

Strategies to improve the medical device life cycle in Mexico

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Abstract

Objective. To analyze the role of stakeholders to three alternative strategies to improve processes and practices regarding the regulation, assessment, and management of orthopaedic medical devices in Mexico. **Materials and methods.** The study was based on document analysis and 17 structured interviews with multiple key actors within the Mexican health system to inform a stakeholder analysis aiming at assessing the political feasibility of these strategies. **Results.** Central level government agencies, those with a relation to quality of care, were identified as most relevant stakeholders to influence the adaption and application of the strategies. Major barriers identified are financial and human resources, and organisational culture towards reform. **Conclusion.** Discussed strategies are political feasible. However, solving identified barriers is crucial to achieve 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.

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

Resumen

Objetivo. Analizar el papel de actores clave ante tres estrategias para mejorar los procesos y prácticas relacionados con la regulación, evaluación y gestión de dispositivos médicos ortopédicos en México. **Material y métodos.** Análisis de grupos de interés (*stakeholder analysis*) basado en un análisis documental y 17 entrevistas estructuradas con actores clave, dirigido a evaluar la viabilidad política de las estrategias. **Resultados.** El papel de las agencias federales de gobierno, principalmente las relacionadas con calidad de atención, fue identificado como central y con mayor poder para influenciar la adaptación y aplicación de las estrategias. Como barreras se identificaron los recursos financieros y humanos, y reorientar la cultura organizacional hacia la reforma. **Conclusión.** Las estrategias discutidas son políticamente viables. Resolver las barreras es importante para lograr cambios que optimicen el ciclo de vida de los dispositivos médicos e influyan positivamente en la calidad de atención y el desempeño del sistema de salud.

Palabras clave: tecnología biomédica; regulación; evaluación; gestión; dispositivos médicos

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Medical devices, together with drugs and other health technologies, comprise one of the six components considered as essential for good health system performance.¹ 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.²⁻⁵ At the centre of the discussion is the improvement of outputs and outcomes of the medical device life cycle (MDLC).⁶ A cohesive medical devices policy, well planned, supported and coordinated among all areas represented by the MDLC stakeholders (i.e. those involved in regulation, assessment, and management) is necessary to meet the population needs and to ensure the quality of health care.⁶

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 'sub-systems' are the public social security institutes (Mexican Institute of Social Security, IMSS and Institute of Social Security and Services for State Workers, ISSSTE) and the state-level health care services (SESA), which function along a large number of private health care providers.^{7,8} 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.^{9,10} The health system is characterized by a distribution of roles 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), an independent governmental organisation is responsible for overseeing the Inter-institutional Commission of the Standard List for Health Supplies; the Federal Commission for the Protection against Sanitary Risks (Cofepris), an autonomous MOH agency, is responsible for the quality and safety of new medical drugs, medical devices and other health inputs; while the National Centre for Health Technology Excellence (Cenetec), a central MOH office, is responsible for health technology assessments, supervision of medical equipment, and clinical guidelines.¹¹ 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'.⁷ The Mexican Congress is discussing the creation of the *Federal Commission for*

the Regulation and Surveillance of Health Care Services and Facilities,¹² 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.

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 (table I).¹³⁻¹⁶ 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), resulting in 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.^{7,9,17-19}

The aim of the present study is to review three alternative strategies to improve the regulation, assessment, and management of orthopaedic medical devices in Mexico with regard to their political feasibility.

Materials and methods

The strategies under review (table I) stem from our previous study,¹⁶ which discusses alternatives to improve the outcomes of the MDLC. In the present study, we reviewed three strategies regarding their political feasibility based on a structured stakeholder analysis to identify key stakeholders, and their potential stake, interest, position and power.²⁰⁻²³

Identifying stakeholders

To identify the most relevant stakeholders we did a general search in *Portal de Obligaciones de Transparencia*, which lists all government units or institutes and their departments and facilitates the access to government information. Further, we complemented the retrieved data by stakeholder information as provided by our previous study findings and documental analysis of information on the identified stakeholders such as recent advancements, or future projects related to the key functions of medical devices. Based on the obtained data we developed a list of most relevant stakeholders regarding medical device regulation, assessment, and management. We classified stakeholders according to four levels: 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 in-

Table I
STRATEGIES FOR THE MEDICAL DEVICE LIFE CYCLE

Areas of medical device life cycle	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 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	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 practice; fluctuation of workforce and insufficient skills of procurement agents regarding complex clinical needs	'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 competencies of procurement agents, and (iii) evaluating outcomes of applied purchasing strategies such as <i>Integral Services</i> .

Source for 'medical device life cycle': Adapted from Development of medical device policies, WHO Medical device technical series⁶
Source for 'strategies': Lingg M, Dreser A, Duran-Arenas L, Wyss K¹⁶

dustry associations). Further, we described their relative importance regarding the regulation, assessment, and management of medical devices.

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. Data collection was based on 17 structured interviews to collect data from the interviewees on themselves but also their opinions on other stakeholders (table II). For the interviews we used a questionnaire* with mainly closed-ended questions 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.

Data analysis

We analysed the retrieved data and information on stakeholders based on four characteristics and regarding each of the three strategies (organized as sub-sections): (i) '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; -(ii) 'Interest' to display the stakeholder's opinion in the strategies based on advantages or disadvantages that these may bring to the stakeholder; (iii) 'Position' to present whether the stakeholder supports, opposes, or is neutral about the strategy; and (iv) 'Power' to differentiate between high to low influence regarding the realization of the strategy. Based on the stakeholder information, we discussed for each strategy its political feasibility.

Ethics

The committee for research and ethics, research division of the medical faculty of the National Autonomous University of Mexico, approved this project (Date of approval: November 4, 2014; oficio no. FMED/CI/SPLR/188/2014; *dictamen proyecto*: 143-2014). 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.

Results

Most relevant stakeholders

Table III displays the most relevant stakeholders. Their relative importance regarding the three strategies is decreasing from the macro to the micro levels at least for 'regulation' and 'assessment' of medical devices. Stakeholders with a relative high importance for regulation is Cofepris, for assessment are Cenetec and CSG, and for management are the 'sub-systems'.

Analysis of stakeholders regarding strategies under review

Table IV displays the most relevant stakeholders regarding each of the three strategies under review ('potential stake'). Further, it summarizes their 'Interest' and indicates their 'Position' and 'Power' towards these strategies.

Findings regarding strategy for improving 'Regulation'

The analysis identifies Cofepris as a stakeholder with high potential stake to 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

* Supplementary file [dataset in internet]. Harvard Dataverse. 2017. <https://doi.org/10.7910/DVN/8fatyz>

Table II
PARTICIPANTS

Stakeholders	Participant N (%)	Male N (%)
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)
Meso level (public and private sector)	2 (12)	1 (50)
Micro level (public and private sector)	2 (12)	2 (100)
Supplier level	3 (17)	2 (67)
Total	17 (100)	14 (82)

Table III
LIST OF MOST RELEVANT STAKEHOLDERS

Level	Stakeholders	Main responsibility	Relative importance		
			Regulation	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 of the Ministry of Health, 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, CENE-TEC	• 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

Table IV
STAKEHOLDER ANALYSIS TABLE

Stakeholders	Potential stake in strategy		Tehno-vigilance		Assessment		Purchasing		Position		Power	
	Tehno-vigilance	As-Purchasing	MS [†]	HS [‡]	MS [†]	NS [‡]	MS [†]	NS [‡]	MS [†]	NS [‡]	MS [†]	NS [‡]
MOH, namely DGCE	MS	MS [†] HS [‡]	Vigilance of quality; patient safety; data availability; quality of health services	Relate decision-making to quality attributes; guide decisions; quality of health services [†]	Transparency on decisions; technology assessment at hospital level; expenditures; evidenced-based decisions [‡]	Balanced quality of health services across sub-systems; expenditures; real cost-benefit [†]	Quality of health services; quality of procurement outcomes; governance of human resource skills [‡]	S	S [†] SM [‡]	S [†] S [‡]	+++	++(+) ^{†,‡} +++
CSG	MS	MS [†] HS [‡]	Quality culture and of health services; broader safety spectrum	In line with current quality efforts [†]	Evidenced-based decisions; quality of health services [‡]	Quality of health services; efficiency and efficacy of healthcare facility [†]	Quality of health services; efficiency and efficacy of healthcare facility [‡]	SM	N [†] SM [‡]	S [†]	+++	++ ^{†,‡} +
COFEPRI	HS	MS [†]	Report quality; stakeholder commitment; quality of health services; prevention of sub-standard products	Requirements for market-approval; engage device supplier to provide high quality; technology evaluation [†]	Technology assessment at hospital level [‡]	Safety of healthworker and patient [†]	Safety of healthworker and patient [‡]	S	S [†]	S [†]	+++	++(+) [†] ++(+)
CENETEC	MS	HS [‡]	Data quality and availability; stakeholder commitment; enhancing knowledge	Data bases; regulations for quality; safe use of products; Stewardship; technology assessment at hospital level [‡]	Technology assessment at hospital level [‡]	Cross-sharing of Genetec expertise [†]	Cross-sharing of Genetec expertise [‡]	S	S [†]	S [†]	++	++(+) ^{†,‡} ++(+)
ANM	NS	MS	Quality of health services; patient safety; broader reasoning of incidents	Data availability; quality of decisions [†]	Technology assessment at hospital level; evidenced-based decisions [‡]	Real outcomes; recognition [†]	Recognition and representation of surgeon's clinical needs [‡]	S	S [†]	S [†] SM [‡]	+(+)	+(+) ^{†,‡} +
PAHO	NS	NS [‡]	Best practice sharing towards other countries; balanced quality of health services across sub-systems	Best practice sharing towards other countries [†]	Best practice sharing towards other countries [‡]	Best practice sharing towards other countries; quality of procurement outcomes [†]	Best practice sharing towards other countries; quality of procurement outcomes [‡]	S	S [†]	S [†]	+(+)	+(+) [†] +
INSP	NS	NS [†]	Research quality; quality culture; data availability	Research quality; decision-making; knowledge [†]	Research culture; decision-making; knowledge [‡]	-	-	N	S [†]	-	+(+)	+(+) [†] -
CONAMED	NS	-	Quality of health services; broader reasoning of incidents and patient-doctor conflicts	-	-	-	-	SM (N)	-	-	+	-
Sub-systems: Centralized and decentralized health services	MS	MS [†] HS [‡]	Balanced quality of health services across sub-systems; data availability; reporting culture; prevention of sub-standard products	Quality of health services; patient safety; expenditures [†]	Quality of health services; patient safety; expenditures [‡]	Real cost-benefit; quality of health services; prevention of problems during clinical practice [†]	Develop specialist procurement group; satisfying outcomes; updating profile requirements [‡]	SM	SM	SM [†] SM [‡]	+++	+++ +++
Orthopaedic community [†]	MS	-	Quality of health services; Balanced quality of health services across sub-systems	Quality of health services; improvement of purchasing outcomes; expenditures	Quality of health services; improvement of purchasing outcomes; expenditures	Prevention of sub-standard outcomes; improvement of doctor service attention [†]	Prevention of sub-standard outcomes; improvement of doctor service attention [‡]	S	-	S [†]	+(+)	-
Medical device community [‡]	MS	NS	Quality of data; knowledge; report quality	Systematic decision-making; improvement of purchasing outcomes; expenditures	Systematic decision-making; improvement of purchasing outcomes; expenditures	Real cost-benefit; quality of health services; transparency on outcomes [†]	Real cost-benefit; quality of health services; transparency on outcomes [‡]	S	SM	S [†]	+(+)	++ ++(+)

* Only few interviewees noted that the required increase in financial and human resources is a critical barrier
 † Orthopaedic association and orthopaedic specialists
 ‡ Medical device industry association and medical device suppliers
 § For strategy component 'quality benchmarks'
 ¶ For strategy component 'technology guidance'
 † For strategy component 'integral services'
 ‡ For strategy component 'procurement agent's competencies'
 +++ 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

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 in a leading position of health technologies].

Cofepris is a critical organization within the Mexican health system and holds the overall responsibility for technovigilance. Other relevant stakeholders considered being moderately supporting the strategy but to be involved in one way are: MOH (in general, but particularly DGCES and Cenetec); the '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.

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 and overseen by CSG.²⁴

Findings regarding strategy for improving 'Assessment'

The analysis identifies DGCES, CSG, and Cenetec as stakeholders with high potential stake to 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. Overall, this would positively influence the decision-making process regarding decision-making attributes.

This would help to fight less for the lowest price and more for the quality [...] [Director of medical device supplier].

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.

Findings regarding strategy for improving 'Management'

The analysis identifies DGCES and 'sub-systems' stakeholders with high potential stake to 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.

[...] the current situation leads to costs to solve failures caused by inferior quality [...] [Ex-director of orthopaedic services at social security institute].

Their 'position' was categorized as supporter of this strategy. The 'power' of DGCES is being considered as moderate and that of social security institutes ('sub-systems') as high.

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. Overall, this would positively influence the decision-making process regarding procurement outcomes.

[...] the procurement agent mentality is still focused on prices [Director of medical device supplier].

Few stakeholders mentioned that the role played by DGCES 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*, which encompasses a range of disposable and non-disposable medical products used for surgery and merges them into one supplier service.

Discussion

The discussed strategies to improve the MDLC were largely perceived to be within the competence of central government (CSG) and MOH agencies: Cofepris, DGCES, 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.^{7,12,25} 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.¹³⁻¹⁵ These findings coincide largely with the literature that portrays public policy-making in Mexico as a governmental-centred process, largely impermeable to civil society participants, but increasingly influenced by the private sector.^{26,27} 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 and social security institutions regarding reforms or guidelines, for example, and how the different social security institutions adapt them. 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 being included into the political agenda at federal level.

The discussed strategies are a matter of multiple actors and interviewees 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 is politically feasible, and 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 2016 Mexico's health systems report to improve technology assessment and regulation of medical devices, and strengthening the role of Cenetec.⁷ 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 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.

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.

Conclusions

This study used a stakeholder analysis as foresight to better understand positions of different groups and institutions to changes to current processes and practices of the MDLC for medical devices. 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. To date, policy makers have endeavoured to advance the regulation, assessment, and management of medical devices. 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. 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.

Furthermore, within the 'sub-systems' a similar fragmentation of the responsibilities of the MDLC is replicated. For example, within IMSS there have their own offices that deal with MDLC responsibilities independently from the MHO agencies.

In Mexico, discussion and proposals by interest groups are slowly gaining momentum on how to improve the regulation, assessment, and management of medical devices. We have the following recommendations to the Mexican policy makers and other stakeholders related to the MDLC: (i) initiating a working group at national level that aims at refining the discussed strategies, (ii) enhancing the communication between different interest groups as identified in this analysis at the meso and macro level, (iii) fostering the role played by ANM and its relation to professional associations.

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