Mind the gap: assessing alignment between hospital quality and its information systems

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We present a method to assess how aligned hospital information systems (HIS) are with quality standards adopted by the organization. Canonical action research is our mode of inquiry, in a district hospital implementing multiple certification standards. We build on the 'ground-truth' provided by healthcare professionals to identify risks and opportunities for HIS developments while contributing to their awareness of its implications. We address different categories of design-reality gaps, namely the organizational, service, process, and individual. The findings suggest that HIS compliance should address five interrelated dimensions of Context, People, Process, IT, and Information/Data. The proposed method allows self-evaluation through gap analysis and a comprehensive assessment of hospital quality, integrating HIS and healthcare processes. Moreover, it supports multiple quality models in hospitals and the development of heterogeneous HIS solutions in different maturity stages. HIS developments should be a priority for hospital quality worldwide; especially in the emerging economies that require methods accessible to their resources, standards compliance, and demographic demands for healthcare.

Keywords: healthcare; information systems; HIS; IS quality; design-reality gaps; compliance.

1. Introduction

Quality management standards such as the recently revised ISO 9001 (ISO, 2015) are widely used for organizational improvement and process management at hospitals (Rodríguez-Cerrillo, Fernández-Diaz, Iñurrieta-Romero, & Poza-Montoro, 2012; Shaw et al., 2014). Additionally, there are several accreditation programs designed for healthcare that require self-evaluation, regulatory compliance, and information transparency (Angst, Agarwal, Gao, Khuntia, & McCullough, 2014). Notable examples are the ACSA accreditation, the Australian Council on Healthcare Standards, or the Haute Autorité de Santé, and Accreditation Canada (Almuedo-Paz, Núñez-Garcia, Reyes-Alcázar, & Torres-Olivera, 2012). But to reach comprehensive organizational

quality (Stylianou & Kumar, 2000), hospitals must look beyond their healthcare processes and into the fit with their information systems (IS). Pressure mounts for (1) timely IT solutions in support of the quality efforts; (2) IT support in the redesign and improvement of healthcare processes; and (3) the adoption of quality policies in the HIS development lifecycle.

Information systems development takes place in regulated contexts that may differ in knowledge expertise, organizational structure, project, team, and individual behaviour (Curtis, Krasner, & Iscoe, 1988; Kautz, Madsen, & Nørbjerg, 2007). Directives that shape the hospital regulatory space (Hancher & Moran, 1989) may be enforced, for example, in the case of legal requirements; or they may be voluntary, for instance, in the case of the adoption of quality standards, codes of conduct, and best practice guides. Compliance with those regulations, both in design and operation of information systems involves dealing with a high number of variables. Such complexity makes IS development methodologies even more relevant nowadays, with the potential to be adapted into specific situations (Avison & Fitzgerald, 2003), namely the highly regulated environments of hospitals. There are design-time and run-time synergies in the development of information systems and quality management systems (Barata & Cunha, 2015). In fact, Ray Paul's definition (Paul, 2007) that "the IS is what emerges from the usage and adaptation of the IT and the formal and informal processes by all of its users" would fit perfectly in modern quality models that are process oriented, require the involvement of all their users, and greater than ever IT support.

Our paper addresses a problem that intertwines IS and quality, namely how to assess hospital information systems (HIS) compliance with quality standards and evaluate the contrasting opinions of healthcare professionals about quality in hospital practice. Our proposal is to evaluate the HIS users' opinions about compliance with a

questionnaire tool. Then, we focus on the design-reality gaps (Heeks, 2006) that may occur in the perceived compliance of hospital managers and service staff. Heeks (2006) suggests that identifying gaps between HIS design conceptions and "the realities of the hospital use context" must address different dimensions such as IT, processes, management systems and structure, or information and it "can be used to address the problem of HIS failure [and success], both as a post hoc evaluative tool and as a pre hoc risk assessment and mitigation tool" (Heeks, 2006). According to Heeks (2006) "the process of successfully introducing an HIS can be seen as a set of reciprocating changes to both design and reality that eventually reach some kind of workable closure between the two".

The overall purpose of the assessment is to find improvements for HIS compliance according to five key dimensions of Context, People, Process, IT, and Information/data (Barata & Cunha, 2013). We present a solution that was applied in two services of a district hospital: emergency and paediatric care. Our case hospital is involved with (1) ISO 9001 (ISO, 2015) certification – under implementation in the emergency service; already implemented in the paediatric unit; (2) ACSA accreditation (Almuedo-Paz et al., 2012) (simultaneously in both services); and (3) the IS quality (Stylianou & Kumar, 2000) development program. In spite of belonging to the same hospital, and being influenced by the same policy, the services in our study exhibit significant differences: in the "laws" that govern their reality, in the focus of their processes, in the motivation of their professionals, and in their IS support. It thus becomes essential to assess and understand the design-reality gap (Heeks, 2006) in different services and within the same service of the hospital. The solution that we propose can be put into practice with minimum resources by the hospital personnel

using questionnaire tools, making it suitable to hospitals in emerging countries that need to improve overall health quality.

The remainder of our paper is organized as follows. In Section 2 we present the background literature for this research, including standards compliance in hospitals (Hu & Xue, 2014), cultural aspects of quality (Kanji & Yui, 1997), and the concept of holistic IS quality (Stylianou & Kumar, 2000). Afterwards, we present our research approach and evaluation criteria. Section 4 details theory building, and a discussion of the results about assessing HIS compliance with gap analysis is offered in Section 5. We conclude by presenting the limitations of our study and proposing avenues for future research.

2. Literature Review

2.1. General quality models in healthcare

A number of quality models are adopted in healthcare. These include (1) more general certification approaches, for example with ISO 9001; (2) excellence models based in total quality management (TQM), namely, the European Foundation for Quality Management (EFQM), the Deming Prize in Japan, or the Malcolm Baldrige National Quality Award (MBNQA) in the USA; and (3) healthcare accreditation programs such as the pioneer Joint Commission International (JCI), the King's Fund Health Quality Service (KFHQS) in the UK, and the General Hospital Grade Accreditation (GHGA) in China (Hu & Xue, 2014; Lee, 2012). There are models specifically developed for healthcare that include a commitment with self-assessment (Almuedo-Paz et al., 2012).

ISO 9001 is one of the most used models to implement a certifiable quality management system (QMS) and there are claims of its benefits in healthcare; for example, in increasing patients' satisfaction, preventing medication-related incidents,

reducing unscheduled returns to the hospital, diminishing complaints, decreasing medical equipment failures, and improving compliance to protocols (Rodríguez-Cerrillo et al., 2012). The current ISO 9001 revision (ISO, 2015) has an increased focus on process management, people involvement in quality efforts, and the adoption of quality principles in daily practice. However, Rakhmawati, Sumaedi, and Astrini (2014) state that ISO 9001 effectiveness in healthcare requires clarification. Nevertheless, the potential problems of ISO 9001 can be addressed by integrating the IS and the QMS, resulting in (Kumar & Balakrishnan, 2011; Poksinska, Eklund, & Dahlgaard, 2006): (1) increased correspondence between the standard and the organizational processes; (2) improved top management involvement; (3) in-depth audit support; (4) reduced paperwork by resorting to IT; and (5) reduced societal gaps, by addressing the requirements of the organizational context, external stakeholders, and different regulations.

Accreditation programs for healthcare such as JCI and ACSA provide specific guidance for healthcare practice and evaluation; for example, using quality checklists. Nevertheless, as presented by Hu and Xue (2014), there are complementarities between accreditation programs and process oriented approaches suggested by ISO 9001, with the potential benefits in creating a QMS that is more adapted to each hospital context, policies, and quality culture (Gallear & Ghobadian, 2004; Kanji & Yui, 1997). One of the challenges for hospitals that adopt multiple quality models is their integration (Hu & Xue, 2014; Sampaio, Saraiva, & Domingues, 2013). As suggested by Jørgensen, Remmen, and Mellado (2006) it is possible to consider (1) "compatibility with cross-references between parallel systems"; (2) "coordination of business processes"; and (3) "an organizational culture of learning, continuous improvements of performance and stakeholder involvement related to internal and external challenges".

A literature review addressing the thematic of quality models in healthcare found that the main obstacles were cultural aspects, excessive bureaucracy and hierarchical structure, leadership problems, poor planning, and "difficulties involved in evaluating healthcare processes and outcomes" (Mosadeghrad, 2013). According to this author, culture is one of the most frequently mentioned difficulties to TOM implementation in healthcare sector. Therefore, organisational culture is the most often ignored component of TQM during the course of TQM implementation. There are powerful sub-cultures such as physicians, nurses and paramedics who have their own interests. They define quality differently and follow specific ways to achieve it". The author concludes that it is necessary to develop a quality culture and an adequate HIS, providing training and the support technologies to incorporate quality principles into daily routines. A recent study presented by Yeh and Lai (2015) reinforces this perspective, presenting key factors for quality management implementation: "top management involvement, inter-department communication and coordination, teamwork, hospital-wide participation, education and training, consultant professionalism, continuous internal auditing, computerized process, and incentive compensation". However, available studies do not provide practical guidance on how to proceed in practice. Quality models must consider the specificities of hospitals, namely the ones described by Wilson (2000): the lack of time, lack of quality-related skills, and, sometimes, even lack of motivation of doctors and nurses for quality management issues. In such a demanding context that is focused on patient health, the comprehensive assessment and improvement of hospital quality is vital; otherwise, both the HIS and the quality management system may become a burden for hospital professionals.

2.2. Hospital quality and IS: a comprehensive perspective

The IS and the quality management system require similar organizational cultures for their success, especially in the promotion of proactive actions and people involvement (Hartman, Fok, Fok, & Li, 2002). However, the difficulty in complying with standards increases when there is a need to integrate different quality models, in different healthcare services, each one with their specificities, multiple priorities, and disparate systems implementation paces.

The information requirements and a framework for supporting ISO 9001 in healthcare was presented by Kostagiolas (2006), suggesting a three-pronged approach to address the requirements of (1) people; (2) processes; and (3) legal and service agreements. Nevertheless, Kostagiolas (2006) focuses on HIS in support of the QMS, requiring practical tools that hospitals can use and not totally exploring the possibilities of quality in support of HIS development. IT has an important role in facilitating quality disclosure and transparency in hospitals (Angst et al., 2014) but, once again, we could not find in the literature a practical and concrete way to apply those lessons in daily hospital practice, nor empirical cases that studied the effect of such type of approaches to assess HIS compliance.

When combined, HIS and quality management contribute to organizational transformation, by promoting cultural changes (Philip & McKeown, 2004), improving quality and performance (Hartman et al., 2002), and IT adoption. However, as Dahlberg and Jarvinen (1997) observe, an overall HIS compliance should be a result of systematic practices.

The work of Stylianou and Kumar (2000) provides foundations to represent a broad perspective of hospital quality and the integrative role of the HIS. According to the authors, enterprise quality includes the quality of business processes and the multidimensional quality of the IS (Stylianou & Kumar, 2000). These authors defend

that it is necessary to address different dimensions of IS quality, including infrastructure, software, data and information, administrative, and service quality. The different dimensions and perspectives reinforce each other for IS success (DeLone & McLean, 2003; Gorla, Somers, & Wong, 2010), but there is a need to address potential gaps between the designed system – according to the hospital quality models and policies –, and the real system supporting daily operations (Heeks, 2006). HIS compliance is at the core of hospital quality (Stylianou & Kumar, 2000). Methods to assess HIS compliance become a necessity and should be accessible to hospitals with diverse quality models and HIS maturity. We suggest that the design-reality gap model proposed by Heeks (2006) can assist this purpose.

3. Research Approach

Our overall research aim is to propose a method that healthcare professionals can use to assess HIS compliance. We are guided by the framework created by Stylianou and Kumar (2000) to integrate HIS quality and the quality of healthcare processes. Moreover, we aim at a method that (1) is adaptable; (2) fosters the participation of the hospital staff; (3) does not require specific IT platforms; and (4) identifies the designreality gaps that may occur between the desired and the running HIS (Heeks, 2006).

According to Baskerville (1999), creating or changing a systems development method is impossible from a socio-organizational viewpoint without intervening in the real world to test it. Action research is an approach that simultaneously aims to improve a problematic situation in the target organization, and contribute to scientific knowledge (Davison, Martinsons, & Kock, 2004; Susman & Evered, 1978). The ideal domain of action research is characterized by a social setting where (1) the researcher is actively involved, with expected benefit for both researcher and organization; (2) the knowledge

obtained can be immediately applied; and (3) the research is a process linking theory and practice (Baskerville, 1999).

To pursue our aims, we have selected the canonical action research, characterized by five phases of Diagnosing, Action planning, Action taking, Evaluating, and Specifying learning (Susman & Evered, 1978). Although formally coming last, learning actually occurs during the entire action research cycle and consists of summing up and documenting of the findings, contributing to theory and practice (Davison et al., 2004; Susman & Evered, 1978). To ensure rigor and validity of our use of CAR in our context, we have evaluated the process using the principles proposed by Davison et al. (2004).

The research project started in 2015 with a diagnosis that included (1) a literature review about quality models in healthcare; (2) an in-depth evaluation of the hospital setting; and (3) the description of the quality culture of the hospital according to the principles that were identified in the quality policy by their administration. We interviewed the quality and risk management commissions (QRMC) of the hospital and of the two services that were selected for our study: emergency and paediatric care. The exploratory results of our action research project are described in Barata, Cunha, and Barata (2015), where we drafted the steps of a synergistic development approach for the IS and the quality management system in healthcare. In the present paper, we describe a substantially extended version of the complete CAR cycle, which now includes (1) a method aligned with Heeks (2006)' design-reality gaps, (2) participatory assessment of HIS compliance; (3) contributions from additional 27 staff members of the hospital; (4) enhanced forms of visualizing design-reality gaps; and (5) specific details that facilitate the transferability of our findings to other hospitals. The next section summarizes the

results of our research according to the sequence of the CAR steps (Susman & Evered, 1978).

4. Theory building: Assessing HIS compliance

4.1. Client-System Infrastructure

According to the official hospital report (2011-2013), they employ 621 professionals and have 154 beds. The hospital is certified by ISO 9001 including (1) healthcare – paediatric care, rehabilitation medicine, day hospital, surgery specialties, and medical specialties; (2) support services such as pharmacy, sterilization, social service, occupational medicine; and (3) different areas of technical support, logistics, and management. In the last decade the hospital was involved in the Joint Commission International accreditation and, more recently, their efforts are towards implementing the ACSA Accreditation Model by 2016. Figure 1 presents the hospital structure for quality management according to the above mentioned models.

<Figure 1 about here >

Figure 1. Organizational structure for hospital quality management.

Top management defines the main strategy and policies that the hospital QRMC must follow in their QMS development. QRMC priorities are the ISO 9001 and ACSA; nevertheless, the commission must also develop the risk management system, attend to specific governmental guides for healthcare, and follow a plethora of legal requirements. There are complex information flows that are distinct for each service, that vary with the service quality models and regulations, and differences in the supporting HIS. The communication between services – each one with a local QRMC – and with the external environment (e.g., auditors and local community) is demanding.

The next section describes the joint diagnosis of the situation by researchers and practitioners.

4.2. Diagnosing

The hospital has a high-level quality policy. However, there are many differences to attend to. First, not all hospital services are certified by ISO 9001 (e.g., emergency), and they exhibit different maturities in quality management. Second, there is a heterogeneous portfolio of IT solutions, most of them integrated, but with weaknesses in supporting quality indicators and audits. According to the QRMC, quality is not a main concern of the IT department, which is mostly focused on clinical processes (e.g., helpdesk and platforms such as the electronic health record), leading to the development by QRMC of countless spreadsheets to support quality. Spreadsheets have spread to each certified service and are now the source of new problems, because they (1) present difficulties to compile reliable and timely indicators; (2) do not ensure information quality; and (3), require extra work for quality certification and accreditation. We confirmed these problems when we interviewed the chief doctor and chief nurse of certified services that expressed their difficulties in updating the quality procedures as necessary, obtaining indicators, and making quality a daily concern.

On the one hand, the hospital faces a period of economic restrictions and staff reduction. Quality can be compromised, with potential risks for patients. For example, (1) the extra work by professionals for information gathering and processing consequently reduces their time for patient care; (2) there is a potential decrease in service quality if quality indicators are not available for hospital processes; and (3) there are potential threats in information quality if IT solutions are not aligned with the standards (e.g., timeliness, reliability, completeness). On the other hand, there are opportunities. We could confirm the exceptional staff dedication and interest in quality

improvement. Moreover, careful HIS design can improve compliance (Bonazzi,

Hussami, & Pigneur, 2010), thus assisting hospital professionals. A summary of the most relevant issues in our diagnosis follows:

- Heterogeneous quality system: not all the departments are already certified;
- Motivation in certified services may decline due to the time spent in HIS errors and bureaucracy;
- The lack of involvement and the difficult communication between IT and quality managers seems to be a well-known and recurrent problem (Barata & Cunha, 2015);
- Services that are starting their quality initiatives need to train all staff members and integrate self-assessment due to the sequent ACSA accreditation (Almuedo-Paz et al., 2012);
- There is a need to improve HIS compliance in different dimensions (Heeks, 2006; Stylianou & Kumar, 2000), to address quality disclosure needs in healthcare;
- Multiple regulations and different quality models (ACSA for more advanced services, ISO 9001 for non-certified services) require integration (Jørgensen et al., 2006; Sampaio et al., 2013);
- Quality policy must be applied to all processes of the hospital. The hospital will migrate to the new version of ISO 9001 (ISO, 2015);
- Self-assessment must be implemented for ACSA accreditation (Almuedo-Paz et al., 2012). There is an opportunity to increase self-assessment use in ISO 9001, as suggested and guided by the complementary standards in its annex B, for example the ISO 9004 and the ISO 10014 (ISO, 2015);

 HIS requirements must be identified for each healthcare process and a joint development plan must be produced. Actions must address both the HIS and the quality of healthcare processes, as suggested by the integrative framework proposed by Stylianou and Kumar (2000).

The quality and risk commission of our case hospital was enthusiastic to adopt a method to assess HIS compliance according to different models for quality that they have to comply to. The next section outlines our action plan.

4.3. Action planning

Our initial action plan for the assessment and development of HIS compliance had the following sequence:

- Prepare the mindset. Present the method to the quality commission, involving both quality and IS professionals in the initial phases (Au & Choi, 1999);
- (2) Diagnose the existing HIS according to the overall hospital compliance strategy and the specificities for each selected hospital service, as presented in the previous section;
- (3) Define a vision according to the administration's strategy and quality policy. At this stage we defined the key principles and standards to follow by the entire hospital;
- (4) Present the method to each local QRMC;
- (5) Diagnose local services according to the set of principles common to the entire hospital, starting with the chief doctor and chief nurse in each service. This task involves a gap analysis (Heeks, 2006) between the local service perspective and the QRMC perspective;

- (6) Define a vision according to the local service (e.g., a specific checklist). This task also involves a design-reality gap analysis (Heeks, 2006) at the service and process levels;
- (7) Diagnose the HIS with the service staff. It is an opportunity to train hospital professionals in the HIS and compliance concerns, especially in the implementation of new quality models being faced. In our setting, ACSA for the entire hospital and ISO 9001 for the emergency service;
- (8) Contrast the perspectives: QRMC vs. local QRMC, local QRMC vs. staff; local QRMC emergency vs. local QRMC paediatric care; emergency staff vs.
 paediatric staff;
- (9) Assess the HIS compliance, integrating the different perspectives of the project participants. The output is a set of charts and action plans to address design-reality gaps (Heeks, 2006), according to multiple viewpoints.

In the next section we describe the action taking phase that was guided by the general plan above.

4.4. Action taking

The steps 1–4 of our action plan were conducted with the hospital QRMC. We created artefacts for evaluating the principles and deployed the questionnaire presented in Barata, Cunha, and Costa (2013) to diagnose HIS compliance. At this point, we identified that (1) the hospital quality policy was not including all the principles suggested by ISO 9001 (e.g., decision based in facts) and the new ACSA accreditation; and (2) HIS quality had deficiencies in the dimensions of infrastructure, software, and service quality.

Next, we involved the local QRMC (chief doctor and chief nurse) for emergency and paediatric care, which allowed us to assess the adoption of quality principles at a local scale. We asked the local QRMC to propose a set of checklist items to diagnose each quality principle in their processes. Over several meetings, we could discuss the gaps in the HIS and QMS: (1) regulatory gaps; for example, between overall hospital principles and quality model requirements that should be adopted in each service; (2) design-reality gaps (Heeks, 2006) between IT, process documentation (procedures), and daily practice; and (3) gaps between the perspectives of doctors and nurses, for example, in the underprovided integration between IT applications in paediatric internment.

Figure 2 represents the dimensions that we considered for assessing HIS compliance and the coexistence of multiple systems in hospital quality.

<Figure 2 about here >

Figure 2. Dimensions of hospital quality assessment (adapted from Barata and Cunha (2013); Heeks (2006); Stylianou and Kumar (2000)).

Those systems can be quality models; for example, ISO 9001 and ACSA in our case, but also the HIS and its multiple dimensions (Stylianou & Kumar, 2000). On the right of Figure 2 we represent the five interrelated dimensions of information systems that we suggest must be addressed for a comprehensive assessment of HIS compliance. The possibility of interrelating different dimensions, namely Context, People, Processes, IT, and Information/Data (Barata & Cunha, 2013), which are aligned with the dimensions proposed by Heeks (2006), allows our IS study to ask "questions that other disciplines are not asking or in addressing problems that others are incapable of addressing" (Hassan, 2014). According to Dey (2001) "a system is context-aware if it

uses context to provide relevant information and/or services to the user, where relevancy depends on the user's task". The hospital context may involve aspects such as the relations with the community, government agreements, and legal obligations. People involvement and process management are mentioned in quality models (Almuedo-Paz et al., 2012; ISO, 2015) and are central aspects in HIS, nowadays usually supported by IT (Paul, 2007). Finally, quality requires evidences in the form of information/data, supporting HIS assessment.

It is suggested to search for gaps at different levels of the organization (e.g., structure and policies), management systems, IT, healthcare processes (e.g., emergency process is different if the patient is an adult or a child), and individuals. We have adopted the model in practice by (1) identifying the hospital systems that should be assessed for gaps; (2) building customizable questionnaires with the participation of hospital managers and staff; and (3) ensuring that the five interrelated dimensions of Context, People, Processes, IT, and Information/Data (Barata & Cunha, 2013; Heeks, 2006) were included in gap analysis.

Figure 3 illustrates the type of gaps that we considered regarding the functional organization of the hospital, aligned with the organizational model presented by Freixo and Rocha (2015).

<Figure 3 about here >

Figure 3. Assessing HIS compliance: organizational perspective.

On the top of the figure we identify the gap between the quality policy defined by the hospital administration and the actual standards, tools, and procedures that are adopted by the quality/IS managers (Level 1 design-reality gaps). It is also possible to identify the gaps between the perspective of both IS and quality managers regarding

HIS issues. We found a discrepancy between the hospital policy and specific principles that are required by their certification schemes (e.g., ISO 9001), but also a distinct perspective when filling the HIS compliance questionnaire. At Level 2 we found potential design-reality gaps between the defined quality standards and its application in distinct services. Moreover, it is necessary to consider differences between services. Level 3 refers to the design-reality gap identified by service staff. It is also an opportunity to contrast the opinion of service managers and service staff.

The questionnaires that we used to assess HIS compliance are presented bellow. The first one is the HIS compliance checklist to assess Level 1 organizational gaps with an extract provided in Figure 4.

<Figure 4 about here >

Figure 4. Assessing Level 1 design-reality gap (questionnaire extract).

Figure 4 presents a sample of items that were used to assess the HIS quality dimension of software quality (Stylianou & Kumar, 2000). Each item was evaluated from 1 (non-existent) to 5 (very good). For the extract represented in Figure 4 we uncovered major discrepancies. For example, for line 3 "user satisfaction is monitored", the median result was 2, suggesting that it is an area for improvement in this hospital. Moreover, the answers given by quality managers and IS managers were discrepant, suggesting that there is an opportunity to discuss the interpretation of "user satisfaction" and to reach a common improvement action for this item. A full description of the questionnaire presented in Figure 4 is available in Barata et al. (2013).

Aiming to assess Level 2 gaps we asked the QRMC to create a checklist for each quality policy selected by the hospital. The customized checklist proved to be useful to

train each service about the quality culture that the hospital intends to develop, in coherence with the overall quality policy defined by the administration.

Figure 5 presents the questionnaire addressing the quality models principles (Almuedo-Paz et al., 2012; ISO, 2015).

<Figure 5 about here >

Figure 5. Assessing Level 2 design-reality gap.

Each principle of the quality model is evaluated by the project participants (using the same scale from 1 to 5) and the standard deviation calculated in the rightmost column, allowing us to identify contrasting opinions among the hospital members. The items with lower grades and higher standard deviation should be a priority to assess HIS compliance. For example, the incidents report (third line from the bottom) and suppliers' involvement in innovation project (last line) are potential issues for HIS improvement.

Finally, Level 3 gaps are assessed with another checklist customized for each service. It is proposed by the local QRMC and serves the goal of identifying gaps between the designed HIS and everyday practice, according to the perspective of the service staff. Figure 6 illustrates some of the graphical assessments made in the emergency service. Our team gathered interviews from doctors, nurses, and assistants, using a checklist that included 24 HIS compliance aspects for the service under evaluation.

<Figure 6 about here >

Figure 6. Assessing Level 3 design-reality gap.

The chart presented in Figure 6 shows questions answered with high grades and with minor divergence among the emergency staff (e.g., Q2(PF) for patient focus, standard deviation = 0.37) and others with lower grade that probably deserve attention (e.g., Q18(SR) for safety and risk management, standard deviation = 1.08). Another possible representation is offered in Figure 7, contrasting different HIS quality dimensions in the perspective of the IS/QRMC teams of the hospital.

<Figure 7 about here >

Figure 7. HIS design-reality gap according to the IS/QRMS teams.

Figure 7 shows differences in the assessment made by the IS team and the QRMC for each HIS quality dimensions (Stylianou & Kumar, 2000). Moreover, there are interesting contrasts, for example, when comparing the high grade of SQ – software quality (median value of 4) and the low grade of SEQ – service quality (median value of 3). These charts can be useful to identify disparate evaluations and, especially, promote a debate about the possible causes of problems and improvement actions in the HIS. It is in the qualitative assessment and discussion phase that improvement actions may emerge to address the design-reality gaps.

4.5. Evaluating

The hospital professionals that participated in our study pointed out the gap analysis and the contrasting of evaluations as strength when compared to a typical consensus evaluation. According to the hospital quality manager, contrasting reinforces the continuous reflection and learning: on the one hand, IS and QRMC teams share their understanding about compliance requirements and specificities of hospital services and processes; on the other hand, hospital staff internalizes quality principles and participates in HIS requirements identification. Interviews and checklists are less

structured when compared to other instruments available for eliciting eHealth requirements. Nevertheless, hospital managers stated that they found the proposed improvement method accessible to both, healthcare and technical staff. They decided to adopt it and expand it to all their services.

We focused our initial action taking on the participation of the hospital directors (quality managers, doctors, and nurses). Then, especially in steps 7–9, we included other members of the hospital staff. This allowed us to reach a deeper assessment of HIS compliance, that emerged from the perspective of HIS users.

Recalling the five principles suggested by Davison et al. (2004) to evaluate our CAR project:

- Principle of the Researcher-Client Agreement. The researchers and the hospital
 managers agreed that CAR was an appropriated approach to contribute for an
 innovative assessment of HIS compliance, simultaneously improving a
 problematic situation in the context of multiple quality models. The organization
 approved and collaborated in a scientific publication of the results;
- Principle of the Cyclical Process Model. The sequence of steps suggested by Susman and Evered (1978) provided guidance to our dual purpose of acting and learning. There was a permanent reflection about the action that we conducted and each new task adjusted to continuously improve the results;
- Principle of Theory. We started our research with a literature review that was useful to frame the problem space and propose an action plan agreed by researcher and practitioners. Theory has an essential role in the entire CAR cycle (Davison, Martinsons, & Ou, 2012), therefore, we continuously compared our results with the existing body of knowledge concluding with a contribution to theory in the form of scientific publications;

- Principle of Change through Action. Action taking included the development of new assessment tools and patterns of action (Pentland & Feldman, 2008) to assist the hospital. The changes occurred in different services, processes, and organizational levels of decision. Moreover, we argue that there is no single design-reality gap in a complex setting such as a hospital: there are multiple perceptions and constructions of designs and realities that HIS development must consider to be successful;
- Principle of Learning through Reflection. The proposed method is a result of a joint reflection by the researchers and practitioners. We learned how we could assess hospital quality, including the HIS in the core of the multiple quality models and management systems adopted. There is a need to address the cultural aspects that shape the organizational regulatory space (Hancher & Moran, 1989), the "ways of working" (Gallear & Ghobadian, 2004) of the hospital, assessing different HIS dimensions.

The next section provides a deeper reflection about the results of this project, jointly made by researchers and practitioners.

5. Discussion

There are multiple design-reality gaps (Heeks, 2006) that hospitals must evaluate, according to distinct perspectives. It is possible that different teams, services, and individuals have different perceptions of the same dimensions under assessment. Our results confirm that hospital quality must include (1) the models adopted by the organization in its processes and (2) multidimensional HIS quality (Stylianou & Kumar, 2000). The first step is to identify the quality systems, its stakeholders, and then develop

the assessment tools including the dimensions for the design-reality gaps (Heeks, 2006; Stylianou & Kumar, 2000).

According to Simon (1996), "everyone designs who devises courses of action aimed at changing existing situations into preferred ones". Our proposal reinforces the benefits of people participation in HIS development. The creation of checklists is an opportunity to (1) communicate hospital policy; (2) clarify the dimensions that compose each system; (3) select the items that represent how they can be measured; and (4) identify better solutions for HIS practice. Nevertheless, the picture only becomes complete when we assess the run-time phase of HIS lifecycle.

During this research we elected to use simple instruments that could be accessible to different hospitals. For this reason, we have focused HIS compliance on the context of general quality standards and selected questionnaires and checklists as the main tools. We searched for multiple dimensions of design-reality gaps, for example, between (1) high level hospital policy and the quality models adopted; (2) two support services, that are the QRMC and IS department; (3) two main healthcare services of the hospital; (4) different clinic specialties (e.g., doctors, nurses, and assistants); and even (5) among the individuals in the same emergency service. In all the dimensions we found that it was an opportunity to assess the "usage and adaptation of the IT and the formal and informal [healthcare] processes" (Paul, 2007).

6. Conclusion

We presented a method to assess HIS compliance guided by the integrative IS quality framework suggested by Stylianou and Kumar (2000), in the context of multiple hospital quality models, distinct maturity, and levels of adoption. The method is supported by customized, non-prescriptive, questionnaires suggesting people involvement at all levels of the organization. It explores and proposes a practical

solution to assess design-reality gaps as proposed by the work of Heeks (2006). Moreover, we argue that contrasting the opinions of healthcare professionals can be decisive in the comprehensive assessment of HIS compliance.

A sentence attributed to Peter Drucker warns us that "culture eats strategy for breakfast". A quality culture involving HIS quality can be built and learned (Schein, 1990), involving hospital professionals in its construction. The proposed method can make a dual contribution of assessing HIS compliance and fostering a hospital quality culture that integrates the HIS in its core.

This research also has limitations. First, the scope of quality is restricted to ISO 9001 and ACSA; we did not include IT related standards, for example the ISO 27001 for information security management or the ISO/TR 14639 for health informatics. Second, in spite of the extensive documentation that we studied and the number of project participants, we only addressed two services of the hospital. Third, the hospital did not have a quality audit during our research, so we could not gather opinions from external assessors. Forth, the positive results must be carefully evaluated due to the Hawthorn effect, warning that the observed participants behaviour could be "related only to the special social situation and social treatment they received" (French, 1950).

Our research also raises new questions and opportunities for further developments. First, there is an opportunity to create new tools for visualization of HIS compliance assessment, comparing different hospital dimensions. Second, our research suggests a solution to integrate complementary quality models (Hu & Xue, 2014) but other standards can be included in the future. Third, we plan to extend the method to all the other services of the participant hospital, providing new sources of information for auditing and HIS improvement. Forth, there is an opportunity to research the impact of HIS development in hospital quality culture, namely, how the hospital policy is affected by the design-reality gap changes, how it affects the healthcare processes and the daily practice of healthcare professionals.

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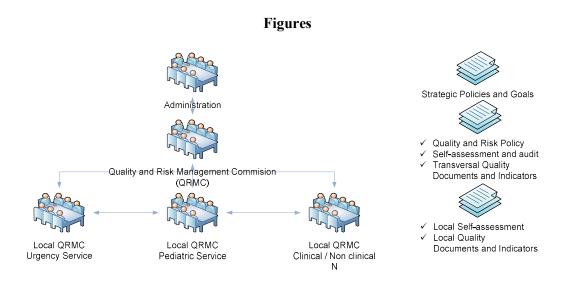


Figure 1. Organizational structure for hospital quality management.

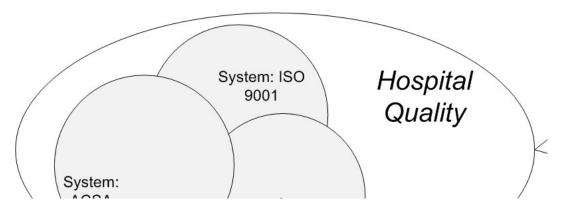


Figure 2. Dimensions of hospital quality assessment (adapted from Barata and Cunha (2013); Heeks (2006); Stylianou and Kumar (2000)).

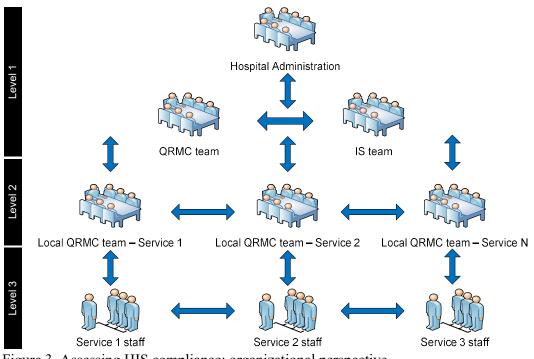


Figure 3. Assessing HIS compliance: organizational perspective.

Software Quality Checklist

(1) Software requirements were identified by the users; (2) Users requests are recorded and appropriated actions taken to improve the software

(1) Business-IT alignment is a permanent concern of management and evidenced in corporate reports and plans; (2) There is a strategic plan that includes IT

User satisfaction is monitored concerning software solutions

The organization can identify every process that each software application support (IT inventory for the process)

There is an integrated perspective of software applications (integration, software is managed as a valuable asset)

(1) The most relevant software has maintenance contracts (if applicable); (2) There is a plan for the evolution and update of internal developed software (if applicable)

Figure 4. Assessing Level 1 design-reality gap (questionnaire extract).

Р	Quality Models Checklist	Median	Std.
			Dev.
PF	Healthcare planning and organization are executed according to each patient and	4,5	
PF	Communication is adequate to the cultural and understanding capabilities of the	3,5	
LI	There is a management commitment to quality	4,5	
LI	Hospital strategy and policy are known by all the professionals	4,5	
LI	There are resources and incentives for putting hospital policy in daily practice	4,0	
EP	The contributions for planning and organization of healthcare processes are welcome	4,0	
EP	There are regular meetings for the discussion of relevant issues in healthcare and	4,0	
	hospital results		
EP	The training is adequate to the needs of each service and professional progression	4,0	
PA	Health quality documentation is known by healthcare professionals	3,0	
PA	Health quality documentation is useful to the healthcare processes execution	3,5	
IM	There is a permanent reflection and evaluation of daily procedures	3,0	
IM	Improvement suggestions are frequent	3,0	
ED	There is a satisfactory level of information/data for the active participation in quality efforts and healthcare	3,0	
ED	Staff opinions are recognized for the clinical decision and service organization	3,5	
ED	The information is complete and reliable for the decision process	3,0	
SR	There is a sistematic evaluation of health risks	4,5	
SR	Measures are taken to mitigate risks	3,5	
SR	Employees are aware about the importance of safety procedures	3,5	
SR	Incidents are imediately reported in the IS	2,5	
RS	There is a cooperation between the hospital and external entities to promote	4,0	
RS	Suppliers are involved in innovation projects and best practice implementation	4,0	

Legend: PF - Patient focus; LI - Leadership; EP - Engagement of people; PA - Process approach; IM - Improvement; ED - Evidence-based decision making; SR - Safety and risk management; RS - Relationship with stakeholders

Figure 5. Assessing Level 2 design-reality gap.

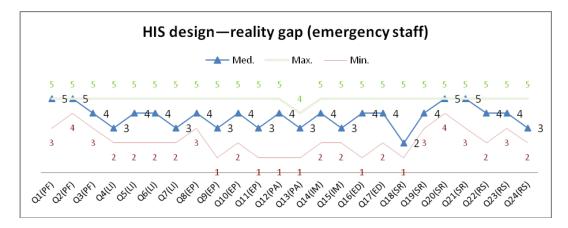


Figure 6. Assessing Level 3 design-reality gap.

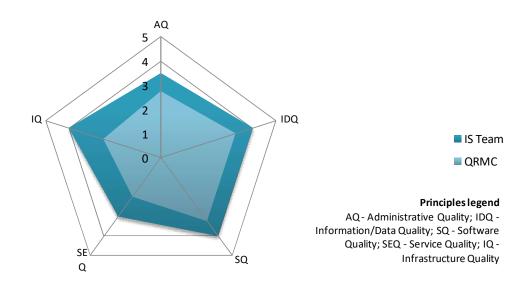


Figure 7. HIS design-reality gap according to the IS/QRMS teams.