

## A Review Of Quality Management Systems In Hospitals

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### Abstract

*This paper aimed to systematically review the quality management systems in hospitals and their outcomes as influenced by different factors. Papers were selected from an academic database using the PRISMA screening and selecting process. The selected papers were discussed under the sections of General, QMS outcomes, DUQuE and DUQuA, and accreditation and certification. QMS adoption has improved care quality outcomes in various ways. Systematic research on QMS under the DUQuE/A projects in seven European countries and Australia have produced many useful insights. Although accreditation and certification improve the trust and image of the hospital, they don't need to improve quality outcomes in all cases. Most papers used the survey method for data collection. More research using mixed methods needs to be done. Expanding the scope of QMS research might enhance our understanding of the processes that produce definite quality outcomes in hospitals. Some limitations of this review have also been discussed.*

**Keywords:** *Quality management, hospital systems, hospitals, review.*

### Introduction

Some basic information on quality management systems in healthcare systems is described <sup>1</sup>in Seelbach and Brannan (2022). Quality means the extent to which a product or service meets its expected standards to the satisfaction of the consumer. Healthcare quality management involves overseeing the implementation of systems, guidelines, and procedures aimed at reducing harm and maximising patient well-being (Dodwad, 2013). According to the Institute of Medicine, quality in healthcare is determined by the extent to which services improve the chances of desired results and align with accepted professional standards (Medicare, 1990). The objective of quality in healthcare is to provide the best possible care from a qualified provider in an appropriate setting for a specific patient. Thus, from patient to patient, the quality requirement may differ. However, common standards of safe, effective, patient-centred, timely, efficient, and equitable care are possible. Integration of the hospital systems to meet all these requirements forms the core of quality management in healthcare systems.

The practice of quality management systems (QMS) involves the use of tools and techniques to organise, standardise, and improve activities involving a product or service aimed at customers. This required continuous data collection and analysis to evaluate the outcomes of QMS and identify any improvements required (Seelbach & Brannan, 2022). QMS is implemented in hospitals. Most hospitals suffer from unstructured coordination of various activities from the entry to exist of the patient, whether inpatients or outpatients. Both healthcare and support systems need to be coordinated well in the hospital. When QMS is implemented properly in any hospital, it leads to organisational benefits of standardisation, a quality-conscious organisation, and service quality, leading to improved patient satisfaction and better care quality. Operationally, QMS leads to cost savings,

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improved productivity, reduced customer complaints and efficient services. Increased trust, enhanced image even internationally, business increase through corporate and institutional customers and third-party payment systems like insurance schemes are other benefits. Quality accreditation, like NABH, is becoming increasingly important in QMS (Consulting, 2023).

This paper aims to provide a systematic review of quality management systems in hospitals. The rest of the paper is organised in the following manner.

The methodology adopted to identify and select papers is described below. In the next section of Results, the selected papers are discussed one by one under different subsections according to the topics dealt with in the papers. The Discussion section provides some tables and charts of analysis of the reviewed papers to facilitate discussions. After the discussion section, the conclusions summarise the main points from this review. This is followed by some recommendations and then suggestions for future research. The limitations of this review are listed at the end.

## Methodology & Results

### Methods

Google Scholar was searched using appropriate search terms for different topics of QMS in hospitals. The identified paper was screened in different steps based on the PRISMA flow diagram. The resultant PRISMA diagram for this review is appended. Only papers published in English were selected. Books were excluded. Although full texts were preferred, abstracts were also included if they contained important information. This process of identifying, screening and selecting yielded 21 papers.

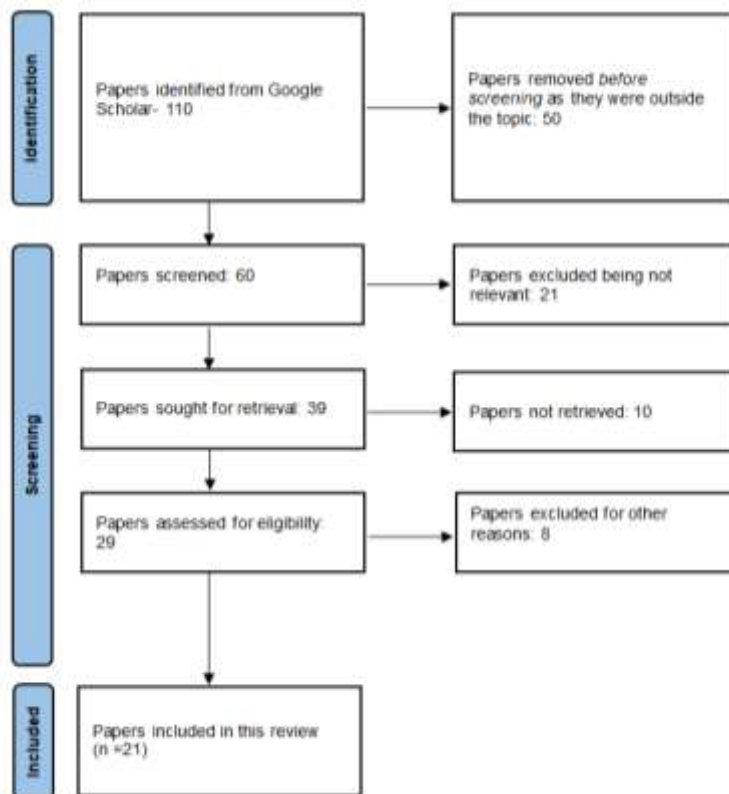


Figure 1: PRISMA

### Results

## General

Most current conceptual frameworks used for hospital QMS have shortcomings, terminology barriers or are too complex. Eggli and Halfon (2003) proposed a rigorous and simple model specific to hospitals based on four entities (patients, activities, resources and effects) and six levels to measure the development of QMS. The proposed model was compatible with other substantiated models, robust in coping with falsifiability and provided flexibility to avoid a too-unilateral approach.

The objective of Wardhani, Utarini, van Dijk, Post, and Groothoff (2009) was to use a systematic review to identify the problems and facilitating factors in the implementation of the quality management system (QMS) in hospitals. The search process yielded 14 papers published between 1992 and 2006. The key success factors of QMS in hospitals were an organisational culture stressing standards and values associated with affiliation, teamwork and innovation, acceptance of change and risk-taking. Technical competence for scientific problem-solving was required for such a culture. QMS functions needed to be distributed clearly across the hospital. A formal quality structure, management leadership and positive interactions between administration and healthcare professionals were also success factors. The constraints of this analysis were the restricted amount of data on the effect of adopting QMS on overall hospital effectiveness. The literature examined only provided evidence of enhanced clinical outcomes. This was because the papers included in the review had less than three years of observation data to assess the impact of QMS implementation. Similar research in the manufacturing sector has indicated that a minimum of 3 years of QMS implementation across the entire organisation, along with a longer time frame, is needed to measure the overall improvement in organisational performance.

In the study conducted by Wagner et al. (2006), the aim was to identify similarities and differences in how QMS is utilised in The Netherlands, Hungary, and Finland. This was achieved through using an evaluation model and analysing the national policies of these countries. The researchers hypothesised that hospitals in countries with government-enforced legislation would have more advanced QMS and engage in more QM activities and that financial incentives are more effective than legislation alone. The findings of the survey conducted among hospitals in these three countries showed that, despite variations in their backgrounds and healthcare systems, the disparities in QMS implementation and QM activities were minimal. On average, 22 QM activities in the Netherlands and Finland and 20 in Hungary were observed. One specific activity of the Netherlands, the client council, did not exist in Finland or Hungary. All other activities existed to some extent in all three countries. The assumption was that a legal requirement of QMS would force the implementation of QMS compared to the implementation being voluntary. The hospitals in the Netherlands and Hungary were expected to be further than the hospitals in Finland. However, the assumption was not proved. The results show that only a minority of hospitals (less than 5%) have developed a QMS (stage 3). There was no real difference between the Netherlands and Finland as most hospitals had implemented various QM activities, but only 3% to 4% had implemented an integrated QMS. Hospitals were much fewer in Hungary than in Finland. Despite the ISO certification of 30% of the Hungarian hospitals, most Hungarian hospitals were still in the preparation stage. On the other hand, most Finnish hospitals have started with the implementation of the QMS. Thus, the second hypothesis was also rejected.

## Measurement of the effect of QMS on outcomes

In a systematic review, Groene, Botje, Suñol, Lopez, and Wagner (2013) observed that although there are methods to evaluate the implementation of QMS, few methods are available to measure the implementation, effectiveness, and outcomes of the implemented QMS. There were many limitations of this review research on quality management systems, such as poor indexing, thus making it difficult to perform a sensitive and specific search. This is further complicated by diverse disciplines being involved in QMS measure development that results in different keywords and publication strategies. The review

included a search for grey literature and secondary sources discussing an already-included instrument. Data extraction focused on psychometric attributes but did not adhere to the recommended standards found in the literature.

In 1998, the Lithuanian Ministry of Health gave its approval for the implementation of QMS in healthcare organisations. According to the regulations, general managers of hospitals were expected to initiate the QMS implementation in their hospitals. The extent of QMS implementation in Lithuanian hospitals was assessed by Buciuniene, Malciankina, Lydeka, and Kazlauskaitė (2006). The results of a survey of 58 general managers of Lithuanian hospitals revealed that QMS is already operating in 39.7% of support treatment and nursing hospitals and under implementation in 46.6% of hospitals. Thus, 13.7% of them were still to implement it. The survey participants perceived the need for QMS positively. However, issues with procedure development and a lack of resources, information, and guidelines slowed down its adoption. The perceived benefits of QMS were improved responsibility and power sharing, better service quality, and higher patient satisfaction. The level of satisfaction was mediocre. However, those general managers who had a good grasp of QMS and ISO had higher satisfaction, and they had trained more employees in quality management.

The findings from a survey of 102 Hungarian hospitals conducted by Makai, Klazinga, Wagner, Boncz, and Gulacsi (2009) revealed that the average hospital scored 24.5 out of 35 for core quality activities and 4 out of 11 for patient safety activities. However, there was a weak correlation between the development of quality management systems and the number of patient safety activities, with only 12% of the variance being explained. The study also found that certification, specifically ISO and professional standards, did not have a significant impact on patient safety. The EnQual questionnaire was utilised for data collection, but there were some limitations to the study, including the potential for positive bias in the self-assessment questionnaires and self-selection bias in the hospital sample. It is also worth noting that the study focused on structure and process measures for both quality management and patient safety, as opposed to outcome measures, which are not currently available in Hungary. However, it is important to note that evidence suggests a relationship between these measures and improved outcomes.

To study the effects of the introduction of QMS in a large rehabilitation hospital, van Harten, Casparie, and Fischer (2002) used an observational framework. The effects were analysed using repeated analyses using the Dutch version of the EFQM model. The introduction of a QMS involved a change process. Hence, the diagnosis of the pre-change was essential. Among the many change-related aspects, training and communication were underestimated. The results showed a strong link between engaging in high-quality activities and experiencing job satisfaction, as well as consistently receiving a high EFQM score compared to national standards.

Thus, it is possible to use process analysis to generate information to guide organisations in the introduction of QMS. The outcome analysis revealed positive effects both in the EFQM score and the staff's work satisfaction.

Aimed to identify whether supply chain management integration empowers QMS or not in some select hospitals of Chandigarh, Mohali and Panchkula, Chadha (2013) used a survey to find that supply chain management integration catalyses the quality management system in the healthcare sector. This finding opened a way for hospitals for supply chain management integration to catalyse the QMS in the healthcare sector.

### **DUQuE and DUQuA**

The results of a survey within the context of the Deepening our Understanding of Quality Improvement in Europe (DUQuE) project (2009 -2013) of 183 quality managers from 7 European countries: France, Poland, Turkey, Portugal, Spain, Germany and Czech Republic were used by Wagner, et al. (2014) to construct a quality management system index (QMSI)

as an instrument to measure the implementation effectiveness of QMS in European hospitals. The conceptual framework used by the authors is given in Fig 2.

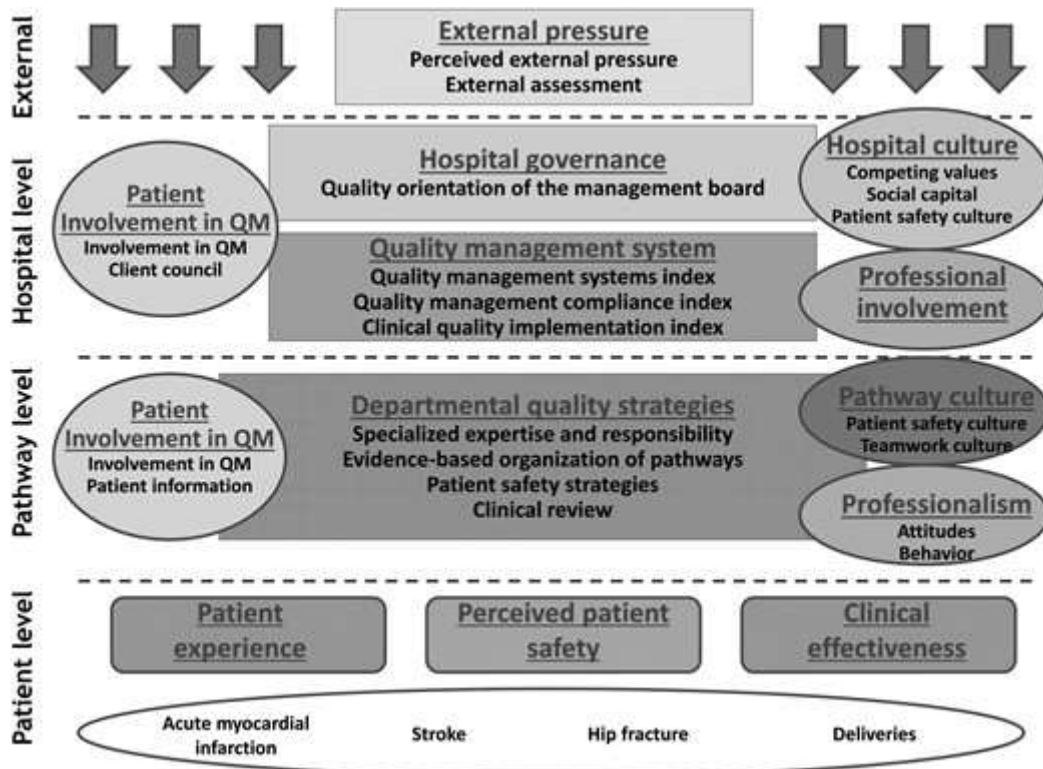


Figure 2: Conceptual model of DUQuE (Wagner, et al., 2014).

The authors identified 46 items for the development of QMSI. All validation tests were satisfactory. The sampled hospitals attained a mean value of 19.7 (standard deviation of 4.7) on the index that ranged from 0 to 27. Hence, the implementation level of QMS in these hospitals was fairly good. The study had a few limitations. The QMSI was based on the perception of the hospital's quality manager. Hence, on-site visits were done to ensure the reasonably reliable nature of survey responses. Despite the random selection of hospitals, selection bias among participating hospitals might have occurred. Especially in some countries, the number of participating hospitals was smaller than what was initially planned for that country. The final study sample was too small to do a cross-culture validation.

In a study conducted by Botje, et al. (2014), survey results from 155 hospitals in seven European countries (Czech Republic, France, Germany, Poland, Portugal, Spain, and Turkey) showed that external pressures had no influence on the implementation of Quality Management Systems (QMS) in those hospitals. However, discussions among executive boards were focused on quality performance in order to identify any necessary improvements in the QMS. The study, which was a part of the DuQuE programme, used three constructs to measure QMS implementation: the Quality Management System Index (QMSI), the Quality Management Compliance Index (QMCI), and the Clinical Quality Implementation Index (CQII). QMSI was based on a quality manager questionnaire and factors such as quality policies, board involvement in quality monitoring, and staff training. The QMSI ranged from 0 to 27. The QMCI, which measured compliance with quality management, was based on factors like quality planning and staff development and ranged from 0 to 16. The CQII, which assessed clinical quality efforts, also ranged from 0 to 14. The authors provided a framework for analysing the results but acknowledged limitations similar to those reported by Wagner, et al. (2014).



In their study, Hammer, et al. (2013) hypothesised that social capital within hospital management boards would be associated with the effectiveness and maturity of QMS in European hospitals. They used a mixed approach to collect data from 188 hospitals in seven countries as part of the DuQuE project. The mean social capital score was 3.3 (on a range of 1-4), and the mean quality management index was 19.2 (on a range of 1-27). Their findings showed a positive correlation between higher social capital and higher quality management system scores. However, the cross-sectional design of the study and limited sample representativeness limited their ability to make causal conclusions. Additionally, results were based on perceptions from the Chief Executive Officer and Quality Manager questionnaires and may not be generalisable. Therefore, further conclusions on the impact of hospital characteristics, organisational culture types, or the number of board members could not be drawn.

As part of the DUQuE project (Deepening our Understanding of Quality Improvement in Europe), the survey responses of 158 professional quality managers and hospital trustees from 7 countries (France, Poland, Turkey, Portugal, Spain, Germany and the Czech Republic) were used by Wagner et al. (2014). The authors noted a clan culture in 33%, an open and development culture in 26%, a rational culture in 25% and a hierarchical culture in 16% of the hospitals. None of these organisational culture types had any effect on the development of QMS, measured as the Quality Management System Index (QMSI), Quality Management Compliance Index (QMCI) and Clinical Quality Implementation Index (CQII). However, an organisational management structure that uses fewer protocols had a less developed QMS compared to a structure that supports innovations in care. A conceptual framework was used for testing the hypotheses. The study had a few limitations. Like all models, the Competitive Value Framework (CVF) used for modelling organisational culture may be a gross oversimplification of reality. Other limitations were the same as those of other studies on DUQuE discussed above.

In a perfect scenario, information on the care procedures, pathways, and results at different levels of a hospital, department, and patient would be routinely and thoroughly recorded, similar to a formally integrated research project and consistently reported. As part of their efforts to gain a deeper understanding of quality in Australia, Braithwaite, et al. (2020) conducted a cross-sectional study of 32 major hospitals situated across various states and territories in the country. Their objective was to investigate the associations between quality management systems at the organisational level, quality management strategies at the departmental level, and measures at the patient level (such as clinical treatment procedures, patient-reported evaluations of care, and clinical outcomes) in the context of the Australian healthcare system. The authors evaluated the improvement structures, procedures, and results of these hospitals. They collected data from the organisation, department, and patient levels for acute myocardial infarction (AMI), hip fracture, and stroke. This information included surveys of quality managers, healthcare professionals, and patients, on-site visits to hospitals, reviews of medical records, and national databases. The data on outcomes and patient admissions were then analysed. The relationships between the measures were assessed through multi-level models based on the framework of the European project Deepening our Understanding of Quality Improvement in Europe (DUQuE). The data used in the study came from 32 hospitals, 119 departments, 31 quality management teams, 1334 healthcare professional surveys, 857 patient surveys, 2401 medical record reviews, and 151 external evaluations. Furthermore, an additional 14,460 patient admissions of 14,031 individual patients were obtained through a secondary source. The research framework is depicted in Figure 3, illustrating the multilevel nature of the study.

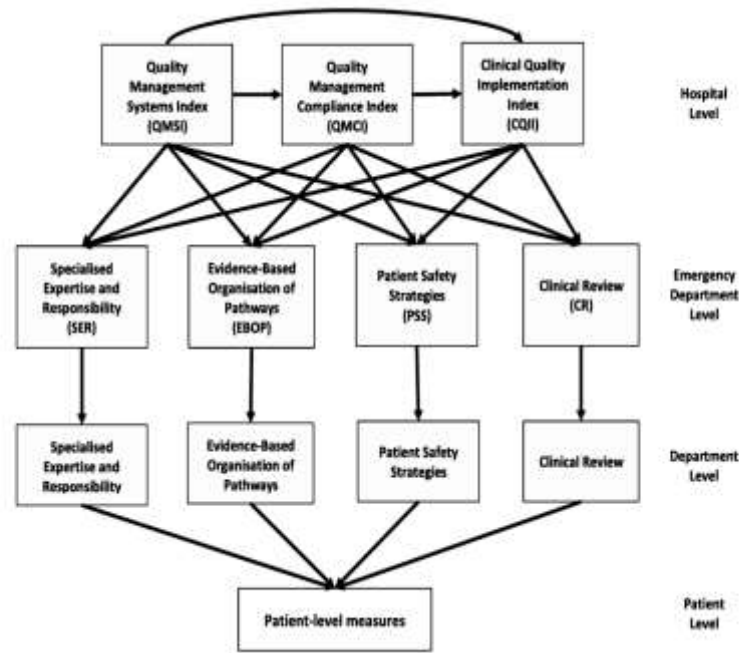


Figure 3: Research framework (Braithwaite, et al., 2020).

The process of data collection is given in Fig 4. The timings of data collection at each stage are explained in Fig 4. The contents of both Fig 3 and 4 have been described above.

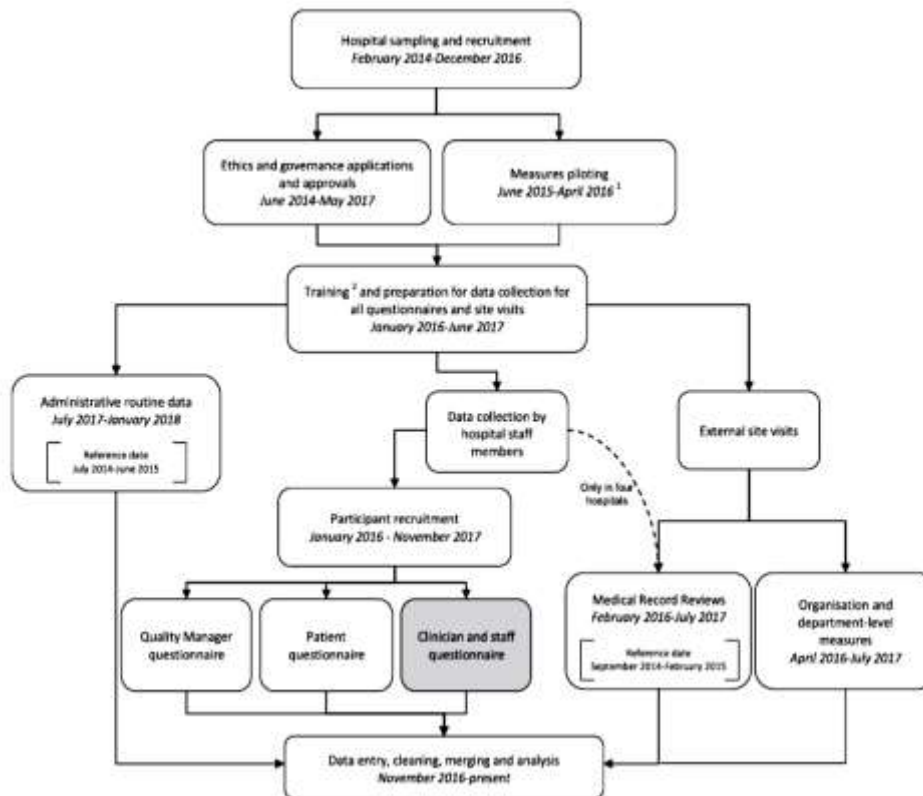


Figure 4: The data collection scheme (Braithwaite, et al., 2020).

The correlation between hospital-level quality management systems, emergency department or department-wide quality strategies, and patient outcomes was not clearly established. While ED-level clinical reviews were found to have a relationship with adherence to treatment guidelines for AMI, hip fracture, and stroke, the direction of this

relationship varied. Overall, this suggests that frontline interventions have a greater impact on care quality than department-level interventions, highlighting the need for multi-faceted strategies. As part of the Deepening our Understanding of Quality in Australia (DUQuA) project,

Clay-Williams et al. (2020) used a simplified directed acyclic graph and timeline to examine the relationship between organisational-level quality structures, improvement and implementation, and department-level measures of safety culture and leadership in 32 large Australian hospitals. Results from a survey of 1332 clinicians showed that higher QMSI scores were associated with more positive safety culture and leadership measures in the emergency department and stroke department but not in the AMI and hip fracture departments. On the other hand, higher QMCI scores were linked to lower teamwork and safety climate ratings in the AMI departments but not in other departments after controlling for QMSI. There was no significant relationship between QMCI and leadership measures in any department after controlling for QMSI, and no correlation between CQII and safety culture or leadership measures in all four departments. The impact of organisational QMS on clinician safety culture and leadership varied depending on the department, with some consistency in patient safety attitudes and behaviours observed across the organisation. However, other factors may also play a role. It should be noted that the DUQuA QMSI and clinician safety culture and leadership scales rely on self-reported data, while the QMCI and CQII scales use external audits of hospital quality processes. Although the two studies utilised similar data collection methods and analysis techniques, differences between the DUQuA and DUQuE scales may affect comparisons between findings from Australian and European hospitals. A potential limitation is the low response rate in some hospitals, which may introduce selection bias.

In their study conducted in Australia, Taylor and colleagues (2020) discovered a positive correlation between QMSI and both QMCI and CQII, based on data from 32 respondents. However, upon adjusting for QMSI, there was no longer a significant relationship between QMCI and CQII. Additionally, the researchers observed a collection of connections between QMSI and department-level indicators, although these were not uniform across all departments. The research was guided by a DAG graph as the theoretical framework.

The data collected in the studies of Kristensen, et al. (2015) involved complete data from 181 hospitals and in-depth data from 71 hospitals from seven European countries (DUQuE), 183 quality managers and 3622 clinical leaders from all hospitals, and 1444 clinical leaders from in-dep h hospitals. The teamwork climate was positive for 67% of clinical leaders and 43% of frontline clinicians. Safety climate was positive for 5 % of clinical leaders and 32% of frontline clinicians. There were positive correlations between the implementation of quality management systems and teamwork and safety climate. The limitations of this study were non-response bias as the survey was used, and as the study was cross-sectional and observational in nature, uncontrolled confounding and reverse causation could have been other sources of bias in the interpretation of results.

The association between the participation of physicians in the management of hospitals and enhanced hospital performance may be partially affected by the implementation of quality control systems. Rotar et al. (2016) aimed to quickly examine the state of doctor involvement in hospital management in 19 OECD countries, thoroughly investigate the phenomenon in 7 OECD countries, and determine if this involvement is linked to greater implementation of quality management systems. To accomplish this, the authors conducted a brief survey among country coordinators in the OECD's Health Care Quality Indicator program and analysed data from the DUQuE project, which focused on the adoption of quality management systems in European hospitals. Their findings revealed that physicians may hold a variety of managerial positions at both departmental and hospital levels, though these roles are often not accompanied by formal decision-making authority. However, when doctor managers did have formal decision-making responsibilities in key strategic areas of hospital management, there was a positive correlation with the level of quality management



system implementation. It should be noted that this study is limited by its cross-sectional design and inability to draw causal conclusions. Additionally, any international research on the involvement of medical doctors in hospital governance must consider the contextual differences between countries, potential selection biases, and limited applicability of findings.

#### **Accreditation and certification**

The Red Cross Hospital (384 beds) in the Netherlands successfully implemented a QMS according to ISO 9001:2000. Van den Heuvel, Koning, Bogers, Berg, and van Dijen (2005) described the processes followed to implement the QMS and obtain the ISO certification. Briefly, the process consisted of first writing a global implementation plan. The department heads analysed and described processes within their departments to identify and implement quick wins in process improvement. The improved process was described in a standardised manner called a procedure. There were 60 procedures. Then, the protocols related to each procedure were made. Protocols gave a detailed description of specific tasks. Processes and activities related to quality assurance were only described. This minimised the documentation of the number of activities and procedures. After the descriptions of all the essential processes and activities were completed, the hospital management produced the Quality Manual. This manual contained descriptions of the organisation, the divisions, the quality system, the policies of the hospital and the current set of performance indicators. An internal audit system completed the QMS. About 50 co-workers were trained to audit. The internal audits resulted in a large number of improvements to our quality management system. Then, the ISO certification was obtained.

Aimed to analyse the effect of implementing the ISO 9001: 2015 QMS on the performance of hospitals in Indonesia, Noviantoro, et al. (2020) used 180 responses from a survey of 15 hospitals that have already implemented ISO 9001: 2015. The results showed that customer focus ISO, leadership principle, people engagement, process approach, improvement principle, evidence-based decision making and relationship management had a positive and significant effect on hospital performance. These independent variables explained 78.6% of hospital performance. A research framework was used to test the hypotheses developed on the relationships of these seven variables.

A survey of 42 Spanish hospitals (>400 beds) by Sangüesa, Mateo, and Ilzarbe (2007) revealed that implementation of QMS in Spanish hospitals was quite extensive, as 71.4% used ISO 9001; 11.9% JC, and 69% EFQM. The combined use of ISO 9001 and EFQM (47.6%) has also been noted.

Accreditation and certification of hospitals may enhance their QMS. The possibility of this effect on ISO-certified 350 Turkish hospitals was assessed by Yıldız, Öztürk, Topal, and Khan (2019) through a survey. ISO certification did not affect the quality of policy documents, quality monitoring by the board, or the training of professionals. On the other hand, ISO certification improved formal protocols for medication and patient handling, analysed the performance of care processes, and evaluated results. Larger hospitals were able to implement these steps better. External assessments are useful for improvements in the QMS scores. However, quality-focused governmental regulations were more important for improving the QMS of small and medium-sized hospitals. However, his/her QMS scores may not lead to improved quality.

#### **Discussions & Conclusions**

Generally, the use of QMS improved the quality of care in hospitals irrespective of national or context. However, not all components of quality were always improved, even in the case of accredited and certified hospitals. It was also not necessary for QMS to always improve care quality. A large majority of papers dealt with DUQuE and its Australian variant, DUQuA.

Some interesting statistics related to this review are discussed below.

Nature of studies-

Fig 5 provides the frequencies based on the nature of the studies. Out of 21 reviewed papers, 45% (10 papers) dealt with DUQuE and DUQuA, 23% (5 papers) with outcomes and 18% (4 papers) with accreditation and ISO certification.

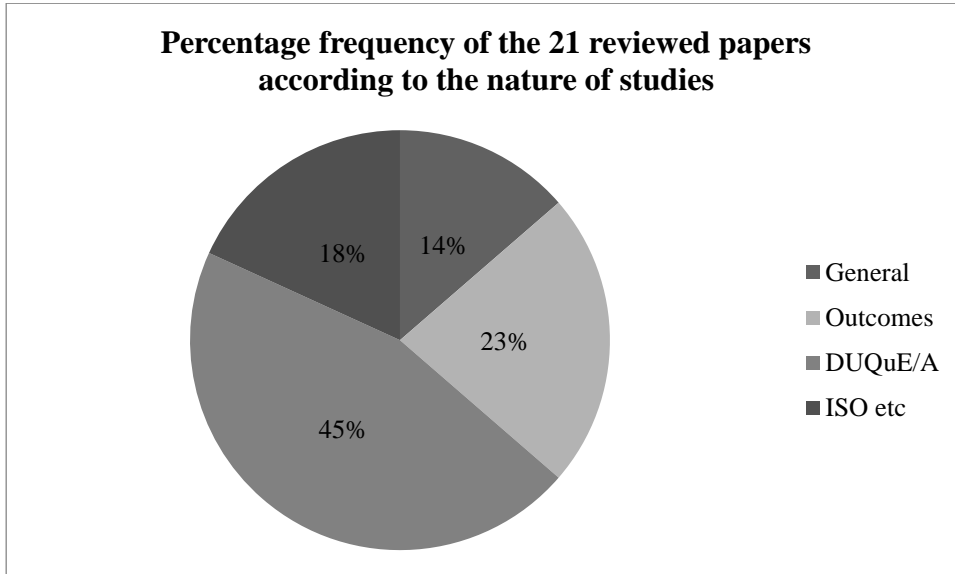


Figure 5: The frequency percentage of the 21 reviewed papers based on the nature of the studies.

Data collection method-

Fig 6 shows that most papers used a survey (14 out of 21; about 67%) as the method of data collection.

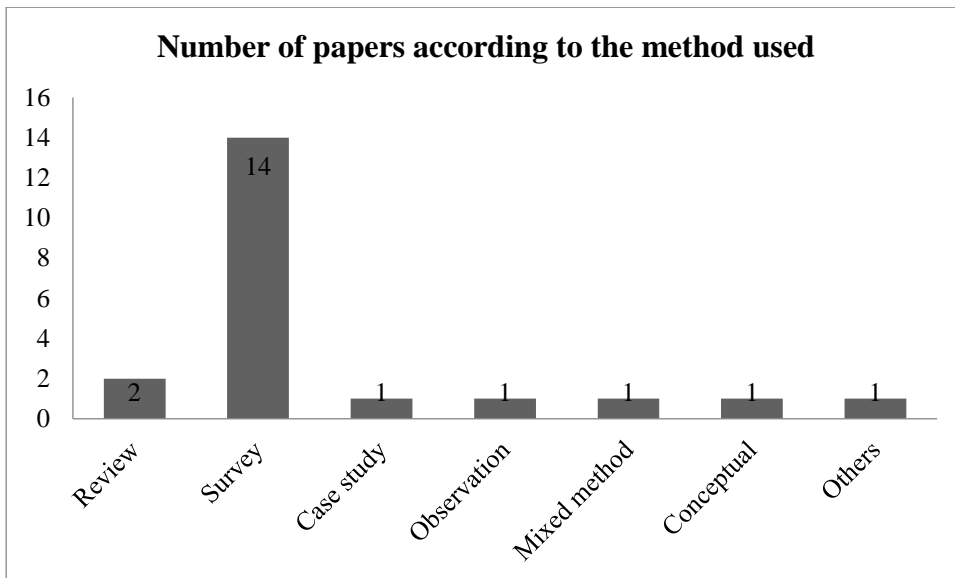


Figure 6: Number of papers according to the method of data collection.

Publication year-

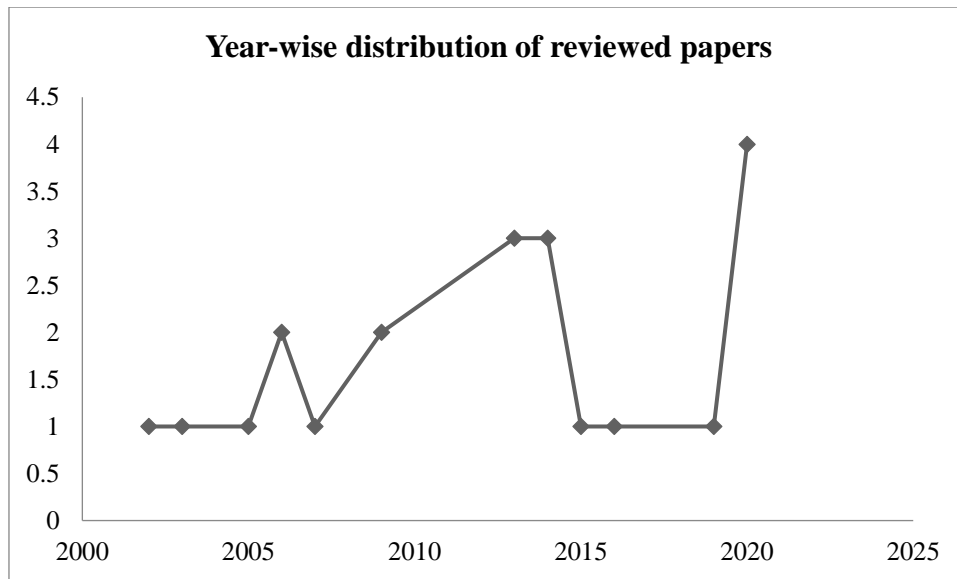


Figure 7: Year-wise distribution of the 21 selected papers.

In effect, the above analysis means DUQuE and DUQuA used surveys for data collection, as can be noted from the above review. The mixed method was used only in one paper. A mixed method is considered to be better than using either a quantitative or qualitative method alone (Creswell & Creswell, 2017). Hence, more studies using mixed methods are required.

The issue of accreditation and certification for QMS is important. The mixed results in this respect need to be resolved through further rigorous research. Similarly, the finding that QMS does not necessarily improve care quality needs to be verified, and if confirmed, the reasons for it need to be investigated.

Although this review highlighted several useful points, many more points need to be studied and revealed.

### Limitations of this review

A few limitations of this review are outlined here. Dependence only on Google Scholar, rather than databases, may not be favoured by those who use the latter routinely. Several papers could be identified using this single search engine, but the review was restricted to 21 papers due to the restrictions on the length of the paper. Abstracts were also included in the selected papers. Although important points were obtained from these abstracts, the possibility of missing important details still exists. The inclusion of a few old papers (2002-2009) would have affected the finding of some new trends from more recent papers.

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