

Association between Patient Outcomes and *Joint Commission International (JCI)* Accreditation in Italy: An Observational Study

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Abstract

Quality in healthcare is a constantly debated topic and has not found a clear definition to date. If we consider the possible quality standards related to health services, the Joint Commission identifies the main criteria that health organizations must respect in order to guarantee patient safety. The Joint Commission International – founded in 1994 by the JC – also accredits organizations in countries other than the USA and Canada to ensure better minimum quality levels. The study investigates the possibility of obtaining a better outcomes of the health structures accredited in Italy by the Joint Commission International compared to the other the other health organizations of the Italian system considering the mortality index as an indicator recognized by the literature as a summary indicator of outcome. The National Outcome Program (PNE) created by the Italian Ministry of Health allows comparative effectiveness researches based on relative risk. This study performs the analysis based on the results of the past three years available and on the volume of activities provided. Given a p-value significance index <0.05, the analysis highlights the absence of a significant difference between accredited and non-accredited structures. The study contributes to the literature on health system outcomes and performance and has relevance considering researches in health tourism and health mobility policies fields.

Keywords: PNE; Joint Commission; medical tourism; index of mortality; healthcare quality standard.

1. Introduction

Quality in healthcare has been a topic debated in literature for some time but it has not yet found a clear definition (Reeves and Bednar, 1994; Mitchell, 2008; Mosadeghrad, 2014; Tradori, Brescia and Biancone, 2019; Biancone *et al.*, 2020). Normally quality in healthcare is defined as quality systems or quality standards, or even considering mixed models (Donabedian, 1981; Chae *et al.*, 2003; Douglas and Fredendall, 2004; Lillrank and Liukko, 2004; Kwan *et al.*, 2019). At present the reality is complex and very often bases these parameters on voluntary organizational efforts (Bode, 2006; Baker *et al.*, 2007; Legido-Quigley and Nolte, 2008). The analysis conducted focuses on quality standards definable as process outcomes (Alkhenizan and Shaw, 2011).

Among the most debated, we find the standards defined by the Joint Commission of American origin that evaluates the health performance of the organization based on minimum standards aimed at guaranteeing patient safety (McIntyre, Rogers and Heier, 2001; Morath and Turnbull, 2005). The American surgeon Ernest A. Codman (Roberts, Coale and Redman, 1987) founded an hospital, called "*End Results Hospital*" (Neuhauser, 2002) in 1911, and launched the "*American College of Surgeons Program*" in 1913 (1917) to evaluate the application of the care provided. Given that out of 692 hospitals (with at least 100 beds each one), only 89 were able to meet the efficiency standards

set by the American College. In 1919, a list of five performance requirements for hospitals was decided to ensure towards an acceptable minimum (Roberts, Coale and Redman, 1987). The percentage of hospitals whose activity was shown to comply with the required standards went from 13% in 1919 to 50% in 1950.

In 1951, to meet both the high costs of various projects and the growing complexity of clinical reality, the *American College of Surgeons* decided to associate with the *American College of Physician*, the *American Medical Association* and the *Canadian Medical Association* in order to found the *Joint Commission on Accreditation of Hospitals* (Jost, 1994). This non-profit organization defined the criterion for evaluating the quality of the "*Optimal Standard*" as a maximum level reachable on the basis of the resources available (rather than an excellent in an ideal sense) leading to the realization of the *Accreditation Manual for Hospitals* (1970) as a primary tool for a systematic hospital accreditation activity (Affeldt, 1980). Such a voluntary accreditation modelled today to the accreditation of approximately 80% of American hospitals by a delegation from the US government (McGreevey, Nadzam and Corbin, 1997; Lam *et al.*, 2018). The Joint Commission born in America in 1951 has two nonprofit affiliate organizations: The Joint Commission Center for Transforming Healthcare aims to solve health care's most critical safety and quality problems and Joint Commission Resources (JCR) offers educational services, publications, and software to complement

your accreditation experience. Joint Commission International, a division of JCR, accredits and certifies international health care organizations.

Currently, the *International Joint Commission* – founded by the Joint Commission – also accredits hospitals in other countries in order to guarantee the quality of services according to standard criteria (Smith and Forgione, 2007; Longo *et al.*, 2017). The American health system has prompted many residents to direct their choice of care to countries where care is cheaper and more accessible (Yousefian *et al.*, 2013). To this end, various health facilities have been accredited, especially in Asia, with the birth of the phenomenon called *medical tourism* (York, 2008; Pafford, 2009; Heung, Kucukusta and Song, 2011). The phenomenon of voluntary accreditation of healthcare facilities, conducted by the *International Joint Commission*, affects not only Asia but also other countries, including Italy (Lemarquand, 1993; Arcari, 2003). The evaluation of the performance of the structures accredited according to the standards of the *International Joint Commission* can increase the definition of better structures in terms of health care and hospitality.

However, numerous American studies show that accredited hospitals do not achieve better quality levels in terms of mortality and patient experience (Lam *et al.*, 2018). Therefore, the question arises as to whether accreditation is related to higher quality of performance and patient safety that can be assessed through the mortality index.

For several years, Italy has launched a *National Outcome Program (PNE)* evaluation program coordinated by the Ministry of Health which, through a process of comparative effectiveness research, allows performance evaluation taking into account various factors. Therefore, through the analysis of the relative risk, this study investigates whether the accredited Italian hospitals are better than the national average, the analysis also takes into account the statistical significance that the program makes available. The healthcare facilities considered are all part of the Italian public national healthcare system as there are no private structures in the PNE surveys.

To date, no studies are investigating the phenomenon of correlations between IJC accreditation and hospitals effectiveness results in Italy. Instead it could be useful, if we consider the new directives which intend to increase the phenomenon of medical tourism in Italy while keeping the phenomenon under control.

2. Literature review

2.1. Joint Commission, Joint Commission International and quality standards

The Joint Commission (www.jcrinc.com) (3-5) is an American non-profit, non-governmental entity founded in 1951 that has accredited over 20,000 healthcare organizations in the United States to date (Roberts, Coale and Redman, 1987). The mission is to improve health care for citizens, in collaboration with other stakeholders, evaluating health organizations, and inspiring them to excel in providing safe and effective treatments of the highest quality and value (Nadzam, 1991). Today the Joint Commission, made up of approximately 500 employees and 700 supervisors, is led by a 28-member Commission, an expression of the associations of nurses, consumers, doctors, clinical directors, administrators, producers, trade union organizations, quality experts, insurers, trainers, etc. The multidisciplinary composition brings to the Joint Commission the most varied experiences in the field of assistance and health policy. The structures that are evaluated and accredited include general, psychiatric, paediatric, rehabilitation hospitals; welfare networks; home service organizations and support services, home infusion therapy and other drug treatment services; hospice; programs for subacute diseases, dementia and long-term care; mental health and detoxification services, services for the disabled, outpatient services; clinical laboratories.

In 1994, the US *Joint Commission* founded the *Joint Commission International (JCI)* in response to numerous requests from hospitals in other countries around the world (Donahue e Vanostenberg 2000). To date, JCI has accredited hospitals and other healthcare institutions in more than 90 countries around the world. JCI currently has three affiliated agencies in Europe, Asia, and South America. To obtain and maintain *The Joint Commission's Gold Seal of Approval* it is necessary to support and pass a site visit on all standards, and accreditation is valid for three years. Besides, JCI works with health care organizations, governments, and sponsors internationally to promote rigorous standards of care and provide solutions to achieve optimal results. JCI experts assist organizations in three ways: accreditation, training, and consultancy services (Robinson, 1995). The development of better standards for patient care and the evolution of results-oriented processes towards the patient has earned her the international recognition of leaders in healthcare.

This is why the *World Health Organization (WHO)* joined JCI to found the first WHO Collaboration Centre for patient safety solutions (Baretich, 2020). A working group developed the international standards made up of 16 members from all over the world, including doctors, nurses, administrators, and policy experts, subsequently reviewed in over ten countries and then discussed in six focus groups. The standards relating to "Patient and family rights" and to "Infrastructure Management and Security" required two specific panels of experts. After the second phase in which the verification process was tested in five countries, the JCI standards were finally approved by the JCI team and JCI board.

Hospital standards are assessed on three levels every three years: the *Joint Commission Committee for international accreditation* proposes variations based on visits and international literature; the proposals are sent to the referents of the participating hospitals to express their opinion on the criteria of relevance, feasibility, and relevance. *The Joint Commission Resources Board of Directors* (team of healthcare experts who oversee define and interpret standards) provides the final opinion on maintaining or modifying current and proposed standards. The manual is republished every three years after consulting the accredited organizations. In the various editions, while keeping the structure firm, the standards have been refined, and the level of requirements has been raised, leading the organizations that accredit or renew accreditation to essential efforts in terms of quality and safety. In this regard it is recalled that since 2009 the International Patient Safety Goals have been introduced which deal with topics such as safety for the prevention of accidental falls, safety in hand washing, safety in the surgical act, safety in the use of high-risk drugs, safety in the identification of the patient and safety in communication between operators, all considered essential standards for obtaining accreditation and fundamental for not endangering the patient's life or safety (Wachter, 2010). The manual contains hundreds of standards that collectively include thousands of measurable elements. The standards are organized into chapters that embrace the hospital organization globally on all processes. The phases that characterize the accreditation process include four phases. The process lasts for a maximum of 26 months. Phase 1 self-evaluation of the possession or not of the requisites required (pre-survey evaluation) (1st month). Phase 2 creation of improvement groups and production of improvement projects to meet the requirements (duration from 12th month to 18th). Phase 3 accreditation visit (survey) (duration from 18th month to 24th). Phase 4 accreditation (duration from 20th month to 26th). During the visit, JCI representatives carry out training and consultancy activities and provide recommendations to facilitate the achievement of standards. If the requirements are achieved, the organization passes the fourth phase and reaches accreditation valid for three years. The possible levels are identified in: accreditation status or accreditation rejected.

2.2. Italian PNE and comparative effectiveness research

The progress of study design and statistical analysis methodologies and the ever-increasing availability and validity of information systems and databases in advanced health systems have highlighted the role of "comparative effectiveness research" (Garber, 1992; Hernán, 2011; Gargon, Gorst and Williamson, 2019). It is intended as a comparative observational assessment of health services and interventions. The comparative assessments of hospitals, by structure, by diagnosis, by procedures, by organizational characteristics, are cases of application of the methods of comparative effectiveness research (de Lemos and Nallamothu, 2020). At the international level, the experiences of comparative assessment among structures have been consolidated for several years.

The Italian National Outcome Program (PNE – Piano Nazionale Esiti) is developed by Italian National Agency for Regional Health Services (AGENAS) on behalf of the Ministry of Health and provides a national level of comparative evaluation of the efficacy, safety, efficiency, and quality of the care produced within the health service. The areas of assessment are, as regards the production function, the individual hospitals, and, as regards the protection or commissioning function, the local health companies. The critical and administrative issues that must have greater relevance are discussed within the PNE Committee, made up of representatives of Regions, Autonomous Province, Ministry of Health and scientific institutions. Design, management, the definition of control, data analysis, and management of the website are carried out by the Epidemiology Department of the regional health service of the Lazio Region, as the PNE operations centre of AGENAS.

Italian PNE measures are evaluation tools to support clinical and organizational auditing programs aimed at improving effectiveness and equity in the National Health System. PNE does not produce rankings, evaluations, or report cards. The process leading to the definition of an outcome indicator begins with a systematic review of the medical-scientific literature relating to the treatment or therapeutic, diagnostic course that is intended to be assessed. The information derived from this first revision phase allows to define a first version of the protocol to be used to conduct preliminary analyzes that will allow to verify the validity of the indicator. The indicators are documented by protocols with an explicit definition of the outcome in the study, of the selection criteria of the cases, of the follow-up times, of the sources of the data and of the factors used for the risk adjustment. The results of the preliminary analyzes are subjected to the evaluation of representatives of the reference scientific societies, panels of experts, and further clinicians discussed within the PNE Committee.

Literature outlines that outcome indicators measure the outcome of a care process in terms of clinical outcomes (e.g., mortality, disease, hospitalizations) (Tu *et al.*, 2003). Their relationship with the measured phenomenon is influenced by several determinants that are not directly correlated with the quality of the care process (risk markers, environmental factors, socio-economic variables), and that must be considered and possibly corrected while figuring indicators. The robustness of the outcome indicators also depends on the time elapsed between the measurement and the actual delivery of the health service. Process indicators measure the degree of adherence of the care process to the reference standards of best evidence-based clinical practice. For this reason, they are considered proxies of the outcomes of the assistance and their robustness, understood as predictive of the clinical outcomes, depends on the strength of the clinical recommendation and the degree of evidence on which they were built. In addition, indicators of activity volumes are calculated for health interventions for which scientific evidence is available of the association between volumes of activity and outcomes of care (Halm, Lee and Chassin,

2002). Finally, the quality of territorial assistance is assessed by measuring the so-called "ambulatory care sensitive conditions" (ACSC), which can be defined as situations in which quality territorial assistance allows avoiding the use of avoidable hospitalizations or early intervention allows preventing complications or more pathologies serious (Ansari, Laditka and Laditka, 2006).

2.3. Index of mortality

In literature, the most used outcome of healthcare service in studies is the rate of intra-hospital mortality within 30 days of discharge (Thomas, Longford and Rolph, 1994; Leyland and Boddy, 1995; Goldstein and Spiegelhalter, 1996; Marshall and Spiegelhalter, 1999, 2001). The *mortality rate* is the ratio between the number of deaths in a community of people over a period of time and the amount of the average population over the same period (Gryfe, Amies and Ashley, 1977). The *mortality rate* measures the frequency of deaths of a population over a period of time and is normally referred to a calendar year. This data is used to verify the negative state of development of a population. The *mortality rate* for a given year is equal to a hundred times the ratio between the number of deaths in that year and the average population. Although some authors have stated that the indicator alone is not enough to define the outcome of treatments (Epstein, 1998; Marshall and Spiegelhalter, 2001), it is also true that it is the easiest to calculate and monitor. Clinical or clinical outcome indicators can be used to solve the problem epidemiological, specific for each pathology, built according to criteria derived from the scientific literature, collected *ad hoc*, or from medical records or documentation directly related to the treatment. This is already happening in some countries due to the mortality rate, which is systematically collected by the hospital and geographical areas, in some cases taking into account the individual characteristics of the patients undergoing edited thanks to the use of the same or similar methodologies. In Italy the National Outcome Program (PNE) already considers this information gathering approach. According to Birkmeyer (Birkmeyer *et al.*, 2002; Ghaferi, Birkmeyer and Dimick, 2011) the analyzes of those kind of dataset overall show an inverse relationship between the volume of activity and mortality, confirming that this association has to do with quality. The study focused – in the Italian context – on the possible relationship between the volume of activity and quality would derive from the fact that the volume can be considered a good proxy of the experience of the providers of the choice of the providers of the citizens. The PNE considers only the statistically significant thresholds for assessing the mortality rate for each health service observed. If the number of cases is not sufficient for the expected mortality rate, the PNE does not present the result.

3. Method

The measure used to determine whether the structure is statistically better than the national average or the benchmarking average is the *Relative Risk (RR)* (Dyer and Sarin, 1982). The RR is calculated as the ratio between two rates / proportions and expresses the excess (or defect) of risk of the group placed in the numerator compared to the group placed in the denominator (Barlow and Prentice, 1988). For example, if for the healthcare organization of residence A the mortality RR compared to Health organization B (reference area) is equal to 2, it can be concluded that the residents in Health Organization A have a risk of death twice higher than that of residents of Health Organization B. Vice versa, if for the Health Organization of residence C the mortality RR is 0.25, the residents of this Health Organization have a risk of death four times smaller than that observed in the reference Health Organization.

For some indicators the measure the association used is the *Hazard Ratio (HR)*, interpretable as an instant RR. The relative risk measure adopted in this case takes into account the mortality rate identified as a useful indicator to define the practical

effectiveness of the treatments, the parameter takes into account comorbidity and specific epidemiological criteria for each pathology (Miettinen, 1970). The data is also related to the volume of activity provided (Landis, 2004). The p-value that the PNE identifies for each mortality rate allows to determine the significance of the same with respect to the national sample (Parvizi, Ereth and Lewallen, 2004; Reid *et al.*, 2009; Devereaux *et al.*, 2012). The value of p represents the probability that the observed Relative Risk differs from one (null hypothesis) only as a result of the case. A p-value close to unity indicates, for example, that a mortality RR is no different from 1; in other words, the mortality rates in the two groups compared are not, from a statistical point of view, significantly different. On the other hand, a low p-value indicates that the difference observed between the two groups cannot be attributed solely to the effect of chance. P-values less than or equal to 0.05 indicate that the mortality rates in the two groups are, from a statistical point of view, significantly different (Afifi and Elashoff, 1967; Marill, 2004; Bailar and Hoaglin, 2012).

3.1. The sample

The analyzed sample was obtained manually from the Joint Commission website. The structures were accredited before 2016.

The sample consisted primarily of 23 healthcare facilities located on the Italian territory. However, 9 structures were not considered as they are not present in the PNE, as they are rehabilitative or diagnostic and do not involve a collection of mortality rates (CDI Centro Diagnostico Italiano S.p.a. – Milan, Ceinge Biotecnologie Avanzate scarl – Napoli, Fondazione Centri di Riabilitazione Padre Pio ONLUS San Giovanni Rotondo – Milano, Istituto Mediterraneo per i Trapianti e le Terapie ad Alta Specializzazione – Palermo, S.D.N. S.p.A. –

Napoli, Santa Chiara Hospital – Trento, UPMC San Pietro FBF – Advanced Radiotherapy Center – Roma, A.p.s.p. Residenza – Valle dei Laghi Cavedine, Casa di Cura Villa San Benedetto – Menni Albese con Cassano. A structure is located on the Vatican territory; therefore, it is not considered in the Italian databases (Ospedale Pediatrico Bambino Gesù – Roma). There were also 5 structures that, by volume of cases treated, did not gather representative mortality data and therefore, were not considered (Centro Chirurgico Toscano Srl – Arezzo; IRCCS Centro San Giovanni di Dio Fatebenefratelli – Brescia, Istituto di Medicina Fisica e Riabilitazione "Gervasutta" – Udine, Giannina Gaslini Children's Hospital – Genova; Presidio Ospedaliero Ospedale dei Bambini – Brescia).

Therefore, the study was able to consider the results of the specialist activities of 8 facilities. These are located as follows: 5 structures in northern Italy, 2 in the south Italy and 1 in the central Italy. The activities which have resulted mappable by structure fall in a range from one to eighteen. These specializations have resulted in having gathered measures of mortality rate detectable thirty days after the different intervention.

4. Result

Accredited Joint Commission Structures present on average a relative risk better than other national health structures, also considering the volume of services performed (see table 1).

In some years the structures do not reach the minimum thresholds of performance volumes in order to be able to consider the data reliable. Nevertheless, the p-value almost always shows a lack of significance of the result, however not confirmed in the three years considered. This result excludes the possibility of affirming a continuity of the significance of the rate concerning the national average in consecutive terms.

Structure and activity mortality rate	RR (ADJ) 2016	P-value 2016	Indeed significant 2016	RR (ADJ) 2017	P-value 2017	Indeed significant 2017	RR (ADJ) 2018	P-value 2018	Indeed significant 2018
1) COT Cure Ortopediche Traumatologiche S.p.A. Messina (Southern Italy)									
Chronic renal failure: mortality 30 days after hospitalization	0.16	0.068	0	0.26	0.057	0	0.52	0.146	0
European Institute of Oncology (Istituto Europeo di Oncologia) Milano (Northern Italy)									
TM kidney surgery: 30-day mortality	0.37	0.322	0	0.41	0.377	0	0.41	0.376	0
TM stomach surgery: 30-day mortality	0.34	0.134	0	0.30	0.188	0	0.37	0.156	0
TM colon surgery: 30-day mortality	0.59	0.369	0	-	-	-	-	-	-
Rectal TM surgery: 30-day mortality	0.80	0.821	0	-	-	-	-	-	-
Surgery for TM lung: 30-day mortality	0.65	0.262	0	-	-	-	0.73	0.418	0
Surgery for TM prostate: 30-day readmissions	1.26	0.301	0	-	-	-	0.99	0.962	0
Fondazione Poliambulanza Brescia Northern Italy)									
Acute myocardial infarction: 30-day mortality	0.83	0.415	0	0.57	0.053	0	0.74	0.277	0
TM kidney surgery: 30-day mortality	0.59	0.612	0	-	-	-	-	-	-
Surgery for liver TM: 30-day mortality	0.95	0.946	0	-	-	-	-	-	-
Brain T surgery: mortality 30 days after craniotomy	1.11	0.807	0	0.68	0.504	0	0.43	0.234	0
Chronic renal failure: mortality 30 days after hospitalization	0.76	0.390	0	0.50	0.082	0	0.80	0.263	0
Isolated Aortocoronary bypass: 30-day mortality	0.34	0.128	0	0.25	0.169	0	0.66	0.558	0
Congestive heart failure: 30-day mortality	1.16	0.318	0	1.20	0.212	0	1.08	0.569	0
Repair of unbroken abdominal aortic aneurysm: 30-day mortality	0.32	0.251	0	0.59	0.466	0	0.66	0.558	0
Non-varicose hemorrhage of the upper intestinal tract: 30-day mortality	0.58	0.226	0	0.79	0.568	0	0.97	0.943	0
Acute myocardial infarction without PTCA: 30-day mortality	0.91	0.724	0	0.60	0.208	0	0.93	0.839	0
Femoral neck fracture: 30-day mortality	0.69	0.326	0	0.91	0.791	0	0.64	0.281	0
Ischemic stroke: 30-day mortality	0.94	0.735	0	0.56	0.021	1	0.47	0.005	1
COPD exacerbated: 30-day mortality	1.20	0.353	0	0.86	0.483	0	1.06	0.751	0
TM stomach surgery: 30-day mortality	0.45	0.173	0	0.35	0.136	0			
TM colon surgery: 30-day mortality	0.66	0.422	0	0.78	0.595	0	0.54	0.223	0
Rectal TM surgery: 30-day mortality	1	0.997	0	-	-				
Acute Myocardial Infarction with execution of PTCA within 2 days: mortality at 30 days	0.92	0.826	0	0.72	0.421	0	0.74	0.277	0
Surgery for TM lung: 30-day mortality	1.79	0.420	0	0.88	0.898	0	1.10	0.923	0

QUALITY MANAGEMENT

Structure and activity mortality rate	RR (ADJ) 2016	P-value 2016	Indeed significant 2016	RR (ADJ) 2017	P-value 2017	Indeed significant 2017	RR (ADJ) 2018	P-value 2018	Indeed significant 2018
2) Humanitas Gavazzeni Bergamo (Northern Italy)									
Acute myocardial infarction: 30-day mortality	0.63	0.232	0	0.86	0.660	0	0.58	0.192	0
Surgery for liver TM: 30-day mortality	0.60	0.611	0	-	-				
Chronic renal failure: mortality 30 days after hospitalization	0.48	0.048	1	0.88	0.662	0	0.36	0.004	1
Isolated Aortocoronary bypass: 30-day mortality	0.16	0.064	0	-	-		0.45	0.177	0
Valvuloplasty or replacement of heart valves: 30-day mortality	0.68	0.350	0	0.52	0.150	0	0.38	0.053	0
Congestive heart failure: 30-day mortality	0.52	0.108	0	0.19	0.020	1	0.55	0.139	0
Repair of unbroken abdominal aortic aneurysm: 30-day mortality	0.53	0.522	0	1.02	0.869	0	1.98	0.24	0
Femoral neck fracture: 30-day mortality	1.98	0.018	1	1.09	0.833	0	0.58	0.281	0
TM stomach surgery: 30-day mortality	1	0.994	0	1.20	0.720	0	0.62	0.508	0
TM colon surgery: 30-day mortality	0.52	0.220	0	0.65	0.421	0	0.23	0.146	0
Surgery for TM lung: 30-day mortality	1.61	0.294	0	0.88	0.822	0	-	-	-
3) Humanitas Istituto Clinico Catanese Catania (Southern Italy)									
Surgery for TM lung: 30-day mortality	0.70	0.727	0	-	-	-	-	-	-
4) IRCCS Istituto Clinico Humanitas Milano (Northern Italy)									
Acute myocardial infarction: 30-day mortality	0.35	0.012	1	0.64	0.159	0	0.57	0.136	0
Acute Myocardial Infarction: 30-day mortality (main diagnosis)	0.35	0.020	1	-	-		0.33	0.006	1
TM kidney surgery: 30-day mortality	0.64	0.532	0	0.80	0.548	0	0.32	0.254	0
Surgery for TM pancreas: 30-day mortality	0.21	0.118	0	-	-	-	-	-	-
Surgery for liver TM: 30-day mortality	0.23	0.140	0	0.85	0.741	0	0.60	0.383	0
Brain T surgery: mortality 30 days after craniotomy	0.63	0.195	0	0.42	0.034	1	0.47	0.032	1
Chronic renal failure: mortality 30 days after hospitalization	0.62	0.032	1	0.37	0.000	1	0.32	0.254	0
Valvuloplasty or replacement of heart valves: 30-day mortality	0.71	0.363	0	0.47	0.131	0	0.47	0.068	0
Congestive heart failure: 30-day mortality	0.27	0.001	1	0.26	0.000	1	0.33	0.006	1
Repair of unbroken abdominal aortic aneurysm: 30-day mortality	0.47	0.453	0	0.18	0.089	0	-	-	-
Non-varicose hemorrhage of the upper intestinal tract: 30-day mortality	0.84	0.725	0	0.59	0.365	0	0.42	0.225	0
Femoral neck fracture: 30-day mortality	0.14	0.050	0	0.18	0.089	0	0.69	0.523	0
Ischemic stroke: 30-day mortality	0.81	0.413	0	0.44	0.016	1	0.52	0.027	1
COPD exacerbated: 30-day mortality	0.40	0.042	1				0.37	0.046	1
TM stomach surgery: 30-day mortality	0.58	0.287	0	0.14	0.051	0	0.49	0.230	0
Acute Myocardial Infarction with execution of PTCA within 2 days: mortality at 30 days	0.38	0.177	0	1.25	0.000	1	0.57	0.136	0
Surgery for TM lung: 30-day mortality	1.38	0.341	0	0.98	0.953	0	0.86	0.722	0
5) Istituto Clinico Mater Domini - Casa Di Cura Privata Spa Castellanza (Northern Italy)									
Acute myocardial infarction: 30-day mortality	0.72	0.463	0	0.57	0.274	0	0.79	0.514	0
TM kidney surgery: 30-day mortality	1.19	0.862	0	-	-	-	-	-	-
Congestive heart failure: 30-day mortality	1.10	0.683	0	1.22	0.413	0	1.39	0.541	0
Femoral neck fracture: 30-day mortality	0.61	0.486	0	0.22	0.136	0	0.50	0.327	0
COPD exacerbated: 30-day mortality	0.92	0.834	0	1.47	0.178	0	1.51	0.130	0
TM colon surgery: 30-day mortality	0.32	0.263	0	0.53	0.382	0	0.32	0.267	0
Acute Myocardial Infarction with execution of PTCA within 2 days: mortality at 30 days	0.36	0.317	0	-	-	-	1.14	0.797	0
6) Policlinico Universitario Campus Bio-Medico di Roma (Center of Italy)									
TM kidney surgery: 30-day mortality	1.46	0.605	0	1.61	0.505	0	1.83	0.399	0
Surgery for TM pancreas: 30-day mortality	2.29	0.090	0	1.38	0.646	0	0.93	0.918	0
Surgery for liver TM: 30-day mortality	0.70	0.726	0	1.50	0.573	0			
Isolated Aortocoronary bypass: 30-day mortality	1.11	0.755	0	1.12	0.740	0	1.90	0.036	1
Valvuloplasty or replacement of heart valves: 30-day mortality	0.51	0.128	0	0.83	0.609	0	1.14	0.720	0
Congestive heart failure: 30-day mortality	0.72	0.389	0	0.32	0.050	0	0.37	0.003	1
Repair of unbroken abdominal aortic aneurysm: 30-day mortality	0.77	0.790	0	1.51	0.477	0	0.91	0.894	0
TM stomach surgery: 30-day mortality	1.68	0.238	0	1.13	0.836	0	1.05	0.932	0
TM colon surgery: 30-day mortality	0.38	0.189	0	0.45	0.279	0	0.21	0.127	0
Rectal TM surgery: 30-day mortality	1.69	0.472	0	1.44	0.615	0	0.82	0.844	0
Surgery for TM lung: 30-day mortality	2.45	0.074	0	2.12	0.098	0	-	-	-

Table 1. Outcome of Accredited Joint Commission Organizations in Italy. Relative Risk (RR) and p-value

5. Discussion

The PNE develops in the Italian Health Service the evaluation of the outcomes of health surgical procedures. These can be defined as the estimate, with observational (non-experimental) study designs, of results of health treatments. The main objectives of PNE concern the comparative evaluation between providers. It is indeed useful in identifying weaknesses, consequences on the accreditation conditions, differences due to geographical location and consequently and finally fairness in health cares access.

The analysis of the performance of healthcare activities on the basis of the thirty-day mortality index, allows to evaluate the structure position, the relative risk and the relative p-value of significance with respect to the national average. This was done taking into account the volume of performance and other determining factors of the index itself.

The analysis conducted over three years shows the lack of a sufficient degree of significance despite the level of performance being almost always better than the national average.

Therefore, it is not possible to claim that accredited health facilities by the *Joint Commission International (JCI)* are better than the others belonging to the Italian health system. Non-accredited healthcare structures figure out performance similar to the one of JCI accredited facilities. There is no significant difference.

The results clearly show the existence of an inverse correlation between the structural features of the national health systems where JCI accredited facilities are located and the relevance of certification as a tool for differentiation. The stronger the first, the lower can be expected to be the second. Italy is among the top countries in terms of care performance. Minimum standards (or *LEA – Livelli Essenziali di Assistenza*) are defined, compulsory and marked out in each district. The Italian health system requires LEA to be implemented by every single facility to guarantee patient safety (France, Taroni and Donatini, 2005). At the same time they represent services that the Italian National Health Service (SSN) provides to all citizens, free of any direct charge or upon payment of a flat fee and financed with the public resources collected through the general taxation (Turati, 2013). The Italian Health Service in fact bases its fundamental principles (Law 833 of 1978) on universality, equal rights and fairness (Guillén, 2002). Since 1978, in Italy, there has been a transition from a mutual system or Bismarck model to a Beveridge model, which in any case factually affects the approach to access to care and accreditation of the health system based on minimum principles and standards (Cichon and Normand, 1994; Simonet, 2009). The American model instead needs a certification for the determination of minimum levels to guarantee the security of access to adequate care as it is based on a neoliberals free-market model (Saad-Filho, 2019).

Universality means an extension of health services to the whole population in compliance with art. 32 of the Italian Constitution that literally says: "*The Republic protects health as a fundamental right of the individual and an interest of the community, and guarantees free care to the poor*". Health has considered to be not only as an individual good but above all as a community resource (Ferrera, 1995). Starting from 1978, the NHS applies this principle through the promotion, maintenance, and recovery of the physical and mental health of the entire population with a widespread organization throughout the country whose services are provided by local health companies, hospital companies, and private affiliated structures with the SSN. All of this facility together aim at uniformly guarantee the Essential Levels of Assistance (LEA) to the entire population.

Equal rights mean that citizens must be able to access the NHS services without any individual, social and economic distinction. Citizens, who do not belong to exempt categories, are required to pay a flat fee – called "ticket" – that varies for each service provided by the LEA. Finally, equal rights mean guarantee of equal health care access in relation to equal health

needs. This main basic principle aims to overcome citizens' inequalities allowing to everybody access to health services.

To recognize equal rights to citizens it is necessary to guarantee fairness that means quality, efficiency, appropriateness and transparency of the service. A fair communication on the Health Service itself is necessary for the citizens. It has to be adequate for his level of education and understanding (informed consent, taking charge) and has to be prepared and provided by doctors, nurses and health workers.

The principles discussed inform the Italian culture and have over time pushed the Italian Healthcare System to guarantee minimum quality standards. The impact on our research is relevant as we saw that it led to not having statistically significant differences between accredited *Joint Commission International* structures and national averages.

It sounds interesting to point out that the JCI accreditation process did not reveal any real improvement even in the American countries where the system is more widespread and constrains the public funding of the Medicare programs (Griffith, Knutzen and Alexander, 2002; Lam et al., 2018).

Therefore, the JCI system seems to find optimal application in countries where no structured health system and rigid controls based on standards aimed at patient health have not been implemented yet. An example is the Asian countries where, although medical tourism is widespread, without accreditation, it would not be possible to pinpoint high level facilities and consequently to guarantee patient safety standards comparable to the levels of western countries (Gupta, Verhoeven and Tiongson, 2003).

6. Conclusion

The study proves that there are no differences in performance between structures accredited according to standards by the *Joint Commission International* and Italian structures.

It should be noted that in Italy the guarantee of the patients is guaranteed in any case by the minimum levels of care (LEA) (Brescia et al., 2017; Campra et al., 2019). The national outcomes program based on comparative effectiveness research, although there are no differences between accredited and non-accredited structures, is nonetheless supportive for carrying out an evaluation of the performance trend compared to the national average. It allows indeed a push towards continuous improvement and redefinition of standards specific for health services.

If health services are guaranteed throughout Italy, albeit with regional differences, then it is possible to affirm that medical tourism and hospitality can be guaranteed regardless of accreditation according to standards defined by the Joint Commission.

Future analyzes should however verify the same assumptions in similar European health systems. It will be necessary to consider the different health systems characteristics and to group them into three main categories – public, private or mixed – considering the country main settings.

The analysis conducted can be helpful for American policymakers, managers, and insurance companies who should guide their choices rather than on standards accredited by the Joint Commission International from the evaluation of individual national culture and settings.

Accreditation seems not to be necessarily synonymous of higher quality. It requires anyway time and higher costs so that not all structures get involved in it. This takes to a kind of adverse selection sometimes excluding good structures from the medical tourism facilities carnet (Greenfield and Braithwaite, 2009; Mumford et al., 2013).

The study can also provide some first indications that can be usefully replicated in other European countries regarding on one hand the expected facilities quality in different European context and on the other tourism and healthcare mobility in Europe. The last research field as been explicitly mentioned in Directive 2011/24/EU entitled "*Patients' rights in cross-border healthcare*".

Finally, despite mortality index, qualitative perception data were not available for the Italian context. The provision and disclosure of information divided by each facility and useful to carry out the same tests and comparisons already implemented in America and in other countries could enable to improve the analysis. For this reason, it is suggested to investigate further in the future, if and when those data-set will be accessible, the phenomenon of quality assessment in health systems in the Italian context.

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