use an inadequate implant size … but there haven't provided another implant…"*	Mexico (O.1._201410091420_MEX)
	"…[t]hey start the surgery and when they are gonna to use the implant system they realize that it is incomplete …"	Mexico (O.1._201409171712_MEX)
	"[E]ach surgeon no matter how experienced he is needs to be trained on a new implant … each patient that is suffering damages due to wrong is not acceptable."	Switzerland (O.1._201408121000_BAA)

Macro level: How does the set-up of HRMD regulations exert influence on procurement?

We asked interviewees from all countries to share their experience and opinions about the role played by HRMD regulations (e.g. market approval, Health Technology Assessments [91], eligibility of HRMD, etc.). Opinions of representatives from European countries and stakeholders of Group 3 and Group 4 from Mexico agreed that it was important to update requirements in the regulations for HRMDs.

Regulations for HRMDs

Health regulations focus primarily on assuring standards of clinical safety, performance, and efficacy of HRMDs [51]. However, this does not prevent sub-standard clinical results in the short- or long-term. The requirements for HRMD include proofs of quality like risk assessments and laboratory analysis based on ISO norms that are important to ensure material safety. However, if HRMDs need to meet no other criteria for judging long-term clinical safety (e.g. adequate implant survival or no early implant failure), the quality of the clinical procedure and outcome may be compromised.

In general, interviewees from all countries pointed out the differences between stringent requirements for pharmaceutical products, and less strict requirements for HRMDs. Most of interviewees in Groups 3 and 4 shared this view. Representatives from Mexico who had little or no concern about current health regulations explained that current regulations mostly focus on HRMDs that have already been approved by the United States or a European country.

The main concern the representatives of European countries shared is that HRMD regulations used insufficient robust clinical evidence for HRMDs. They were concerned that market approval of orthopaedic HRMDs were poorly regulated because they were generally designed to ensure clinical safety such as material

conformity checks based on ISO norms. But this approach does not focus on long-term clinical safety (e.g., post-operative survival rate of an implant). Some European representatives wanted to see clinical trials, or at least prospective studies, to become a mandatory part of the health regulation process for HRMDs.

Regulations for the eligibility of HRMDs

Recently, HTAs for HRMD have been criticized as not being based on available clinical evidence [51]. In general, the concern was that HTAs were often not followed up or updated [82], or not fully applied using inadequate methodology (mainly European countries). The role played by HTAs [92] differs between countries and the focus of the role of HTAs is sometimes shifted as guiding decision-making based on rather rigid evaluation criteria.

In Mexico, an inter-institutional committee under the Secretariat of Health, uses HTA findings to decide which technologies are eligible for purchase (national standard list). This list guides strongly procurement decisions in the public sector in a way so that differences between similar medical devices are insufficiently taken into consideration. Different public social security systems may tailor the standard list to their needs. Most interviewees from Mexico thought of the standard list as a kind of quality seal for HRMDs. However, some Mexican representatives said that HTAs did not always meet the highest standards because they had methodological weaknesses. These respondents thought the standard list as in need of being updated to eliminate out-dated technologies and correct wrong or very generic descriptions of HRMD technologies (e.g. according to material specification).

Representatives from European countries did not see the same problems. Both the UK and Germany commonly conduct HTAs and use their findings to decisions about reimbursement lists only. But representatives from the UK, Switzerland and Germany also questioned the significance of HTA findings and questioned whether HTA

methodology was adequate for HRMDs. In Switzerland, HTAs receive less attention but inform decisions about reimbursement lists.

Meso level: How do procurement regulations and practices align with expectations of clinical practice

We asked interviewees from all countries to share their experiences and opinions about the forces that shape the interplay between actors in procurement. Stakeholder groups from European countries made similar statements; representatives from Mexico had different opinions and experiences.

Procurement processes regulations

Healthcare providers have different avenues to consolidate purchase power. The largest concern was about to closely align procurement to clinical procedures, so that it met, for example, the clinical requirements of orthopaedic specialists. Regulations that emerged from a centrally organized procurement process system were associated with sub-standard delivery of healthcare due to inefficient alignment of procurement and clinical procedures.

In Mexico, it is common to regroup purchase demand at regional and national level and per social security system so as to increase purchase power. This is why procurement processes in Mexico are bureaucratic and highly standardized. The Mexican law offers two options for evaluating offers of HRMD that are listed in the standard list: 1) Percentage and points or cost-benefit to choose the highest scored medical device, and 2) using the Binario evaluation to choose the cheapest medical device among those that meet device requirements. Most representatives from Mexico were satisfied with the tender system, but did not always agree with the way offers were evaluated. They were concerned about the negative effect it might exert on clinical practice.

European care providers use different ways to consolidate their purchasing demand. In Germany, a hospital belongs to a purchasing syndicate, or negotiates independently with suppliers. Some Europeans emphasized that a buying syndicate can exert adverse influence (provide HRMD that does not satisfy clinicians needs). In the UK, many trusts or hospitals use the services of, for example, organizations like the “NHS supply chain”, which negotiate prices for their members. In Switzerland, procurement is almost entirely left to hospitals and clinicians. Buying syndicates are rare and Swiss interviewees mostly seemed to like their independent system. In European countries, most orthopaedic HRMDs are reimbursed through DRG-based payment systems, which cover expenditures of service deliverers like hospitals. All European stakeholders agreed that when DRG systems were introduced, it pressured them to lower costs but it was not associated with a general decline in quality. For example, in the UK, procurers must balance cost expectations against quality of the HRMD.

Programmes targeting quality and supporting procurement

We identified a variety of programmes designed to prevent purchase of sub-standard orthopaedic HRMDs. Some of these fill gaps in HRMD regulations for obtaining commercial approval, since approval is often based on insufficiently robust clinical evidence [93]. These programmes were initiated and are operated by government, orthopaedic associations, or orthopaedic specialist groups but not all countries have them. Representatives from European countries were convinced of the importance of these programmes that, for instance, use e.g. implant survival data from a national arthroplasty registry to inform decision-making. But representatives from Mexico, which has no similar programmes, had a different opinion.

In Mexico these types of program don’t exist. Stakeholders mentioned one regional project in Mexico that had been initiated by an association of orthopaedic

specialists in collaboration with a pharmaceutical company. The program was intended to make orthopaedic clinical practice in Mexico more transparent by defining methods for collecting and analysing clinical data. Groups 3 and 4 underlined the need for quality assurance programmes that support areas of decision-making like procurement processes and clinical procedures, but most stakeholders were not specifically concerned about this. Some thought the failure to define and introduce such programmes was due to (i) missing or recently discovered interest in integrating clinical evidence into decision-making and, (ii) a fragmented and segmented health system with different social security systems, which made it hard to ensure all systems equal access to all pertinent clinical evidence.

In the European countries, stakeholders were clear about the importance of clinical evidence for HRMDs. In the UK, these programmes or initiatives focus on quality and support for procurement: the “Orthopaedic Data Evaluation Panel” [55]; “Beyond Compliance”; and, the national joint registry. The Orthopaedic Data Evaluation Panel provides a due diligence on orthopaedic HRMDs. Beyond Compliance offers to clinical supervise new HRMDs before they are widely used, and where clinical evidence is not yet robust. In Germany, EndoCert and the German arthroplasty registry offer support. EndoCert certifies centres of arthroplasty based on minimum quality standards and defines requirements (e.g. minimum of 100 arthroplastic hip or knee surgeries per year, at least two main surgeons at the hospital facility, at least 1 of these surgeons is specialized in orthopaedic surgery) [94]. In Switzerland, we identified only the Swiss implant registry that is embedded in the national association for quality development. Most of the European stakeholders thought that registries support decision-making and improve quality in clinical practice.

Micro level: How procurement practices can influence clinical practice and

outcome

We identified several themes in the transcripts that described factors in the procurement process that influence clinical practice and outcomes. These were primarily identified by Mexican stakeholders and include factors related to (i) cost; (ii) knowledge; (iii) clinical evidence, and (iv) the setting for procurement. The themes found in transcripts by European stakeholders were rare and not the same as the themes in the transcripts of Mexican stakeholders.

Factors related to cost: Importance of lowest acquisition price

In Mexico, price is often more important than clinical considerations, in the selection and contracting phase of procurement. Many of the Mexican stakeholders thought this detrimental to the clinicians' clinical practice and to quality of care. For them, this focus on buying at the lowest price was the root of the problem. Some Mexican stakeholders said that clinical evidence was often unavailable and thus could not factor into procurement.

In the UK, Switzerland and Germany, interviewees did not think price was paramount in decision-making, though many interviewees said that when their DRG system was introduced, pressure to cut costs influences procurement practices. They did not, however, see this as a negative. For example, cost-benefit analysis is useful for choosing between competing HRMDs with similar characteristics, but which may have different clinical long-term effects. Some interviewees from Germany explained that price could take priority over important clinical factors for one specific buying syndicate. But European interviewees commonly saw clinical evidence data as relevant and necessary to inform procurement.

Factors related to knowledge: Lack of orthopaedic specialist on decision-making committees

Most of the interviewees from European countries, and most from group Groups 3

and 4 from Mexico, provided examples for the importance of the orthopaedic specialist to decision-making on HRMDs. But the role of the orthopaedic specialist in decision-making of a HRMD was different in the European countries under review and Mexico.

Many representatives from Mexico said that orthopaedic specialists were not very involved in decision-making, and that this was typical for the public hospital they worked for. This was generally true for Mexican stakeholders from Groups 3 and 4, and was partially true of some stakeholders in Groups 1 and 2. This was mentioned for all public social security systems and care providers of the Secretariat of Health. Two exceptions for care providers of the Secretariat of Health were the National Institute of Rehabilitation and the National Institute of Nutrition.

Representatives from European countries said that orthopaedic specialists are typically closely involved in most instances. For instance, they emphasized that surgical expertise is essential to determine if switching from one HRMD to another, cheaper HRMD would have disadvantages for clinical practice or outcome.

Factors related to clinical evidence: Rigid evaluation criteria do not sufficiently differentiate between similar orthopaedic HRMDs

Long-term clinical results of similar HRMDs are important and should be always considered during decision-making, but countries used this data differently for procurement. Representatives from European countries argued that only an expert in orthopaedics could evaluate long-term clinical results and decide what implications they had for similar HRMDs.

Most representatives from Mexico said market approval and HTA findings often determined decisions on similar HRMDs, rather than basing them on long-term clinical effects. They said most Mexican social security systems assign procurement administrators and decision-making boards to make those decisions and these focus

on conformity to material specifications and cost-benefit aspects; however, these boards did not include orthopaedic experts.

Factors related to the procurement setting: Procurement framework can influence quality of service received

Short-term tenders that procure large quantities of HRMDs are very common in Mexico, but not in European countries. In Mexico, stakeholders from Groups 3 and 4 but also few stakeholders from Group 1, reported that short-term tenders affect clinical practice. We isolated three themes: (i) the available selection of implants for treating different types of patients may be limited; (ii) sets of implant and instruments may be incomplete, and (iii) there is a learning curve for orthopaedic specialists for each new HRMD system. Representatives from Mexico said they sometimes need to treat patients with sub-optimal implants, or that they didn't have the right HRMD sizes or instruments. Only few representatives thought the learning curve was an obstacle to their clinical practice. They liked being exposed to different HRMDs, but regretted that they were unable to gain long-term clinical experience on a specific HRMD. Stakeholders from Europe spoke hypothetically on these themes, but their situation was different from Mexican stakeholders. They pointed out that short-term contracts lead to short-term use of an orthopaedic implant, which would make it impossible to gain adequate experience with a given.

4.5. Discussion

We found that in the European countries under review, there is substantial attention being given to regulations, which provide the market approval and influence the framework for the procurement of HRMDs. In Mexico, however, there are rarely similar discussions or concerns because they have not identified any reason so far to evaluate or update the current regulations for HRMDs. Mexico does not have procedures in place to prevent sub-standard quality of HRMDs and apply post-

market surveillance across all social security institutions. For instance, increased incidence in European countries under review of post-operative problems resulting from the use of metal-on-metal hips, or after breast implants, sparked wide discussion about HRMDs. This heightened the attention to health regulations for HRMDs and has recently spurred the EU to redefine the requirements for CE marking (founded on EU safety), health and environmental protection requirements before a product is placed on a market. In Mexico, however, in 2016 the inter-institutional committee responsible for the standard list of medical devices introduced a specific catalogue of technologies related to orthopaedics and traumatology [1]. The committee has identified the need that these medical devices require specific attention.

Our findings demonstrate for procurement processes that the three European countries compared to Mexico don't have similar concerns with regards to their procurement processes. Deficiencies of procurement regulations and practices identified from representatives in Mexico were almost absent in European countries. Table 4.4 summarizes the relevance of concerns about regulations of HRMDs and procurement processes, and about factors influencing procurement for all groups and study countries.

Table 4.4. Relevance of concerns about regulations of HRMDs and procurement process, and about factors influencing procurement

Stakeholder group	Mexico	Switzerland	Germany	UK	Total
Regulations for market approval					
Group 1	-	+++	+++	+++	**++(+)**
Group 2	-	++	++	+++	**+(+)**
Group 3	++	+++	+++	+++	**++(+)**
Group 4	++	+++	+++	+++	**++(+)**
Total	**+**	**++(+)**	**++(+)**	**+++**	
Regulations for eligibility					
Group 1	+	++	+++	+++	**++(+)**
Group 2	-	+++	++	++	**+(+)**
Group 3	++	+++	+++	+++	**++(+)**
Group 4	++	++	+++	+++	**++**
Total	**+**	**++**	**++(+)**	**++(+)**	
Procurement regulations and practices					
Group 1	++	-	-	-	**(+)**
Group 2	-	-	-	-	**-**
Group 3	+++	-	+	-	**+**
Group 4	+++	-	+	-	**+**
Total	**++**	**-**	**(+)**	**-**	
Programmes targeting quality and supporting procurement					
Group 1	+	-	-	-	**(+)**
Group 2	+	-	-	-	**(+)**
Group 3	++	-	-	-	**(+)**
Group 4	++	-	-	-	**(+)**
Total	**+(+)**	**-**	**-**	**-**	
Factors influencing procurement					
Cost	+++	-	+	-	**+**
Knowledge	+++	-	+	-	**+**
Clinical evidence	+++	-	-	-	**+**
Procurement setting	+++	-	-	-	**+**
Total	**+++**	**-**	**(+)**	**-**	

+++ very relevant ++ moderate relevant + relevant - not relevant

Taken together, our findings for the impact of procurement on clinical practice and outcomes demonstrate that:

1) In Mexico and compared to the three European countries, price is often more important than other criteria such as the effect of different orthopaedic HRMDs on clinical outcomes. Basing procurement decisions on the Binario option may cause

this problem. Since decisions do not rely on detailed assessments of HRMDs that consider the effects of variants of similar orthopaedic HRMDs on clinical practice and outcome, knowledge of Mexican orthopaedic specialists is insufficiently integrated in decision-making.

2) Mexicos' concern is cutting cost and controlling for corruption. Short-term, high-volume tenders cut costs and provide transparency that protects against corruption. The force these tenders exert on clinical practice may not leave much room for improvement without adequate health technology policies. European countries also face cost pressure, especially since the introduction of DRG systems, but the long-term focus (clinical results) and projections of European procurement systems prevent some of the problems Mexico faces.

3) Mexican orthopaedic specialists are rarely involved in procurement decision-making, but orthopaedic specialists do not generally hold against this. It may be that it is difficult to voice strong critique about inconveniences caused by the very rigid centrally organized procurement process system, which is largely disconnected from clinical practice. In European countries it would be unthinkable to exclude the orthopaedic specialist from decision-making, perhaps since professional associations, are involved in setting standards and exert great deal of influence in the health system.

This study proves a connectivity between procurement and clinical practice but does not set a standard; given that the identified aspects crucial to the procurement process, future studies analysing procurement processes are needed before it becomes apparent what aspects and factors within a health system finally determine procurement regulations and practices.

The limitations and strengths of the study

We believe this is a novel investigation of procurement processes for HRMDs as it

examines the influence these processes may exert on clinical practice. We identified specific aspects of procurement practices, using orthopaedic HRMDs as our example, and showed how they influence clinical practice and fail to prevent sub-standard medical care. We included a range of stakeholders, but did not include patients or representatives from rehabilitation centres. Thus, representation of stakeholders of the micro level is incomplete and we only considered orthopaedic HRMDs, this limits our ability to generalize our findings.

4.6. Conclusion

Procurement processes for orthopaedic HRMDs may have an impact on clinical practice and outcomes. Health technology regulations require continuous improvements to prevent sub-standard clinical results in the short-term or long-tem. Regulations and practices for decision-making of procurement for HRMD may have a large influence on clinical practice. In all the health systems we reviewed, there was tension between cost and quality, and concern about the interaction between procurement and the user (orthopaedic specialist). A favourable relationship between procurement and clinical practice is one where orthopaedic specialists are parties to the procurement process, and post-market surveillance data informs decision-making. We are not yet sure if cost is the predominant obstacle in procurement for HRMD in Mexico, or if other factors, like the way clinical data is managed, have as great an effect. We found that Mexico does not assure and monitor long-term effects on the health of patients implanted with HRMDs.

List of abbreviations

DRG, Diagnostic related groups; HCDM, Healthcare Delivery Model; HRMD, High-risk Medical Device; HTA, Health Technology Assessment; NHS, National Health Service; NICE, National Institute for Health and Care Excellence; OECD, Organisation for Economic Co-operation and Development; PAHO, Organización

Panamericana de la Salud (Pan American Health Organisation); UK, United Kingdom; WHO, World Health Organization

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Availability of data and materials

The data supporting our findings is contained within the manuscript and within Table 4.3. The original transcripts of all interviews will not be shared due to confidentiality reasons.

Authors' contributions

All authors were involved in the outline of the paper. ML has made substantial contributions to conception and design, acquisition of data, analysis and interpretation of data, and drafting the manuscript. KW and LD have been involved in revising the manuscript critically for important intellectual content and structure, and have given final approval of the version to be published.

Authors' information

ML is a PhD candidate and has worked from 2009 – 2012 in the area of orthopaedic medical devices in Mexico as an employee of a medical device supplier. She gained a significant understanding of procurement processes and in relation to orthopaedic clinical procedures. This research is part of a larger study to explain the connection

between procurement processes for orthopaedic HRMDs in Mexico and clinical procedures, and to provide a proposal plan how to improve procurement outcomes.

Competing interests

The authors declare that they have no competing interests.

Consent to publish

Not applicable.

Ethics and consent to participate

The ethical committee of the Autonomous University of Mexico approved this research project (Date of approval: November 4th 2014, FMED/CI/SPLR/188/2014). The study was submitted to the ethical review committee of Northwest and Central Switzerland overseeing research activities at the University of Basel. Given the characteristics and the involved methods, the committee exempted the study by decision letter dated 24th June 2014 from an ethical review. Along the national guidelines of the Health Research Authority Decision Tool, no formal ethical approval was required for the United Kingdom. Similarly in Germany, guidelines of the ethic committees of the State Chambers of Physicians for “Nordrhein”, “Hessen”, “Baden-Württemberg”, and “Bayern” waive the present study from formal ethical approval (paragraph 15 of the medical professional code of conduct and their requirements for studies to be registered). All interviewees gave written informed consent before the interview.

5. How does the knowledge environment shape procurement practices for orthopaedic medical devices in Mexico?

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5.1. Abstract

Background:

In organisational theory there is an assumption that knowledge is used effectively in healthcare systems that perform well. Actors in healthcare systems focus on managing knowledge of clinical processes like, for example, clinical decision-making to improve patient care. We know little about connecting that knowledge to administrative processes like high-risk medical device procurement. We analysed knowledge-related factors that influence procurement and clinical procedures for orthopaedic medical devices in Mexico.

Methods:

We based our qualitative study on 48 semi-structured interviews with various stakeholders in Mexico: orthopaedic specialists, government officials, and social security system managers or administrators. We took a knowledge-management related perspective (i) to analyse factors of managing knowledge of clinical procedures, (ii) to assess the role of this knowledge and in relation to procurement of orthopaedic medical devices, and (iii) to determine how to improve the situation.

Results:

The results of this study are primarily relevant for Mexico but may also give impulsion to other health systems with highly standardized procurement practices. We found that knowledge of clinical procedures in orthopaedics is generated inconsistently and not always efficiently managed. Its support for procuring orthopaedic medical devices is insufficient. Identified deficiencies: leaders who lack guidance and direction and thus use knowledge poorly; failure to share knowledge; insufficiently defined formal structures and processes for collecting information and making it available to actors of health system; lack of strategies to benefit from synergies created by information

and knowledge exchange. Many factors are related directly or indirectly to technological aspects, which are insufficiently developed.

Conclusions:

The content of this manuscript is novel as it analyses knowledge-related factors that influence procurement of orthopaedic medical devices in Mexico. Based on our results we recommend that the procurement mechanism should integrate knowledge from clinical procedures adequately in their decision-making. Without strong guidance, organisational changes, and support by technological solutions to improve the generation and management of knowledge, procurement processes for orthopaedic high-risk medical devices will remain sub-optimal.

Keywords: Medical devices, Procurement, Healthcare systems, Orthopaedic, Knowledge management

5.2. Background

Healthcare systems are knowledge intensive environments [95], where knowledge is a resource that must be efficiently managed [96]. “Knowledge management” and the “system thinking approach for systems’ knowledge” are systematic approaches to identifying, capturing, developing, sharing, and efficiently using knowledge [97, 16]. When healthcare systems take these approaches, resources like knowledge are used more efficiently [98-102]. Many knowledge frameworks exist and they encompass different strategies [103] to improve the systematic handling of knowledge and potential knowledge within systems [80]. In healthcare systems, stakeholders are concerned, for example, with knowledge from clinical procedures. This knowledge is created by processing different types of information, and is derived from health data, as well as clinical data, which includes (i) patient-related

information, and (ii) management information bearing on processes and outcomes, such as the health status of a population [104].

In healthcare systems actors focus on managing knowledge of clinical procedures like clinical decision-making to improve patient care [105-108] and activities to assure healthcare worker and patient safety [109] (e.g. healthcare working conditions that influence patient outcomes). Using this knowledge effectively and efficiently requires a substantial understanding of factors determining its management. In the general theory of knowledge management the understanding of these factors (success or context factors) varies [103] but can be grouped along four dimensions. These dimensions originated from a study comparing 160 knowledge management frameworks and describing these dimensions as [80]: people (culture, people skills, and leadership); organisation (processes and structures); management (strategy, goals, and measurement); and, information technology (infrastructure and applications).

In healthcare systems, knowledge of clinical processes is an important resource across all stages of healthcare delivery (clinician, care provider facility, social security system, regulation, etc.) [110]. Understanding the management of knowledge in the context of these dimensions and across different stakeholders involved is necessary to solve or prevent problems related to knowledge. For instance, when organisations have to manage complaints and adverse events of medical devices, they must consider more than just organisational factors (processes, structures, etc.); they also need to engage relevant stakeholders working out strategies to prevent problems influencing clinical procedures and affecting healthcare worker and patient safety [109]. A complaint is a complication occurring in the course of pre- or intra-operative procedures like, for example, the positioning of a cap liner into the cap due to surgical technique, accompanying instruments or not visible damages to the liner. An

adverse event is an undesirable occurrence for a patient and associated with the use of a medical device that requires extra treatment or the removal of an implanted medical device. For instance, a few years ago several removals of specific breast implants (quality of used material) and hip resurfacing implants (metal debris damaging bone) were necessary [36, 111].

These products are high-risk medical devices (HRMD) as they are highly regulated because they remain in the patient. Examples for HRMDs are those used in reconstructive surgery (breast implants, hip or knee implants) or in the treatment of diseases (coronary stents). Post-market surveillance plays an important role and encompasses the monitoring of the safety and effectiveness of medical devices once they are on the market and used in clinical settings [53]. This is an important function within a healthcare system because HRMDs often remain in the patient body. Healthcare systems and healthcare providers must integrate all four dimensions into their processes for capturing, developing, sharing, and effectively using knowledge and for building administrative frameworks [112, 113]. The contribution of information technology in order to manage big data across different levels of an organisation and healthcare system is significant.

Adequately managed knowledge can support administrative processes, such as procurement [112]. Procurement decision-making determines the devices and accompanying services used for the treatment of patients, and is knowledge-intensive [114]. Procuring HRMDs is a process in which administrations or procurement agents use certain information from various parties to inform purchasing decisions. Based on information it is the goal of procurement to purchase goods that have an optimal combination of high quality and low price [115]. The ways the health system or social security system manages knowledge will shape the way knowledge is used by procurement. The administrator or agent may only use rigid information

about acquisition price and product specifications. Little is published about how knowledge of clinical procedures or information related is used in relation to administrative processes like procurement [88, 115].

Purpose

This research is part of a larger study to improve the understanding of the connection between procurement processes for orthopaedic HRMDs in Mexico and clinical procedures. In our previous study we observed that in Mexico, mutual knowledge support (e.g. use of knowledge from arthroplasty registries) does not adequately benefit procurement and clinical procedures of orthopaedic HRMDs. In Mexico, orthopaedic speciality belongs to a concept of high level care attention and studies reported that high level care attention is still in need of being strengthened [116]. The role played by procurement is important because it provides clinicians with products and services. Previous research about public procurement in Mexico focused on one of the social security institutes providing an action plan for procurement officers, information systems and supplier performance. The aim of our study is to analyse knowledge-related factors that influence procurement of orthopaedic HRMDs in Mexico and is governed by three objectives:

- Analyse factors of managing knowledge of clinical procedures.
- Assess the role of this knowledge and in relation to procurement of orthopaedic medical devices.
- Determine opportunities to improve the situation.

5.3. Methods

Study framework

Our research approach is based on a working framework presented in Figure 5.1, which is guided by two considerations (i) procurement supports healthcare delivery and (ii) procurement decision-making is knowledge sensitive.

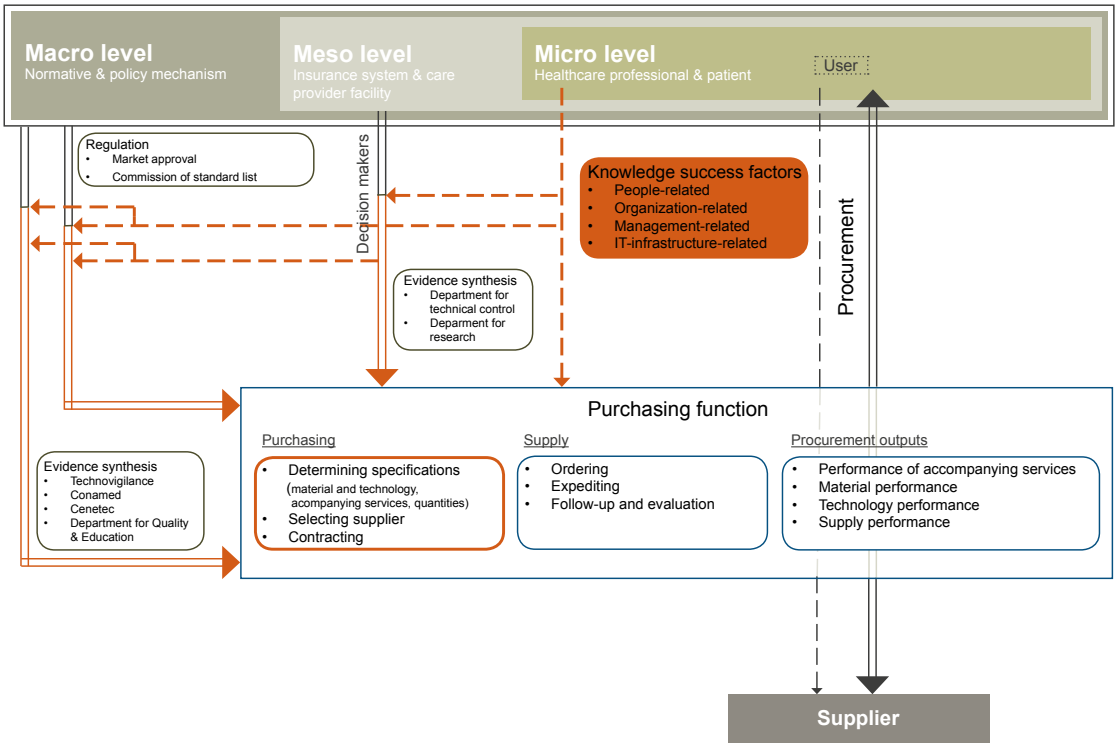

Figure 5.1. Research approach model

First, we defined three healthcare delivery levels based on the healthcare delivery model [7]: 1) macro (normative and policy mechanism); 2) meso (insurance system & care provider facility); and, 3) micro (orthopaedic specialist and patient). Differentiating between these levels is a crucial aspect of our research because public procurement in Mexico and procurement decisions take place at the meso level and not at the micro level. The user is employed by the social security institute or ministry of health and has little autonomy during procurement decision-making in respect to select a medical device. This differs from other healthcare systems where users are self-employed and the procurement mechanism used by healthcare providers is independent of a central purchasing function [79]. Second, we explain procurement based on the supply link framework [66] and embed it along the three healthcare delivery levels. Procurement has three main actors: supplier; procurement

administration (purchaser); and, internal customers (at the meso level) and users (at the micro level). The interaction between the main actors is shown by arrows and defined by (i) procurement (administrator or agent) and internal customer or user, and (ii) procurement and supplier. Third, we implemented the four knowledge management dimensions [80] as the underlying concept of this research approach and used them as orientation to analyse factors of managing knowledge (healthcare delivery levels), to assess the role of knowledge from clinical procedures and in relation to procurement, and to identify findings having the ability to improve managing knowledge.

Research method

The study was based on: (i) semi-structured interviews with healthcare system stakeholders that represented macro and meso levels (Group 1) to analyse how knowledge of clinical procedures is managed among the knowledge management dimensions; and (ii) semi-structured interviews with orthopaedic specialists who represent the micro level (Group 2) to assess the role of knowledge from clinical procedures and in relation to procurement of orthopaedic medical devices.

Rationale and validity of selected research method

We chose this approach because a quantitative approach would not have given us enough data and because there were so few prospective participants representing the macro level and low-to-moderate number of prospective participants representing the meso level. To ensure validity and reliability we used several strategies. First, during interviews we probed deeply to uncover attitudes and open up new dimensions of a problem, and to urge the stakeholder to describe their personal stake in the process. Secondly, we triangulated data by defining a heterogeneous sample of stakeholders per group, and finally, we used different interview guides (described in “data collection”) that we pre-tested with few stakeholders from Mexico.

Study population and participant selection

We interviewed 48 people and their composition is presented in Table 5.1.

Table 5.1. Composition of participants

Expertise of participant	Group 1 n	Group 2 n
Total	25	23
Macro level		
Regulation	4	0
Evidence synthesis	6	0
Orthopaedic association	3	0
Other expert	2	0
Meso level		
Institution	4	0
Care provider facility	6	0
Micro level (orthopaedic specialist employed by different institutes)		
Social Security – IMSS	0	8
Social Security – ISSSTE	0	4
Social Security – PEMEX, SEDENA	0	3
Ministry of Health	0	8

IMSS, Instituto Mexicano de Seguro Social (Mexican Institute of Social Security); ISSSTE, Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado (Institute of Social Security and Services for State Workers); PEMEX, Petróleos Mexicanos (Mexican Petroleums); SEDENA, Secretaría de la Defensa Nacional (Secretariat of National Defense)

We identified and recruited participants for interviews by (i) searching listings from the ministry of health and industry for orthopaedic HRMDs, national academic experts, orthopaedic specialists, organisations, hospitals, and institutions to identify potential interviewees and (ii), we asked interviewees to recommend other stakeholders. We based the sample on two criteria: (i) recruit a heterogeneous sample across different stakeholders; and (ii) stakeholder being involved in or familiar with regulations of medical devices, healthcare delivery of medical devices, procurement and provision of medical devices in Mexico. Sampling was rooted in a maximum variation strategy [90, 117].

Data collection

The study was done in Mexico (Federal District and State of Mexico). In this area the

concentration of arthroplasty surgery across the country and the representation of important government officials or key stakeholders of healthcare providers is high. In Mexico, healthcare providers belong to an institution of the social security sector (IMSS, ISSSTE, PEMEX, SEDENA, MARINA) that operate on national level or to the ministry of health (Seguro Popular de Salud, SEDS, Programa IMSS-O) [70].

We approached prospective interviewees between February and March 2015 them by email or phone. Before we invited them to an interview, the principal investigator talked or wrote to them. Interviews took place at the office of the interviewee or at a place the interviewee selected (e.g. conference room at work). Interviews averaged 23 minutes (min=18 min, max=35 min). Interviewees had a choice of being interviewed in Spanish or English. We used a file naming system and anonymised interviewees by generating a list of archival numbers. The principal investigator interviewed Group 1 participants and some Group 2 participants. A research assistant interviewed the rest of the participants from Group 2. Of the 48 interviews we conducted, 96% were face-to-face, and 4% were phone interviews. We audio recorded all interviews and transcribed them with F5 software [89]. The principal investigator and two assistants transcribed the interviews, and the principal investigator reviewed them again. The interviewers used semi-structured interview guides including open-ended questions that encouraged interview participants to freely describe their opinions, thoughts and experiences (Table 5.2). Participants were not compensated monetary or otherwise.

Table 5.2. Extraction of interview guide questions

Group 1	
Q1	On which organizational levels did Mexico achieve the required quality assurance of already established quality assurance programs? Please explain how.
Q2	Which organizational level manifests the biggest barrier to translate efforts of quality assurance into results?
Q3	Please describe your opinion on quality assurance and clinical efficacy as contributing elements for the provision of medical devices?.
Q4	Please describe how clinical data from the clinical practice level is transferred back to the institutional level and how to the national level?
Q5	Please describe the general consciousness of Mexican stakeholders for the contribution of clinical evidence to their practice.
Q6	On which organizational levels or specific areas do you observe weaknesses with regards to the consciousness?
Q7	Other countries say that it is a challenge to assure clinical effectiveness of a medical device without the support of clinical evidence? Only product safety is not sufficient for high-risk medical devices. Based on which attempts or programs Mexico tries to manage this situation.
Q8	Please describe what this means for the clinical practice and outcome of the patient?
Q9	What actions are needed to improve this situation?
Group 2	
Q1	What should be the relation of the orthopaedic surgeon and the procurement of medical devices?
Q2	Please describe your role and knowledge in terms of the procurement of medical devices?
Q3	Please describe what this means for yourself as surgeon who takes over the responsibility for the clinical outcome of the patient?
Q4	In Mexico it is common practice to procure the majority of medical devices through tenders and to award based on the best price (respecting its listing in cuadro basico). What is your experience on that?
Q5	Please describe how you perceive the outcome of the procurement in terms of your clinical practice, the quality of supplier service, and the intrinsic quality of the product?
Q6	How is clinical evidence and clinical data considered?
Q7	Please describe how long you can stick to the same implant system in your public institution. Please distinct between trauma and reconstruction devices?
Q8	Please describe what this means for the clinical practice and outcome of the patient?
Q9	What actions are needed to improve this situation?
Q10	How do you currently obtain sustainable information on clinical safety of a medical device?

Data analysis

We used our research approach model as a working framework and opted to analyse the findings by the four knowledge management dimensions because in this way, we were able to describe the connectedness and interaction between the actors directly or indirectly involved in procurement based on knowledge-related factors. Other research approaches concerned with knowledge management have been used as well but for different research questions. We iteratively analysed the content of all interviews [90] in MAXQDA software version 11 [118] and to systematically inferred interdependencies between the experiences and opinions of stakeholders. First, we closely read each transcript (data orientation) during initial coding. Second, we clustered codes for similar themes and interrelated concepts (data reduction). Third, we revised our list of themes, improved codes and clustering if necessary, and clarified ambiguous statements (data display). Lastly, we drew on the themes we identified as deficiencies in the role and management of knowledge (conclusion drawing). The principal investigator analysed all data. Table 5.3 provides an extraction of relevant statements.

Table 5.3. Extraction of relevant statements

Themes	**Illustrative quotations**	**Interviewee**
People-related factors		
Leadership	"At the strategic or functional level they define and develop and promote an idea and there is a disposition but after that they are failing with the implementation."	Group 1, Macro – International Expert O.2._201503101730_MEX
	"There was once, in the past two administrations, during president Fox and president Calderon, very interesting quality assurance strategies for all public institutions. Again, mostly based on interpersonal quality and what the different institutions and the different facilities… what they achieved in terms of quality… depended a lot of the interest of particular clinical groups."	Group 1, Macro - Evidence synthesis O.2._201502231200_MEX
	"So in Mexico we have the problem that they don't talk to each other, they don't understand each other and there is no governance… so that the way how they solve the problem is rather voluntary than an organizational or systemic matter."	Group 1, Macro - Evidence synthesis O.2._201502271200_MEX
Knowledge competence	"The research culture here in Mexico is unfortunately very low in comparison with the culture of other north American or European countries…"	Group 1, Macro – Society O.2._201503191830_MEX
	"We still don't have a clear consciousness of the importance of implementing quality assurance measures at the system level. Quality concerns are concerned mostly of few groups within institutions. So I think the big challenge, the first initial challenge would be to develop a better consciousness of the importance of continuous improvement. This is I think the main challenge."	Group 1, Macro - Evidence synthesis O.2._201502231200_MEX
	"… sometimes we receive drugs of very good quality. But sometimes we receive very bad quality because procurement doesn't focus on this… As long as a drug passed the requirements of the health regulation of COFEPRIS there is a market…"	Group 1, Macro - Evidence synthesis O.2._201502271200_MEX
Knowledge sharing	"The doctors don't always accept to provide this information. Let's think about health records. This is really a problem that the doctors use them correctly… the information that is collected is little reliable."	Group 1, Macro – International Expert O.2._201503101730_MEX
	"The problem is that many don't fill in the type of incident … they don't provide the name of the product. Therefore we cannot make a match and process the complaint adequately…"	Group 1, Macro - Evidence synthesis O.2._201503120900_MEX
	"… nobody notifies about adverse reactions in this country..."	Group 1, Macro - Evidence synthesis O.2._201503091215_MEX
Mutual learning &	"… they are still duplicating their efforts… but what is difficult to change is the	Group 1, Macro –

skills	burocratic territory of each institute and there is no incentive that could motivate them to focus on a common purpose… an therefore they make what they can but not always coordinated…"	International Expert O.2._201503101730_MEX
	"I believe that we have to improve the quality … conceiving a better interrelation between COFEPRIS and other federal units of the secretariat of health."	Group 1, Macro - Evidence synthesis O.2._201503091215_MEX
	"Because we don't have, neither the resources and very probably we don't have the expertise needed to follow up and to organize this kind of interventions."	Group 1, Macro – Society O.2._201503232000_MEX
Organization-related factors		
National processes or structures	"… apart of adverse events there is no intermediate information available. So there is a lot of information that we loose… as surgeon you are very limited with regards to access information…"	Group 1, Macro - Evidence synthesis O.2._201503091215_MEX
	"I believe the weakest area is the federal with COFEPRIS and the strongest area is the Consejo de Salubridad General by means of CENETEC which is step by step better involved in the evaluation of medical technologies in a broad sense."	Group 1, Meso - Institution O.2._201503121800_MEX
	"The problem is that no one makes a follow-up of the output of results. Recently the secretariat of health has started to establish an evaluation system of the performance of hospitals."	Group 1, Macro – International Expert O.2._201502240930_MEX
Organizational processes or structures	"They provide us with some type of report, they inform us in general about number of prosthesis and patients… but we don't receive more information."	Group 1, Meso – Institution O.2._201502241600_MEX
	"Further many federal units have different organizational structures so that this makes the situation even worse… they are heterogeneous so that en some units they are well organized… but in others there doesn't even exist such an organization to adapt specific programmes…"	Group 1, Meso – Hospital O.2._201503171700_MEX
	"When you ask what is the number of intra hospital infections that we have in Mexico nobody can provide you with a general number… this is something that haven't been established in Mexico."	Group 1, Macro – International Expert O.2._201502240930_MEX
Management-related factors		
Strategy	"… programmes are established, they are effused like documents to be used but rarely there is a control if these programmes are realized… especially at the level of the secretariat of health… There is a deficiency beginning at the central legal level up to the state level where there are no adequate strategies to implement a program to improve quality."	Group 1, Meso – Hospital O.2._201503171700_MEX
	"The healthcare systems remains in the 21st century or migrated back to the 20th	Group 1, Macro -

	century. What I want to say is that this system is focusing to cover crises, episodes, but does not attend patients."	Evidence synthesis O.2._201502271200_MEX
	"…we are not using the information. We are collecting it and we are organizing it, we have the conditions to use it at very different levels, at the clinical level, at the top management level, but we are not using it. "	Group 1, Macro - Evidence synthesis O.2._201502231200_MEX
Goal	"The problem is that we are affiliating people and little by little starting to guarantee regular access to comprehensive service. Unfortunately the overall quality of the services that are being provided is still very low especially at the ambulatory level. So, it is good, that we are expanding coverage, but we need to expand coverage with quality. If not, we are misspending the resources we have mobilized. "	Group 1, Macro - Evidence synthesis O.2._201502231200_MEX
	"Recently a new epoc has started where we can say what are the palliative aspects that impacted … The famous collateral damages or additional expenses, or I had to keep the patient hospitalised longer because I could not operate him because the implant failed."	Group 1, Meso – Hospital O.2._201503130830_MEX
	"If you go to a hospital and you want to certify it and you ask them "Is there technical support for cardiotocography in the urgency unit", the answer may be yes but no one would ever ask if they also know how to interpret the data."	Group 1, Macro - Evidence synthesis O.2._201502261200_MEX
Measurement	"… the interesting thing is that there were no indicators for the number of prescriptions that are aligned with the clinical guidelines."	Group 1, Macro - Evidence synthesis O.2._201503091215_MEX
	"And so, here most time the evaluations stop evaluating the existence of a product…"	Group 1, Macro - Evidence synthesis O.2._201502261200_MEX
	"…The infrastructure is limited and this is a serious problem because there is interest … but also the money is an important limitation…"	Group 1, Macro - Evidence synthesis O.2._201502261115_MEX
Information technology-related factors		
Infrastructure	"… There are two problems that I can identify: One is the absence of basic information systems … our information is in general not systemised."	Group 1, Macro – International Expert O.2._201503101730_MEX
	"Our registries are not complete, they are not reliable because not everything is registered. Therefore it is an idea of numbers… but a precise number requires a good registry with a very good systematisation…"	Group 1, Meso - Hospital O.2._201502251245_MEX
	"…There might exist a lot of data in the different social security systems or within the same system but they are not in a single database"	Group 1, Macro - Evidence synthesis

Applications	“And one of the more serious problems is the information system. They are not based in patients, they are based in medical consultations, in hospitalization…”	O.2._201502250830_MEX Group 1, Macro - Evidence synthesis
	“In some institutes … they do have an electronic health record, but it is another deficiency that our country was not able so far to consolidate the electronic health records on national level…”	O.2._201502271200_MEX Group 1, Macro - Evidence synthesis
	“… it is very difficult in the big hospitals and not all do have a health record, there are big hospitals that have health records but they don’t use it.”	O.2._201502261200_MEX Group 1, Macro - Society
		O.2._201503191830_MEX
Factors related to the role of knowledge from clinical procedures		
Relation of orthopaedic specialist and procurement	“… because the procurement process here in … is rather confidential, not all doctors participate, and sometimes it is very superficial so that it is only about affirmative or negative, but … often someone like a doctor doesn’t participate.”	Group 2, Micro - Social Security
	“They don’t take into consideration the surgeon to take decisions because often the administrators decides and they buy things that no one uses.”	O.2._201502241300_MEX Group 2, Micro – Ministry of Health
	“… this decides the head of the department together obviously with the hospital director and … it is like a rather private situation…”	O.2._201503121730_MEX Group 2, Micro - Social Security
		O.2._201503121830_MEX
Knowledge informed decision-making	“…no because it is expected that they (COFEPRIS) have taken care of it, they have test it and everything is good and this is not true, many time not.”	Group 2, Micro - Social Security
	“… many times the decision-making is based on the material type and economical aspects or the cost of these implants.”	O.2._201503241330_MEX Group 2, Micro - Social Security
	“No, I think it is very bad (information flow between micro and meso level) what is exchanged between us because we have requested a meeting between the people of the Seguro Popular and us to explain which material is good and adequate for the patients. But this has never taken place…”	O.2._201503181300_MEX Group 2, Micro – Ministry of Health
		O.2._201503131230_MEX

5.4. Results

We found that knowledge is not necessarily generated and managed efficiently enough to support procurement of orthopaedic HRMDs. Generally, interviewees thought this is a problem at the meso level and related to the dimensions “people” and “organisation”. Table 5.4 shows the relevance of inadequately managed knowledge for all four dimensions, at the macro, meso, and micro level.

Table 5.4. Relevance of inadequately managed knowledge for all four dimensions and healthcare delivery levels

Dimension	Macro level	Meso level	Micro level	Total
People	++	+++	++	++(+)
Organisation	++	+++	++	++(+)
Management	+	++	+	+
Information technology	+	++	++	+(+)
Total	+(+)	++(+)	++	++

+++ very relevant ++ moderate relevant + relevant

The problems that were associated at the macro, meso and micro levels, for the various knowledge-related factors, influence the role of knowledge from clinical procedures and in relation to procurement of orthopaedic HRMD. The results of our study show that this leads to procurement decision-making that is insufficiently informed by this knowledge and thus negatively influences the provision and use of orthopaedic HRMDs. In Table 5.5 we summarize themes that describe these problems based on the knowledge management dimensions and the role of knowledge for procurement.

Table 5.5. Summary of management and role of knowledge

Topic	Identified themes
Dimension "people"	• Absence of a mutual learning culture specifically for HRMDs. • Inadequate knowledge sharing culture to manage complaints. • No sustainable commitment to clinical knowledge-informed quality assurance programmes. • Failure to engage people in generating knowledge. • Organisations unable to generate knowledge. • Uncertainty how to apply knowledge correctly. • Failure to identify the relevance of post-market surveillance data.
Dimension "organization"	• Absence of structures to improve handling and management of complaints and adverse events across departments. • Absence of structures to obtain adequate information of data from clinical procedures.
Dimension "management"	• Failure to develop strategies that merge the interests of the different sectors to achieve federal knowledge goals. • Weak exchange of information between federal units and insufficient to create synergies. • Failure to implement strategies that can adequately measure e.g. the clinical performance of MDs.
Dimension "information technology"	• Non-electronic patient data collection and records. • Lack of infrastructure for collecting national post-market surveillance data. • Need for an application that monitors performance of MDs in clinical use.
Role of knowledge	• Rigid evaluation criteria like demand calculation. • Lack of orthopaedic experts on decision-making committees. • Importance of lowest acquisition price. • Feedback loop on performance of HRMD between users and administrators.

We divided our findings into three levels: (i) dimensions of managing knowledge, (ii) the role of knowledge from clinical procedures and in relation to procurement of HRMD, and (iii) opportunities to improve the situation.

Dimensions of managing knowledge

People-related factors as barriers

One of the management theory expectations that can be applied to this analysis is that if the culture of knowledge is well established among the actors in a healthcare system, knowledge can be adequately managed. However, the results of this study show that knowledge is not adequately managed at the meso level. To a lesser degree, this is also true at the macro and micro levels. Many stakeholders reported that there is not enough knowledge leadership (e.g., guidance and direction in using knowledge) or competence to ensure knowledge will be efficiently managed and used. The culture of knowledge sharing and mutual learning is underdeveloped. We found a number of themes in the transcripts that described the effect of people-related factors on knowledge management, related to (i) leadership, (ii) knowledge competence, (iii) knowledge sharing, and (iv) mutual learning.

Leaders direct the people who generate or manage knowledge. Some stakeholders emphasized the strong influence that key leaders have on directing and implementing knowledge sharing initiatives, or on continuing strategic quality assurance initiatives. Initiatives are often discontinued or disrupted when the initiator moves on to other tasks or passes the responsibility to others.

> *"[T]here was once, in the past two administrations… very interesting quality assurance strategies for all public institutions… what they achieved in terms of quality… depended a lot of the interest of particular clinical groups."* (Group 1, O.2._201502231200_MEX)

Knowledge competence and sharing allow people to integrate knowledge effectively into their work. Some participants mentioned this because in the area of clinical research and investigation of orthopaedic speciality little is published by Mexican orthopaedic specialists in scientific journals and they related this to lack of interest, a general weakness of the medical education system, or the work framework for

medical specialists in public hospitals. For orthopaedic specialists in other countries, the publication track record is important for their career paths.

> *"[T]here is little culture to publish scientific work… few are really dedicated to this… because of a missing focus during the medicine study and because of high workload at the public institutes… and so it is difficult to focus on research."* (Group 1, O.2._201503191330_MEX)

Some participants reported that care providers from the secretariat of health partially manage knowledge more efficiently than did social security systems. For instance, The National Institutes of Speciality (e.g., the National Institute for Rehabilitation) have a more developed system for managing and using knowledge than the regional hospitals of the secretariat of health. We found that this is a consequence of various people-related factors.

> *"…[t]his is all a process and we are all at different levels and a lot of what can be achieved in each process can be related to the interest of research groups intra- or extra-institutional… but we are not all at the same level… some haven't started yet."* (Group 1, O.2._201502251245_MEX)

Organisation-related factors as barriers

Efficient management and use of knowledge is facilitated if actors effectively use processes and structures in a healthcare system. But the results of this study show that knowledge is often inadequately managed at the meso level. This is less of an issue at macro and micro level. The formal processes and structures are insufficient to facilitate efficient management and use of knowledge because post-market surveillance data is inadequate. Thus, information flows insufficiently, knowledge spreads poorly, and there is little synergy created by processes that run in parallel. Interview participants described organisation-related factors that, in their view, contributed to the failure of national organisations to manage knowledge adequately,

especially on a process or structural level, such as the organisational processes or structures of social security systems or care providers of the secretariat of health.

Many participants pointed out that current formal processes and structures make it difficult to collect adequate post-market surveillance data because they inadequately integrate knowledge about clinical procedures.

> *"… [t]he principal weakness of the Mexican system is at the post-commercialization…"*
>
> (Group 1, O.2._201502261115_MEX)

Clinical data collection starts with clinical procedures and needs to be established, e.g., a post-market surveillance system. Some interviewees said that current processes and structures do not connect the meso and micro levels well enough; data collection is inconsistent, so clinical procedures do not generate adequate knowledge.

> *"…[a]part of adverse events there is no intermediate information available. So there is a lot of information that we lose… as a surgeon you are very limited with regards to access information…"* (Group 1, O.2._201503091215_MEX)
>
> *"[B]ut you don't follow up (clinical cases). You know when you follow up, this is when there is any complication…"* (Group 2, O.2._201503111600_MEX)

Some participants claimed that medical specialists often have restricted access to information that coordinates meso level actors from departments like administration or research and quality. Medical specialists rely on a limited set of data to perform clinical procedures or research, and there are no monitoring processes for following up clinical cases over the long-term.

> *"[T]hey provide us with some type of report, they inform us in general about number of prosthesis and patients… but we don't receive more information."*
>
> (Group 1, O.2._201502241600_MEX)

Further, participants noted that formal processes and structures that intended to improve quality did not allow actors in a health system to create synergy with other actors running in parallel. They also noted that these are poorly coordinated because the health system is fragmented and segmented. Creating synergies improve outcomes of single processes or strategies like national programmes and initiatives.

> *"…[t]hey are still duplicating their efforts… but what is difficult to change is the bureaucratic territory of each institute and there is no incentive that could motivate them to focus on a common purpose… an therefore they make what they can but not always coordinated…"* (Group 1, O.2._201503101730_MEX)

For instance, formal processes and structures for the management of complaints related to the use of HRMD at the macro level: The National Commission for Medical Arbitration [119] receives complaints from patients about service attention of care providers, and the Department of Technovigilance of the Federal Department of Health and Human Services of Mexico (COFEPRIS) also documents HRMD complaints but on the level of e.g. adverse events (e.g. metal debris cause damage to bone reaction; bone cement insufficiently attaches to cemented implant surface; pelvis cap anchoring technology leads to early loosening of implant) and reported by the physician or medical device supplier. However, CONAMED and COFEPRIS have no processes in place to share and mutually learn from these complaints.

Management-related factors as barriers

Knowledge strategy, goals, and measurement (e.g., knowledge control, measurement criteria, performance indicators) provide direction to actors in a healthcare system. Actors can then manage and use knowledge efficiently and follow-up on strategies, thereby increasing the effectiveness of their strategies and goals. Some stakeholders felt they were not given adequate direction. This was moderately prevalent at the meso level, but rare at the macro and micro levels. Our

analysis revealed several themes where stakeholders related the failure to manage knowledge adequately to management-related factors, since these failures were observed in strategies, goals, and measurement of (i) federal units, (ii) care providers of the secretariat of health, (iii) social security systems, and (iv) healthcare professionals.

The participants reported that it is difficult to fulfil the national goals in the health system since the coordinating role of the ministry of health is weak, particularly in the relations with the social security organizations and the health systems in the sovereign states in the country. Thus, care providers may thus not apply national strategies because they are not obliged to.

> *"…[p]rogrammes are established, they are effused like documents to be used but rarely there is a control if these programmes are realized… There is a deficiency beginning at the central legal level up to the state level where there are no adequate strategies to implement a program to improve quality."*
>
> (Group 1, O.2._201503171700_MEX)

Some participants explained that strategies are sometimes based on goals but are still disconnected from clinical procedures or rely on other data that may not fully represent clinical needs. For example, in recent years, many clinical guidelines have been written and introduced. Stakeholders who know clinical procedures complain that the goal of introducing so many clinical guidelines took precedence over developing strategies to benefit clinical procedures and processes.

> *"[A]nd if we had focused to develop clinical guidelines for a limited number of diseases and have made the implementation strategy more carefully with measurements and incentives we would have another scenario… Now the problem is big because I don't know how the clinical guidelines will be updated…"*

(Group 1, O.2._201503101730_MEX)

Federal units do not have well-established strategies to effectively collaborate with each other, as seen with CONAMED and COFEPRIS.

"… [C]OFEPRIS… Consejo de Salubridad General… Cuadro Basico… CENETEC… and these four federal entities have been quite disconnected…"

(Group 1, O.2._201503091215_MEX)

There was a similar problem at the meso level. Departments for research and quality look at HRMD failures through the lens of material specification or technology. They focus strongly on the indications of the standard list for HRMDs "Cuadro Basico", but do not seek to gain knowledge from the observations that orthopaedic specialists generate during clinical procedures. These observations might include other types of product failures like anatomical aspects of HRMDs, steps in inserting or removing a HRMD, or special components of the instrument that cost clinicians a lot of time.

Information technology-related factors as barriers

Infrastructure and applications create the technical environment where knowledge is managed within and between the different levels of healthcare delivery. Information technology is an important aspect to transfer and process knowledge [97]. Some interviewees pointed out inadequate knowledge management being moderately prevalent at the meso and micro levels, and less prevalent at the macro level. Technological support is less efficient at the meso and micro levels, where administrators and healthcare professionals operate. The problem consists of information being insufficiently collected and analysed. For several themes, interviewees associated the failure to manage knowledge adequately with the absence of technological solutions.

Some stakeholders pointed out that current applications are not set up to run analyses of interest, like determining the performance of HRMDs in use. They said

that there is limited infrastructure for sharing clinical data with healthcare professionals or other care providers within the same public sector. Some explained that insufficient infrastructure and failure to systematise data makes it hard to merge data from different public sectors.

> *"…[T]here are two problems that I can identify: One is the absence of basic information systems … our information is in general not systemised."* (Group 1, O.2._201503101730_MEX)

For instance, CONAMED uses a web-based system to collect information about clinical incidents, which are reported mainly by patients. Aligning this system with databases from the social security systems would increase the knowledge that could be drawn from these data. A few stakeholders reported that one of the social security sectors is working with CONAMED to do this. There are few adequately developed applications that collect and store patient data. Applications that monitor the performance of HRMD are incomplete or unavailable.

> *"[I]n some institutes … they do have an electronic health record, but it is another deficiency that our country was not able so far to consolidate the electronic health records on national level…"* (Group 1, O.2._201502261200_MEX)

Role of knowledge from clinical procedures and in relation to procurement of orthopaedic HRMD

Orthopaedic HRMDs are procured in Mexico through an administrative process that relies on standardized regulations to consolidate purchase power. These are mainly based on tender processes that regroup different purchases to increase purchasing power and negotiate better prices from suppliers. The results of this study show that knowledge from clinical procedures is insufficiently integrated into procurement decision-making. Many stakeholders thought this was caused by standardized procurement regulations and problems with knowledge exchange between

orthopaedic specialists and administrators or between management levels of care providers. We found a number of themes, which described the very small role played by knowledge of clinical procedures.

A number of interviewees indicated that orthopaedic specialists are insufficiently involved and that procurement applies rigid evaluation criteria like demand calculation based on consumption history, and conformity controls based on technical or material specifications. However, stakeholders are very interested in procurement decision-making that integrates the orthopaedic specialist.

> *"[T]hey don't take into consideration the surgeon to take decisions because often the administrators decides and they buy things that no one uses."* (Group 2, O.2._201503121730_MEX)

Some interviewees claimed that when procurement did involve medical specialists, they were often not in orthopaedics or were unfamiliar with local clinical needs. Hiring of responsible staff that could contribute to improving the outcome of procurement decision-making was inconsistent.

Other respondents stated that decision-making was strongly influenced by the lowest acquisition price. In our first study informants already noted this. Orthopaedic specialists attribute their inferior role in decision-making to the acquisition price factor.

> *"…[i]t is a straight situation of money, this is the only thing that really matters…"* (Group 2, CP_O.2._201503311600_MEX)

Another theme that some participants emphasized was the formal complaint management processes. They noted that these did not influence procurement decision-making enough because complaints were not well-managed. For example, a group of orthopaedic specialists repeatedly received sub-standard quality of orthopaedic HRMDs, even after they had submitted formal complaints. They were

eventually able to change their local procurement practices to incorporate knowledge from clinical procedures and post-market surveillance data of HRMDs. This change was only possible because the specialists insisted on escalating their complaints to upper-level management in their social security system, over several years. This situation seems exceptional. According to stakeholders of other healthcare providers, the problem of receiving sub-standard quality of HRMDs and services has not been solved.

> *"[L]et's say that I think that these companies can't afford to manage the volume of the hospital and for example the other day I wanted to implant a femoral cup size 52 but I only had available size 50 and 54 and so I had to implant the cup size 50."* (Group 2, O.2._201503181600_MEX)

Opportunities to improve the situation

Based on the first two objectives of this study we depicted which knowledge-related factors may lead to a situation of inconsistently generated knowledge of orthopaedic clinical procedures and in the context of procurement. The third objective of our study aimed to identify opportunities that may improve this situation by drawing on the findings of the previous two objectives and by asking interviewees what they believe is needed to improve the situation.

Many factors that we identified during the thematic analysis are related directly or indirectly to technological aspects, which we found are insufficiently developed.

> *"[W]ell, I believe it is a matter of stewardship… of the ministry of health where clinical evidence should be regulated, from the clinical guidelines, the eligibility of goods and their regulation, monitor the clinical practice and provide feedback; overall, feedback… regulated for the private and public sector"* (Group 1, O.2._201503091215_MEX)

"[I]n some institutes, in some hospital centres of third level attention… there, electronical patient dossiers exist… however, and this is another deficiency, our country was unable to consolidate them at a national level, as it was proposed by the previous administration." (Group 1, O.2._201502261200_MEX)

For public procurement in Mexico we believe that there is an opportunity to develop an action plan how to improve the management of systems' knowledge across all social security institutes and ministry of health. Options of information technology may provide a basis in order to improve the intersections that procurement has with the knowledge environment (areas and activities relating to evidence and knowledge synthesis).

Procurement is an administrative area that is influenced by four principal aspects: Policy mechanisms and regulations; key procurement actors; degree of procurement centralization; and, criteria used to make procurement decisions [88]. In Mexico, public procurement varies from highly centralized to decentralized but procurement practices are highly standardized. Key procurement actors belong to the meso level but not to the micro level. The results of this study show that opportunities to improve the current situation were often associated with "key procurement actors" or "criteria used to make procurement decisions".

"[T]o improve we have to destroy the chains that limit the genuine commitment of doctors to look for a system, an implant of a quality; his decision nowadays is rather next to financial or administrative decisions. I believe we have to give greater emphasis to the doctor who is finally the user of implants…" (Group 2, O.2._201502251340_MEX)

"[F]or me, at least in my institute that the technical advise is taken again into consideration…" (Group 2, O.2._201502271600_MEX)

"[T]here should be communication of the directive of the Sector towards the doctors… it should therefore integrate heads of departments and between them reach a consensus and a way to define the required materials to treat patients. (Group 2, O.2._201503131230_MEX)

The mechanism of public procurement in Mexico may not allow to actively integrating users in decision-making but there are opportunities to better integrate user knowledge. For instance, monitoring relevant aspects of clinical procedures that are important to assure the healthcare worker and patient safety by modifying the needs assessment strategy in the course of upcoming tenders.

5.5. Discussion

In the Mexican Healthcare System and on behalf of the Ministry of Health many changes have taken place especially since 2006, such as comprehensive reforms to improve the health system [120-122], sectorial health programmes or research to improve quality across various dimensions [60, 76, 123-125]. This is an important strength of the system because it is frequently concerned with situations lacking the ability to make progress in their performance.

Based on our findings it was evident that stakeholders in Mexico recognize that knowledge is an important resource but they are not able to manage it effectively and efficiently. The examples provided by the interview participants lead to important factors that trigger this situation and which we identify as information technology-related factors. The knowledge-related problems reported by interviewees focused strongly on "People" and "Organisation" but are connected to information-technology. For instance, participants referred to problems of systematic databases, not using synergies and being unable connecting the variety of systems' knowledge. Without adequate infrastructure and applications to manage big data across the different healthcare delivery levels knowledge-related problems summarized in Table 5.4 and

5.5 cannot be solved adequately. In Mexico, policy makers have already identified the added value of information technology supporting procurement. For instance, the introduction of *Compranet* as application that provides transparency in respect to expenditures and awards of public tenders, and which operates mainly on the meso and macro level. We did not identify applications established that are based on a systematic approach to manage knowledge from clinical practice and connecting to procurement.

Overall we found that in Mexico the knowledge environment influences procurement regulations and practices of orthopaedic HRMDs in the following ways: 1) deficiencies in the healthcare system's ability to manage knowledge of clinical procedures efficiently; and 2) deficiencies in the management of knowledge from clinical procedures and post-market surveillance data as it directly relates to procurement. Analysing knowledge-related factors, guided by considering the four knowledge management dimensions, lead us understand which factors trigger ineffective and inefficient knowledge management. The findings of this study point out knowledge-related opportunities for procurement practices of orthopaedic HRMDs in Mexico.

We found that the ability of procurement administrators or agents may improve when knowledge of orthopaedic clinical practices is adequately integrated in decision-making processes [88]. Procurement administrators or agents are concerned with providing the right quality of the purchased products (manage product complexity) and accompanying services (prevent commercial uncertainty) [67, 126]. Studies focus on knowledge gaps about buyer-supplier relationships [84] but not with knowledge-related factors influencing procurement and purchasing of HRMDs.

In our study we found that factors triggering the ineffective and inefficient use of knowledge can be associated with poorly developed technological solutions at the level of clinical procedures. We believe that there is an opportunity in managing knowledge in the field of orthopaedic HRMDs by adequately applied information technology solutions. Studies are concerned with health information management and technology and how it can be utilized to improve important outcomes and overall quality of care in different healthcare settings [127-130]. The interest in knowledge-related topics in healthcare systems is often focused on clinical informatics to promote patient care and safety like, for example, clinical decision-making. In this context, many studies report about eHealth solutions (managing single and aggregated health information for healthcare professionals, patients, and healthcare consumers), and applying it in clinical decision-making [98, 100, 131, 132] like, for example, the use of electronic patient dossiers operating at both the clinician and patient level.

Further, managing big data becomes more relevant [133] and we found that the use of options supporting knowledge management in the field of orthopaedic HRMDs by information technology applications are promising [130]. In the field of orthopaedics many policy makers use already approaches of information technology to guide decision-making. Examples for this are national arthroplasty registries [35], and approaches that build on such arthroplasty registries like, for instance the “Orthopaedic Data Evaluation Panel” [55] in the UK. ODEP is defined as a supporting decision-making instrument for procurement. ODEP rates implant survival data based on clinical information and clinical evidence. It represents a guideline for procuring orthopaedic HRMDs and is established by the National Institute for Health and Care Excellence of the UK. ODEP rates implant survival data based on clinical information and clinical evidence level, received from the “National Joint Registry”

(NJR) of the UK. The NJR collects information on orthopaedic joint replacement surgery from clinical procedures, and monitors the performance of orthopaedic implants. Other healthcare systems like, for example, Germany and Switzerland, integrate information from arthroplasty registries into their quality agenda [134, 94]. Without using information technology applications to manage big data it would not be possible to inform procurement decision-making adequately with information and knowledge of clinical practice.

We found that knowledge-related factors influencing procurement practices are not a unique finding for Mexico and orthopaedic HRMDs. The results of this study are primarily relevant for Mexico but may also give impulsion to other health systems with an increase of centralized procurement, like for example: Collaborative procurement hubs (e.g. United Kingdom), and national or regional purchasing groups (e.g. France, Germany) [84, 88, 130].

Limitations and avenues for further research

Our study has several limitations. First, even we have opted a sampling based on a maximum variation technique, we did not include (i) a larger number of stakeholders representing the meso level of different social security systems, and (ii) patients or representatives from rehabilitation centres to provide a broader range of attitudes of the micro level. Secondly, our ability to generalize the findings was limited as we only considered orthopaedic HRMDs. Third, attitudes of stakeholders from other states may differ from those of the State of Mexico and the Federal District. Fourth, we did not take a formal knowledge management approach to clearly differentiate, e.g., between knowledge management systems and information systems. More research is needed to clarify some issues raised in this study. What programmes could be established to improve the contribution of clinicians to knowledge management practices? What do our findings mean for the national health budget? Answering

these questions is imperative to improving the generation and management of knowledge about clinical procedures as it is related to the procurement of orthopaedic HRMDs in Mexico.

5.6. Conclusions

We believe this is a novel investigation of knowledge-related factors that influence procurement and clinical procedures for orthopaedic medical devices in Mexico. We identified specific aspects of knowledge and related them to procurement practices, using orthopaedic HRMDs as our example, and showed how they are related with clinical practice. We explored the perceptions of a range of healthcare actors around the topic of generating and managing knowledge for improved procurement processes of orthopaedic devices. We showed that knowledge is an important resource, identified factors along the dimensions of knowledge management and healthcare delivery levels that create barriers, and discussed them in the context of administrative processes. The deficiencies we identified should motivate researchers to further clarify the relationship between clinical procedures and administrative processes in the knowledge environment.

Stakeholders in Mexico recognize that knowledge is an important resource, but they are not able to manage it effectively and efficiently. A favourable approach would be when procurement administrators exchange more knowledge with orthopaedic specialists who have performed surgical techniques, know the clinical properties of implants, and are familiar with the services provided by suppliers (e.g., the condition of instrument sets and availability of implant type or size), to improve procurement outcome. Without adequate solutions of managing knowledge for orthopaedic services, procurement processes for orthopaedic HRMDs will remain sub-optimal. Mexico needs versatile solutions for the meso level and the federal level of the Mexican healthcare system so as to better analyse information and data from

clinical procedures. Many of our findings can be attributed to poorly developed information technology aspects. Improving options of managing knowledge by information technology may positively influence the impact of procurement decision-making on clinical practice and improve the healthcare worker and patient safety in the long-term.

Abbreviations

CENETEC, Centro Nacional de Excelencia Tecnológica en Salud (National Centre for Health Technology Excellence); COFEPRIS, Comisión Federal para la Protección contra Riesgos Sanitarios (Federal department of health and human services of Mexico); CONACYT, Consejo Nacional de Ciencia y Tecnología (National Council of Science and Technology); CONAMED, Comisión Nacional de Arbitraje Medico (National commission for medical arbitration); e.g., Exempli gratia; etc., Et cetera; HRMD, High-risk medical device; IMSS, Instituto Mexicano de Seguro Social (Mexican Institute of Social Security); IMSS-O, Programme of Ministry of Health for non-insured population living in specific states or areas: Instituto Mexicano de Seguro Social – Oportunidades (Mexican Institute of Social Security - Opportunities); ISSSTE, Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado (Institute of Social Security and Services for State Workers); MARINA, Marine; NJR, National Joint Registry; ODEP, Orthopaedic Data Evaluation Panel; PEMEX, Petróleos Mexicanos (Mexican Petroleums); SEDENA, Secretaría de la Defensa Nacional (Secretariat of National Defense); SESA, Servicios Estatales de Salud (State Health Services); WHO, World Health Organization

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Authors' contributions

All authors were involved in the outline of the paper. ML has made substantial contributions to conception and design, acquisition of data, analysis and interpretation of data, and drafting the manuscript. KW and LD have been involved in revising the manuscript critically for important intellectual content and structure, and have given final approval of the version to be published.

Competing interests

The authors declare that they have no competing interests.

Ethics

The ethical committee of the Autonomous University of Mexico [82] approved this project (Date of approval: November 4th 2014, FMED/CI/SPLR/188/2014), and the Ethical committee from northwest and central Switzerland (Switzerland) exempted it from ethical review under Swiss law (June 24th 2014). All interviewees gave written informed consent before the interview.

6. Attitudes of orthopaedic specialists towards effects of medical device purchasing.

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6.1. Abstract

Objective:

To assess viewpoints of end-users concerning the purchasing process of high-risk medical devices and to discuss the relevance of technology assessments at the hospital level and other potential areas for improvement of purchasing processes.

Methods:

We used a cross-sectional study and assessed the attitudes and thoughts of orthopaedic specialists. The study took place between June and October 2015 in Mexico.

Results:

We collected data from 187 orthopaedic surgeons. Involvement of orthopaedic specialists in purchasing was reported by 86%. However, clinical practice was perceived as negatively influenced by purchasing outcomes by 92%. The problems were described as: material failure; effectiveness of medical devices; obsolete medical device technology; incomplete provision of implant / instrument sets; delayed provision of implants and instruments.

Conclusions:

To prevent sub-standard outcomes of purchasing decisions, this study and the current literature suggest that health technologies should be assessed during the purchasing process, end-users should be adequately involved, and decisions should be based on multiple criteria including clinical impact in the short-term (e.g. primary stability of implant) and long-term (e.g. survival of implant). The focus on Mexico is particularly novel and provides insights into a health system where Health Technology Assessment (HTA) is mainly present at the macro level and be used for the listing of medical device technologies in the standard list. This study concludes that Mexican stakeholders of the purchasing process underestimate the contribution

of HTAs at the level of purchasing decisions. HTA in Mexico has improved over the past years but still requires more advancement.

Keywords:

Medical devices, Purchasing, Orthopaedic, Healthcare delivery, Decision making, Mexico

Acknowledgements

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6.2. Introduction

The assessment of medical devices is an important function to support the appropriate introduction and use of health technology. Policy makers increasingly adapt health technology assessments [108, 135, 136] to evaluate high-risk medical devices (HRMDs). This serves to either assess different types of health technologies (e.g. anatomic cementless knee prosthesis of different bearing surfaces indicated for a knee joint replacement) or to assess different medical device brands grouped into the same class of health technology (e.g. different anatomic cementless knee prosthesis indicated for a knee joint replacement). HRMDs remain in the patients body and are grouped into the risk class III of medical device regulation, which includes knee joint implants [22]. Health Technology Assessments (HTA) contribute to decision making at the macro level (e.g. decisions about the listing of technologies in the National Formulary) as well as at the meso level (e.g. decisions about the purchasing of medical devices). The latter evaluation type is described in the literature as a hospital-based HTA or mini-HTA. Studies show that these can have a

major impact on decision making and decision outcomes [137-139], for example, preventing intra- and post-operative failures. High quality information is important for conducting HTAs [140].

Mexico lacks regional and national initiatives for the advancement of high quality of information on orthopaedic HRMDs and HTAs at the level of purchasing decisions [141, 142]. Between 2014 and 2015 we qualitatively analysed the regulation, assessment, and management of orthopaedic HRMDs to understand how they influenced clinical procedures. This analysis provided the starting point for the present article and the findings suggest that (i) decision making processes focus on mechanical and technical specifications and fail to integrate a broader spectrum of decision criteria such as clinical long-term outcomes of medical device brands; and (ii) orthopaedic specialists are not adequately integrated into decision making because their main role is to physically evaluate medical device brands that have been taken into consideration for decision making by the purchasing entity.

In Mexico, HTAs are conducted by the Centre for Excellence in Health Technology (CENETEC), which is a specialized agency of the Ministry of Health to support policy decisions. Their reports are used by the Inter-institutional Commission of the National Formulary for Health Supplies to decide whether a new health technology will be listed or not in the National standard list. To date, the literature lacks studies about the relevance of HTA activities at the level of purchasing in Mexico. The Mexican health system is highly segmented and fragmented [70] and characterized by a public/private mix of hospital providers. The public sector represents the majority of treatments and encompasses various social security institutions and decentralized state healthcare systems (SESA). Studies about purchasing are of interest because tenders are frequently selected as a purchasing scheme and the organisation of purchasing decisions (e.g. at hospital level or

regional level) is based on the demand for a medical device of a single hospital, or a region covering several hospitals, or the entire social security institution. This determines how much decision autonomy is left to the hospital level. Reviewing the information provided by the governmental website *Compranet* [143], which was established to make public procurement activities in Mexico transparent, shows that the scope of tenders among the different social security institutions and SESA has varied considerably over the past years and that financial aspects dominated decision making.

This cross-sectional study assessed the attitudes and thoughts of orthopaedic specialists regarding their role in purchasing decision making of HRMDs, their experience with purchasing processes and the relationship to clinical results, as well as potential areas for improvement. Based on the above criteria we discuss the relevance of adequate technology assessment and potential areas for improvement of purchasing processes.

6.3. Materials and Methods

The study is based on primary data collected through a survey, representing end-users of orthopaedic HRMDs. Our research approach is based on a working framework and presented in Figure 6.1.

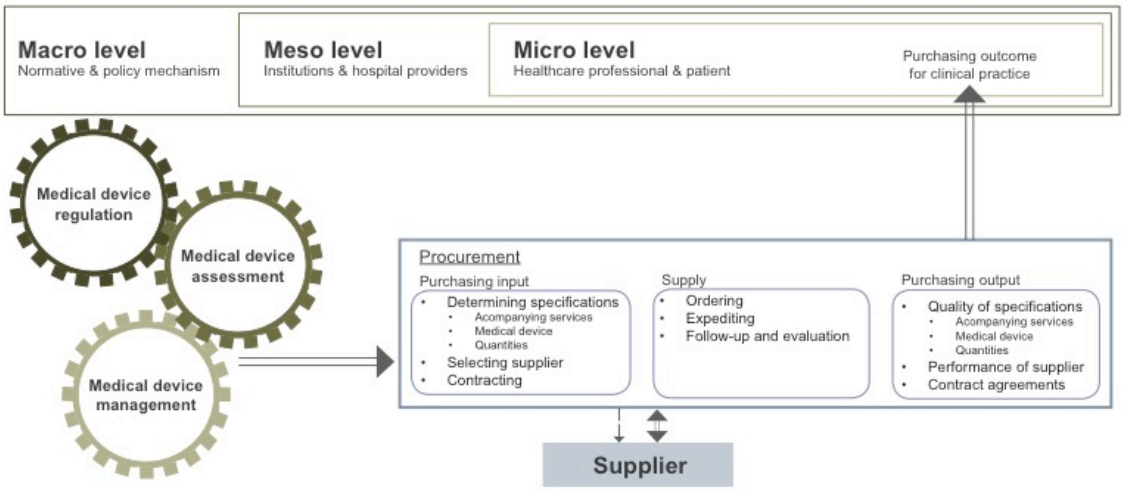

Figure 6.1. Working framework

The framework is guided by two considerations: (i) end-users have low purchasing decision autonomy, and (ii) purchasing fails to integrate a broader spectrum of decision criteria such as clinical long-term outcome of medical device brands. The framework influenced the data collection and analysis in three ways. Firstly, the framework helped to describe the role of orthopaedic specialists in purchasing decision making. Secondly, it was used to assess their experience with purchasing processes and the relationship to clinical results. Thirdly, ratings of them on areas for improvement of outcomes of purchasing processes were obtained.

Study population

The study population was defined as orthopaedic specialists in Mexico. Data or data sources listing orthopaedic specialists and orthopaedic procedures in Mexico are not publicly available, and the associations of orthopaedic specialists or national academies do not provide an accessible database on which this study would have been able to draw from. Based on information received from the associations of orthopaedic specialists, suppliers of the medical device industry, and pharmaceutical companies, we estimated a total of approximately 1,700 orthopaedic specialists in Mexico. Further, we estimated a total of 26,000 orthopaedic procedures (hip and

knee joint replacement), of which 45% are concentrated in the State of Mexico and the Federal District. We used the estimated data on orthopaedic specialists and procedures as orientation for the data collection.

Sampling

We used a non-probability (purposive) and maximum variation sampling technique [90] to reach a heterogeneous group of participants with a sufficient number of orthopaedic specialists per subgroup, defined by four participants' characteristics: state; sector; care level; and work experience. The characteristic 'sector' is important because the public sector is divided into services provided by social security institutions for the employees, and state healthcare systems, which cover the population that is self-employed or without an insurance cover. For the web-based survey, we searched listings of public hospitals, private hospitals, and associations of orthopaedic specialists to identify potential participants. For the paper-based survey we selected the sample from attendees of a national conference of orthopaedics in Mexico.

Data collection

We selected two routes of data collection (web- and paper-based questionnaire) and used a structured self-administered questionnaire (Supplementary File 6.1).

Supplementary File 6.1. Questionnaire

Survey among orthopedic surgeons

This **anonymous** conducted survey serves to investigate the relation of procurement of orthopaedic high-risk medical devices and its effects on orthopaedic clinical procedures.

Thank you contributing this research and answering the following questionnaire that will require **approximately 8 minutes**. We kindly ask you to indicate your answers in the highlighted areas.

If you wish to contact us before or during you are answering questions of this questionnaire you may contact the following person:

- Main researcher: Myriam Lingg (Email: myriam.lingg@unibas.ch)
- Supervisor [82]: Dr. Luis Duran Arenas (Email:

lduran19@liceaga.facmed.unam.mx)

- Supervisor (Switzerland): Dr. Kaspar Wyss (Email: kaspar.wyss@unibas.ch)

>>> Thank you that you participate in this survey. We appreciate a lot your support and will be pleased to share with you our findings after finishing this investigation.

Question 1

In which **public sector** are you mainly practicing orthopaedic surgeries? Please indicate with an X your answer.

IMSS	☐	PEMEX	☐	SEMAR	☐
ISSSTE	☐	State services	☐	Others	☐
SEDENA	☐	SSA	☐	Only private	☐

Question 2

Where do you realize your main professional work?

State	
Zip code	

Question 3

To which level of medical care attention does your institution belongs to? Please distinguish between "level 1 = family unit", "level 2 = general hospital" and "level 3 = UMAE or specialized unit"

Level 1 "Familiar"	☐	Level 2 "General"	☐	Level 3 "Especializada"	☐	Private	☐

Question 4

Since **how many years** are you practicing in the field of orthopaedic surgeries?

Number of years:	

Question 5

Please describe the **responsibilities of key persons** for the procurement process of your public sector? Please indicate with an X your answer.

	... material planning	... quality of supplier service	... medical device technology	... clinical efficacy of deivice	... No opinion

Director of hospital is involved with regards to …	☐	☐	☐	☐	☐
Head of orthopaedic unit is involved with regards to …	☐	☐	☐	☐	☐
Head of specialized sub-unit is involved with regards to …	☐	☐	☐	☐	☐
Specialized surgeon is involved with regards to …	☐	☐	☐	☐	☐
Resident is involved with regards to …	☐	☐	☐	☐	☐

Question 6

Please describe **your role** in the procurement process of the public sector and the decision-making? Please indicate with an X your answer.

	Fully agree	Agree	Partially agree	Little agree	Don't agree
I can influence the material planning	☐	☐	☐	☐	☐
I can influence the clinical efficacy of a medical device	☐	☐	☐	☐	☐
I can influence the medical device technology	☐	☐	☐	☐	☐
My opinion on material planning (volumes, sizes, etc.) gets considered	☐	☐	☐	☐	☐
My opinion on the clinical efficacy of medical device gets considered	☐	☐	☐	☐	☐
My opinion on the medical device technology gets considered	☐	☐	☐	☐	☐
The decision-making complies with my clinical needs concerning material planning	☐	☐	☐	☐	☐
The decision-making complies with my clinical needs concerning clinical efficacy of medical device	☐	☐	☐	☐	☐
The decision-making complies with my clinical needs concerning medical device technology	☐	☐	☐	☐	☐

Question 7

Please describe **how much you perceive** your clinical practice and patient outcome affected by the following aspects? Please indicate with an X your answer.

	Fully agree	Agree	Partially agree	Little agree	Don't agree
Quality of medical device - material failure	☐	☐	☐	☐	☐
Quality of medical device - effectiveness of medical device	☐	☐	☐	☐	☐
Product portfolio - medical device does not meet patients' needs	☐	☐	☐	☐	☐
Product portfolio - obsolete medical device technology	☐	☐	☐	☐	☐
Accompanying services – incomplete provision of sets	☐	☐	☐	☐	☐
Accompanying services – delayed provision of implants and instruments	☐	☐	☐	☐	☐

Question 8

Please describe **how much you perceive an impact** of the procurement process on your clinical practice and patient outcome? Please indicate with an X your answer.

	Fully agree	Agree	Partially agree	Little agree	Don't agree
… wrong material planning	☐	☐	☐	☐	☐
… low clinical effectiveness of medical device	☐	☐	☐	☐	☐
… limited product portfolio	☐	☐	☐	☐	☐
… inferior medical device technology	☐	☐	☐	☐	☐
… low quality of instruments	☐	☐	☐	☐	☐
… sub-standard services received from medical device supplier	☐	☐	☐	☐	☐

Question 9

Please describe **how much you can solve** these problems without failing in your clinical practice? Please indicate with an X your answer.

	Solve without difficulty	Solve with Little difficulty	Solve with lots of difficulty	Almost cannot be solved	Cannot be solved	No opinion
Quality of medical device - material failure	□	□	□	□	□	□
Quality of medical device - effectiveness of medical device	□	□	□	□	□	□
Product portfolio - medical device does not meet patients' needs	□	□	□	□	□	□
Product portfolio - obsolete medical device technology	□	□	□	□	□	□
Accompanying services – incomplete provision of sets	□	□	□	□	□	□
Accompanying services – delayed provision of implants and instruments	□	□	□	□	□	□

Question 10

Do the following aspects **contribute to an improvement** of your clinical practice and the patient outcome? Please indicate with an X your answer.

	Fully agree	Agree	Partially agree	Little agree	Don't agree	No opinion
Tender culture: Sustainability and long-term clinical evidence of medical devices	□	□	□	□	□	□
Digital access to clinical data from hospital to national level	□	□	□	□	□	□

Reporting system on clinical efficacy of medical devices on hospital and national level	□	□	□	□	□	□
Diffusion of scientific investigation on hospital and national level	□	□	□	□	□	□
Cooperation between orthopaedic societies, academic level and government units	□	□	□	□	□	□
Integral strategy approach between government units to control and monitor quality on clinical practice level	□	□	□	□	□	□

Question 11 (end of questions)

Please describe how you perceive that the following **aspects are considered** in your public sector. Please indicate with an X your answer.

	Strongly considered	Considered	Partially considered	Almost not considered	Not considered	No opinion
Tender culture: Sustainability and long-term clinical evidence of medical devices	□	□	□	□	□	□
Digital access to clinical data from hospital to national level	□	□	□	□	□	□
Reporting system on clinical efficacy of medical devices on hospital and national level	□	□	□	□	□	□
Diffusion of scientific investigation on hospital and national level	□	□	□	□	□	□
Cooperation between orthopaedic societies, academic level and government units	□	□	□	□	□	□
Integral strategy approach between government units to control and monitor quality on clinical practice level	□	□	□	□	□	□

The questions were developed based on the results of two preceding studies [141, 142]. The questionnaire was pre-tested on five orthopaedic specialists in Mexico. We captured responses for questions regarding purchasing using a 5-point Likert scale.

The questionnaire used to collect the data was administered on an online platform, SurveyMonkey®, and at a scientific conference.

The web-based data collection took place between June and October 2015 utilizing SurveyMonkey® to inform orthopaedic specialists about the survey and to collect their answers to the questionnaire. We made additional contact through email to identify orthopaedic specialists in order to increase participation rate. The paper-based data collection took place on April 29 - 30 2015 and was conducted by two research assistants that were trained in the study procedures for administering questionnaires to study participants. We collected data from attendees of the "XXVIII National Mexican Conference of Orthopaedics and Traumatology 2015". The two research assistants presented our study at this conference during registration and coffee break, informed attendees about the survey and asked them if they were interested to participate in the survey.

Data analysis

For the data analysis, we merged both sets of data and applied descriptive statistics. Ordinal scaled variables were transformed into a binary outcome by grouping the first two categories (e.g. "fully agree" and "agree") into "1" and all other categories into "0". Descriptive analyses were conducted using STATA software version 14 (STATA/IC 14.1 StataCorp). The data was tabulated and proportions were compared between categories using the chi-squared test. We used Fisher's exact test to examine the significance of the association between specific variables of interest, and assessed the level of agreement between responses to different items using the kappa statistic [144].

Ethics

This project was approved by the ethical committees from Autonomous University of Mexico [82] (Date of approval: November 4th 2014, FMED/CI/SPLR/188/2014) and by

the Ethical committee from northwest and central Switzerland (Switzerland) exempted it from ethical review according to Swiss law (Date of exemption: June 24th 2014). All interviewees gave written informed consent before the interview.

6.4. Results

Sample description

We identified a total of 600 eligible orthopaedic specialists from the web-based search and 215 orthopaedic specialists during the conference (Figure 6.2).

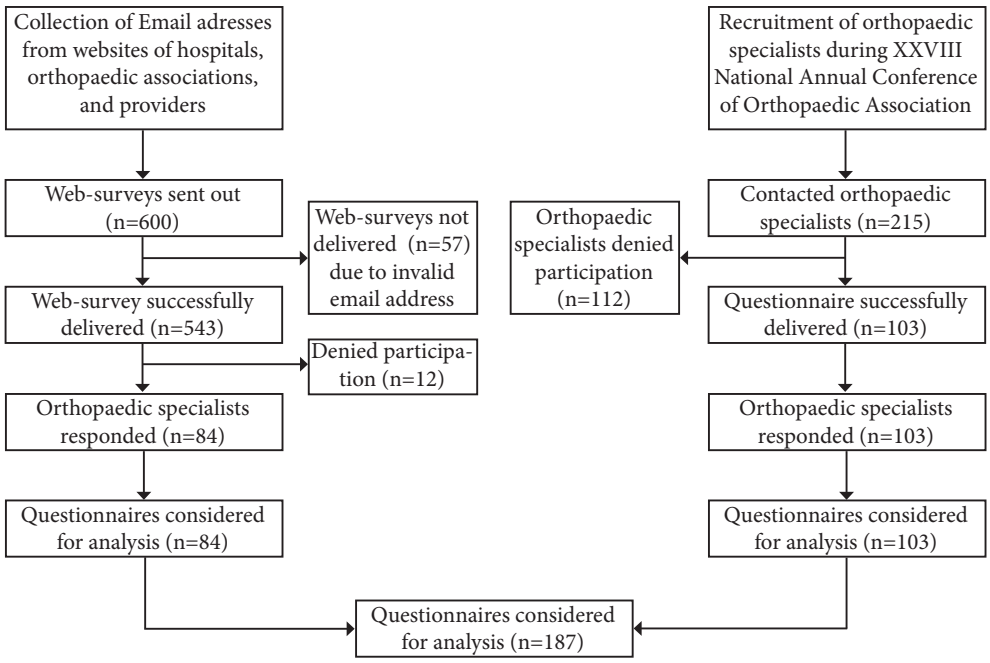

Figure 6.2. Survey process

Overall, 187 orthopaedic specialists agreed to participate in the survey, representing a 23% response rate based on the number of orthopaedic specialists contacted directly. Approximately half of the respondents had more than 15 years work experience, and a fifth had less than 5 years (Table 6.1). Most respondents were

working in the public sector (68%, n=127), and located in the Federal District and State of Mexico (58%, n=108).

Table 6.1. Characteristics of respondents by recruitment route

Characteristics	Total sample N (%)	Web-based N (%)	Paper-based N (%)
Total	187 (100)	103 (55)	84 (45)
Care level			
Primary care	0 (0)	0 (0)	0 (0)
Secondary care	43 (23)	10 (12)	33 (32)
Specialist care	84 (45)	40 (48)	44 (43)
Private	60 (32)	34 (40)	26 (25)
Sector			
Public – Social Security Institutions IMSS	79 [23]	32 (38)	47 (46)
Public - State Healthcare System & others	48 (26)	18 (21)	30 (29)
Private	60 (32)	34 (41)	26 (25)
State			
State of Mexico and Federal District	108 (58)	54 (64)	54 (52)
Other states*	79 [23]	30 (36)	49 (48)
Work experience			
Up to 5 years	40 (21)	8 (10)	32 (31)
6 to 15 years	61 (33)	27 (32)	34 (33)
More than 15 years	86 (46)	49 (58)	37 (36)

There were some differences in the characteristics between those recruited through the web-search and those recruited via the conference. Those attending the conference mostly worked in the public sector, had less seniority, and were located in other states. However, there were no indications that these differences affected the attitudes of the participants.

Our study was concerned with purchasing processes in the public sector. Nevertheless, 60 participants reported working in the private sector and of these 58%

had more than 15 years work experience and only 10% had up to 5 years work experience. In Mexico, orthopaedic specialists often work in both the public and private sector and after their retirement from the public sector, continue working in the private sector. These participants reported on their experience when they previously worked in a public sector or opinions about purchasing in public sectors. We present the data as a whole and describe any relevant differences between orthopaedic specialists from the public and private sector. Table 6.2 summarizes the responses of the participants by key themes.

Table 6.2 Questionnaire responses on role of involvement, problems in clinical practice, effects of procurement, and aspects improving clinical practice

	Total	Agreed with at least one statement to be involved	Agreed to have an affected clinical practice	Agreed to see effects of procurement on clinical practice	Agreed on at least on aspect improving clinical practice	Agreed that most of these aspects are not considered in public sector
	N	N (%)	N (%)	N (%)	N (%)	N (%)
Total	187	161 (86)	161 (86)	172 (92)	173 [23]	121 (65)
Care level						
Secondary care	43	35 (22)	40 (25)	42 (23)	42 (24)	29 (24)
Specialist care	84	74 (46)	74 (46)	82 (45)	82 (48)	48 (40)
Private	60	52 (32)	47 (29)	57 (32)	49 (28)	44 (36)
Sector						
Public	127	109 (68)	114 (71)	124 (68)	124 (72)	77 (64)
Private	60	52 (32)	47 (29)	57 (32)	49 (28)	44 (36)
State						
Mexico & DF	108	94 (58)	92 (57)	104 (57)	102 (59)	66 (55)
Other states*	79	67 [23]	69 (43)	77 (43)	71 (41)	55 (45)
Work experience						
Up to 5 years	40	35 (22)	38 (24)	40 (22)	37 (21)	25 (21)
6 to 15 years	61	51 (32)	53 (33)	60 (33)	55 (32)	43 (35)
More than 15 years	86	75 (46)	70 (43)	81 (45)	81 (47)	53 (44)

Orthopaedic specialists role in purchasing decision making

Of the 187 surveyed orthopaedic specialists, 86% agreed with at least one statement that they had some form of involvement in decision making: “I can influence” (81%), “My opinion is considered” (72%), and “It contributes to my clinical needs” (69%). There was no evidence of a difference for the area of purchasing inputs: “Planning of material and quantity” (88%), “Effectiveness of medical device” (82%), and “Medical device technology” (74%). Fisher’s exact test for the three areas of purchasing inputs always resulted in 0.00. Interrater reliability provided a kappa between 0.63 (substantial agreement) and 0.84 (almost perfect agreement) [144]. Those who thought they had some form of involvement in decision making had good agreement in the area of purchasing inputs.

We observed a slightly lower proportion of participants indicating to have some form of involvement in decision making concerning orthopaedic specialists employed by the social security institution, Mexican Institute of Social Security (IMSS). The answers of participants in respect to other characteristics had little variation in terms of their care level (“Secondary care: 81%; “Specialist care”: 88%; “Private”: 87%), their location in the country (“Mexico & DF”: 87%; “Other states”: 85%) or their work experience (“Up to 5 years”: 88%; “6 to 15 years”: 84%; “More than 15 years”: 87%).

Problems in clinical practice and associated with purchasing

Of the 187 surveyed orthopaedic specialists, 161 (86%) reported that their clinical practice has been exposed to one of the following situations: “Material failure” (64%), “Low effectiveness of medical device” (63%), “Available medical device does not meet patients’ needs” (51%), “Obsolete medical device technology” (47%), “Incomplete provision of sets” (68%), and “Delayed provision of implants and instruments” (72%). However, 172 (92%) reported effects of purchasing on clinical practice (purchasing output attributes), including: “Wrong material planning” (89%),

“Low clinical effectiveness of product” (83%), “Inferior medical device technology” (79%), “Limited product portfolio” (83%), “Low quality of instruments” (85%), and “Sub-standard services received from medical device supplier” (87%). Participants agreed slightly more to have an affected clinical practice based on “Quality of services received” and “Material planning”. Fisher’s exact test for problems in clinical practice always resulted in 0.00. Inter-rater reliability resulted in a kappa between 0.26 (fair agreement) and 0.62 (substantial agreement) [144]. Those who reported that they had an affected clinical practice or saw effects of purchasing on clinical practice had a moderate agreement in the area of purchasing output attributes.

We observed a slightly lower proportion for experiencing problems in their clinical practice in terms of care level “Private” (78%), and work experience “More than 15 years” (81%). The answers of participants in terms of other characteristics had little variation: care levels (“Secondary care”: 93%; “Specialist care”: 88%), sectors (“IMSS”: 94%; “ISSSTE”: 100%; “SSA”: 84%; “Other”: 83%), and work experiences (“Up to 5 years”: 95%; “6 to 15 years”: 87%). We did not observe a difference for participants looking at the characteristic states (“Mexico & DF”: 85%; “Other states”: 87%).

Relationship between orthopaedic specialists being involved in purchasing and orthopaedic specialists experiencing problems in clinical practice

Among the respondents who had some type of involvement in decision making, many stated they had problems in their clinical practice in general (n=137), which was related to the availability of materials and effectiveness or technology of medical device, or reported seeing effects of purchasing on clinical practice (n=147), which was specified as low effectiveness of medical device, lack of meeting patients’ needs, obsolete medical device technology, lack of complete and adequate services provided through supplier. Fisher’s exact test to examine the significance of the

association between participants reporting that they have some form of involvement and problems in clinical practice resulted in 1.00. Fisher's exact test between participants reporting that they have some form of involvement and their clinical practice has been exposed to problems associated to purchasing resulted in 0.722. The Kappa statistic was below 0.2 for affected clinical practice in general and for effects of purchasing on clinical practice.

Aspects that may improve clinical practice

Overall, 93% reported at least one aspect by which clinical practice could be improved: "Sustainable clinical long-term data of medical devices", "Access to electronically stored clinical data", "Report system on clinical effectiveness of a medical device", "More clinical research", "Cooperation between medical associations", "Academic representations and federal agencies", and "Better monitoring of quality in clinical practice".

We observed a slightly lower proportion of participants working in the private sector reporting that there are aspects that may improve clinical practice for two groups of characteristics: care level ("Private": 82% against "Secondary care": 98%; "Specialist care": 98%) and sector ("Private": 82% against "IMSS": 100%; "ISSSTE": 91%; "SSA": 97%; "Other": 97%). Overall, 65% responded that most of these aspects were not or almost not considered in their public sector.

6.5. Discussion

In this cross-sectional study among orthopaedic specialists we assessed viewpoints of end-users concerning the purchasing process of HRMDs. We identified two important findings: (i) the majority of participants agreed with at least one statement that they had some form of involvement in purchasing; (ii) many participants reported experiencing problems in their clinical practice and they associated several of them with purchasing. In Mexico, agents of the purchasing process are responsible for

preparing or realizing the needs assessment; this depends on whether the tender covers the demand for a single hospital or several hospitals. The heads of orthopaedic department and end-users provide information on the expected demand for new procedures and suggests the type of technologies needed for the expected surgeries. The orthopaedic specialist who is working within the team of the orthopaedic department is generally integrated in the purchasing process based on physical conformity checks of medical device specifications [141, 142]. This is reflected by the answers of participants concerning their influence on and the consideration of their opinion for a medical device technology. However, the answers on decision making suggest that the way in which decisions are made is not always well linked to end-users. In our previous studies we found that the decision autonomy of the end-user is relatively low, and that medical devices are not always evaluated based on post-market data once that they have been listed in the standard list [141, 142].

Many of the identified areas of problems that participants reported may originate from the current practices of purchasing processes for orthopaedic HRMDs in Mexico. A previous study on purchasing identified similar findings for outcomes of purchasing practices exemplary for the social security institution IMSS [60]. In the function of healthcare delivery, the main process occurs at the clinical level between clinicians and patients [7]. For the production of direct services to the patient, the support of administrative processes such as purchasing is essential and it increasingly influences clinical practice and outcomes [145, 84, 60, 88]. Understanding the performance of these processes in healthcare systems is important because they support clinicians with products such as medical devices that are critical for the patient treatment [62, 66, 68, 79, 115]. Evaluating orthopaedic HRMDs at the meso level based on a systematic assessment scheme such as mini-

HTA may bridge the gap between purchasing inputs and outputs, and thus improve purchasing decision outcomes. HTA in Mexico has improved over recent years [78] but requires still more advancement.

Few of the identified areas of problems that participants reported may originate from post-market regulations for HRMDs in Mexico at the meso and macro level. This may be attributed to the experience of end-users that their complaint systems do not sufficiently contribute to solving their problems in clinical practice [141, 142]. However, in our previous studies, we also found that end-users often tend to neglect reporting these problems. When these problems are rarely discussed or addressed by the end-users, decentralized organs such as COFEPRIS that encompasses the Mexican Technovigilance department cannot exert their influence on post-market surveillance.

This study provides insight into viewpoints of end-users for purchasing of orthopaedic HRMDs and into the potential contribution of HTAs at the level of purchasing decisions. Given the known needs for improvement of purchasing outcomes and aspects that may improve clinical practice, a critical analyses of purchasing processes will be necessary to determine real practice relevance and to define improvement plans. Those analyses should integrate how purchasing decisions influence the type of problem that end-users experience in their clinical procedures.

Limitations

For this study, we used non-random sampling, which does not necessarily guarantee the sample being representative for the population of orthopaedic specialists in Mexico. However, this study includes 187 end-users working as orthopaedic specialist, and is based on a purposive sampling. Thus it covers different groups of surgeons in terms of work experience, state within Mexico, and at the health service

attention level. The sample represents approximately more than 10% of orthopaedic specialists who practice orthopaedic surgery. Furthermore, in this study we collected data from end-users employed by different public institutions and self-employed orthopaedic specialists. Tender processes vary among institutions and over time and thus influence the response behaviour of participants. Therefore, this study does not provide insight into purchasing inputs related to a specific tender scheme. Instead this study provides insight into viewpoints of end-users on purchasing outcomes in general. These insights suggest that purchasing processes are in need of more detailed investigations.

6.6. Conclusion

The findings of this study suggest that purchasing processes need to be further investigated in more detail. The outcomes of purchasing decisions have been little investigated and a better understanding of these will contribute to the strengthening of the purchasing of HRMDs. Neglecting problems that end-users experience during their clinical practice leads to the continuation of sub-standard provision of purchasing outputs and increased burden of risk for both the orthopaedic specialist and the patient. To prevent sub-standard outcomes of purchasing decisions, this study and the current literature suggest that technologies should be assessed during the purchasing process, end-users should be adequately involved, and decisions should be based on multiple criteria including clinical impact in the short-term (tissue trauma, rehabilitation duration, primary stability of implant, etc.) and long-term (survival of implant, material performance, etc.).

The focus on Mexico is particularly novel and provides insight into a health system where HTA activities are mainly realized at the macro level. However, this does not solve the need for adequate evidence-based evaluation of health technologies at the hospital level. This study concludes that Mexican stakeholders of the purchasing

process underestimate the contribution of HTAs at the level of purchasing decisions. HTA in Mexico has improved in recent years but needs more advancement.

List of abbreviations

CENETEC, Centro Nacional de Excelencia Tecnológica en Salud (National Centre for Health Technology Excellence); COFEPRIS, Comisión Federal para la Protección contra Riesgos Sanitarios (Federal Commission for the Protection against Sanitary Risks); CSG, Consejo de Salubridad General [1]; HRMD, High-risk medical device; HTA, Health Technology Assessment; IMSS, Instituto Mexicano de Seguro Social (Mexican Institute of Social Security); ISSSTE, Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado (Institute of Social Security and Services for State Workers); WHO, World Health Organization.

Conflict of interests

None.

7. The regulation, assessment, and management of medical devices in Mexico: How do they shape the quality of delivered healthcare?

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7.1. Abstract

Background: Policies for health technologies such as medical devices are essential and contribute to improved quality of healthcare. The regulation, assessment, and management represent important functions of medical devices. Insufficiently developed interactions between these functions impact the quality of delivered healthcare. To date studies lack to analyse these functions in a broad way.

Objective: Analyse the regulation, assessment, and management of orthopaedic medical devices in Mexico and how they shape healthcare.

Design and methods: This qualitative study included 42 stakeholders involved directly or indirectly in the regulation, assessment, or management for orthopaedic medical devices in Mexico.

Results: The fragmentation of responsibilities for medical device functions may be a central aspect of our findings concerning challenges reported by interviewees. Strengthening technovigilance based on improved reporting across healthcare institutions emerged as pathway to improve medical device regulation. With regard to improving the medical device assessment, a comprehensive update of the standard list represents a relevant opportunity. Integrating advanced quality attributes into procurement processes regarding decision-making, purchasing strategy, and procurement agent is needed to fostering the management.

Conclusions: This study provides a broad analysis of medical device functions within a health system and highlights in this specific context how improvements might be achieved. It addresses a broad range of interest groups represented by policy makers, health service providers, managers and administrators of healthcare facilities, and doctors with an interest in health technologies. In this paper we highlight important themes that influence outputs and outcomes of the regulation, assessment, and management and discuss strategies in fostering these areas. To

date, the regulation, assessment, and management of medical devices are rarely analysed in a broad way, even though these functions importantly contribute to the successful implementation of health technology policies. The quality of delivered healthcare is influenced by the performance between and within these functions. In Mexico, little discussion has been raised on challenges of the regulation, assessment, and management of medical devices. Changes to current processes and practices can improve outputs and outcomes of these functions and positively influence the quality of delivered healthcare. Stakeholder involvement and commitment is essential to this.

Keywords: assessment; health technology; management; medical device; Mexico; regulation

7.2. Background

Policies for health technologies such as medical devices are essential to assure equitable access to high quality and affordable devices and their appropriate use and thus contributing to improved quality of care [37]. The World Health Organization (WHO) emphasizes the importance of developing and implementing health technology policies within the context of a national health plan. WHO indicated that 34% of 145 countries have a health technology national policy in place that is part of the national health programme [38]. Mexico is one of these countries and has established several government agencies (Table 7.1) and defined regulations that support policies for health technologies. This is key to organize and support, and strengthen important functions for medical devices. These functions are the regulation, assessment, and management of medical devices and compose important areas of the Medical Device Life-Cycle (MDLC) (Table 7.2) and support healthcare delivery at different organizational levels within the health system.

Table 7.1. Principal actors involved in the regulation, assessment, and management of medical devices in Mexico

Stakeholders	**Main responsibility**	**Relative importance for MDLC areas**		
		Tehno-vigilance	Assessment	Purchasing
• Sub-secretariat for Health System Integration and Development, **SIDSS**	• Government agency whose mission is to propose to the MOH national policies that improve the quality of social health services; issues the Mexican Official Norms (NOM)	**++**	**+++**	**++(+)**
• Departments of Sub-secretariat for Health System Integration and Development	• General directorate of health planning and development, **DGPD**: Governmental organization and unit under the authority of the SIDSS whose mission is to steer	**++**	**+++**	**++(+)**

	the strengthening of health services among policy makers, and giving guidance to improve health services sustainable and cultural based on populations' needs. • General directorate of quality and education, **DGCE**: Governmental organization and unit under the authority of the SIDSS whose mission is to ensure that the quality and safety of health services, including human resources of the health sector and the regulatory environment of social health supplies is aligned with national policies.			
• General Council of Health, **CSG**	• Sanitary authority directly accountable to the President • Council whose mission it is to strengthen the governance and the articulation of the National System of Health. Founded: 1917 • Publishes the standard list of Health Supplies • Holds the Inter-institutional Commission of the standard list for Health Supplies whose mission is to manage the approved technologies in the standard list for Health Supplies • Auditing of hospitals with regards to quality standards (certification process)	**++**	**++(+)**	**+**
• Federal Commission for the Protection against Sanitary Risks, **COFEPRIS**	• Decentralized organ of the MOH whose mission is to protect the population against medical risks derived from the introduction of new medical drugs, medical devices and other health inputs. Founded: 2002 • Sanitary Authorization Commission whose mission is the market approval of medical products and technologies. • Technovigilance department whose mission is to implement and realize post-market surveillance. • Support function of "Sanitary Authorization Commission" whose mission is to provide technovigilance reports for the renovation of market approval.	**+++**	**++**	**+**
• National Centre for	• Governmental organization and	**++**	**++(+)**	**++(+)**

Health Technology Excellence, **CENETEC**	unit under the scope of the SIDSS whose mission is to contribute to the development and governance of the National Health System in Mexico based on: Health Technology Assessments, Supervision of medical equipment, Telemedicine, Clinical guidelines. Founded: 2004 • WHO collaborating centre.			
• Sub-systems: Centralized and decentralized health services	• Functionary with national responsibilities within the sub-system; director of healthcare facility; procurement agent • Functionary with local responsibility: Head of orthopaedic department	**+++**	**++(+)**	**+++**

+++ strong relation ++ moderate relation + low relation - no relation

Table 7.2. Important outputs and outcomes oft he MDLC areas (adapted from WHO [19, 46])

Areas	**Description**	**Outputs**	**Outcomes**
Regulation	Safety and efficacy are in the focus of this phase to aim population safety. Key elements are performing testing, safety assessment & post-market reporting using criteria of safety and quality standards.	Mandatory compliance	Assuring minimal standards of quality
Assessment	Serving the population is in the focus of this phase to aim population health. Key elements are systematic analysis and critical review using epidemiology and evidence data.	Recommendations on highly complex technologies	Responsiveness and maximization of clinical outcomes and cost-effectiveness

Management	Health service providers are in the focus of this phase. Key element is the operational management of technology life-cycle using needs analysis and reliable device availability for clinical use.	Operational rules and guidance for all medical devices	Improved health delivery; sustainable availability of high-quality and safe devices

Besides the development and implementation of health technology policies, WHO emphasizes the importance of the commitment for, and realization of a continuous improvement plan within and between the areas of the MDLC in order to strengthen the implementation of national health technology policies and to contribute to improved health [37]. This can be achieved when necessary interactions between these areas are established because of their interdependence. To date, there are indications of questions regarding different attributes of the MDLC for orthopaedic high-risk medical devices (HRMDs) in Mexico and their influence on clinical practice and thus on the delivered quality of healthcare [141, 142, 146-148]. HRMDs are implanted in the human body (such as a knee joint implant) and are therefore recommended subject to the highest level of pre-market and post-market regulation [22]. To date, little is known how these attributes affect outputs and outcomes of the MDLC and its meaning for quality of healthcare. The articles 83, 179 and 180 of the current Medical Device Regulation of Mexico indicate that there are no specific regulations for HRMDs differentiating them from lower risk medical devices.

The Mexican health system is a complex system with multiple actors encompassing a public private mix of hospital providers [70]. The national healthcare system is decentralized with planning, management, and regulatory authority shared at the federal and state-level [72, 73]. In Mexico, the different sub-systems of

healthcare (social security and state-level healthcare systems (SESA)) are disconnected and the level of healthcare and outcomes between these sub-systems varies [32]. This leads to a fragmentation of responsibilities with regard to the MDLC areas, which might affect the ability of policymakers to comprehensively oversee the MDLC in Mexico.

The aim of the present study is to analyse challenges of the regulation, assessment, and management of orthopaedic medical devices in Mexico and their impact on outputs and outcomes of the MDLC. Further, we discuss possible ways forward in fostering the regulation, assessment, and management and their influence on the quality of delivered healthcare.

7.3. Methods

Our research approach is based on a working framework (Figure 7.1), which is guided by two considerations: (i) MDLC represents key functions for medical devices and as a whole it is a functional system contributing to improved health, and (ii) important stakeholders related to the MDLC exert their influence at the macro level (regulation and policy mechanism), meso level (public healthcare institutions and care provider facilities), and micro level (healthcare professional and patient).

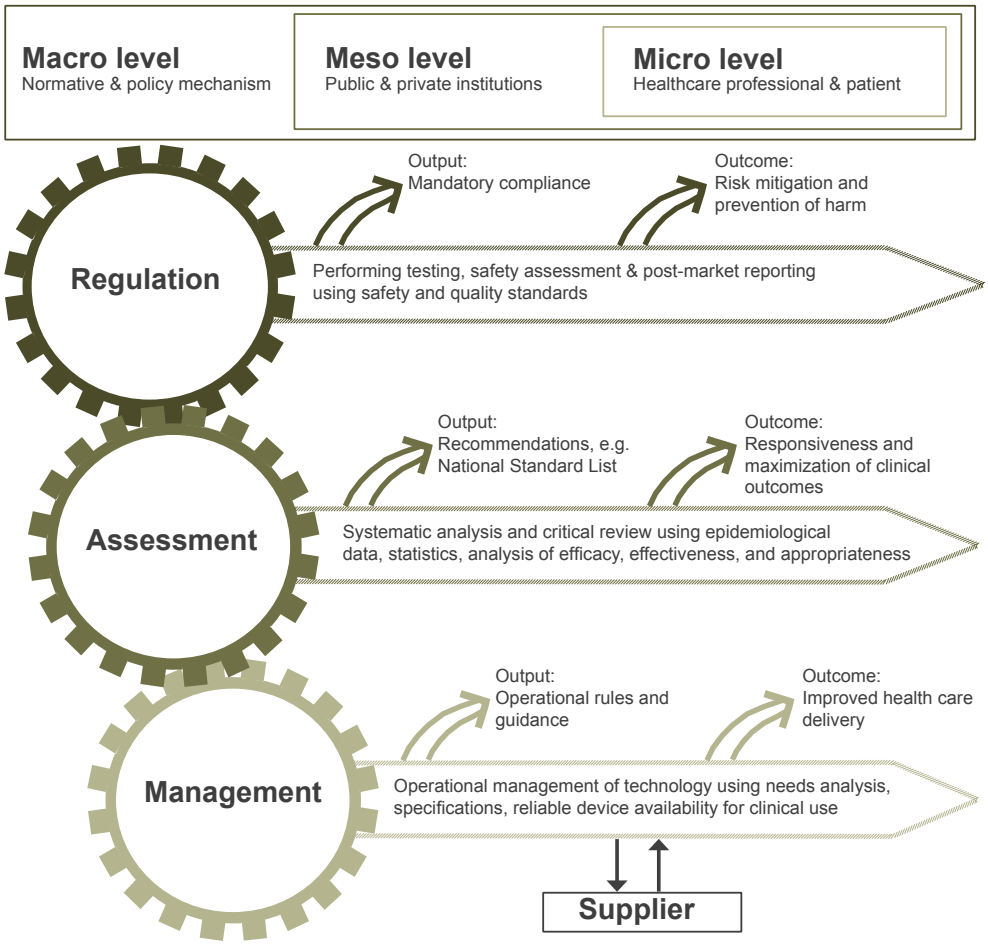

Figure 7.1. Working framework

The framework guided the data collection and analysis. This research is part of a larger study to investigate the relation between the regulation, assessment and management of orthopaedic HRMDs in Mexico and their impact on clinical procedures.

Study population and recruitment

The study was done in Mexico. We identified and recruited participants for interviews by searching listings from the governmental offices, public sector, orthopaedic specialists (public and private sector), organisations, medical device supplier. We used a maximum variation sampling [90] to recruit key stakeholder based on three sample criteria: (i) stakeholders influencing MDLC areas; (ii) stakeholders influencing

between MDLC areas; and (iii) stakeholders that have potential to influence MDLC areas in the future.

Data collection

In total 42 interviews were conducted between April and May 2016 by the principal investigator and a research assistant. The principal investigator and a research assistant conducted interviews in Spanish. We used a file-naming system and anonymized interviewees by generating a list of archival numbers. We used face-to-face interviews (n=39) and phone interviews (n=3) (Table 7.3).

Table 7.3. Respondent characteristics

Stakeholder group	**Participant**	**Male**	**Higher management level**
	N (%)	N (%)	N (%)
Group 1 (macro level)	24 (57)	16 (63)	18 (58)
(i) Having direct relation to MDLC areas	11 (46)	5 (45)	8 (73)
CSG, MOH, General directorates	4 (36)	3 (75)	4 (100)
COFEPRIS, CENETEC	6 (55)	2 (33)	3 (50)
International organization or experts for Mexican health system	1 [23]	0 (0)	1 (100)
(ii) Indirect relation to MDLC areas	13 (54)	11 (85)	10 (77)
MOH, General directorates	3 (23)	2 (67)	2 (67)
National institutes, organizations, or experts concerned with public health, quality of health services, or patient safety	8 (62)	8 (100)	6 (75)
International organization or experts for Mexican health system	2 (15)	1 (50)	2 (100)
Group 2 (meso level)*	5 (12)	2 (40)	4 (80)
Financing / provision of health services	3 (60)	1 (33)	3 (100)
Quality of health services	2 (40)	1 (50)	1 (50)
Group 3 (micro level)*	9 (21)	7 (78)	2 (22)
Orthopaedic specialists	9 (21)	7 (78)	2 (22)

Group 4 (supplier)	4 (10)	3 (75)	4 (100)
Medical device industry association	1 (25)	0 (0)	1 (100)
Medical device supplier	3 (75)	3 (100)	3 (100)
Total	**42 (100)**	**28 (67)**	**28 (67)**

*Social security institutes and State-level healthcare systems

All interviews were audio recorded, transcribed, and reviewed again by the principal investigator with the exception of one interview owing to employer requirements and we used an interview protocol. The interview guide (supplementary file 7.1) was previously validated among a small group of persons familiar with medical device regulation, assessment, and management.

Supplementary File 7.1. Extraction of interview guide questions

Question block 1	
	Introduction: The regulation, assessment, and management (procurement) of medical devices are confronted with the product complexity. Product complexity encompasses the limited knowledge regarding clinical safety of high-risk medical devices that are implanted in the human body, and the clinical long-term performance of them. The interrelation of multiple actor who are directly or indirectly involved with the regulation, assessment, and management of medical devices are crucial because they influence the mechanism behind product complexity such as knowledge and evidence synthesis, guidance, etc.
Q1	What is your opinion about these aspects of the regulation, assessment, and management of medical devices?
Q2	Is it important to manage product complexity and what aspects are important?
Q3	Who or which area of the health system should be responsible to improve the management of product complexity?
Question block 2	
	Introduction: Nowadays health technology policies consider to regulate medical devices based on market approval, health technology assessments, and procurement decision-making boards. Two dimensions are crucial to outreach a successful management (procurement) of medical devices: (i) involving relevant stakeholders in decision-making processes, and (ii) relying on high quality of data and information provided by the environment of procurement (represented by regulation and assessment).
Q1	What is your opinion about these dimensions of the regulation, assessment, and

	management of medical devices?
Q2	Is it important to strengthen these two dimensions of the management of medical devices and what aspects should be strengthened?
Q3	Who or which area of the health system should be responsible to strengthen these dimensions?

Question block 3

	Introduction: One important task of the management of medical devices (procurement) is to evaluate offers based on product specifications. For this multiple information is needed. Decision committees encompassing managers, administrators and clinicians realize this during a stepwise process to prevent sub-standard quality. However, results of a survey among 187 orthopaedic clinicians showed that they perceive their clinical practice affected by the outputs and outcomes of procurement.
Q1	What is your opinion about these aspects of the management of medical devices?
Q2	Is it important to change aspects of procurement and in what aspects do you think?
Q3	Who or which area of the health system should be responsible to change these aspects?

Data analysis

To assess views of stakeholders on challenges of and possible ways forward in fostering the MDLC areas, we thematically analysed the transcripts [149]. MAXQDA software (version 11, VERBI GmbH) was used to aid data management. To describe the views of stakeholders regarding challenges, first, we closely read each transcript. Second, we deductively coded one-third of the transcripts based on the themes of our conceptual framework and inductively coded for new themes. Third, we clustered codes into categories, revised the final list of codes and categories. Fourth, we systematically applied coding to all transcripts and drew on important themes. The principal investigator analysed all primary data alone, which implies a limitation of validity check. To integrate the views of stakeholders regarding possible ways forward in fostering MDLC areas into the discussion of the present study we analysed them in the context of the key findings, the findings of our previous studies and the results of our background research on current medical devices reforms and policies.

7.4. Results

The results of this study are structured along the areas regulation, assessment, and management and summarized by their importance in Table 7.4. Illustrative quotations are presented in Table 7.5.

Table 7.4. Frequency of discussed themes regarding challenges in organizational practice

MDLC areas	**Total**	**Group 1**	**Group 2**	**Group 3**	**Group 4**
Regulation	++(+)	++(+)	++(+)	++	+(+)
Assessment	++(+)	++(+)	+	++	+++
Management	++(+)	++	++	+++	+++

+ low intensity; ++ some intensity; +++ high intensity

Table 7.5. Quotations of interviewees

Quotations	**Stakeholder group**
Area of regulation: Reporting culture of adverse events and complications during clinical practice	
„Often they don't know that there is a regulation for technovigilance.“	Macro level
„... we explained to the health professionals that finally they are the ones who complain about a product that fails and that the product does not provide the required results. However, me as authority how can I take notice about that <complaints> if they <end-users> dont make notifications, if they don't report failures than I cannot find it out and if I don't find it out I cannot react, if I dont react the things stay as they are.“	Macro level
„... not only the bad quality of the materials but also the bad service which they provide for technical assistance... This type of complaint converts into an internal report and stays there, I am sorry that I have to say that.“	Micro level
„... do you believe that the authorities of the institutions don't know the needs that exist?“	Macro level
Area of assessment: Decisions about the eligibility of HRMDs	
„... we noticed the extremely poor culture of science that was present in the area of technology assessment.“	Macro level
„As a result of poor regulation every buys what he wants and we complain about lots of things...“	Meso level
„A lot of people said as well that we should skip the institutional standard lists.“	Macro level

Area of assessment: Decisions about the eligibility of HRMDs	
„I believe that the first error of the pseudo transparency of implant procurement is that they buy at the lowest price.“	Macro level
“It's incredible that a surgery has to be cancelled because the supplier did not arrive with the material ... Which economic penalty can compensate this damage to the patient...”	Micro level
“… a serious problem of the servicio integral is that they decide which brands they include in their service packages ... Cheaper products so that they make more profit.”	Supplier
„... there are constant changes, when a new person comes sometimes he dosent has sufficient preparation to realize a tenders.“	Micro level
„... the procurement agent knows the standard list but little about the basics of a joint implant.“	Supplier

Area of regulation: Reporting of adverse events and complications during clinical practice

There was some degree of consensus among interviewees that technovigilance activities (post-market surveillance of approved medical devices) should be strengthened across all levels of health-care delivery, but mainly at the meso level (healthcare institutions). Further, these activities may contribute to a wider scope of decision-making such as purchasing decisions. In Mexico, monitoring activities for HRMD safety and performance take place under the supervision of the Technovigilance department of the Federal Commission for the Protection against Sanitary Risks, which relies on the reporting of healthcare institutions. Interviewees noted that the reporting of healthcare institutions is sub-optimal. The federal Technovigilance department encompasses decentralized departments of the SESA and the responsible technovigilance actors at the social security institutions. Few interviewees thought that they did not see significant advances in technovigilance activities since its introduction in 2013 and thought that it was not implemented sufficiently. They noted that technovigilance often only exists on paper rather than in daily practice. Interviewees provided different reasons for this. Many interviewees

thought that monitoring the safety and performance of HRMDs was insufficiently developed for a long time. Some interviewees from the macro level noted that a major difficulty to improve technovigilance was to coordinate the different sub-systems of the Mexican health system. They stated that the commitment of users and suppliers to inform technovigilance officers about adverse events and incidents is irregular and activities at the meso level provide insufficient guidance to HRMD users.

Intra-operative complications are negative outcomes of using HRMDs during surgery and accompanying services such as instruments, implant sets, surgical technique, or technical assistance of supplier during surgery. Some interviewees stated that users report intra-operative complications to procurement administrators so that they can be managed in the context of service and delivery contract duties. But some noted as well that managing information about these complications is essential as these failures may influence medical outcomes in the long-term, considering their nature and frequency. Further, few interviewees noted that the awareness of the involved stakeholders about how reporting can contribute to decision-making at the meso and macro levels is low. Some interviewees thought that establishing an effective reporting system and infrastructure may contribute to the strengthening of the evidence of intra-operative complications, which is contributing to technovigilance.

Area of assessment: Decisions about the eligibility of HRMDs

Many interviewees indicated that the eligibility of orthopaedic HRMDs was not regulated thoroughly enough. Some interviewees noted that the current version of the standard list for orthopaedic and osteosynthesis medical devices still included several obsolete technologies or misleading descriptions. They noted that a major difficulty is that, by law, these changes to the standard list require formal modification

requests from, e.g., a social security institution or a medical device supplier. Neither the inter-institutional committee nor the General Council of Health can implement such changes independently. Some interviewees thought that solving these problems of eligibility requires, among else, strong governance and improvement plans. They noted that updating the standard list is important, but only as a prerequisite rather than as a sustainable step in improving the post-market regulation of HRMD eligibility. Despite the national standard list (macro level), each public health institution manages its own standard list for health supplies (meso level). Few interviewees thought that it was necessary to unify these standard lists into one single standard list.

Area of management: Procurement decision-making, purchasing strategy, procurement agent competencies

In Mexico, decision-making is strongly guided by conformity checks of HRMD specifications (e.g. material, mechanical characteristics, dimensions) and lowest-price offers [141, 142, 146]. Many interviewees thought that the applied procurement regulations and practices in use have not advanced over the past years. Some interviewees noted that decision makers had difficulties understanding differences between medical device brands in terms of their clinical performances (e.g. implant survival rate, primary stability of implant, implantation based on surgical technique). They thought that improved and systematic risk assessment of HRMDs might elucidate risks in a wider scope with the potential to lead to a more thorough use of public budgets, such as Health Technology Assessments (HTA) at hospital level. They noted that medical devices are currently not assessed sufficiently such as implant survival rate. Some interviewees thought that integrating aspects of quality more thoroughly could contribute to the changing of decision-making criteria.

Some interviewees thought that solving deficiencies of specific purchasing strategies could positively influence procurement outcomes and the quality of services provided, respectively. They noted that nowadays outcomes are affected by sub-optimal supplier performance; suppliers are often unable to respond timely with material and technical support to contract assignments because they are often contracted shortly before the contract period started. Many interviewees noted that the increasing use of the bundling of services through *Servicios integrales* requires more quality control. A *Servicio integral* encompasses a range of disposable and non-disposable medical products used for surgery and merges them into one supplier service. Some interviewees noted that this facilitates the public sectors' administrative processes, but it also removes the procurement administrators' control of the final selection of the orthopaedic HRMD brand.

Some interviewees explained that decision makers underestimated the role played by the procurement agent who is concerned with administrative tasks and processes to support needs assessment or analysing supplier offers. They thought that procurement agents should have minimal professional skills underlined by specific certificates so that they were able to understand clinical needs better and to not affect negatively procurement results. Many noted that administrators often have difficulty understanding the clinical needs of users and underestimate the consequences of their decisions about clinical procedures. Some of the interviewees mentioned the importance of continuous training; it could contribute to changing a purely administrative passive support into a more integrated service function. Until now, little attention has been paid to the continuous education of procurement agents.

7.5. Discussion

Interview participants identified important challenges in relation with the MDLC areas in Mexico (affecting policy outputs and outcomes), which might influence the quality of care. With regard to regulation, reporting of adverse events was perceived as the most important challenge; assessment is challenged by several obsolete or wrongly described technologies in the standard list for orthopaedic and osteosynthesis products; while integrating advanced quality attributes into procurement processes was a mayor issue raised regarding the area of management. According to interviewees, subjacent to these challenges is the fragmentation of responsibilities with regard to the MDLC areas and the disconnection of the several sub-systems of healthcare. Overall we found that this causes a lack to support well-integrated MDLC areas and translates into sub-standard outputs and outcomes. In consequence the multiple actors have difficulties to improve the quality of delivered healthcare. Possible ways forward in fostering the regulation, assessment, and management of medical devices in Mexico are:

- Regulation: Strengthening technovigilance
- Assessment: Updating the Standard list for orthopaedic and ostheosynthesis medical devices
- Management: Introducing a decision-making guidance with focus on quality attributes for decision-making, purchasing strategy, and procurement agent competencies

We found that strengthening technovigilance can potentially improve outputs and outcomes of the regulation in the following ways: It can influence the compliance of involved stakeholders (e.g. for post-market reporting) and contribute to improved quality. To strengthen technovigilance three aspects may be considered: (i) including

technovigilance tasks in the requirement catalogue of hospital certifications, (ii) fostering inter-institutional technovigilance guidelines, and (iii) implementing a technovigilance code of conduct (for hospital providers, health-care workers and suppliers). Further, in the literature we found that countries having a well-functioning post-market surveillance system complement their regulatory tasks by integrating specific approaches into the regulators' work to evaluate health technologies or define benchmarks for quality standards [58, 59].

We found that introducing a guidance focusing on quality attributes can improve outputs and outcomes of the assessment and management in the following ways: It can enrich decision-making by knowledge about clinical longterm performance of medical devices, and improve clinical outcomes and cost-effectiveness. Further, it can influence operational rules and guidance for orthopaedic HRMDs and contribute to improved quality of delivered of healthcare. To introduce stronger quality attributes the following aspects may be considered: (i) introducing quality benchmarks for orthopaedic procedures (e.g. survival rate requirements) and establishing survival rate expectations for new listed technologies; and (ii) Introducing HTA at the level of hospitals or purchasing groups that allow to integrate a risk assessment of orthopaedic HRMDs into decision-making. Further, we found that in the United Kingdom the National Institute for Health and Care Excellence defines recommendations including benchmarks, e.g., for the quality of hip prostheses, as "the new joint should work well in at least 95% of hip replacements over 10 years, instead of the current 90%" [57]. These recommendations contribute to the maximization of clinical outcomes and cost-effectiveness and can be reflected in risk assessments for orthopaedic HRMDs [55, 56]. Understanding the role played by decision makers concerning the absence of high-quality data is an important insight into procurement activities such as purchase and supply [150, 151].

We found that enhancing competencies of procurement agents can improve outputs and outcomes of the management phase in the following ways: It can influence operational rules and guidance for orthopaedic HRMDs and contribute to improved healthcare delivery. To enhance competencies of procurement agents the following aspects may be considered: (i) Updating requirements for core competencies needed for procurement agents, and (ii) integrating procurement agents into evaluation tasks of outcomes of applied purchasing strategies such as *Integral Services*. Further, in other countries the orthopaedic specialist still has high decision-making autonomy, which alleviates some responsibility from the procurement agent. Thus we had difficulties to find examples emphasizing the aspect of enhancing competencies of procurement agents.

This study highlights important findings in a national context. However, some of the problems that we have discussed in this study might emerge in a similar way in other health systems as well. For instance, the Swiss healthcare system is characterized by a decentralized structure and the autonomy of the cantons is relatively high. However, the healthcare legislative allows for initiatives and programmes that benefit the whole sector; the fragmentation of responsibilities regarding the MDLC areas is relatively low. For instance, Switzerland did face similar challenges relating to post-market surveillance and the level of clinical long-term data available for orthopaedic medical devices. They have introduced a national arthroplasty registry, which is overseen by the National Association for Quality in healthcare facilities. This was only possible by substantial commitment of the different parties concerned by the registry such as policy makers at national and decentralized level, insurances, associations of orthopaedic surgeons, and the medical device industry associations. The Mexican healthcare system is characterized by various sub-systems of health service provision. The healthcare

legislative limits the authority of central MOH offices to establish initiatives or programmes regarding medical devices that could benefit the whole sector. For instance, the social security institutes apply their own regulations for the assessment and management of medical devices. We found that this fragmentation of responsibilities influences the ability of policy makers to carry forward promising ways to improve outputs and outcomes of the MDLC areas. However, the relation between the MOH and sub-systems is in a transition and some recent advances demonstrate that [32, 82, 152]. As next steps for the policy making process in Mexico we recommend to take into account that the integration of stakeholders such as the National Academy for Medicine, the associations of orthopaedic specialists, and the associations of the medical device industry might benefit the establishment of initiatives and programmes to improve the MDLC areas, and help to partially overcome the fragmentation of responsibilities.

Limitations of the study

For this study, we used non-random sampling, which does not necessarily guarantee the sample being representative for the population of person involved in the regulation, assessment, and management of medical devices in Mexico. However, this study includes 42 stakeholders working in the field of regulation, assessment, management or clinical practice. Thus it covers different groups of stakeholders in terms of expertise. We were not granted permission to include employees of the Mexican Institute of Social Security, which is the largest social security institution in Mexico, because of its research study approval policies. Further, the sampling is based on a maximum variation strategy and may constitute a selection bias. The interpretation of the findings that served to define possible ways forward to fostering the regulation, assessment, and management of orthopaedic medical devices is a subjective process.

7.6. Conclusion

This study provides a broad analysis of medical device functions within a health system and highlights in this specific context how improvements might be achieved. It addresses a broad range of interest groups represented by policy makers, health service providers, managers and administrators of healthcare facilities, and doctors with an interest in health technologies. In this paper we highlight important themes that influence outputs and outcomes of the regulation, assessment, and management and discuss strategies in fostering these areas. To date, the regulation, assessment, and management of medical devices are rarely analysed in a broad way, even though these functions importantly contribute to the successful implementation of health technology policies. The quality of delivered healthcare is influenced by the performance between and within these functions. In Mexico, little discussion has been raised on challenges of the regulation, assessment, and management of medical devices. Changes to current processes and practices can improve outputs and outcomes of these functions and positively influence the quality of delivered healthcare. Stakeholder involvement and commitment is essential to this.

To overcome the impact of the fragmentation in the Mexican health system, policy makers could orientate on what other countries with a similar complex health sector are doing to improve outputs and outcomes of the MDLC such as the United States, Germany, or Switzerland. An important advance is that the Ministry of Health is developing a new policy that targets to strengthen technovigilance across all sub-systems. This is a promising way forward in fostering the regulation and to fully engage all stakeholders. This study may contribute to show to policy makers additional ways forward in fostering the regulation, assessment, and management towards improved quality of delivered healthcare.

List of abbreviations

HRMD, High-risk medical device; HTA, Health Technology Assessment; MDLC, Medical Device Life-Cycle; SESA, Servicios Estatales de Salud (State-level healthcare systems); WHO, World Health Organization.

Ethics

The ethical committee of the Autonomous University of Mexico [82] approved this project (Date of approval: November 4th 2014, FMED/CI/SPLR/188/2014), and the Ethical committee from northwest and central Switzerland (Switzerland) exempted it from ethical review under Swiss law (June 24th 2014). All interviewees gave written informed consent before the interview.

Consent for publication

Not applicable.

Availability of data and materials

The data supporting our findings is contained within the manuscript and within Table 7.5. The original transcripts of all interviews will not be shared due to confidentiality reasons.

Conflicts of interest

The authors declare that they do not have conflicts of interest.

Funding source

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Authors' contributions

All authors were involved in the outline of the paper. ML has made substantial contributions to conception and design, acquisition of data, analysis and interpretation of data, and drafting the manuscript. AD, KW and LD have been

involved in revising the manuscript critically for important intellectual content and structure, and have given final approval of the version to be published.

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procedures, and to provide a proposal plan how to improve procurement outcomes.

8. Survival Rates, an opportunity to improve orthopaedics

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8.1. Introduction

Studies concerned with the epidemiology of hip and knee joint replacements show that the demand for primary joint replacements and revision surgery is growing [24, 25]. To control the financial impact of joint replacement, it is important to achieve good implant duration rates because the health expenditures of revision surgery are significantly higher than primary joint replacement [153]. Arthroplasty register data shows that the clinical performance of hip and knee implants in the long-term demonstrate a strong variation [26]. Using poorly performing implants increases the revision risk. Yet, little is known about health policies encompassing strategies to decrease the use of poorly performing hip and knee implants. The objective of this study is to analyse the contribution of duration rate benchmarks as recommendations for decision-making and to discuss the health economic contribution of introducing duration rate benchmarks in Mexico.

8.2. Issues related to orthopaedic high-risk medical devices

Medical device regulation is challenged with the mismatch of the information validity needed for market approval and evidence from actual use of high-risk medical devices (HRMD) [49-51, 18]. One reason for this is that pre-market regulation is mainly based on conformity assessments and does not include findings from clinical long-term outcome studies [51, 52]. HRMDs are implanted in the human body and are therefore recommended, subject to the highest level of pre-market and post-market regulation [22].

Policymakers from other countries are frequently concerned by effectively ensuring standards of clinical safety, performance and efficacy of HRMD [47, 48]. Countries use different strategies to ensure or monitor safety and performance of medical devices such as strengthening post-market regulation [54, 40]; monitoring clinical treatment outcomes by introducing arthroplasty registers [34]; assessing

HRMD risk through post-market due diligence programmes [55]; classifying implant quality [56] and establishing revision rate benchmarks to prevent the use of poorly performing implants [57]. These strategies are frequently integrated into regulators' work and help bridge the gap of evidence and uncertainty [58, 59].

Epidemiology of Joint Replacements and in the Context of Age

Joint replacements in Mexico will increase and life expectancy may be an important indicator for the development of joint replacement demand. In Mexico, life expectancy has improved over the past 15 years [29], the incidence of osteoarthritis increases rapidly in patients over 50 [30] and in obese population [31], which is a serious health burden in Mexico [32]. Patients who have already received a joint replacement are exposed to revision surgery by the increase in years since primary surgery took place.

Revision Surgeries in the Scope of Quality Concerns

The clinical long-term performance of HRMD is an important input parameter for decision-making, because it determines the future need of revision surgery. Many countries have access to high-quality data on joint replacements, which they use to evaluate medical outcomes [34, 26, 35]. Using poorly performing medical devices is one of the reasons for high revision rates. For instance, increased incidence of post-operative problems resulting from the use of metal-on-metal hips led to higher hip revision rates [36]. However, in Mexico medical device regulation does not include clinical long-term performance of HRMD in their quality agenda with exception of the federal techno-vigilance department and health technology assessments, the findings of which are used to include technologies on the standard list for eligible health technologies. Between 2014 and 2015, we conducted studies in Mexico on the regulation, assessment and management of orthopaedic HRMD [141, 142, 146]. These studies showed quality concerns related to post-market regulation and

procurement of orthopaedic HRMD. In Mexico, several governmental offices as well as a number of non-governmental stakeholders are involved in the regulation, assessment and management of medical devices. Nevertheless, reviewing articles 83, 179 and 180 of the Medical Device Regulation of Mexico shows that there are no specific regulations for HRMD differentiating them from lower risk medical devices. Further, before 2016, HRMDs were included together with other medical devices in a general standard list (Standard List for Medical Care Products).

8.3. Policy implications

Health Economic Analysis

In health systems, decision-making takes place at different levels of healthcare delivery to allocate limited resources optimally [154]. Health economic analysis significantly contributes to this and encompasses important perspectives to attribute cost and benefit to specific healthcare provisions. Economic costs for joint replacements are high [155] and are differentiated into direct costs (hospital admissions, medical examinations, drug therapy), indirect costs (losses in productivity resulting from absence from work) and intangible costs [154]. The direct costs associated with joint replacements are high and driven by the cost of surgery, hospitalization and rehabilitation. Different methods are available to conduct health economic evaluations based on specific health economic principles that inform policy decisions, encompassing the efficiency and effectiveness of medical treatments [156].

At the policy level, health economic analysis is increasingly taken into consideration. For instance, HTA are a form of policy research that seeks to inform policy makers about the clinical and economic value of health technologies such as medical devices and includes findings derived from results of health economic analysis [157, 37]. Further, in orthopaedics health economic analysis increasingly

receives more attention due to its financial impact [158]. It is an essential element in decision-making and HTAs at purchasing decision-level are increasingly discussed [139, 140, 138, 137].

Duration Rate Benchmarks

A promising strategy to ensure quality is to implement guidance for duration rate benchmarks [153]. For instance, these are used in the UK and they are important in the regulation of HRMD, used to improve outcomes. The National Institute for Health and Care Excellence [57] defines recommendations including benchmarks for the quality of hip prostheses for example, as “the new joint should work well in at least 95 percent of hip replacements over 10 years, instead of the current 90 percent” [57]. This is an important contribution to decision-making processes because it suggests that decision makers should thoroughly review all available evidence.

In Mexico, no data is available on national implant duration rates. However, policymakers in Mexico could introduce such benchmarks and request decision-makers consult duration rate data from countries with an arthroplasty register or consult the findings of risk assessment programmes as they are used in the Netherlands or the UK [56, 55].

8.4. Conclusion

The use of survival rate benchmarks may have a positive impact on revision rates and their financial burden. Introducing these duration rate benchmarks may improve the eligibility of medical devices, strengthen quality assurance and enhance organisational governance. The Mexican health system lacks high-quality data for orthopaedic surgeries. However, average duration rates from different arthroplasty registries could be used as reference. Economic analysis in orthopaedics provides a powerful tool for the evaluation of health-care technologies and treatment strategies [159].

More research analysing the potential financial impact of using duration rate benchmarks may provide important findings. In the case of Mexico, even though no high-quality data is available, sufficient information of implants purchased in the past is publically available. It is stored at the electronic contracting system *Compranet* of Mexico. To apply economic analysis, the data from Compranet and average duration rates from different arthroplasty registries could be used.

9. Strategies to improve the Medical Device Life-Cycle in Mexico

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9.1. Abstract

Objective: To analyze interests, positions, and power of stakeholders to three alternative strategies to improve processes and practices regarding the regulation, assessment, and management of orthopaedic medical devices in Mexico.

Method: The study was based on document analysis and 17 structured interviews with multiple actors within the Mexican health system to inform a stakeholder analysis aiming at assessing the political feasibility of these strategies.

Results: The majority of respondents had a positive position towards the discussed strategies. Major barriers are: required increase in financial and human resources, and organisational culture towards reform. Governmental bodies concerned with quality and cost-effectiveness of health services were the actors with highest potential to influence the adoption and implementation of the strategies.

Conclusion: Discussed strategies are political feasible; these entail changes directed to improve outputs and outcomes of medical device life-cycle and positively influence the quality of health care and the health system's performance.

9.2. Background

Medical devices, together with drugs and other health technologies, comprise one of the six components considered as essential for good health system performance [16]. Accordingly, the regulation, assessment, and management of medical devices receive increasing attention by policy makers and health system experts involved in efforts to attain universal coverage of safe, equitable and high-quality health services [54, 41, 18, 160]. At the centre of the discussion is the improvement of outputs and outcomes of the Medical Device Life-Cycle (MDLC) [37]. A cohesive medical devices policy, well planned, supported and coordinated among all areas represented by the MDLC stakeholders is necessary [37] to meet the population needs and to ensure the quality of health care.

In a series of previous studies we analysed critical aspects between and within key MDLC functions and discussed ideas about desired changes to overcome identified challenges [141, 142, 146, 161] (Table 9.1).

Table 9.1. Challenges between and within MDLC areas and possible strategies

MDLC Areas	Description	Outputs	Outcomes	Challenges identified in Mexico	Strategies
Regulation	Safety and efficacy are in the focus of this phase aiming population safety. Key elements are performing testing and safety assessment prior to market approval and post-market reporting using criteria of safety and quality standards as part of technovigilance.	Mandatory compliance	Assuring minimal standards of quality	Technovigilance is not sufficiently applied by the multiple actors; lack of data availability; data quality across sub-systems not balanced	**'Strengthening Technovigilance'**:(i) including technovigilance tasks in the requirement catalogue of hospital certifications, (ii) fostering inter-institutional technovigilance guidelines, and (iii) implementing a technovigilance code of conduct (for hospital providers, health-care workers and suppliers).
Assessment	Meeting the population health needs. Key elements are systematic analysis and critical review using epidemiology and evidence data.	Recommendations on highly complex technologies	Responsiveness and maximization of clinical outcomes and cost-effectiveness	Standard list includes obsolete descriptions and technologies; system lacks to consider dynamic clinical long-term data such as survival rates; no initiatives aim at advancing quality of information regarding orthopaedic medical devices; Health Technology Assessments at purchasing level missing or characterised by sub-standard methodology	**'Amplifying quality attributes for assessments by clinical long-term aspects'**: (i) introducing quality benchmarks for orthopaedic procedures (e.g. survival rate requirements), and (ii) introducing technology guidance
Management	Health service providers are in the focus of this phase. Key element is the operational management of technology life-cycle using needs analysis	Operational rules and guidance for all medical devices	Improved health delivery; sustainable availability of high-quality and safe devices	Lacking quality guidelines regarding implant survival; problems that end-users experience during clinical practice are not well responded by the system and not reflected by changes in organizational	**'Introducing orthopaedic specific purchasing strategy'**: (i) introducing HTA at the level of hospitals or purchasing groups that allow to integrate a risk assessment of OMDs into decision-making, (ii) enhancing core

	and reliable device availability for clinical use.			practice; fluctuation of workforce and insufficient skills of procurement agents regarding complex clinical needs	competencies of procurement agents, and (iii) evaluating outcomes of applied purchasing strategies such as *Integral Services*.

Source: MDLC adapted from WHO [19, 46] Challenges and strategies adapted from [previous studies]

The findings highlighted that the overall MDLC system in Mexico is not coherently outlined and set-up across the regulatory, the assessment, and the management domains of orthopaedic medical devices (OMDs), and that this results in a situation that the quality of services delivered to patients is sub-optimal. This finding resonates with concerns raised by other authors regarding the regulation, assessment, and management of health services in Mexico at different levels of health care delivery [78, 72, 38, 32, 11].

In this study, we use a stakeholder analysis [81, 162-164] to analyse interests, positions, and power of stakeholders involved in the MDLC to three alternative strategies (see table 1) to improve processes and practices of the MDLC in Mexico.

The Mexican health system is composed by a complex structure that includes various sub-systems in charge of health service regulation, financing and provision. Most important providers are the public social security institutes and the state-level health care services (SESA), which function along a large number of private health care providers [32, 70]. The Ministry of Health (MOH) and its departments enact regulations and recommendations at the federal level for the public and private sector, but the sub-systems (such as social security institutes) comply with these in different ways due to their specific legal regulations and embedment [72, 73]. The health system is characterized by a distribution of roles and responsibilities across a substantial number of actors resulting in a fragmentation of responsibilities.

This fragmentation of roles and responsibilities is well illustrated with regard to medical devices: the General Health Council (CSG) (responsible for overseeing the Inter-institutional Commission of the Standard List for Health Supplies), the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), and the National Centre for Health Technology Excellence (CENETEC) [165]. Notwithstanding their important achievements, it has been stressed that the functioning of these agencies

has room for improvement; specially, with regard with their linkage with guidelines for the quality of care and with assuring value for money across all sub-systems [32]. The Mexican Congress is discussing the creation of the *Federal Commission for the Regulation and Surveillance of Health Care Services and Facilities* [166], which could generate momentum for the uptake of a broad spectrum of aspects concerning quality in health care and this may support outcomes of the MDLC areas; therefore, the stakeholder analysis presented here comes in a timely manner.

9.3. Methods

Demarcating the analysis

This study encompasses three strategies regarding the regulation, assessment, and management of orthopaedic medical devices as displayed in table 9.1. We used a national level of analysis collecting data from the multiple stakeholders directly or indirectly related to these strategies.

Identifying stakeholders

For this study, we developed a list of most relevant stakeholders regarding medical device regulation, assessment, and management (Table 9.2).

Table 9.2. General list of stakeholders

Level	Stakeholders	Main responsibility	Relative importance		
			Regultion	Assessment	Management (Purchasing)
Macro	• Sub-secretariat for Health System Integration and Development, **SIDSS**	• Government agency whose mission is to propose to the MoH national policies that improve the quality of social health services; issues the Mexican Official Norms (NOM)	++	+++	++(+)
	• Departments of Sub-secretariat for Health System Integration and Development	• General directorate of health planning and development, **DGPD**: Governmental organization and unit under the authority of the SIDSS whose mission is to steer the strengthening of health services among policy makers, and giving guidance to improve health services sustainable and cultural based on populations' needs. • General directorate of quality and education, **DGCE**: Governmental organization and unit under the authority of the SIDSS whose mission is to ensure that the quality and safety of health services, including human resources of the health sector and the regulatory environment of social health supplies is aligned with national policies.	++	+++	++(+)
	• General Council of Health, **CSG**	• Council whose mission it is to strengthen the governance and the articulation of the National System of Health. Founded: 1917 • Publishes the standard list of Health Supplies • Holds the Inter-institutional Commission of the standard list for Health Supplies whose mission is to manage the approved technologies in the standard list for Health Supplies • Auditing of hospitals with regards to quality standards (certification process)	++	++(+)	+
	• Federal Commission for the Protection against Sanitary Risks, **COFEPRIS**	• Decentralized regulatory organ of the MoH whose mission is to protect the population against health risks, including those derived from the introduction of new medical drugs, medical devices and other health inputs. Founded: 2002 • Sanitary Authorization Commission whose mission is the market	+++	++	+

		approval of medical products and technologies. • Technovigilance department whose mission is to implement and realize post-market surveillance. • Support function of “Sanitary Authorization Commission” whose mission is to provide technovigilance reports for the renovation of market approval.			
	• National Centre for Health Technology Excellence, **CENETEC**	• Governmental organization and unit under the scope of the SIDSS whose mission is to contribute to the development and governance of the National Health System in Mexico based on: Health Technology Assessments, Supervision of medical equipment, Telemedicine, Clinical guidelines. Founded: 2004 • WHO collaborating centre.	++	++(+)	++(+)
	• National Academy of Medicine, **ANM**	• Professional association of doctors that promotes scientific corporation, organises congresses and continuous professional education; consultant organization of the Federal Government of Mexico that proposes and discuss among its affiliates solutions to the main health problems of the Mexican society.	+	+(+)	+
	• International organization / health system expert	• e.g. Pan American Health Organization, **PAHO**	+(+)	+(+)	+
	• National Institute of Public Health, **INSP**	• Governmental academic institute that conducts research and teaching on public health.	+	+	-
	• National Commission for Medical Arbitration, **CONAMED**	• Contribute to guarantee the right of health protection and to improve the quality of health providers in terms of intervening in case of patient/health provider conflicts.	+	-	-
Meso	• Sub-systems: Centralized and decentralized health services	• Functionary with national responsibilities within the sub-system; director of healthcare facility; procurement agent • Functionary with local responsibility: Head of orthopaedic department	+++	++(+)	+++
Micro	• Orthopaedic community	• Association of orthopaedic specialists such as SMO, AMECRA, AMOT, SMCC, SMOP • orthopaedic specialists	+(+)	-	++(+)
Supplier	• Medical device community	• Medical device industry association such as ASEMED or AMID • Medical device supplier	+	+	+

+++ strong relation ++ moderate relation + low relation - no relation

We classified stakeholders into those belonging to the (i) macro level (normative and policy mechanism), meso level (service provision), micro level (specialists and orthopaedic associations), and supplier level (medical device suppliers and medical device industry associations). Many of the stakeholders relevant to this study belong to the macro level in charge of overall regulation and steering of the Mexican health system. We identified potential participants 'list of stakeholders' by using four data sources: (i) the government website *Portal de Obligaciones de Transparencia,* which lists all government units or institutes and their departments and facilitates the access to government information; (ii) listings of orthopaedic specialists; and (iii) stakeholder information of our previous study as additional data source.

Data collection

We contacted prospective participants between November 2016 and January 2017 by email and presented our study rationale and research. We used a maximum variation sampling to recruit stakeholders to achieve a balanced variety of stakeholders and diversity of data (supplementary file 9.1).

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Supplementary File 9.1. Questionnaire

Questionnaire

During this interview we will ask you to share with us your opinion about possible ways forward in fostering the regulation, assessment, and management of high-risk medical devices. You may not feel comfortable to discuss each of the possible ways forward and we kindly ask you to choose those that you feel most comfortable with. If you do not feel comfortable to answer any of the following questions please do not hesitate to tell the interviewer.

Questionnaire for possible way forward # ____

When you choose to answer not on you or your organization bur ***on other organizations, departments, or persons*** please move directly to question Q9 and don't answer Q1 to Q8

Q1. What are the potential benefits to you and your organization of this possible opportunity for improvement? Please provide short examples or key words

Potential benefit #1	Potential benefit #2	Potential benefit #3

Q2. What are the potential disadvantages to you and your organization concerning this possible opportunity for improvement? Please provide short examples or key words

Potential disadvantage #1	Potential disadvantage #2	Potential disadvantage #3

Q3. Which of these categories describe best your opinion on this possible opportunity for improvement?

Support	Moderate support	Neutral	Moderate oppose	Oppose
□	□	□	□	□

When you answered ***"support" or "moderate support" or "neutral"*** proceed with question Q4 to Q6 and skip Q7 to Q9

When you answered ***"oppose" or "moderate oppose"*** proceed with question Q7 and skip Q4 to Q6

Q4. Which aspect(s) of the described opportunity for improvement do you support?

Aspect #1	Aspect #2	Aspect #3

Q5. For those aspects of the opportunity for improvement that you support:

In what manner would you demonstrate this support?	
Would you take the initiative in supporting this opportunity for improvement or would you wait for others to do so?	
Do you have financial or human resources available to support this opportunity for improvement?	

Q6. Under what conditions would you choose NOT to support this opportunity for improvement?

Q7. Which aspect(s) of the described opportunity for improvement do you oppose?

Aspect #1	Aspect #2	Aspect #3

Q8. For those aspects that you oppose:

In what manner would you demonstrate this opposition?	

Would you take the initiative in opposing this opportunity for improvement or would you wait for others to do so?	
Do you have financial or human resources available to support this opportunity for improvement?	

Q9. Under what conditions would you choose NOT to oppose this opportunity for improvement?

Q10. What other organizations, department or persons do you think would support or oppose this opportunity for improvement? Please fill in the name and mark if they rather support or oppose

Organization #1:				
Support	Moderate support	Neutral	Moderate oppose	Oppose
□	□	□	□	□

Organization #2:				
Support	Moderate support	Neutral	Moderate oppose	Oppose
□	□	□	□	□

Organization #3:				
Support	Moderate support	Neutral	Moderate oppose	Oppose
□	□	□	□	□

Q11. Do these organizations have financial or human resources available to support this opportunity for improvement? Please fill in with YES or NO

Organization #1		Organization #2		Organization #3	
Yes □	No □	Yes □	No □	Yes □	No □

Q12. With which of these organizations do you or does your organization has an alliance? Please fill in with YES or NO

Organization #1		Organization #2		Organization #3	
Yes □	No □	Yes □	No □	Yes □	No □

If you have answere in Q10 ***"support" or "moderate support" or "neutral"*** answer Q13 and Q14. Otherwise this questionnaire stops here

Q13. If an organization was classified as "support" "moderate support" or "neutral" what are the potential benefits to these organizations of this possible opportunity for improvement? Please provide key words

Organization #1	Organization #2	Organization #3

Q14. If an organization was classified as "support" "moderate support" or "neutral" would this organization take the initiative to actively support this opportunity for improvement? Please fill in with YES or NO

Organization #1		Organization #2		Organization #3	
Yes □	No □	Yes □	No □	Yes □	No □

Opportunities for improvement chart

Related to regulation / safe use	Related to assessment / quality	Related to management / safe use
Opportunity 1: Strengthening technovigilance Potentially can improve the overall reporting competencies and data generation on incidents and other complications. • Including technovigilance tasks in the requirement catalogue of hospital certifications. • Introducing inter-institutional technovigilance guidelines. • Implementing a technovigilance code of conduct (for hospital providers, health-care workers and suppliers).	Opportunity 2: Introducing quality benchmarks Potentially can prevent the purchasing of sub-standard medical device brands • Evaluating orthopedic medical devices among else on their survival rate. • Defining and introducing benchmarks as „do-not-do-recommendations“ and thus as additional decision-making guidance to ensure quality.	Opportunity 4: Strengthening the delivery and service modality Potentially can improve and ensure the provision of standard quality • Evaluating the cost-benefit of INTEGRAL SERVICES. • Monitor quality of delivered services (of supplier) and its influence on clinical practice.
	Opportunity 3: Introducing technology guidance for decision-makers Potentially can improve the outcome of decision-making processes at the level of purchasing. • Applying a risk-assessment of orthopaedic medical devices based on a systematic technology guidance including long-term clinical performance data. • Introducing Health Technology Assessments at the level of purchasing decisions for tenders or local purchase to evaluate differences in clinical performance among different medical device brands.	Opportunity 5: Enhancing competencies for procurement agent Potentially can ensure that procurement agents acquire advanced competencies to improve their overall performance and their understanding of high-risk medical devices and doctors needs. • Re-defining core competencies for procurement agents. • Developing a capacity development plan for procurement agents.

Data collection was based on (i) 17 structured interviews to collect data from the interviewees on themselves but also their opinions on other stakeholders, and (ii) complemented by findings from our previous studies and detailed review of grey literature on the identified stakeholders. For the interviews we used a questionnaire (supplementary file 9.2) with mainly closed-ended using a 5-point Likert scale. The questionnaire was previously tested among three Mexican stakeholders. We used a file-naming system and anonymised interviewees by generating a list of archival numbers.

Supplementary File 9.2. Participants

Stakeholder group	**Participant** N (%)	**Male** N (%)
Group 1 (macro level)	10 (59)	9 (90)
MOH	2 (20)	1 (50)
COFEPRIS	1 (10)	1 (100)
CSG and CENETEC	2 (20)	2 (100)
Others	5 (50)	5 (100)
Group 2 (meso level)*	2 (12)	1 (50)
Group 3 (micro level)*	2 (12)	2 (100)
Group 4 (supplier)	3 (17)	2 (67)
Total	17 (100)	14 (82)

*representing public and private sector

Analysing stakeholder's interest, position, and power (Data analysis)

A structured data analysis approach [81] was followed and applied triangulation based on peer debriefing. First, we classified the stakeholders regarding their 'potential stake' to distinguish between stakeholders potentially important to carrying the discussed strategy forward, considered being moderately valuing with the

strategy, or not important to carrying the discussed strategy forward. Second, we characterized the stakeholders by using three characteristics: (i) ‘Interest’ to display the stakeholder’s opinion in the strategies based on advantages or disadvantages that these may bring to the stakeholder; (ii) ‘Position’ to present whether the stakeholder supports, opposes, or is neutral about the strategy; and (iii) ‘Power’ to differentiate between high to low influence regarding the realization of the strategy.

9.4. Results

Table 9.3 provides indications of the different stakeholders positions toward the three strategies: (i) Strengthening technovigilance, (ii) Amplifying quality attributes for assessments by clinical long-term aspects, and (iii) Introducing orthopaedic specific purchasing strategy. We identified the Department of Quality and Education of the Ministry of Health (DGCE), CSG, COFEPRIS, CENETEC as the main stakeholders to influence the adoption and implementation of the discussed strategies in terms of ‘power’. Stakeholders that were identified to have some potential to influence the strategies (but not being main stakeholders) were identified as social security institutions at the meso-level, healthcare providers at the micro-level, and medical devices suppliers.

Table 9.3. Stakeholder table

Stakeholders	Potential stake in strategy			Interest based on perceived advantages***			Position			Power		
	Tehno-vigilance	Assessment	Purchasing	Tehno-vigilance	Assessment	Purchasing	Tehno-vigilance	Assessment	Purchasing	Tehno-vigilance	Assessment	Purchasing
MOH, namely DGCE	**MS**	**HS**[1] **MS**[2]	**MS**[3] **HS**[4]	Vigilance of quality; patient safety; data availability; quality of health services	[1] relate decision-making to quality attributes; guide decisions; quality of health services [2] transparency on decisions; technology assessment at hospital level; expenditures; evidenced-based decisions	[3] Balanced quality of health services across sub-systems; expenditures; real cost-benefit [4] quality of health services; quality of procurement outcomes; governance of human resource skills	**S**	**S**[1] **SM**[2]	**S**[3,4]	**+++**	**++(+)**[1,2]	**++**[3]
CSG	**MS**	**MS**[1] **HS**[2]	**NS**[4]	Quality culture and of health services; broader safety spectrum	[1] in line with current quality efforts [2] Evidenced-based decisions; quality of health services	[4] quality of health services, efficiency and efficacy of healthcare facility	**SM**	**N**[1] **SM**[2]	**S**[4]	**+++**	**++**[1,2]	**+**
COFEPRIS	**HS**	**MS**[1]	**NS**[4]	Report quality; stakeholder commitment; quality of health services; prevention of sub-	[1] requirements for market-approval; engage device supplier to provide high quality; technology	[4] saftey of healthworker and patient	**S**	**S**[1]	**S**[4]	**+++**	**++(+)**[1]	**+(+)**

				standard products	evaluation							
CENETEC	**MS**	**HS**[1,2]	**MS**[4]	Data quality and availability; stakeholder commitment; enhancing knowledge	[1] Data bases; regulations for quality; safe use of products; quality culture [2] stewardship; technology assessment at hospital level	[4] cross-sharing of Cenetec expertise	**S**	**S**[1,2]	**S**[4]	**++**	**++(+)**[1,2]	**+(+)**
ANM	**NS**	**MS**	**NS**[3,4]	Quality of health services; patient safety; broader reasoning of incidents	[1] data availability; quality of decisions [2] technology assessment at hospital level; evidence-based decisions	[3] Real outcomes; recognition [4] recognition and representation of surgeon's clinical needs	**S**	**S**[1,2]	**S**[3] **SM**[4]	**+(+)**	**+(+)**[1,2]	**+**[3]
PAHO	**NS**	**NS**[2]	**NS**[4]	Best practice sharing towards other countries; balanced quality of health services across sub-systems	[2] Best practice sharing towards other countries	[4] Best practice sharing towards other countries; quality of procurement outcomes	**S**	**S**[2]	**S**[4]	**+(+)**	**+(+)**[2]	**+**
INSP	**NS**	**NS**[1]	**-**	Research quality; quality culture; data availability	[1] research culture; decision-making; knowledge	-	**N**	**S**[1]	**-**	**+(+)**	**+**[1]	**-**
CONAMED	**NS**	**-**	**-**	Quality of health services; broader reasoning of incidents and patient-doctor conflicts	-	-	**SM (N)**	**-**	**-**	**+**	**-**	**-**
Sub-systems: Centralized and	**MS**	**MS**[1]	**HS**[3,4]	Balanced quality of health services	[1] Quality of health services, patient	[3] Real cost-benefit; quality of health	**SM**	**SM**	**SM**[3]	**+++**	**+++**	**+++**[3]

decentralized health services				across sub-systems; data availability; reporting culture; prevention of sub-standard products	safety; expenditures	[4] Develop specialist procurement group; satisfying outcomes; updating profile requirements						
Orthopaedic community*	**MS**	**-**	**MS**[3,4]	Quality of health services; Balanced quality of health services across sub-systems	-	[3,4] Prevention of sub-standard outcomes; improvement of doctor service attention	**S**	**-**	**S**[3,4]	**+(+)**	**-**	**++**[3]
Medical device community**	**MS**	**NS**	**NS**[3,4]	Quality of data; knowledge; report quality	Systematic decision-making; improvement of purchasing outcomes; expenditures	[3,4] Real cost-benefit; quality of health services; transparency on outcomes	**S**	**SM**	**S**[3,4]	**+(+)**	**++**	**+(+)**[3]

+++ High ++ Moderate + Low
HS Important stakeholder for carrying the discussed strategy forward MS Being considered as stakeholder moderately supporting the strategy
NS Stakeholder not important for carrying the discussed strategy forward
S support SM support moderately N neutral OM oppose moderately O oppose
* Orthopaedic association and orthopaedic specialists
** Medical device industry association and medical device suppliers
*** Only few interviewees noted that the required increase in financial and human resources is a critical barrier
1 for strategy component 'quality benchmarks'
2 for strategy component 'technology guidance'
3 for strategy component 'Integral services'
4 for strategy component 'procurement agent's competencies'

Strengthening Technovigilance

The analysis identifies COFEPRIS as an important stakeholder (potential stake) for carrying technovigilance strengthening forward. Its 'interest' is relatively focused on the following advantages that this strategy would imply for their own organisation: improving report quality of e.g. incidents; achieving stakeholder support; improving quality of health services; preventing sub-standard products. Its 'position' was categorized as supporter of this strategy. The 'power' of COFEPRIS is being considered by different stakeholders as high, because technovigilance is one of its responsibilities.

> *"… improving the quality of reports and the culture of reporting. Reports are essential and often the commitment of the stakeholders is missing…" (employee of COFEPRIS)*

Other relevant stakeholders considered being moderately supporting the strategy but to be involved in one way are MOH, DGCE, CENETEC, sub-systems (different actors in charge of health service regulation, financing and provision), orthopaedic community and medical device community. Their 'interest' is relatively focused on 'access to data' such as data quality and availability; stakeholder support; enhancing knowledge. Their 'position' was categorized between supporter and moderate supporter, and the level of their potential influence ranged from moderate to low.

COFEPRIS is a critical organization within the Mexican health system and holds the overall responsibility for technovigilance. Its financial and human resources should be increased to pursue the objective to strengthen technovigilance based on improved reporting of healthcare facilities and professionals and based on processing and analysing the increased amount of received reports. The strategy 'strengthening technovigilance' is overall feasible and a broad group of stakeholders indicated high interest toward this strategy. Few stakeholders mentioned that the

requirement catalogue for hospital certification, which is not compulsory, should include as well technovigilance as a component. In Mexico, hospital certification is aligned to the Joint Commission requirements [109] and overseen by CSG.

Amplifying quality attributes for assessments by clinical long-term aspects

The analysis identifies DGCE, CSG, and CENETEC as important stakeholders for carrying forward quality attributes of medical device assessments. Their 'interest' is focused on the following advantages that this strategy would imply for their own organizations: relating decision-making to quality attributes of medical devices; guiding decisions on eligibility of medical devices; improving quality of health services; generating transparency on decisions; introducing technology assessment at hospital level; controlling expenditures; being in line with current quality efforts; improving data bases; creating regulations for determining quality of medical devices; assuring safe use of products; strengthening decisions about medical device eligibility. Their 'position' was categorized as supporter of this strategy. The 'power' of these three stakeholders was being considered as moderate, because clinical long-term aspects of medical devices as dynamic quality attribute haven't been in the focus of any of these stakeholders so far.

> *"It is essential because it represents measuring results… it will help to know prior to purchasing a medical device its quality…" (Director of a MOH department)*

Other relevant stakeholders considered being moderately supporting the strategy but to be involved in one way are COFEPRIS, National Academy of Health (ANM), sub-systems, and orthopaedic community (e.g. orthopaedic specialists and orthopaedic associations). Their 'interest' is focused on the following advantages that this strategy would imply for their own organisations: promoting transparency and evidence-based decisions. Their 'position' was categorized between supporter and moderate

supporter of stronger quality attributes of assessments, and the level of their potential influence low to high.

"This would help to fight less for the lowest price and more for the quality…" (Director of medical device supplier)

To date, not one MOH department alone is responsible for this type of quality strategy. The power and leadership of CENETEC's power and leadership should be increased to integrate stronger attributes such as implant survival rate into the assessment and decision-making for OMDs. Few stakeholders mentioned that such strategy requires an increase in human resources but that recent budget cuts may currently not allow allocation of required financial resources to pursue such strategy.

Introducing orthopaedic specific purchasing strategy

The analysis identifies MOH and sub-systems of healthcare as important stakeholders for carrying forward an orthopaedic specific purchasing strategy. The 'interest' of these two actors is focused on the following advantages that this strategy would imply for their own organisations: achieving similar level of quality of health services across sub-systems; improving the management of financial resources; achieving cost-benefit; improving quality of health services; improving quality of procurement outcomes; enhancing human resource skills; preventing problems during clinical practice; developing procurement specialists based on medical speciality for high-risk class medical devices; satisfying outcomes; updating profile requirements of procurement agents. Their 'position' was categorized as supporter of this strategy. The 'power' of MoH is being considered as moderate and that of social security institutes (sub-systems of healthcare) as high.

"… the current situation leads to costs to solve failures caused by inferior quality…" (Ex-director of orthopaedic services at social security institute)

Other relevant stakeholders considered being moderately supporting the strategy, but to be involved in one way are CENETEC and the orthopaedic community. Their 'interest' was focused on the following advantages that this strategy would imply: cross sharing expertise between involved stakeholders, and prevention of sub-standard outcomes. Their 'position' was categorized as supporter, and the level of their potential influence low to high.

> *"… the procurement agent mentality is still focused on prices" (Director of medical device supplier)*

Few stakeholders mentioned that the role played by DGCE should be strengthened to enhance the competencies of procurement agents and to realize subsequent effects of improved outcomes of purchasing strategies such as *Servicio Integral*.

9.5. Discussion

The discussed strategies to improve the MDLC were largely perceived to be within the competence of central government agencies, namely COFEPRIS, CSG, DGCE, and CENETEC. These are the different interest groups that have started looking deeper into needs that this study focuses on; however, in Mexico as in other countries the discussion about challenges or weaknesses regarding the MDLC areas develops slowly [32, 166, 167]. For instance, at the government level the MOH is developing a new policy that aims to strengthen technovigilance across all sub-systems of the health-system. One aspect of this policy is to integrate technovigilance into the requirement catalogue for hospital accreditation. Further, the participation of the private sector (industrial-commercial sector) in the policy-making increases and will contribute to enrich policy discussion by their interests. At the same time the participation of the public and professional associations in decision-making remains limited [141, 142, 146]. We found that ANM can act as visionary for

at least orthopaedic associations and therefore play an important role to change this situation in the future.

During this study we only identified significant differences regarding the power of the multiple actors to potentially influence policy (in favour). Central level government agencies were perceived as those with greater power to influence policies. In this sense, we found that the policy environment is in favour of developing such strategies and no one strategy seems to be preferred over the other. This leads to the impression that they are all politically feasible. However, organisational culture towards reform and leadership is a barrier. This came up in some of the interviews and was referred to the relation of national government offices (macro level) and social security institutions (meso level). For instance, the sub-systems tend to adapt the national standard list to their needs. Further, any strategy that intends to change processes or practices of the MDLC functions requires to be included into the political agenda at federal level.

For all three discussed strategies, only few interviewees identified disadvantages thereby however the costs of introducing and operating each strategy were mentioned. The discussed strategies were a matter of multiple actors and emphasized the role played by the social security institutions regarding the successful realization of any changes to processes and practices in order to improve outputs and outcomes of the MDLC areas. Overall, we found that improving the MDLC may positively influence the health system performance regarding two central aspects. First, it may increase quality of care e.g. at the level of health care professionals because their clinical practice will be less affected by sub-standard medical devices and patients will benefit from orthopaedic medical devices that create less burden of revision. Second, it may support the health system's efficiency by post-market surveillance activities that effectively identify medical devices of sub-

standard clinical long-term performance, and improve decision-making through improved technology assessments.

OECD recommended specifically in its report from 2016 to improve technology assessment and regulation of medical devices, and strengthening the role of CENETEC [32]. We found that good progress has been made in the authorisation and safety of new technologies through COFEPRIS. Still, however, not enough is known about the quality and outcomes achieved by the multiple social security institutes. A national and comprehensive approach to collect data of the quality of care remains lacking. At the level of medical device assessment, CENETEC has the potential to be strengthened in its role and take on a more extensive responsibilities in e.g. producing Health Technology Assessments (HTAs). Analyses should not just be applied to new treatments but to existing ones as well, to encourage value for money across the system. Rather than just focussing on services for the uninsured provided by the MOH health services, CENETEC's remit should expand to cover the social security institutes as well. The expansion of CENETEC's role will require increased investment, and modification of its legal status may also be necessary. Currently, it operates as a subsidiary unit within the MOH and is limited in its ability to contract with external bodies. Re-establishing CENETEC as an independent and decentralized office would solve this issue [32].

Limitations

This study has several limitations. We used the stakeholder analysis as foresight, which deals with uncertainty but helps as well to probe system boundaries. Additionally, the way in which we conducted and interpreted the analysis is not value free and potentially may have resulted in some bias. The stakeholder analysis did not reveal any group that presented itself as opposed to any of the three strategies. In-depth analysis of each strategy is necessary to assess direct or indirect

improvements of cost-benefit aspects of health technologies, patient safety, workforce, quality of health care and performance of organisational processes that aim at discussing them in greater detail in the context of financial and human resources of the identified 'main stakeholders' for each strategy.

9.6. Conclusion

In Mexico, discussion and proposals by interest groups are slowly gaining momentum on how to improve the regulation, assessment, and management of medical devices. Changes to current processes and practices can improve outputs and outcomes of these functions and positively influence the quality of health care and the health system's effectiveness. Stakeholder involvement and commitment of different interest groups are essential to this in order to establish consensus and to move forward. However, needs for improvement are rarely analysed in a broad way, even though these functions contribute importantly to the successful implementation of health technology policies. The coordination of changes among stakeholders is complex in Mexico due to the longstanding distribution of roles and responsibilities across multiple organisations. To build on the three areas that were subject to this stakeholder analysis, we propose to initiate working groups at national level that aim at refining the discussed strategies. This study may help enhance the policy environment and the communication between different interest groups as identified in this analysis. At the level of OMDs advances in policies and organisational practice are necessary.

List of abbreviations

ANM, Academia Nacional de Medicina (National Academy of Health); CENETEC, Centro Nacional de Excelencia Tecnológica en Salud (National Centre for Health Technology Excellence); COFEPRIS, Comisión Federal para la Protección contra Riesgos Sanitarios (The Federal Commission for the Protection against Sanitary

Risks); CONAMED, Comisión Nacional de Arbitraje Medico (National commission for medical arbitration); CSG, Consejo de Salubridad General (General Council of Health); DGEC, Dirección General de Calidad y Educación (General Directorate of Quality and Education); e.g., Exempli gratia; etc., Et cetera; HTAs, Health Technology Assessments; INSP, Instituto Nacional de Salud Publica (National Public Health Institute); MDLC, Medical Device Life-Cycle; MOH, Ministry of Health; OMD, orthopaedic medical devices; PAHO, Pan American Health Organization; SESA, Servicios Estatales de Salud (State Health Services)

Ethics

The ethical committee of the National Autonomous University of Mexico [82] approved this project (Date of approval: November 4, 2014, FMED/CI/SPLR/188/2014). No formal ethical approval was needed from the ethical committee from Northwest and Central Switzerland (Switzerland), which exempted it from ethical review under Swiss law (June 24, 2014). All interviewees provided informed consent before the interview.

Consent for publication

Not applicable.

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Authors' contributions

All authors were involved in the outline of the paper. ML has made substantial contributions to conception and design, acquisition of data, analysis and interpretation of data, and drafting the manuscript. AD, KW and LD have been

involved in revising the manuscript critically for important intellectual content and structure, and have given final approval of the version to be published.

10. Discussion

This Ph.D. extends on the current knowledge on critical aspects between and within key MDLC functions. The research further discusses the potential way forward in Mexico so to overcome identified challenges. The starting point of this research was the MDLC function 'management' of orthopaedic medical devices. We identified a broad range of themes regarding problems within or between the MDLC areas, discussed their meaning in relation to the goal of the MDLC, and explained its relevance with reference to the quality of health care. We generated findings that help to enrich the knowledge about critical aspects, which result in barriers of reforms within the Mexican health system. In the literature these barriers are often described as (i) limited financial resources, (ii) efficiency and quality of the health system, and (iii) fragmentation of the health system [71, 165]. These barriers and the fragmentation of the health system are not unique for Mexico; other countries such as Argentina, Ecuador, El Salvador, or Nicaragua are confronted with a similar situation [168, 169].

10.1. Methodology with reference to the validity of findings

The methodology adopted to frame this study was based on a multi-methodological approach mainly using qualitative research methods. We chose this approach because a purely quantitative approach would not have given us enough data and there were so few prospective participants representing the macro level and low-to-moderate number of prospective participants representing the meso level. We found that this contributed importantly to the validity of the applied research methods. For this research we collected data from a variety of stakeholders (166 interview participants and 187 survey participants) during five sub-studies between June 2014 and January 2017.

To ensure internal validity of the findings we used several strategies. First, during interviews we probed to uncover attitudes and open up new dimensions of a problem and urge the stakeholder to describe their personal stake in the process. Secondly, we used a maximum variation sampling technique to recruit stakeholders and to achieve a balanced variety of stakeholders and diversity of data. Third, for in-depth and semi-structured interviews, we used different interview guides to meet the different profiles of stakeholders that we pre-tested with few stakeholders from Mexico. Finally, we used inductive and deductive methods to generate findings and to support validity. Taking these strategies into consideration, we found that the internal validity of the findings is relatively high.

With regards to external validity, this Ph.D. research may have few limitations even though the conclusions we were able to draw from the findings did not change during the different sub-studies but became more precise. We chose an overall qualitative research approach because a quantitative approach would not have given us enough data to explain current problems and opportunities of the MDLC in Mexico. Even though we intended on ensuring saturation by a maximum variation sampling strategy external validity may be compromised because we mainly collected data from stakeholders representing the micro and meso levels that were located in Mexico City. Attitudes of stakeholders from other states may differ from those of the State of Mexico and the Federal District. Therefore, the interpretation of the findings of the sub-studies using a qualitative method is a subjective process. Finally, we did not compare the findings from the single sub-studies with other countries similar as Mexico. A comparison may support the validity of the findings and proposed strategies for other countries with similar problems.

10.2. Main findings

Main findings with reference to 'regulation'

Our research showed that in Mexico technovigilance receives relatively high attention by policy makers but that stakeholders of the MDLC underestimate its contribution regarding improving MDLC outcomes. With reference to normative and organisational aspects technovigilance is well established. This is an important aspect of strengthening systems for medical device regulation and not all Latin American countries have equally advanced with reference to their pre- and post-market regulation [170, 171]. Our findings show that there is a need to strengthen technovigilance regarding its implementation across the various sub-systems (at the meso and micro levels) with reference to post-market surveillance such as quality and quantity of reports received from the meso and micro levels. This need may be similar to other countries with a fragmented health system such as Argentina, Ecuador, El Salvador, or Nicaragua even though literature lacks data on this [168, 169]. Currently, the number of reports from health care providers regarding adverse events or incidents or any other form of observations at the clinical practice level is relatively low in Mexico. But also high-income countries are concerned with regulatory processes and clinical evidence produced [172].

The understanding of potential health risks associated with the use of sub-standard HRMDs is still insufficiently anchored in the mind-set of the multiple stakeholders. In Mexico stakeholders believe that the market approval process contributes sufficiently to the prevention of sub-standard quality of HRMDs. In comparison to high-income countries with an arthroplasty registry for example, we found that government agencies concerned with technovigilance have identified the need to strengthen post-market surveillance activities to better monitor clinical long-term performance of HRMDs aiming to take necessary actions [35, 34, 26, 153, 43, 24, 58, 173]. Further, in Mexico, post-market surveillance is not providing significant value to decision-making and this may be similar in other LMIC. But post-market

surveillance activities in high-income countries are providing significant value to decision-making. Technovigilance outputs are already linked to programmes monitoring the performance of HRMDs such as in the United Kingdom or the Netherlands [55, 56].

Main findings with reference to 'assessment'

Our research showed that in Mexico, HTA still adds too little value to the effectiveness of decisions. However, HTA-based evidence can help to optimize decision-making processes [174]. To date, HTA at the level of hospitals has not received a lot of attention yet even though it may provide important benefits to the quality of health care and to the health system's effectiveness. Further, the adoption of medical devices is less stringent than for drugs and assessments for medical device technologies don't specify the brand or model. The introduction of a specific standard list for orthopaedic and osteosynthesis medical devices in 2016 is an important advance regarding risk class differentiation. But there is a growing need for rational priority setting using HTA and other policy tools to improve medical device assessment. Current applied HTA methodology at the national level and the absence of HTA at the hospital level are critical barriers for improving outcomes of the MDLC. As there was some controversy about the contribution provided by current HTA methodology to decision-making during the first sub-study, we decided to also support the above described finding with a study focusing on the management of data, information, and knowledge within the MDLC at the macro, meso and micro level of health care delivery. We found that data, information, and knowledge are not managed appropriately across the sub-systems and on the national level, thus impacting all MDLC functions. This study helped us to specify the finding with reference to the knowledge culture of stakeholders related to the MDLC functions

and to describe the role played by HTA at the national and hospital level for the Mexican health system.

For other LMIC that commit to universal health coverage, a study showed that there is a growing need for rational priority setting using HTA and other policy tools [175-179]. Countries increasingly identify the need to institutionalize and strengthen health technology assessment. For example, Colombia *„has been advancing with firm steps, articulating legal support, with the infrastructure required in responding to challenges that arise from efficient use of health technology“*, Brazil is focussing on strengthening the link between HTA and evidence-based policy, and Argentina, Chile and Ecuador are still in the early phase of HTA implementation [180-185]. In high-income countries, HTA at hospital level is already advanced and recommended or applied to add value to decision-making [186-189]. Policy makers and stakeholders of ‘assessment’ are paying more attention to improving HTA [190, 91, 191].

Main findings with reference to ‘management’

Our research showed that stakeholders of the MDLC in Mexico underestimate the role played by procurement regarding purchasing of orthopaedic HRMDs. ‘Procurement’ receives little attention even though the actors involved in procurement or impacted by procurement decisions observe relevant challenges and problems. Decisions are either based on simple decision criteria or impacted by lowest-price offers. Further, stakeholder involvement is low and decision-making is insufficiently guided by HRMD relevant aspects such as the consideration of clinical long-term performance of an implant. As there was some controversy about the involvement of orthopaedic specialists during the first two sub-studies, we decided as to support this finding with a survey among orthopaedic specialists. We found that orthopaedic specialists are often involved in a simple decision-making setup. This set-up means

orthopaedic specialists are not able to add significant value to purchasing decisions such as knowledge from clinical practice (intra-operative observations, post-operative observations, handling, etc.). In relation to 'procurement', we took notice of reports that came to similar conclusions: PricewaterhouseCoopers report from 2015 [152] and OECD report from 2016 [32].

For LMIC we did not identify literature, which describes the involvement of stakeholders in decision-making. However, aspects of purchasing and the role played by cost-related decisions have been discussed previously [192]. In high-income countries the input of orthopaedic specialists is providing significant value to decision-making but depending on the procurement scheme and policies, this value is impacted by final cost-related or cost-containment decisions of procurement [88, 193, 194]. The management of medical devices is still not sufficiently studied and only few research provide important insights [195, 196].

10.3. Policy relevance of findings

Since we started interviewing stakeholders about the MDLC of orthopaedic medical devices, we have noticed increased interest by different stakeholders regarding the themes that our research covered. We expect that this Ph.D. will encourage the policy discussion about the MDLC of orthopaedic medical devices and other HRMDs in Mexico but also encourage health system experts from other middle-income countries to draw more attention to their MDLC. To date, there is a dearth of literature about concerns regarding the MDLC and only few studies provide similar insights into the MDLC [197]: *"Health care systems have considered the introduction of health technologies a linear process in which different stakeholders (innovators, manufacturers, regulators, health technology assessors, reimbursement bodies, health care providers, health care professionals, patients, and citizens) did interact in*

each of the steps of the process, but were not involved in a continuous dialogue and knowledge exchange.“

This research may contribute to advancements because it represents a broad overview of important aspects of the MDLC of medical devices in Mexico and discusses ways of fostering the MDLC. First, this Ph.D. provides important insights into a selection of themes at the level of policy environment, which could encourage policy makers to move forward with the improvement of outputs and outcomes of the MDLC areas. Second, it indicates how the little integration between the sub-systems and the MOH can lead to inefficiencies at the level of service provision and it shows possible ways towards improvement. Third, it provides important insights into improvement needs for the MDLC functions such as ‘regulation’, ‘assessment’, and ‘management’. Fourth, it shows that the integration of multiple stakeholder positions about outputs and outcomes of the MDLC for HRMDs is necessary to identify and analyse current needs and problems. Finally, it shows that stakeholders involved in the MDLC have a positive attitude towards changes to current processes and practices, but that aspects such as an increase in financial and human resources may be critical barriers.

Some of the findings of this research may be relevant for middle-income countries that do have a national policy on health technologies and have established a regulatory agency, a national health technology assessment unit, and a national health technology management unit. According to WHO, Argentina, Brazil, and Ecuador, for example, comply with a national policy on health technologies besides other middle-income countries [38]. Thus, the identification of possible steps forward in fostering the MDLC areas in Mexico provides a helpful and sustainable orientation for similar countries in terms of: (i) reflecting on their own health system performance from a new point of view, and (ii) critically analysing the proposed strategies of this

Ph.D. thesis for the Mexican health system regarding its possible application in the context of the health system of other countries. It may contribute to enhancing the policy environment and deliberation between different interest groups that are potentially affected by similar problems as discussed in this research.

The MOH, its departments and affiliated institutions at the macro level govern and regulate important parts of the MDLC. In Mexico, the fragmentation of responsibilities of the MDLC areas, which has been conditioned by the health system structure, has recently received more attention from different stakeholders and is subject to the current policy discussion. The suggested changes of current processes and practices of the regulation, assessment, and management can improve outputs and outcomes of these functions and positively influence the quality of health care and health system's effectiveness. Much of the generated evidence that this research produced is based on interviews with stakeholders representing important areas of the Mexican health system. Many of these stakeholders have the power to influence processes and practices of the MDLC. They have also been contributing to the definition or specifying ideas of strategies with reference to improve MDLC functions. We found that due to this and based on continuous feedback that we received after publishing our findings that this research may have high policy relevance regarding influencing current and future policy discussion in Mexico. However, policy relevance for other countries may be limited in terms of benchmarking and not contribute directly to accelerate any policy discussion.

During the various sub-studies we found that the management of data and information is a critical aspect of the performance of the MDLC and forms already part of the policy discussion in Mexico. Our research provided insights into problems related to data and information, and how this might have an influence on outputs and outcomes of the MDLC. Managing data and information adequately is not a problem

unique for Mexico or other LMIC. Overall, information technology in health systems is in a transition [198, 199]. The focus on knowledge-related factors (second sub-study) allowed us to better explain the relation of MDLC functions such as 'management' and clinical procedures for orthopaedic medical devices in Mexico. We showed that knowledge is an important resource, identified factors along the dimensions of knowledge management and healthcare delivery levels that create barriers, and discussed them in the context of administrative processes. Stakeholders in Mexico recognise the value of knowledge as important resource, but they are not able to manage it effectively and efficiently. This study demonstrated that many themes describing problems of the MDLC functions may be attributed to poorly developed information technology aspects. Our findings are policy relevant in general because information technology in health systems increasingly receives more attention and in specific for Mexico. One outcome of the policy discussion regarding information technology in Mexico is the development and implementation of SINBA, the National System of Basic Information in Healthcare, which is expected to solve some of the identified problems. Managing the huge amount of data and information, and to add value to decisions influencing the quality of health care and the health system's effectiveness, is essential. We expect that by sharing our findings we can encourage the different interest groups in Mexico to further invest time in strategies to solve this problem and to contribute to the development of SINBA.

Policy relevance of findings with reference to 'regulation'

Technovigilance is an important element of post-market surveillance (after market approval). Our study provided insights into problems related to an insufficient implemented technovigilance across the multiple sub-systems of health care. Our findings may be policy relevant at the level of 'regulation' because they address

several aspects that are currently inconsistently covered by the Mexican health system: (i) medical devices continuously conform to the requirements for safety and performance, (ii) problems or changes in safety and performance of medical devices are well detected and acted on in an effective and timely manner, (iii) medical device post-market surveillance are effective to cover national responsibilities, (iv) market surveillance based data is used to be aligned with standards of safety and performance. Further, our findings may reinforce the already on-going policy discussion of how to strengthen technovigilance. In the centre of this discussion lies the quality and quantity of reports from the meso and micro level. Our findings regarding 'regulation' may be policy relevant for other Latin America countries such as Colombia where difficulties regarding the implementation of technovigilance is explained and is a matter of culture [200]. Further, in 2012 a working group on medical devices for the region of Latin America has been established. Its goal is to strengthen the regulatory capacity for medical devices in the region of the Americas [171, 201]. The policy relevance of our findings for high-income countries may be low because their policy discussion regarding technovigilance is already advanced [202].

Policy relevance of findings with reference to 'assessment'

Government offices and other stakeholders concerned with the eligibility of medical devices in Mexico are in a transition; they have started to better distinguish between the different medical device risk classes and the different requirements that HTA should have. Our findings may contribute to improving the development of HTA and increasingly using HTA-based evidence for decision-making processes. In that way, HTA may support purchasing decisions of medical devices that have a short life-cycle in terms of technological advancements. To date, HTA in Mexico is little

discussed in literature and we expect that our findings will encourage researcher to draw more attention to this topic [78].

Our findings may contribute to improving the development of HTA in other LMIC countries, which may have similar problems [178]. In 2011, a Regional Network of HTA for the Americas was established aiming *"to promote and strengthen HTA through regional exchanges of information to support decision-making on regulation, use and replacement of technologies, improvements in the quality of care and rational use of technologies, and contribute to the sustainability and equity in access to health systems"* [203]. The frequent exchange of experiences and best practice between the member countries may contribute to the overall development of HTA in the Americas. However, the findings of this research are less relevant for high-income countries which are rather focusing on optimizing their current HTA processes and use of HTA-based evidence [204]. However, disinvestment strategies may have policy relevance for these countries as well. Going beyond ad hoc positive or negative inclusion lists and using disinvestment strategies for orthopaedic medical devices ("do not do recommendation") may be an important step forward in the work of HTA agencies in general as shown by the example of the United Kingdom, and strengthens evidence-based decision-making. This is not only relevant for Mexico but also for other countries in general.

Policy relevance of findings with reference to 'management'

Stakeholder involvement and technology guidance for decision-making currently do not form part of the policy discussion in Mexico. Looking at different health systems we found that there was always tension between cost and quality, and concern about the interaction between the area 'management' and the user (orthopaedic specialist). In the function of healthcare delivery, the main process occurs at the clinical level

between clinicians and patients [7]. For the production of direct services to the patient, the support of administrative processes such as purchasing is essential and it increasingly influences clinical practice and outcomes [60, 84, 88, 145]. Our findings may be policy relevant because they show that (i) a better technology guidance of decision-making may be beneficial to preventing sub-standard quality of implants, and (ii) an improved relationship between 'procurement' and 'clinical practice' where orthopaedic specialists have certain decision autonomy to represent their clinical needs sufficiently may be beneficial to bridging the gap between purchasing inputs and outputs.

Our findings may be policy relevant for other LMIC where procurement is based on public tendering and where HTA don't specify the brand or model of a medical device [205]. In high-income countries, stakeholder involvement and technology guidance for decision-making form part of the policy discussion [84] and our findings may be less relevant to these countries. Research on procurement in comparison to LMIC is not only focused on cost-containment but also on aspects that may optimize decision-making [206-208].

10.4. Perspectives for future research work

In this research we presented possible strategies of improvement in the context of a stakeholder analyses. In a group process, we assessed not only the stakeholders' position on different changes of processes and practices of the MDLC but also their opinions on stakeholders who might be directly involved in the proposed changes, and opinions regarding the possible positions that these stakeholders might have. However, such strategies that address changes in current processes and practices of the MDLC areas must be co-created with involvement of the relevant stakeholders, which was not subject to this Ph.D. study. Our future study suggestion for the MDLC in Mexico is to co-create specific activities with the identified relevant stakeholders

per proposed changes of current processes and practices and to assess their technical and political feasibility.

Many health systems are undergoing a critical analysis of their regulation and technology assessments. A general trend in European countries is linked to knowledge management in terms of learning from clinical outcomes and identifying sub-standard qualities that incorporate a health burden to the patient more quickly. To date only few studies represent a critical analysis of these aspects for middle-income countries. Our second study suggestion is to describe recent advancements regarding the MDLC of medical devices in other middle-income countries (e.g. Argentina, Brazil, or Ecuador) and to identify possible changes of current processes and practices of the MDLC areas. Overall, this will contribute to a better understanding of challenges that middle-income countries do have in comparison to high-income countries regarding the improvement of the MDLC areas in their countries.

In Mexico, there is still little integration between the orthopaedic associations and government units but there is a need to change this. A first move forward might be strengthening the relation between the National Academy of Medicine and the orthopaedic associations. This may contribute to continuous communication, defining overall needs of the interest group ‘orthopaedic specialists’ and initiating programmes aiming to improve clinical practice.

11. Conclusions

The MDLC represents an on-going cycle of inputs, outputs, and outcomes aimed at improving the quality of health care. The relevance and importance of a well-functioning MDLC is growing in both high- and middle-income countries. A broad analysis of the MDLC and the relation of important functions for medical devices are

rarely the subject of literature. Studies specifically either focus on aspects of the 'regulation', 'assessment', or 'management' of medical devices. While 'regulation' and 'assessment' are often analysed in a broader health system context, 'management' is often analysed in a relatively close context of operative aspects. Through this thesis, new evidence on the MDLC was generated and the holistic perspective supported the integrative understanding of problems that result from single MDLC functions.

Only some of the findings that our research has produced have been discussed in the literature before such as the complexity of the Mexican health system or sub-standard outputs of procurement processes. The complexity of the Mexican health system is a barrier for initiatives and programmes that address all sub-systems, and policy makers are unable to assure a similar level of health care between these sub-systems [32]. The country made important progress in ensuring and improving the quality of health care. However, researchers suggest Mexico continue searching for ways to strengthen its healthcare system by improving the delivery of healthcare in terms of coverage [125, 147, 209-213], and translating financial resources into more effective, equitable and responsive health services to achieve better quality [165, 32].

This research is novel in terms of its specific focus on key MDLC functions and on orthopaedic medical devices. Further, it was timely because some of the presented themes are currently undergoing policy discussion in Mexico. To be precise, the Mexican Congress is discussing the creation of the *Federal Commission for the Regulation and Surveillance of Health Care Services and Facilities* [166], which could generate momentum for the uptake of a broad spectrum of aspects concerning quality in health care and this may support outcomes of the MDLC areas.

The MDLC system in Mexico is not coherently outlined and set-up across the regulatory, the assessment, and the management domains of orthopaedic medical devices. This results in a sub-optimal quality of services delivered to patients. This finding resonates with concerns raised by other authors regarding the regulation, assessment, and management of health services in Mexico at different levels of health care delivery [11, 32, 38, 72, 78]. Further, policy makers from Mexico insufficiently integrate the relevance and importance of a well-functioning MDLC into their policy discussion. LMIC compared to high-income countries may still be in a process of defining and establishing government agencies or processes that are necessary to adequately support their MDLC. In high-income countries, MDLC functions are well defined and established and policy discussion is geared towards aspects of optimizing the outcome of the MDLC. Policy makers and other stakeholders related to the MDLC in Mexico may benefit from consulting the outcomes of policy discussion in high-income countries.

The new evidence produced by our research shows that neglecting the problems related to the MDLC functions leads to the continuation of the sub-standard provision of quality of health care and low health system's effectiveness. Based on the findings of this research we have the following recommendations to the Mexican policy makers and other stakeholders related to the MDLC:

- A government agency is needed to broadly oversee, monitor and report on quality-related issues within the health system. To date, no government agency is responsible for the uptake of a broad spectrum of aspects concerning quality in healthcare.
- Decision-makers should apply an integrative approach of selecting medical devices to better prevent an economic and health burden due to disconnected processes and practices of the MDLC functions.

- Specific policies and organizational practice targeting orthopaedic medical devices are necessary. To date, Mexico lacks initiatives or programmes, and research studies focussing on this. Further, there is a need to improve the understanding of the quality of the delivered health care in a broad way such as analysing it in the context of the MDLC areas.
- Technovigilance needs to be strengthened to improve the understanding of potential health risks associated with sub-standard HRMDs. Particularly, post-market surveillance should providing significant value to decision-making.
- Data, information, and knowledge need to be managed appropriately across the sub-systems of health care provision. The National System of Basic Information in Healthcare [74] is an important step forward but needs to uptake orthopaedic specific variables as well to increase transparency on treatment performance, burden of revision, etc.
- Technologies should be assessed during the purchasing process by applying strategies such as risk assessment, the adequate involvement of end-users, and basing decisions on multiple criteria including clinical impact in the short-term (tissue trauma, rehabilitation duration, primary stability of implant, etc.) and long-term (survival of implant, material performance, etc.).
- The methodology applied to technology assessments for evaluating HRMDs needs to be adapted to the gold standard and HTAs at the level of hospitals should be introduced.
- Decision-making needs to distinguish between different risk classes of medical devices because decisions on complex medical devices are based on simple decision criteria. Particularly, the understanding of potential health risks associated with the use of sub-standard HRMDs is still insufficiently anchored in the mind-set of the multiple stakeholders.

- 'Procurement' needs more attention so that actors involved in procurement or impacted by procurement decisions are less confronted by problems. Particularly, procurement agents need more guidance and support to improve purchasing decision-making, and knowledge of orthopaedic specialists should be better integrated into the decision-making process.

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Curriculum Vitae

PERSON

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Name	Myriam Anna Veronika
Birthdate	29th June 1981, Wiesbaden, Germany
Nationality	German
Martial Status	Married, three children
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PROFESSIONAL EXPERIENCE

Since 09/2017 — **European Center of Pharmaceutical Medicine** (Basel, Switzerland)
External collaborator
- Technology related evaluations regarding treatment costs, prevalence & incidence, etc.
- Focus: Swiss market

11/2009–12/2012 — **Smith & Nephew Mexico, S.A. de C.V.** (Mexico City, Mexico)
Marketing Manager – Orthopaedic
- *Capex & Stock strategy*
- *Sales & Marketing strategy, Portfolio Management & Launches*
- *Congresses, events, trainings*
- *Coordination of product specialists, Mexico City sales force & scrub nurses*

Motivation of change: Decision to move to Zurich due to job opportunity of husband

04-11/2009 — **Heraeus Kulzer México, S.A. de C.V.** (Mexico City, Mexico)
Regional Product Manager Latin America
- *Distributor Management (Mexico and Central America)*
- *Competitor and market analysis (North and South America)*
- *Market launches (Colombia, Mexico)*
- *Product and customer trainings (Latin America)*

09/2006-01/2009 — **Heraeus Medical GmbH** (Wehrheim, Germany)
Global Product Manager – Bone Cements
- *Portfolio Management & Trainings*
- *Complaint management*

EDUCATION

02/2014-09/2017	**University of Basel (Basel, Switzerland)**, PhD candidate University of Basel (Switzerland) and "Swiss Tropical and Public Health Institute" (Switzerland) • PhD Thesis: "The regulation, assessment, and management of orthopaedic medical devices in Mexico: Crucial aspects, problems, and steps to improve it." Submitted 06/2017 • Date of graduation: Sep 19th 2017 • Grade: Cum Laude
Since 07/2014	**SSPH+ program in Public Health** (Switzerland), student • Total ECTS achieved: 31.0
05/2013–02/2014	**Additional courses with focus Public Health** (Switzerland), student • Prelimanary courses for PhD starting in 2014 • Total ECTS achieved: 10.5
08/2001-05/2006	**University of Passau** (Passau, Germany), student • Diploma / Master in Business Economics • Grade: 1.9

SKILLS

Language	• German (native speaker) • English (fluent and able to negotiate) • Spanish (fluent and able to negotiate)
Research	• Quantitative research: advanced knowledge • Qualitative research: advanced knowledge • Systematic review: Basic knowledge
IT	• MS Office / SAP / Content Management / InDesign / Stata / MaxQDA / Endnote •
Others	• Certification in "Professional Sales Skills" / Certification in "Professional Presentation Skills" / Certification in "Moderation of Meetings"

PUBLISHED MANUSCRIPTS

09/2017	**Mexican Health Review 2017** Status: Published

M. Lingg. Survival rates: An opportunity to improve orthopaedics.

08/2017 **Salud Pública de México**
Status: Review
M. Lingg, A. Dreser, K. Wyss, L. Durán-Arenas.
Strategies to improve the Medical Device Life-Cycle in Mexico.

04/2017 **International Journal of Technology Assessment in Health Care**
Status: Published
M. Lingg, E. Merida-Herrera, K. Wyss, L. Durán-Arenas.
Attitudes of orthopaedic specialists towards effects of medical device procurement.

03/2017 **Safety in Health**
Status: Published
M. Lingg, A. Dreser, K. Wyss, L. Durán-Arenas. The regulation, assessment, and management of medical devices in Mexico: How do they shape the quality of delivered healthcare?

06/2016 **BMC Medical Informatics and Decision Making**
Status: Published
M. Lingg, E. Merida-Herrera, K. Wyss, L. Durán-Arenas. How does the knowledge environment shape procurement practices for orthopaedic medical devices in Mexico?

06/2016 **BMC Health Services Research**
Status: Published
M. Lingg, E. Merida-Herrera, K. Wyss, L. Durán-Arenas. Effects of procurement practices on quality of medical device or service received: A qualitative study comparing countries.

POSTER AND ORAL PRESENTATIONS AT CONGRESSES AND CONFERENCES

11/2017 Swiss Public Health Conference 2017, Basel, Switzerland
1) Poster presentation “Using survival rate benchmarks as „do not do recommendations“-rule to reduce the financial impact and burden caused by joint implant revision surgeries.”

11/2016 9th European Public Health Conference, Vienna, Austria
Poster Presentation “Attitudes of orthopaedic specialists towards effects of medical device purchasing”

04/2016 Geneva Health Forum 2016, Geneva, Switzerland
1) Oral Presentation “How does the knowledge environment shape procurement practices of medical devices in Mexico? A qualitative study”
2) Poster Presentation “When is procurement expected to harm clinical practice? A qualitative study comparing countries”

04/2016 XXVIII National Mexican Conference of Orthopaedics and Traumatology, Mexico D.F., Mexico
1) Oral Presentation “¿Cómo impacta el proceso de compras en la práctica clínica? Estudio cualitativo comparando países”
2) Oral Presentation “¿Cómo impacta el ambiente de conocimiento las prácticas del proceso de compra de

	dispositivos médicos ortopédicos en México?"
10/2015	8th European Public Health Conference, Milan, Italy Poster Presentation "When is procurement expected to harm clinical practice? A qualitative study comparing countries"
09/2015	9th European Congress on Tropical Medicine and International Health 2015, Basel, Switzerland Poster Presentation "When is procurement expected to harm clinical practice? A qualitative study comparing countries"

MEMBERSHIPS

Since 2016	Public Health Schweiz (Switzerland)