A Discussion Paper
on
Technical Standards for Health Care Systems
(revised 15th December 1997)

INTRODUCTION

Information Technology in Health Care is a rapidly developing discipline in Hong Kong. However, it is still a relatively new discipline and we only started into full gear just after 1991 in both the public and private sectors in Hong Kong.

The Hong Kong Hospital Authority IT Division now overlooks over 42 public institutions which cater for 92% of hospital service. For the remaining 8%, some of the 11 private hospitals are using computer automation for the purposes varying from patient billing and accounting, to laboratory and radiology systems nowadays. Primary health care, which is shared by the Department of Health and the private practitioners, has just started to make some progress in the use of Information Technology.

So, the parties involved in discussing the issue of technical standards in health care should include the Hospital Authority, Department of Health, the private hospitals and the private medical practitioners. In addition, academic bodies involved in health care researches and medical insurance bodies could be indirectly related to the issue. In any case, the scenario where technical standards issues could be discussed and negotiated is a much more simpler situation in health care sector than in other commercial issues.

Medical Informatics is an emerging discipline that has been defined as the study, invention, and implementation of structures and algorithms to improve communication, understanding and management of medical information. Standards in medical information would be required as a collection of specifications that has been endorsed by some groups so that they may all agree on these issues and therefore

share data easily.   These groups could include those within the same organizations such as the Hospital Authority, or between organizations such as public hospitals and private medical practitioners, or even between organizations and the public.

Over the last few years, there has been a major effort devoted to formalizing standards for healthcare in the international scene.   It is also a prime time now for Hong Kong to look into the establishment of standards in this rapidly developing discipline.   It is vital that such standards are fully "open", whether developed by formal standards bodies or otherwise.   The objective of the present study is to give recommendations so that different organizations in health care could have a reference for future development.   It is too premature for us to impose strict limitations in allowing different health care providers to try their new initiatives, particularly in the relative new and rapidly developing field.

Broadly speaking there are several categories of standards related to health care. These could include:

1. Standards that describe messages used to interchange information among healthcare information systems.
2. Standards for code values that represent medical concepts.   These may be used to populate data fields in messages or may be used in databases to assure that the information therein may be compared with that from other information systems.
3. Standards that describe medical knowledge.   These can include rules for decision making or expressing clinical pathways, medical logic (rules), semantic relationships among concepts, *etc.*

In practice, standards that are essential in supply chain management are also important in the health care industry as the industry also indulges heavily in material acquisition, procurement, stock inventory control, *etc.*

Owing to time constraint, the present study would be adopting a limited scope within the technical aspects of standards related to orthodox medicine.   Issues regarding the standards in the quality of health educational material distribution, information needs of the community on disease care and health services, which are strictly speaking NOT a technical issue but rather more on a moral issue, though equally important but would not be considered at the present time.   Special local requirements for alternative and traditional Chinese medicine have been considered and they conform largely to the similar approach with orthodox medicine.

THE STUDY APPROACH

1. Current initiatives in international standards will be identified and listed for reference. International organizations responsible for these issues will be identified.
2. The standards requirement for major health care issues in Hong Kong will be examined. The initiatives adopted will be identified.
3. The two will be compared to see if appropriate recommendations could be made.
4. Different stakeholders, namely Hospital Authority, Department of Health and Private Sectors will be consulted on the recommendations.
5. Final recommendations will be made.

THE STUDY GROUP

The group consisted of the following representatives:
1. Dr CP Wong, Chairman, Hong Kong Society of Medical Informatics
2. Mr Lawrence Yipp, Hong Kong Productivity Council (convenor)
3. Mr Anthony Cheung, Senior System Manager, IT Division, Hospital Authority
4. Ms Joycelyn Cheung, System Manager, IT Division, Hospital Authority
5. Dr CP Ho, Hong Kong Medical Association
6. Dr Alfred Tang, Estate Doctors Association
7. Dr Patrick Wong, Baptist Hospital
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9.

INTERNATIONAL ORGANISATIONS

At the international level, there are three principal standards organizations – ISO (the International Organization for Standardization), IEC (the International Electrotechnical Commission) and ITU-TS (the International Telecommunications Union, Telecommunications Standards Sector – previously CCITT). The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies from some 90 countries established in 1947. However, little of the work product is directly related to healthcare informatics. Though many are related to equipment. The World Health Organization also holds working groups working on standards including coding and classification of diseases.

At the European level, there are three principal standards bodies recognized by the Commission of the European Union. These bodies are CEN, CENELEC (Comite Europeen de Normalization Electrotechnique) and ETSI (European Telecommunications Standards Institute). In 1991, CEN/TC 251 (Comite Europeen de Normalization Technical Committee 251 in Medical Informatics) was set up, together with the regional workshops EWOS/EG MED (European Workshop in Open Systems Expert Group in Medical Informatics). The work of CEN/TC 251 is contained in a Directory (currently at version 1.8) which defines all the work items, together with the Working Group to which they are assigned.

In the United States, work of medical informatics generally preceded that in Europe. Notable organizations are the Institute of Electrical and Electronic Engineers (IEEE), the American Society for Testing and Materials (ASTM), the American College of Radiology and the National Electrical Manufacturers' Association (ACR/NEMA). The various bodies concerned with medical informatics standardization in the USA coordinated their efforts by creating a "Health Informatics Standards Planning Panel" (HISPP) under the auspices of the national standards body, ANSI.

At the international academic scene, the International Medical Informatics Association Working Group 16 on Healthcare Informatics and Telematics Standards was formed at the IMIA General Assembly Meeting in Vancouver, Canada in July 1995 under the chairmanship of Geroges JE De Moor. It serves as a catalyst for the possible creation of an ISO TC (Technical Committee). It is developing an Inventory of Standards which attempts to collect the existing initiatives worldwide.

THE STUDY TOPICS & RELEVANT STANDARDS IDENTIFIED

Technical standards in Health care could be conveniently divided into seven categories. These classifications are widely adopted worldwide by the International Medical Informatics Association and the CEN/TC 251. Relevant standards which are prevalently adopted by many countries are also listed for reference.

1. Healthcare Information Modeling and Medical Records

   - ASTM E1239 Standard Guide for Description of Reservation/ Registration Admission, Discharge, Transfer (R-ADT) Systems for Automated Patient Care Information Systems

   - ASTM E1384 Standard Guide for Description for Content and Structure on an Automated Patient Health Record

   - ASTM E1633 Specification for the Coded Values Used in the Automated Primary Record of Care

   - ASTM E1714 Guide for the Properties of a Unique Healthcare Identifier

   - ASTM E1715 Specification for an Object-Oriented Model for Registration, Admitting, Discharge and Transfer (R-ADT) functions in Computer Based Patient Record Systems

   - ASTM E1744 Guide for a View of Emergency Medical Care in the Computerized Patient Record

   - ASTM E1769 Guide for Properties of Electronic Health Records and Record Systems

   - MEDIS-DC Health Care Card System Standardization Manual

   - CEN/TC 251 The Electronic Healthcare Records Architecture

   - CEN/TC 251 Standard Architecture for Healthcare Information Systems

   - CEN/TC 251 Healthcare Information Framework

2. Healthcare Terminology, Semantics and Knowledge Bases

   - ICD-9CM International Classification of Diseases Version 9 with Clinical Modifications with procedure codes

   - ICD-10 Next generation of diagnostic codes developed by WHO

   - Read Codes: a comprehensive set of codes used to describe the care and treatment of patients

   - SNOMED: The Systematized Nomenclature of Human and Veterinary Medicine, a large and comprehensive multi-axial code system for medical vocabulary developed by the College of American Pathologists

   - UMLS: a cross referenced collection of codes and other data and knowledge sources developed by the National Library of Medicine

   - DSM-IV: diagnostic codes maintained by the American Psychiatric Association

   - ASTM E1284 Standard Guide for Nosologic Standards and Guides for Construction of New Biomedical Nomenclature

- ASTM E1460 Specification for Defining and Sharing Modular Health Knowledge Bases

- CEN/TC 251 Vital Signs Information Representation

- CEN/TC 251 Expression of the Results of Measurements in Health Sciences

- CEN/TC 251 Structure for Classification and Coding of Surgical Procedures

- CEN/TC 251 Structure of Concept Systems – Vocabulary

- CEN/TC 251 Registration of Coding Schemes

- CEN/TC 251 Categorial Structure of Systems of Concepts – Medical Devices

- CEN/TC 251 Time Standards for Healthcare Specific Problems

- CEN/TC 251 Medical Informatics Vocabulary

- CEN/TC 251 Medicinal Product Identification

3. Healthcare Communications and Messages

- HL7 Health Level Seven

- IEEE Draft P1157 and related series: Standard for Healthcare Data Interchange

- IEEE 1073 and related series: Standard for Medical Device Communications

- ASTM E1238 Standard Specification for Transferring Clinical Observations Between Independent Systems

- ASTM E1394 Standard Specification for Transferring Information between Clinical Instruments

- ASTM E1467 Specification for Transferring Digital Neuro-physical Data Between Independent Computer Systems

- ASTM E1713 Specification for transferring Digital Waveform Data between Independent Computer Systems.

- CEN/TC 251 Standard Communications Protocol for Computerized Electrocardiography

- CEN/TC 251 Identification, administrative, and common clinical data structure for Intermittently Connected Devices used in Healthcare

- CEN/TC 251 Medical Data Interchange: Information System to Modality Interface

- CEN/TC 251 Registration of Information Objects used for EDI in Healthcare

- CEN/TC 251 Request and Report Messages for Diagnostics Services Departments

- CEN/TC 251 Messages for Patient Referral and Discharge

- CEN/TC 251 Methodology for the Development of Healthcare Messages

- CEN/TC 251 Messages for Exchange of Healthcare Administrative Information

- CEN/TC 251 Investigation of Syntaxes for Existing Interchange Formats to be used in Healthcare

- ANSI ASC X12N Message Standards for Insurance in Healthcare

4. Medical Imaging and Multimedia
   - DICOM v3.0 Digital Imaging and Communications in Medicine
   - CEN/TC 251 Medical Imaging Communication MEDICOM ENV 12052:1996
   - CEN/TC 251 Media Interchange for Medical Imaging Communication
   - CEN/TC 251 Medical Image Management – Part 1: Storage Commitment Service Class

5. Clinical Laboratory Information Systems
   - ASTM E792 Standard Guide for Computer Automation in the Clinical Laboratory
   - ASTM E1029 Standard Guide for Documentation of Clinical Laboratory Systems
   - ASTM E1246 Standard Practice for Reporting Reliability of Clinical Laboratory Computer Systems
   - ASTM E1381 Standard Specification for the Low-Level Protocol in Transferring Messages between Clinical Laboratory Instruments and Computer Messages
   - ASTM E1466 Specification for the Use of Bar Codes in Clinical Laboratory Specimen Management
   - ASTM E1639 Guide for Functional Requirements of Clinical Laboratory Information Management Systems
   - ASTM E1612 Specification for Representing Clinical Laboratory Test and Analyte Names
   - CEN/TC 251 Supporting document to ENV 1613:1995; Messages for Exchange of Laboratory Information
   - CEN/TC 251 Messages for Exchange of Laboratory Information
   - CEN/TC 251 Concept Structure for Nomenclature, Classification and Coding of Properties in Clinical Laboratory Sciences

6. Healthcare Security and Privacy, Quality and Safety
   - ASTM E1762 Guide for Electronic Authentication of Health Care Information
   - CEN/TC 251 Security Categorization and Protection for Healthcare Information Systems
   - CEN/TC 251 Algorithm for Digital Signature Services in Healthcare
   - CEN/TC 251 Secure User Identification for Healthcare – Management and Security of Authentication by Passwords – Healthcare Oriented IT Security

7. Supply Chain Management issues related to the Health Care Industry
   - UN/EDIFACT

IMPORTANT INITIATIVES

1. HL7: Health Level Seven is a health care application protocol founded in 1987 and accredited as a Standard by the American National Standards Institute (ANSI) in 1994. Level Seven refers to the highest level of the International Organization for Standardization (ISO) communications model for Open Systems Interconnection (OSI) – the application level. Issues within the application level include definition of the data to be exchanged, the timing of the exchange and communication of certain errors to the application. This level supports such functions as security checks, identification of the participants, availability checks, negotiating exchange mechanisms and, importantly, structuring the data exchanges themselves. HL7 focuses on the interface requirements of the entire health care organization. It allows development along the fastest possible track to the unique requirements of already installed hospital and departmental systems, some of which use mature technologies. The current Standard is frequently referred to HL7 Version 2.2 Standard (though the HL7 Version 2.3 Ballot Draft #3 is also available). The Hospital Authority IT Division functions at present are all conforming to this standard as far as possible.

2. DICOM & MEDICOM: (Medical Imaging Communication) The Medical Image and Related Data Interchange Format Standard MEDICOM (ENV 12052:1996) references the DICOM (Digital Imaging and Communications in Medicine) 3.0 Standard, developed by ACR/NEMA (American College of Radiology/National Electrical Manufacturers Association). CEN/TC 251 /WG 4 contributed to the development and review of DICOM 3.0, thus ensuring that European industry and user needs were included. By basing this Standard on DICOM, CEN has facilitated world-wide harmonization of Medical Imaging Communication Standards with existing industry standards. This Standard facilitates interoperability of medical imaging equipment by specifying:

    a. A unique architecture for Communication in Medical Imaging;

    b. For on-line communication, a set of protocols to be followed by devices claiming conformance to the Standard as well as the syntax and semantics of Commands and associated information which can be exchanged over a network interface using these protocols.

    c. For off-line communication, a set of media storage services to be supported by devices claiming conformance to the Standard as well as a File Format and a medical Media Storage Directory structure to facilitate access to the images and related information stored on an interchange media;

INITIATIVES IN NEIGHBOURING COUNTRIES

At the Asia Pacific rim, Japan and Australia have done much work in the development of technical standards for some years. Singapore and the Philippines have also shown some initial moves just recently towards forming a similar committee as in Hong Kong.

THE LOCAL INITIATIVES

In the Hospital Authority the following International Technical Standards in Health Informatics have been or will be adopted in some of their IT Systems:

1. ASTM E1381 – Laboratory Information System LIS adopted for analyzers (Standard specifications for low level protocol in transferring messages between clinical laboratory instruments and computer messages)
2. ASTM E1394 –Laboratory Information System LIS adopted for analyzers (Standard specifications for transferring information between clinical instruments)
3. ASTM E1384 – Clinical Management System CMS: under study (Standard description for content and structure of computer based patient record)
4. WHO ICD 9CM – Clinical Management System CMS: adopted (World Health Organization – International Classification of Diseases Version 9 with Clinical Modifications
5. WHO ICD 10 – CMS will be adopted
6. SNOMED – LIS adopted (The Systematized Nomenclature of human and veterinary medicine)
7. DICOM – Radiology Information System RIS will be adopted (Digital Imaging and Communications standard)
8. HL7 – Health Level Seven: will be adopted

Currently, common coding systems such as the Hospital Authority master disease code table (an adjunct tool for cross-referencing ICD9CM) have been used across systems between different hospitals. The Patient Card System also interfaces with organizations outside Hospital Authority (the HK Polytechnic University Student Health Service)

THE SCOPE OF TECHNICAL STANDARDS APPLICATIONS

Technical standards in health care could be important in the following different scope of service arenas:

1. Between different devices and machines: e.g. autoanalyzers and medical imaging devices.
2. Within the same organizations: e.g. sharing of information within Hospital Authority hospitals.
3. Between public and private hospitals: e.g. patient records transfer, medical imaging transfer.
4. Between Government and the health care providers: e.g. reporting disease statistics annually.
5. Between hospitals and private practitioners: e.g. patient referral and reply letters.
6. Between health care providers and the public citizens: e.g. medical educational materials (where moral and accuracy standards are more relevant)

The working group considers that at the present moment, basic technical standards between devices and within the same organization are more important. Whereas further development in standardization is concerned, the minimal standards regarding patient medical record information transfer between hospitals and private practitioners are more important issue than others. The use of Chinese Characters and Chinese format of medical information and classification is generally regarded not as a problem as the issues of two-byte representation and conformation to international classification of diseases and medical knowledge are usually followed.

DRAFT RECOMMENDATIONS:

1. In view of the relatively new development and rapid expansion of IT in health in Hong Kong and also in the international scene, it is likely that any recommended Technical Standards should be as 'open' as possible. Unless clearly necessary, a rigid restriction is not recommended. Users should be encouraged to observe the experience of others both locally and internationally before they decide what they should conform to.

2. However, as widely used in HA Hospitals and also a statutory requirement for all health care providers to report the annual statistics of diseases to the Government, the WHO ICD9CM World Health Organization International Classification of Diseases Version 9 with Clinical Modifications will be recommended as the standard in Disease Coding.

3. Furthermore, the DICOM Digital Imaging and Communications Standard should also be recommended as it is the most popular version used in the world and different standards may hinder ready communications between institutions, unlike textual information.

4. As interchange of patient medical record data is considered an important issue in health care, the minimum technical standards in regulating the content of a patient medical record should be developed in Hong Kong. This should be agreed between different parties concerned.

5. Standards relating to Medical Optical Cards and Smart Cards are also required to avoid florid proliferation of different devices and systems in the territory.

6. Issues related to quality and standards related to information needs of the community on disease care, nutrition, medicine, medical services, *etc* should also be addressed, preferably in conjunction with local medical associations and academic bodies. Furthermore, the special local requirements for Traditional Chinese Medicine and alternative medicine should be addressed in the future.

7. All international and local initiatives should be updated and compiled regularly and put in a suitable web site for all health care providers to share.

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