

Design and Implementation of a Hospital Quality Assurance Program (H-QAP)

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Categories & Subject Descriptors

D.2.19 [Software Quality/SQA]: Quality Concepts, J.3 [Life & Medical Sciences] Health, Medical Information Systems.

Abstract: The purpose of this paper is to present the development of a Hospital Quality Assurance Program, H-QAP. People and Medical Devices, including software, cannot be separated in the healthcare environment, and clinical and software engineering staff are often expected to work together to ensure software systems success. However, this often results in conflicting definitions of success. H-QAP was developed as a result of researching the source of problems characteristic of the live clinical environment. It is designed to overcome these conflicts through compliance with evidence-based best practice in the management of patients and software systems.

Introduction

Software systems embedded within hardware devices such as cardiographs, infusion pumps and ventilators are increasingly prevalent in healthcare settings. Additionally, software systems integrate data from devices and applications which collect, store, manipulate and report clinical data. Software within hardware devices has long been regulated through authorities such as U.S.A. Food and Drugs Administration (FDA). Standalone software has recently been deemed a medical device (MD) (Sidebar 1) in its own right in the European Union. We expect that this will result in Health Information Systems (HIS) coming under regulatory scrutiny.

The MD industry must produce efficient and reliable products from a business and regulatory perspective. What is not often recognised is that, following deployment of software and to ensure success, the focus must shift to implementation in healthcare settings such as hospitals. This requires a partnership between healthcare staff and vendors/software engineers and involves the development of unique relationships between a significant variety of stakeholders with varying needs, interests and objectives. Healthcare staff and software engineers can have different expectations from software. Healthcare staff can have little understanding of software and may be averse to its use. Software engineers need to be aware of specific development and implementation requirements for MD's, one of which is compliance. Adding to the complexities, clinical stakeholders have different governance structures, leading to disparity of goals in the management of patient care and different understandings and definitions of quality. To ensure all stakeholders unite in their objectives, strong governance is required.

Software systems management throughout healthcare settings varies significantly and lack of standardisation may prevent optimal outcomes. High-profile cases such as Therac-25 accidents [1] have become influential, but how can quality in other systems be assured? Implementation of quality assurance (QA) and risk management structures for software is required. In hospitals, this can be done through structured Clinical and Healthcare Audit (C&H audit) programs, incorporating risk management. C&H audit, has been defined by Health Service Executive (HSE), Ireland as involving the comparison of "current practice to evidence based best practice in the form of standards, identifying areas for quality improvement and implementing changes to practice to meet the standards" [2]. Consequently, C&H audit extends beyond clinical evaluation

to other areas of healthcare such as software systems and staff management. In addition, clinical audit is mandatory in Ireland for doctors [3] and radiologists (EU Law (SI 478/2002)) [4]. As software's increasing prevalence in hospitals increases software engineers' influence, it is imperative that software engineers understand and become involved in C&H audits.

One of the authors, Louise Reid, leads Clinical Audit for a group of hospitals, overseeing the development of C&H audit. She led the development of a Hospital Quality Assurance program (H-QAP) with her colleagues. One of its aims is ensuring that HIS provide optimum benefit. H-QAP was developed over three stages:

- Analysis of published research and standards;
- Review of relevant hospital inquiries;
- Action research in hospital.

We discuss how the research output from each stage influenced H-QAP, showing that knowledge and intention is inadequate unless a strong governance structure exists as specified by H-QAP. We present where software systems and software engineers fit into the QA process to assure HIS success. We present the current version of H-QAP, illustrated with examples from its implementation in the Radiography Department.

Hospital Quality Assurance Program Development

Stage 1: Analysis of published research and standards

We systematically reviewed published research, along with software quality models and existing hospital quality standards, establishing requirements for high clinical information quality. Relevant legislation such as HSE Quality and Risk Management Standard [2], Health Insurance Portability and Accountability Act [5], and U.S.A. Food and Drug Administration regulations [6] was fundamental to H-QAP content. We noted the importance of information quality and the risks associated with poor quality. As DeLone and McLean [7] outlined, information system success requires impact on information quality, system quality, service quality, intention to use, use and user satisfaction. In the health industry, confidentiality and privacy must be assured.

Additionally, risk must be proactively identified and managed prior to occurrence of incidents. Risk must also be managed reactively following incidents. H-QAP accounts for these.

As software is now classed as a MD, we reviewed software standards from a healthcare perspective. Vispi Shroff and co-authors [8] state that the software process model, Capability Maturity Model Integrated (CMMI) [10], “was found to be the model that mapped most successfully to HSE’s Quality and Risk Management Standard.”[2]. We reviewed this model along with IEEE Standard for Software Quality Assurance Plans, IEEE Std. 730-2002 [9]. Key findings from [8] relevant to H-QAP development include:

- Clear lines of distinction between hardware and software, and the impact of changes in software are not outlined in the FDA Code of Federal Regulations [6];
- There is no explicit focus in existing FDA regulation on stand-alone software;
- The focus of the healthcare industry is on patient privacy and security with very little focus on integrity and accuracy;
- Medical devices at present are categorized into three (US) or four (EU) different categories based on the potential impact they may have on patient health but the definitions of risk factors remains ambiguous;
- The proliferation of smartphone application stores have resulted in an increase in healthcare applications becoming readily available. Regulatory or quality guidelines are not implemented on these.

The authors developed a software quality plan for hospitals based on the CMMI [8], and we took this as a basis for H-QAP, integrating it further with regulation and legislation.

Our analysis indicated that software systems be managed within a broad QA program, but did not establish the existence of a validated hospital QA program. Such a program is required to assure optimum and safe use of MDs within the hospital environment. H-QAP fills this gap.

Stage 2: Review of previous relevant inquiries

We analysed the outcomes of five high profile inquiries (see Sidebar 2), establishing common themes, findings and recommendations through the use of content analysis. Two of these

reports focus on radiology while the others were seminal reports for healthcare in Ireland and the UK.

Each of the inquiries sought to establish causes of accidents, injuries and near misses in the clinical field. While some findings do not focus on software systems (e.g. *quality assurance requires more than dedication and commitment*), some are specifically software focused - *use of existing information systems must be optimised and existing software systems significantly improve outcomes and minimise the effects when things go wrong*. Others, though not focused on software are indeed relevant (e.g. *proactive and reactive risk management must be continually in place and continually reviewed standards must be set*). Indeed, it is reported in the Bristol Inquiry that "*Bristol was awash with data but was at the same time singularly uninformed.*" Following our review of inquiries we included formal structures such as communication strategy, audit committee and stakeholder analysis within H-QAP. Additionally, we used the DeLone and McLean model [12] to measure HIS quality, thus using measurable standards.

Analysing the inquiries provided an understanding of factors that may lead to risk and breaches of patient safety within the hospital environment. QA must involve all stakeholders interacting with HIS and necessitates a culture of continuous quality improvement, supported by those in governance roles. QA must be introduced in a structured, simple manageable program as part of daily hospital activity. Staff must review findings regularly and change quickly in response to problems. Root cause analysis can be used to correct process issues and increase compliance. Topics for improvement are chosen where quality is low or priority is high. Specifically, in H-QAP, in the Topic Selection layer (fourth) information systems quality is a specific focus and it requires compliance with standardised care.

Stage 3: Action Research in Hospital

Using action research [13] and action inquiry [14] we carried out research in a hospital with 698 beds and 2,344 employees. We found that information systems are used in a variety of ways – systems are used hospital wide, systems are used specifically by single departments and systems are used personally by clinicians. There is no integrated electronic patient record

(EPR) and the primary medical record is paper based. Using the DeLone and McLean IS Success Model, we reviewed four systems– the Emergency Department software system, two Clinical Nurse Specialist databases and the Hospital In-Patient Enquiry (HIPE) database.

Data quality varied widely. One system had 100% use of data and greater than 95% accuracy, while another had never been used and some fields were 100% inaccurate, despite data being entered regularly. We held interviews with key stakeholders such as a software engineer, radiographers, clinical nurse specialists, consultants and data entry personnel. Key findings include:

- Many healthcare staff have little understanding of data quality;
- Requirements engineering processes are often not used during systems development;
- Software such as Microsoft Excel allows healthcare staff, not qualified in software engineering and without an understanding of compliance, to implement systems;
- Little emphasis is placed on data reporting even when available;
- Healthcare staff are reluctant to use information where quality cannot be assured;
- When systems information is not used, data quality degenerates;
- Stakeholders' variety leads to different system expectations;
- Lack of significant investment in software systems results in difficulties integrating old and new;
- Lack of compliance with standards has resulted from a lack of proactive management relating to compliance;
- Budget and staffing cuts have impacted on time traditionally given to quality programs;
- Software compliance is not seen as a priority by healthcare staff.

Overall, our research has demonstrated a lack of a structured planning and maintenance program for HIS. Software engineers and IT vendors were not enabled to work in partnership with healthcare staff to assure quality and safety of systems. When systems were underutilised, data quality deteriorated, leading to lack of confidence and ultimately less use. Additionally, we noted inefficient use of existing systems with staff 'working around' processes.

Contrary to this, one system, HIPE, had high data quality and use. HIPE staff have a high standard of training. Data is used, reports are provided within six months and there is constant feedback, with a local QA program in place.

Given the varied problems identified, we included a variety of approaches for information quality improvement in H-QAP. Through understanding current hospital situations, strengths and weaknesses of existing quality processes were established. Any high impact program to be implemented would need to be simple and inform the decision to work with small sample sizes, including the Rapid Cycle Escalation Process [11].

Description of Hospital Quality Assurance Program

H-QAP (Figure 1) consists of 6 layers, completed inwards. The Governance Layer (sixth) establishes the relevant person or persons in authority and places them in control of the program. They ensure that other layers are set-up and reviewed. The fifth layer, Structure, requires that a committee of key stakeholders is set up. This should include staff who bring knowledge and influence, and, where software is under review, software engineers. This committee's responsibility is to develop and maintain a prioritised suite of quality protocols. Using the healthcare staff's clinical knowledge and software engineers' information systems knowledge, they ensure the QA program is high profile, staff are aware of any changes and risks of noncompliance are properly assessed. If issues arise beyond committee or departmental control, they are escalated to hospital management. The Topic Selection Layer ensures that the QA program is holistic and based on the requirements of the patient. Implementation of this layer requires weekly topic choices which are prioritised based on risk of non-compliance. Each topic, if not reviewed in the previous six months, increases in priority. The Quality Layer (third) recognises that 'Good structure increases the likelihood of good process, and good process increases the likelihood of a good outcome' [12]. Structures, (equipment, software, education policies) are the physical entities required to ensure compliance. Process involves reviewing how things are done. Is the policy being followed? Are software implementation processes efficient? Review of outcomes requires understanding of whether the desired outcome for patients or from a medical device is achieved. Therefore, in the

case of an Information Management System, the net benefits (desired outcome) would be that staff have access to an up to date suite of Policies/Procedures/Protocols guidelines (PPPGs). From a structural perspective, it is important to have a software management program in place to ensure the system is managed safely. There should be policies ensuring all PPPGs are available on the system and staff are trained to do this. The process perspective reviews whether staff are actually doing what is required of them - writing PPPGs and uploading and downloading the system. It reviews adherence to software management and safety processes.

The Audit (second) Layer is adapted from recognised audit processes [13]. At this layer, objectives and standards of the audit are defined. An example would be to improve the use of the Information Management System through achieving compliance of 100% of existing PPPGs stored. Data is collected, measured against this standard, practice changed if required and re-audit carried out. The Rapid Escalation Layer (first) is then implemented. Healthcare staff's requirements will be managed and governed by those with capacity to do so. We implemented this layer using the Rapid Cycle Escalation Process [11]. Here, information through posters (Figure 2) and compulsory education is provided. Root cause analysis occurs at each step, correcting process issues and ruling out circumstances beyond the control of auditees. From a software systems perspective, the Delone and McLean model is used to scientifically check whether performance is maximised. If not, the software engineers must follow up and resolve issues.

This simple rapid cycle QA program, H-QAP, assures best practice compliance, ensuring prioritised topics are managed to achieve net benefits within the live clinical environment. It ensures areas are revisited quickly thus increasing sample size without losing prioritisation of clinical/risk significance. Governance relevant to the individual topic is put in place in advance to ensure changes actually happen. Local governance and rapid escalation caters for domain complexity.

Implementing H-QAP

Our new understanding of the hospital's variety and complexity - each department having different sets of systems, standards for use of systems, risks associated with systems, sets of

demands, goals, objectives and barriers to compliance - supported the decision that our program must be applied at departmental level rather than hospital level. Given that we have seen a requirement that governance drives the quality program, we incorporated specific structures, including a committee, communication strategy and stakeholder analysis to produce a team of relevant stakeholders. A very simple, manageable continuous program was required to ensure that systems achieve net benefits. However, this must run as part of a fully integrated QA program.

For example, following a review of the PACS system within the Radiology Department, we observed the net benefit of the system is that the patient receives a correct diagnosis within an acceptable time frame and in line with the ALARA (As Little As Reasonably Achievable) Principle for radiation, as too much radiation can cause cancer. The radiographer uses the medical device to take an image, the image is linked to the correct patient and stored on the device, the image is then reviewed by a consultant radiologist and a diagnosis is made. For a correct, safe diagnosis there are a number of stages to be considered:

- The machine must be developed and maintained correctly (system quality);
- It must be calibrated by a team of physicists to ensure it performs as it should including providing the dose of radiation asked of it (system quality);
- An engineer must support maintenance (system and service quality);
- It must be used correctly by the radiographer to take a clear image (information quality);
- The image must be linked to the correct patient (use and system quality);
- The image must be archived (use and system quality);
- The radiologist must review the image, report a diagnosis on the correct patient to the correct treating physician in a timely fashion (use and system quality).

As can be seen from this list, the net benefits of the system will only be achieved within a structured holistic environment involving different stakeholders. Our program asks that each step is taken individually and the amount of effort applied to the achievement is dictated by the risk of non compliance.

Through the implementation of H-QAP, we noted that, in the radiology department, a large number of shoulder X-rays using the PACS system were being rejected by the radiologist. This implied poor information quality and caused re-takes of the images, thus increasing radiation to the patient, increasing the workload on clinical staff and delaying diagnosis. The lack of quality was then examined under three headings - structure, process and outcome. This showed that the images were rejected due to lack of standardisation between radiologists' requirements from a shoulder X-Ray compounded by a lack of standardisation in what radiographers were providing. The system was working correctly from a technical perspective but was still not achieving success.

The key governance staff (radiography and radiology leads) developed policy ensuring radiologists agreed a requirement (angle/contrast/view) for a shoulder X-Ray and radiographers were aware of and provided that X-Ray, defined objectives (reduce rejection rate), set standard ($\geq 95\%$ compliance with policy), ensured data collection (number of relevant x-rays), reported the data (information poster, formal department meetings) and re-audited. What is important is that a small manageable sample size was initially collected. We implemented Rapid Cycle Escalation Process [11] until the desired standard was achieved. Speed of escalation was decided in advance and was dependant on the risks of non-compliance. Once this problem was solved, we were then able to move back up the spiral choosing other areas to investigate. This ensures holistic success of the software system regardless of who the stakeholder is.

Conclusion

To conclude, it is important to reflect on what the development of H-QAP gives to patients, healthcare staff and the software engineering community. We have seen that good structures lead to good processes which in turn lead to good outcomes. For example, our implementation of H-QAP within the radiology department has decreased the number of re-taken X-Rays, reduced patient exposure to radiation and removed this excess requirement from the system. We showed the X-Ray system to be compliant with departmental standards. In other departments, we are collecting and analysing data during C&H audits with a view to implementing H-QAP. H-QAP is fair as the escalation process is known prior to audit and it

gives staff an opportunity to correct practice prior to governance and consequence. Education provided to staff ensures professional development. Incorporating the DeLone and McLean model ensures that all relevant aspects required for management of each software system are incorporated in H-QAP, despite multidisciplinary aspects and domain complexity. System use is better, data is more accurate and staff are working together towards a unified goal of achieving net benefits. Due to the simplicity and regular reviewing of small sample sizes, process issues come to light quickly and are fixed rapidly. Where indicated by high risk, the topic is examined in greater detail involving further review of larger sample sizes.

H-QAP requires that different stakeholders must work in partnership to develop and achieve common goals. It provides a framework for software engineers to engage with healthcare staff by integrating software quality and maintenance with clinical management of the patient, thus creating a common platform for both clinical care and software management.

The next phase of this program involves validation of H-QAP across the other hospital departments before validation in another hospital.

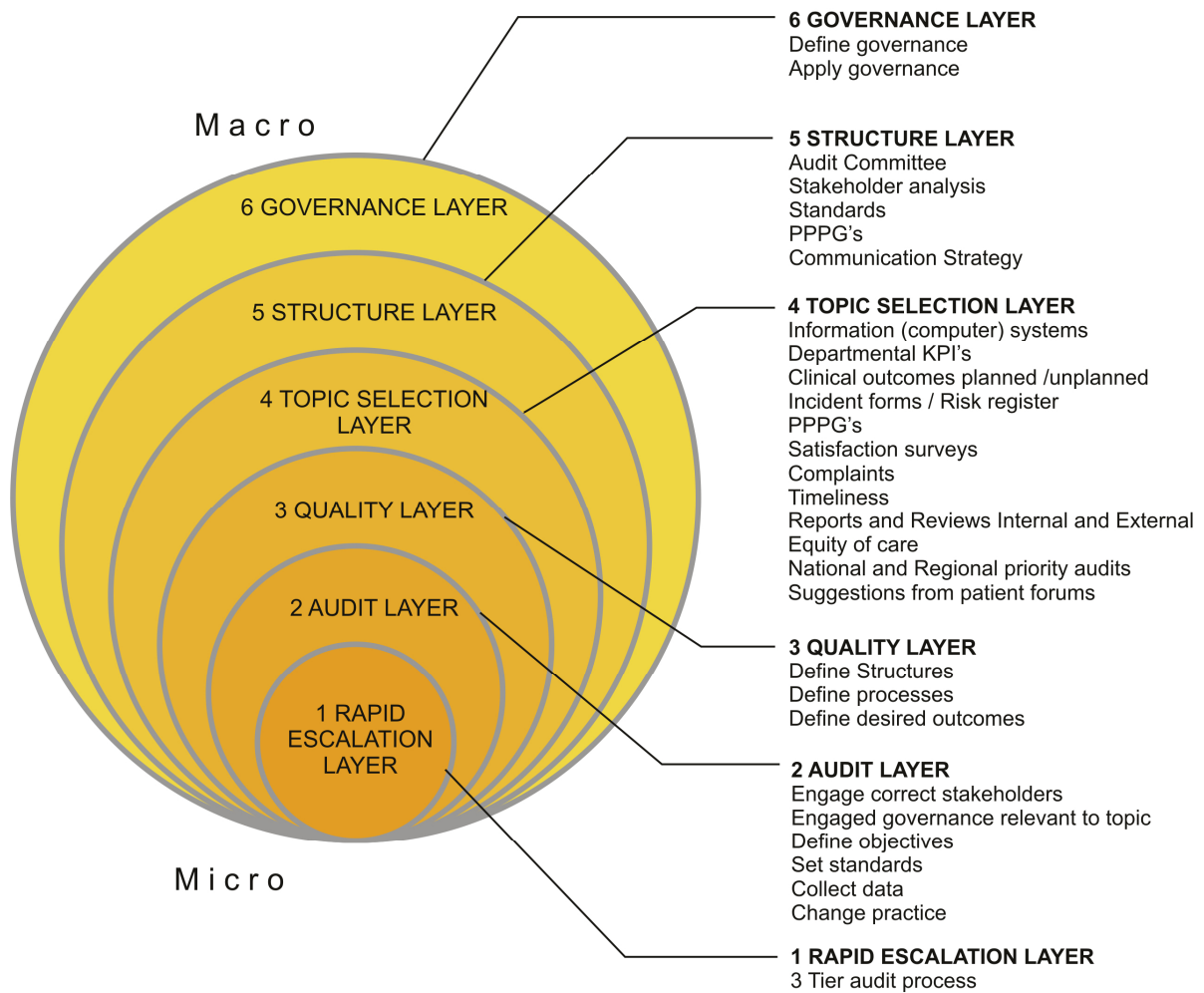
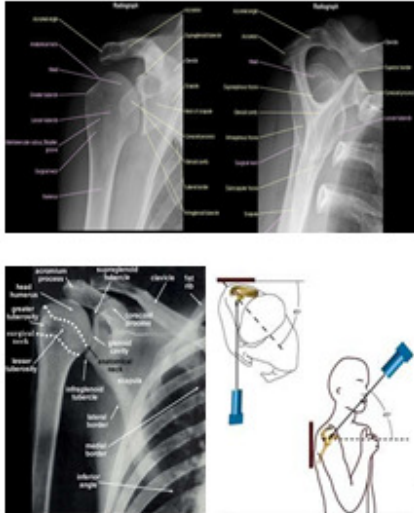


Figure 1: H-QAP Layers and protocols

Departmental Shoulder Protocol



Title: To determine compliance with departmental radiography imaging protocols of the shoulder.

Aim: To achieve 95% compliance with Departmental Radiography Imaging Protocols of the shoulder

Results

Shoulder studies compliant = 13
Shoulder studies non-compliant = 3
64% compliance achieved in Audit 1

Root Cause Analysis:

- Centring incorrect
- Acromio-clavicular joint not visible

Suggestions for improvement:

- Centre on the coracoid
- Use prescribed exposures
- Do not use a grid
-

Action: Refresher poster displayed for 7 days next to work station. Re-audit to follow in 7 days.

Figure 2: Information Poster - a simple and effective display for staff [11].

Sidebar 1: Software is a Medical Device.

The European Union recently declared that software, including standalone software, in a medical setting may be classed as a medical device. The relevant definitions are:

- EU Directive 2007/47/EC [1] - “It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device. Software for general purposes when used in a healthcare setting is not a medical device.”
- EU Directive 93/42/EEC [2] - “‘medical device’ means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of: - diagnosis, prevention, monitoring, treatment or alleviation of disease,-diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,…”

[1] Official Journal of the European Union, September, 2007.

[2] European Union Council Directive 93/42/EEC, June 1993.

Sidebar 2: Hospital Inquiries

Some of the earliest and most prominent cases of system failure due to poor software quality were the Therac-25 accidents between 1985 and 1987 where patients received fatal overdoses of radiation. [1, main paper]

Statistically below average outcomes for procedures with the removal of patients uteruses were investigated the Lourdes Hospital. [1]

Above average death rates for children undergoing heart surgery was the focus of the Bristol Inquiry. [2]

Higher than average death rates for patients of a General Practitioner was investigated in the Shipman Inquiry. [3]

The Tallaght review was into the reasons leading to unopened General Practitioner referrals and unread X-rays. [4]

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Acknowledgements

This work is partially supported by the European Commission through TRANSFoRm, DG INSFO (FP7 247787) and by Science Foundation Ireland through Lero - the Irish Software Engineering Research Centre (<http://www.lero.ie>) grant 10/CE/11855.

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