

Software Implementation of a Healthcare Quality Management System Based on ISO9000 Standards

Bassam Hussein¹, Hassan Bazzi², Walid Hassan³, Ali Hage-Diab⁴, Amin Haj-Ali⁵ and Hassan Khachfe^{4,6*}

¹Department of Industrial Engineering, Lebanese International University, Lebanon

²Department of Electrical and Electronics Engineering, Lebanese International University, Lebanon

³Thomson Reuters, Scholarly & Scientific Research Office, Beirut, Lebanon

⁴Department of Biomedical Engineering, Lebanese International University, Lebanon

⁵Department of Computer and Communications Engineering, Lebanese International University, Lebanon

⁶Center for Quality Assurance, Institutional Assessment and Scientific Research (QAIASR), Lebanese International University, Lebanon

Article Information

Received date: Feb 17, 2016

Accepted date: Mar 22, 2016

Published date: Mar 28, 2016

*Corresponding author

Hassan Khachfe, Center for Quality Assurance, Institutional Assessment and Scientific Research (QAIASR), Lebanese International University, Beirut, Lebanon, Email: hassan.khachfe@liu.edu.lb

Distributed under Creative Commons CC-BY 4.0

Keywords Healthcare; Quality Management System (QMS); Quality Assurance; ISO; Standardization

Abstract

This paper provides a description of an integrated, web-based and fully automated healthcare institution quality management system. The system includes many features and applications that provide better alignment with quality assurance strategy and best practices benchmarks. It is based on a proven design approach that supports and enhances the quality of medical and healthcare services. The different stakeholders are provided with a common framework for designing, implementing, controlling, evaluating and improving these services. The software system is customizable and scalable in the sense that additional functionality based on the needs and requirements of individual institution can be easily implemented or supported.

Introduction

Constant upgrading of the quality of healthcare centers is a key priority at institutional, national, regional, and international levels [1]. This priority should be an objective that would be best achieved and sustained through the adaptation of a well-defined quality management standard with a proven success track record. In recent years, many such standards were developed and made available to various industries and sectors. However, the International Standardization Organization (ISO) standards gained overwhelming popularity and became the benchmark across the globe. The ISO 9000:2008 defines a management system as a set of interrelated or interacting elements to establish policy and objectives and to achieve those objectives. Along the same lines, the same standard defines QMS as a management system to direct and control an organization with regard to quality [2]. In other words, QMS is a mechanism or work procedure to achieve and sustain quality. In other words, it may be considered as a system that includes documentation listing guidelines that define work procedures. This covers quality manuals, instruction manuals, and records. In addition, it deals with the management of resources such as people, equipment and material. The work procedures prescribed by the QMS must be based on the technical nature of the work that ensures high quality products or services.

Recent charted European agreements placed the objective of increasing the attractiveness of healthcare institutions and promoting medical tourism [3] as a key objective along with quality improvement requirements (e.g., the EU-OECD agreement on healthcare indicators [4], EUPHORIC Project [5], etc.). This trend has been very evident across the globe where healthcare facilities are racing to adopt international quality standards either voluntarily or through regulation in the country of operations. Quality improvement is the most important function to establish in ongoing healthcare organization and needs to be done via special projects [6].

To achieve such key objectives, most of the current systems follow the classical methodology of cyclic planning, implementation, assessment and review, and examine the process as a relative and contextual concept. That cyclic process in nature is depicted in Figure 1 [7]. The above approach is usually adopted to avoid the creation of a pervasive and unequivocal definition of healthcare quality. An effective Quality Management System (QMS) targets the systemic development and communication of a customer-focused mission, strategies, and action plans. There by, listening and responding to customers' needs and expectations, empowering employees to keep improving and increasing their satisfaction with their work processes and environment, and gathering and analyzing Key Performance Indicators (KPIs) to enhance organizational and process results are of immense importance for good governance of an institution [8].

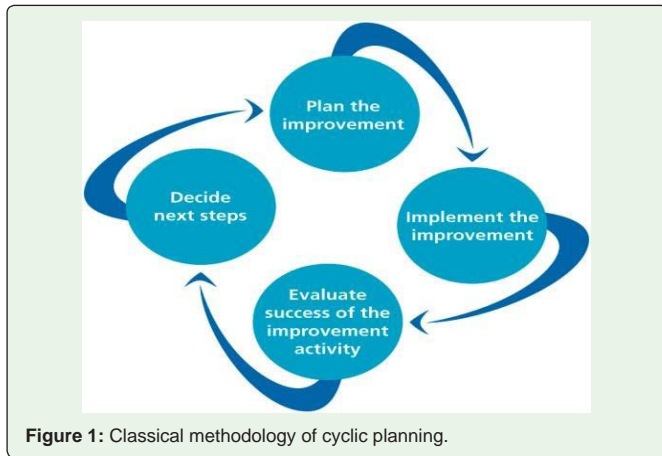


Figure 1: Classical methodology of cyclic planning.

Consequently, an integrated web-based Healthcare Institution Quality Management (HIQMA) system has been implemented to improve medical and healthcare services ensuring quality. The main goal is to ensure patients’ safety through effective and efficient quality management. The system attributes include several applications, starting with a quality handbook for the individual beneficiary organizations, continuing with the reformed professional training and advisory services concepts, and ending with the developed service guidelines. In addition, scalability and customizability are intrinsic characteristics of the system. These attributes ensure that different stakeholders are provided with a common framework for designing, implementing, evaluating and improving these services in a continuous and sustainable manner.

This paper describes the design, architecture and functionality of the HIQMA system as well as some of its attributes and services. In Sections 3, 4 and 5, the system is described in details. Section 6 outlines the governance and standards compliance dimensions. Section 7 presents some results and impact assessments. Further enhancements are described in Section 8. The paper conclusions are finally captured in Section 9.

System Description

Managing quality performance requires a comprehensive approach that has a dynamic nature in terms of agility and customization. This becomes highly important when dealing with healthcare institutions as they must carefully consider and control their activities to ensure all quality requirements are met. The integrated web-based automated HIQMA system that was built, has been designed to assist such organizations in implementing and maintaining this comprehensive approach by delivering tools structured around the ISO 9000 family of international standards for quality management taking into consideration the special needs and features for healthcare services [9]. A screen shot of the main user interface is depicted in Figure 2.

HIQMA is a centralized management system that provides a portal to critical quality information and facilitates quality performance improvement through requirement tracking, notifications and real-time management reporting. It has been designed to streamline and automate quality management processes of any medical organization and assist in the effective implementation of wide quality initiatives on a “use per need basis”. The software system is 100% web-based,

highly configurable QMS that helps organizations track, analyze, and report on quality management in addition to streamlining existing processes and enforcing their application.

The system was deployed for the first time in Lebanon in early 2011. Since then, the system has been deployed in 10 medical institutions covering 5 private hospitals with 100+ bed capacity, 2 polyclinics and 3 medical labs. As a part of the system’s development and evolution plan, a new version of the software is installed every 6 months in all locations.

Typically, the new software releases include bug fixes, further enhancements and new features. In an attempt to ensure customer satisfaction and continuous quality improvement, an annual on-line customer survey is conducted [10].

Data was obtained by administrating a structured-questionnaire survey comprised of 20 questions covering 4 distinctive areas: functionality, compliance, efficiency and quality control. A quantitative scale of 1-5 is used (5 = strongly agree; 4 = agree; 3 = neutral; 2 = disagree; 1 = strongly disagree). The survey is shown in Table 1. In the first survey conducted in early 2012, a total of 5 institutions responded to the survey and an average score of 3.90 was recorded. In the second survey conducted in early 2013, a total of 7 institutions responded to the survey giving the system an average score of 4.36. Lately, a third survey was conducted earlier this year where 10 healthcare institutions responded. The overall average score was 4.42. This suggests that the system has evolved significantly and is a viable candidate for wider deployment and adoption by other medical entities. In the next sections, the main features of the system will be described in further details [10].

System Architecture

High level view

The implementation of a QMS system is an intensive activity that involves relatively complex steps. In addition to the technical aspects, many other factors influencing the implementation of such systems must be taken into consideration. According to Wardhani, et al., organization culture, cultural type, degree of employee empowerment, the strategic approach, the size and ownership, customer focus, and the paradigm in solving problems are reported and identified as the critical factors in QMS implementation. The

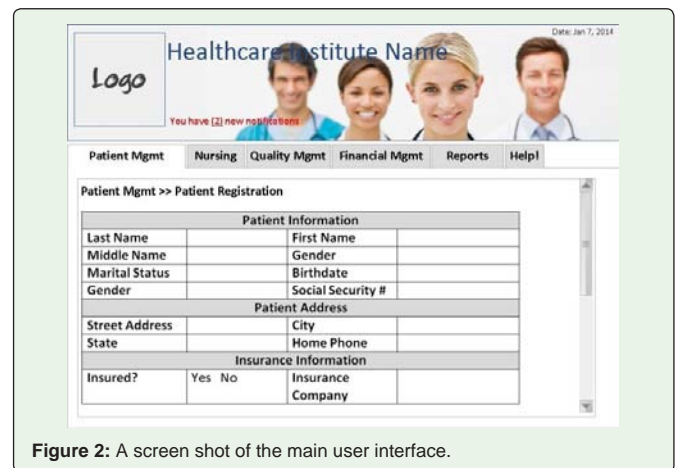


Figure 2: A screen shot of the main user interface.

Table 1: HIQMA system satisfaction survey.

HIQMA System Satisfaction Survey					
Form ID: HSSU-2013a					
Institute:	Language used:	Period as HIQMA user:			
To what degree do these statements describe the conditions at your institution?					
Please rate each statement on the following scale:					
1=Strongly Disagree	2=Disagree	3=Neutral	4=Agree	5=Strongly Agree	
	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
The system is easy to use					
The system is easy to navigate through					
The system has many login errors					
The system crashes so often					
The system shows many errors					
The information in the system is accurate					
The system is well organized and efficient					
The system has security vulnerability issues					
The system is effective in quality control					
The system is too slow					
Quality of reports is acceptable					
Quality reports are of acceptable content					
The KPIs have enough entry fields					
KPI owners have limited access to the required fields					
Data entry is cumbersome					
The system has language problems					
Users showed initial resistance to the introduction of the system					
The system interacts well with the backbone servers					
The system has helped us improve quality control operations					
We are satisfied with the overall performance of the system					

degree of QMS implementation will be higher in proportion to the degree of employee empowerment, risk-free environment and innovation emphasis. These may be represented as the features of a less hierarchical culture, less bureaucracy and complex structure, more risk-taking and innovative strategic approach [11].

At the top level, the HIQMA system is based on multi-tier web application architecture. The main components of that architectures being the web-clients (with special mobile features), the quality orchestrator, and the data vault (database and file system). The architecture is depicted in Figure 3 below.

HIQMA allows multiple client types and platforms through browser-based and platform-based (Apple IOS, Android, Windows Mobile) applications. The browser-based access is being made default for effective deployment.

The quality orchestrator follows a layered architecture. The rationale behind selecting this type of architecture hinges mainly on a maintenance quality attribute. This quality attribute gives flexibility of in replacement of platform/technology at any level in the hierarchy, and thus freeing the dependencies on a specific platform/technology.

At the base of the quality orchestrator lays the network layer. This module abstracts the detailed implementation of the web servicing and security authentication from the layer above. All components required for the proper integration of web server and security authority are lumped into the network infrastructure module. This layer provides services to the Quality Process Manager layer without exposing the intricacies of the implementation. Such services includes: authentication results, structured query results, etc.

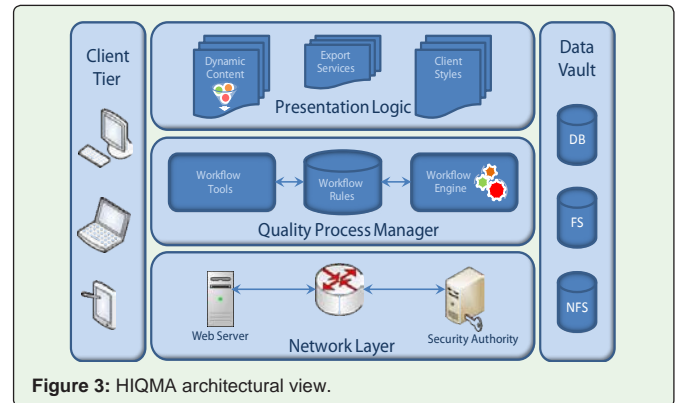


Figure 3: HIQMA architectural view.

The Quality Process Manager is the main part of the system. Due to its pivotal role, this layer represents the core of the design. The major components of this layer are: the workflow rules database, the workflow engine, and the workflow tools. This layer is designed with flexibility and scalability being the major requirements.

The quality process workflow is not hardcoded. On the contrary, the workflow tool allows the creation, editing, and deletion of any quality process workflow. The details of any workflow are saved in the workflow rules database in XPD (XML Process Definition Language) format. The workflow engine uses the workflow database to automate the process steps during any execution.

The quality process manager hides all its detailed implementation from the presentation layer. The services provided to the presentation logic layer includes all processes needed to render process steps and/or data exports to clients.

The last part of the architecture is the data vault. This is simply a conundrum of data services (database, local file system, network file system, etc.). These services are responsible for serializing any information to/from any process. Due to its importance, this part will be discussed in details in the following section [10].

Database view

Today, it is a common requirement that health solutions provide stakeholders with significant data for compilation and analysis. As such, HIQMA has an integrated database module that is responsible for the processing and storing of various collected data. The diagram captured in Fig. 4 shows a simplified snapshot of the database entities

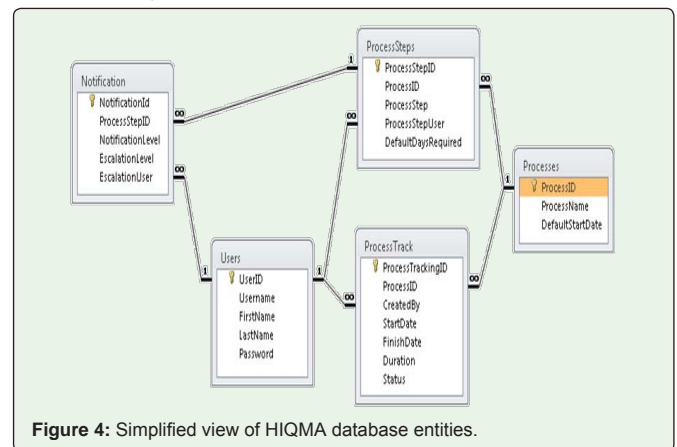
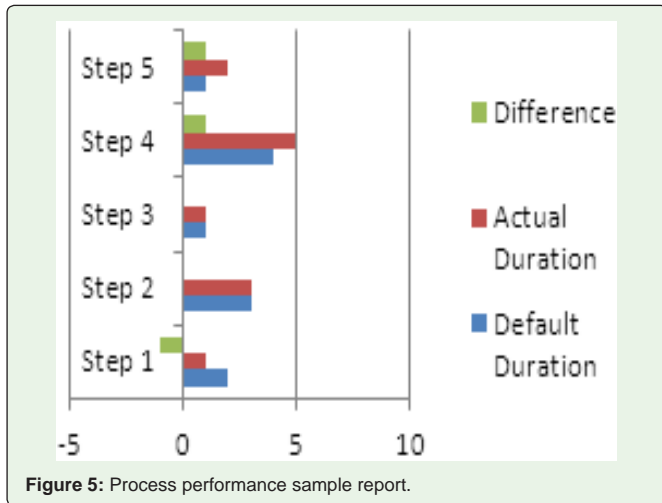


Figure 4: Simplified view of HIQMA database entities.



used in process logging and tracking. The actual implementation is much more complex and would rather require further technical insights and details that are not deemed as out of the scope of this paper.

The logging and tracking is controlled by three tables: Process Track, Process Steps, and Notification. The tables are connected to other tables like Users and Processes. The Processes table contains the unique identifier of each process, its name, as well as Default Start Date, which states the date/time the process has to be initiated. The Users table contains the information about the users of the system. These two tables are needed to fill required fields in logging and tracking. Sample records of these tables are shown below.

User ID	Process Name	Default Start Date
1	Performance Appraisal	Jan-1-2014

User ID	User Name	First Name	Last Name	Password
1	adayekh	Ayman	Dayekh	****

For each process in the system, a number of records are defined in Process Steps table. These records contain the following parameters:

- Process Step ID: A unique identifier for the process step.
- Process ID: The unique identifier of the process.
- Process Step: An integer number that specifies the sequential order of the process stages.
- Process Step User: The unique identifier of the user responsible for handling this step.
- Default Days Required: An integer number specifying the default number of days required for this step to be completed.

The table Process Steps is used to set a predefined sequence of each of the processes' steps. It also defines the normal duration each step requires; as well as the user whose intervention is needed for the process to move onwards. A sample record of the table Process Steps is shown below.

Process	Record
Process Step ID	1
Process ID	1
Process Step	1
Process Step User	1
Default Days Required	2

The above record, given the previous samples, states that the process "Performance Evaluation", has the user "Ayman Dayekh" responsible for the first step; and it should take normally two days to finish.

The table Process Track logs the actions taken by each user in every step along with a timestamp. The records for Process Track are:

- Process Tracking ID: A unique identifier for the log record.
- Process ID: The unique identifier of the process.
- Created By: The unique identifier of the user being logged.
- Start Date: The timestamp at which the user initiated the process step.
- Finish Date: The timestamp at which the user ended the process step and passed it to the other user.
- Duration: A calculated field specifying the number of days needed by the user to finish the step. In other words, it is the period between the Start Date and Finish Date.
- Status: This field specifies if the step is in progress or completed. The default value is "in progress".

A sample record of the Process Track table is shown below:

Process	Record
Process Tracking ID	1
Process ID	1
Created By	1
Start Date	Jan-2-2014
Finish Date	Jan-3-2014
Duration	1
Status	Completed

It must be noted that the Finish Date and Duration fields will remain empty until the user finishes the step. The status field will be set to "Completed".

By combining the information from the tables above, the management can view as a report, the baseline of the process against the actual timeline needed. It can also clearly show which steps are taking more than required and by which user. If a process is hanging, a simple query on the Process ID will show where the process has stopped or is in progress [10].

A sample report on the performance of a process incident showing the default duration, actual duration, and difference in days is shown in Figure 6.

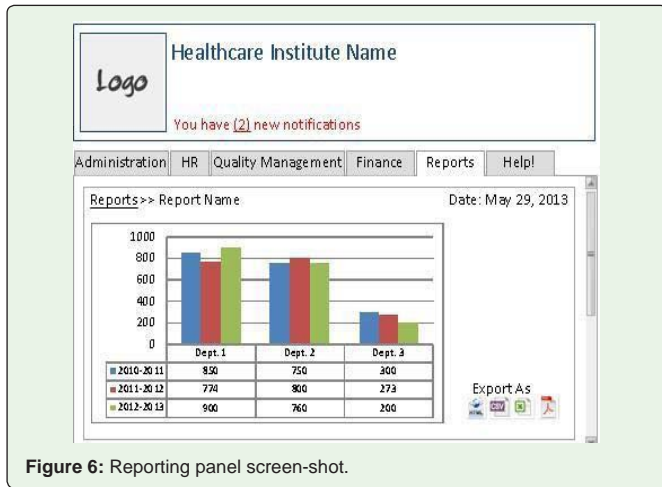
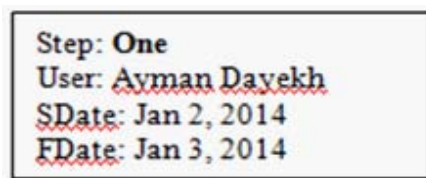


Figure 6: Reporting panel screen-shot.

By clicking on any of the steps, the following information will be displayed:



The last table is the Notification table. It contains the warning and escalation levels for each of the processes' steps. Here is a summary of its fields:

- Notification ID: A unique identifier for the record.
- Process Step ID: A unique identifier specifying the unique identifiers for the process and process step.
- Notification Level: The number of days after which the system should notify the user.
- Escalation Level: The number of days after which the system should escalate the delay caused by the user.
- Escalation User: The user to be notified when escalation is required.

A sample record of the Notification table is shown below:

Notification ID	1
Process Step ID	1
Notification Level	2
Escalation Level	3
Escalation User	2

The record above is related to step one of process one, "Performance Appraisal". If the user of step one has not started or finished the step in two days, the system will automatically notify him/her by an email or pop-up alert. The system will automatically notify the user specified in the Escalation User file if the responsible user has not started or finished the step in three days [10].

HIQMA open source reference implementation

The architecture described in the previous section showed an important attribute, namely, layer-to-layer portability. By this attribute, the architecture is not implementation dependent on any technology/product. This value-added dimension allows institutions employing HIQMA to revert to any economical implementation that suits the reliability requirements [10].

The basic servers required to implement HIQMA will include:

- Linux: Acting as main OS and file server.
- Apache HTTPD: Web servicing component.
- Apache Tomcat: Application server.
- MySQL (or MariaDB): Database server.
- Orchestra: BPM orchestrator.

Main Features

Web-based application

From a technical perspective, the system is web-based, with all of its features and their respective functionality accessible through any web browser. It can be hosted inside the healthcare institute's Local Area Network (LAN) infrastructure with open or confined access from outside the establishment's premises. The system can also be hosted online using any preferred hosting service provider or cloud hosting services. In addition, it offers a deployment model for organizations preferring to outsource hardware and software maintenance. Roll-out of the system can be completed for any given location worldwide in less than 6 hours enabling users with a URL, username and password to access the system from –virtually– any Internet access point. According to recent findings, web-based interfaces reduce the learning curve of medical or administrative staff that can begin to work with the system shortly after installation and incorporate it in their daily tasks and activities [12].

Centralized activities management and customization

Through a friendly Graphical User Interface (GUI), the system provides the user with a workplace that is easy to work with through a variety of summary screens, task menus and drop-down lists. These features are accessed by a regular user according to his/her assigned privileges and/or role(s).

A regular user may access a user specific task summary screen that summarizes the responsibilities in sequential order. Users can be presented with this screen upon login, ensuring single click access to their most critical information. Management personnel have access to a personalized menu that provides visibility over current activities and pending assignments of the medical staff tasks. Management system coordinators and senior personnel have access to a complete listing of tasks by location, department, region or corporation as a whole.

The system tracks "who" is doing "what", "when", "where" and "how". It doesn't just store this information; rather, it automates such information through notifications and tracking mechanisms. All tasks, forms and assignments can trigger an email notification to the appropriate responsible person. Every email notification includes a



Figure 7: Quality management panel displaying KPI graph.

hyperlink that sends the user directly to the task detail screen within the system. This screen provides further instructions, downloads, as well as fields, to record activity completion and uploads related documentation. The system ensures nothing falls through the cracks with an escalating email notification feature. The system can be configured to escalate the email notification of tasks pending completion. This feature is extremely flexible and can be configured to send any number of emails to any number of people to ensure tasks are completed on time [10].

Embedded forms and processes

The application is pre-loaded with numerous forms, checklists and common processes for all the necessary activities that are common in almost all healthcare institutions. The availability of such material helps the user complete needed tasks and activities in a controlled manner where human mistakes are minimized. Detailed process description is always displayed whenever the user invokes or triggers any activity that involves that respective process. If multiple processes are involved within a specific operation, then all of them will be made available to the user for consultation, help and cross-checking. This makes the application a fail-proof approach, ensuring that quality requirements compliance is maximized and chance of making errors is minimized. This naturally leads to improved Quality of Service (QoS) and better risk management.

It is worth noting here that research shows that there is a link between patient safety culture and quality management and they are both positively correlated with each other. Furthermore, adverse medical events, as injuries to patients that arise from mistakes and accidents during medical treatment are called, can be result of human errors, technological errors, or a system that failed to detect these mishaps and prevent them [13]. The support of embedded forms and processes within HIQMA contributes to the minimization of human errors as the healthcare staff would typically be applying a streamlined approach without much margin for maneuvering or discrepancies.

Flexible reporting

There are several ways quality information can be presented and reported [6]. The HIQMA system is designed to streamline the flow of information throughout the healthcare institution. Institutions can mirror their hierarchical structure within the database, and

this enables data to flow from a site, to a department, to a unit, to institute-wide, to regional or other locations in the case of multi-center organizations. Each location, division, department or other type of unit can manage its structures independently, and can have varying levels of hierarchy.

Data within the system will roll-up to appropriate management levels instantly in real-time without the need for lengthy manual traditional processes and procedures. The system has a centralized reporting tool that makes sharing information easy. Users at all levels of the organization can generate reports that summarize performance status and requirements. All reports can be generated in the most popular formats (HTML, PDF, .DOC or .XLS). Reports can be configured online through the web-based interface. A screenshot capturing the reporting panel is shown in Figure 7. Information related to control is not only of interest to internal stakeholders but also to external ones as well. Special attention, however, is required when detailed control information from varying departments is aggregated and simplified to fit public reporting using a single indicator [6].

The primary concern of any healthcare institution is to treat patients in the most effective manner with the best possible quality care but at a reasonable cost. The HIQMA system provides a tool to assess the performance of daily operations using Key Performance Indicators (KPI). This allows institutions using this system to determine if they are on the right track toward achieving their goals. The HIQMA system provides predefined KPIs common to most healthcare organizations in accordance with ISO 9001 standards and best practices. Executives and managers can add, delete, or edit the predefined KPIs to provide custom designed indicators.

The KPIs include a myriad of titles related to customer and employee satisfaction, finance, and market growth. Each KPI starts by defining the short term or long term goal to be realized, identify the KPI to measure the goal, rate the KPI, communicate, implement, measure monitor and improve, and back to redefining the goals to be realized [10].

Standard KPIs provide quick start for the management process and allow the manager to experience the benefits of the system in a relatively short period. As the manager becomes more familiar with the system, the HIQMA database expands to fit plans of the new goals. It is important to state that the full potential of the HIQMA system can only be realized with capable and experienced executives and managers who have proper quality management training and receptive attitudes. KPIs can help in the lesson learning process, retrospectives, where mistakes are viewed as opportunities for future enhancements and improvements. The predefined KPIs are selected according to the SMART test. SMART stands for: Specific, Measurable, Achievable, Realistic, and Time-bound. Each KPI is rated according to its impact service excellence, efficiency, and financial impact. The KPIs are defined with hierarchy and ownership established around the role of the organization. No KPI should have dual ownership to prevent confusion over responsibilities and help stay away from micromanagement. Executive KPIs have global level whereas line managers have day-to-day operations level. During monitoring and measurement, the owner of the KPI is notified automatically on any deviations from the set threshold levels. Real time alerts are emailed to the owner of the KPI [14].

Detailed formulas, target values, definitions, and references for each KPI are provided. Typical KPI fields include: KPI Title, Owner, Description, Rationale, Target, Collection Frequency, Reporting Frequency, Calculation, Data Sources, References and Web Links, Metric Reporting Requirements. Specific KPI titles for hospital as an example include: inpatient raw mortality rate, harm events per 100 patient days, bed turnover, readmission rate, occupancy rate, average length of stay, average cost per discharge, patient satisfaction, total operating margin, cash receipt to bad debt, claims denial rate, and days of cash on hand [15]. A snapshot of KPI reporting is illustrated in Figure 7.

Mobility

The rapid growth of information and computer technology and the emergence of high speed wireless communication have revolutionized the use of software and provided users with unprecedented mobility. Nowadays, users are almost always connected using a wide variety of portable and mobile devices. HIQMA was designed and implemented to take advantage and make use of this mobility.

The user is provided with great agility where the system may be accessed from any computer or mobile device from anywhere as long as there is a connection to the hosting server (LAN, WLAN, or Internet). This provides the users with instant access to data at all times. Mobility certainly improves business performance, increases organizational efficiency and decreases response time.

Furthermore, the healthcare organization may elect to use cloud computing to store and backup data. This further enhances the user experience and provides much needed mobility and security where redundancy of data is supported and risk management is handled inherently [10].

Security

The system has a robust security management console that enables access to the modules, locations and functionality to be controlled for each user and user group. System administrators, who have access to the security module, can manage user access and the views available to user groups, as well as view the history of user visits dates and time stamps. In addition, encryption of the user credentials and data is included upon login and throughout the authentication and authorization process in order to minimize the risk that such crucial information is compromised.

The User/Permissions module of the system allows a top level administrator to assign permissions and roles for each user individually or as part of a security group. The functional permissions of each user are assigned based not only on the actions he/she is supposed to perform, but also down to the data level he/she is required to manipulate. For example, two different users may have the same role and permissions but each can perform his/her permissions on a specified set or pool of data by department, patient, or others [10].

Multi-lingual support

The system has a dynamic user interface that is available in multiple languages. Newly translated interfaces are continually being added. The system currently supports English, French, Arabic and Farsi languages. Additional languages support is being worked on and an extended set of languages is expected to be supported in

the next version of the system slated for the second half of 2014. The system technology is developed in such a way that the interface's language can be changed by the user according to the languages requested by the medical organization. In addition, data entry in multiple languages is also currently supported. Although the system does not translate data, it does provide a centralized roll-up capability of data in multiple languages. This process is fully automated through a localization module, which accesses the database that has tables of all systems strings, which are visible to the end user [10].

Governance and Compliance

Governance

Organizational leadership is one of the enabling factors for implementing a QMS especially in the healthcare sector. In terms of quality, leadership involves efforts by senior leadership and management executives leading by example to integrate quality improvement into the strategic planning process and throughout the entire organization and to promote quality values and techniques in the workplace practices and environment. Even though most of the leadership and quality theories refer to top management, research reveals that there are other various sources of quality leadership, i.e., from the top management, middle management governance board, senior physicians, voluntary "heroic individual" physicians, or senior respected nurses. On the one hand, it is generally accepted that any bottom up quality action might fail without support from the hospital top management. On the other hand, studies also noted some successful instances of implementation [11].

For instance, in any healthcare organization, small or large, adding, demoting, or changing forms and procedures is a procedure by itself. The users will require training on the new procedures and forms, and the printed documents require replacement to reflect new changes. Many techniques and approaches may be used in order to achieve this. However, technology is an important enabler for such initiatives. This is where HIQMA comes into play and may be considered as a valuable asset in this regard.

The system's technical structure with respect to workplace, rules, forms, and menus takes into consideration future changes and enhancements of the business rules and practices of the medical institution. Any updates to the forms or procedures are done directly on the system, and once committed, the institution ensures adherence to the new forms and rules instantaneously. At the end of the day, this process should be viewed as an evolving and continuous one where processes are reviewed constantly [10].

ISO compliance

The software application is not only structured as per the ISO 9001 standards with all the modules that address each of its requirements, but also contains many unique features that facilitate on-going continuous improvements [16]. It is designed specifically for healthcare institutions implementing or maintaining a QMS based on ISO standards. The ISO standard is considered as a general purpose standard applicable across the industry [17]. In addition, it drastically improves internal or third party audit results by adhering to the ISO modules summarized in Table 2 [2].

The actual performance of any activity within the healthcare facility is measured against well-established and pre-defined KPI's.

Table 2: A Summary of supported ISO 9001:2008 Requirements.

ISO 9001 2008 Requirements	
Clause	Title
5.3	Quality Policy
5.4.1	Quality Objectives
5.4.2	Quality management system planning
5	Management responsibility
5.1	Management commitment
5.5.1	Responsibility and authority
5.5.2	Management representative
6.6.2	Competence, awareness and training
5.5.3	Internal communication
7.2.3	Customer communication
4.2	Documentation requirements
4.2.2	Quality manual
4.2.3	Control of documents
8.5.2	Corrective action
8.5.3	Preventive action
7.6	Control of monitoring and measurement devices
8	Measurement, analysis and improvement
8.2	Monitoring and measurement
8.2.3	Monitoring and measurement of processes
8.2.4	Monitoring and measurement of product
8.3	Control of nonconforming product
8.4	Analysis of data
4.2.4	Control of records
8.2.2	Internal audit
5.6	Management review
5.6.2	Review input
5.6.3	Review output

The KPI's are supposed to be set according to the following criteria as recommended in the literature:

- Determining which quality performance indicators are required to provide the most reliable and valid healthcare quality picture.
- Determining the rules regarding how each performance indicator has to be measured.
- Measuring performance indicators by healthcare organization staff.
- Verifying results and measurements independently that can be compared with a certified independent auditor's work and findings.
- Aggregating and transforming quality information into an overall hospital-score on one or more dimensions [6].

Results and Impacts

So far, the system has been recently deployed in a number of healthcare institutions in addition to a number of medical colleges

and universities. Certainly, each sector has its own flavor of the system but a number of common conclusions could be derived from their deployment and operations. Some of the captured highlights maybe summarized as follows:

- Seamlessly orientating the users to clearly understand and easily satisfy the quality requirements and needs.
- Continuing improvement in the institution by adopting quality as a philosophy. This is a crucial requirement for adopting a Total Quality Management (TQM) approach, which is essential for business sustainability.
- Presenting defined and consistent processes and guaranteeing their successful completion as long as processes are done in a timely manner according to the standards.
- Adhering to preventing instead of supervising, thus ensuring that the costs of preventive measures are less than those of close supervision or micro-management. This is a proactive step rather than a reactive one.
- Utilizing a single, institution-wide system to manage all quality management information and initiatives. This becomes especially relevant in multi-location institutions.
- Automating the tracking, management, and notification of the QMS stakeholders.
- Providing web-based tracking forms, analysis tools, and roll-up reporting to facilitate continual improvement and measurement of key performance indicators.
- Centralizing the management of quality related activities and requirements and driving the medical institution performance.
- Experiencing robust document control and management for all quality related procedures and policies.
- Optimizing the overall healthcare services efficiency of the institution.
- Producing reductions in costs while increasing quality and thus optimizing and improving the overall healthcare services efficiency [10].

The outlined findings are based on preliminary on-line surveys that were done by the institutions where the system was deployed and on thorough discussions with the various stakeholders through the formal review and evaluation process. Furthermore, the following lessons learned and retrospectives were also noted:

- A common, and rather classical, issue is faced in most of the institutions, which is related to the resistance to change, especially in institutions where some staff personnel have a low adaptation capability to non-paper based systems.
- Changes and updates in automated quality management systems belong in general to the service/product provider which limits the capability and the capacity of the institution to abrupt changes in running processes, which might be needed in some cases where non-ordinary circumstances are present (Example: change management in risky zones).
- Helping institutions to obtain and maintain certification or accreditation.

- For institutions with low number of patients and specialties, the cost of such a system will increase the overhead and somehow lower the quality/price ratio. Usually, such institutions are oriented towards systems with fewer modules, thus leading to a limited access to all the benefits of the system.
- Institutions with simple – or no – Information Technology (IT) departments will face the problem of hosting and managing the system servers. Such institutions are advised to go with the cloud hosting solution to minimize the overhead and transfer the risks to the hosting service provider.

Many institutions that deployed this system found the need to update some of their forms, rules, and procedures early in the definition phase. The structured and logical methodology the system uses can spot flaws in procedures and regulations. In addition, it allows the institution to do a major review on the consistency and integrity of its existing quality management system [10].

Furthermore, some institutions reported that they were able to score higher patient satisfaction rates when the system was adopted. This was done using questionnaires or interviews. This information was obtained at reasonable costs and was especially relevant for improving patient and client services and quality planning. The relevance of the system lies in its ability to provide service quality information. This is lined up with Deming [18] who reasons that, as quality improves, waste is eliminated, costs are reduced, and financial performance improves

Finally, a primary driver for accredited healthcare organizations is to ensure that quality management is adopted as a strategy within the organization. The principal reason is being maintaining and sustaining formal accreditation. Accreditation usually involves: measuring an organization against other equivalent organizations and providing feedback to the accredited organization on progress towards quality goals, and areas requiring greatest attention. This is known as benchmarking and is recognized as a significant incentive for organizations, as they measure their own performance against others [19]. As described earlier, HIQMA is compliant with ISO; an internationally renowned standard and benchmark.

Further Enhancements

As in any software application, the HIQMA system is open to a huge set of enhancements in the future. Currently, we have three main enhancement features and propositions that are being assessed and considered. As a matter of fact, the system was planned for implementation using an agile project management approach where development is feature driven rather than frozen scope driven. This was intentionally done in anticipation of adding new functionality as the system evolves and grows.

The first enhancement is to develop an add-on module to the system that is able to collect data from multiple institutions and organizations. This pool of data will result in a knowledge base that will allow the analysis of quality management practices on national or international levels. It will also give insights on how institutions interpret and understand quality, as well as propose best practices and procedures. Such feature may be important to specialized professional and regulatory bodies. This may also contribute to better alignment and streamlining of the good practices and the improvement of the bad ones.

The other enhancement is to allow healthcare institutions with well-established IT departments and infrastructure the capability of creating and designing their own forms and workflow from a Graphical User Interface (GUI) without the need to write any software code or do any programming. As explained earlier, this is partially done and is already supported for customized KPIs but needs expansion to an extended set of functionality [10].

A long-term proposition is to add a “Learn Mode” module powered with artificial intelligence code that reads and interprets the system’s technical logs to automatically propose enhancements to procedures and policies. The “Learn Mode” can be set to individual parts of the system or to the whole set of enabled modules.

Conclusion

The good healthcare service is not only a social responsibility, but also a good contributor to economic competitiveness and welfare in a global knowledge-based economy. Many challenges face medical services, including developing and upgrading the skills of the existing workforce, promoting labor mobility, diversifying customer base, and – most importantly – planning and implementation of education and training services. All of the above require that the management of such programs be handled with care and innovation, on the one hand to maintain a quality culture in the institution, and on the other, to keep up with a the competitive edge of the services rendered. A QMS can be identified as an important factor for creating and promoting safety environment in healthcare organizations.

The integrated web-based HIQMA system can meet these challenges, and more. The system tackles the details of ISO standards and medical services peculiarities, and delivers a high quality, high performance package for use by the various healthcare institutions, irrespective of their specializations. The system provides an environment for the design and execution of processes using quality management principles. ISO 9000 can effectively help healthcare organizations to better manage continuous quality improvement for reducing adverse events while facilitating synergy with regulatory processes [13].

Such an approach proved to be efficient, robust and reliable in all the sites where it was deployed and tested as per the conducted surveys of existing institutions. This aligns well with the findings of research suggesting that the implementation of software control systems is significantly associated with either improvements in or higher levels of quality of care as measured by process or outcome measures [20]. Furthermore, the system is a definite asset for continuous quality improvement, total quality management and sustainability.

References

1. H Khachfe, B Hussein, W Hassan, H Bazzi, A Dayekh, A Hage-Diab, et al. An Integrated, Web-Based, and Automated Healthcare Institution Quality Management (HIQMA) System. GLOBAL HEALTH 2013: The Second International Conference on Global Health Challenges. 2013; 28-32.
2. ISO 9001:2008, Quality Management Systems – Requirements, Geneva, 2012.
3. N Dib, J Freer and C Gray. Service-Level Agreements at the Hudders field NHS Trust. International Journal of Health Care Quality Assurance. 1998; 11: 96-101.
4. Department of Health and Consumers (SANCO) European Commission. Healthcare Quality Indicators. 2013.

5. M. Torre. EUPHORIC Project Final Report – An Evaluation of Health Systems to Improve the Quality of Treatment. 2009.
6. J van den Heuvel, GC Niemeijer and RJ Does. Measuring Healthcare Quality: the Challenges. *International Journal of Health Care Quality Assurance*. 2013; 26: 269-278.
7. M Munechika, S Tsuru and Y Iizuka. Quality Management Approach to Healthcare. European Organization for Quality (EOQ) Congress, Dubrovnik, Croatia. 2009.
8. American Healthcare Association. Guidelines for Developing a Quality Management System (QMS) for Long Term Care Providers. 2010.
9. D Hoyle. ISO 9000: Quality Systems Handbook. ARRB Group Limited. 2001.
10. H Khachfe, B Hussein, H Bazzi, A Dayekh and A Haj-Ali. HIQMA: A Rigorous Healthcare ISO9001 Quality Management System. *Journal of Computer and Communication*. 2013; 11: 1452-1458.
11. V Wardhani, A Utarini, J van Dijk, D Post and JW Groothoff. Determinants of Quality Management Systems Implementation in Hospitals. *Health Policy*. 2009; 89: 239-251.
12. S Cao, J Grundy, J Hosking, H Stoeckle and E Tempero. Architecture for Generating Web-Based, Thin-Client Diagramming Tools. *The IEEE International Conference on Automated Software Engineering*. 2004; 270-273.
13. M Bernstein, P Hebert and E Etchells. Patient Safety in Neurosurgery: Detection of Errors, Prevention of Errors, and Disclosure of Errors. *Neurosurgery Quarterly*. 2003; 13: 125-137.
14. T Facklam. Certification of Persons: ISO/IEC DIS 17024. General Requirements for Bodies Operating Certification of Persons. *ISO bulletin*. 2002.
15. D Parmenter. Key Performance Indicators (KPI): Developing, Implementing, and Using Winning KPIs, John Wiley & Sons, 2010.
16. K Snyder and P Paulson. Healthcare Information Systems: analysis of healthcare Software. *Hospital Topics*. 2002; 80: 5-12.
17. A Ferreira and R Machado. Software Process Improvement in Multimodel Environments. *The IEEE Fourth International Conference on Software Engineering Advances*. 2009; 512-517.
18. EW Deming. *Out of the Crisis*. MIT Center for Advanced Engineering Study. 1986.
19. D Montagu. Accreditation and other External Quality Assessment Systems for Health Care. DFID Health Systems Resource Centre. 2003.
20. K Coleman, B Austin, C Brach and E Wagner. Evidence on the Chronic Care Model in the New Millennium. *Health Affairs*. 2009; 28: 75-85.