Quality Management Approach to Healthcare – Its Meaning and Significance

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Abstract:*Public needs for healthcare quality and safety are growing more than ever before. One of the potent and highly promising approaches to this challenge is to apply concept and methodology of quality management. To be applied successfully, it is needed to understand characteristics specific to healthcare and to recognize that the healthcare is a socio-technology. This paper discusses the meaning and significance of application of quality management approach to healthcare, which is one of the most important subjects in the field of quality management.*

Quality management has an inherent advantage of "focusing on quality" and "addressing systems (processes and resources)." This can be also effective in healthcare. Good-quality and high-efficiency work is supported by "technology," "management," "people" and "organizational culture." In applying quality management to healthcare, it is necessary to place a focus on management technology while fully recognizing importance of inherent technology, as well as to understand the importance of establishing body of knowledge and technology infrastructure in well-organized structure. In addition, recognizing the healthcare is a socio-technology, it is needed to incorporate a collection of the knowledge into a society in the form of "shared knowledge", "knowledge infrastructure" and "utilization".

When the whole social knowledge promotes to establish "healthcare quality and safety science", the "body of knowledge" on healthcare quality and safety is shared by whole society, and all concerned people of insight are organized, then this is a milestone of the "quality management approach to healthcare."

Key Words:healthcare quality and safety, QMS, technology, healthcare social system, socio-technology

1. Growing interest in healthcare quality and safety

There is a book with sarcastic title: “Curing Health Care.” (Berwick, Godfrey and Roessner, 2002)This is a report of an epoch-making project on healthcare quality.In this project, 21 hospitals in the U.S. worked on quality improvement, supported by quality professionals in industry, and demonstrated effectiveness of Total Quality Management (TQM).As a quality professional in Japan, I cannot read this report serenely.Learning from the quality-driven success in Japan, this project aimed at applying the industry’s quality improvement method to hospitals.When Japan was being carried away by the bubble economy, the U.S. was making a steady effort both in enhancement of industrial competitiveness by focusing on quality and in application of quality approach to healthcare.

In January 1999, misidentification of patients took place in Yokohama City University Hospital between a patient to be treated with pulmonary surgery and another to be treated with cardiac surgery.Soon after this incident, mix-ups of drugs took place.In February 1999, a patient died in Tokyo Metropolitan Hiroo Hospital because a nurse intravenously administered antiseptic solution instead of anticoagulant.Triggered by these incidents, reporting of malpractice to the police increased in Japan, which raised public concern for healthcare quality and safety.

In April 2001, Ministry of Health, Labor and Welfare established Medical Safety Office, and momentum was heightened to meet the social demand for healthcare quality and safety.Hospitals carried out a variety of activities to enhance healthcare quality and safety while practical studies to

apply quality management concept/methodology to healthcare were actively conducted.As demonstrated in the above-mentioned successful project in the U.S., quality management, which raised quality of industrial products by utilizing quality concept and management methodology, can be applied to the healthcare sector and is expected to make a significant contribution.

It is necessary, however, to give thought to whether the quality management proven effective in industry can be successfully applied to healthcare as it is.This has a lot to do with whether management philosophy in industry pursuing quality is suitable and appropriate to management principles in the healthcare sector.It also depends on whether the healthcare sector can correctly understand and interpret quality concept/methodology.In addition, when quality management is applied to healthcare, it is necessary to give considerations to the fact that healthcare is "socio-technology."To establish healthcare quality and safety, all the parties concerned must make a collective effort because there are limitations to actions taken only by healthcare providers.In this sense, just like energy, communication, transportation, social safety etc., healthcare should be considered as social technology, i.e. technology which society must be equipped with.

2. Effectiveness of quality approach in healthcare (Iizuka and Munechika, 2006)

Different approaches can be applied to healthcare quality and safety.How much potential does the quality management approach have, compared with the different candidates?In the U.S., a successful application of the quality management approach was reported in the late 1980s as mentioned above, and since then cases of similar improvement have been reported.In Japan as well, some hospitals implement concept of patient-centric healthcare, small group activities, etc. and have attained some positive results.Is the quality management approach effective universally?

The quality management features universal strength derived directly from its core concept, i.e. "focus on quality" and "address a system (processes and resources)."Quality is fundamental.Quality affects every characteristic such as cost, delivery, volume, safety and environment.Root cause of problems which look like cost- or delivery-relevant is actually quality in many cases.If quality is broadly interpreted, it will be possible to manage every quality-relevant problem by using methodology of the quality management.Focusing on a system (processes and resources) is nothing more or less than focusing on input parameters to get a positive result, which is the universal principle of effective and efficient management.

When applied appropriately, therefore, the quality management approach is deemed effective for healthcare.The following aspects are especially important:

- Contribution of quality to business management: to understand that ensuring quality is more important than superficially-defined economic performance in business management
- Customer-oriented: ideas that perception of those who are provided with value must be respected rather than logic of value providers: to recognize importance of "objective-oriented" approach
- Quality of work: to consider "quality" in everything and to recognize that an expression of "quality of work" will open the way for business improvement
- Concept of management: to recognize "management" as "all activities to efficiently and continuously achieve an objective," which enables you to achieve an objective rationally based on values different from surveillance/control
- PDCA cycle: to run a cycle of P (Plan), D (Do), C (Check) and A (Act) so as to improve level of management
- Fact-based control: to recognize that fact-based approach is important in every situation
- Process control: to learn and understand ideas that processes need to be controlled to get a positive result when working on improvement of processes
- Placing a high value on people: to recognize that people are the most important to maintain and improve quality and that it is important to understand people's strength and weakness and develop a management system highlighting respect to people
- Improvement through all member participation: to recognize that it is important and effective to have all members of an organization participate in improvement

- Problem-solving: to solve diversified problems on one's own by using scientific problem-solving methods so as to promote improvement

3. Principles for good quality and safe healthcare provision systems

3.1Requirements for Excellent Work System

Following the discussions in preceding sections, let's consider the methods to effectively apply healthcare concepts and methodologies into healthcare. Firstly we will discuss requirements for value provision to customers and society, which is a fundamental purpose of an organization, in general terms.Good-quality and high-efficiency work is supported by "technology," "management," "people" and "organizational culture."

"Technology" is defined as a reproducible methodology necessary to achieve an objective.To deliver a desired result, inherent technology specific to products/services sector, needs to be made available.To assure healthcare quality and safety, it is necessary to establish knowledge, technology and methodology specifically required for healthcare quality and safety; e.g. knowledge and technology for medical treatment, empirical knowledge about when people are apt to make a mistake, an effective means to prevent people from making a mistake, method, know-how and principles to promote good-quality work.

"Management" is defined as a methodology to continually and efficiently achieve an objective by utilizing the inherent technologies.Generally speaking, people can not necessarily do what they should do to achieve an objective even if they perfectly know what they should do technically.To solve this problem, it is essential to establish practicable work procedures based on science, technology, theory and textbook.These work procedures will enable people to do what they are expected do in their day-to-day work.Specifically essential technology and knowledge need to be incorporated into the work procedures, and in parallel, a management system to enable people to effectively apply the technology and knowledge must be established and implemented.It is also necessary to clearly define responsibility and authority, establish a system and build in a mechanism.

"People" is defined as those who implement work by using the established technology and management method to make use of the technology.People must be equipped with capability (knowledge and skill) and motivation.Otherwise things will not be implemented as planned, and consequently expected results will not be delivered.Training of knowledge, technology and skill is critical.Also as a part of training, people should be encouraged to understand and appreciate rationale and significance of work procedures.At the same time, a mechanism needs to be developed to have people actively participate in preparation, revision and implementation of work procedures and submit suggestions for improvement.

"Organizational culture" is defined as climate and values of an organization which support technology and management and influence people's way of thinking and doing.The three elements, namely technology, management and people, do not necessarily determine everything in daily work.In order to implement good-quality and professional work, it is important to establish organizational infrastructure including organizational values, culture and climate which discipline people's behavior.It is necessary to cultivate and disseminate organizational philosophy, precept, culture, tradition, and DNA.

3.2 Technology and Management

This section will discuss the two requirements, out of the four presented in Section 3.1, that make the most direct contribution to quality and safety.The first one is "technology" specific to a product/service.In the case of healthcare, it is not possible to provide appropriate medical treatment without healthcare-specific knowledge such as what diseases patients may potentially suffer, what conditions patients may develop, what change may take place in different patient conditions and which

medical interventions may be appropriate.Basic knowledge and basic technology for healthcare are also essential.

The second one is “management” to enable an organization to utilize the inherent technology.Excellent technology, if any, will be useless unless it is shared within the entire organization.Knowledge and technology owned by an organization will be useless unless a work system to use them at an appropriate time in an appropriate way is established.In this sense, management can be defined as a technology, i.e. a reproducible methodology, to achieve an objective by utilizing a product/service-specific technology.

Which of the two technologies, “inherent technology” or “management technology” is more important? It is a tough question, but the answer must be inherent technology. This answer can be supported by the fact that level of a management system cannot exceed level of an inherent technology which is embedded in the management system. Nevertheless we should not underestimate importance of management technology. A definition of management technology, “a technology to make an effective use of inherent technology,” may be hard to understand. This definition can be paraphrased as “a method to successfully implement a methodology designed to deliver a desirable result without fail” or “a technology to prevent people from repeating the same mistake.”

An inherent technology, even if it is well established, will not necessarily ensure delivery of a good-quality product/service.Mistakes and failures are often repeated in daily work.When an inherent technology is established, you can make a success at first.Unless you can reproduce the method which brought about the initial success, however, you will not be able to ensure the continued success.Well-thought-out design of a work system is critical in order to prevent people from repeating a technical mistake induced by the essentially same cause of the first mistake.Profound meaning of management technology is very hard to be understood since management technology is a highly advanced technology.Management technology, however, is essential to maintain and improve healthcare quality not as art which is totally dependent on a personal competence but as science, i.e. a reproducible methodology to acquire and apply knowledge.In order to apply quality management to the healthcare sector, healthcare organizations need to place a focus on management technology while fully recognizing importance of inherent technology.

3.3 Visualization, structuration and standardization of inherent technology

As described in Section 3.2, it is “technology” out of the four requirements that makes the most direct contribution to quality and safety.In the history of quality management, it was not necessarily easy to apply quality management to other sectors than manufacturing sector.This is because inherent technologies in these other sectors were not well visualized, structured and standardized.In order to efficiently realize a good-quality product/service, technologies specific to planning, designing, realization, delivery and servicing of the product/service are essential.In addition, “management” is also necessary to make an effective use of these inherent technologies.Unless the inherent technologies are visualized and systematically described as explicit knowledge, however, a management system, even if it is well established, will become a mere façade.This is a typical case where ISO 9001 management system becomes useless.

To enhance healthcare quality and safety in an effective manner, it is essential to establish body of knowledge and technology infrastructure.For example, it is necessary to identify processes which produce value in healthcare, describe inputs and outputs of these processes, and accumulate knowledge about causes and effects to be considered.It is also important to develop technology and methodology which enable healthcare staff to utilize the established technology and knowledge. This aspect is important particularly for healthcare quality and safety.

What becomes clear after going through these discussions is importance of knowledge structuration in a way to suit the healthcare sector.What is expected in healthcare is to perform an appropriate medical intervention which is adapted to patient condition to improve the condition.Healthcare knowledge,

therefore, needs to be structured in a way to meet this expectation.Patient Condition Adaptive Path System (PCAPS) (Iizuka, Tsuru and Munechika, 2010, 11, 12 and 13)is one of the clinical knowledge structuration techniques which is developed based on this way of thinking.The same approach can be taken for patient safety.We will become able to predictively assess threats for safety and prevent them by developing body of knowledge about 1) potential risks specific to characteristics and nature of hospital operation processes, 2) a mechanism to bring the potential risks into actual and 3) measures to avoid or mitigate these risks.

3.4 Quality management system (Iizuka, Munechika and Uehara, 2006)

Implementation of quality management requires a dedicated system, which is referred to as “quality management system (QMS).”QMS is a system to dynamically link various daily quality-related activities with each other and manage them in a comprehensive way.QMS is a management system, which is composed of processes and resources (people, materials, money and information), to define quality policies and objectives and to achieve the objectives.Under the QMS, multiple persons and functions cooperate with each other and manage quality of processes and resources required to achieve business goals.To assure quality and safety, various activities need to be carried out in various functions and at various levels.Quality assurance system chart illustrates correlation of these activities.A quality assurance system chart to cover all activities of healthcare organizations will enable us to clearly understand where each process is located in the entire QMS and how it connects and relates with other processes.

The objective of developing QMS is to achieve customer (patient) satisfaction.In other words, QMS is developed to provide good-quality and safe healthcare.To achieve this objective, it is necessary to have 1) knowledge and technology specific to healthcare, and 2) a system to make an effective use of the knowledge and technology.This system includes work procedures, people who work to the procedures, facility and equipment and other resources.The work procedures specify who shall apply the knowledge and technology required to achieve the work objectives in what way and when.In other words, the work procedures serve as a foundation to enable an organization to make a good and systematic use of practical means necessary to achieve the work goals.People are important as a resource.To improve quality of people, an organization should identify capability that they need to acquire, and then develop a mechanism for training, human resource development and increase of motivation.In order to make a full use of inherent technology, an elaborate framework is essential to encourage a number of people to recognize each other’s roles and cooperate with each other toward a shared goal.QMS plays a brilliant role as a framework.In the experience in the manufacturing sector, 90% of failures and reworks are attributed to poor maturity of QMS while inherent technology is well established.

Management technology is equally important to inherent technology for healthcare.QMS model is essential as a model of management technology suitable for the healthcare sector and it should be shared by all those concerned.

4. Healthcare as a socio-technology(Iizuka, Tsuru and Munechika, 2011)

One of the important aspects of quality management approach to healthcare is to recognize that the healthcare is a socio-technology.Here, socio-technology is defined as a technology to be owned collectively by society as a whole.Gaining patient satisfaction in healthcare service requires more than high-level knowledge, first-class technology and outstanding management of healthcare service providers. Appropriate healthcare service cannot be provided unless many aspects such as related sectors including medical device sector and pharmaceutical sector, social system including regulation, politics and administration, and preparedness and values of service receivers including patient and local community are all excellent. In this sense, the level of healthcare can be said to represent the level of the society.

Socio-technology for sound healthcare services is considered to be realized in the following forms:

- Shared knowledge
  - Principles: Shared recognition about healthcare quality and safety principles
  - Basic model of BOK: Shared recognition about basic structural model of body of knowledge (BOK)
- Knowledge infrastructure
  - Establishment of BOK: Development of BOK (technology and management); Consensus building among experts
  - Availability of knowledge: Infrastructure to disseminate and promote knowledge; Consulting; Opportunity for networking
  - Acquisition of new or advanced knowledge: Method to acquire new or advanced technical achievements; Upgrading of knowledge contents
- Implementation
  - Implementation and application of BOK contents in healthcare organizations
  - Improvement of the application level in healthcare organizations

Table 1 classifies different socio-technologies in two groups discussed in Sections 3.2, 3.3 and 3.4, namely “technology” and “management,” and it also summarizes in which forms these socio-technologies are owned.

Table 1.Forms of socio-technologies in healthcare

Form of socio-technology \ For quality/safety		Inherent technology(Clinical expertise, technique and skill, and safety techniques and skill)	Management (Organizational management for healthcare quality and safety)
Shared knowledge	Shared recognition about principles and basic models	Basic model of clinical process Principles of healthcare safety	Healthcarequality and safety principles Quality management principles
Knowledgeinfrastructure	BOK structure and knowledge contents	Structural model of clinical knowledge Clinical knowledge contents Clinical operation flow Safety techniques contents	Healthcare quality management system model Healthcare safety management system model Hospital work process model Introduction/promotion model
	Accessibility Applicability	Distribution of clinical contents Provision of software application programs for clinical knowledge application	Internet, Publication Training, Study meeting Consulting
	New knowledge acquisition method Improvement of knowledge contents	Visualization of new technical achievements Analysis Transformation to knowledge	Visualization of new technical achievements Analysis Transformation of to knowledge
Implementation	Application in healthcare organizations Application in society and region Improvement of method to apply to organization	Application of clinical knowledge in hospitals Application in regional or national level Regional alliance Improvement of application methodology Feedback for improvement of clinical knowledge contents	Application of healthcare management system in hospitals Application at regional or national level Improvement of application methodology Feedback for improvement of healthcare management model

In this table, “shared knowledge” means, for example, that basic concepts in quality management described in section 2 are shared by a people concerned. It also means that the followings are recognized and accepted as the shared principles of healthcare quality and safety by the society.

Principle 1: Patient focus – Shift from focus on healthcare providers’ values to patient-centered healthcare

Principle 2: Human factor – Understand people’s weakness and support them rather than blame them

Principle 3: System-oriented – Shift from dedication and repentance of individual to system-oriented assurance and improvement

Principle 4: Participation of all people – Shift from total reliance on specialists to all people participation

Principle 5: Analysis of failure – Shift from looking for whom to blame to learning lessons for future improvement

In addition, it also means that a basic model for technology and management knowledge infrastructure required for healthcare quality and safety are shared and regarded as shared knowledge in society. For example, an excellent model for clinical processes is established as a “patient condition adaptive intervention process” which seeks to perform an appropriate medical intervention adapted to ever-changing patient condition to improve the condition.

“Knowledge infrastructure”means a situation that a knowledge infrastructure required in the healthcare sector by using a model built based on the principles discussed above is establishedso that healthcare players can use the knowledge infrastructure to apply necessary knowledge.First, a body of knowledge (BOK) for healthcare quality and safety system should be established.BOK composed of clinical expertise, clinical technologies and clinical skills needs to be visualized in a way appropriate for healthcare processes.Promotion of healthcare safety requires a model identifying inherent risks in healthcare processes and structural visualization of knowledge about risk control measures.The BOK should become a collective intellectual property of society, so that it will be made available to everyone.In addition to the above-described knowledge infrastructure of healthcare-specific inherent technology, a knowledge infrastructure relating to healthcare quality management should be established, which contains excellent system models, standard work procedures and knowhow about organizational management to assure healthcare quality and safety by effectively utilizing the healthcare-specific inherent technology.

Second, a method to acquire knowledge about healthcare quality and safety should be developed. At present, although there are a number of patient cases from which we could learn a lot, unfortunately we are not able to extract knowledge from the cases or make a use of the knowledge, which results in recurrence of similar failures. We must overcome this unfortunate reality. The basis of scientific approach is inductive method. It is necessary to develop a method to extract essential knowledge about healthcare quality and safety from patient cases, experience and accidents, analyze it, and share it in society.Third, an infrastructure, mechanism and opportunity to disseminate, promote and exchange the knowledge should be provided.To be more specific, we need to build a knowledge base in which the established knowledge about healthcare quality and safety is stored.The knowledge base needs be made available to provide society with the latest achievements in the field of healthcare quality and safety.

“Implementation” means to establish a social knowledge infrastructure for healthcare quality and safety and, in parallel, to encourage individual healthcare organizations to develop, implement and improve good-quality and safe healthcare operation system based on the social knowledge infrastructure.The knowledge structure should be applied not only in each individual healthcare organization but also at regional and national level.Also a mechanism should be developed to encourage healthcare organizations and society to actively participate in the process of improvement and enhancement of the knowledge infrastructure.

In quality management approach to healthcare, establishment of “healthcare socialsystem” described in this section is one of the key areas to be addressed.

5. Who will Realize Healthcare Quality and Safety?

In mid 1980s, I had an opportunity to participate in a quality management symposium held in China as a panelist. In the panel discussion, one of the delegates asked me, “Why is quality good in Japan?” I said, “Because Japanese purchasers are highly aware of quality.” Then one of the panelists asked me, “What should we do to raise quality awareness among the public?” I answered, “We should inform the public that good-quality goods are available.”

Who is responsible for building good-quality and safe society?It is customers who build a quality-focus society.It is society and citizens that build safe society.Regardless of sectors, all reforms are initiated by public opinion.Citizens’ voice will be a trigger to start developing safe culture and designing incentives for good-quality and safe society.Society will remain unchanged unless citizens change. How are opinion leaders, who stimulate and nurture public opinion, developed?We believe that opinion leaders will be developed when “healthcare quality and safety science” is established to foster right values and public opinions supporting good-quality and safe society.Knowledge base for healthcare quality and safety will be shared in society, in which people acquiring right knowledge will be gradually organized.Eventually sea change will take place.

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