The Impact of ISO Certification of Healthcare Services on Complaints and Litigation—A Children's Hospital's Perspective

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Abstract: Background: Gertrude's Children's Hospital is the longest established paediatric hospital in East and Central Africa. It admits over 6,000 patients annually and attends to over 300,000 outpatients through twelve outpatient facilities. The high exposure due to large patient numbers coupled with variation in practice by a large pool of doctors, nurses and other healthcare workers poses a high risk for adverse events, client complaints, and litigation. The hospital was ISO 9001: 2000 certified in 2008, recertified in 2011 and in 2014 in order to standardize practice and therefore mitigate against this risk. Objective: To establish the impact of ISO certification of healthcare services on complaints and litigation at the Gertrude's Children's Hospital. Methods: This was a retrospective study, through a review of hospital records covering medical legal issues over a period between 2001 and 2013. Results: The study revealed that after ISO certification in 2008, there was a 47.4% decline in complaints, 65% increase in adverse events reported. While the number of litigations was low throughout the period there was a drop to zero in the last two years of the review period. Conclusion: While a number of positive benefits have been linked to accreditation, there is more need for research in this area. Continued, empirical and evidence-based research on accreditation is important as questions continue to be raised regarding the value and impact of accreditation, not only in healthcare but also in a diverse range of fields.

Key words: Quality, healthcare, ISO certification, patient safety, litigation.

1. Introduction

In developing nations, hospitals are complex organizations and there are a number of strategies in place to ensure there is the provision of acceptable standards of care. One of these approaches is ISO certification, an internationally recognized evaluation process used to assess the quality of health services provided [1, 2]. ISO certification serves as an external platform to assess and determine whether a healthcare organization meets the standards set in place by an authorized organization: governmental or nongovernmental [3]. The standards are often applicable, predetermined, published and set in place to

encourage continuous quality improvement efforts within the ISO certified organizations [4].

The ISO (International Organization for Standardization) is the largest developer of international standards worldwide. ISO is an independent, voluntary, non-governmental membership organization [5]. Kenya is one of the member countries, and is on the forefront of the implementation of these international standards especially the ISO 9000 family, which focuses on quality management [6]. ISO 9001: 2008, is an internationally recognized certification system categorized under the ISO 9000 family. This system sets out the requirements of quality management, with a strong client focus. It helps to ensure the end-users receive consistent, good quality services, which in turn reflect on the development and improvement of the

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services provided by the organization [7]. A number of organizations in the Kenyan healthcare industry have implemented ISO 9000. However, although the number of organizations implementing these standards is on the increase, there is little conclusive evidence demonstrating the process actually improves the quality of care offered [8, 9].

Gertrude's Children's Hospital is the longest serving established paediatric hospital in East and Central Africa. The hospital was founded in 1947 and to date is dedicated to providing care and treatment exclusively to children. The hospital also has a separate Trust registered called "Gertrude's Hospital Foundation", which works with other partners to help others access healthcare. This is a really active part of raising the funds to invest in hospital improvements. Gertrude's Children's Hospital operates a busy inpatient unit and is building a model of outreach into the wider community. In a competitive market, forming an early relationship with children and their families is important and a well organized clinic, in a convenient location and staffed with skilled and well-qualified professionals is an important part of this strategy. The model is very successful and won a Millennium Development Goal Award and is being copied by other providers in the country.

Over the years, the hospital has witnessed a dramatic expansion from the hospital campus; their services are now being offered at various satellite clinics across the country. At these local clinics, the hospital services are largely focused on primary care to children. This means it is seeing almost 5 times more patients in local clinics than come to the hospital campus; a total of over 300,000 visits, which dwarfs the 6,000 admissions on average, per year. With the increase in outpatient attendees, inpatient admissions and vast expansion across networks, in addition to dealing with children, who are a vulnerable population, Gertrude's Children's Hospital set out to implement and establish internationally recognized standards. Furthermore, by reaching out into peripheral clinics to offer child health,

immunization, vaccination, primary care and operating seven days a week, the hospital is exposed to great risk of poor service delivery, clinical care errors and adverse events as a result of the high numbers of patients attended and the variation in practice from the many doctors and medical staff working at the hospital.

The Gertrude's Children's Hospital, therefore set out to implement ISO certification, primarily based on the robust standards offered under the ISO 9000 family. The hospital set out a quality and safety team including champions per department to train and sensitize all staff and the implementation of the process was a step-wise process: (1) Appointment of a patient quality and safety officer; (2) Identification of champions from all sections and departments; (3) Training and sensitization of all staff while creating all standards for the accreditation audit. On successful completion, the hospital was ISO 9001: 2000 certified and in July 2008. In September 2011, the hospital was recertified ISO 9001:2008 and was recertified in 2014.

However, to date there have been no studies to investigate the impact of the ISO certification at Gertrude's Children's Hospital on patient care and outcomes, the reliability of the process on the quality of the organization, or the impact on litigation. This study was therefore designed to examine the relationship between certified quality management system, and performance. Specifically, the impact of ISO certification on the number of complaints filed through lawsuits and to the Medical Practitioners and Dentists Board of Kenya.

2. Material and Methods

This was a retrospective study conducted at the Gertrude's Children's Hospital in Nairobi, Kenya over a period between 2001 and 2013 through a review of hospital records covering medical legal issues. The study further evaluated the impact of certification on the quality of healthcare provided based on the number of inpatient admissions and outpatient visits during the period.

2.1 Health Information System

The hospital has implemented and utilizes the Kranium® Health Information System (India). This is a comprehensive, modular and integrated system, built for care providers and patients. The data analyzed was obtained from three modules of the Health Information System:

(1) Medical records module for maintaining comprehensive medical records for each patient. It caters to both inpatient and outpatients, and provides reports on patients within and outside the hospital.

(2) Inpatients management module for handling patient admissions transfers and discharges.

(3) Outpatients management module for registering patient visits to the various local clinics and at the hospital campus, manage patient queues and record consultation details.

The hospital has also implemented and utilizes Q-Pulse® Quality Management System into which all adverse events, complaints, and interventions were documented.

2.2 Data Collection

Customer feedback was collected from 5% of patients over the years and complaints were entered into the Q-Pulse® Quality Management System. Similarly interventions, adverse events were documented in Q-Pulse® Quality Management System as and when identified. Litigations were documented and tracked by the head of Clinical Services. Q-Pulse was reviewed over the period in question and complaints, adverse events, and interventions extracted. Litigations were extracted from the Quality and Safety board committee minutes.

2.3 Statistical Analyses

Statistical analysis was performed using SPSS Version 17. A bivariate correlation analysis was carried out with the number of complaints, number of adverse events, number of interventions to correct variation in practice that could otherwise lead to an adverse event,

number of litigations, outpatient activity and inpatient admission as variables.

3. Results and Discussion

This is the first study in Kenya to assess the impact of the certification process, on complaints on litigation on a healthcare organization. The study further evaluated the impact of ISO 9000 certification on the end-user satisfaction based on inpatient admissions and outpatient attendee numbers. The results presented here demonstrate the accreditation process has a positive impact on a healthcare organization. There was a marked decline in the complaints filed against the hospital, furthermore, following certification there was a marked increase in the number of patients seeking hospital services, which can be classified under improved customer satisfaction, one of the primary outputs of ISO 9000 certification.

3.1 Complaints and Litigation

The study revealed, after ISO certification in 2008, there was a 47.4% decline in complaints. During this period there was a notable decline in litigation and since 12th August 2011, not a single complaint of medical legal nature has been recorded in a court of law or with the Medical Practitioners and Dentists Board of Kenya as shown in Table 1.

3.2 Inpatient Admissions

In addition, following the certification there was a general trend in increase of inpatient admissions and this trend was reflected even following the 2008 accreditation. The hospital has since experienced a marked increase in patient numbers in comparison to the pre-certification period. The inpatient admissions averaged 6,270 per year, a 5% increase annually as shown in Fig. 1.

3.3 Outpatient Attendees

There was also a marked increase in outpatient attendees over the period of the study, and this averaged

Table 1 Legal and medical legal complaints filed against the Gertrude's Children's Hospital for the period, 2001-2013.

Year	Complaints	Litigations	Adverse Events	Interventions
2000				
2001		1		
2002		1		
2003		0		
2004		0		
2005		2		
2006		2		
2007		0		
2008		1		
2009		4		
2010	348	2	113	392
2011	204	2	282	129
2012	164	0	166	104
2013	183	0	186	68

Fig. 1 Total number of inpatient admissions at the Gertrude's Children's Hospital for the period, 2001-2013.

at 143,518 visits annually a 14% increase (Fig. 2).

3.4 Correlation Analyses

Statistical analyses, as shown in Table 2 below, demonstrates, while the correlation between the number of complaints and the occurrence of adverse events is negative, it is both weak and insignificant. The number of adverse events and interventions is also negatively correlated.

It is therefore reasonable to conclude that the intervention process to improve care outcomes, the general drop in complaints, interventions, and adverse events, as depicted in Table 1, were as a result of standardization and implementing certification requirements improved quality of service. The activity increased over the years was either as a result of good quality or the number of complaints, adverse events, litigations, and interventions dropped despite activity

Fig. 2 Total number of outpatient attendees at the Gertrude's Children's Hospital for the period 2001-2013.

Table 2 Correlation between the number of complaints and the occurrence of adverse events following implementation of the ISO 9000 quality management system.

Correlations				
		Number of Adverse Events	Number of Interventions	Number of Complaints
Number of Adverse Events	Pearson Correlation	1	-0.601	-0.551
	Sig. (2-tailed)		0.399	0.449
	N	4	4	4
Number of Interventions	Pearson Correlation	-0.601	1	0.981*
	Sig. (2-tailed)	0.399		0.019
	N	4	4	4
Number of Complaints	Pearson Correlation	-0.551	0.981*	1
	Sig. (2-tailed)	0.449	0.019	
	N	4	4	4

* Correlation is significant at the 0.05 level (2-tailed).

growth. The strong positive and significant correlation between the number of complaints and the number of interventions observed is not surprising because a good quality system requires both a proactive intervention process and a good system of capturing and addressing customer complaints. These two if done well are likely to lead to less litigation because either adverse events that could lead to litigation are prevented or complaints that could lead to litigations are addressed. This is

exactly what happened here.

Overall, the decline in complaints and litigation are indicators of success of the implementation of ISO 9001:2008 because customer satisfaction is the focus of the ISO 9000 quality management system family [10]. The decline reflects improved patient satisfaction in the quality of healthcare services provided at the Gertrude's Children's Hospital over time. The successful implementation of the ISO 9000 quality

management system results in reduced variation in administrative and clinical structures and processes, and overall improvements in quality within the organization [11]. Furthermore, improved communication and collaborations within the organization, with external stakeholders and community partners at large [12, 13]. This finding also supports previous investigations that report certification can serve as a risk mitigation strategy and an opportunity for decreased liability costs [13].

The increase in inpatient and outpatient numbers is attributed to the improved quality of services, which is bound to have a direct impact on the entire organizational image. Successful ISO 9000 certification has been linked to cooperation and personal commitment among the employees of the organization [14], which is then reflected in improved ability to attend to a larger pool of patients as seen in this case. Results comparing ISO certified and non ISO-certified organizations demonstrate ISO certified institutions are at a comparative advantage. Certified organizations report higher levels of customer satisfaction, company profitability and productivity [15], greater awareness of quality delivery [16] and improvements in evaluation systems and operational effectiveness, which in turn advance positive health outcomes [17, 18]. In the healthcare industry, the emphasis is on human lives and the quality of service at the hospitals and clinics, has a direct impact on patient satisfaction.

In today's dynamic healthcare environment, ISO certification is a powerful tool, an essential component applied to strengthen quality improvement and drive patient safety initiatives. Therefore, organizations that participate in the accreditation process, confirm their commitment to patient safety, improved efficiency, quality improvement and this is a demonstration of transparency in terms of accountability. On the other hand, governmental and non-governmental institutions that set the accreditation standards, provide a comprehensive look at the challenges and successes

that an organization may experience, and design themes in the context of service delivery. Furthermore, data from the accredited firms, serves as a valuable resource to healthcare providers, and policy makers thus contributing to the ongoing decision-making and quality improvement agendas on the national front.

There is a good body of evidence on the positive impact of general accreditation programs including the ISO 9000 family. One study focusing on the healthcare industry highlights, successful implementation of accreditation programs, improved the structure of the healthcare organization and thereby improved clinical outcomes [18]. A blinded, random and stratified study evaluating health service accreditation as a predictor of performance across nineteen hospitals, established accreditation has a positive impact on clinical performance in healthcare organizations [19]. An additional study established a positive relationship between ISO 9000 certification and firm performance, especially operational and business performance [20]. These findings, in addition to the present study, encourage efforts towards the continuous implementation and support of general accreditation programs including ISO 9000 as these lead to improved quality of healthcare services.

Gertrude's Children's Hospital was initially founded based on a generous donation and has now developed into a charitable trust, meaning all profits are ploughed back into the hospital. Furthermore, the hospital is often reliant on donors for the purchase of expensive paediatric equipment it requires to remain an up-to-date organization. Therefore the successful running of the hospital is largely dependent on a positive relationship with the donors, positive outcomes, patient satisfaction and transparency so as to ensure trust is maintained both with the donors and the patients. This study clearly demonstrates the positive impact of ISO 9000 accreditation in the healthcare industry. This quality management system is built around management principles [21]; four of which are reflected under the Gertrude's Children's Hospital

implementation program. These include (1) Customer focus: the hospital witnessed a marked increase in patient numbers, both outpatient attendees and inpatient admissions, which was based on understanding the patient current and future needs; (2) Leadership: the program implementation began with the appointment of a patient quality and safety officer, followed by identification of champions from all sections and departments, who took the lead in terms of training and sensitization prior to the audit; (3) Involvement of people: hospitals are complex organizations therefore the success of the ISO certification was based on teamwork from all departments and (4) Continual improvement as evidenced by the recertification in 2008 and in 2014, which is a voluntary process and a public display of the institution on their commitment and willingness to improve on the services rendered.

The findings of this study therefore reflect the positive impact of undertaking the accreditation process. However, for continued success, there is need to educate and incorporate behaviour change component models in relation to the benefits of implementing accreditation programs among the general public and also among the healthcare professionals. Furthermore, ISO certified organizations should establish adequate monitoring systems, follow set procedures and carry out frequent reviews of the new systems in place.

4. Conclusion

While a number of positive benefits have been linked to accreditation, there is more need for research in this area. Continued, empirical and evidence-based research on accreditation is important as questions continue to be raised regarding the value and impact of accreditation, not only in healthcare but also in a diverse range of fields.

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