

SHORT THESIS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY (PhD)

Evaluation of quality models and external evaluation techniques used in Hungarian hospitals

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1. INTRODUCTION

Due to the increase in life expectancy the people who need medical attention because of their incurable chronic disease has increased considerably. At the meantime, the cost of the latest medical technologies and the demand for high quality of care from the citizens has further put strains on the healthcare systems all around the world. If no solution is found governments will not be able to provide adequate care for all of their citizens. Among the various methods to tackle this problem the introduction of quality management in healthcare was seen as a viable approach to improve the effectiveness of the treatments and to increase patient satisfaction as well.

This notion was first made official in 1997 when the Committee of Ministers of the Council of Europe recognised that in order for healthcare institutions to provide high quality of care for their patients the development and implementation of quality improvement systems (QIS) in healthcare is an essential pre-requirement. The Recommendation No. R (97) 17 published by the Council of Europe covered the areas in which the development and implementation of QIS in healthcare should be made. It also described all the aspects of quality improvement that a healthcare provider should consider and provided a framework and guidelines on how to model QIS, in addition to what research activities should be done related to it. However, the recommendation did not give any guidelines for example on how to systematic monitor quality.

In 2006 the Council of Europe of the European Union published a recommendation in which they support the quality management systems (QMS) and quality improvement programmes in order to promote patient safety. Although, these are not laws that all member state of the European

Union must comply, they did influence national health policy makers in the right direction.

The Act CLIV of 1997 on Health introduced the first written objectives of QMS within the Hungarian healthcare system. The 121st paragraph of the Act states that the goal of QMS are (i) the continuous improve of quality, the exploration and planning of the process of service, the prevention of mistakes, (ii) the identification and correction of shortcomings regarding delivery, (iii) the exploration of causes behind the shortcomings, the reduction of damages and expenses and (iv) the compliance of both professional and quality requirements and the development of organizations' own set of rules. Nevertheless, the Act was not specific enough and did not described the daily practices of quality management, the processes that needs to be established, and the necessary indicators to measure the various aspects of healthcare. On the other hand, it did made internal quality management systems mandatory for each and every healthcare institutions within Hungary. Nevertheless, external quality management systems (external evaluation techniques) were only recognized, but were not made mandatory for the healthcare providers. This is not a unique feature of Hungary, as there is a common belief that making quality models mandatory would only lessen the potential benefits and could degrade quality management systems to mere paperwork activity.

Despite of not being mandatory in most European countries, many healthcare providers voluntarily undergo such assessments. In Hungary, experts state that healthcare providers – such as hospitals – do this for the following reasons: (i) they want to prove that they follow the requirements written in law, (ii) due to lack of experience regarding quality management they want to gain help from the organizations doing the peer review, (iii) perceived governmental pressure, (iv) better chance for winning tenders,

(v) the hope for higher financial payments, and (vi) following the trend of other medical institutions. In addition, the official webpages of the creators and maintainers of these quality models promise various benefits concerning how the organizations can improve their processes and outcomes as well.

Quality models are very prevalent in hospitals, and several high quality studies have been conducted in order to identify the potential consequences and benefits of having these. Thus far very limited number of investigations have been conducted in Hungary in the field and the goal of the present thesis is to narrow this gap. However, it should be noted, that this is not the first PhD thesis that deals with quality models among Hungarian hospitals. Previously, Erika Takács completed a similar study; however, her work was mainly based on qualitative research and theoretical analyses, while our investigations described in this thesis are based on quantitative analyses. Thus, the two approaches complement each other favourably.

2. OBJECTIVES

The last published results on what kind of quality models were used by the Hungarian hospitals were based on a database regarding 31st December 2013. Because with time this database became obsolete, it was a worthwhile endeavour to conduct a new survey and update the results. Also, in order to understand how ISO 9001 impacts quality related activities with and without healthcare-specific standards in Hungarian hospitals, and to see what characteristics might initiate hospitals to join a preparatory project of accreditation the following four objectives were established:

- 1) To update the information regarding the usage of quality models among Hungarian hospitals.

2) To investigate how ISO 9001 and HHCS certifications are associated with quality management, patient safety, patient rights, and human resource management activities among Hungarian hospitals.

3) To determine if a difference already existed between the hospitals – in areas such as the maturity of quality management, patient information and identification, internal professional regulation, surgical procedures, pressure sore prevention, infection control, as well as the quality managers' opinion of the usefulness of quality management and clinical audit – before the decision of joining or not joining the nationwide preparatory project for the BELLA accreditation was made.

4) To investigate how the financial status of the hospitals might have influenced the decision to apply for the preparatory project of the BELLA accreditation.

3. METHODS

3.1 DATA COLLECTION

To fulfil the second objective the database of the 2009 national hospitals survey was used. This survey was conducted by the Health Insurance Supervisory Authority (EBF) among Hungarian hospitals nationwide between February and May of 2010. The questionnaire used in the survey consisted of 517 questions which were arranged in 14 modules: namely quality management, patient safety, patient rights, human resource management, organ donations, VIP services, waiting list handling, care for children, assisted reproduction, cardiology, emergency care, oncology, maternity care, and prenatal care. All questions asked about the conditions prevalent on 31st December 2009. In late 2010 the EBF ceased to exist

without a legal successor. Thus, no one had analysed nor published the results of this survey.

The former head of the EBF handed over the database of the 2009 survey to us, and the Department of Health Policy of the Hungarian Ministry of Health Capacities granted permission to use it for research purposes.

To answer the third and fourth objectives the data obtained by the 2013 national hospitals survey were analysed. This survey was conducted by a research group within the Faculty of Public Health, University of Debrecen. The research group was led by Sándor Gódné, and consisted of Barnabás Margitai, Tibor Gáll and the author of this thesis. The questionnaire of the 2009 Health Insurance Supervisory Authority was the foundation the 2013 survey.

The revised questionnaire was much shorter than its predecessor and consisted of 144 questions regarding general information about the institution, quality management, patient information, patient identification, internal professional regulation, safe surgery, pressure sore prevention, and infection control. The quality management dimension consisted of activities related to quality planning, quality control, quality assurance, and quality improvement. Both patient information and patient identification were part of the same dimension. The first part of these questions asked when the patient was informed and by whom, while the second part asked if there was a local protocol on how to identify patients and if so, which patient groups were included in it. In the dimension of internal professional regulation we asked questions about having a reanimation team, and about the usage of local protocols and clinical audit. The questions of the safe surgery dimension were based on the World Health Organization surgical safety checklist. Finally, the dimensions of pressure sore prevention, and infection

control asked questions on how these activities were conducted and how these activities were documented.

At the end of the of quality management and internal professional regulation dimensions, seven questions were asked from the heads of quality management about the benefits of quality management in general, and three questions were asked on the usefulness of clinical audits. While most of the questionnaire asked questions with single or multiple-choice answers, the special questions addressed to the heads of quality management had a continuous answer option from 1 to 5. Each and every question in the 2013 national hospital survey asked the conditions valid on 31st December 2013.

It is worth noting that because of the alterations this questionnaire cannot be compared to the one regarding 2009. This also means that it is not possible to do a longitudinal analysis with the two datasets. Although this can be considered as a missed opportunity, after much deliberation the decision was made that it is more important to provide up to date and relevant information to Hungarian health policy makers than to do such longitudinal study.

Before the national survey was conducted, permission was obtained from the National Institute of Quality and Organizational Development in Healthcare and Medicines (GYEMSZI). The data collection was conducted via the EvaSys program (EvaSys Education Survey Automation Suite, Version 6, Electric Paper Evaluationsysteme GmbH, Lüneburg, Germany). The data collection was organised in two phases. The first phase lasted from February to June 2014, and all of the 113 hospitals of the Hungarian Hospital Alliance were asked to participate. Due to the low response rate, the Department of Health Policy of the Hungarian Ministry of Human Capacities was requested to support the second phase of the survey. This phase lasted from October to December 2014, and because the Department issued a circular, the response rate rose considerably. At the end of the second phase of the survey 81

hospitals (71.7% response rate) completed the questionnaire. In these hospitals the total number of beds was 51,246 (73.7% of all beds in all Hungarian hospitals) and the annual patient flow regarding 2013 was 1,757,843 (73.7% of all patient flow in all Hungarian hospitals).

In order to satisfy the first objective another hospital survey was conducted between May and June of 2017. This survey was done by the very same research group that did the previous national hospital survey. The questionnaire was very similar to the one used three years prior. However, based on the feedback from the hospitals and on the results, some questions were altered, and other new ones were added in order to get more precise information. For example, considering the ISO 9001 and the HHCS we also asked if the hospital had at least one of these, then which organization granted the certification. All questions asked the conditions valid on the 31st December 2016. However, one key difference from previous surveys was that only the hospitals which were owned by the National Healthcare Service Centre (ÁEEK) were asked in this survey. This decision was made due to the fact that only the ÁEEK gave us permission to do an inspection within its hospitals after the survey was completed (registration number of the letter: AEEK/002523/2017). The chance to do such inspection was imperative, as some Hungarian experts in this field questioned the reliability of the data gained from the 2013 national hospital survey. Even though we believe that the dataset was reliable, we wanted to avoid such accusations. The online survey was conducted with the EvaSys program, and of the 98 hospitals 90 had completed the questionnaire (91.8% response rate). In the answering hospitals the total number of beds was 54,322 (93.4% of all beds in ÁEEK owned hospitals) and the annual patient flow regarding 2016 was 1,712,957 (90.2% of all patient flow in ÁEEK owned hospitals).

3.2 DATA PROCESSING

The original database of the Health Insurance Supervisory Authority 2009 survey covered 165 Hungarian hospitals. However, because their characteristics were not homogeneous, the following case definitions and data processing step were introduced. First, all non-general hospitals were excluded from the study. In Hungary, a hospital is considered a general hospital if it provides inpatient medicine for adults, inpatient medicine for children, surgery, and obstetrics. Hospitals which were integrated into larger hospitals and thus their management team had no autonomous decision-making rights were also excluded. In addition, because some university hospitals reported data only at the departmental level they had to be excluded from the study as well. Finally, by adapting the DUQuE project's research protocol, the decision was made that the remaining hospitals had to have more than 130 beds. In order to make sure that the response rate remained sufficient after these exclusions, the National Health Insurance Fund's Annual Report on Hospital Bed Size and Patient Flow for 2009 was used as a point of reference.

After the case definition and data processing steps the remaining hospitals were grouped according having ISO 9001:2008 or HHCS certifications. The first group consisted of hospitals that had neither of these certifications, while the second group included hospitals having

ISO 9001:2008 certification only, the third group had the HHCS certification only, and finally, the fourth group of hospitals had both certifications.

Because not all modules of the database were relevant for our study, of the original 14 only four dimensions were retained. These were quality management, patient safety, patient rights, and human resource management.

It is worth mentioning, that the human resource management in this study should not be confused with the term ‘human resources’ in the Medical Subject Headings (MeSH), because the questions within this dimension are not about solving the demand, supply, distribution, recruitment and the use of personnel, but rather about how the management ensured its employees’ wellbeing. Regardless, both the patient safety and the patient rights dimensions are in synch with the definitions provided by the MeSH. Although, the term quality management is not mentioned in the MeSH database, in our study this dimension includes of activities related to quality planning, quality assurance, quality control, and quality improvement.

Due to the fact that some questions had simple ‘yes’ or ‘no’ options, while others gave the institution the option to specify how it performs a particular activity, in cases with more than two answer options, the answers were dichotomized. This means that every negative answer was coded ‘0’ while every positive answer was coded ‘1’. For each hospital, the answers of a particular dimension were summed, and the percentage was calculated from the possible maximum score of that dimension.

The hospitals which answered the 2013 national hospital questionnaire were also heterogeneous in their characteristics. Thus, a similar strategy was applied to exclude the hospitals that did not fit into the requirements of this study, and all non-general hospitals with fewer than 130 beds were ignored. One university hospital had to be excluded, too, because it provided answers only at a departmental level, and another hospital was also eliminated because it participated in the creation of the BELLA accreditation standards and thus might have been already influenced by the standards. The National Health Insurance Fund’s Annual Report on Hospital Bed Size and Patient Flow was used to check the response rate of all general hospitals in Hungary on the 31st of December 2013.

Similarly as in the case of the 2009 database survey, the questions regarding quality management and patient care activities were dichotomized after the aggregation of positive answers for each hospital by dimension. The opinion of the heads of quality management on the usefulness of quality management and clinical audits were treated separately. The former had a possible score between 7 and 35, while the later between 3 and 15. The next step was to calculate the possible maximum score for each and every dimension. However, in the 2013 national hospital survey was extended by the possible answer of “I cannot/do not want to answer the question.” In many cases the hospitals took the opportunity and selected this answer. Furthermore, (in some rare instances) some questions remained unanswered. To tackle these problems, the answering ratio for the questions for each dimension had to be 90% or higher. In those situations when a hospital answered less than 90% of the questions of the dimension, that particular dimension was ignored in the statistical analysis for the given hospital.

The institutions' overall debt in Hungarian forints (HUF) was used as an indicator to determine the financial status of a given hospital. The relevant data were obtained from the Hungarian State Treasury (MÁK) for each general hospital regarding the last month of 2013. Due to the various sizes of the hospitals in our study, the hospitals' debt was calculated per the number of beds and per number of patients discharged in the year 2013, respectively.

The National Healthcare Service Center (ÁEEK) provided the list of hospitals participating in the nationwide preparatory project for the BELLA accreditation. This was the basis for dividing those hospitals that answered the previously described 2013 survey and were not excluded from the analysis into the groups of participating and non-participating hospitals.

3.3 STATISTICAL ANALYSIS

The statistical methods used for the analyses of the 2009 and 2013 databases were very similar. In both cases Cronbach's α were used to determine the internal reliability of each dimension, and Kolmogorov-Smirnov tests were applied to check the normality of each distribution, grouped by the hospitals relevant to the study. Spearman correlations were used to assess the possible connection between the dimensions. For the 2009 analysis Kruskal-Wallis test was applied to determine the significant differences between the hospitals groups and the size of the effect was calculated using eta-squared values, while in the 2013 analysis Mann-Whitney U test and independent t-test were used depending on the normality of the distributions.

The normality of distribution was rejected if the P value was <0.01 . The size of the effect was deemed to be small if $\eta^2 < 0.06$, medium if $0.06 \leq \eta^2 < 0.14$, and large if $\eta^2 \geq 0.14$. The internal consistency of the dimensions and the overall score were considered unsatisfactory if the Cronbach's α was $P < 0.6$, questionable if $0.6 \leq P < 0.7$, and satisfactory if $P \geq 0.7$. Regarding all of the other calculations the level of significance was set to < 0.05 . In all cases the statistical analyses were performed with the SPSS 22 software program (SPSS for Windows, Version 22.0, IBM Inc., Released 2013. Armonk, NY, USA).

For the 2016 national hospital survey only descriptive statistics were used to illustrate the key findings regarding the usage of quality models within the Hungarian hospitals.

4. RESULTS

4.1 OVERVIEW OF QUALITY MODELS IN HUNGARIAN HOSPITALS

90 hospitals completed the national hospital survey of 2016. As described earlier, since only hospitals owned by the ÁEEK were asked, other types of hospitals such as university hospitals and private hospitals did not participate in this survey. This means that the result from the survey can only be generalized to all Hungarian hospitals with caution. Of the many questions, one asked what kind of certification does the hospital had, and what kind of rewards they got in the past.

According to the hospital survey data of 2016 the most common certification is the ISO 9001 – Quality Managements System (QMS) with 68.9%. The second is the Hazard Analysis and Critical Control Point certification (46.5%), the third is the Hungarian Health Care Standards certification (37.8%) and the ISO 14001 – Environmental Management certification (21.1%) is the fourth most commonly used certification. Only a few hospitals have the EN 15224 – Health Care Services, Quality Management Systems certification (2.2%), the ISO 15189 – Medical Laboratories certification (3.3%), the ExcellenCert certification (1.1%), the ISO 27001 Information Security Management certification (1.1%) and the OHSAS 18001 – Occupational Health and Safety Assessment Series certification (3.3%). None of the hospitals claimed to have ISO 26000 – Social Responsibility, ISO 50001 Energy Management Systems or ISO 22001 Food Safety Management Systems certifications.

Of the various awards, both kinds of “Hospital of the year” awards seem to be the most common with 10% from the Ministry of Human Capacities

(EMMI) and 5.6% from the organization Házipatika. Also, of the hospitals 4.4% got the IIASA-Shiba Award and 3.3% some kind of regional award.

4.2 ASSOCIATION BETWEEN THE APPLICATION OF ISO 9001:2008 ALONE OR IN COMBINATION WITH THE HHCS AND QUALITY-RELATED ACTIVITIES

Following the exclusion of inapt hospitals from the original 2009 database 55 general hospitals were found to be suitable for analysis. These hospitals represented 74.3% of all general hospitals with more than 130 beds in Hungary in that year (n=74). Out of these 16 had no certification, 19 had ISO 9001:2008 only, 2 had HHCS only, and 18 had both ISO 9001:2008 and HHCS certifications. Due to the insufficient sample size, two hospitals having HHCS certifications only were excluded from further analysis.

The Cronbach's alfa showed satisfactory internal consistency in the dimensions of patient safety and human resource management, while the overall score was questionable, and for both quality management and patient rights the scores were below the level of acceptance.

The Spearman's correlation matrix revealed significant positive connection between the dimensions of quality management and human resource management, patient safety and patient rights, and patient safety and human resource management. However, it is worth noting the in all cases the level of correlation was weak. This means that there was no meaningful connection between these dimensions, and they could be analysed separately.

Hospitals having both ISO 9001:2008 and HHCS certifications had the highest median scores in all dimensions and in the overall scores. Also, hospitals with ISO 9001:2008 only had higher medians compared to the

hospitals with no certifications in the dimensions of quality management, human resource management, and in the overall scores.

The results of the comparative statistics demonstrated that both the hospitals with ISO 9001:2008 and HHCS certification and the hospitals with ISO 9001:2008 only significantly outperformed the hospitals without certification in the areas of quality management, human resource management and overall scores.

4.3 INVESTIGATION OF THE CONDITIONS AFFECTING THE JOINING OF HUNGARIAN HOSPITALS TO AN ACCREDITATION PROGRAMME

Due to the exclusion criteria 44 general hospitals remained from the 2013 database. These hospitals represent 73.3% of all general hospitals in Hungary in that year (n=60). Of the 44 hospitals fourteen took part in the preparatory project of the BELLA accreditation. Since the remaining thirty were not involved in this project, their answers were used for comparison.

Because of the 90% answering criterion thirty-four answers were excluded at the dimensional level. According to the Kolmogorov-Smirnov test the normality of data varied according to dimension and participation.

The Cronbach's alfa scores indicate satisfactory internal consistency in the dimensions of quality management, pressure sore prevention, as well as in the opinion of the head of quality management on quality management itself and on clinical audits. However, the Cronbach's alfa value was questionable for safe surgery and below the acceptance of patient information and identification, internal professional regulation and infection control.

The correlation matrix in demonstrated significant positive connection between the dimensions of quality management and internal professional

regulation, infection control and pressure sore prevention, internal professional regulation and opinion on clinical audits, and finally the opinion on quality management and opinion on clinical audits. Since all these correlations are at moderate-level, a common explanatory factor underlying these dimension can be ruled out, and thus the dimensions could be assessed independently from each other.

The comparative statistics revealed no significant differences in any of the dimensions when comparing the group of participating general hospitals with the group of non-participating hospitals.

In addition, despite of the fact that the general hospitals which participated in the preparatory project had both lower means of debt – per bed number and debt per the number of discharged patients – as compared to those that did not join, neither of the outcomes were significantly different.

5. DISCUSSION

5.1 IMPLICATIONS OF THE RESULTS

From the national hospital survey of 2016 we know that the most commonly used quality model was the ISO 9001 QMS. However, a slight decrease was identified in the usage of both ISO 9001 and HHCS between 2014 and 2016. This decline was most probably due to the emergence of the EN 15224 certification and to the TÁMOP projects associated with the BELLA accreditation. The key message here is that Hungarian hospitals can no longer be considered homogeneous in the usage of quality models which might lead to variations in the performance in quality management and healthcare related activities. Also, performing quantitative researches in the future will be much more challenging, as all of these quality models must be included in statistical analyses.

Since both ISO 9001:2008 alone and with healthcare-specific standards showed a significantly better score regarding quality management and human resource management, it can be assumed that ISO 9001:2008 is indeed associated with these activities. In one of the study carried out within the MARQuIS research project quality management was a sub-dimension of the management dimension, and the association between management with ISO 9001 was not assessed alone, rather it was investigated together with other accreditations. This means that our work is the first quantitative research had which revealed a direct positive connection between ISO 9001 and quality management activities in hospital care.

Although a positive association was identified between ISO 9001:2008 and human resource management, the cause and effect relationship has not been clarified. Despite the fact that ISO 9001:2008 is having requirements considering human resources, it does not include assessments for the prevention of employee burnout, regular surveys of employee satisfaction or provisions for health promotion services for staff members. In conclusion, it is very difficult to decide whether ISO 9001 indirectly promotes these activities or if the organizations that are proactive in human resource management are also more likely to implement ISO 9001.

Similarly as in another study conducted within the MARQuIS project, no significant connection was found between ISO 9001:2008 and patient safety activities. This is due to the fact, that ISO 9001 contains no healthcare-specific requirements at all.

Also, in synch with the finding of a MARQuIS study, patient rights were not significantly associated with ISO 9001:2008. Therefore it can be concluded that ISO 9001 and other quality models in general are not associated with patient rights activities.

When combining ISO 9001:2008 with HHCS no significant benefits were shown. A possible explanation is that the requirements of the HHCS are not sufficiently specific in some instances and the standards are not relevant enough. Another possible explanation might be that although the standards were sufficient, there were various barriers hindering their integration into the everyday practice. Possible examples of such barriers might be the low degree of self-initiative among those involved, a lack of team structure, incomplete team meetings, a lack of coordination, rotating residents, limited resources and too much change within the organization. It is also worth mentioning that even in 2009 there was a serious staff shortage among Hungarian hospitals. Although, there is no compelling evidence to decide which of these factors might have played a significant role, still we can conclude that because of the possible negative effect of the previously mentioned barriers, the implication of healthcare-specific standards alone does not lead to better or safer healthcare.

The best results were exhibited by the hospitals that had more than one quality model; which is consistent with the findings of the DUQuE research project. However, the advantages were only true in the median scores, and no significant differences were identified when these hospitals were compared with those that only had ISO 9001:2008 certification. This questions the assumption, that implementing more than one quality model always brings the best results. In addition, if the implementation of certifications would provide a genuine benefit, then it would be still unclear if this benefit is associated with the complementary nature of the HHCS to the ISO 9001:2008 or because the managers maintaining both certifications are more dedicated to a high quality of care. The same way, as in both the MARQuIS and DUQuE research studies the results presented in this study cannot give us a definitive answer to the question.

The implications for the BELLA accreditation are straightforward. Since no significant advantages were found among the hospitals prior to the application for the preparatory project, if the accreditation will be available for the Hungarian hospitals then future differences can be solely attributed to this quality model. Also, the assumption that the hospitals only joined the EU-funded project for financial benefits is questioned by the result that the average debt rate of these hospitals was lower to those that abstained participation.

The results derived from the analysis of the 2013 database question the assumption that there might be an independent explanatory factor explaining both the intent for accreditation and high quality of care. Due to the fact that no statistically significant differences were found between the two groups of general hospitals, we can state that the accreditation is not a method that selects hospitals which already perform better, but should be seen as a tool that can contribute to the further development of hospital activities. From this comes the important conclusion that the benefits identified by previous quantitative studies regarding hospitals are indeed due to the accreditation.

5.2 STRENGTHS AND LIMITATIONS

The 71.6% participation rate for the analysis of the 2009 survey and the 73.3% for the analysis of the 2013 survey regarding all general hospitals in Hungary can be considered exceptionally high. In both cases, the results and conclusions can be generalized to all Hungarian public general hospitals. Although fewer hospitals were included in both analyses than in the international MARQuIS (71) and DUQuE (73) projects, the even distribution of each sub-group in both Hungarian surveys was ideal for conducting cross-sectional studies. In addition as both surveys were conducted in a single

country confounding factors such as different financial environments and national health policies were absent.

However, no private hospital was taking part in any of the two studies. This is due to the fact that (i) there are not that many private hospitals in Hungary, (ii) they provide specialized care in most of the cases and (iii) they rarely participate in academic or government surveys. Thus, the result presented in this thesis cannot be generalized to private hospitals.

The questionnaire of the 2009 national hospital survey reflected the priorities of the Health Supervisory Authority (EBF). Therefore, the topics analysed can be considered important on a professional level. Although, many questions were altered for the 2013 national hospital survey, these changes were only made to gain more in depth information in specific areas. However, the most noteworthy limitation of the two surveys is that both questionnaires were originally created for a national report, not for research purposes. This means that some of the specific steps were ignored that would be necessary for the validation of the questionnaires. The low Cronbach's alpha scores in many dimensions in both investigations can be attributed to this shortcoming. Despite of this limitation, it is worth mentioning that many dimensions showed reliable internal consistency.

Both the MARQuIS and DUQuE projects used questions in which the answers reflected the four stages of the plan-do-check-act (PDCA) cycle. In contrast to these European projects in both of our national studies by dichotomizing the answers for the statistical analysis only the question "what" the organizations were doing was assessed and the question "how" was somewhat ignored.

The analysis of the 2009 survey did not address the question how long the hospitals had their ISO 9001 and HHCS certifications or which accredited

certification agency granted it. Another relevant problem is that not all certification agencies operating in Hungary obtained their accreditation from a Hungarian authority that may result in the potential variation in interpreting the ISO standard.

The questions of the 2013 national hospital survey had an option “I cannot/Do not want to answers the question”. This answer acted as a double-edged sword. Although this option prevented hospitals from giving false information on specific activities, this had also led to a situation where not all questions were answered in each dimension per hospital. This has resulted in the weakening of the overall level of evidence that can be drawn by the statistical analysis. However, using valid information is more important than having a higher number of samples; thus, the benefit of introducing this option in the questionnaire outweighed the overall costs.

Although there are many limitations listed, if we also consider both the strengths and the quantitative methods used in our investigations, these limitations do not undermine the key messages presented in this thesis.

5.3 RECOMMENDATIONS FOR HUNGARIAN HEALTH POLICY MAKERS

When contemplating the best possible solution for Hungarian hospitals regarding the usage of quality models several factors have to be taken into consideration. First and foremost, it is unclear which type of model is most suited for healthcare. According to the MARQuIS research project hospitals with accreditation performed better in the fields of management, clinical practice and patient safety than hospitals with certification, however, ISO certified hospitals got better scores in areas of both patient-centredness and cross-border patient-centredness. In addition, thus far there was not a single study conducted in which the two quality models would have been compared

to each other regarding the important outcomes of healthcare, such as mortality, length of stay, patient satisfaction or employee satisfaction. Therefore, at the moment there is no sufficient evidence for claiming either quality model better than the other.

Another important factor that needs to be considered is that Hungary did not participate in either the MARQuIS or the DUQuE research projects. Thus, it is uncertain how the general European findings can be applied in the Hungarian hospitals. When analysing quality management related topics among Hungarian hospitals, one has to consider that (i) ISO certification is present for more than two decades, (ii) according to the latest data 68.9% of hospitals have ISO 9001 certification and (iii) there is a serious medical staff shortage in healthcare.

Furthermore, despite the fact that the preparatory project for the BELLA accreditation was completed in November 2015, up till now the BELLA accreditation has not been granted and this quality model has not been made available for the healthcare providers. Since no official statement has yet been released on the future of the BELLA accreditation, multiple possible scenarios must be considered when making recommendations for health policy makers in this topic.

If policy makers decide to support the BELLA accreditation, then depending on the initial success two outcomes may occur. (i) Either a sufficient number hospital would apply for the accreditation and they would demonstrate a positive impact of BELLA on the process and outcome of healthcare. This will most likely result in the further fragmentation of healthcare-specific quality models among hospitals. (ii) However, if the number of applying hospitals would be too low or the promised benefits would fall short, then health policy makers must take a definitive action and find another solution.

If policy makers decide not to support the BELLA accreditation the following factors have to be taken into consideration. Although EN 15224 has healthcare-specific requirements it was designed at an all European level and it might not be sufficiently specific to solve the quality management in the Hungarian hospital care. In addition, based on our findings, the HHCS was not associated with better patient safety. If we sum up all the information presented in this section of the thesis, four main strategies/plans can be recommended to policy makers:

Plan 1. Revise the HHCS and integrate it with the MSZ EN ISO 9001:2015 standards: This strategy could be appealing, since many Hungarian hospitals already have both ISO 9001 and HHCS certifications. This would prompt the auditors of the organizations accredited for granting HHCS certification to accumulate the experiences and feedbacks gained in the past decade. Such revision would require governmental support, but the project could be done in a relatively short time.

Plan 2. Revise the HHCS and integrate it with the MSZ EN 15224:2017 standards: Compared to the first strategy, this would require a higher degree of intervention, since not many hospitals have an EN 15224 certification. However, the EN 15224 has international recognition which could be beneficial for cross-border patient-centred care.

Plan 3. Integrate the existing standards of the BELLA accreditation with the ISO 9001:2015 standards: The BELLA accreditation has in depth and relevant standards with a high emphasis on patient safety. If the accreditation process is rejected, the standards could be still used and altered in a way that would be compatible with the ISO 9001 standards. Since the standards are already available, minimum effort has to be invested to achieve this goal.

Plan 4. Integrate the existing standards of the BELLA accreditation with the MSZ EN 15224:2017 standards: The original goal of the BELLA accreditation was to apply for the ISQua accreditation and thus gain international recognition. However, without a complete programme, this is not possible. Therefore, it might be a good strategy to integrate the accreditation standards with the EN 15524.

Each strategy has its own strengths and weaknesses that have to be carefully evaluated before making the final decision. However, regardless of which quality model(s) will the health policy makers support, it is imperative that they understand that these are just one of many tools that is required to provide high quality care in hospitals. For a comprehensive hospital care system it is essential (i) that the latest evidence based medicine is implemented and checked via clinical audits, (ii) that in accordance with Total Quality Management principles all the staff members take part in the continuous improvement, (iii) and the top management must provide a supportive environment that promotes the culture of high quality of care within the entire organization.

SUMMARY

The most common quality models used in European hospital care are ISO certifications, EFQM excellence model, visitate, and accreditation. Most studies thus far have focused on the impact of accreditation despite of the widespread application of ISO 9001. Overall, many positive benefits can be attributed to both accreditation and ISO 9001. However, it was still yet unknown how ISO 9001 performs with and/or without healthcare-specific standards, and what hospital characteristics may contribute to the introduction for an accreditation programme. The overall goal of the analyses presented in this thesis was to answer these questions. For the first investigation the database of the 2009 Health Insurance Supervisory Authority survey was used, while for the second one the databases from the 2013 national hospital survey and from the Hungarian State Treasury were utilised. 53 and 44 Hungarian general hospitals were included in the two statistical analyses, respectively. We found that hospitals with ISO 9001 alone or in combination with the HHCS significantly outperformed hospitals with no certifications in terms of quality management and human resource management. However, no significant differences were observed when the hospitals with both certifications were compared with hospitals with ISO 9001 only. Therefore health policy makers should consider supporting ISO 9001 and/or EN 15224. Also the creation of an integrated quality model for healthcare should also be considered. When comparing the hospitals that joined the preparatory project for a newly developed BELLA accreditation programme to those that did not, no statistically significant differences were found in any of the examined outcomes. Thus, provided that the BELLA accreditation programme launches, then future differences between the accredited and non-accredited hospitals could be solely attributed to this quality model.

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List of publications related to the dissertation

1. **Dombrádi, V.**, Margitai, B., Dózsa, C., Csenteri, O. K., Sándor, J., Gáll, T., Gődény, S.:
Investigation of the conditions affecting the joining of Hungarian hospitals to an accreditation programme: a crosssectional study.
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