

# **The Guideline of the Personal Health Data Structure to Secure Safety Healthcare**

**- The balance between use and protection to satisfy the patients' needs -**

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## Abstract

**Purpose:** To inform about the impact of a recent movement towards a policy to develop integrative networked Electronic Health Record (EHR) as a basis for cooperation among care teams and with patients and in support of safe patient care in Japan.

**Methods:** The author headed a commission developing policy for Health Record (HR) structure and its computerization. It executed two questionnaire surveys as the basis for its work. One survey assessed the current state of computerization of Health Record in the hospitals certified by Japan Council for Quality Health Care (JCQHC). The other survey assessed the attitudes towards a specific EHR system in the Hiroshima university hospital and its affiliate hospitals.

**Results:** The survey of the above hospitals showed that most have computer supported administrative procedures, but only few computer-based health records. The attitudes of the Hiroshima EHR users show that while they expect efficiency and quality improvements, there is also apprehension that the system in use might lower practical efficiency and compromise patient safety. Accordingly, health recording requirements and storage policy have been restructured and communicated to the hospitals.

**Conclusion:** These insights led to the initiation of curricula educating "Health Information Technologist" which is promoted by Japan Association Medical Informatics and the criterion of Chart Review Promotion of JCQHC. They will also lead to recommendation for improved and advanced EHR.

## 1. Introduction

In Japan, for over 30 years, IT application in the healthcare field has been based on hospital administration. However, for the past 20 years, our interest has been shifting to EHR. The government subsidizes the healthcare IT sector with over 300 million dollars annually. Nevertheless, the resulting products are still not necessarily fit for clinical application.

Since the Ministry of Health and Labor issued the basic design of the EHR in 2001, the computerization of the health record has met with increasing public interest. Additionally, the "IT policy objectives package 2005" released by Japanese government [1] will accelerate EHR development.

As a next step, we plan to develop a Healthcare Navigation system over the next 5 years.

Another motive for the increased attention to quality is a number of adverse or incorrect events that were identified in the clinical process. As a result, the management of the safety of the healthcare process and the manner of disclosure of patients' information have become high priority issues.

The HR should serve as the basis for process and outcome evaluation. However, currently HR quality varies so widely that it is unlikely to serve as the basis for developing patients' confidence in the healthcare process.

## 2. Background

Though the EHR is expected to decrease the variation in record quality, there is still no consensus on its social role. The idea that it is just the computerized version of the paper record still prevails. In our view, it will be necessary to develop it beyond that into the key medium for interaction of specialists in medical care.

Despite our effort to reflect the care process in the system operation, the current system in the opinion of medical staff is so complicated and unusable that it might impinge on operational efficiency and threaten patient safety. We are guided by the notion that the standardization of the HR will lead to standardizing the safety of the healthcare process.

In order for the standardized HR to become the basic medium for the interaction of specialists and patients in the practice process, we have to comprehend the HR from the perspective of safety and quality of healthcare and reevaluate its computerization to arrive at a better blueprint for the next generation health system.

## 3. Research organization and activity

The Chart Review Committee (CHC) headed by the first author consists of 35 appointed members: healthcare system investigators (5), chart review specialists (15), and clinical specialists (7 medical doctors and 8 nurses) of member hospitals of the Patient Safety Promotion Organization of Hospitals certified by the Japan Council for Quality Health Care (JCQHC).

The JCQHC is the nationally authorized organization, which accredits hospitals based on neutral assessment

with academic perspectives in order to improve the quality of healthcare. In May 2005, there were over 1,600 accredited hospitals, and 898 hospitals were also members of the Patient Safety Promotion (PSP) council, an independent organization. Since PSP established CHC in 2004, its projects have focused on the EHR structure as a strategic tool to improve medical care safety through the following initiatives:

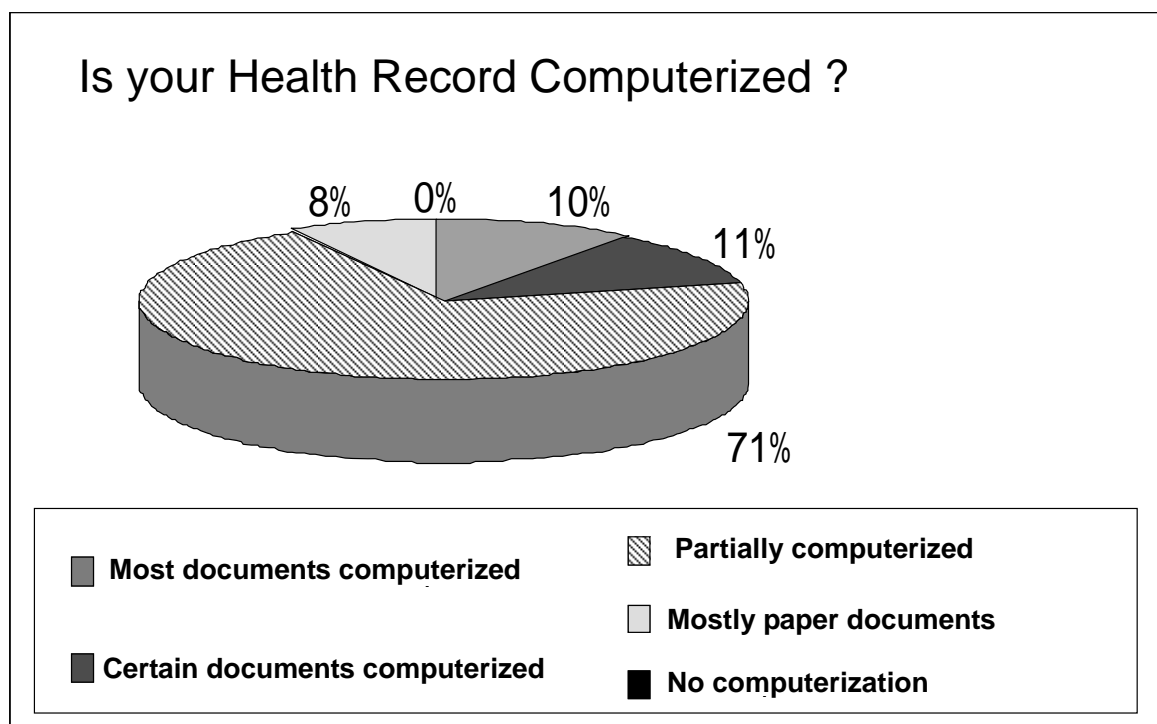
- 1) A survey of the actual status of inspection and evaluation of HR structure in the participating hospital,
- 2) Development of guidelines for HR structure with emphasis on clinical safety management and on making these guidelines available to the hospitals,
- 3) In this context, the advantages and disadvantages of HR computerization were analyzed in relation to their potential role in evaluating the quality of care process.

#### 4. Survey of the health record inspection and evaluation in PSP member hospitals

A questionnaire was mailed to 1370 PSP member hospitals by CHC in 2004, and 972 hospitals (70.9%) replied. The number of beds under operation ranges most evenly from across 100 beds or lower to over 500 beds or more

##### 4.1 Computerization circumstances

In 92% of hospitals, Patient Data were computerized, but health data documentation systems as “official document” is computerized in only 21% (Fig.1).



*Fig.1 Computerization of Personal Health Data in the Responding Japanese Hospitals.*

##### 4.2 Inspection condition on the HR

Sixty three percent of the hospitals serve as the center of clinical education and training for interns.

Among these hospitals, 62% have the management sections of HR, and 86% of them have review or inspection committees for the HR.

#### 5. Recommended Health Record Structure

##### 5.1 Hypothesis of Chart Review Committee

In order to make the HR the key medium for organized medical service involving a variety of specialists, the HR Structure Guideline as composed by CHC is based on the following seven principles.

### **(1) Compliance with Personal Health Information Act**

Healthcare records must be structured in compliance with the Personal Healthcare Information Act and related laws so that inpatients can control their personal information flow and at the same time rely on;

- a) Confidentiality
- b) Disclosure of personal information to patients
- c) Correction of errors
- d) Restricted use of personal information.

Careful documentation is required in order to protect the dignity of the inpatient and his/her family even after his death.

The primary use of information for the medical care of the patient has to be strictly distinguished from the secondary use, including social availability of information. In addition, the patient must be informed of the purpose of secondary information use in advance in order to protect his/her dignity.

Appropriate information use should be guaranteed by appointing a managing specialist of healthcare information in every facility.

### **(2) Healthcare records as communication media in team practice**

In addition to records on medical treatment, operation, and anesthesia produced by doctors, organic coordination of documentation is also required for nursing records, rehabilitation records, records of pharmaceutical management and conduct, nutrition conduct, and medical consultation records.

In order to show the interrelation in team medical care, the form of document organization and filing should be documented.

The organization of the medical service is considered to be appropriately reflected by team-sequenced form of records, which integrates prioritized and ordering issues, setting targets, treatment plans, recording requested orders and their results, as well as conduct confirmation, and outcome evaluation.

Especially, the problem list and the care follow-up are expected to be integrated, precisely indicating the specialists' reasoning.

### **(3) Target-oriented description**

The target of medical care, which ranges from short and mid to long term goals in physical, psychological, and social life environment, should be defined and documented.

The action plan for achieving the target must be specified.

The target and action plan need to be adapted to changes in the patient's physical condition and circumstances.

### **(4) The guarantee of generalization**

Since various events and episodes occur in parallel during the care process, and the general condition of a patient and care process should be easy to grasp, it is necessary to arrange and specify medical care conducted and documented by other medical staff, so that specialists with diverse viewpoints can cooperate in achieving the same treatment goal.

The lists of problems, targets, and the plan of action are to be placed at the beginning of the file, and an interim summary is to be included in the process records. It is crucial that each episode consists of the compact and clear description on facts, events, subjective/objective problems, assessments, plans, interventions, outcome evaluation, and a plan to the next stage.

In reappearance of problems, the previous listed number is reused. While, in the case of unlisted episode the new number is added for achieving continuity.

In order to promote information availability of the patient and his/her family, the use of jargon or abbreviations is discouraged in favor of understandable terminology.

### **(5) The guarantee of continuity**

For newly emerging conditions, whether related to medical or nursing treatment, including interview, observation, measurement, evaluation, diagnosis, planning, procedure, treatment, and evaluation of outcome, recording of the date of occurrence is required.

Recording of time is desirable when complex medical treatment is conducted during a single day. The start of an episode of the disease process, the time relation of change, the service sequence among several attending specialists should all be systematically described for easy understanding.

When reference is made to past episodes of medical or nursing care, the date and time of episode and those of the recording should both be documented.

### **(6) The guarantee of authenticity**

Objective description of events is required. Accurate verbs should be used in expressions of speculation and

inference.

The newest data should be shown. Basically, an episode must be recorded as soon as it is recognized while the staffs concerned are on duty. (At latest within the same day)

In the EHR, a permanent preservation file is required in order to avoid replacing the original records.

“Documentation errors” of care should be positively corrected. The date and time of correction, those of the recording of the outdated information, the content before and after correction, and the name of corrector all have to be documented.

Basically in correcting handwritten healthcare records, after double lines are drawn to show the incorrect content, new content is added. Use of correction fluid and erasers is not allowed.

In documentation, simple writing errors, which do not affect recorded context, serial correction stamps, and signatures, are unnecessary.

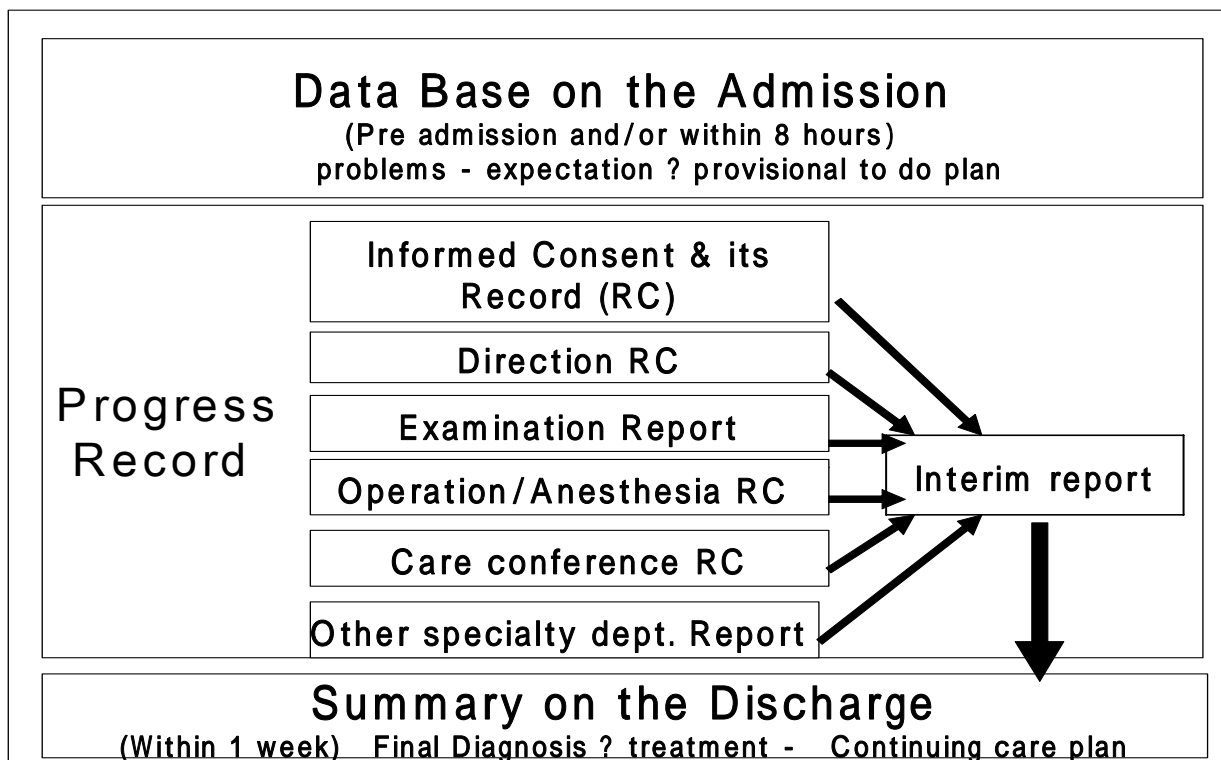
#### (7) The guarantee of original records

Information meant to serve as official records should be shown individually according to forms such as the first record form for public insurance healthcare, patient charts, ordering forms, process list, operation and anesthesia reports, summary, and test results.

Medical facilities, which use both handwritten records and EHR, need to define the official form for each healthcare record.

### 5.2 Structure of health record and its requirements (Fig 2)

According to our guidelines, the basic structure of the HR is defined as follows. The HR is divided into the admission document, progress record, and discharge summary.



*Fig.2 Recommended Structure of health Record*

#### (1) Admission Record

For the admission record, the documentation must be completed from before admission to within 8 hours after admission. It has to include the problems of a patient, which have to be identified with respect to their association with the primary disease to be treated of the associated diseases, including goal of treatment, and the immediate action plan for achieving the treatment goal.

**(2) Progress Record**

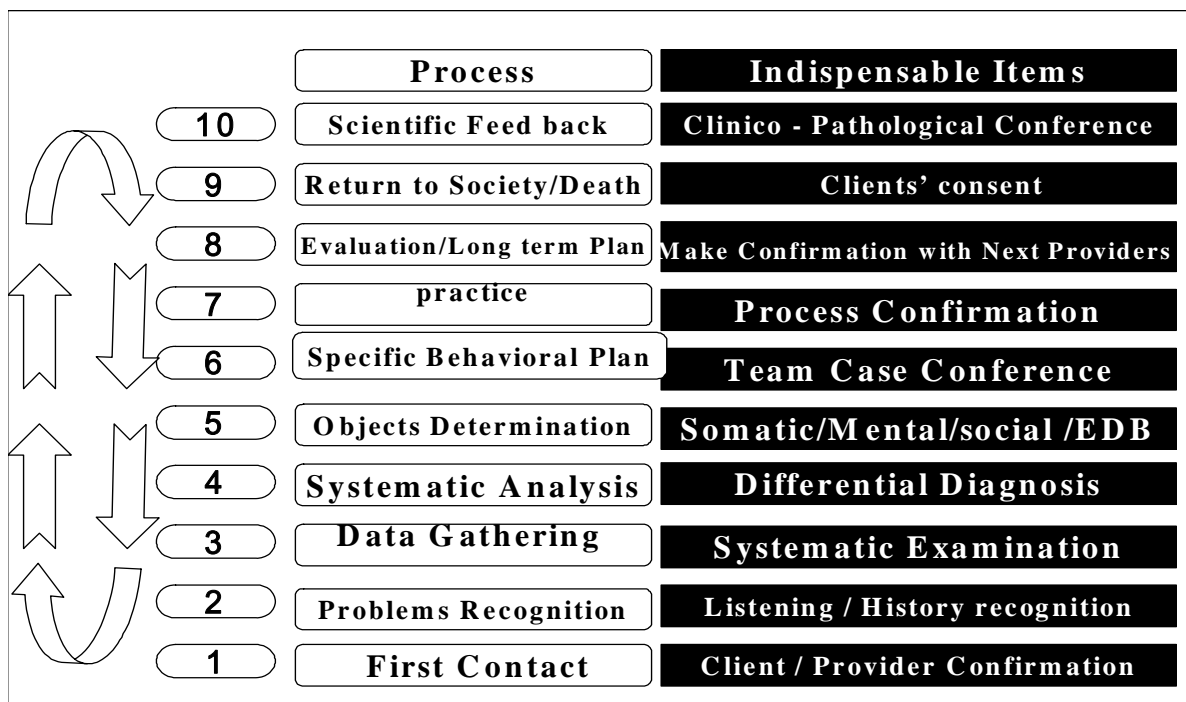
In the Progress Record, a number of items must be systematically recorded with individual interim reports as required. This includes records of requested examinations and procedures, reports on the results of examinations, operation/anesthesia records, care conference records involving different specialties, and other specialty department reports. Besides, the point is they need records of informed consent when necessary.

**(3) Discharge Summary**

The Discharge Summary, a summary of the care process and treatments in the hospital, must be completed within 1 week after discharge. The primary, accompanying, and associated diseases have to be specified by recording according to ICD10. The outcome of the treatment and an action plan for continued healthcare are also required.

In order to develop patient-oriented healthcare, the progress record should put the top priority on how informed consent is reached. Specifically, three stages, which are pre-clinical treatment, treatment process, and its outcome, must be described. (Fig.3)

In addition, it is important to take into account that a patient has the right to refuse the treatment plan as proposed and explained by healthcare specialists. Therefore, the description should not be restricted to the simple recording of specialist’s explanation and its outcome but should allow the patient to understand the explanation of his/her case as a basis for the treatment decision.



*Fig.3 Indispensable Informed Consent & Process Record through the clinical process*

**6. The actual contribution of the EHR to the safety of medical care**

**6.1 Healthcare Navigation System (HNS)**

The HNS has to facilitate safe team practice see Fig.4.

Here, as a practical case of safety management, Healthcare Navigation System is presented.

(A model of the HNS, which is the core of the EHR in the Hiroshima University Hospital, may serve as a practical example of the implementation of HNS in the service of safety management. [2])

EHR data are recorded not only by physicians, but also by all co-workers. This may be the basis for team communication and a reliable way of treating in such a way that the evidence of conducted practices is traced.

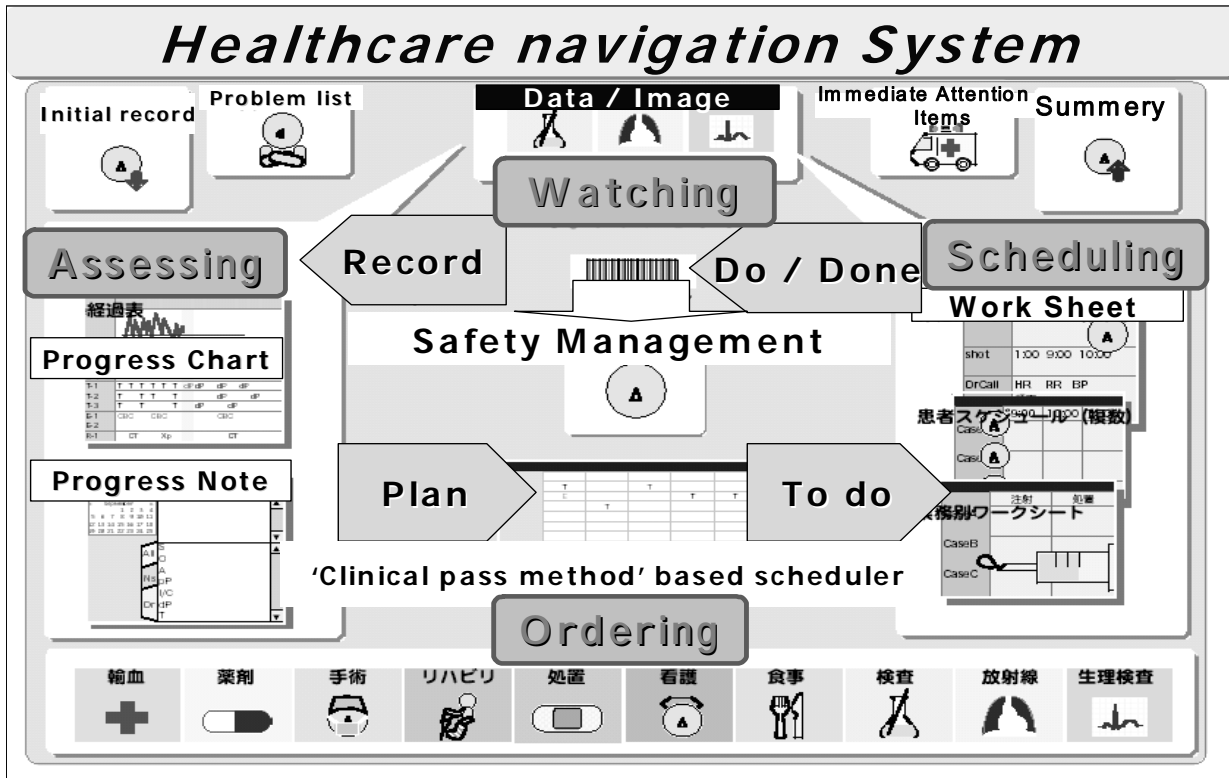


Fig. 4 the Index browser of Healthcare Navigation System; Specialists are able to access suitable function module on demand with this integrated browser.

## 6.2 Contribution to safety healthcare

The system is designed to share the information among all attendants and the patient concerned to promote team practice, which is expected to enhance safety and high-quality medical care as well as rational hospital treatment.

Modules of HNS are available not only to the physicians but also to all other health professionals concerned.[3]

A physician may give orders to other professionals who show order confirmation signed on the same browser. The interactions of information management in the clinical process are implemented and presented on a browser chronologically and iteratively.

## 6.3 Responsibilities for data users

Using conventional technology, it is difficult to fit our traditional handwriting with the clinical process. (In Japan, the common procedure for "official document" is simultaneous recording by physician himself with conducting medical treatment except operation or invasive treatment record. It is unusual that physicians make oral record of the findings of his patients' condition, results of examination and treatment and so on.)

In the case of the Hiroshima University Hospital and associated hospitals, the process of problem identification, target setting, planning, ordering, order confirmation, result reporting, and evaluation are carried out with a combination of computerized and manual documentation.

A questionnaire survey of all healthcare staff of several hospitals in Hiroshima was conducted, focusing on assessing the perceived advantages and disadvantages of the EHR on medical care safety and operation efficiency.

The results are the following:

### (1) Advantages of the EHR

The perceived advantages of the EHR include:

- Availability of objective information; the medical and nursing care process are documented in line with the organizational rules such as operation management, procedures, and recording forms.
- The need for repeated copying is reduced, which potentially increases operation efficiency. Furthermore, some specialists answered that computerization was effective in overcoming the drawbacks of handwritten records.

## **(2) Disadvantages of the EHR**

These contrast with the following perceived disadvantages:

- a) Security assurance is difficult; Accidental system troubles disrupt recording or daily operation. Sometimes, a stored record is deleted.
- b) It is difficult to draw attention to specific issues in the clinical process; with handwriting, it is easy to emphasize important parts of a document.
- c) Lack of flexibility in operation; specifically, slow response. Due to the complicated screen layers and monotone screen layout and presentation, the recording operation is made difficult.
- d) Time sequences are difficult to represent; information retrieval is difficult, especially across different data classes, such as test results and pharmaceutical history (Database structure has to be improved.)
- e) Interactive use involving several specialties is particularly inconvenient. This impacts team care negatively. (Traditionally, specialized sections have evolved independently, which now leads to the need to integrate these separate systems.)

## **7. Discussion**

In Japan, the development of hospital computerization has traditionally focused on support of patient treatment and the cost efficiency of the public health insurance system. Now we are facing the practical issues of the EHR. This raises several questions:

- 1) What is appropriate period for long-term storage of personal health data (PHD)?
- 2) How can we appropriately protect the patient's privacy and dignity in the use of these data?

To find a balance between the legal goals and the patient's interest is not easy.

### **7.1 The Structure of Japan Personal Data Protection Act**

The Japan Personal Data Protection Act was established in May, 2003. After adding new clauses such as the obligation of organizations dealing with personal data (Hospitals, healthcare facilities, nursing homes and so on in the medical field), it was put into effect in April, 2005. [3]

Since the act urges that ministries which manage the project "should develop the guidelines for the right" use of personal data, the National Life Council issued a guideline on personal data protection based on the fundamental principles and anticipated future direction of the act. [4]

Under the ongoing sophisticated computerization, and with consideration of the usefulness of personal data to both the public and private sectors, the act aims to protect personal right and benefit, including individuality, dignity, and property. This is expected to lead to well-balanced data access. [5]

It is not too much to say that medical services rely on the accumulation and use of PHD.

Besides, without doubt, "right" data access is the key to the improvement in public health and the development of science.

Here, the Personal Data Protection Act will be refocused in order to optimize medical care.

### **7.2 The requirements for EHR functionality**

The following principles have been defined for EHR functionality:

- a) Security, authenticity, accessibility on demand, and preservation
- b) Convenient and reliable documentation in accordance with the need of the medical staff during the team treatment process
- c) Support for prompt overview and easy generalization of medical treatment process on demand
- d) Information sharing by all staff concerned

On the other hand, despite our effort to fit the care process to system operation, the current imperfect system has, in the opinions of the healthcare staff, the potential to become so complicated and unusable that it might decline the operation efficiency and threaten safety.

We therefore have to re-evaluate the structure; functionality and architecture of our HR system from the perspective of safety and healthcare quality in order to arrive at a better blueprint for the next generation system.

### **7.3 Policy for the Structure of the Distributed EHR**

For the distributed EHR, temporary notes are distinguished from Official Clinical Data.

- (1) Temporary Note: In the clinic, temporary notes are made and preserved as memoranda in response to event occurrence in the healthcare process.

They serve as working documents that can be rewritten and reorganized (within a day), and from these memoranda, official clinical data are derived that can be disclosed".

- (2) Official Clinical Data: This class contains the statements in the electronic medical record that may be



disclosed. Statements can be confirmed by examination results and image data which are fixed format and unchangeable (additional data can be acceptable). (Fig.5)

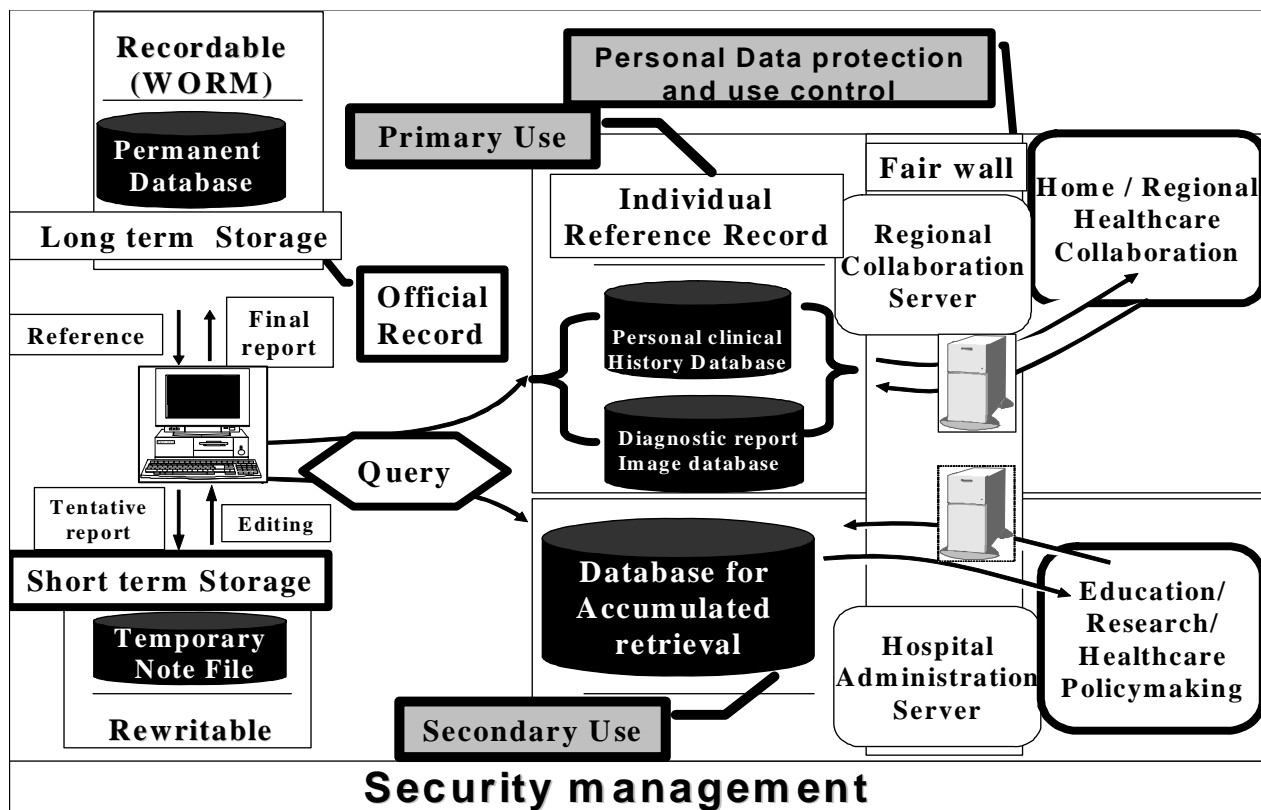


Fig.5 Conceptual chart of electronic health record in Hiroshima University Hospital and affiliate Institutes

### 8. Conclusion

Information technology guided communication should be the priority for the future in order to enhance the patient's participation in his healthcare, as well as safe management of team practice. In addition, our concept for the next generation EHR emphasizes safety management and patient participatory health care. Though the EHR is expected to render documentation quality more comparable, its social comprehension has not yet reached a consensus, and the idea that it is just the computerized version of the traditional paper record is still prevalent.

Technically, standardization of data content, of delivery procedures, and access control procedures are urgently needed.

Three years ago, the Japan Association of Medical Informatics (JAMI) launched the human development program to educate Healthcare Information Technologists (Health IT)". Now, at the end of 2005, there are 3843 Health Information Technologists. This is expected to contribute to a solution of the identified issues.

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