June 20, 2011 (Monday) Pre-Congress Seminars

KEMPINSKI HOTEL CORVINUS **Erzsébet tér 7-8, Budapest V.**
REGINA BALLROOM I. **Monday 10:00 – 18:15**

2.3. QUALITY IN HEALTHCARE

Session Chair: ***Yoshinori Iizuka****, University of Tokyo, Japan*

14.30 Healthcare as a Socio-technology
Yoshinori Iizuka, University of Tokyo, Japan

Iizuka, Yoshinori (Japan), Vice President of the International Academy for Quality (IAQ)

Professor, School of Engineering, the University of Tokyo. Graduated from the University of Tokyo in 1970. His research has focused on quality management, including TQM, ISO 9000, structured knowledge engineering, healthcare social system engineering, software quality and nuclear safety. He has played important roles, including President of Japanese Society for Quality Control (JSQC) for 2003-2005, Chair of Deming Application Prize Committee, and Vice President of IAQ (International Academy for Quality). He was awarded Deming Prize for Individuals in 2006.

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14.55 Structured Clinical Knowledge and its Application as a Socio-technology – PCAPS
Satoko Tsuru, University of Tokyo, Japan

Tsuru, Satoko (Japan)

Professor, School of Engineering, the University of Tokyo. Graduated from School of Medicine, Hiroshima University in 1985. After graduation she had engaged in research and education as a research assistant, lecturer and Associate Professor at School of Medicine in Hiroshima University. In 2003 she joined the University of Tokyo. Her research has focused on quality management for healthcare, healthcare informatics and public health.

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2.3. QUALITY IN HEALTHCARE

Session Chair: ***Yoshinori Iizuka****, University of Tokyo, Japan*

15.20 Scheme for Healthcare QMS and its Implementation as a Socio-technology – QMS-H Model
Masahiko Munechika, Waseda University, Tokyo, Japan

Munechika, Masahiko (Japan)

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Quality in Health Care

Healthcare as a Socio-Technology

Iizuka Y.[1], **Tsuru S.**[2], **Munechika M.**[3]
1, 2: The University of Tokyo, Tokyo, Japan
3: Waseda University, Tokyo, Japan

Summary of the Session
Healthcare is regarded as a "socio-technology". Here, the socio-technology is a technology (= reproducible methodology to achieve an objective) which must be possessed by a society as a whole. Along this line, the level of healthcare represents the level of the society.

To achieve quality in general, the necessary conditions are inherent technology (or domain specific technology) and management that makes the best use of the technology. This session discusses the required body of knowledge (BOK) to be possessed by a whole society and the way of application of the societal knowledge.

First, Prof. Iizuka presents the concept of socio-technology for healthcare and discusses the form of socio-technology for healthcare. Second, Prof. Tsuru gives a structured model for clinical knowledge to be used in clinical processes, and discusses its application as a knowledge-base for healthcare social system. Third, Prof. Munechika presents a scheme for quality management system model for healthcare and its implementation in hospitals.

Structure of the Session
Session Chair: *Yoshinori Iizuka, University of Tokyo, Japan*

14.30	Concept of the Socio-technology for Healthcare *Yoshinori Iizuka, University of Tokyo, Japan*
14.55	Structured Clinical Knowledge and its Application as a Socio-technology - PCAPS *Satoko Tsuru, University of Tokyo, Japan*
15.20	Scheme for Healthcare QMS and its Implementation as a Socio-technology - QMS-H Model *Masahiko Munechika, Waseda University, Tokyo, Japan*
15.45	Panel Discussion with the Lecturers

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Concept of the Socio-technology for Healthcare

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Summary
It should be noted that healthcare is a "socio-technology". Here, the socio-technology is defined as a technology, i.e. a reproducible methodology to achieve an objective, to be owned collectively by whole society. In this line, the level of healthcare can be said to represent the level of the society.

The necessary conditions for good quality products and services in general are the inherent technology (or domain specific technology) and management (including people and organizational values) that makes the best use of the inherent technology. These two types of technologies should be systematically established for the customer value provision management system.

Healthcare as a socio-technology needs to be supported by a series of socio-technologies including;
- Social common sense about healthcare quality and safety principles,
- Social knowledge infrastructure for clinical knowledge, technology and expertise,
- Social knowledge base for healthcare management system model,
- Social infrastructure to promote utilization of the knowledge, and
- Implementation of these knowledge and technology in hospitals.

This paper discusses overall picture of healthcare quality and safety as a "socio-technology", including its meaning, significance, scheme and mechanism.

Keywords
socio-technology, healthcare quality and safety, structured knowledge, social infrastructure

1. Healthcare as Socio-technology

1.1 Quality Management Approach to Healthcare Quality and Safety

Along with an increasing trend of medical accidents, public needs for healthcare quality and safety are growing more than ever before. To address this challenge, the healthcare sector implements various activities to enhance healthcare quality and safety and is actively engaged in joint research to apply concept and methodology of quality management, which has been promoted mainly for manufactured products, to its services. It is high time to start taking a structured approach to healthcare quality and safety though there is a long way to go. Quality management (TQC and TQM), making a considerable contribution to various businesses especially to manufacturers throughout the world, has remarkably improved quality of manufactured products through dissemination of significance of quality concept and popularization of quality management methodology. The quality management principles are applicable to the healthcare sector and expected to make a significant difference.

It is difficult to apply quality management as-is to the healthcare sector although it was proven to be very effective in the industry. This is partly because management philosophy to pursue quality may not fit in with healthcare business model. This is also partly because the healthcare sector may not correctly understand and appreciate concept and methodology of quality management which worked perfectly well in the industry.

1.2 Healthcare as Socio-technology

There are other things we need to consider when we apply quality management model to enhance healthcare quality and safety. Efforts of healthcare service providers alone can not enhance healthcare quality and safety sufficiently. In other words, collective efforts of all healthcare players are essential. In this sense, healthcare, just like energy, communication, traffic and transportation and social security, must be recognized as a "socio-technology."

The term of “socio-technology” used in this paper is defined as a technology to be owned collectively by society, while the “technology” has a broad meaning of “a reproducible methodology to achieve an objective.” As mentioned above, efforts of healthcare service providers alone cannot enhance healthcare quality and safety sufficiently. Healthcare quality and safety is to be accomplished by the whole “healthcare social system” composed of all healthcare players (healthcare organization: acute hospital/ …, healthcare staff: medical doctor/nurse/co-medical, patient/patient’s family/local community, insurance company, regulatory authority/administrative authority, mass media, academia: university/ … etc.).

Therefore we can not treat good quality of healthcare in the same way as good quality of common manufactured products. Causes for poor quality of common manufactured products are usually found in providers of those products. Poor healthcare quality, however, reflects poor quality of relevant society itself. Technology (methodology to achieve an objective) relating to healthcare is the comprehensive technology which society must be equipped with.

In order to assure healthcare quality and safety which currently draw global attention as essential social needs, it is important for the entire society to correctly recognize that healthcare is socio-technology and to collectively make an all-out effort to establish healthcare quality and safety management technology as a socio-technology. The three papers presented in this session will discuss the basic concept, methodology and implementation of the framework of healthcare as socio-technology.

2. Principles of Healthcare Quality and Safety

2.1 Requirements for Excellent Work System

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, sector-specific technology, i.e. reproducible methodology, 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 above-mentioned sector-specific technologies which can also be referred to as “inherent technologies.” Generally speaking, people can not necessarily do what they are supposed do to achieve an objective even if they perfectly know what they are supposed to 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. Even if technology is well established and incorporated in work procedures, neither quality nor safety will not be assured without people equipped with necessary knowledge, skill, motivation and commitment. An organization needs to be managed in a way to provide people full of knowledge, skill and motivation with an opportunity to play an active part in their daily work.

“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, DNA etc.

2.2 Technology and Management

This section will discuss the two requirements, out of the four presented in Section 2.1, that make the most direct contribution to quality and safety. The first one is "technology" specific to a product/service. If you want to design, manufacture and distribute an automobile, for example, you need to acquire huge amount of technical knowledge about steel characteristics, internal combustion engine etc. Unless you grasp structure of your customers' needs (which customer/market segment has what kind of needs), you will not be able to conduct an appropriate product/service planning. In the case of healthcare sector, you will not be able 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" system to enable an organization to utilize the above-mentioned 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 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.

These two requirements can be rephrased as "inherent technology" (or "intrinsic technology", "product-specific technology", or "domain-specific technology") and "management technology." Inherent technology is defined as a technology specific to a product/service to be provided. Examples of inherent technology include knowledge and technology relating to design of product/service, knowledge and technology relating to realization of product/service and knowledge and technology relating to evaluation of product/service. Management technology, on the other hand, is defined as a technology to support inherent technology, perform day-to-day work effectively and efficiently, and solve various operational problems effectively. Examples of management technology include a method to run an organization, quality management, cost management, QFD (quality function deployment) and statistical technique. In short, inherent technology is a technology specific to a product/service while management technology is a technology to make an effective use of inherent technology.

Which of the two technologies 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 can not exceed level of an inherent technology which is embedded in the management system. A splendid management system alone is not sufficient to deliver a product/service to satisfy customers if technology and knowledge specific to the product/service remains poor.

Nevertheless we should not underestimate importance of management technology. The earlier 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.

2.3 Visualization, Structuration and Standardization of Inherent Technology

As described in Section 2.2, 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. Quality management, which is also referred to as "management technology" or "management science," is a methodology and philosophy to make a considerable contribution to this management. 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.

In the past, quality management made a brilliant success in the manufacturing sector. It was because, for example, the manufacturing sector succeeded in correctly identifying potential technical causes of defects when they worked to reduce defects. Even for an unknown phenomenon, the manufacturing sector was able to speculate its generating mechanism fairly correctly because technologies and knowledge of this sector such as automobile engineering and metallic materials science were systematically organized. Management technology like quality management worked effectively in the manufacturing sector because inherent technologies were established fairly well.

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 values 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. Professionals of leading-edge fields generally tend to be interested in research and development. They tend to focus their interests on highly novel and creative research topics and case studies, such as development of new diagnosis and medial treatment, demonstration of efficacy of new drugs and study of rare patient cases. It is quite obvious that these research and development activities are essential for further technology evolution. It is equally important, however, to establish a technology to make a good use of plain and common technologies at an appropriate time in an appropriate way. In other words, it is equally important to establish a technology standard to maintain quality. A sector which is supported only by a leading-edge technology is immature as an industry, and such sector is hard to be sustainable. A sector which makes light of management technology is also immature as an industry.

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) is one of the clinical knowledge structuration techniques which is developed based on this way of thinking. The same approach can be taken for 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.

2.4 Quality Management System Model

We discussed meaning and significance of management technology in the previous sections. How should we introduce and implement this profound technology when we run an organization? The manufacturing sector mastered management technology by adopting and promoting quality management. Quality management gave specific guidelines particular for "management," "people" and "organizational culture" out of the four requirements for quality and safety. Reviewing history and experience in the manufacturing sector, we believe it a good idea that the healthcare sector also makes a use of quality management.

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.

3. Healthcare as a Socio-technology

3.1 Forms of Socio-technology

As mentioned in Section 1.2, healthcare is a socio-technology, i.e. a technology to be owned collectively by society as a whole. Gaining patient satisfaction in healthcare services requires more than high-level knowledge, first-class technology and outstanding management of healthcare service providers. Appropriate healthcare services can not 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. The same thing applies to safety and security in general. Safety of aircraft, traffic, factory and nuclear power plant, environment and energy management, information and knowledge infrastructure, and social security such as crime control are all socio-technologies to be owned collectively by society as a whole. Healthcare quality and safety is also an important socio-technology in this context.

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

- Social common sense
  - Principles: Common recognition about healthcare quality and safety principles
  - Basic model of BOK: Common 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 2.2, 2.3 and 2.4, 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)	Management (Organizational management for healthcare quality and safety)
Social common sense	Common recognition about principles and basic models	Basic model of clinical process	Healthcare quality and safety principles Quality management principles
Knowledge infrastructure	BOK structure and knowledge contents	Structural model of clinical knowledge Clinical knowledge contents Clinical operation flow	Healthcare quality management system model Healthcare safety management system model Hospital work process model Introduction/promotion model
	Accessibility Availability	Distribution of clinical contents Provision of software application program 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 of technical achievements to knowledge	Visualization of new technical achievements Analysis Transformation of technical achievements 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 region 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

3.2 Transforming Approach to Healthcare Quality and Safety to Social Common Sense

3.2.1 Principles to Work on Healthcare Quality and Safety

In order to make healthcare a true socio-technology, we want to recognize correct approach toward healthcare quality and safety as social "common sense." For example, we want the followings to be recognized and accepted as the common healthcare quality and safety principles:

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

Principle 1 is the basic in quality science, namely "customer-oriented." Why does healthcare also regard patient focus, patient-centered and patient satisfaction as justice? Is it fair that patient having no expertise judges whether healthcare services supported by advanced medical technology and their end results are good or bad? Springhead of quality science is a philosophy that you can not say a thing is good unless other people recognize it. No transactions, including healthcare services, do any good unless someone appreciates them or unless the counterpart finds them good.

Principle 2 means that we need to give considerations to "people" who have significant influence on healthcare quality and safety. A cause for a mistake can not be found in the person who made the mistake. It is found in a way the person did things. Or the mistake is attributed to mismatch between people and a system. Weakness in the system prompts people to make a mistake. It is not right to blame people for mistakes.

Designer of a work system must give considerations to human nature and characteristics.

Principle 3 suggests that we should identify essential elements to achieve an objective and manage them in a comprehensive way. Total reliance on personal effort of individual healthcare staff members will deliver a limited result. Provision of healthcare services needs to be managed as a system.

Principle 4 means that we should not leave everything to a few specialists. We must build a mechanism to facilitate participation of all those concerned. Quality is influenced by activities of all members of an organization. It is those who work at the front line that correctly understand true causes for and meanings of various quality-related problems.

Principle 5 suggests that we should learn lessons from "failures" including mistakes, incidents and accidents to pursue continual improvement. Failures represent lack or weakness of the existing system, technology and knowledge. We should regard failures as precious experience and analyze them closely to learn a lot of lessons for future improvement.

3.2.2 Knowledge Model

In order to make healthcare a true socio-technology, it is necessary not only to establish a common recognition about principles of healthcare quality and safety but also to have a basic model for technology/management knowledge infrastructure required for healthcare quality and safety shared and regarded as common sense in society.

As discussed in Section 2, sound healthcare provision requires two different technologies, namely inherent technology and management technology. On top of that, it is important that knowledge of these two technologies will be visualized in a structure suitable for the healthcare sector.

Core technologies in the healthcare sector are clinical expertise, clinical technology and clinical skill. It is necessary to develop excellent models for these core technologies relating to clinical practices. It is possible to assume that a healthcare process is a "patient condition adaptive intervention process" which seeks to perform an appropriate medial intervention adapted to ever-changing patient condition to improve the condition. Based on this assumption, the following models can be built, for example:

(1) Identify and recognize patient condition
   - Present patient condition: Identify and recognize present patient condition
   - Possible patient condition: The entire picture of possible patient conditions and transition paths through the conditions

(2) Set up a target
   - Ultimate target: Ultimate target of patient condition; Expected achievable condition
   - Tentative target: Tentative target of patient condition; Tentatively-expected achievable condition

(3) Medical intervention plan
   - Medical intervention strategy: The entire picture of possible transition paths to ultimate target and medical intervention strategy to achieve the target; Transition logic between medical treatment units
   - Medical intervention plan: Medical intervention plan to achieve tentative target (medical treatment plan)
   - Adaptive plan to respond to patient condition: Immediate response plan adapted to possible change in patient condition (conditional instruction)

(4) Intervention
   - Intervention: Intervention in accordance with medical intervention plan; Medical treatment in accordance with the plan
   - Monitoring: Monitoring of change in patient condition; Monitoring of change in patient condition in order to decide whether any response is necessary
   - Response to condition: Immediate response adapted to potentially-expected change in patient condition

As a structured visualization model of clinical process based on the above concept, the authors have proposed "Patient Condition Adaptive Path System" (PCAPS). The next presentation in this session will describe PCAPS in detail.

Healthcare quality and safety requires appropriate technologies and methodologies to organizationally implement healthcare-specific knowledge. These technologies and methodologies need to be systematized in such a form as basic concept, management system model, work process model and organizational promotion model. In order to make the systematization successful and effective, it is necessary to develop principles and

basic concepts, based on which the above models are built. And these principles and basic concepts need to be commonly recognized in society. Examples of the principles include patient-oriented (patient-centered), system-oriented and process-focused, and people-centered system design. It would be possible to develop principles specifically applicable to the healthcare sector by slightly modifying the quality management principles for manufactured products. The details will be presented in the third presentation in this session.

3.3 Establishment of Knowledge Infrastructure

In order to make healthcare a true socio-technology, it is necessary to establish a knowledge infrastructure required in the healthcare sector by using a model built based on the principles discussed in Section 3.2 so that healthcare players can use the knowledge infrastructure to apply necessary knowledge. If the concepts presented in Section 2 are used as a ground for next-step discussions, what needs to be done next is to develop clinical expertise, clinical technologies and clinical skills as well as a model for healthcare quality and safety management system in order to share knowledge essential for healthcare quality and safety in society.

3.3.1 Establishment of Body of Knowledge (BOK)

The first step is to establish a body of knowledge (BOK) for healthcare quality and safety system. BOK composed of clinical expertise, clinical technologies and clinical skills needs to be visualized in a way appropriate for healthcare processes. PCAPS, which is proposed by the authors as a tool to structure knowledge necessary for medical diagnosis and treatment, will be one of the approaches to help enhance BOK contents. It is also necessary to establish a standard work flow in order to ensure implementation of clinical work processes. The next presentation in this session will discuss these issues in detail.

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. “QMS-H model” proposed by the authors is one of the models of this knowledge infrastructure relating to healthcare quality management. The QMS-H model visualizes what quality and safety management functions a healthcare organization has and how a healthcare organization can systematize them to run its organizational activities to assure healthcare quality and safety. The details of the QMS-H model will be discussed in the third presentation in this session.

3.3.2 Accessibility to Knowledge

The second step is to provide an infrastructure, mechanism and opportunity to disseminate, promote and exchange the knowledge. 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.

In order to disseminate clinical knowledge, an environment needs to be created in which clinical knowledge contents to be shared in society will be distributed to appropriate healthcare organizations in a timely manner. Software application also needs to be made available to support an effective use of these clinical knowledge contents.

Just like the clinical knowledge, the QMS-H model needs to be disseminated and promoted through publication, Internet, seminar, study meeting and consulting. Appropriate support should be also made available for application of the QMS-H model.

To disseminate adequate knowledge, significance of regulation and standardization should be also studied. Recommended practices for healthcare quality and safety should be disseminated in society in a form of guideline or regulation.

3.3.3 Acquisition and Improvement of Knowledge

The third step is to develop a method to acquire knowledge about healthcare quality and safety. 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.

urthermore a method needs to be developed to improve and enhance the existing operational knowledge contents by learning from experiences accumulated in the real world.

In fact, social consensus building process is extremely important in order to share these improvements in society as common intellectual property. It is necessary to establish a scheme to systematically accumulate knowledge and technical achievements in BOK, to enable numerous healthcare players to use the BOK to provide advanced healthcare services, and to improve the BOK based on experience accumulated by its users.

3.4 Application in Society

To make healthcare a true socio-technology, it is necessary 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 described in Section 3.3.3.

3.4.1 Application of Structured Clinical Knowledge in Hospitals

As a first step to apply the knowledge infrastructure of healthcare quality and safety in society, the structured clinical knowledge should be applied in healthcare organizations to pave the way for the next step in which correct healthcare services will be widely applied and healthcare technologies will be shared in society. Each healthcare organization should apply structured clinical knowledge, such as PCAPS (Patient Condition Adaptive Path System), which is designed based on unique characteristics of healthcare processes to promote medical intervention appropriately adapted to ever-changing patient condition. When this structured clinical knowledge is applied at a regional level, a sophisticated regional alliance will be realized in the healthcare sector.

It will also become possible to improve contents of the structured clinical knowledge shared in society if experience gained through application of the structured clinical knowledge in healthcare organizations is accumulated and shared. This process of improvement will serve as a strong driver to upgrade healthcare services in the entire society.

3.4.2 Establishment of Healthcare Quality Management System

The second step is to design and develop good-quality and safe healthcare operation system. Based on the above-described application of structured clinical knowledge, comprehensive healthcare quality management system needs to be developed. And by applying the knowledge which constitutes the basis of the model of such healthcare quality management system, healthcare work system needs to be designed and developed. At the same time, it is necessary to establish a mechanism to train and motivate people and to encourage them to participate in healthcare quality and safety activities.

3.4.3 Improvement of Work System

The third step is to develop a mechanism to improve healthcare work system. First of all, it is important to develop procedures to appropriately analyze problems when they take place. These procedures should include a method to present proposals for adequate system improvement of the work process where problem occurred, and a method to appropriately check if proposals for system changes do not trigger any adverse side-effects which may make the system worse rather than better. Once it is decided to change the system, relevant standard work procedures need to be revised in a way to reflect the change. Standard work procedures need to be maintained appropriately to accurately reflect what is going on in day-to-day operation.

A new essential knowledge about quality and safety acquired as a result of analysis of problems needs to be accumulated as an organizational knowledge, so that it can be used in the future. It is also necessary to enhance organizational capability to carry out this third step, e.g. analysis capability, capability to study side effects and capability to extract and acquire essential knowledge.

4. 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.

Structured Clinical Knowledge and its Application as a Socio-technology – PCAPS

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Summary
One of the main elements of the healthcare socio-technology is a structured clinical knowledge. This knowledge will be commonly shared in a healthcare social system. The structured clinical knowledge will play an important role as a foundation for healthcare quality and safety, and a basis for upgrading the level of clinical processes in each hospital. It will be the most important to establish body of structured knowledge on clinical processes to be shared in a healthcare social system.

Several years ago, we developed Patient Condition Adaptive Path System (PCAPS). It describes an overall flow of possible clinical pathways that a patient's disease state may trace and detailed medical judgment and treatments for each disease state. The application of PCAPS makes it possible to implement proper medical interventions according to disease state. Medical records kept in the PCAPS will give useful information on the patient's state, the interventions at the state and the effects of the interventions. Through the analysis of these records, it is possible to improve the standard treatment plan.

This presentation discusses a variety of forms of socio-technology on clinical knowledge, including the effectiveness and significance of the structured clinical knowledge, infrastructure for sharing the knowledge, and application of the knowledge in each hospital.

Keywords
PCAPS, socio-technology, clinical knowledge, standardization

1. Characteristics Unique to Healthcare: Condition-Adaptive Intervention Model

1.1 Condition-Adaptive Intervention

Healthcare needs to be designed as a “condition-adaptive” service coping with disease specificity, patient individuality and patient condition change. Medical interventions may trigger temporary deterioration of independence and treatment-induced complications since medical treatment is a high-risk practice accompanying human body invasion. To assure patient safety, therefore, strong medical intervention needs to be followed by around-the-clock patient condition monitoring and immediate intervention when necessary.

In the field of highly complex and demanding healthcare, it is difficult to rely totally on each individual medical staff member in realizing patient safety and quality assurance. Healthcare needs to be recognized as a critical social technology and established as a social system. It is important to evolve knowledge to provide healthcare ensuring patient safety and quality assurance from “personal knowledge” to “organizational knowledge.”

Among the knowledge necessary to refine healthcare into a social system, clinical knowledge, which is medical-specific technology (expertise), serves as a core to materialize patient safety, quality assurance and quality management.

The clinical knowledge lies in clinical processes. By visualizing clinical processes, therefore, it will become possible to identify the clinical knowledge. And by embedding the identified clinical knowledge into clinical processes in a structured manner, it might become possible for the healthcare sector to reuse existing knowledge and extract new knowledge.

The authors have developed a structured model of clinical processes, “PCAPS: Patient Condition Adaptive Path System[1][2][3].” This model will enable healthcare players to identify hidden and untapped “clinical knowledge to realize healthcare quality and safety” in clinical processes. By embedding the identified clinical knowledge into clinical processes, it will become possible to reuse knowledge. It is necessary to establish a mechanism to continually repeat a cycle of “extraction of clinical knowledge → reuse of clinical knowledge → improvement and enhancement of clinical knowledge” as a part of the healthcare socio-technology. The

PCAPS model has a potential to make a contribution to establishing such mechanism in the healthcare socio-technology. Table 1 shows a framework of perspectives essential for the socio-technology. This paper also discusses current progress of a process to establish the socio-technology.

Table 1: Overview of clinical knowledge structuration technology aiming at making healthcare a true socio-technology

Form of socio-technology \ For quality/safety		Technology	Element
Social common sense	Principles Consensus building	Condition-adaptive intervention model	Conceptual model
Knowledge infrastructure	BOK Knowledge contents	Structure (CPC, US and Master) PCAPS contents Work flow	Condition-adaptive intervention process model Integration system Content development processes Standardization technique
	Accessibility Applicability	Distribution of PCAPS contents Provision of software application program	Business model for distribution of PCAPS contents Administrator Builder Analyzer
	New knowledge acquisition method Improvement of knowledge contents	Visualization Analysis Transformation of technical achievements to knowledge	Intervention logic Interpretation of guidelines Interpretation of clinical history records Analysis
Application in organization	Application in healthcare organizations Application in society and region Improvement of method to apply in organizations	Application and implementation of clinical knowledge in hospitals Application in region Regional alliance Improvement of application methodology Feedback for improvement of BOK	Implementation and promotion process Business model for PCAPS implementation Method for improving PCAPS contents

1.2 Consensus Building

Consensus building essential to make healthcare a true socio-technology is a twofold: “academic consensus building” and “consensus building in team medicine.”

In order to build academic consensus, it is necessary to identify justified condition-adaptive medical intervention by using a scientific technique. In addition, consensus about better clinical processes needs to be built in each technical domain. Such scientific academic consensus building is essential and useful for the society. The academic circles should be aware that it is their social mission to propose a better condition-adaptive medical intervention.

At actual clinical front, consensus building in healthcare team is important. Neither doctor nor other healthcare specialist alone can provide healthcare services. Team medicine composed of multiple healthcare specialists is essential. It is important to build consensus about “better practices (standards)” among healthcare specialists from different fields as well as from the same field.

1.3 PCAPS as a Condition-Adaptive Intervention Model

1) “Unit”: a basic building block for healthcare quality and safety management

The condition-adaptive medical intervention model is used to apply “medical intervention” to transform “current patient condition” to “target condition.” Medical interventions such as surgical operation and drug therapeutics accompany human body invasion, and thereby it may cause complications and side-effects (Note: A term of “adverse event” is recently used as a technical term.). Therefore such healthcare activities as “patient condition monitoring” and “immediate response to stabilize patient condition” need to be performed. Once a target condition is safely achieved in a unit, the target condition of the unit will be regarded as a “current condition” in a next unit and the next unit will be initiated.

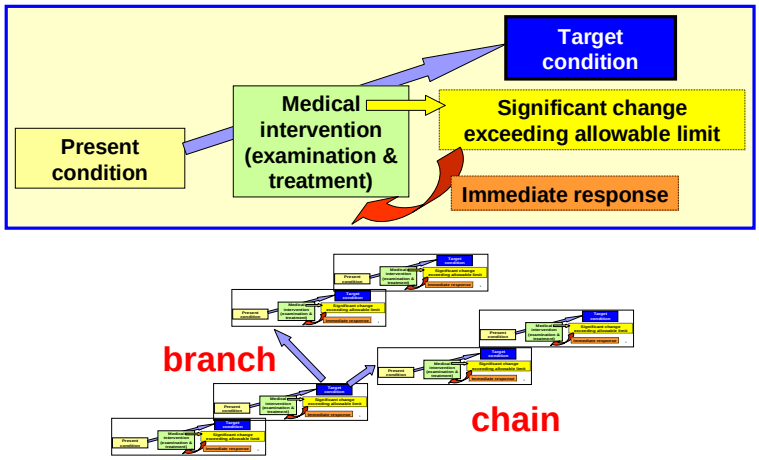


Fig.1 The basic module of Healthcare process

2) Chain of units: Overhead view of condition-adaptive intervention to transform current patient condition to target condition

PCAPS is expressed as an overhead view of an entire clinical path. It places "patient condition" as a core, to which multiple "target conditions" are linked. A unit is formed for each target condition. Multiple units are arranged one after another, being branched or converged from time to time, toward an ultimate target condition. In this way, the PCAPS overhead view illustrates the entire clinical path, visualizing how patient condition changes over time.

In each unit, healthcare services adapted to patient condition are provided until target condition in the unit is achieved. Once the target condition is achieved, the ongoing unit is completed. Then a next unit most suitable for the patient condition at the time of completion is determined by medical staff with help from the transfer logic navigation. This procedure is repeated so as to enable a patient to go through most suitable units one after another. Accordingly history of healthcare services which the patient received is accumulated.

Meanwhile there are situations in which patient condition changes in such a way that a series of healthcare services in the ongoing unit become no longer suitable. In other words, condition of patient in the unit changes significantly to exceed the patient condition adaptation limits of the unit. In order to cope with such situation, PCAPS is equipped with a logic of immediate transfer to a new unit which is most suitable for the changed patient condition. When amount of postoperative bleeding exceeds the upper limit of adaptation of the ongoing unit, for example, transfer to a unit to address bleeding will take place.

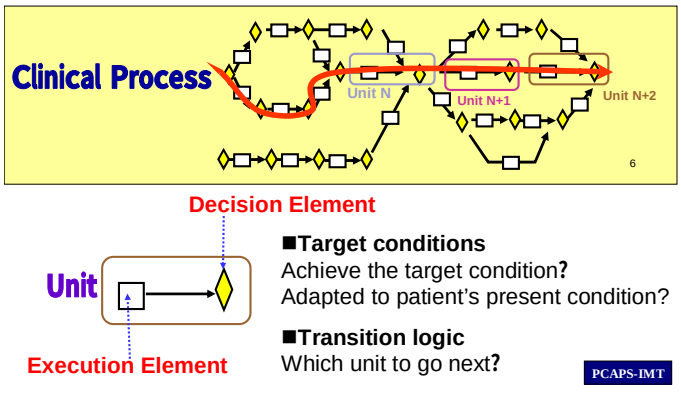


Fig.2 Conceptual Model of PCAPS: Patient Condition Adaptive Path System

2. Knowledge Infrastructure: Structure and Contents

2.1 Structured Body of Clinical Knowledge: Structure

PCAPS is composed of three knowledge frames: 1) Clinical Process Chart, 2) Unit Sheet and 3) PCAPS Master.

Clinical Process Chart is an overhead view of clinical path consisting of a chain of units (an expected overall clinical process), illustrating a general flow and an overall picture of possible medical treatments for a disease.

Unit Sheet is composed of specific healthcare tasks in a unit, condition monitoring, immediate response, target condition of the unit and transfer logic, and features the following functions:

1) well-planned medical intervention: a function to provide healthcare tasks necessary to achieve a target condition
2) condition monitoring: a function to monitor patient condition in the unit
3) immediate response: a function to address changes of patient condition in the unit to stabilize the patient condition at an early point
4) monitoring of progress toward the target condition: a function to track progress toward the target condition of the unit
5) transfer logic: a function to direct a new unit to transfer when the target condition is achieved or when the ongoing unit can no longer adapt to changing patient condition, and to guide the transfer to the new unit in an appropriate manner

PCAPS Master is a database developed particularly for the healthcare tasks among the five frameworks built in Unit Sheet, namely “healthcare tasks,” “patient condition to watch,” “conditional direction,” “target condition” and “transfer logic.” PCAPS Master features a hierarchical structure having five categories: 1) examination, 2) medical treatment, 3) observation, 4) nursing care and 5) information provision. For each of the five categories, healthcare tasks with different nature are gathered in the database.

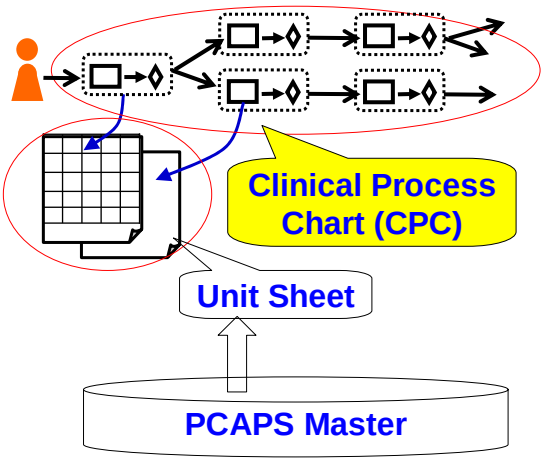


Fig.3 Three framework of PCAPS for Clinical knowledge Structuring

2.2 Structured Knowledge Contents

1) Design and systematization of content development processes (visualization, structuration and standardization)

Each individual content of PCAPS is intended to be standardized. To this end, the content development process, whose final deliverable is a standard content, has been designed, being composed of the following three steps:

Step 1: Initial-version design
Step 2: Verification, evaluation and improvement
Step 3: Approval

An organization carrying out these three steps has the following organizational structure. For the final step of approval, three types of organizational structure are planned. At present, Type 1 “Standard Approval Board in PCAPS Study Group” is in operation. It is desirable, however, to move to Types 2 and 3 gradually.

Step 1: Initial-version design (Domain-specific content development team in PCAPS Study Group)
Step 2: Verification (Group of hospitals carrying out verification / PCAPS secretariat)
Evaluation (Domain-specific content development team / PCAPS secretariat)
Improvement (Domain-specific content development team)
Step 3: Approval
Type 1: Standard Approval Board in PCAPS Study Group
Type 2: Central clinical hospital of each relevant domain
(e.g. National Cancer Center, National Cerebral and Cardiovascular Center)
Type 3: Academic organization
(e.g. academic society, Society of Guideline Evaluation and Improvement Using Society)

The content development requires ① new content design technique, ② verification technique and ③ rules for approval. Through the PCAPS study carried out from 2004 through 2010, the initial version of ①,② and ③ has been developed and established. For consensus building, ② verification technique is particularly important. There are about 100 hospitals registered to cooperate in this verification process, and every year some of them volunteer to submit actual clinical history records of patients to be used as a reference in the verification process. Newly-developed or improved contents are verified every year by referring to these clinical history records.

The verification analysis is implemented in the following way. Unit-to-unit transfer history on Clinical Process Chart is analyzed to identify "departure" from potential transfer route(s). Causes of the identified departures are analyzed and classified into several departure types. Departure takes place when suitable units and routes necessary to transfer to suitable units are not available on Clinical Process Chart. Departure type is determined by studying causes of departures. Similar actions can be taken to prevent departures in a departure type. Analysis of departures and their causes enable medical staff to effectively add new units and routes to Clinical Process Chart.

"Coverage ratio" is defined as proportion of the cases reaching the final unit (discharge from hospital) among those cases whose histories are actually tracked on Clinical Process Chart. Coverage ratio is an indicator to demonstrate how good Clinical Process Chart is as a standard. Depending on coverage ratio, different improvement measures should be taken against Clinical Process Chart.

Measures to improve Clinical Process Chart can be determined by the departure type. Clinical Process Chart will be improved by adding new units and routes. The departure type indicates which unit needs to be added and how a route should be defined. Clinical Process Chart is considered to be improved when missing units and routes are added, and then it is recognized as a standard to be used by multiple hospitals. When coverage ratio is less than 80%, Clinical Process Chart should be improved first and then verified in another fiscal year or in another hospital.

Table 2. Survey in 2005-2009 for Verification and Refinement of PCAPS-CPC

Verification in 2005

	Ischemic heart disease	Total prostatectomy	Cerebral infarction	Infant bronchial asthma	Diabetic insulin introduction	Fracture of neck of femur	Total
No. of cases	136	137	302	228	80	141	1024
No. of hospitals	8	9	7	7	9	7	

Summary of Verifications

Item/Year	2006	2007	2008	2009
No. of hospitals	55	51	35	44
No. of beds	20,033	18,317	15,795	2,009
No. of PCAPS contents	26	19	32	11

28

2) Type of PCAPS contents

Different types of PCAPS contents need to be developed, depending on where and how they are used. The PCAPS content with the highest need is "PCAPS content for clinical practice" which is used in routine healthcare services at hospitals and medical clinics. This type of PCAPS content is developed for each domain such as gastroenterological surgery and gastroenterological medicine. What is being developed at present is knowledge contents of this type.

It is also possible to develop PCAPS contents for the purpose of research and survey including a) clinical research, b) research and development of industrial product, c) survey to evaluate regional healthcare services and d) survey to evaluate governmental healthcare policies and measures. These contents need to be designed more precisely and in more focused way than the contents for routine healthcare services, so that they can acquire historical information on route of interest and relating implementation data. Some contents are too detailed and complex to keep their implementation record in routine healthcare services. For the purpose of research and survey, however, people do not find it troublesome to use such detailed contents to keep implementation record as a structured implementation summary. PCAPS contents for the research and survey purpose, therefore, often become very complex in structure.

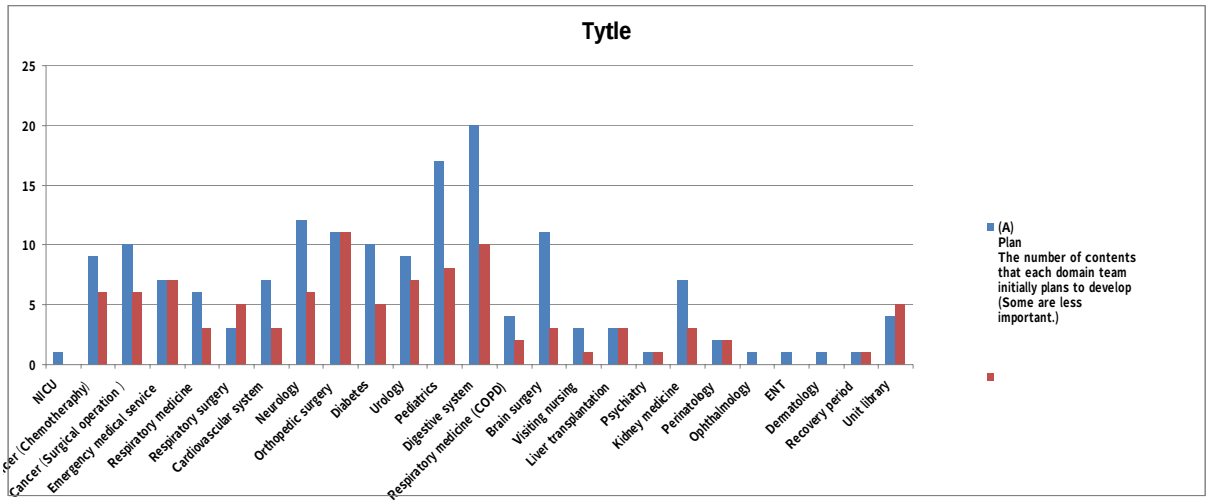
PCAPS contents constitute very good training aids for education and self-learning as they present appropriate and correct medical treatment models in a form of structured knowledge. A PCAPS structured implementation summary, which is a record of patient-specific plan preparation process using PCAPS contents, serves as an important medical intervention simulation training aid since it is a record of medical practices carried out in accordance with standard contents representing best practices. A hospital adopting the PCAPS model will be able to accumulate excellent structured implementation summaries. These structured implementation summaries will support various clinical decision-making processes.

3) Progress of PCAPS electronic content development

What is actively being developed at present is "PCAPS content for clinical practice" which is used in routine healthcare services at hospitals and medical clinics. They are being developed for each technical domain in accordance with the above-described content development procedure. As of May 2011, PCAPS contents for 25 different domains are planned to be developed while those for 22 domains are being developed. As many as 98 contents have been completed out of 123 contents planned for development (achievement rate of 79.7%). In addition, 86.7% of the 98 contents completed have been already verified and established as standard contents.

Table 3 Development of PCAPS contents

		(A) Plan The number of contents that each domain team initially plans to develop (Some are less important.)	(B) Plan The number of contents that each domain team currently finds it necessary to develop (All of them are important.)	(C) Actual (The number of contents published) =The number of important contents / contents with high patient coverage =The number of contents completed)	Target achievement rate (%) Contents completion rate (C)/(B)	(D) The number of contents verified by clinical process simulation developed based on actual clinical history records of patients (=The number of contents verified)	Target achievement rate (%) Clinical process simulation implementation rate (D)/(C)
1	NICU	1	1	0	0.0	0	0
2	Cancer (Chemotheraphy)	9	9	6	66.7	6	100.0
3	Cancer (Surgical operation)	10	10	6	60.0	5	83.3
4	Emergency medical service	7	7	7	100.0	7	100.0
5	Respiratory medicine	6	6	3	50.0	3	100.0
6	Respiratory surgery	3	3	5	166.7	5	100.0
7	Cardiovascular system	7	3	3	100.0	3	100.0
8	Neurology	12	2	6	300.0	6	100.0
9	Orthopedic surgery	11	11	11	100.0	11	100.0
10	Diabetes	10	5	5	100.0	3	60.0
11	Urology	9	9	7	77.8	6	85.7
12	Pediatrics	17	4	8	200.0	8	100.0
13	Digestive system	20	20	10	50.0	10	100.0
14	Respiratory medicine (COPD)	4	4	2	50.0	2	100.0
15	Brain surgery	11	11	3	27.3	3	100.0
16	Visiting nursing	3	1	1	100.0	1	100.0
17	Liver transplantation	3	3	3	100.0	1	33.3
18	Psychiatry	1	1	1	100.0	1	100.0
19	Kidney medicine	7	3	3	100.0	3	100.0
20	Perinatology	2	2	2	100.0	1	50.0
21	Ophthalmology	1	1	0	(-)	0	(-)
22	ENT	1	1	0	(-)	0	(-)
23	Dermatology	1	1	0	(-)	0	(-)
90	Recovery period	1	1	1	100.0	0	0.0
100	Unit library	4	4	5	125.0	0	0.0
Total: 25 domains		**161**	**123**	**98** 79.7%		**85** 86.7%	



2.3 Design of implementation flow to use knowledge contents in clinical practices

When PCAPS standard contents in which structured clinical knowledge is embedded are in place, it will become necessary as a next step to design a model to make an effective use of them. At a hospital, a series of activities are carried out: a) distribution of PCAPS standard contents, b) reception of PCAPS standard contents at a hospital, c) preparation and registration of hospital-specific standard contents by customizing the received PCAPS standard contents, d) application of the registered hospital-specific standard contents to a patient, e) preparation of patient-specific clinical plan by customizing the applied hospital-specific standard contents, f) direction of medical intervention to be performed for each patient, g) implementation of medical intervention, h) preparation of a structured implementation summary by entering the implementation data, i) clinical evaluation and management evaluation by analyzing the structured implementation summary, and j) implementation of improvement actions based on the evaluation results. It is possible to design a business model to plan, develop and provide various services and products which support the above-described activities.

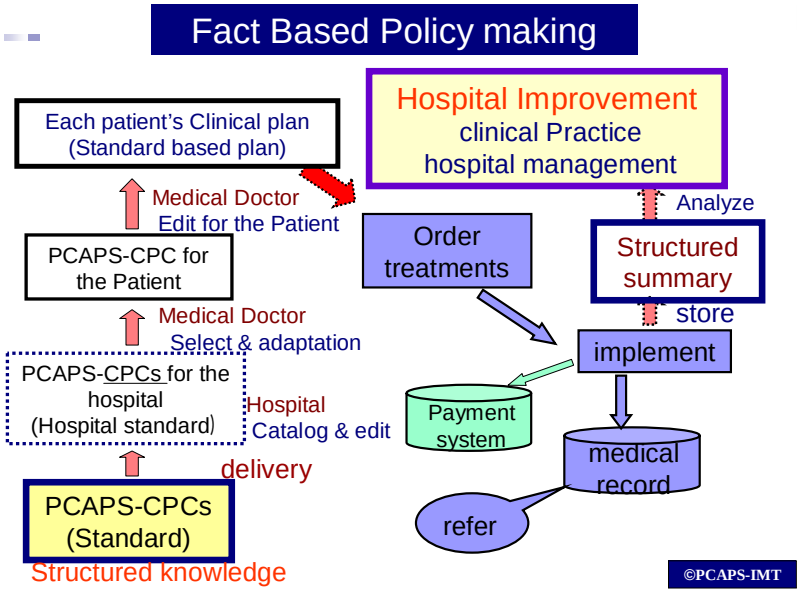


Fig. 4 Design of implementation flow

2.4 Preparation and Application of PCAPS Contents through PCAPS Integration System

PCAPS contents are prepared by Builder in the PCAPS integration system. Standardized PCAPS contents are distributed and they are applied to patients by Administrator to serve as a tool to support routine healthcare services. Along with implementation of the PCAPS contents, implementation records are entered to prepare a structured implementation summary. Data in the structured implementation summary is sent to Analyzer to be analyzed.

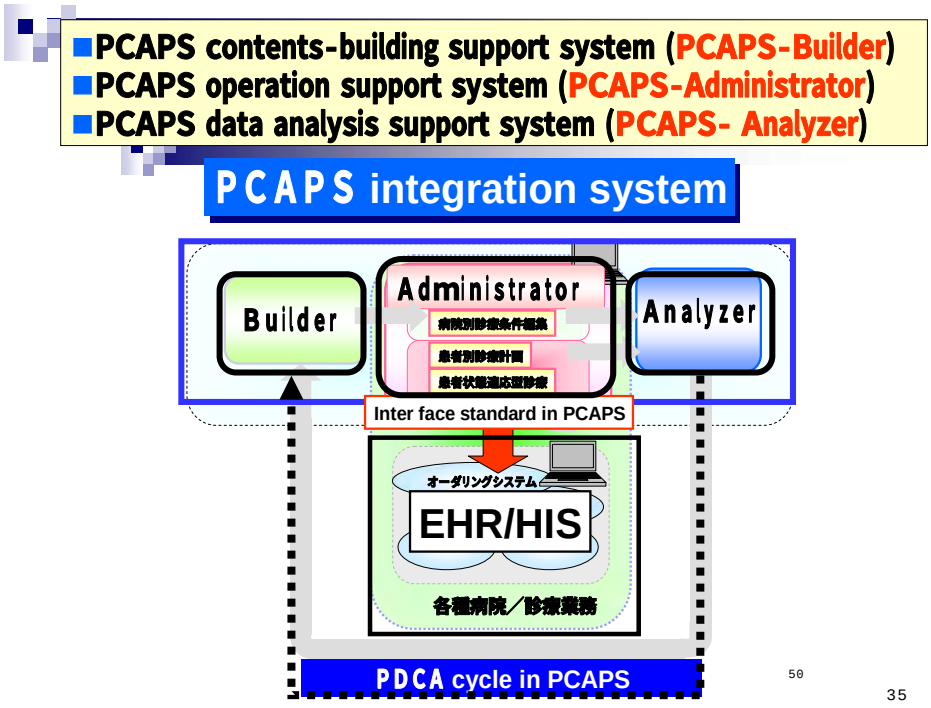


Fig. 5 Improvement of content through PCAPS integration system and PDCA cycle

3. Knowledge Infrastructure: Utilization

3.1 Assurance of Accessibility: Content Distribution Business Model

Expected users (customers) of PCAPS contents are ① healthcare staff and hospital,② educational institution

and student, ③ academic organization and researcher, ④ manufacturer and business organization and ⑤ public agency (local and national governments).

Contents for business use can be categorized as follows:

Clinical-based contents
Survey- and research-based contents
Contents for specific need (to be newly developed for each business organization)
Use of existing contents (New contents specifically serving a particular survey purpose can be developed by dividing a unit in existing contents or by setting a new route.)

The following business sectors are targeted:

To support clinical practices at hospital
- Distribution of standard contents
- Preparation and support of implementation of standard contents
- Support of in-house data summarization at hospital
- Routine analysis
- Advanced analysis
- Benchmarking

To support healthcare policies and measures of local government
To support academic society
To support research and development at university and company
- Preparation and distribution of necessary contents
- Support of research and development environment setting
- Collection of data
- Summarization of data
- Analysis of data
- Consulting

To support evaluation and improvement of product at company
- Usage survey for medical devices, medical materials, drugs, etc.
- Analysis
- Proposal for evaluation and improvement
- Consulting

3.2 Assurance of Applicability: the PCAPS Integration System, namely Builder, Administrator and Analyzer

It is possible to develop a mechanism to assure applicability for different access needs by using three application software programs in the PCAPS integration system, namely Builder, Administrator and Analyzer.

Sharing of and consensus about medical treatment process in healthcare team
Support of healthcare service plan preparation
Support of implementation
Support of recording (Preparation of analyzable structured implementation summary)
Support of analysis

4. Knowledge Infrastructure: New Knowledge Acquisition Method

4.1 Visualization, Analysis and Sophistication to Knowledge

By using the PCAPS contents in which clinical processes are visualized, it is possible to store existing clinical history records of patients in a structured way. This will make it possible to trace back routes taken in clinical path, patient conditions and their duration and thereby to transform clinical history records to analyzable data. By analyzing the transformed data, unidentified new intervention logic can be extracted.

4.2 Enhancement of Overall Quality of Clinical Practices

PCAPS contents have a potential to enhance overall quality of clinical practices by removing doctor-to-doctor and hospital-to-hospital variations of healthcare services.

Identification of doctor-to-doctor variations: By comparing patient-specific clinical plans prepared by different medical doctors for those cases characterized with the same contents and the same routes in clinical

path, it might become possible to identify uniqueness of each medical doctor in terms of his/her healthcare services. This kind of benchmarking is expected to encourage medical doctors to learn from each other and adopt clinical designs delivering better outcomes, which leads to elimination of doctor-to-doctor variations in healthcare services.

Identification of hospital-to-hospital variations: Healthcare service guidelines presented by academic societies can be embedded into PCAPS contents. This means that hospitals can demonstrate that they implement standard healthcare services according to relevant guidelines when they use PCAPS standard contents. By performing gap analysis to identify differences between PCAPS standard contents and hospital-specific standard contents that a hospital has developed based on the PCAPS standard contents, it is possible to identify departure of the hospital-specific standard contents from relevant healthcare service guidelines.

5. Application in Organization

5.1 Application in Healthcare Organization

In fiscal 2011, a series of implementation experiments will be performed in which PCAPS contents are implemented by PCAPS Administrator. The implementation experiments cover some characteristic technical domains and contents. The following technical domains are selected:

Application in acute hospital:	Surgical operation
	Drug therapeutics
	Cancer treatment
Application in recovery-stage hospital:	Rehabilitation hospital
Application to perinatal medical care:	Regional central hospital/medical clinic
Application to home medical care:	Visiting nursing station
Application to alliance:	
	Alliance among healthcare specialist teams within a hospital
	Alliance among neighboring healthcare service processes
	Alliance between low-risk and high-risk healthcare services (Alliance between general medical services and advanced medical services)

5.2 Application in Region and Society

For regional application, two aspects are considered: 1) application to regional healthcare service alliance and 2) evaluation and improvement of regional healthcare service plan. Application of PCAPS contents will make it possible for each region to collect data to prepare scatter diagram etc. and to identify strength and weakness in regional healthcare services. By comparing the number of lymph node dissections (lymphadenectomy) in a region with that in another region, for example, it can be revealed whether advanced healthcare services are being adopted in the region.

Through similar procedures, it is also possible to evaluate and improve healthcare service policies and measures implemented by government agencies.

5.3 Improvement of method to apply PCAPS contents in organization

As organizations keep using PCAPS contents, method to apply them in organizations is expected to be theorized and further improved.

Acknowledgment
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Scheme for Healthcare QMS and its Implementation as a Socio-technology – QMS-H Model

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Summary
The most important condition to establish healthcare as a socio-technology is the establishment of technology. This technology is classified into product-specific and management technology. In this paper, we focus on the latter, particularly the establishment and operation of a quality management system (QMS), which are key to providing healthcare at an organizational level. In addition, we discuss the necessary conditions for its establishment as a socio-technology.

The QMS model for healthcare is termed as the quality centered management system for healthcare (QMS-H), and we discuss the form it should assume and the necessary type of Body of Knowledge (BOK). To establish a QMS-H socio-technology, it should not be mere knowledge but must be possessed and widely utilized by society. We, therefore, discuss the necessary elements to achieve this. Furthermore, even if the QMS-H model and BOK are established, it is not easy to introduce and promote them in hospitals. Since we are trying to implement them in several hospitals in a QMS-H research group, we will also discuss some practical cases.

Keywords
Quality Management System for Healthcare (QMS-H), Total Quality Management Framework, Spread and Enlightenment, Practicing QMS-H, QMS-H Research Group

1. Introduction

In recent years, healthcare has greatly developed and become complex and work in this profession has become more specialized. Quality assurance at the organizational level is essential to provide safe and reliable healthcare, as is symbolized by the term “team healthcare.”

Healthcare as well as energy, communication, transportation, and nuclear power have a major impact on society, and providing safe and reliable healthcare is essential for the creation of a safe and reliable society. However, the society must be equipped with the necessary technology in order to provide the same. We call such technology “socio-technology,” which must be possessed by a society as a whole.

The most important condition to establish healthcare as a socio-technology is the establishment of technology. This technology is classified into product-specific and management technology. In this paper, we focus on the latter, particularly the establishment and operation of a quality management system (QMS), which are key to providing healthcare at an organizational level. In addition, we discuss the necessary conditions in the establishment of healthcare as a socio-technology.

The ISO 9000:2005 defines QMS as a “management system to direct and control an organization with regard to quality.” In other words, QMS is a mechanism or work procedure designed to achieve and maintain quality. More concretely, we might describe it as a system that uses documents to list the guidelines defining work procedures, such as quality manuals; instruction manuals; records; and resources, for example, people and equipment.

QMS has been used in a manufacturing industry since a long time; it has established itself as a method of providing high quality products. However, since healthcare and industry have very different quality-control dimensions, developing an appropriate QMS model specifically for the needs of the healthcare sector is an urgent task. The QMS model for healthcare is termed as the quality centered management system for healthcare (QMS-H), and we discuss the form it should assume and the necessary type of Body of Knowledge (BOK).

To make QMS-H socio-technology, it should not be mere knowledge but must be possessed and widely utilized by society. In other words, if medical staffs wish to use the BOK, they should have access to it. We also discuss the necessary elements in the development of such a situation.

Furthermore, even if the QMS-H model and BOK are established, it is not easy to introduce and promote them in hospitals. For example, the development of a methodology is necessary, and the technology to operate the model effectively and efficiently must be developed. Since we are trying to implement the model in several hospitals in a QMS-H research group, we will also discuss some practical cases.

2. QMS-H Model

2.1 Framework of TQM

The form and elements of QMS-H might be derived through an analogy with the QMS model applied in manufacturing industry and modified according to the features of the healthcare sector. A typical QMS model that has produced excellent results is total quality management (TQM). The Union of Japanese Scientists and Engineers (JUSE), the body promoting TQM, organized a TQM committee in 1996 and defined the concept of TQM. The committee concluded that TQM is composed of a philosophy, core management system, QC methods/techniques, and operation technology.

Philosophy implies the basic concept for implementing quality management, including the definition of quality, involvement of people, kaizen, the next processes are our customers, the management cycle (PDCA cycle), process control, management by fact, respect for humanity, and so on. This philosophy defines the behavioral principles and background to the system and method/technique described below.

The core management system is a management mechanism to implement quality-first management and realize the model's philosophy. In particular, daily management, policy management, and cross-functional management are fundamentally important in TQM. The quality assurance system is a core system to achieve quality. The mechanism and organization for quality assurance are included in the system along with quality improvement activity and a management system to deal with serious quality problems and apply quality assurance information. Furthermore, cost management and delivery management are also elements of the core management system.

The QC methods/techniques comprise those that are widely used in problem solving and goal achieving. They include statistical methods; the QC story, which is a general problem-solving method; new QC 7 tools, which deal with language data; product planning 7 tools; strategy planning 7 tools; QFD; reliability methods including FMEA and FTA, and so on.

Operation technology includes various devices for the promotion of TQM. There are a number of methods to promote TQM, such as the installation of a TQM promotion office, suggestion schemes, QC circles, diagnoses by top management, creation of QC teams, and so on.

2.2 Overall Picture of the QMS-H Model

Although a slight modification of the elements described in section 2.1 is required for the adaptation to healthcare, these elements are essential for QMS-H as well. We now discuss the key elements in QMS-H, according to the framework.

2.2.1 Philosophy

What are the important behavioral principles and basic concepts behind QMS-H? We can refer to the philosophy of TQM, the quality management principle in ISO 9000, etc. to answer this question. We examined QMS-H from the viewpoint of the focus and weak points in healthcare, and we listed the following six items.

(1) Customer focus
High quality implies the fulfillment of customer requirements. This is an established concept in manufacturing industry. However, several people feel that with regard to medical professionals, providing high technology healthcare is the same as providing high quality care. Since patients do not have any knowledge about healthcare technology, the standard of the medical professionals tends to determine what is good. However, the standard should typically be that of the customer. Treatment that is not accepted by a patient is meaningless.

On the other hand, owing to the patients' lack of knowledge regarding healthcare technology, they cannot ascertain which treatment is the best. It is important for medical professionals to determine treatment approaches by taking the patients' conditions, situations, and expectations into account.

(2) Visionary leadership

Visionary leadership involves leadership that has a vision; it determines a clear policy to realize this vision and leads people in the proper direction to achieve it. Although quality improvement is a necessary activity, the incentive for its attainment is very weak in healthcare. For example, decreasing the number of malpractice incidents does not lead to increased revenue. Under the circumstances, to promote quality improvement, it is essential for the top management to consider quality to be important, embrace the vision, and of their own accord, lead the activity.

(3) Process approach/system approach
What is expected in healthcare is quality assurance through systems and not through individual skills. The concept that a good process produces a good product must be understood, and quality improvement must be attained by improving work procedures and mechanisms. Although highly skilled professionals are always an asset, the techniques they employ must be visualized and reproduced as organizational techniques, to improve the practice of all in the organization.

Since, in healthcare, a culture that focuses on those who have skills is entrenched, attempts at standardization of processes across organizations are delayed and improvement is slow. In recent years, the significance of providing healthcare at an organizational level has been acknowledged by use of the term “team medicine,” and a process approach/system approach is gaining favor.

(4) Management/object orientation
Management means all the activities required to achieve objectives efficiently. The rotating PDCA cycle is an effective and efficient measure for the management. Selecting management items is important in the rotation of the PDCA cycle. To select the management items, the end results desired must be clarified. This is basic to grasping a problem and essential for problem solving.

However, medical professionals are not good at selecting management items with clear objectives. Although the reason is unknown, they often select activities as objectives, such as “Do something twice a month” or “Operate XX system.” They must understand the significance of the PDCA cycle and perform object orientation.

(5) Involvement of people/participation by everyone
Involvement of people implies that everyone thinks about what to do and fulfills his/her responsibility. In team medicine, high quality healthcare can be provided when every professional fulfills his/her responsibility.

The involvement of people also implies that “everyone is aware of the importance of quality and everyone participates in all the activities,” which is the most effective and efficient way to attain quality. In hospitals, almost everyone performs routine work. It is very difficult to secure full-time personnel to work on quality improvement owing to budget restrictions. Healthcare is an industry in which the involvement of people is necessary.

(6) Human centered management
Human centered management is the organizational management in which people are respected; it is based on the concept that organizational performance is determined by people. Even though a large amount of equipment and IT systems are often used in healthcare, it is still a labor-intensive industry. The possibility of determining quality by human knowledge, skill, and motivation is higher than that of other industries. Since the more people grow, the more quality improves, it is important to provide opportunities for self-growth through problem solving.

Although high-tech medical devices and IT systems are introduced, various defects occur, due to mismatching between the interface or operating procedure and human characteristics. Work systems need to be designed using devices and IT systems that consider human characteristics.

2.2.2 Core Management System

We should define the work processes of a hospital and visualize the relationships among those processes in order to clarify the QMS-H at the macro level. We defined the work processes typical of a hospital, examined how to incorporate the elements into the QMS-H, and described the relevant quality assurance system in a chart. This chart is quite large; hence, we only describe the outline of the system.

Medical care is obviously the core process in a quality assurance system. The two management processes—support-process and function-liaison management—support the core process. Framework and cross-functional management serve to manage the overall directions of these three processes. The former three management processes correspond to daily management, and the latter two to policy and cross-functional management. These three management processes, which are daily management, policy management and

cross-functional management, are indispensable for healthcare as well.

We extract and deploy 57 functional elements that are necessary for the five management processes in our QMS-H. For example, policy management, system assessment (internal audits, management reviews, etc.), and system improvements are included as part of the framework management function, whereas admission management, medical care management, and discharge management form part of the medical-care process management function. Our research group has examined a method that realizes these functions.

Just as the quality assurance system is regarded as the core system in TQM, the healthcare safety management system is essential in healthcare. The system should be operated as part of QMS. Historically, the promotion offices of QMS and the safety management have been separate, but integrating their operations is desirable.

In the healthcare safety management system, the management of incidents is a key function. A mechanism for immediate action when an incident occurs, such as the incorrect treatment of a patient and the explanation to the family, must be prepared. More important is the establishment of an incident report system. This system is used to prepare a report of an incident in a specified format, analyze it, and link it to the improvement of the QMS. Almost all the hospitals have a similar system. However, their effectiveness is questionable since there is insufficient time for an analysis, the issues are not prioritized, and countermeasures consist of merely calling attention to problems, etc.

2.2.3 Method/Technique

TQM has focused on the development of problem-solving methods such as the QC story and statistical method. The concept of statistical quality control (SQC) was emphasized and the statistical method was essential to the performing of management on the basis of facts.

Although there are some cases where the statistical method is useful in healthcare, it is not as important as in industry owing to the features of healthcare. The methods to be focused on are the visualization and standardization of jobs and the incident analysis method.

Visualizing and standardizing current work procedures will improve quality, as will rotating the PDCA cycle. If the current work procedure cannot be visualized, we cannot determine if the procedure is good or bad.

Healthcare is a service industry and work procedures adapted to the patient's condition are required. This is quite different from the manufacturing industry in which the final product is completed by using uniform material and pre-determined work routines. We use a process flow chart (PFC) as the prescription method of the healthcare work procedure, which makes it possible to visualize and standardize healthcare work easily.

We developed clinical PFCs to describe the processes involved in the diagnosis and treatment offered to patients from the time of hospitalization to discharge. Since it is not possible to describe all the processes in a single PFC, a PFC includes only those processes that are routinely used in the diagnosis and treatment. Other processes are sometimes presented as subroutines using software engineering, in order to describe the methods in a layered structure. The PFC for a subroutine is designated as a "sub-PFC." Furthermore, all the activity elements useful in creating standardized and systematic PFCs are included in the list of activity elements. The activity elements list is standardized, and the elements are arranged to help in managing and improving the diagnosis and treatment processes by including the processes routinely performed by medical professionals. Shimono[1] has proposed a unit process and process flow as a prescription method of individual work.

With the visualization and standardization of work procedures, a common issue in any industry is managing and improving the QCDSE of management elements. However, in healthcare, the "S" (Safety) in QCDSE is the focus. Almost all the jobs relate to human life, and safety is the most important aspect in comparison to other industries. Thus, the development of a method to analyze incidents and plan countermeasures is critical.

In healthcare, medication error and falling are two major problems. For incidents that come under the former, we must establish a safe medication procedure, and we have already developed a method to realize a process approach and plan countermeasures, including error proofing aimed at human centered systems. On the other hand, falling is primarily caused by factors related to the patient. Methods to analyze the relation between a patient's condition and incidents and plan countermeasures considering the patient's condition are necessary. We have already developed such methods.

2.2.4 Operation Technology

A detailed plan is needed for the introduction and promotion of QMS-H in organizations, even if the QMS model is completed. Several mechanisms are needed to make QMS activity continuous and involve everyone. At the least, methodologies of introduction and promotion, activation and mutual enlightenment of individuals and their organization, as well as the exchange of information are required. Unfortunately, such methodologies were not developed as systematic knowledge in TQM. Developing them is, therefore, a key issue to establishing healthcare as a socio-technology.

First, a methodology of introduction and promotion of QMS-H is needed. We developed 11 steps for it through our experience of introduction and promotion in three hospitals, as follows.

Step 1: Learning what QMS-H is
Step 2: Defining the position of QMS-H and identifying an attainable policy/target
Step 3: Appointing a person/group in charge of introducing and promoting QMS-H
Step 4: Declaring the top management's intention to introduce and promote QMS-H
Step 5: Designing QMS-H and clarifying its relationship to the activities thus far
Step 6: Planning a detailed schedule for the introduction of each QMS-H element
Step 7: Determining the organizational structure of the group tasked with introducing and promoting it
Step 8: Organizing a seminar to educate members regarding QMS-H activities
Step 9: Starting activities according to the plan and managing progress
Step 10: Starting the operation of QMS-H
Step 11: Improving QMS-H on a continual basis

We introduced and promoted QMS-H in five hospitals according to these steps. We can deploy a concrete plan of introduction and promotion by using the steps as a basis. In this fiscal year, we are applying the steps to two new hospitals and verifying if we can introduce them more effectively.

We found that the visualization of job processes is the most important element of step 9. Furthermore, we believe that both introduction and promotion must be implemented autonomously, without the use of consultants.

Second, we must build an organizational structure for promotion. In industry, a department such as the TQM promotion office is set up. In healthcare, the same function is needed even if the hospital is small. From our experience, one full-time staff member and several part-time staff can operate it in a hospital containing 500 beds. To deploy activities to each department, a committee such as a QMS promotion committee, which is composed of representatives from each department, is usually organized.

Since job rotation that involves reshuffling occupational categories is not performed in hospitals, a core member must be cultivated in each occupational category. Moreover, the hospital director should be the chair of the QMS promotion committee or the committee should be under the immediate supervision of the director.

Third, QMS education for personnel is essential for its smooth introduction and promotion. For this purpose, we developed a basic seminar for QMS-H. The curriculum is composed of 14 items required to introduce QMS-H. Each item takes three hours of instruction time. The items are divided into 5 categories: basic concepts of QMS, visualization of job processes, tools needed for improvement, healthcare safety management, and methods of introducing and promoting QMS-H.

With regard to operation technology, we needed a methodology of activation and the mutual enlightenment of individuals and their organization, different from the methodology described above. QC circles, suggestion schemes, employment performance evaluations, etc. are performed in some hospitals. In the future, we must verify which scheme is effective.

3. Spread of Information about the QMS-H Model

The QMS-H model and BOK described in section 2 will not spread if people who aim to utilize them cannot easily access them. QMS in industry primarily evolved due to each company's effort, though there were also many mechanisms for spreading it to society. These are essential elements to establish healthcare socio-technology as well.

3.1 Promotion Body

In Japan, JUSE and the Japanese Standards Association (JSA) lead quality management (QM) promotion. Both bodies provide and enhance BOK and provide the incentive to spread knowledge and information about QM by

means of publishing books, organizing seminars, helping with implementation, holding informational events, maintaining research groups, and offering prizes/qualifications. The Japanese Society for Quality Control (JSQC) is in charge of academic research promotion.

For the promotion of QMS-H, such a promotion body is needed. Measures that the body would take to promote it are as follows.

- Provision of BOK: Publishing books, organizing seminars
- Assistance with implementation: Consultation, assisting with the education in each hospital
- Improvement of BOK: Research group, introduction of cases, symposia, academic journal
- Provision of incentive for promotion: Quality awards like the Deming prize, qualification scheme

Up to the present, the three abovementioned bodies and other bodies in the healthcare sector have published a limited number of books and organized seminars for the spreading of information and knowledge about QMS-H. Other activities have not been sufficiently implemented.

There is the opinion that certain academic societies in the healthcare sector should lead these activities. However, it is difficult to introduce this since too many academic societies exist in each specialty category. In 2006, the Japanese Society for Quality and Safety in Healthcare was founded, and this body is expected to become the promotion body.

3.2 Publishing and Learning of Practical Cases

In the evolution of Japanese TQM, the Deming prize played an extremely important role. The winners of the prize published mechanisms, methods, and techniques developed by their practice. Companies that aimed to introduce and promote TQM could apply very newly developed mechanisms, methods, and techniques to their own businesses, as well as utilize the knowledge gained at seminars and through books.

Many other opportunities to learn from practical cases, other than the Deming prize, were made available. These included QC forums, QC Circle forums, academic symposia, and so on. At these events, businessmen from various industrial sectors presented practical cases, learned new methods, and enlightened each other. Policy management and the QC process chart are examples of techniques spread through this activity.

Unfortunately, in recent years, with the trend of companies regarding intellectual property as a source of profit, fewer practical cases have been published. In the healthcare sector, there exists a culture wherein one publishes and shares newly developed treatments so that the horizontal penetration of lessons learned is quite easy, owing to the product of healthcare being the same. If practical cases were published, they would be an effective measure to spread knowledge and information about QMS-H.

Though the academic societies of the healthcare sector are very active, inherent technologies, such as those used in medical cases, are the main issue. In the future, research into management technology should be conducted; healthcare QC forums where new management technology is publicized and medical staff can learn about it is necessary.

3.3 Standard

Standards are established by consensus and approved by a recognized body; they provide for common and repeated use, rules, guidelines, or characteristics for activities or their results, and aim at the achievement of the optimum degree of order in a given context (ISO/IEC Guide 2). A typical international standard is the one ISO/IEC publishes, and other bodies such as those found in a specific area, those representing a nation or institution, and companies lay down standards as well. Standards can be an effective measure to spread knowledge and information about concepts and methodology.

For example, ISO 9001 is an international standard of the QMS model; the model is widely known combined with a certification scheme. In Japan, the Japanese Industrial Standard (JIS) is widely used in industry.

A factor in the slow progress of improving healthcare quality is the delay in achieving standardization. The delay in achieving standardization for treatment methods, which is at the core of the inherent technology spread, is a major problem. Moreover, problems often occur because work procedures and mechanisms related to treatment processes are not standardized. For example, miscommunication occurs because there is no standardized rule for writing a prescription. In developing electronic medical records, each hospital that introduces this system develops its own individual master terms since standard master terms are not defined. This is an ineffective approach.

In industry, JSA as the standardization promotion body promoted the enactment and spread of JIS. Although there has been some progress in healthcare standardization owing to some promotion bodies, it is insufficient. A standardization base, such as a Japanese Medical Standard, is needed. The contents of the standard should become part of the education of medical faculty as well. Furthermore, manufacturers of medicine and medical equipment should develop and produce their products according to a specific standard, taking aspects of the product safety into account. Standardization is an important element in establishing healthcare as a socio-technology.

3.4 Utilization of information and communication technology

From 1960 to 1980, TQM in Japan greatly evolved, and since this period, information and communication technology (ICT) has undergone great changes. Back then, paper media such as books or direct communication through consultations were the measures used to communicate BOK. Although these are also important measures today, ICT may be able to spread knowledge and information more efficiently.

Promotion bodies make it possible to provide information via websites. E-learning is well evolved and can provide easy learning opportunities for medical staff who are too busy to participate in a seminar. Education can be effectively presented through slides and PowerPoint notes.

4. Practicing QMS-H: Activity of the QMS-H Research Group

The authors have been a part of the QMS-H research group since the past four years, in order to determine the manner in which QMS-H can be effectively implemented in hospitals. The purposes of the group are as follows.
1) Proposing a QMS-H model in accordance with the needs and characteristics of the healthcare sector.
2) Planning an effective and efficient process for introducing and promoting QMS-H.
3) Preparing an organizational structure for introducing and promoting QMS-H and systematizing the necessary learning. The group provides effective cases of implementing the BOK regarding QMS-H.

The group works as follows: First, the hospitals in charge of developing a QMS model collaborate with us to develop the model and a method for introducing and promoting the same. The hospitals in charge of verifying the model try to introduce and promote the model autonomously; during the verification trial, we provide the hospitals with any assistance required with regard to the introduction and promotion of the model. Following this, we have monthly meetings with the two hospital groups (one in charge of developing the QMS model and the other in charge of verifying the same), where the progress is reviewed and issues encountered during the introduction and promotion are discussed. After such meetings, the results and conclusions of the discussions are incorporated and the work of promoting the model continues.

The details of the hospital part of the research group are shown in Table 1.

Table 1 Hospitals in the QMS-H Research Group

	Hospitals	Care Type	#bed	QMS Operation, Certification
A	Koga General Hospital	Acute	363	certified in 2002
B	Jyoto Central Hospital	Acute	233	certified in 2003
C	Aso Iizuka Hospital	Acute	1165	started operations in 2006, certified in 2008
D	Sendai Medical Center	Acute	698	started operations in 2007, certified in 2008
E	Ooguno Hospital	Nursing home	174	started operations in 2007, certified in 2009
F	Maebashi Red Cross Hospital	Acute	592	started operations in 2007, to be certified
G	Musashino Red Cross Hospital	Acute	611	started operations in 2009, not aiming for certification
H	Satte General Hospital	Acute	192	started operations in 2009, to be certified
I	Saitama National Hospital	Acute	350	started operations in 2011, to be certified
J	Kawaguchi Municipal Medical	Acute	539	started operations in 2011, to be certified

Although hospitals A and B already possess the ISO 9001 certification, they aim to redevelop their QMSs since the current systems in place are such in name only. Hospital C first introduced QMS-H in a single department and later implemented it across the entire hospital. Hospitals D, E, F, G, and H have no prior experience with QMSs. Note that hospitals A, B, and C developed the QMS-H model, while hospitals D, E, F, G, and H verified the same. Hospitals I and J attended the symposium in 2010 that published the results of the QMS-H research group. They recognized the necessity of introducing QMS-H and have participated in the group since fiscal year 2011. They are verifying if they can introduce and promote QMS-H more effectively and efficiently than in the past by using the QMS-H model and BOK.

Of the 9,000 hospitals in Japan, around 200 are ISO 9001 certified. The majority of the 200 hospitals used external consultants for certification. In our research group, we emphasize that the participating hospitals must visualize their QMSs on their own and develop it themselves. We believe that it is only by adopting this approach that the hospitals will be able to establish an effective QMS. Note that the ultimate goal of each hospital is not an ISO 9001 certification, but the establishment of a QMS that ensures the quality of healthcare remains consistently high.

At present, although only half the work on the establishment of the QMS-H has been completed, the basic foundations of QMS-H have been laid, and many hospitals have now obtained the ISO 9001 certification, some since the past four years. At present, the most significant issues and outcomes of our work are shown in Table 2. In the first two years, the main issues were establishing a foundation of QMS-H. This involved the visualization and standardization of healthcare procedures and implementation of daily management practices on the basis of these procedures. In fiscal 2009, the third year of the QMS-H research group, two hospitals began to improve at the organizational level on the basis of the hospital policy. In fiscal 2011, half of the hospitals are fostering improvement at the organizational level due to policy management. Furthermore, they are making efforts to spread the knowledge and information about QMS-H to encourage a greater involvement by people.

Table 2 Issue and Outcome of the QMS-H Research Group

Issue	Outcome
Clarification of necessary processes	QMS-H model
Visualization & standardization of job processes	Visualization of treatment & nursing processes
Documentation	Documentation system
Check in PDCA cycle Management index	Method of internal audit Examples of management index
Introducing & promoting QMS-H	Step of introducing & promoting QMS-H Deployment of introducing & promoting the plan
Development methods for management & improvement	Method of analysis of medication incidents, method of planning countermeasures Model for planning the management to prevent falling Mapping model for healthcare jobs & people
Improvement at the organizational level Achievement of policy & objectives	Method of problem solving on the basis of the hospital policy
Education system	Systematizing the contents of quality & safety education for healthcare Basic seminar for QMS-H

5. Conclusion and Future Issues

As described above, of the 9,000 hospitals in Japan, a small number have implemented QMS-H. Since QMS-H is a mechanism or work procedure designed to achieve and maintain quality, every hospital must operate QMS-H in the same way as industrial companies do. If questions such as “Has your hospital introduced QMS-H?” are broached, QMS-H has not become the common norm. If conversations regarding questions such as “Have you got any good ideas for implementing QMS-H?” or “I have a problem in implementing QMS-H” are entered into between medical staff, it is a good sign that the first step toward its becoming the common norm has been taken. The first step in creating a healthcare socio-technology is to make QMS-H common knowledge.

QMS-H might become a common norm if 500 to 1,000 hospitals out of the 9,000 hospitals in Japan implement it. However, we cannot spread it simply through the activity of the QMS-H research group described in section 4. The QMS-H model and BOK described in section 2 and the scheme described in section 3 is essential for the

enlightenment and spread of QMS-H.

The research group has introduced activities to spread the model across the healthcare sector, other than among the group members. Although this is a first step in establishing healthcare as socio-technology, it represents a steady progress.

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Reference

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