

Continuous Quality Improvement System (CQIS) and the Hospital Information System (HIS)

Tomi Thomo

Universiteti Europian i Tiranes, Blv. "Gjergj Fishta", Nd 70, H1, Tirana, Albania

Abstract

The adoption of Hospital Information Systems (HIS) aims at the achievement of the desired level of quality. Quality is a major concern for HIS attempting to continuously control the large number of defining parameters. However, quality is characterized by its tendency to be redefined according to the holding nosocomial conditions, the way hospitalization services offered to the patients, the adopted medical technology, the availability of resources, and the applying workload. Thus, there is a continuously holding need for reconsidering the way of offering the hospitalization services. The Continuous Quality Improvements System (CQIS) is dedicated to monitor the operation of HIS and provide the exact required information to make the proper decision in order to achieve the desired, each time, level of Quality offered by the HIS to the end users and the patients. Hence, an information technology system must be provided to oversee the operational results of HIS and support the decision making process of the hospital's administration reconsidering the HIS functional terms.

1. Introduction

The Continuous Quality Improvement System (CQIS) includes the set of functionalities allowing to ameliorate the quality level of the provided hospitalization services. The improvement is achieved performing a cyclic processing operation following the well-known and clearly define Quality process (Plan-Do-Act-Check) [Ref-1]. In other words, CQIS provides the sufficient and necessary functionalities to apply the four stages cyclic quality process. First, define the desired level of quality, second, evaluate the obtained operational level based on actual measured performance, third, make decisions supported by evidences to achieve the desired level, and eventually, forth, set the plan to obtain the desired level of quality. The operation of CQIS must be facilitated by a Hospital Information System (HIS) since it documents the activities of all important and vital processes carried within the nosocomial organization to succeed in the provision of the necessary and required medical services. CQIS sensors must be fused within the HIS organizational structure to achieve the desired level of Quality of Services (QoS) indices.

The operational area of hospitals is characterized by dynamism due the continuously changing functional terms of operation such as the availability of hospital's resources, workload, and applying technology. The continuous improvement of the offered hospital services has always been a requirement by the hospitals administration. Hospitals resist to adopt methods, standards, protocols, and best practices without a sound and complete prepared plan. The desired, each time, results can be obtained with the applying organizational infrastructure, the availability of the necessary resources, the adequacy of the plan, and the obtained outcomes. CQIS needs to be coupled with HIS in order to support the hospitals administration with dependable means for decisions making on well-defined level of Quality of Service (QoS) and taking advantage of the currently available artificial intelligence.

The rest of the paper continues with the examination of the contemporary literature, it examines the hospital environment from the Quality point of view, it analyzes the functional and operational requirements of CQIS, it considers the impact on HIS, it proceeds with the implementation plans, and it concludes with considerations about future research.

2. Characteristics of the proposed CQIS

The characteristics of the performed work in this paper are provided below. There are presented the five more outstanding characteristics.

The nature of HIS is about a hospital's system consisted of skillful personnel, software and hardware devices, IT networks, data, processes, procedures, and specific work tasks [1]. The purpose of HIS is the storage, retrieval, transformation, and dissemination of information within the hospital [1]. HIS is based on IT communication over virtually many and complex channels storing information, using various electronic devices, following predefined processes, procedures, and carrying specific tasks. Thus, HIS forms a seeming static framework to perform the tasks assigned by the administration of the hospital. However, the dynamic nature of the operation of the hospital requires frequent adjustments to meet the dynamic business - medical requirements. Hence, the first point of our work is about the need of a software system or a mechanism, performed by CQIS, to rectify the HIS operation in such a way that the desired level of quality is proved to be achieved by the evidential stored data.

The HIS rectified operation behavior due to CQIS presence is based on the proper processing of the stored data and the associated made decision. Nevertheless, the processing operation on the HIS data must be performed on a variety of different and incompatible types of data. For instance, the patients admission data must be compared and correlated to the analytical laboratory results to draw specific conclusions and make decisions accordingly. Processing requires the employment of the means to process dissimilar data from various sources within HIS to perform inferences, deductions, and inductions. In such cases, the extraction-transformation-loading (ELT) approach is employed. The ETL approach provides the necessary means for the adaptability of workflows exchanging data and integrating processes among different HIS sub-modules [2]. Hence, the second point of our work is about the integration of various HIS modules based on the data provided by the carrying workflows and the achievement of inter-process communication belonging to different modules of HIS.

The decisions required to be made for the rectification of the HIS operation must be well documented and based on objective evidences. Such evidences must be based on the stored data. However, the stored data schema, received from internal or external sources, must be realized by the hospital's administration supporting the decision making system. In other words, HIS must be equipped with an additional database that provides a single point of managerial information for reporting and analysis purposes supporting the decision-making process [3]. Hence, the third point of our work is about the availability of management information to support the decision-making process.

The necessary management tools for the hospital administration to perform the decision-making process must be readily available by CQIS. The architectural aspects

of CQIS must provide the means to make available key-performance indicators (KPIs) to improve performance [4]. However, KPIs must be capable of representing quantitatively and qualitatively involved business magnitudes such as quality, cost, and delivery services [5]. Moreover, HIS operational adjustment needs the prioritization of the performed processes and it needs the application of evident tools such as Analytic Hierarchy Process (AHP) consisted of a structured technique for organizing the analyses of complex decisions [6]. Also, CQIS must be present the proper architecture facilitating the production route of offered services by the hospital providing the associated and necessary details for each workflow in a manner analogous to the one performed in the industry [7]. In addition, the CQIS architecture must provide the facilities to handle the failures of HIS to achieve its goals in a systematic manner [8]. Hence, the forth point of our work is about the availability of an architectural structure capable of providing readily available the necessary information to support the decision-making process.

The HIS functionality achieving to obtain the set aims and goals must be directed by a decision-making process based on evidential data. The applying methodologies require the proper software infrastructure sharing computer resources and data. The application of the theory of constraints [9] requires the availability of both the proper software architectural structure and the adequate data schemata. Hence, the fifth point of our work is about the availability of an architectural software structure along with the matching data structures allowing the accommodation of well-known methodologies such as ISO quality framework (ISO 9001), FMEA, Six Sigma and Lean Six Sigma.

3. Relative Literature

The approach of quality improvement is capable of transforming healthcare [10] provided the successful application of specific methodologies which are providing results rely on successive measurements of reliable data. The applying methodologies are based on the fundamental cycle of Quality (Plan-Do-Act-Check) and each method is specifically attempting to obtain the previously defined goals. The ISO standards (e.g. ISO 9001) are attempting to develop a managerial framework without providing the necessary warranties of the achieved level of quality since it is defined by the end-user based on the set requirements of operation [11, 12]. The reliability of ISO has been improved due to the carrying certification process by independent - notified bodies. The proposed CQIS approach is extending its capabilities beyond the ISO standards border lines to transform healthcare services in order to warranty the quality improvement.

Quality improvement is performed by repeatedly examining the obtained level of QoS applying at specific workflow point dedicated methods. However, the applied industrial methods of failure classifier [13] to assess the performing processes reliability, the production route card [7] describing in details the conditions of the performing workflows, the FMEA method for preparing data to be fed for assessing and managing the associated risks of the carried processes [14], the Six Sigma method for smoothing the variation of procedures execution [15] meeting the patients' expectations, and the Lean Six Sigma method for minimization the waste of the resources [16] include time as a resource, they all have been considered independently. CQIS is called to facilitate the application of processing methods to

provide intermediate or final results to support the decision-making process performed by the hospital's administration.

The achievement of a specified level of quality in the hospital, the organizational structure and the IT systems must be reconsidered reforming the operational terms [17]. There is the perception that quality improvement must be achieved by employing tools such the Disease Related Groups (DRGs) and internationally recognized codification systems such as the International Code of Diseases (ICD) [18] without providing the means to measure directly the level of quality. Instead, DGRs along with ICD provide the means for indirect measurement of the level of quality. However, the structural infrastructure of CQIS can accommodate both DRGs and ICD codifications. In the same direction, the employment of key-performance-indicators (KPIs) as evidences must be escorted by a clearly defined procedures including the activities of collecting data as evidences, analyzing and interpreting the data, auditing, an finally, feedback to managers [19]. On the other hand, CQIS provides the structural readiness to be capable of reforming the operational terms of HIS, accommodating tools such as DRGs, ICDs and KPIs.

CQIS requires support from a local multidisciplinary team of within the hospital to supervise total quality management and re-engineering activities [20]. In addition, hospitals must have available training services to support the operation of CQIS to overcome the inertia of change and the hesitation caused by the locally holding cultural conditions [20]. The local multidisciplinary team has a managerial instrument to examine the obtained achievements [21] which has to be implemented with software means and coupled with HIS. CQIS requires training services, as any other HIS software module, to explore the capabilities and apply the locally holding conditions. The experience and the accumulated knowledge earned from other sectors of business activities concerning quality, methodologies, and practices on IT systems has to be adjusted and applied to achieve improvement in the provided quality [22].

4. The HIS environment's requirements

The currently holding perception about the operation of a HIS is the adoption of as many international standards and protocols as possible. However, standards and protocols are addressing just a part of a HIS scope missing the entire spectrum of hospital operations and functionalities. In addition, the standards and protocols are incapable of meeting peculiarities revealed from the locally holding economic, social, and cultural conditions. Adopting standards and protocols in the everyday practice focuses on the application of well known and pre-approved good-practices. However, the hospitals are improvising applicable solutions with the locally holding conditions and thus jeopardizing the success of the standards and protocols application. Hence, the fidelity of the resulting application of the adopted standards and protocols depend on the embedment of the locally holding conditions at the hospital.

The hospitals choose the certification of the applying standards in order to prove the adaptation of specific standards and become more attractive to the relative market. The insurance sector and the market of healthcare urges hospitals to get certified with internationally recognized standards to ensure that the offered services follow predefined and acceptable methods.

The introduction of international standards assists the hospitals to adopt well recognized standards achieving the convergence to widely acceptable models such as

Health Level Seven (HL7). The adoption of international standards in the HIS software provides the capability of minimal interventions to achieve, at least, semantic interoperability. The interoperability for hospitals presents two folds. Firstly, serving the patients when there are successive hospitalizations transferring vital information concerning the medical records from a hospital to another. Secondly, the comparison among hospitals requires the evaluation of compatible values base on analogously applying methods and procedures.

5. Quality and Quality measurements

The HIS user interfaces provide the means to acquire raw data through well and adequately designed forms. The collected data can be processed to reveal the holding level of quality. Also, the gathered data can feed properly designed indices to inform the hospitals' administration about more complex administrative mechanism, processes, and procedures. The HIS reporting system can present the obtained data in predetermined formats to express the level of the achieved productivity, predetermined indices, and QoS of various operations and workflows.

The operation of HIS provides the capability to properly determine the parameters which are reflecting the level of the holding quality. Those parameters are fed with data from the HIS user interfaces and with proper processing can reveal the obtained performance. Therefore, the hospitals' administration can receive continuous flow of information regarding critical and important parameters from the hospitals' operations.

6. Functional performance of CQIS

The CQIS is a fictitious or virtual mechanism which is fused within HIS allowing to set the levels of acceptable performance. At the center of this virtual mechanism is evaluation providing the decision support means for continuous reconsideration of the set level of performance after reexamination of the set level of the achievements of execution of the applying parameters. Also, CQIS provides the organizational facilities for the examination and analyses of the embedded risk, hazards and opportunities. Hence, CQIS is a virtual mechanism with elements distributed in the entire body of HIS structure.

CQIS is giving the current level of quality by calculating and evaluating the available data obtained by HIS. The performed calculations provide indices -which are obtained from the gathered HIS data. The formed indices are assessed, appraised, and evaluated to provide additional information to support the decision support system of CQIS. The evaluation methodology includes well-known methods such as FMEA, PHA, FTA etc.

The selection of the quality indices must be chosen in a way that several confirmations and verifications are in place. The quality indices form an acyclic network structure characterized by interdependences among the participating nodes-indices. The inter-relationships among the indices provides the necessary cross-checking about the indices values and statistical trends.

7. Placement of a CQIS

CQIS must be considered as an independent module of HIS. However, CQIS must be coupled with HIS in order to provide the benefits of its use. The operation of CQIS is

considered to be completely transparent to the end users of HIS. The CQIS must be facilitated by an adequate internal functional structure permitting the interconnection with HIS and match with the corresponding organizational structure.

The major building blocks of CQIS form an acyclic network. The first building block refers to the declaration of the followed policies. The second building block refers to the aims and set targets. The third block concerns the management of the associated risk. The fourth block is about the encountered exceptions. The fifth block refers to the internally and externally carried procedures. The sixth block concerns the duties of the users. The seventh block refers to the processing unit of the CQIS. The formed acyclic graph is depicted in Figure-1.

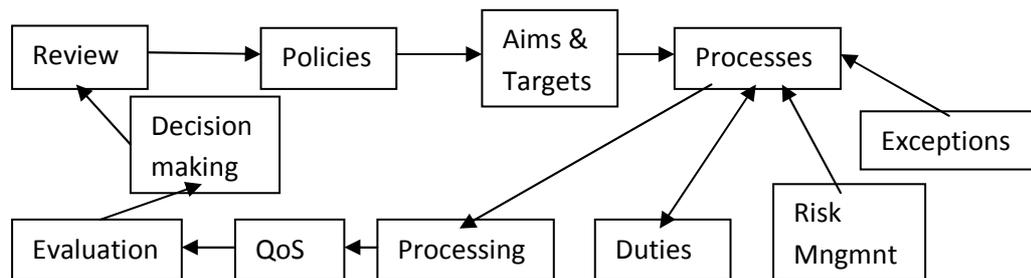


Figure-1. The CQIS internal structure

CQIS is closely coupled with HIS. Such a coupling presents two layers, the first layer concerns the rules applying on the operation of HIS while the second layer is about the evidential data at the database level. Thus, for each HIS software module, there are two levels of correspondence between CQIS and HIS. A typical interaction of CQIS and HIS is depicted in Figure-2. CQIS supervises the operation of the applying rules for each HIS software module and obtains objective evidences about the precise application of the applying rules. The rules are consisted of hospital business instructions for performing the intended purposes. For instance, there is a set of rules applying on the patients' admission which directs the HIS software module to perform the intended work task in the pre-determined fashion. The applying rules contain and manipulate the exceptions and the associated managerial restriction for mitigating the associated risk. The obtained evidences are collected and classified in order to be processed accordingly before the set evaluation procedures.

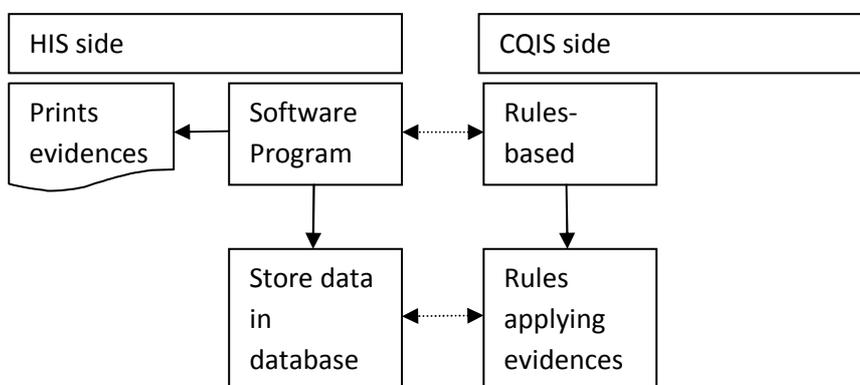


Figure-2. Coupling of CQIS and HIS

8. HIS with a CQIS - organizational changes

The adoption of CQIS introduces additional roles in the organizational chart. Additional duties must be considered corresponding to the collection, evaluation, and review of the data to satisfy the decided and applying policies. Such duties are usually contributed to existing posts in the hospital's organizational chart forming committees to get synchronized under the supervision of an appointed manager. The newly introduced roles are about the supervision of the CQIS activities, decisions to be made for improving the offered QoS and advising of the hospital's administration. The representative of such a committee, usually a quality manager, presents the resulting performance data, the proposed decisions by the committee, and the set aims for improving the hospital's performance based on the evidential data. The rest of the roles which follow the HIS procedures are transparently supervised without realizing any CQIS intervention.

9. Implementation of a CQIS

The implementation of a typical CQIS involves at least two phases. The first one regards the development of the core modules of CQIS. The second phase is about the implementation of the interfaces with HIS. Both phases can be developed independently provided the adoption of proper standardization. In addition, the coupling of CQIS with HIS requires sufficient information about the data management and storage activity performed in HIS.

The implementation of CQIS must follow a bottom-up fashion. The processing unit must proceed to all the rest of the CQIS units since it receives data for processing from all the rest of the CQIS units. Then, it follows the development of the unit containing the users' duties. The implementation carries on with the unit administering and managing the carried procedures since it must be connected with both the processing and the users' duties units. The implementation goes on with placing the exceptions handling unit which enriches further the carried procedures' unit. The implementation continues with the risk management unit. The development works carry on with the implementation of the quality targets' unit. The implementation ends with the development of the policies module. The described bottom-up development fashion allows the inclusion of ordinary quantified types of data along with the qualitative data that need some additional processing. Such a traversing requires the development of the proper qualitative scales to express properly the quantitatively obtained data.

The implementation of CQIS is usually following the installation of HIS expressing the need for continuous improvement. Thus, CQIS can either be an independent software module that eventually must be connected with HIS or be among the rest of the HIS software modules. In either case, CQIS must be coupled with HIS performing the necessary interconnections. The coupling of CQIS with HIS is obtained using software links either at the level of software applications or at the database level. In most of the cases, it is considered more efficient to perform the connection between CQIS and HIS at the storage level since it is completely transparent to the end-users.

10. Impact on HIS

The introduction of CQIS module impacts the HIS performance. The objective evidences obtained by the data gathered in HIS feed the data structures acting as

criteria upon which decisions are made by CQIS. The decisions made upon the collected data guide the Hospital's Administration to change the applying policies or alter the operation of HIS in order to achieve the set goals. Such alterations in HIS operation impact the flow of the carried processes, the involved procedures, and the way certain works are performed with HIS. Consequently, accustomed processes, procedures, and specific works change or adapted to the expressed needs by CQIS that dictate the requirements to achieve the desired improvement.

The operation of CQIS provides valuable information to Hospital's Administration. The operation of HIS may change based upon the decisions made by the Administration in order to achieve the set quality characteristics. However, changes in HIS may cause changes to CQIS depending upon the extension of the performing changes. The performed changes in HIS must be documented in order to follow up the obtained versions of the resulting software system. Similarly, the decisions made by the Hospital's Administration must be properly documented to avoid repetitions and conflicts on the changing software code.

The changes dictated by the decisions made based on CQIS criteria cause changes in the HIS workflows and the sequences of the HIS interfaces. The performed changes in HIS operations must be adequately documented providing evidential support for the alterations and HIS versioning. The supporting documentation must provide the objective evidences along with the drafts of the existing and the changed process or procedure. The documentation must be classified according to CQIS demands. Hence, a reliable management scheme must continuously support the HIS maintenance.

The operation of CQIS provides valuable information regarding the performance of HIS and consequently, the efficiency of the Hospital's organizational goals referring to departments and clinics, as well as, the patients' treatments. The main effect from the operation of CQIS is about the demanded changes in the operation of HIS. In other words, HIS is no longer a static implementation but upon the obtained data, there are made decisions altering the flows of the carried processes. Therefore, the changes in HIS affect the way performed the personnel's daily works providing the required rationalized reasoning.

11. Implementation plan

The objective to develop CQIS is directly related with the desire to control the offered QoS of the hospital services applying HIS. Actually, CQIS is going to declare and dictate the necessarily required adjustments to the HIS' operation. CQIS provides the means to make available evidences about the required changes in the HIS' functionality. The evidences are received from the HIS operation and received transparently from the end-users. Then, the evidential data is presented properly to support the associated decision making process carried by the hospital administration. Hence, the aim of the implementation plan is the development of an IT system that receives transparently data from HIS, performs the adequate processing of the received data, presents the data to the decision makers, records the made decisions, and eventually, sets the level of QoS until the next observation of HIS performance. Therefore, the objective of the implementation plan is the development of an IT system that is going to follow the performance of the applying HIS and continuously regulating the its efficiency and effectiveness to obtain the set level of quality.

The operational characteristics of CQIS must be capable of allowing the achievement of coupling with the HIS that supports. Also, CQIS must present such a structure that it can cooperate with any HIS. The provision of CQIS with HIS data as well as feeding HIS with CQIS data can be accomplished with automatic set-ups, semi-automatic procedures, or manually. CQIS must be equipped with software modules that support the decision making process carried by the hospital's administration. In that sense, CQIS must be aware of the carried HIS processes, procedures, and work tasks. In addition, CQIS must accommodate and apply the decided policies as well as the level of quality desired to be achieved by HIS. Also, CQIS must facilitate the risk management and the periodic review of HIS operation in order to define the HIS operational exceptions. Moreover, CQIS must be equipped with software modules that achieve the development, after the proper processing, of the desired, in each case, report. Therefore, CQIS must operate in such a way that achieves cooperation with any installed HIS.

The implementation of CQIS is based on open source tools which are freely available over the internet. The operation of CQIS requires a browser since it uses HTML (hyper-text mark-up language) at the presentation level. Then, at the processing level PHP (hyper-text pre-processor) applies which is executed at the server supporting CQIS. Afterwards, at the storage level, CQIS is supported by a relational database management system such as MariaDB. The software structure of CQIS is consisted of dedicated software modules which are supported by web hooks or web services to exchange data with the associated HIS. The coupling of CQIS and HIS depends on the HIS readiness to export operational data. In any case, CQIS must have available web services to receive plain text data for processing. On the other hand, CQIS must be capable of exporting data in the requested data formats which may require some additional programming effort. Hence, CQIS is going to be developed with well-known open source tools in order to provide the technical standardization which is necessary for splicing with HIS permitting the involvement of IT professionals without restrictions. Thus, CQIS must make publicly available the requirements for its connection with any HIS.

The implementation of CQIS provides the means to other information systems to transfer data. For each CQIS module there must be developed the corresponding software programs that allow the transfer of data from and to HIS. CQIS is planned to provide the set of RESTfull APIs along with the calling requirements, the characteristics of each API. and explanations about the usage of each API. Similarly, the authentication mechanism is going to be provided publicly for protection and security reasons. The authorized hospital IT administrators are going to be given access to dedicated web services to provide, automatically or manually, the necessary information required for the CQIS operation. The repertoire of the available web services are going to be provided at the CQIS administrator's maintenance web page.

The implementation plan for CQIS presents three stages. The first stage is consisted of eight (8) phases and concerns the development of the CQIS modules. The first phase involves the development of the database schema including registry of the carried activities and a dictionary for the adopted terms and concepts. The second phase refers to the development of the web services which are necessary for enriching the CQIS database tables with HIS data. The third phase concerns the development of the CQIS end-users interface. The fourth phase is about the development of the processing module. The fifth phase is dedicated to the development of the machine

learning applications. The sixth phase is related to the development of the decision support system. The seventh phase concerns the reporting module. The last phase, is dedicated to the development of the administrator's software modules for the CQIS house-keeping.

The second stage is consisted of four (4) phases. The first phase of the second stage is about testing and debugging. The second phase concerns the trials of the developed CQIS including stress testing. The third phase refers to the development of the necessary on-line documentation of the developed system. The fourth phase of the second stage refers to the development of the training materials.

The last stage of the implementation plan is dedicated to the trial operation of the developed system. CQIS web services are going to be used to receive data from and send data to HIS. Then, the decision support module is going to be tested applying the predetermined use-cases. It follows the testing of the reporting module which indirectly provides evidences about the appropriateness in the operation of the processing module. At every step of the carried trials the CQIS documentation and the training material is going to be examined. The delivery of the developed system is going to include a training system environment, a programming development environment, and a completely functional CQIS system.

12. A practical Example

The implementation of the CQIS can applied on an existing HIS. The continuously carried process of the examination of quality for the inpatients and the financial sustainability of the hospital can be performed using DRGs. In such a case, DRGs are going to be followed by CQIS with the development of diseases related packages. Such packages can be defined and structured in CQIS and receive data from HIS while the packages performance evaluation can be carried by CQIS. The decisions made based upon the values of the developed packages can influence the operation of HIS. CQIS is equipped with the adequate facilities to respond to such challenges taking advantage of the registry and dictionary software modules. Thus, the hospital's administration can make decisions on which parameters of the HIS operations must be properly adjusted and which flows must be altered.

13. Conclusions and future Research

Connecting CQIS with HIS interfaces is constituted a dynamic software system. The functionality of CQIS provides the evidences for the HIS changes in order to achieve the desired quality level. In other words, the operation of CQIS defines the operational areas of HIS that must undergo changes. The decision making is still left to the dedicated personnel receiving the results of the CQIS operations. Such documented results are taken advantage by the Administration to order the HIS changes.

The existence of CQIS is necessary along with the operation of HIS since it constantly regulates the HIS operation to achieve the quality aims. The defined level of the offered quality is examined and evaluated processing the collected HIS data. The performed processing on the collected data is carried out in accordance to the instructions provided by CQIS. In other words, the operation of CQIS is analogous to a feedback loop providing the means to make the specific changes for the performance improvement. The major benefit of the CQIS operation is

accommodation, facilitation, and performance comparisons which are based on quantitative and qualitative data. The evaluations performed by CQIS lead to make decisions by the Administration in accordance to the provided policies.

The embedded evaluation methodologies and the applied strategies in CQIS can be performed either by the dedicated personnel or by the properly designed software modules. The employment of machine learning and artificial intelligence methods provide the capability to automate the CQIS functionality regulating the nature of obtaining continuous improvement on the HIS operation. However, the introduction of artificial intelligence weaves CQIS into HIS making almost transparent its operation. Moreover, the development of software interfaces controlled by artificial intelligence methods brings CQIS to become an indispensable part of HIS.

The employment of CQIS in HIS provides the means to control the operation of HIS in order to achieve the set level of quality. Thus, CQIS must be equipped with the necessary agility to respond to the HIS performance accordingly. In addition, CQIS must be capable of presenting a decision support system for the HIS empowering users to change the HIS operation to achieve the desired functionality which leads to the desired level of quality.

References

1. O'Brien, J., & Marakas, G. M., *Management Information Systems*, (2008), The McGraw-Hill Companies, New York, USA.
2. Vassiliadis, P., Simitsis, A., & Skiadopoulos, S., Conceptual modeling for ETL processes, In *Proceedings of the 5th ACM international workshop on Data Warehousing and OLAP*, (2002), ACM, 14–21.
3. Inmon, W. H., *Building the data warehouse*, (2005), John Wiley & Sons, Vol.3.
4. Barchetti, U., Bucciero, A., Guido, A. L., Mainetti, L., & Patrono, L., Supply Chain Management and Automatic Identification Management convergence: Experiences in the Pharmaceutical Scenario, *Supply Chain Coordination and Management*, (2011), 978–953.
5. Jacoby, D., *Measuring sourcing performance: What's the mystery?*, *Purchasing*, (2005), Vol.134.
6. De Ambroggi, M., & Trucco, P., Modelling and assessment of dependent performance shaping factors through analytic network process, *Reliability Engineering & System Safety*, (2011), Vol.96, 7, 849–860.
7. Production Route Card, Available from: <http://www.enotes.com/americanscholar/q-and-a/what-meant-by-job-card-route-card-used-production-99397>, accessed on 30. 04. 2019.
8. Sahno, J., Shevtshenko, E., Karaulova, T. and Tahera, K., Framework for continuous improvement of production processes, *Journal of Engineering Economics*, (2015), Vol.26, 2, 169–180.
9. Goldratt, E. M., Schragenheim, E., & Ptak, C. A., *Necessary but not sufficient*, (2011).
10. Batalden PB, Davidoff F What is “quality improvement” and how can it transform healthcare? *BMJ Quality & Safety* 2007;16:2-3. (available at: <https://qualitysafety.bmj.com/content/16/1/2>, Accessed: 07.04.2019)
11. Reid, R. Dan. and Sanders, Nada. R., *Operations Management: An Integrated Approach*, (2004), Management Science, Vol.2.

12. ISO 9000 Standards, (available at: http://www.iso.org/iso/home/standards/management-standards/iso_9000.htm, Accessed: 07.04.2019).
13. Karaulova, T., Kostina, M and Sahno, J., Framework of reliability estimation for manufacturing processes, *Mechanics*, (2012), Vol.18, 6, 713–720.
14. ICH Q9 Quality Risk Management, European Medicines Agency Inspections,(2006)
15. Van den Heuvel, J., Does, R. J., & De Koning, H., Lean Six Sigma in a hospital, *International Journal of Six Sigma and Competitive Advantage*, (2006), Vol.2, 4, 377–388.
16. Sahno, J., &Shevtshenko, E. Quality Improvement Methodologies for Continuous Improvement of Production Processes and Product Quality and Their Evolution, In 8th International DAAAM Baltic Conference Industrial Engineering, (2014), 181–186.
17. Hudelson P, Cléopas A, Kolly V, et al What is quality and how is it achieved? Practitioners' views versus quality models *BMJ Quality & Safety* 2008;17:31-36.
18. Sabanović Z, Masić I., Computerized information system support in continuous quality improvement in hospital care, *Med Arh.* 2001;55(2):113-6. Croatian, PMID: 11769040.
19. Jan Mainz, BirgitteRandrupKrog, BodilBjørnshave, Paul Bartels, Nationwide continuous quality improvement using clinical indicators: the Danish National Indicator Project, *International Journal for Quality in Health Care*, Volume 16, Issue suppl_1, April 2004, Pages i45–i50, <https://doi.org/10.1093/intqhc/mzh031>
20. Klein, Donald; Motwani, Jaideep; and Cole, Beth, "Continuous Quality Improvement, Total Quality Management, and Reengineering: One Hospital's Continuous Quality Improvement Journey" (1998). Peer Reviewed Articles. 6. https://scholarworks.gvsu.edu/mgt_articles/6
21. Stacie Petter, William DeLone& Ephraim McLean, Measuring information systems success: models, dimensions, measures, and interrelationships, *European Journal of Information Systems* Volume 17, 2008 - Issue 3, Pages 236-263 | Received 30 Dec 2006, Accepted 15 May 2008, Published online: 19 Dec 2017 (available at: <https://doi.org/10.1057/ejis.2008.15>).
22. F. Bruder Stapleton MD, James Hendricks PhD, Patrick Hagan MHSA, Mark Del Beccaro MD, Modifying the Toyota Production System for Continuous Performance Improvement in an Academic Children's Hospital, *Pediatric Clinics of North America*, Volume 56, Issue 4, August 2009, Pages 799-813.