Assessing the value of accreditation as a strategy for safer healthcare in Uruguay

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Evaluación del valor de la acreditación como una estrategia para una atención de salud más segura en Uruguay

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RESUMEN EJECUTIVO

Introducción

La acreditación de servicios de salud desde 1999 fue ganando espacio como una estrategia de regulación, asociado con un interés aumentado en la seguridad del paciente. La acreditación consiste en la evaluación voluntaria y periódica de los servicios, realizada por un agente externo, contra una serie de estándares. Aunque la mayoría de los programas de acreditación tienen similitudes, usualmente se adaptan a las políticas locales. Desde la reforma del Sistema Nacional Integrado de Salud en Uruguay, se ha enfatizado la necesidad de la mejora de la seguridad del paciente, y diferentes partes han propuesto como parte de la solución la implementación de la acreditación.

Objetivos y Metodología

Para analizar los efectos de la acreditación de hospitales, y entender las perspectivas de diferentes partes interesadas en Uruguay, un estudio observacional fue realizado. Incluye una revisión bibliográfica de revisiones analizando la acreditación, a través de un análisis narrativo, y un análisis temático de nueve entrevistas semiestructuradas, realizadas a tomadores de decisión uruguayos, elegidos mediante un muestreo intencional.

Resultados

Siete revisiones bibliográficas fueron identificadas e incluidas para el análisis, después de evaluar su metodología. Poca evidencia de una asociación entre la acreditación y los efectos sobre la estructura, procesos y resultados fue encontrada. Algunos de los ejemplos de asociaciones son la re-estructura de las áreas de enfermería, el efecto en la sustentabilidad financiera, y la implementación de buenas prácticas. Sin embargo, no se pudo identificar evidencia consistente sobre la cultura, los resultados o la visión de los usuarios. Mientras la financiación, un cuerpo de dirección comprometido y una organización acreditadora fuerte pueden ser identificados como facilitadores de la implementación, recursos escasos y cultura organizacionales adversas son identificados como posibles barreras.

Entre los nueve entrevistados se encuentra un amplio entendimiento del concepto de acreditación. Se espera que, a través de una mejor adherencia de pautas y políticas de seguridad del paciente, evaluaciones periódicas y una aproximación sistémica, la acreditación mejoraría la seguridad del paciente. También se entiende como una manera de mejorar la cultura de seguridad de los médicos y de los cuerpos de dirección. Aunque algunos reparos fueron presentados concerniendo el estilo de gestión y el rol de la política en la gestión, así como con la factibilidad de la implementación de la estrategia, los

entrevistados concuerdan en que la acreditación mejoraría la seguridad del paciente en Uruguay, y por lo tanto debería ser contemplada como una solución.

Discusión

Aunque la evidencia presenta resultados inconsistentes, la formulación de políticas es influenciada por otros elementos. Mientras que diferentes instituciones abogan por la acreditación, algunos de los grupos más poderosos (entre otros los médicos y los cuerpos de dirección) son reactivos y podrían no apoyar la medida. A su vez, intentos pasados por implementar la acreditación han fallado, y los programas actuales de seguridad del paciente no han sido lo efectivos que se esperaba. Sin embargo, se entiende que la acreditación podría mejorar la seguridad en el contexto de la reforma nacional de la salud.

Conclusiones y Recomendaciones

Aunque la literatura estudiada presenta una pobre metodología, algunas conclusiones pueden ser alcanzadas. Mientras que la actitud de la enfermería es favorable a la acreditación, la de otros grupos es inconsistente. Las investigaciones analizando la asociación con cambios en la estructura, procesos y resultados no fueron concluyentes, excepto por el aumento en la adhesión a pautas y estándares. A pesar de la pobre evidencia, diferentes actores consideran que la implementación de la acreditación, como una estrategia de mejora de la calidad, tendrá un efecto positivo en la cultura sobre la seguridad del paciente y en los resultados. Sin embargo, se expresó preocupación acerca de la viabilidad de su aplicación, sobre todo en cuanto al rol de la política, el estilo de gestión y los limitados recursos humanos y económicos. Teniendo en cuenta el interés de las partes interesadas, el contexto nacional y la evidencia actual algunas recomendaciones pueden ser realizadas:

- Recomendación 1: Establecer objetivos de seguridad del paciente y medidas de impacto, y evaluar el desempeño de los servicios de salud.
- Recomendación 2: Seleccionar el programa de acreditación apropiada: opciones, la aceptabilidad y la sostenibilidad.
- Recomendación 3: Implementar un programa piloto.
- Recomendación 4: Coordinar los esfuerzos concurrentes a la seguridad del paciente.

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2 ACKNOWLEDGEMENTS

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The data analysed was gathered by myself and the process of the analysis was discussed with Prof Black. A first complete draft was read and commented by my supervisor close to the submission date.

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3 ABBREVIATIONS

ACS	American College of Surgeons
ASSE	Administración de Servicios de Salud del Estado (Administration of State's Health Services)
COSEPAs	Comité de Seguridad del Paciente (Patients' Safety Committee)
DECASEPA	Departamento de Calidad y Seguridad del Paciente (Department of Quality and Patient Safety)
DIGESA	Dirección General de la Salud (National Health Authority)
INACAL	Instituto Nacional de Calidad (National Institute of Quality)
IOM	Institute of Medicine
JUNASA	Junta Nacional de la Salud (National Health Board)
LMIC	Low- and Middle- Income Countries
MoH	Ministry of Health (Ministerio de Salúd Pública)
PAHO	Pan-American Health Organisation
RCT	Randomised Control Trial
SNIS	Sistema Nacional Integrado de Salud (Integrated National Health System)

4 INTRODUCTION

4.1 PATIENT SAFETY

Patient safety is defined as the first domain of quality, associated with the "freedom from accidental injury".[1] Although the error is present in any human endeavour, it was not until 1999, after the IOM publication of *Err is Human: Building a safer health system*, that patient safety started to be considered by the health community and users as a major public health issue. Efforts were then focused by professionals, the public, governments and organisations on the improvement of safety outcomes.[2, 3] At this time, the approach changed from a reactive incident analysis perspective to a whole-systems' scrutiny to provide safe care rather than preventing error.[4]

In complex systems such as healthcare, different elements can interact driving to error. The revision of systems, to provide safer care should include the various structures within the organisation. Therefore, it should take into account the clinical areas (e.g. wards, medical and nursing departments), but also areas such as managerial and administrative areas.[5]

4.2 REGULATION STRATEGIES

Regulation is defined by Ensor and Weinzierl as the "actions initiated, although not necessarily implemented by Government to address failures in the existing public and private health care system and to promote current policy objectives".[6] Amongst the regulation strategies, several have been applied worldwide, focused in two segments: the regulation of healthcare professionals, and the regulation of services.

Through registration and licensing of professionals and providers, the health authorities can control the provision of healthcare to develop a coordinated system, limit moral hazard[1], and maximise welfare.[8]

Two main procedures are used to regulate professional practice: licensing and certification. Licensing is usually through professional self-regulation, with decentralised regional or national bodies, which maintains an annually updated register of the professionals licensed to practice.[9] Licensing usually includes the review of the entry requirements into the

[1] Moral hazard is the situation were in an agreement, one of the parties has an incentive to act for its own benefit, while the other is does not benefit from the action.[7]

profession, and then the payment of an annual fee to renew the license. These bodies can review the license if the conduct of the professional is questioned.[10] Certification is also a periodic process, usually associated with the demonstration that the professionals have acquired new training or that they have gained specialist knowledge.[11]

There are three main regulating processes for health services: licensing, certification and accreditation. Health services in most countries have to comply with certain minimal quality standards to obtain a license to provide a service. As well as this, licensing allows the governments to control the availability of health providers, their distribution and the services provided.[9] Licencing is usually associated with inspections to ensure the requirements are met. Certification in health services usually means that a service has a specific capacity not required by the licensing process, showing that the service abides by certain standards.[9, 11]

4.3 ACCREDITATION

The third regulating strategy for health services mentioned is accreditation. The accreditation of health services has been increasingly used, as a voluntary system, sometimes associated with fees for the initial assessment and the maintenance of the accreditation status.[12] It consists of a periodic evaluation by an external visitor (accreditatior) of the services, against a set of health-specific quality management standards.[13]

In 1917, the American College of Surgeons (ACS) adopted the “End results systems hospital standardisation”, developed by Ernest Codman (1910), and started their “Minimum Standards for Hospitals” programme. It consisted of a set of requirements covering elements of the structure (training of personnel) and processes (periodic staff meetings and clinical review and recording of interventions).[14] In 1951, the ACS with other health organisations created the Joint Commission on Accreditation for Hospitals, implementing the requirements established by the ACS.

Since it was formed in 1917, the concept of accreditation has developed to become a comprehensive strategy assessing healthcare functions, organisations and their networks, focusing on the structure and processes.[12, 15] The premise behind accreditation is that adhering to standards based on evidence would improve the quality and safety of the service.[16] The focus of accreditation is risk reduction.[8]

On a different subject, health leaders have shown that in market-based health systems, it can be used as a marketing tool to differentiate between providers.[17]

Many countries have adopted accreditation, with a substantial expansion of the use of the strategy since the 1990s in Europe, making it the most common external mechanism for quality improvement today.[12] Although most programmes have similarities, they are usually adapted to specific country policies.[18] In a report presented by the WHO, 35 accreditation programmes were identified in 47 countries, most of which were based on the United States' system.[12] Half of the programmes are publicly funded, and increasingly used as a means of regulation and public accountability. Payments by providers to accreditation agencies are usually required to maintain the accreditation status.

4.4 POLICY PROBLEM

Since 2005, Uruguay is undergoing a reform in the Integrated National Health System (SNIS), where significant changes have been done on the financing, management, and healthcare provision model. As part of this change, and aligned with the patient safety policies developed by the Ministry of Health (MoH), different stakeholders involved in the MoH, in public providers, and in the National Institute of Quality (INACAL), are proposing changes to improve the quality of care, including accreditation. However, no analysis was made public on the feasibility of the implementation of accreditation and the impact on patient safety.

As per the Institute of Medicine (IOM), quality of care can be defined as the "degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge".[19] This insists upon the fact that high-quality systems do not translate necessarily into good outcomes.[20] With this in mind, the analysis of the strategy to be applied must be comprehensive and consider its effectiveness and efficiency, and feasibility in the specific context.

4.5 BACKGROUND

Since the reform of the SNIS in Uruguay, significant efforts have been put in the development of national policies to improve the quality of care (effectiveness, safety, humanity and equity[21]).[22] However, the provision of safer care was particularly emphasised through the development both of national and institutional strategies encouraged by the international context and some never-events[2] in local hospitals in August 2006.[24] Two

[2] Never-events are mostly preventable, serious patient safety events, which would probably not occur if preventive strategies were put in place.[23]

months later an advisory group was established at the MoH to suggest the best strategies to reduce adverse events in healthcare organisations.

In 2008, a regulation was passed by the MoH, which required that every provider should have a patient safety committee.[25] These committees are responsible for advising management on best strategies to prevent adverse events and develop safer care.

Several national guidelines were proposed, as presented in a conference by the responsible of the National Quality and Safety Department (DECASEPA) in April 2015. These are focused on disruptive behaviours and behavioural agreements, rational and safe drug use, staff training in patient safety and culture development.[26]

4.6 CURRENT RELEVANCE

Although the health services accreditation strategy was not covered in the presentation by the DECASEPA, in a previous one done by a high ranking MoH civil servant in 2010, it was highlighted as an opportunity to develop safer care. In this presentation, organised by the INACAL, accreditation is acknowledged as one of the main strategies in the mission of the DIGESA, the national health authority dependent of the MoH.[27]

However, this interest in accreditation was not new in Uruguay. In 1994 a taskforce, with the support of the Pan-American Health Organisation (PAHO), started working on the development of accreditation standards for Uruguayan hospitals, which was published in 1996.[28] However, this strategy was not successfully implemented. The policy was promoted again by different stakeholders in 1998 and 1999, but again it failed to develop.[29]

More recently, in the last quarter of 2015, the need for health services accreditation as a patient safety strategy was raised. To start with, its need was emphasised in a series of events organised by the INACAL and the main public healthcare provider (ASSE).[30] In December, the Director of the National Quality and Safety Department (DECASEPA), when referring to a never-event in a public hospital, mentioned the measures proposed by the Joint Commission on Accreditation of Healthcare Organisations as a way to prevent such situations.[31] Finally, towards the end of December, the Minister of Health presented the 2020´s National Health Objectives which was expanded by the publication of the National Health Objectives in May 2016. In the Objective 72, it is specified the need for the construction of an accreditation system for best practice for a set of services.[32] However, it is important to recognise that this strategy of accreditation actually described a strategy closer

to a certification system of individual areas rather than what is internationally recognised as accreditation.

4.7 POLICY INFORMATION MISSING

After a literature review both in peer-reviewed journals and in grey literature, no evidence was found of an analysis on this subject in Uruguay. This project may consequently, be useful as a tool for deciding about the appropriateness of the health services accreditation as a patient safety strategy in Uruguay.

4.8 RESEARCH QUESTIONS

- What is the impact of health services accreditation on patient safety as regarded by the international experiences and evaluations?
- What is the perception among Uruguayan stakeholders, of health services accreditation in terms of usefulness to improve safety, and feasibility to implement in public and private services?

5 OBJECTIVES

5.1 GENERAL OBJECTIVE

Analyse the benefits and drawbacks of hospital accreditation, focusing on the impact on patient safety. Understand the perspectives of Uruguayan stakeholders interested in the subject because of their role as academics, policy makers or their role in health services providers.

5.2 SPECIFIC OBJECTIVES

i. Review the impact of accreditation of hospitals on patient safety.
ii. Understand the perception of hospitals accreditation and its role as a strategy to improve safety amongst Uruguayan stakeholders.
iii. Understand the perception of benefits and drawbacks of implementing hospital accreditation in Uruguay amongst stakeholders.

6 METHODOLOGY

6.1 HYPOTHESIS

Accreditation is a useful method of improving the safety of care and is acceptable in Uruguay.

6.2 STUDY DESIGN AND DATA COLLECTION

This is an observational study, with a qualitative analysis performed using data collected through two different strategies: a literature review of the impact of health services accreditation as a patient safety strategy; and semi-structured interviews to understand the perception of Uruguayan stakeholders over the role, benefits and drawbacks of health services accreditation as a patient safety strategy.

The protocol, the information sheet for the interviewees and the informed consent forms for this study were approved by the LSHTM's MSc Ethics Committee as shown in Appendix 11.1. Local ethics committee "Comité de Ética de la Fundación Salud Dr Auguto Turenne" declared that the current protocol did not require further review according to local regulations (see Appendix 11.2).

6.2.1 Literature review

A search of the published literature was performed on July 21st, 2016 in the following databases: Pubmed (01/01/1980-01/04/2016), Web of Science (1980-2016), Scopus (>1979), Lilacs, Scielo (1980-2016), and HMIC (1980-2016). The search was performed using the terms Accreditation, Hospital, Health Service and Patient Safety, connected with Boolean operators AND and OR according to the Appendix 11.3. This strategy intended to capture a broad search on the topic. All the results were imported into EndNote X7.5 to manage the citations.

The following selection criteria were applied through filter strategies when available in the databases search engines, or search strategies in EndNote:

Inclusion criteria:

i. Studies analysing hospital accreditation, focusing on the assessment or evaluations of the strategy.
ii. Studies covering patient safety elements.
iii. Papers in English and Spanish will be included.

iv. Studies published between January 1980 and April 2016.
v. Literature reviews.

Exclusion criteria:

i. Accreditation of professionals in health services, or of teaching and educational techniques in health services.
ii. Accreditation of technological elements or non-clinical areas in hospitals.
iii. Other languages than English and Spanish.
iv. Articles, opinion papers, letters, lecture notes, conference proceedings and papers with no references.

Exploring the citations of studies allowed to include other relevant references through a snowballing technique. The abstracts of the remaining articles were read in the selection process.

6.2.2 Interviews with stakeholders

Nine interviews were held with Uruguayan stakeholders involved with management, or quality and patient safety, between June 20th and July 7th, 2016. The interviewees were coordinated through local liaisons.

6.2.2.1 Sampling strategy

A purposive sampling process was carried out, choosing politically important people, representing different perspectives,[33, 34] with the aim of obtaining rich answers, and the views of those who could be directly or indirectly involved in policy-making. An in-depth analysis was aimed for each of the interviews performed. The interviewees included:

i. Decision-makers in patient safety and quality of care policies, in the following roles: professional, academic.
ii. Public and private health services decision-makers.
iii. User representative.
iv. Senior clinician or thought leaders in patient safety.

6.2.2.2 Interview planning

Semi-structured, 30 to 45 minutes', audio-recorded interviews were carried out via Skype or similar, in Spanish. A list of the intervening stakeholders is provided as the Appendix 11.4. At the start of every interview, consent was verbally ratified.

Each interview consisted of four basic questions (see Appendix 11.5), while prompts were used to deepen the understanding of elements raised by the interviewee. This semi-structured approach to interviewing was meant to prevent leading questions and to facilitate

the interviewees to focus on the aspects relevant to their perception.[35] The data obtained in all interviews were anonymised to prevent the identification of the stakeholder in the report.

6.3 DATA ANALYSIS

6.3.1 Literature review

The quality of the methodology of the included literature was critically assessed through the AMSTAR checklist framework for systematic reviews, regardless of the type of review defined by the authors. Each study included in the review was classified as low, medium or high quality.[36]

The full texts were then examined to synthesise the findings through a narrative approach.[37] The synthesising approach was performed through the extraction of data from the results presented in the reviews, as well as the extracts of the original studies included in the reviews in their main bodies, tables or appendices.

The data were extracted in two sections. The first represented the three core elements according to Donabedian's strategy for quality assessment of health organisations: structure, processes, and output.[38] The second section included elements that could facilitate or obstruct the implementation of the strategy. As well as this, within each section, thematic groups identified by Greenfield and Braithwaite were used to aid in the analysis.[39]

6.3.2 Interviews with stakeholders

The data from the recording of the interviews were merged with notes taken during them. The data were analysed through a thematic approach following Attride-Stirling systematised extraction strategy.[40] The process included the coding of the data, grouped subsequently in basic, organising and global themes. The different orders of themes were then used to analyse the original data. While the analysis was performed in Spanish, the organising themes, global themes and the extracts from the interviews were translated into English.

7 RESULTS

7.1 LITERATURE REVIEW

The initial search strategy provided 1956 citations which fit the search criteria. After an initial round of processing, 813 citations were deleted because for being duplicates or meeting exclusion criteria through terms search strategies. Of the remaining citations, eight were identified as literature reviews or systematic reviews.

The quality of the included literature was assessed using the AMSTAR tools for systematic reviews.[36] Table 1 presents a summary of the quality of the methodology according to the AMSTAR checklist (see the complete results in Appendix 11.6), the number of studies included in each review, and the number of citations relevant to this research.

Table 1 - Assessing the reviews' quality with AMSTAR tool through the score and quality level, and the total number of studies and number of relevant studies included in each review.

Review	Score*	Quality level	Studies reviewed	Relevant citations
Al-Awa et.al. [41]	0	-	-	-
Alkhenizan and Shaw [17]	3	Low	17	15
Brubakk et.al. [42]	8	High	24	4
Greenfield and Braithwaite [39]	5	Medium	66	58
Hinchcliff et.al. [43]	7	Medium	122	120
Ng et.al. [44]	4	Medium	26	26
Scott [45]	3	Low	102	4**
Tabrizi el.al. [46]	5	Medium	83	1

*Number of positive answers
**Number of studies analysing accreditation

Only one of the reviews was catalogued as high quality, while four were medium quality and two were low quality. The review by Al-Awa[41] was excluded for it did not state the methodology for the analysis.

The extraction sheet with the data used for the analysis is included in the Appendix 11.7.

The following sections will present, firstly, an analysis of accreditation and its effectiveness, as portrayed in the seven systematic reviews included in the analysis. The second subsection involves the analysis on facilitators and barriers to the improvement of patient safety.

7.1.1 The effectiveness of accreditation on the structure of organisations

The effect of accreditation on the structure of organisations can be analysed through different perspectives. These include the effect on the health care professionals, on the material resources including facilities and finances, and on the organisational structure.

In their systematic review, Greenfield and Braithwaite[39] show the usefulness of accreditation as an opportunity to reflect on the operations of the organisation,[47] and to develop the initial insights into quality defects and priorities for hospitals.[48] A study performed by Duckett explores the changes produced by accreditation on the structures.[49] It highlights that the most significant effects are on the nursing structure, and on physical facilities and safety elements, while the least significant were on areas associated with medical staff. However, different degrees of change were found in administration and management, review systems, and hospital role definition and planning. This sense of improvement is supported by Alkhenizan[17] who references an Australian survey where accreditation is perceived as a promoter of a better structure for quality.[50]

Hinchcliff[43] analysed the organisational impact and change mechanisms in its review. However, no conclusions were presented for these aspects due to the methodology of the included articles. As an example of the change mechanisms, a study was referenced which demonstrates that in those members of staff participating in accreditation, there was a heightened awareness of the relevance of safety.[51] Ng[44] discusses the effect of accreditation, exemplifying its effect on the organisation through the study of Braithwaite et.al.[52], which highlights a positive correlation between accreditation performance and organisational culture and leadership.

Greenfield and Braithwaite raise different elements regarding the financial aspects of accreditation. While an author stated that it is an essential investment and demonstrated the commitment with quality,[53] another author questioned if it was a good use of resources[54]. An analysis done by Zarkin revealed that smaller and rural hospitals had a higher economic burden as accreditation costs are similar, regardless the size and location of the institutions.[55] Ng presents a study where it is found that hospitals accredited by JCAHO had higher costs for their clinical services.[56] The impact on financial resources was analysed by Hinchcliff in fifteen studies. Accreditation is represented as a source of pressure and a threat to the sustainability of the organisation, while Cleveland highlights these effects in Low- and Middle- Income Countries (LMIC).[57]

7.1.2 The effectiveness of accreditation on the processes of organisations

As mentioned earlier, the redesign of processes is an important consequence of accreditation. Among the main effects explored are the organisational impact of these changes, and the effect on the systems that the changes produces. As well as this, the impact on quality measures was assessed.

As presented by Alkhenizan and Shaw, accreditors, managers and key staff perceive that accreditation promotes good practices,[58] improves communication, and commitment to evaluation and quality of care activities.[50] Brubakk[42] includes a systematic review which found a positive impact of accreditation on hospital and professional practice.[59] Ng presents the results of a study that concludes that accredited hospitals show more progress implementing patient safety standards and medical error management than non-accredited ones.[60] In the same line, Greenfield and Braithwaite reference a study which shows that accreditation is associated with better performance, more documentation and better health and safety training procedures.[61] However, although another study showed improved work procedures, some of the sectors participating did not believe that quality had improved.[62] Concerns of increased paperwork and decreased adaptability were raised. This agrees with the perception of senior hospital staff and accrediting staff that mentioned the bureaucratic and prescriptive aspects of the strategy.[47]

The effect of the introduction of accreditation on processes of care can be found in Greenfield and Braithwaite review. It is mentioned that participating in the accreditation process enabled the staff to introduce continuous quality programmes, to consider exit surveys and improve documentation,[47] and improve the dissemination and quality of guidelines.[63]

The effect of the changes in processes is not consistent. While Hinchcliff presents two studies that demonstrate an association between the accreditation status and quality measures,[64, 65] another study shows a lack of association.[66] Greenfield and Braithwaite present a study agreeing with this point, showing that accreditation failed to detect error prone systems.[67]

7.1.3 The effectiveness of accreditation on the outcomes of organisations

The impact of accreditation on the outcomes can be analysed from different perspectives. While the impact on outcomes has been considered, the perception of professionals on the impact on the outcomes, and the effect on patient satisfaction have also been explored.

Professionals' attitude towards accreditation varies according to the context and their role in the organisations. While nurses' perception of the effect on quality is consistently positive, as reported by Alkhenizan,[68, 69] senior managers have different attitudes. For example, they and accreditators think of accreditation as an important stage in the hospital's evolution in France,[47] and hospital owners in India agree on the need for accreditation, and its possible use as a marketing tool.[70] On the other hand, in a survey, a high number of problems are associated with quality improvement activities, as well as integration and utilisation of information.[71] Concerns with the cost-effectiveness were also raised by rural administrators[72] and by senior staff[73].

The effect on outcomes was explored in five of the literature reviews. In only three of eleven studies in Greenfield and Braithwaite's review there was a positive association between accreditation and outcome.[74-76] In the rest, no significant association was found.[56, 77-81] The only identified RCT, carried out in South Africa, found that although accredited hospitals had higher compliance with process standards, no improvement in outcome was observed.[68] Also, a study showed a dangerous disjuncture between outcomes and accreditation.[82] Hinchcliff, on the other hand, analysed the effect on outcomes in nine studies, six of which had a positive association, including the association of the accreditation of primary stroke centres and lower 30-day adjusted mortality.[83] However, one of the studies described that while the prevalence of adverse events such as infection may be reduced with accreditation protocols, more complex strategies might require other approaches.[84] Scott[45] references a study that shows that accreditation fails to identify poorly performing institutions before revelations of poor care.[85] Similarly, in the review published by Tabrizi[46], a study refers that none of the accreditation programmes was strong on effectiveness and efficiency.[86]

The effect on consumers' views or patient satisfaction is far less explored. Greenfield and Braithwaite present a study which finds no relationship between hospital accreditation scores and patient satisfaction.[87] Hinchcliff supports this view after analysing thirteen studies. Ng refers as well to a study which describes that the accreditation status is not related to consumer involvement.[52]

7.1.4 Facilitators and barriers to accreditation

From the reviews analysed, different elements can be interpreted as facilitators or barriers to the development and implementation of accreditation processes.

The perception of professionals towards accreditation can be understood as facilitators or barriers according to specific contexts. For example, Greenfield and Braithwaite present a

study where professionals show a positive perception towards accreditation, considering an effective strategy to assure safety.[88] On the other hand, Alkhenizan presents a study which expressed doctors' scepticism on accreditation, to which they felt unaccountable.[89]

Among the facilitators, Ng refers to the impact of prospective funding through a study which describes it as the strongest driver for accreditation, while fostering organisational development.[90] This is in line with studies presented by Greenfield and Braithwaite which refer to management as the most important entity to successfully achieve accreditation.[91] The role of the managers is also highlighted by Alkhenizan. In a qualitative study, it is mentioned that managers conceive accreditation as quality affirming. In such cases, the accreditators, managers and key staff perceive managers as committed to accreditation.[58] Purchasers, according to another study, take into account the accreditation characteristics of institutions when choosing the plans to offer to their users.[18] The role of the regulatory agency was highlighted in Alkhenizan's paper while presenting a study which reflected that these bodies have the strongest impact on hospitals' efforts to improve patient safety.[92] Ng includes a study which shows that independent quality bodies dedicated to quality improvement in hospitals can minimise political interference.[93]

Several elements may prevent the fulfilment of accreditation and the improvement of safety. A study presented by Ng states that an organisational culture resistant to change might limit the adoption of the strategy.[93] The same study reported that if it accreditation is linked to payments or reimbursements, hospitals might respond with opportunistic behaviours to access the funds. Another study states that if accreditation of health services is made compulsory and if it is associated with resource allocation, institutions might do merely enough to get accredited.[94] The absence of governmental leadership and national coordination produces little integration and consistency among strategies.[95]

In their review, Greenfield and Braithwaite include studies where it is stated the difficulty of health professionals to comply with standards and meeting information requirements,[88] specifically with multidisciplinary process-related issues.[71] Another study states that the expertise and financial resources constraints undermine the viability of an accreditation programme.[96] This is affirmed by a study included in Hinchcliff's review which mentions that human and financial resources can be a possible concern.[97]

7.2 THE URUGUAYAN STAKEHOLDERS PERSPECTIVE

In the following paragraphs, the main aspects covered in the nine interviews to the stakeholders will be discussed. Firstly, the understanding of accreditation is explored.

Secondly, the understanding of the role of the current strategies, and the possible role of accreditation will be covered. Thirdly, the analysis of the views on patient safety culture in the health services and the accreditation's effect on it will be presented. Fourthly, issues regarding the management of the health services and the health system will be discussed. Lastly, some considerations will be discussed relating to the implementation of accreditation as a patient safety strategy in Uruguay.

7.2.1 Understanding of accreditation

All interviewees highlighted the importance of an authorised accrediting agency that evaluates health services, through the analysis of the compliance of applicable and predetermined standards. Only three interviewees referred to the accreditation process as voluntary, while none mentioned that a payment to the accreditation agency is usually required.

7.2.2 Existing strategies which have not accomplished their objectives

A clear tension between what the current strategies are intended to do, and what they have delivered is referred amongst all interviewees. Several of the patient safety programmes developed by the DECASEPA in the last decade are regarded as positive, but there is a consensus that the effort, although good, is not enough. The focus on the accomplishment of the strategies is usually ascribed to the MoH, rather than on the institutions. This is referred to be similar to the inability of the MoH to demand the mandatory licensing of health providers. Only in two interviews were strategies on patient safety other than the officially promoted mentioned, in both cases regarding experiences of accreditation of health services. Two organising themes will be described in this global theme: patient safety planning, and patient safety implementing.

Although the plans promoted by the MoH are referred to as a positive start, these are viewed as an incomplete strategy. It is argued that the development of the Patient Safety Committees (COSEPAs) does not help to focus on patient-centred care, but rather support non-systemic approaches to quality. The focus in some strategies, such as a surgical checklist and prevention of hospital-acquired infections, help to identify the approach as fragmented.

> *There is no consciousness (in the MoH) about which is the true objective of these strategies and peoples' understanding. People see the strategies as: <More compulsory paperwork that the MoH ask us to submit; do it as you can*

and then we will see>. We lack a systemic view of the patient safety strategies.

This is seen as part of the reason justifying low intensity of work in the COSEPAs and a reactive response to patient safety rather than a proactive view. Another aspect highlighted is the flexibility among the institutions to regulate the work of the COSEPAs. This is highlighted by seven interviewees, mentioning that different providers implement the COSEPAs in a nominal way, work reactively to events or specific demands of the MoH, or by saying that some institutions have no working COSEPA.

The work (of the COSEPAs) is excellent… The implementation started as everything starts. Afterwards, the work and level of commitment diminished, reducing the frequency of the meetings… Now it meets when specific events or activities require it.

There is a positive perception amongst the interviewees about the role of accreditation in the existing patient safety strategies. The periodic evaluation required by accreditation systems is perceived as a way to force compliance with patient safety policies, and the start of a systemic approach to quality in health services.

The accreditation for the whole institutions, rather than for specific departments would be of great use… It could help fulfil other strategies and needs, improving the control and evaluation (of programmes).

As well as this, the strategy is understood as a mechanism where standardisation of clinical practice, through the use of processes, would improve patient safety.

The accreditation would basically promote the standardisation of the structure, processes and output, to commit to good quality standards… This would allow making (the institutions) comply with norms that would benefit patient safety.

None of the interviewees shed any doubt on the effectiveness of the measures developed or accreditation. This seems to be associated with the sense of “need” and “need to fight for” better quality of care, and of the development of “vital” evaluation systems.

7.2.3 The Patient Safety culture in the organisations

Associated with the relatively recent launch of patient safety policies in Uruguay, quality culture is understood as an element in development. However, it is still understood as a

problem that affects different groups involved in health care provision. This global theme is built on two organising themes: current culture in the organisations, and potentialities.

The culture of organisations, together with flaws in the development and implementation of the strategies by the MoH, are seen as the main barriers to the development of patient safety strategies both in private and public health providers. This is mainly associated with a poor commitment from medical professionals and management teams. These groups are described as reactive to specific situations and demands from the MoH.

> *From 60 or 70 Executive Directors, around ten are involved in these strategies. Many others only see them as boxes to check, and it shows. In those institutions, the COSEPAs do not participate in strategies.*
>
> *After working for a while in patient safety, you understand that the patient safety culture leaves a lot to be desired… We are in a very reactive, initial development of the consciousness… The style of the medical duty and the multi-employment produces a different interest to one of the nurses, who are committed to it.*

As seen in the preceding fragment, a differentiation of the involvement of different groups of professionals in the programmes involved is performed. This was highlighted by five interviewees.

> *The nurses had a much better response to patient safety strategies. There was also a group of doctors, with postgraduate studies in management, which were actively involved. Another proactive group was the Pharmaceutical Chemists, which because of their training, are used to applying quality strategies.*

Most interviewees state that accreditation would improve the awareness of patient safety, supporting the current strategies, and increase the diffusion of the interest in patient safety.

> *(Accreditation) will contribute enormously to inculcate in the institutions the culture of continuous improvement, risk analysis, and proactive attitude which would be included in the processes.*

Nonetheless, the education of the health professionals is conceived as one of the main drivers of change in patient safety culture. Interviewees referenced the importance of courses that are or could be provided by the MoH, local universities and other institutions.

7.2.4 Professionalism of management required

Management and stewardship of the health system are referred amongst interviewees as a limiting factor for improvement of safety. This is associated with two main elements: relative underdevelopment of the managerial profession, and the role of politics in decision making. Two main organising themes were identified: Management of health services, and the State's role in stewardship.

It is argued that health services are managed in a reactive way, with short-term objectives rather than medium or long term strategies. This is mentioned by participants as a consequence of limited resources, underdevelopment of the managerial teams, and the involvement of political leadership in private but mainly in the public provider (ASSE. Also, it is mentioned that the relative underdevelopment of the professional managers as opinion leaders, facilitates the absence of an active leadership towards safer care.

> *Strategies for patient safety require a medium or long term commitment. And that kind of strategy is difficult to have in health services today… Policies change and also management teams change, changing the rules at the organisation.*
>
> *There are issues in the management… There is no standard attitude… We have in the country a primacy of the political designation in the public providers, which has a negative effect.*
>
> *If someone asks how it is managed (in the institutions), there is no model, it is what is happening, what is going on… Each institution is managed with no systemic approach.*

Similar elements are raised for the MoH. As well as limited human and economic resources of the MoH, the structure of the health system governing bodies has a significant role. This has a political effect on decision-making, as effective leverage in control of compliances of targets is reduced. Private providers argue that as ASSE (the main public provider) does not fulfil some of these targets, they should not be forced to comply with them either.

> *As long as all the structures are political, and the reasons for the designations (in ASSE and the MoH) are political instead of technical, there will be no way out… Management has to be depoliticised.*
>
> *The MoH cannot have an active policing role of the system. When the institutions have a problem with the JUNASA because they have not fulfilled a*

target or compulsory objective, they are not punished or it is weak… The JUNASA has a strong influence of the Executive Power, and that favours that the institutions which are controlled and forced to commit to objectives, sometimes are protected.

The implementation of an accreditation strategy is viewed as a possible solution to these issues. It is mentioned that it would increase the commitment of the management teams, as it can be used as a management tool, which helps setting an objective considering safety.

The accreditation forces the management to respond to regulations (regarding patient safety). Here many of them are interested in solving the daily issues. This could change this perspective.

Although it is mentioned that the implementation of the strategy is necessary or a good opportunity for the improvement in patient safety by different interviewees, some suggested the possibility that health services will require extra funds to accredit the organisations.

It is also suggested accreditation is important as a marketing and promotion strategy. In the context of multiple providers, differentiation in terms of accreditation scores was referred to be useful to provide choice to the users.

7.2.5 Accreditation in Uruguay

There is a consensus among stakeholders that improvement in patient safety in Uruguay is needed. While all of the interviewees agreed that accreditation would have overall beneficial effects, three spontaneously referred to accreditation as a quality strategy to pursue. The analysis will be presented through three organising themes: Difficulties in the implementation, basis of the accreditation, and accrediting institutions.

Difficulties in the implementation. Attempts have been made to develop an accreditation system in Uruguay but didn't go through. An interviewee highlighted some issues that might be a threat for the implementation of this strategy. Amongst them, the possibility of obtaining an independent accreditation agency might be limited by the characteristics of the country and healthcare professionals: small population, wide multi-employment amongst health professionals, and a strong role of politics affecting the objectivity of the institution.

The strategies work in a context… In our context (the accreditation) has been impossible to develop. The surveyors, as well as the accreditation agency,

must be independents… we are a small country, and it is difficult to have the conditions necessary for these systems

Basis of the accreditation system and Accrediting institution. Six interviewees agreed that to implement successfully such a strategy, incentives where needed. Two main incentives were highlighted: explicit public recognition of the accredited institutions, and the inclusion of accreditation as a health services target[3]. Some participants felt that healthcare providers should be legally bound to apply for the accreditation.

The incentives for providers are two: recognition and financing… The main incentive should be a kind of award, recognising the accreditation of the services. Some of the money for health services targets which are being evaluated because of their ineffectiveness could also be reassigned…

The only solution is that, in a first moment, the accreditation is launched as a voluntary programme, where accredited institutions will be publicly recognised by the MoH. That will drive others to accredit their institutions… Eventually, half of the providers will be accredited, and then the strategy can be compulsory.

Other elements which should be aimed are transparency and the production of information for the use of the services, the MoH or the public, and increase consideration of patients' experience and rights including choice.

Different institutions were considered by seven interviewees to be able to carry out the strategies. All of them argued the importance of the role of the MoH in the development of the plan, but there was consensus on the need for independence from it. The institutions suggested were the FNR, for its experience financing and accrediting highly specialised medicine services, or a new organisation associated or advised by institutions working in quality in Uruguay as INACAL and UNIT, an ISO certifier. Both the FNR and INACAL were considered to be important developers of the consciousness of the need to develop an accreditation system.

[3] Health service targets are a Pay-For-Performance strategy that complement the payment through capitation to providers.[22]

8 DISCUSSION

8.1 SUMMARY OF FINDINGS IN THE LITERATURE

As a consequence of the aims and objectives of accreditation, changes in the structures and processes of health services have to be developed. Preceded by the rethinking of the processes of the organisation, accreditation leads to modification of the structures. However, health services are complex systems where the professional role of the staff, and its organisation in a professional bureaucracy, play a major role.[98] In this context, the power of decision-making is decentralised both horizontally and vertically, and the structures are not appropriate to adapt their processes to new circumstances. This is reflected in the significant changes in the nursing structures and less important change in medical areas.

The organisational impact and the impact that accreditation, defined by Greenfield and Braithwaite as change mechanism, has not shown consistent results. However, in some studies, a correlation between accreditation and organisational quality culture was identified, and an RCT identified increased commitment to quality standards.

Despite the fact that accreditation can successfully help to implement and disseminate guidelines, patient safety standards, and continuous quality programmes, its effect is not clear. To start with, some studies report that workers have a perception of increased workload, and a lack of improvement of safety. These perceptions are supported by inconclusive or inconsistent results regarding the impact on quality measures and indicators. In the RCT mentioned above, the increased compliance with standards in accredited facilities was not correlated with improved outcomes. Other studies showed that accreditation systems could fail to identify poor quality of care. The study by Faunce et.al. explain that the different significance in effect may be associated with the limited effect that accreditation may have in complex processes which involve clinical work.[85]

The impact on user experience has not been widely studied, despite growing interest in health research. Available research shows inconclusive results regarding patient-reported experience, satisfaction, and participation.

Research on the financial impact of accreditation is also scarce. However, research on the perception of its impact tends to agree on the consideration of the burden for the organisation of the process. This impact is questioned in cost-effectiveness terms, and in the sustainability of such programmes.

Several elements affect the implementation of accreditation. While the perceptions of some health professionals might encourage implementation, others might be sceptical of its effectiveness. What is more, in organisations with a culture resistant to change, implementation might be limited. However, the firm involvement of management and the association of accreditation to funding are described as major drivers of change. Some concerns are raised however with the link between accreditation and payment, as studies show that opportunistic behaviour may be fostered. This behaviour might be prevented by the establishment of independent quality bodies within the services. As well as this, the role of the accrediting agency is critical to the development of the strategy, and it is said that a weak role of the government leading the implementation limits the consistency of the plan.

Although three different elements are described as major influences on the development of accreditation (i.e. management, funding linked to accreditation, accrediting agency), the incentives of the different strategies seem to have effects at the various levels of organisations.

As barriers to implementation, two main issues are reported. Firstly, the difficulties of professionals to meet the requirements of the new standards, including the paperwork overload and new multidisciplinary processes. Secondly, the possible constraints of trained professionals in quality, and of economic resources.

8.2 IMPLICATIONS OF FINDINGS IN THE URUGUAYAN CONTEXT

While the evidence shows inconsistent results, the process of decision-making and policy formulation is more complex than applying knowledge based on the scientific evidence. Kingdon presents the process of agenda setting and policy making as three separate streams that represent: the perception of the problem as something important; the analysis of the problem and possible solutions; and the tendencies of different groups regarding the issue.[99] The process of policy making is influenced, therefore, by the intersection of these streams, in policy windows, which might not always be related to scientific evidence, but for example by a crisis or external shock.

Walt and Gilson described in 1994 a triangle framework for policy analysis.[100] As shown in Figure 1, the framework includes the following components: the content of the policy; the context that frames the policy; the actors involved and the dynamics of power; and the process of agenda setting and evolution of the policy's objectives. Despite being a very simplified model for the understanding of the interactions in a complex system, this framework helps with the consideration of the different elements of policy-making.[100]

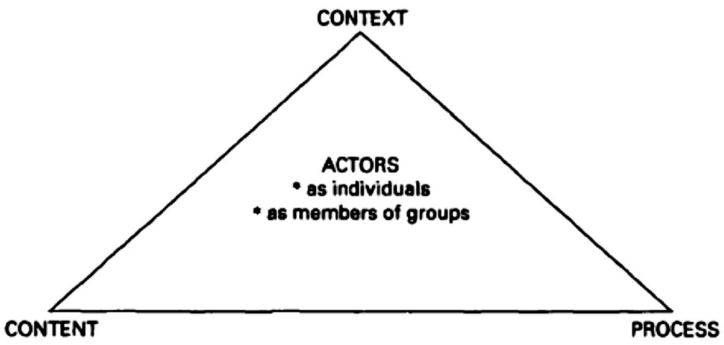

Figure 1 - Walter and Gilson's model for health policy analysis.[99]

In this case, the actors to be considered are the MoH, health services, health professionals, organisations involved in quality and therefore safety (e.g. INACAL, UNIT), universities, and users amongst others. The context includes the development of the SNIS reform with its new governance, the providers and their characteristics, and the development of quality strategies in health services. The process can reflect the evolution of patient safety in Uruguay, and the dynamics of the coexistence of the different actors and the context, showing the agenda setting process. The content is given by the current interest in the development of patient safety strategies and specifically of implementing accreditation.

8.2.1 Actors

As understood from the standpoints of the different stakeholders interviewed, there is a major need for progress in the development of patient safety strategies. Some of the interviewees find accreditation the solution to this issue, while all of them mention that accreditation would be helpful to improve safety. Therefore, not only the high-ranked public servants support the development of accreditation, but also thought leaders and professionals involved in patient safety.

While formal institutions such as governments have an important role in policy making, interest groups also influence policies in pluralistic democracies. Amongst the most active interest groups identified in the agenda setting are the FNR and INACAL. However, as mentioned by Buse, Mays and Walt the medical professionals are one of the most significant interest groups influencing the government.[101] Considering the relatively reactive attitude from doctors and management regarding patient safety mentioned by some of those interviewed, their support on the measure is not as clear as that of the interviewees.

8.2.2 Context

The SNIS reform established a new governance system through the JUNASA. In this structure, within the MoH, decision-making is shared by four representatives designated by the government, and representatives from the providers, workers and users. The strong role of the government in the board is considered by different actors as a liability, as it maintains a political role in the decision-making process, reducing the chances of the application of sanctions if required. As an example, it is repeatedly mentioned that the lower compliance of health regulations by ASSE, does not allow the JUNASA to effectively require the private providers to comply with them.

Although the plans promoted by the MoH in patient safety are considered as a positive action, these are mentioned to be incomplete. The high flexibility in the institutions to apply the strategies and the notion of fragmentation are part of the criticisms that were mentioned. What is more, the strategies have not been successful in improving the quality culture amongst different health professionals, including doctors and managers. It is also argued that the programmes launched by the MoH were not supported by adequate training to professionals and students of health professions.

8.2.3 Process

The idea of establishing an accreditation system to improve safety started around 1997, with the first meetings and the elaboration of standards. However, this experience was not successful for different reasons, including the context of the country and political elements.

With the creation of the DECASEPA, the focus on patient safety was raised. However, the initiatives around accreditation presented by different actors were not translated into taskforces or interdisciplinary groups working on the strategy. Again, elements from the Uruguayan context, including limited human and economic resources at the MoH and political elements have prevented further progress.

8.2.4 Policy

Accreditation is seen as a strategy to improve and complement the current patient safety policies by developing a systemic approach. The importance given to the need of improvement in patient safety seems to affect the way the strategy is evaluated. This can be interpreted when they prioritise the magnitude of the effect (compulsory role of evaluation and involvement of all areas of services), rather than the effectiveness or efficiency of the strategy. Some interviewees even mention the possibility of making accreditation compulsory, while others said it should be incentivised by the state.

The interviewees mentioned different objectives as reasons to implement accreditation, but they all highlighted the importance of a locally adapted system. The standardisation of clinical practice, transparency, evaluation and increased consideration of patients' experience are some of the objectives that accreditation should aim at. As a consequence, it is referred that the culture of the organisations would shift towards a quality and patient-centred culture, through a systemic approach to these issues.

8.3 LIMITATIONS

Both the literature review and the analysis of the interviews are subject to limitations. To start with, the search strategy was intended to have a broad number of results. However, the search was focused mainly in health databases, while policy and management databases and grey literature might have presented a wider variety of results.

Regarding the reviews included in this study, only one was classified as per the before mentioned AMSTAR framework as of high quality, and only two had presented a quality analysis of the studies included. However, most of the reviews included considerations of the poor methodology of the papers included in them. These considerations were based on the poor level of evidence of the studies because of their methodological design. Except for one RCT identified, the rest of the designs do not allow the determination of causal links between interventions and outcomes. Furthermore, the use of ambiguous outcome measures, the diverse focus of the studies, and the relatively small number of studies reporting patient outcomes, do not allow results to be generalised or to draw conclusions about several issues.

As to the interviews, the main limitation is the sampling process. The relatively small number and the underdevelopment of quality systems and patient safety strategies causes that the interested people present a homogenous view about the topic. Other sampling strategies, such as theoretical, might have presented different accounts regarding the issue.

During the analysis of the data, the effect of the interviewer and the questions was considered. However, no significant conditioning was found in any of the interviews. As well as this, because of the professional and academic involvement of the different interviewees on the development of accreditation, no significant effect of the intervention (i.e. information provided or interview) is expected to affect the accounts regarding the use of the tool or its impact.

While the view of decision makers and thought leaders was included in the sample, perspectives of other health professionals not actively involved in patient safety were not included. Considering the data provided by the literature review performed, a significant difference in the perception of safety strategies may have been found between different groups of professionals.

Finally, as the current project is produced as a part of the fulfilment for a Master's degree, the use of different researchers to collect and analyse the data was not possible. This would have reduced researcher bias, and improved the depth of the analysis both of the literature review and of the interviews.

9 CONCLUSION AND RECOMMENDATIONS

Patient safety has taken a primary role amongst the public health strategies in different countries since 1999, after the IOM report “To Err is Human…”. However, it was in 2006 that the issue started taking greater relevance in Uruguay, after a series of never-events occurred in local hospitals, in the context of the SNIS reform.

However, the interest in safety strategies was demonstrated years before this. As an initiative of institutions such as FNR, INACAL and different thought leaders, the country has been reviewing the need for the implementation of an accreditation system since 1997. Although these movements failed to situate the policy at the top of the health agenda, since 2015 the use of accreditation was increasingly mentioned by different high-ranked public servants.

The different studies reviewed, highlighted the poor methodological quality of the literature. However, some conclusions can be reached. While the attitude of nurses was favourable, the perception of the other groups such as managers and doctors is inconsistent. This may be linked to the lack of clarity of the outcomes chosen to assess such a strategy. In a similar way, studies analysing the association of accreditation with changes in the structure, processes and outcomes are not conclusive, except for the increase in compliance with guidelines and standards.

In the Uruguayan context, the strategy for accreditation is regarded amongst stakeholders as a positive way to improve the patient safety culture and outcomes. Although this cannot be justified by existing evidence, the adoption of a systemic approach to quality improvement is regarded as a solution for the fragmentation of the current strategies enforced by the MoH. It is also understood as a way to develop a deeper involvement and consciousness regarding patient safety by different professionals. However, concerns were raised on its feasibility because of the current role of politics in management and decision-making, the professional development of managers and staff leading this process, and the context of economic restrictions.

While the elaboration of a compulsory accreditation system might seem to be a solution to avoid the resistance from different groups, this would not represent the usual understanding of accreditation. What is more, a compulsory system would require a policing body. However, the policing agency of the health authority has shown to be ineffective, as no

significant actions are taken with institutions that do not license their facilities. The development of incentives, both economic and recognition, might be better options.

Taking into consideration the interest in patient safety of the different stakeholders interviewed, national policies regarding patient safety, and the context regarding the National Health Objectives 2020, some recommendations based on the traditional understanding of accreditation as a voluntary system can be made.

Recommendation 1 – Set the objectives and assess the performance

The first step to establish a strategy to improve the safety of care should be the definition of the aims that the system is pursuing. The objectives should be translated into measures to assess the current safety of services. The impact measures should also be constructed to evaluate the effect of the intervention, in terms of effectiveness and the economic impact.

The analysis of the data gathered should be presented to the health professionals directly and indirectly involved in the provision of care. This will allow them to assess their performance and reflect upon changes needed to improve the quality of the services provided. The data should also be provided to the health authority.

Recommendation 2 – Select the appropriate accreditation programme: options, acceptability and sustainability.

Considering the views of the interviewees, and the fact that most countries have adapted to their local context, the health authority together with leading institutions in quality management should consider the alternative accreditation programmes. This should consider the span of accreditation (e.g. whole hospitals, services), what will be evaluated (e.g. structure, processes, outcomes), the period of validity of accreditation, incentives for the providers, and the agency responsible for implementing the programme. The acceptability of the approach should be analysed, including the willingness of health providers to accredit their services, and of health professionals to engage with the standards required. A costing analysis should be performed, taking into account the societal perspective, to determine the sustainability of the programme, including the cost of the accreditation agency to develop and run the programme, the costs to providers to redesign their systems to implement it, and any costs accounted to the MoH.

Recommendation 3 – Implement a pilot programme

If the strategy is shown to be both sustainable and acceptable, the following recommendation can be implemented. Taking into account the scarce evidence supporting the strategy, but the support from the different organisations, a piloting process should be performed to analyse the strengths and weaknesses of the programme developed. This should intend not only to perfect the current strategy but also to develop the knowledge to analyse the usefulness of the tool, in terms of effectiveness as a patient safety strategy.

A random sample of health services providers should be selected and invited to participate in the pilot, assuring confidentiality of the data gathered. The sample should consider elements such as current safety of services, location, and number of users, amongst other elements. The pilot should assess the implementation process and the impact of the strategy through the indicators developed as per the previous recommendation. The data gathered should be analysed considering the characteristics of the institutions participating in the pilot, and used to improve the programme and to assess its effectiveness.

Recommendation 4 – Coordinate concurrent efforts addressing patient safety

Regardless of the acceptability and sustainability of the accreditation programme, the individual efforts from different organisations should be pulled together and coordinated. The role of education imparted by different organisations was highlighted. However, it is mentioned that these fall short of the needs of the system and of the health professionals. As well as this, the perception of a fragmented strategy to improve patient safety is seen as an obstacle to committing the professionals with it.

Education, as mentioned by Black, is usually the first tool suggested for improving the quality of an organisation.[102] Although the concept of patient safety is known, as mentioned the risk awareness is low. The training should be focused on raising this awareness, rather than developing a broad knowledge of patient safety amongst all the professionals.

Other tools as mentioned by Black, should also be considered to improve patient safety.[102] To incentivise compliance with patient safety strategies, the measures analysed could be used to show improvement of the safety of care in the services analysed, working both as feedback for the professionals and as a base for socio-behavioural incentives.

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11 APPENDICES

11.1 APPENDIX PROTOCOL WITH INFORMATION SHEET AND INFORMED CONSENT FORM

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

MSc PH (HSM) Research Project Proposal

Research project title *"Understanding health services accreditation as a strategy for safer healthcare: A stakeholder analysis in Uruguay"*.

Research Project Proposal Version	*Date of Version*
1.0	*03/04/2016*
1.1	*05/04/2016*

1 INTRODUCTION

1.1 TITLE

Understanding health services accreditation as a strategy for safer healthcare: A stakeholder analysis in Uruguay.

1.2 SUMMARY

Since the reform of the National Health System in Uruguay, there has been significant interest in the development of national and institutional strategies for the improvement of the quality of care (effectiveness, safety, humanity, equity), with particular concern for safety. With the creation of a National Patient Safety Committee within the Department of Quality of Care and Patient Safety of the Ministry of Health (MoH), several strategies have been targeted to develop safer healthcare.

In the last quarter of 2015, in several opportunities different Uruguayan stakeholders have been including health services accreditation as a possible strategy to improve patient safety. Among these stakeholders, it can be identified civil servants at the MoH (including members of the National Patient Safety Committee), the National Institute of Quality (INACAL), and health services' managers. Meanwhile, no consistent evidence can be found in international peered review journals regarding the impact of accreditation on healthcare safety.

Taking these points into account, my proposed summer project is a policy analysis concerning the understanding of health services accreditation, its usefulness in improving safety, and the possibility of its implementation nationally in Uruguay, in public and private hospitals. To accomplish this, a comprehensive literature review focused on international experiences and its evaluations, will be performed. This will be complemented with interviews with Uruguayan stakeholders occupying roles in the MoH, the INACAL, healthcare providers and user representatives.

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2 CONTENTS

3 RATIONALE FOR THE RESEARCH

3.1 POLICY PROBLEM

Uruguay is undergoing since 2005 a very important reform in the National Health System, where significant changes have been done in the financing, the management and in the healthcare provision model. As part of this change, some stakeholders involved in the Ministry of Health (MoH), in public providers, and in the National Institute of Quality, are proposing changes to improve the quality of care, including health services accreditation (HSA). However, no analysis was made public on the feasibility of the strategy and on the impact on patients´ safety outcomes.

3.2 BACKGROUND

Since the reform of the National Health System in Uruguay, significant efforts have been put in the development of national policies to improve the quality of care (effectiveness, safety, humanity and equity).[1] However, the provision of safer care was particularly emphasised through the development both of national and institutional strategies. After a regulation passed by the Ministry of Health (MoH) in the year 2008, the creation of institutional patients' safety committees was compulsory for every provider.[2] These committees must create their own policies, and follow national guidelines provided by the National Committee for Patient's Safety and Errors in Medicine.

Several national guidelines have been proposed in the last years, as presented by the responsible of the National Safety Programme in April 2015. These are focused in disruptive behaviours and behavioural agreements, rational and safe drug use, staff training in patients´ safety and culture development.[3]

3.3 CURRENT RELEVANCE

Although the health services accreditation strategy was not covered in the mentioned presentation, in a previous presentation done by a high ranking MoH civil servant in 2010, it was highlighted as an opportunity to develop safer care. In this presentation, performed in the National Institute of Quality (INACAL), the accreditation is acknowledged as one of the main strategies as per the Mission of the DIGESA, the national health authority.[4]

More recently, in the last quarter of 2015, the need of health services accreditation as a patient safety strategy was addressed in several opportunities. To start with, the need of such strategies was remarked in a series of events organised by the National Institute of Quality and the main public healthcare provider (ASSE).[5] In December, the responsible of the National Safety Programme, referring to an adverse event in a public hospital, mentioned the measures proposed by the Joint Commission on Accreditation of Healthcare Organisations as way to prevent such situations happening again.[6] Finally, towards the end of December, the Minister of Health presented the 2020´s National Health Objectives. In the Objective 4.6, it is specified the need for the construction an accreditation system for healthcare services in Best Practices.[7]

3.4 POLICY INFORMATION MISSING

No evidence has been found of analysis on this subject in Uruguay, after a literature review both in peer-reviewed journals and in grey literature. For the peer-reviewed journals search, LILACS, Scielo and Pubmed were used, with the terms *Uruguay OR Montevideo AND Accreditation OR Acreditacion*. For the search for grey literature, two methods were used: Google search engine, using the terms *Uruguay OR Montevideo AND Accreditation OR Acreditacion AND Health OR Salud OR Services OR Servicios OR Care*; and the online library of the Universidad de la República (University of the Republic - Uruguay) with the terms *Acreditacion AND Salud*.

The mentioned 2020's National Health Objective 4.6 mentions explicitly that this point is under construction, so no specifications of the accreditation process are public yet.

The project may consequently, be useful as a tool for the decision of the appropriateness of the health services accreditation as a safety of care strategy in Uruguay, and the consideration of possible weaknesses to take into account if it was to be put into practice.

3.5 RESEARCH QUESTIONS

- What is the impact on patients' safety of health services accreditation strategies as per international experiences and evaluations?
- What is the perception among Uruguayan stakeholders, of health services accreditation strategies in terms of usefulness to improve safety, and feasibility to implement in public and private services?

4 OBJECTIVES

4.1 GENERAL OBJECTIVE

Analyse the benefits and drawbacks of accreditation strategies for hospitals regarding the impact on patient safety. Understand the perspectives of Uruguayan stakeholders interested in the subject because of their role as academics, policy makers or their role in health services providers.

4.2 SPECIFIC OBJECTIVES

1. Review the impact of accreditation of hospitals, on patient safety.
2. Understand the perception of hospitals accreditation and its role as a strategy to improve safety, among Uruguayan stakeholders.
3. Understand the perception of benefits and drawbacks of implementing hospital accreditation in Uruguay, among Uruguayan stakeholders.

5 RESEARCH METHODS

5.1 HYPOTHESIS

Accreditation is a useful method of improving the safety of care and is acceptable in Uruguay.

5.2 LITERATURE REVIEW

5.2.1 Search strategy

The databases Pubmed, Web of Science, Scopus, Lilacs, Scielo, and HIMIC will be used to identify for peer-reviewed articles.

The terms of the research question will be used as the basis for the search terms, which will include variations and synonyms. These main keywords will be Accreditation, Health Services, Hospital, Safety, and Quality. The same terms will be used combined by Boolean operators "AND" and "OR" in the different databases.

From the selected articles, with a snowballing procedure, relevant references will be analysed for inclusion and exclusion criteria.

5.2.2 Inclusion criteria

i. Studies analysing hospital accreditation processes, focusing on the assessment or evaluations of the strategies.
ii. Studies covering patients' safety elements.
iii. Papers in English and Spanish will be included.
iv. Studies published between January 1980 and April 2016.
v. Articles or reviews

5.2.3 Exclusion criteria

i. Accreditation of individuals or professionals in health services, or of teaching and educational techniques in health services.
ii. Accreditation of technological elements or non-clinical areas in hospitals.
iii. Other languages than English and Spanish.
iv. Opinion papers, letters, lecture notes, conference proceedings and papers with no references.

5.2.4 Summarising and interpreting findings

The articles which fit the criteria will be consolidated through the main attributes or themes of the analysis, in order to compare against similar papers. These attributes will then be used to analyse the data obtained from the stakeholders' interviews.

5.3 STAKEHOLDER INTERVIEWS

5.3.1 Sampling strategy

A purposive sampling process will be carried out, with a theoretical approach. Political important cases will be chosen, representing different points of views on the topic. The theoretical approach is

considered to include views not previously considered when designing the sampling method.[8, 9, 10] Taking into account the aforementioned, interviewees will be included from the following areas:

i. Decision-makers in patient safety and quality of care policies, in the following roles: professional, academic, political.
ii. Public and private health services decision-makers.
iii. User representatives.
iv. Senior clinician.

The interviewees will be recruited with the help of a local liaison, Prof Dr Marisa Buglioli, Director of the Preventive and Social Medicine Department of the Faculty of Medicine of the Universidad de la Republica (Uruguay). Prof Buglioli is a high ranked civil servant at the MoH and was deeply involved with the health system reform. She agreed to put me in contact with the different stakeholders mapped.

Some of the possible interviewees targeted, form part of the following organisations: National Patient Safety Committee; Department of Quality and Patient Safety of the MoH; National Infections Committee; members of management teams at the public provider (ASSE), and at private providers (AEPSM, MU, HB, MP); INACAL and Faculty of Medicine.

Eight to eleven interviews will be held among the mentioned organisations, actively including people representing both opinions (for and against HSA). For every planned stakeholder to be interviewed, there are one or more alternatives mapped in case the first option does not agree to participate.

5.3.2 Interview planning

Semistructured, 30 to 45 minutes' interviews will be carried out via Skype, in Spanish with the mentioned stakeholders. The interviews will be recorded with iFree Skype Recording in mp3 format.[11] A backup recording system will be implemented through the use of a digital audio recorder.

A set of guiding questions (Appendix 1) will be used in every interview, being possible to emphasise depending on each case in different aspects. This set of questions and the interview process will be piloted before the beginning the data collection. To minimise bias, both the questionnaire and the interviews will be analysed after each session, exploring flaws that affect the flow of the interviews. As well as this, although the names of the interviewees will be listed, the data obtained in all interviews will be anonymised, making it impossible to identify the stakeholders' views in the report.

5.3.3 Ethics

Although the study does not hold ethical considerations, written informed consent forms (ICF) in both English and Spanish (Appendices 2 and 3) will be sent by email to the interviewees. It will be queried in a first contact if the ICF is understood and if so, a signed electronic version (scanned or digital signature) should be sent to the researcher. Before the beginning of the interview, it will be asked if the consent is still valid. The research proposal and ICF were reviewed and approved by a local ethics committee.

5.3.4 Data analysis

The interviews will be analysed, detecting codes and themes within each interview. These will be compared with the other interviews, looking for concordant and conflicting elements, in order to construct conceptual networks.[12] As well as this, the networks and elements detected in the interviews will be compared to the findings in the literature review.

The data will be stored on a local hard drive in a password-protected laptop, and backed up in encrypted files, in the H: drive at LSHTM's servers, through Filr App. The data processed will be translated into English for the report.

6 POLICY RELEVANCE

Apart from the mentioned national relevance in Uruguay of the subject HSA, some other elements make this proposed research project relevant. To start with, relatively little evidence to support its effectiveness is available as per recent systematic reviews.[13] As well as this, it has been reported in other reviews focusing on the efficiency, due to methodological problems in the research no conclusions can be taken in this aspect.[14] At the same time, some positive elements have been associated with HSA, including promoting change in organisations' culture and in the professional development of health professionals.[15]

With a political sampling, the possibility of acceptance of the consideration among decision makers of the report broadens, and results as more influential.[10]

The project report, along with the Spanish version of the executive summary, is expected to be distributed to key decision-makers both at the public healthcare provider and the MoH. This will have the intention of explaining the current knowledge regarding HSA in the international literature, and the understanding of Uruguayan stakeholders who will are involved with the patients' safety policies.

7 PERSONAL EXPERIENCE

The current research project is performed as part of the London School of Hygiene and Tropical Medicine's assessments for the Master degree course in Public Health (Health Services Management stream).

[redacted]

The current research project is being supervised by Prof. Dr Nick Black, Professor of Health Services Research at the London School of Hygiene and Tropical Medicine. Co-editor of Journal of Health Services Research & Policy, his research is focused on the assessment of the quality of health care and the performance of health care providers, in the fields of surgery, critical care and dementia care.[17]

7.1 CONTACT INFORMATION

Student details	[redacted]
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8 TIMELINE AND BUDGET

8.1 TIMELINE

- Stage 1. Development of research proposal
- Stage 2. Ethics clearance in LSHTM Ethics Committee and in Uruguayan Ethics Committee.
- Stage 3. Approval of research Project.
- Stage 4. Data collection: literature review.
- Stage 5. Data collection: interviews.
- Stage 6. Data analysis.
- Stage 7. Writing Project report.
- Stage 8. Submission of Project report.

	March/16	April/16	May/16	June/16	July/16	August/16	September/16
Stage 1							
Stage 2							
Stage 3							
Stage 4							
Stage 5							
Stage 6							
Stage 7							
Stage 8							07-SEP-2016

8.2 BUDGET

No significant expenditure is expected. Any expenses will be covered by the investigator.

9 RESEARCH PROJECT PROPOSAL REVIEW

V1.0: Not applicable

V1.1: Section 5.3.1 – Sampling method changes from 'political' to purposive.

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11 APPENDICES

11.1 APPENDIX 1 – INTERVIEW QUESTIONS

What do you understand by the term health services accreditation?

What is your belief about its usefulness?

How do you believe it could influence patient safety in Uruguay?

What do you think are the benefits and downsides of applying this strategy in Uruguay?

11.2 Appendix 2 – Informed consent form – Information Sheet

LONDON SCHOOL of HYGIENE & TROPICAL MEDICINE

Informed Consent Form for MSc PH (HSM) Research Project

Research project title *"Understanding health services accreditation as a strategy for safer healthcare: A stakeholder analysis in Uruguay"*.

Information Sheet Version	*Date of Version*
1.0	*01/04/2016*

1 Information Sheet (English version)

1.1 Introduction

My name is [redacted] currently s[redacted] am pursuing as well a Master's degree in Public Health (Health Services Management stream) at the London School of Hygiene and Tropical Medicine (LSHTM), through the Chevening Scholarship. As part of the Master's course I am carrying out a research project, which I would like you to participate in.

1.2 Research project

I want to explore the perception of health services accreditation, and particularly hospital accreditation, as a strategy for safer healthcare, among Uruguayan stakeholders. These will include members in the National Patient Safety Committee, Department of Quality and Patient Safety of the MoH, National Infections Committee, members of management teams at the public provider (ASSE), and at private providers (AFPSM, MU, HB, MP), and INACAL and Faculty of Medicine.

The perceptions gathered from the interviews, will help to analyse the Uruguayan stakeholder's perspectives regarding usefulness of the tool and feasibility of its implementation. This information will be supplemented with information gathered from an extensive literature review on the topic.

1.3 Type of Research Intervention

The research will involve your participation in a 30 to 45 minutes, semi-structured interview, regarding your perceptions of health services accreditation, and specifically your perceptions of health services accreditations as a patient safety strategy in Uruguay. A set of questions will be asked, but there will be place to explore other questions not included in the set.

1.4 Participant Selection

I want to invite you to participate in this research because of your role in policy-making in health care, and/or as a decision-maker in health services. I think that your experience, knowledge and views on the

topic, gained through your role, would be an important contribution to the help in the understanding of this question.

1.5 Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not.

1.6 Procedure

We are inviting you to take part in this research project. If you accept, you will be asked to participate in a 30 to 45 minutes' interview, via Skype or similar, where I will ask you a set of questions to understand your opinion on the mentioned topic. If you wish not to answer any question, or temporarily or permanently suspend the interview, you may do so. As well as this, if during the interview you wish to withdraw your consent and not participate at all in the research, you may do so.

The interview will be recorded, but it will be confidential, and no one else except me [redacted] will have access to the information documented during your interview. No-one will be identified by name on the recordings, which will be kept securely in digital formats, password protected. The recordings will be stored as per the LSHTM's Research Data Management Policy (2014).

1.7 Benefits and Risks

There are no benefits expected in taking part of the research. However, the participation will help us understand the current perceptions of stakeholders from different areas in the Uruguayan Health System towards health services accreditation.

There is a risk that you feel that a particular question might expose you in any way (e.g. professional, personal). Please in such case, let know the interviewer. You do not have to answer questions with which you are not comfortable.

1.8 Reimbursements

No incentive will be provided to participate in the research.

1.9 Sharing the Results

The research project report will be published in the LSHTM for public access. As well as this, participants of the research and other stakeholders in Uruguay might receive copies of the report if requested.

1.10 Right to Refuse or Withdraw

You may not participate in the research if you want so, and you may stop participating or withdraw your consent at any point during the process.

1.11 Who to Contact

If you have any question regarding the project please contact the researcher. In case you would rather contact someone independent, you can communicate with the Local Ethics Committee.

Researcher	[redacted]
Local Ethics Committee	Comité de Ética de la Fundación Salud Dr Augusto Turenne President: Dr Gustavo Arroyo, PhD Email: Address: Tel.:

This proposal has been reviewed and approved by Comité de Ética de la Fundación Salud Dr Augusto Turenne, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact _____.)

2 HOJA DE INFORMACIÓN (VERSIÓN EN ESPAÑOL)

2.1 INTRODUCCIÓN

Mi nombre es [redacted] estoy actualmente realizando m[redacted]. Estoy realizando también una Maestría en Salud Pública (con foco en la Administración de Servicios de Salud) en la London School of Hygiene and Tropical Medicine (LSHTM), a través de la Beca Chevening. Como parte del curso del Maestría, estoy llevando a cabo un proyecto de investigación, del cual me gustaría que participe.

2.2 PROYECTO DE INVESTIGACIÓN

Quiero explorar la percepción entre actores uruguayos, de la acreditación de los servicios de salud, y en especial de la acreditación de hospitales, como estrategia para lograr una atención sanitaria más segura. Se incluirán miembros del Comisión Nacional de Seguridad del Paciente y Prevención del Error en Medicina, Departamento de Calidad y Seguridad del Paciente del Ministerio de Salud Pública, Comité Nacional de Infecciones, miembros de los equipos de gestión en el proveedor público (ASSE), y en proveedores privados (AEPSM, MU, HB, MP) y INACAL y la Facultad de Medicina.

Las percepciones recogidas en las entrevistas, ayudarán a analizar las perspectivas de las partes interesadas en Uruguay, con respecto a la utilidad de la herramienta y la viabilidad de su aplicación. Esta información se complementará con información obtenida de una extensa revisión de la literatura sobre el tema.

2.3 TIPO DE INTERVENCIÓN INVESTIGACIÓN

La investigación incluirá su participación a través de una entrevista semiestructurada, de unos 30 a 45 minutos, dónde se cubrirán la percepción de la acreditación de servicios de salud, y en concreto su

percepción de la acreditación de servicios de salud como estrategia de seguridad del paciente en Uruguay [redacted] para explorar otras cuestiones, no incluidas en [redacted]

2.4 La selección de los participantes

Lo quiero invitar a participar en esta investigación debido a su papel en la formulación de políticas de salud, y/o como un tomador de decisiones en servicios de salud. Creo que su experiencia, conocimientos y puntos de vista sobre el tema, adquirida a través de su rol, serán una importante contribución en la comprensión de esta cuestión.

2.5 La participación voluntaria

Su participación en esta investigación es completamente voluntaria. Es su decisión si desea participar o no.

2.6 Procedimiento

Le estamos invitando a participar en este proyecto de investigación. Si acepta, se le pedirá participar en una entrevista de unos 30 a 45 minutos, a través de Skype o similar, donde voy a hacerle una serie de preguntas para comprender su opinión sobre el tema mencionado. Si no desea responder a cualquier pregunta, o suspender temporal o permanentemente la entrevista, puede hacerlo. Si durante la entrevista desea retirar su consentimiento y no participar en absoluto en [redacted], puede hacerlo.

La entrevista será grabada, pero será confidencial, y nadie excepto yo [redacted] tendrá acceso a la información documentada durante su entrevista. Nadie será identificado por su nombre en las grabaciones, que se mantendrán de forma segura en formato digitales, protegido por contraseña. Las grabaciones se almacenarán de acuerdo con la Política de Gestión de Datos de Investigación de la LSHTM (2014).

2.7 Beneficios y riesgos

No habrá beneficio personal alguno por participar en la investigación. Sin embargo, la participación nos ayudará a entender las percepciones actuales de los actores de diferentes áreas en el Sistema de Salud de Uruguay hacia la acreditación de los servicios de salud.

Existe el riesgo de que sienta que una pregunta en particular podría exponerlo de alguna manera (por ejemplo, profesional, personal). Por favor, en tal caso, hágale saber al entrevistador. Usted puede decidir no responder aquellas preguntas que no lo hagan sentir cómodo.

2.8 Compensación

No se proporcionará ningún incentivo o compensación para participar en la investigación.

2.9 Diseminación de los resultados

El informe del proyecto de investigación será publicado en la LSHTM para el acceso público. Además de esto, los participantes de la investigación y otras partes interesadas en Uruguay podrán recibir copias del informe si así se solicita

2.10 Derecho a no participar o retirar el consentimiento

Usted puede decidir no participar en la investigación, así como dejar de participar o retirar el consentimiento en cualquier momento del proceso.

2.11 A quién contactar

Si usted tiene alguna pregunta sobre el proyecto, por favor póngase en contacto con el investigador. En caso de que prefiera contactarse con alguien independiente, usted puede comunicarse con el comité de ética local.

Investigador	[redacted]
Comité de Ética Local	Comité de Ética de la Fundación Salud Dr Augusto Turenne Presidente: Dr Gustavo Arroyo, PhD Email: Dir.: Tel.:

Esta propuesta ha sido revisado y aprobado por el Comité de Ética de la Fundación Salud Dr. Augusto Turenne, que es un comité cuya tarea es asegurarse de que los participantes en la investigación están protegidos de cualquier daño. Si desea conocer algo más acerca de la IRB, el contacto _____.)

3 Information sheet reviews

V1.0: Not applicable

11.3 APPENDIX 3 – INFORMED CONSENT FORM – CERTIFICATE OF CONSENT

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

Informed Consent Form for MSc PH (HSM) Research Project

Research project title *"Understanding health services accreditation as a strategy for safer healthcare: A stakeholder analysis in Uruguay"*.

Certificate of Consent Version	*Date of Version*
1.0	*01/04/2016*

1 CERTIFICATE OF CONSENT / *FORMULARIO DE CONSENTIMIENTO*

I have been invited to participate in a research project to understand the perception of health services accreditation in Uruguayan stakeholders as a patient safety strategy.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

He sido invitada a participar en un proyecto de investigación para entender la percepción de los servicios de acreditación de la salud, entre actores uruguayos, como una estrategia para la seguridad del paciente.

He leído la información anterior, o me la han leído a mí. He tenido la oportunidad de hacer preguntas al respecto y cualquier pregunta que me han hecho han sido respondidas satisfactoriamente. Doy mi consentimiento voluntariamente a ser un participante en este estudio.

Print Name of Participant *Nombre del Participante*	
Signature of Participant *Firma del Participante*	
Date / *Fecha (DD/MM/AAAA)*	

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Confirmo que el participante tuvo la oportunidad de hacer preguntas acerca del estudio, y todas las preguntas formuladas por el participante han sido contestadas correctamente, de la mejor manera posible. Confirmo que el individuo no ha sido obligado a dar su consentimiento y el consentimiento ha sido dado libremente y voluntariamente.

Page 1 of 2

Print Name of Researcher *Nombre del investigador*	
Signature of Researcher *Firma del investigador*	
Date / *Fecha (DD/MM/AAAA)*	

A copy of this ICF has been provided to the participant. / *Una copia de esta ICF se ha proporcionado al participante.*

2 CERTIFICATE OF CONSENT REVIEW

V1.0: Not applicable

11.2 APPENDIX LOCAL ETHICS APPROVAL: ORIGINAL AND TRANSLATION

FUNDACIÓN SALUD "DR. AUGUSTO TURENNE"

Montevideo, 01 de mayo 2016

Sres. London School of Hygiene & Tropical Medicine

Con respecto a la Propuesta de Investigación – Maestría en Salud Pública (orientado a Administración de Servicios de Salud) - Versión de la propuesta de investigación / Fechas 03/04/2016 y 05/04/2016

Con Título del proyecto de investigación "Comprensión de la acreditación de los servicios de salud como estrategia para una atención sanitaria más segura: Un análisis de las partes interesadas en el Uruguay" del [redacted]

El Comité de Ética Independiente en Investigación Clínica de la Fundación Salud "Augusto Turenne" del Sindicato Médico del Uruguay, declara: **que dadas las características del mencionado protocolo, por la regulación del Uruguay no requiere ser analizado por un Comité de Ética.**

Sin más saludamos atentamente

Dr. Gustavo Arroyo, Presidente

Dr. Gabriel Antoniol, Secretario

Dr. Alfredo Toledo, Director Fundación Salud

Montevideo, May 1, 2016

Dear Sirs. at London School of Hygiene & Tropical Medicine

With regard to the Research Proposal - Master of Public Health (Health Services Management stream) - Revision of the research proposal / Dates 03/04/2016 and 05/04/2016

With title of the research project "Understanding health services accreditation as a strategy for safer healthcare: A stakeholder analysis in Uruguay" by [redacted].

The Independent Ethics Committee on Clinical Research of the *Fundación Salud "Augusto Turenne"* from the *Sindicato Médico del Uruguay*, declares that given the characteristics of the mentioned protocol, Uruguay regulation need not the protocol to be examined by an ethics committee.

Yours sincerely

Dr. Gustavo Arroyo, President

Dr. Gabriel Antoniol, Secretary

Dr. Alfredo Toledo, Director *Fundación Salud*

11.3 APPENDIX SEARCH STRATEGY

11.3.1 Pubmed search

((("health service/hospital" OR Hospital OR "hospital")) AND ((Patient safety) OR "patient safety")) AND ((Accreditation) OR "accreditation")

Timespan: 1980/01/01-2016/04/01

Results: 634 results

11.3.2 Scopus

(TITLE-ABS-KEY (accreditation) AND TITLE-ABS-KEY (patient safety) AND (TITLE-ABS-KEY (hospital) OR TITLE-ABS-KEY (health service))) AND DOCTYPE (ar OR re) AND PUBYEAR > 1979 AND (LIMIT-TO (LANGUAGE , "English") OR LIMIT-TO (LANGUAGE , "Spanish")) AND (LIMIT-TO (DOCTYPE , "ar") OR LIMIT-TO (DOCTYPE , "re"))

Results: 993

11.3.3 LILACS

Hospital [Words] and Accreditation [Words] and Patient Safety [Words]

Results: 5

11.3.4 Web of Science

(TS=((Health Service OR Hospital) AND (Accreditation) AND (Patient Safety))) AND DOCUMENT TYPES: (Article)

Timespan: 1980-2016.

Results: 282

11.3.5 HMIC

((Health Services or Hospital) and Accreditation and Patient Safety).mp. [mp=title, other title, abstract, heading words]

limit 1 to yr="1980 - 2016"

Results: 30

11.3.6 Scielo

(Health Services OR Hospital) AND (Patient Safety) AND (Accreditation)

Results: 6

11.3.7 Exclusion criteria search

- ACGME
- duty hour
- work hour
- primary care
- general practice
- family medicine
- >2016/04/30

11.4 APPENDIX STAKEHOLDERS INTERVIEWED

- Dr. Homero Bagnulo, specialist in Internal Medicine, Intensive Medicine and Infectology
  President of Honorary Management Committee at FNR (2000-2005)
  President of Hospital-Acquired Infections Assessing Commission at MoH - Uruguay (1994-2013)
  President of Patient Safety and Prevention of the Medical Error at MoH - Uruguay (2006-2012)

- Dr. Marcelo Barbatto, specialist in Intensive Medicine
  Director of the DECASEPA – MoH - Uruguay
  Director of Intensive Unit at Hospital Maciel - ASSE

- Dr. Santiago Elverdín, specialist in Health Services Management. Diploma in Public Health and Health Technology Assessment
  Manager at Management and Health Services Control of Banco de Prevision Social
  Assisting Professor in Health Services Management Unit of the Department of Preventive Health – School of Medicine – Universidad de la República – Uruguay

- Lic Rocío González, nurse specialized in intermediate and intensive care and cardiac surgery. Diploma in Quality Management in Health Services.
  Subcoordinator of the Uruguayan Nursing Network for Patient Safety
  Assisting Professor in Health Services Management Unit – School of Nursing – Universidad de la República – Uruguay
  Coordinator of COSEPA – CCOU

- Mr. Wilfredo Lopez, users' representative
  Director at ASSE (2008-2015)

- Dr. Amparo Paulós, specialist in Health Services Management, Diploma in Health Services Management.
  Deputy General Manager and Technical Director (in functions) – ASSE
  Auditor for Licensing of Health Services Division – MoH – Uruguay
  Lecturer Diploma in Health Services Management – CLAEH – Uruguay (2013-2015)

- Dr. Ana María Rodriguez, specialist in Intensive Medicine
  Associate Professor in Department of Anesthesiology – School of Medicine – Universidad de la República – Uruguay
  Member of COSEPA at Asociación Española Primera en Socorros Mutuos

- Dr. José Luis Rodríguez Bossi, specialist in Intensive Medicine and MSc in Health Services Management. Diploma in Quality in Health Services and in Management of Patient Safety
  Responsible for Quality Management – SUAT (1996-1998)
  Responsible for Accreditation of hospitals – CCOU (2006-2010)
  Member of Health Committee – INACAL (starting 2011)
  Lecturer of "Quality in Health Services" – Universidad Católica del Uruguay

- Dr. Ana Sollazzo, specialist in Health Services Management, Diploma in Public Health
  Associate Professor in Health Services Management Unit of the Department of Preventive Health – School of Medicine – Universidad de la República – Uruguay
  Academic Coordinator of Diploma in Health Services Management - School of Medicine and School of Economic and Management Sciences – Universidad de la República – Uruguay
  Experience in Health Services and Clinical Management, and Quality Management.

11.5 APPENDIX GUIDE FOR INTERVIEW – QUESTIONS

11.5.1 Spanish version

- ¿Qué entiende por acreditación de los servicios de salud?
- ¿Cuál es su opinión acerca de la utilidad de la estrategia de acreditación en servicios de salud?
- ¿Cómo cree que podría influir la acreditación en la seguridad del paciente en Uruguay?
- ¿Qué cree usted que son las ventajas y desventajas de la aplicación de esta estrategia en Uruguay?

11.5.2 English translation

- What do you understand by health services accreditation?
- What do you think is the use of the health services accreditation strategy?
- How do you believe that the accreditation could influence patient safety in Uruguay?
- Which do you believe are the advantages and disadvantages of applying the strategy in Uruguay?

11.6 APPENDIX CRITICAL APPRAISAL FOR SYSTEMATIC REVIEWS: AMSTAR FRAMEWORK

	Al-Awa et.al. [41]	Alkhenizan and Shaw [17]	Brubakk et.al. [42]	Greenfield and Braithwaite [39]	Hinchcliff et.al. [43]	Ng et.al. [44]	Scott [45]	Tabrizi el.al. [46]
1. Was an 'a priori' design provided?	No	No	No	Yes	No	No	No	No
2. Was there duplicate study selection and data extraction?	No	No	Yes	No	Yes	No	No	Yes
3. Was a comprehensive literature search performed?	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?	No	No	Yes	Yes	Yes	No	No	Yes
5. Was a list of studies (included and excluded) provided?	No	No	Yes	No	No	No	No	No
6. Were the characteristics of the included studies provided?	No	Yes	Yes	No	Yes	Yes	No	Yes
7. Was the scientific quality of the included studies assessed and documented?	No	No	Yes	No	Yes	CA	CA	No
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?	No	No	Yes	Yes	Yes	Yes	Yes	No
9. Were the methods used to combine the findings of studies appropriate?	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
10. Was the likelihood of publication bias assessed?	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
11. Was the conflict of interest included?	No	Yes	Yes	Yes	Yes	Yes	No	Yes

CA: Cannot answer; N/A: Not applicable

11.7 APPENDIX EXTRACTION SHEET

The following table presents direct quotes from the included reviews, used to build the narrative review.

Review	Year	Input	Processes	Outcomes
Alkhenizan and Shaw[17]	2012	• **Hurst, 1997** - Community hospital managers were committed to TSHAS. Staffs were also keen to see the program continue to evolve. Majority of managers were happy with the accreditation program. They felt that the accreditation program affirm quality of services, spread good practices and involve staffs at all levels. [58] • **Kreig, 1996** - A large majority of respondents agreed that the accreditation program had been of significant benefit to their organisation. The benefits covered improving communication, commitment to best practice, information available for evaluation activities and quality care activities, improved structure for quality, greater focus on consumers, supporting planned change, and, staff management and development.[50]	• **Pomey et.al. 2004** - Accreditation preparations represented an important stage in the hospital's evolution according to 82.7% of the non-caregivers, 77.4 percent of the caregivers, 71.9% of the administrative staff and 65 percent of the medics. Moreover, 67% also considered that the process touched all of the hospital's personnel. The accreditation preparation process was experienced essentially as "bureaucratic" by 80.9% of the caregivers, 77.3% of the administrative staff, 76.1% of the non-caregivers and 65.2 % of the medics. The process was qualified as being "rigid" (55.3%), "participatory" (52.5%), "consensual" (46.4%) and finally"concrete" (45.4%). [47] • **Hurst, 1997** - Community hospital managers were committed to TSHAS. Staffs were also keen to see the program continue to evolve. Majority of managers were happy with the accreditation program. They felt that the accreditation program affirm quality of services, spread good practices and involve staffs at all levels. [58] • **Kreig, 1996** - A large majority of respondents agreed that the accreditation program had been of significant benefit to their organisation. The benefits covered improving communication, commitment to best practice, information available for evaluation activities and quality care activities, improved structure for quality, greater focus on consumers, supporting	• **Salmon, 2003** – In the large randomized controlled trial, the (QAP) nurses' overall perceptions of care (*n* = 1048), at the accredited hospitals increased significantly (59% to 61%), compared to the control hospitals (declined from 61% to 57%). [68] • **El-Jardali, et.al., 2008** – In a large rigorous survey conducted in Lebanon (*n* = 1048), nurses perceived a significant improvement of results in quality in hospitals as an outcome of accreditation. [69] • **Pomey et.al. 2004** - Accreditation preparations represented an important stage in the hospital's evolution according to 82.7% of the non-caregivers, 77.4 percent of the caregivers, 71.9% of the administrative staff and 65 percent of the medics. Moreover, 67% also considered that the process touched all of the hospital's personnel. The accreditation preparation process was experienced essentially as "bureaucratic" by 80.9% of the caregivers, 77.3% of the administrative staff, 76.1% of the non-caregivers and 65.2 % of the medics. The process was qualified as being "rigid" (55.3%), "participatory" (52.5%), "consensual" (46.4%) and finally "concrete" (45.4%). [47] • **Nandraj et.al., 2001** - There was an overwhelming agreement on the need for accreditation. They felt that accreditation should cover governmental hospitals, and hospitals should be graded in an accreditation scale. There was a high level of support for the classical features of

Review	Year	Input	Processes	Outcomes
			planned change, and, staff management and development.[50]	accreditation including: voluntary participation, a standards based approach to assess hospital performance, periodic external assessment by health professionals, and the introduction of quality assurance measures to assist hospitals in meeting these standards. Hospital owners, professional bodies and government officials all saw potential - though different - advantages in accreditation: for owners and professionals it could give them a competitive edge in a crowded market, while government officials viewed accreditation as a mean to increase their influence over an unregulated private market. Areas of disagreement emerged; for example, hospital owners were opposed to government or third party payment bodies having a dominant role in running an accreditation system.[70] • **Pongpirul et.al., 2006** - More than 90% of both groups thought that there had been problems in the items such as 'quality improvement (QI) activities' and 'integration and utilization of information'. The items considered by health care professionals as major obstacles included 'adequacy of staff' (34.6%) and 'integration and utilization of information' (26.6%), for example. For surveyors, 'integration and utilization of information' was ranked highest as presenting a major obstacle (43.9%), followed by 'discharge and referral process' (31.7%) and 'medical recording process' (29.3%). The rank orders for the 24 items as problems and major obstacles were similar in both groups (Spearman's rank correlation 0.436, *P* = 0.033 and 0.583, *P* = 0.003, respectively). All items were identified by most health care professionals (range 72.9–94.9%) as problems for hospital QI. Of

Review	Year	Input	Processes	Outcomes
				these, >90% thought that there had been problems in the items 'QI activities'(94.9%), 'integration and utilization of information' (93.5%), 'promotion of staff participation' (92.6%), communication among departments' (92.3%), 'clinical practice guideline development' (91.3%), and 'efficiency of maintenance system' (90.2%). Items considered by health care professionals as major obstacles to hospital QI included 'adequacy of staff' (34.6%), 'integration and utilization of information' (26.6%), 'promotion of staff participation' (24.0%), 'budget for QI activities' (21.4%), and 'multidisciplinary care' (21.3%). [71] • **Brasure, et.al., 2000** - More than 70 percent of respondents did not think that the perceived benefits from accreditation worth its cost. More than 70 percent of respondents did not think that the perceived benefits from accreditation worth the demands on staff time. Nearly 80 percent of the respondents listed cost as a reason why they did not participate. [72] • **Kreig, 1996** - A large majority of respondents agreed that the accreditation program had been of significant benefit to their organisation. The benefits covered improving communication, commitment to best practice, information available for evaluation activities and quality care activities, improved structure for quality, greater focus on consumers, supporting planned change, and, staff management and development. [50] • **Fairbrother and Gleeson, 2000** – Significant levels of negative feedback received; principal concerns related to perceptions that the process is unwieldy and it offers little value for patient care delivery for the resources required. [73]

Review	Year	Input	Processes	Outcomes
Brubakk et.al.[42]	2015		• **Group MK, 2010** - The Matrix Knowledge group searched the literature in 2010 and found 56 articles that addressed the impact of hospital accreditation [16]. The vast majority of these studies used surveys with standardized questionnaires, and reported staff, patient and stakeholders' perceptions of impact. Overall they reported a positive impact of accreditation on hospital and professional practice. Only the South African cluster-randomized controlled trial was consistent with the inclusion criteria of our study. [59]	
Greenfield and Braithwaite[39]	2008	• **Pomey, 2004** – Preparations for accreditation provided hospital staff with an opportunity to reflect on the operation of the organization. At the same time, staff experienced the accreditation process as bureaucratic.[47] • **Duckett, 1983** – Accredited hospitals could be differentiated by significant changes in six areas: administration and management, medical staff organization, review systems, organization of nursing services, physical facility and safety, hospital role definition and planning. Most affected were nursing organization and physical facilities and safety; least change was found in areas most directly associated with medical staff [49]. • **Daucourt and Michel, 2003** – The study showed wide heterogeneity in the summaries on accreditation and in accreditation agency decision-making for different size and status hospitals. Also provided initial insight into common quality defects and priorities for hospitals. [48] • **Rockwell at.al., 1993** – Case study of a neuropsychiatric hospital which questioned whether the quality of care was improved	• **Gough and Reynolds, 2000** – Most laboratories thought accreditation had resulted in better laboratory performance with more documentation and better health and safety training procedures. A significant proportion of participants (managers/clinicians) considered accreditation to be overly bureaucratic, inefficient and expensive. A concern that accreditation covered the domains of other regulatory bodies was also expressed. [61] • **Verstraete et.al., 1998** – A small majority of participants (medical technologists) preferred working in an accredited laboratory. They experienced that accreditation improved the traceability of work and improved the procedures. A large majority of participants considered that accreditation increased their workload. Two laboratories did not think accreditation improved the quality of results. Concerns were accreditation increased paperwork, decreased adaptability and perception that attention directed to processes rather than quality. [62] • **Pomey, 2004** – Preparations for accreditation provided hospital staff with	• **Gough and Reynolds, 2000** – Most laboratories thought accreditation had resulted in better laboratory performance with more documentation and better health and safety training procedures. A significant proportion of participants (managers/clinicians) considered accreditation to be overly bureaucratic, inefficient and expensive. A concern that accreditation covered the domains of other regulatory bodies was also expressed. [61] • **Pomey, 2004** – Preparations for accreditation provided hospital staff with an opportunity to reflect on the operation of the organization. At the same time, staff experienced the accreditation process as bureaucratic.[47] • **Simons et.al., 2002** – Development of a trauma program and commitment to meeting national guidelines through the accreditation process appeared to be associated with improved outcome after injury. [74] • **Sheahan, 1999** – Described a program, developed to meet an accreditation standard, that helped focus a large acute private hospital on patients. [75]

Review	Year	Input	Processes	Outcomes
		by the accreditation process and the costs constitute an appropriate use of resources. [54] • **Zarkin et.al., 2006** – Methadone treatment sites faced similar accreditation costs regardless of characteristics such as size and location. Rural and smaller sites incurred a greater burden from accreditation. There was no significance difference in cost for a site regardless of accreditation outcome; nor did previous accreditation affect the cost. [55] • **Mihalik et.al., 2003** – A study of expenditures in accreditation argued that the costs should be seen as an essential investment and demonstration of commitment to quality. [53]	an opportunity to reflect on the operation of the organization. At the same time, staff experienced the accreditation process as bureaucratic.[47] • **Juul et.al., 2005** – Hospital combining both a clinical trial and participation in an international accreditation program led to a significant improvement of both dissemination and quality of guidelines on perioperative diabetic care. [63] • **Grasso et.al., 2005** – During an accreditation survey, experienced surveyors failed to detect an error-prone medication usage system (shown by an independent audit). This raised questions about the validity of survey scores as a measure of safety. [67]	• **Chen et.al., 2003** – The association between quality of care and survival for acute myocardial infarction was examined for accredited and non-accredited hospitals. Non-accredited hospitals displayed lower quality than accredited hospitals. However, there was considerable variation in performance among accredited hospitals. [76] • **Hadley and McGurrin, 1988** – Analysis revealed a weak relationship between accreditation or certification status and the indicators of quality of care (the characteristics examined were average cost per patient, per diem bed cost, total staff hours per patient, clinical staff hours per patient, percent of staff hours provided by medical staff bed turnover, and percent of beds occupied). Accredited or certified hospitals were more likely to have higher values on specific indicators than hospitals without accreditation. [56] • **Mazmanian et.al., 1993** – Survey of accredited and non-accredited (rehabilitation) programs suggested no significant differences in the organization and delivery of cognitive rehabilitation therapy. [77] • **Dean Beaulieu and Epstein, 2002** – A study to determine the characteristics of accredited plans, their performance on quality indicators and the impact on enrolment. The results showed accreditation did not ensure high-quality care. It is positively associated with some measures of quality, but it did not ensure a minimal level of performance. [78] • **Miller et.al., 2005** – No significant relationships existed between categorical accreditation decisions (JCAHO) and quality indicators. [79]

Review	Year	Input	Processes	Outcomes
				• **Snyder and Anderson, 2005** – Hospitals that participate in a quality improvement program were no more likely to show improvement on quality indicators than were hospitals that did not participate. [80] • **Barker et.al., 2002** – Medication errors were found to be common in a stratified random sample of organizations. A significant number (7%) of potentially harmful errors were identified. Accreditation of a facility was not associated with a lower error rate. [81] • **Salmon, 2003** – Those hospitals participating in an accreditation program improved their compliance with accreditation standards; non-participating hospitals did not. However, there was no observed improvement on the quality indicators. [68] • **Griffith et.al., 2005** – There was a potentially serious disjuncture between outcome measures and accreditation evaluations. Data showed no relationship of substance, and a confusing pattern of minor and sometimes conflicting associations. [82] • **Heuer, 2004** – No relationships were identified between hospital accreditation scores and patient-satisfaction ratings, suggesting a dissociation between them. [87] • **Collopy et.al, 2000** – feedback from accrediting agencies accepted to improve both the processes and outcomes. • **Ito and Sugawara, 2005** – Positive association between hospital accreditation and public disclosure of accreditation reports.
Hinchcliff et.al.[43]	2012	**Organisational impacts.** The impacts of accreditation on organisational processes, policies and environments were examined in 62 studies. As listed in table 4, several key subthemes were explored in these studies, including the extent to which accreditation	**Relationship to quality measures.** Quality measures incorporate items defined as indicators of organisational performance rates and patient or healthcare consumer outcomes. Overall, 65 studies examined the relationship between accreditation and different quality	**Relationship to quality measures.** Quality measures concerning patient outcomes were only examined in nine studies, highlighting a critical knowledge-gap. Examples of patient outcome measures used to examine accreditation impacts include survival rates and

Review	Year	Input	Processes	Outcomes
		programmes promote: standardisation of care processes; increased compliance with external programmes or guidelines (eg, clinical best-practice); development of organisational cultures conducive to quality and safety; implementation of continuous quality improvemen **Change mechanisms.** Overall, 41 studies explored how the activity of preparing and undergoing accreditation promotes change in health service organisations. As shown in table 4, four main mechanisms responsible for organisational changes promoted by accreditation programmes were identified: engagement of staff in quality improvement activities, such as self-assessment; promotion of quality systems of care; documentation, collation and use of data for internal and external benchmarking; and implementation of best-practice guidelines. • Greenfield et.al., 2011 - In one study, staff participation in an accreditation process was found to have promoted a quality and safety culture that crossed organisational and professional boundaries. [51] **Financial impact of accreditation.** Fifteen studies examined or included some work on aspects of the financial impacts of accreditation. However, potential financial benefits were not specifically examined, highlighting a crucial issue requiring additional research. Participation in accreditation programmes was considered to require considerable financial resources, and the return on this investment is questioned. The overlap and duplication that can occur among accreditation, regulatory and contractual requirements is identified as a source of financial pressure. • **Cleveland et.al., 2011** – The costs required to administer accreditation	measures. Only 28 studies involved comparisons of accredited and non-accredited health services or health service units. • Examples of positive findings concerning the relationship between accreditation and organisational performance levels include: a trend between accreditation outcomes and clinical indicator performance in hospitals; an association between chest pain centre accreditation and compliance with quality measures regarding acute myocardial infarction [65]; and a relationship between accreditation and hospital performance on publicly reported evidence-based processes of care measures. [64] **Accreditation programme assessment.** A total of 42 studies examined the development and impacts of accreditation programmes. A combination of positive, negative and neutral impacts were identified (see table 4). Several notable concerns are identified in the literature, including the perceived low quality of some programme standards, and discrepancies between accreditation findings and the results of quality or practice audits.[66]	falls. Of the nine studies, six found positive associations between accreditation and patient outcome measures. • **Lichtman et.al., 2011** – For example, hospitals with accredited primary stroke centres had lower 30-day risk-standardised patient mortality compared with non-accredited hospitals.[83] Other studies produced inconsistent results (ie, associations were found between accreditation and some outcomes but not others) or identified no associations. • **Thornlow and Merwin, 2009** – In addition, it was noted that while certain adverse events, such as infection rates, may be reduced by preventive protocols that are reflected in accreditation standards, other more complex events may require multifaceted strategies that are less easily translatable into standards. **Consumer views or patient satisfaction.** Despite the increasing role of patients or consumers within contemporary healthcare systems, only 13 studies considered the relationship between accreditation and consumer views or patient satisfaction. The literature indicates that accreditation has an undefined impact on the views or satisfaction of consumers or patients. • **Braithwaite et.al., 2010** - Trend between accreditation outcomes and clinical indicator performance in hospital.

Review	Year	Input	Processes	Outcomes
		programmes—particularly in LMICs—are described as a threat to their ongoing sustainability. [57]		
Ng et.al.[44]	2013	• **Braithwaite et.al., 2010** – Accreditation performance was positively correlated with organisational culture and leadership, and a positive trend was observed between accreditation and clinical performance. Accreditation was unrelated to organisational climate and consumer involvement. [52] • **Hadley and McGurrin, 1988** – JCAHO-accredited hospitals had higher values of average cost per patient, per diem bed cost, clinical staff hours per patient, % of staff hours provided by medical staff, bed turnover and % of beds occupied than hospitals without accreditation. Higher values on the 7 hospital characteristics (outcome measures) may reflect conditions necessary for better quality of care. [56]	• **Hosford, 2008** – JCAHO accreditation was an effective intervention to reduce medical errors while medical error reporting and increased public awareness were not effective. Progress of implementing patient safety standards and medical error management system was more substantial in JCAHO accredited hospitals than non-accredited hospitals. 74% Hospitals provided training to the key personnel who were responsible for implementation of quality improvement strategies, and 96% hospitals provided staff training related to quality improvement. [60]	• **Braithwaite et.al., 2010** – Accreditation performance was positively correlated with organisational culture and leadership, and a positive trend was observed between accreditation and clinical performance. Accreditation was unrelated to organisational climate and consumer involvement. [52]
Scott[45]	2009			• **Faunce and Bolsin, 2004** – Multiple instances exemplify failure of accreditation surveys to identify poorly performing institutions shortly before public revelations of scandalously poor care. [85]
Tabrizi et.al.[46]	2011			• **Williams et.al., 1990** – The effectiveness and efficiency of health care services is of increasing interest to government, funders, and consumers. None of the programs was strong on this attribute [86]

Review	Year	Facilitators	Barriers
Alkhenizan and Shaw[17]	2012	• **Hurst, 1997** - Community hospital managers were committed to TSHAS. Staffs were also keen to see the program continue to evolve. Majority of managers were happy with the accreditation program. They felt that the accreditation program affirm quality	• **Stoelwinder, 2004** – Doctors are unaware or skeptical of accreditation; doctors hold concerns about how safety and quality of care should be measured; and doctors perceive themselves to be

Review	Year	Facilitators	Barriers
		of services, spread good practices and involve staffs at all levels. [58] • **Scanlon and Hendrix, 1998** - Ninety-four percent of the purchasers surveyed indicated they require plans to provide them with "performance" information as a condition for contracting. Health plan accreditation is the most common measure that purchasers require (100 percent) and use (94 percent) in contracting decisions. [18] • **Devers et.al., 2007** - Quasi-regulatory organization (the Joint Commission on Accreditation of Healthcare Organizations) has been the primary driver of hospitals' patient-safety initiatives. The most frequently mentioned initiatives are designed to meet the JCAHO requirements. Respondents explicitly noted that they were working to meet JCAHO standards, or the major initiatives they listed mapped clearly back to JCAHO's policies and requirements. They can be grouped into three related JCAHO areas: (1) developing better processes for reporting, analyzing, and preventing sentinel events (this includes responding to sentinel event alerts, particularly those concerning patient falls and use of patient restraints); (2) meeting patient-safety standards, including increasing hospital leadership's knowledge of, and accountability for, patient safety and creating a nonpunitive culture; and (3) meeting all or specific JCAHO patient-safety goals, particularly improving communication and the accuracy of patient identification. The most frequently mentioned patient-safety activity was improving medication safety, which is related to six of the eleven patient-safety goals for 2003.[92]	accountable within a professional framework (self/patient/colleagues) not to the organizations in which they worked. [89]
Brubakk et.al.[42]	2015	-	-

Review	Year	Facilitators	Barriers
Greenfield and Braithwaite[39]	2008	• **Casey and Klingner, 2000** – Accredited organizations cited positive benefits of the accreditation process. Most indicated that they would reapply for accreditation. Accredited organizations discussed challenges complying with standards and meeting the information requirements. [88] • **Peterson, 2003** – The manager was the most important entity in achieving a successful accreditation outcome. Managers, who were perceived as participative, have more years of experience, had written more self-studies, and whose faculty support the accreditation process, were likely to have more positive accreditation outcomes. [91]	• **Casey and Klingner, 2000** – Accredited organizations cited positive benefits of the accreditation process. Most indicated that they would reapply for accreditation. Accredited organizations discussed challenges complying with standards and meeting the information requirements. [88] • **Pongpirul, 2006** – Healthcare professionals (physicians, dentists, pharmacists, and nurses) had been facing many problems with multidisciplinary process-related issues of an accreditation standard. Surveyors experienced difficulties in conveying the core quality improvement concepts to the professionals. [71] • **Bukonda et.al., 2003** – Serious resource constraints, both financial and expertise, had undermined the ongoing viability of the Zambian hospital accreditation program. [96]
Hinchcliff et.al.[43]	2012	**Professionals' attitudes towards accreditation.** There were 38 studies that assessed health professionals' attitudes towards accreditation using multiple methods. As illustrated in table 4, the literature highlights that health professionals view accreditation as an effective method of promoting high quality organisational processes and patient safety, and are more likely to remain satisfied and employed in accredited organisations.	• **Davis et.al., 2011** – other studies found that health professionals have concerns regarding the human and financial resources required for organisations to participate successfully in accreditation programmes. [97]
Ng et.al.[44]	2013	• **Shaw, 2004** – The strongest drive for hospital accreditation was the prospect of access to additional funding. Organisational development was one of the major motives of hospital management to implement accreditation programme. [90] • **El-Jardali, 2007** – Hospitals might adopt opportunistic behaviours with the aim of gaining the accreditation if the hospital funding mechanisms are linked to the accreditation. Setting up an independent body dedicated to quality improvements in hospitals can minimise the political interference to the hospital accreditation policy. Barriers for effective implementation of hospital accreditation policy included organisational culture of resistance to change. [93]	• **El-Jardali, 2007** – Hospitals might adopt opportunistic behaviours with the aim of gaining the accreditation if the hospital funding mechanisms are linked to the accreditation. Setting up an independent body dedicated to quality improvements in hospitals can minimise the political interference to the hospital accreditation policy. Barriers for effective implementation of hospital accreditation policy included organisational culture of resistance to change. [93] • **Pomey et.al. 2005** - Accreditation may be regarded as an inspection rather than a CQI process if it is mandatory. Hospitals may adopt strategic behaviours aimed at merely attaining accreditation if the accreditation results are used for resource allocation. The use of accreditation results should be clear and using it for financial sanction is not recommended. [94] • **Shaw, 2001** – Different voluntary and statutory external assessment programmes needed to be integrated to ensure valid standards, consistent assessment, transparency, and public accountability. Accreditation programmes should be patient-centred, clinically focused, complementary to internal quality improvement and results should be publicly available. Absence of government lead and lack of

Review	Year	Facilitators	Barriers
			national coordination were the causes for various accreditation programmes developed with little integration, consistency, and reciprocity. [95]
Scott[45]	2009	-	-
Tabrizi et.al.[46]	2011	-	-