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Volume 1 Issue 5

2003

ISSN 1479-649X

The Journal on Information Technology in Healthcare

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Subscriptions

The Journal on Information Technology in Healthcare is published 6 times a year. 2004 subscription prices (6 issues) are :

| | Institutional | Individual |
|-------------------|---------------|------------|
| Great Britain | £120 | £100 |
| Europe | €200 | €180 |
| USA | US\$220 | US\$180 |
| Rest of the world | £135 | £115 |

Payment can be made by cheque or banker's draft. Cheques should be made payable to The Journal on Information Technology in Healthcare. Subscription orders and requests for sample copies should be sent to: JITH, 72 Churston Drive, Morden, Surrey, SM4 4JQ, UK. E-mail: subscriptions@jith.net. Fax : +44 (0)870 130 1572.

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Publisher: Health Technology Press, 72 Churston Drive, Morden, Surrey, SM4 4JQ, UK.

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Typeset by Toby Matthews, Oxford.

Printed by Saleh Aldossry, KSA.



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CONTENTS

- Towards Global Inter-operability: Health Level Seven as the Enabling
Technology
Stephen Chu 313
- The Use of Health Informatics to Improve Health and Healthcare
W. Ed Hammond 321
- Laboratory Data Exchange Using HL7-Interface Engine
*Po-Hsun Cheng, Jin-Shin Lai, Fong-Ming Shyu, Heng-Shuen Chen,
Jer-Junn Luh, Sao-Jie Chen* 331
- Synthesising the Technologies of Web Services and Intelligent Agents
to Build an HL7/XML-Based Infectious Disease Reporting System
*Ruey-Kei Chiu, Chih-Yung Yang, Chia-Ching Huang, Kuo-Ching Tsai,
Chien-Lung Chan, Kevin Chang* 343
- An Open Source Intelligent HL7 Agent for Integrating Laboratory
Information
An-Jim Long, Chien-Tsai Liu, Polun Chang 357
- Archetypes, GEHR, openEHR and Electronic Health Records
Ping Yu 369



Towards Global Inter-operability: Health Level Seven as the Enabling Technology

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INTRODUCTION

Episodic healthcare delivery has characterised healthcare service models of the past. This model was effective and suitable for dealing with acute illnesses and accidents, but over the last two decades an increasingly elderly population and advances in medical treatment have changed the focus of healthcare delivery to provision of services for the chronically ill. Today up to seventy percent of patients presenting to healthcare agencies have chronic illnesses^{1,2}. The acute care model is not ideally suited or effective for dealing with these patients. Optimal medical management for patients with chronic illnesses requires an integrated or coordinated care model. This entails multi-disciplinary care with sharing of patient information and knowledge by individual carers. One possible means of achieving this is through the longitudinal electronic healthcare record (EHR).

The EHR is regarded as the ultimate health information documentation and communication tool. It will in its complete form contain all the patient's relevant medical history from birth to death irrespective of where, when and by whom they have been treated. The record will be accessible to authorised healthcare professionals anywhere in the world. This geographical independence of the record is important in view of global trends in population movement. For example, in Australia and New Zealand population censuses have demonstrated that intra-nation population movements occur at the rate of 15–20% per year³. Inter-nation migration also happens very regularly, although at varying rates for different countries. These population movements, increasing globalisation and international travel will mean that to be successful an EHR system will have to adopt a distributed architecture. A major obstacle to its current implementation is the heterogeneity that characterises the existing distributed architecture and disparate health IT systems. Effective exchange of information and knowledge cannot at present easily or readily take place between different health providers.

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HEALTH LEVEL SEVEN: THE INTER-OPERABILITY SOLUTION

To achieve effective data exchange between different systems it is necessary to have common standards. In the mid-1980s, Health Level Seven (HL7)⁴ was established to develop healthcare data messaging standards. Its goal is to improve interoperability among heterogeneous medical information systems. Two levels of interoperability need to be addressed:

- Syntactic inter-operability
- Semantic inter-operability

Syntactic inter-operability refers to the ability to transfer data in a systematic orderly manner, for example, the grammatical arrangement of words in sentences. For inter-healthcare system inter-operability, this also means standardisation of the data and message structure. A high degree of success in accomplishing this has been achieved with HL7 Version 2. This was first released in 1988 and has been modified over the years to the present Version 2.5. Its global applicability to healthcare messaging standards is reflected in the fact that it is used in 24 different countries and by 90% of US healthcare facilities.

Semantic inter-operability refers to the uniformity of the medical content and definitions of the healthcare concepts used in the records. Achieving agreed standards for this is a more complex problem. This is due to the fact that medicine has a large vocabulary and lacks a universally standardised terminology or accepted classification of diseases. For example, a patient with lung disease may be labelled as suffering from chronic bronchitis by one physician, chronic obstructive airways disease by another and chronic obstructive pulmonary disease by a third. Each of these definitions may have slightly different meanings to different physicians which in turn may influence management. Uniformity in terminology is important when data is being shared between different carers. It is also essential if data is to be subject to data mining or collation for research. This could, for example, be used to determine the aetiology or most effective treatment for a disease.

Creating a universally accepted terminology *and* persuading healthcare professionals to use it is a major challenge. Examples of systems proposed include:

- The Unified Medical Language System (UMLS)
- International Classification of Disease (ICD)
- Systematized Nomenclature of Medicine (SNOMED)
- Logical Observation Identifier & Codes (LOINC)

HL7 Version 2.5 and Version 3 have a mechanism for users to specify standardised codes for clinical concepts and the coding systems used in the healthcare data exchanged. A Reference Information Model (RIM) has also been created to support development of Version 3 messaging. Key data elements described in the RIM are linked to vocabulary tables. By supporting the use of structured, codified clinical concepts in the standard message protocols, HL7 provides an environment for achieving semantic inter-operability in HL7 messages⁵.

Another challenging area is finding an effective way to represent contextual relationships between interrelated clinical concepts. The use of ‘Act-Relationship’ object class and ‘Context-Lock-Indicator’ object in HL7 Version 3 addresses the ‘context relations’ representation gaps that exist in Version 2.5. For example, a patient diagnosed as being HIV positive may not wish his family to know the diagnosis. The ‘Act-Relationship’ can be used to link the confidentiality consent status of the diagnosis data to the person who imposes the confidentiality constraint on the data. The ‘Context-Lock-Indicator’ can be used to link a set of interrelated laboratory tests together or to link observation/complication findings to certain medication/treatment. The following example shows the use of ‘Context-Lock-Indicator’ and ‘Act-Relationship’ to bind a set of laboratory tests together indicating that they should be read together.

```
<observation V="CBC">
  <context_lock_ind V="T"/>
  <!-- means you shouldn't interpret the nested
        observations without the outer observation.
        the value (V) of which is set to "CBC" (complete blood count).. -->
  <act_relationship V="COMP">
    <context_control_cd V="C"/>
    <!-- means that the acts in this act relationship
          "conduct" the context of the outer observation,
          including name of patient, and when required
          other participations e.g. who performs the tests, etc... -->
    <observation V="HGB">
      <value V="14.3"/>
    </observation>
    <observation V="PLT">
      <value V="117"/>
    </observation>
    <pertinentInformation typeCode="MFST">
      <act_procedure V="Blood Transfusion">
        <value V="3 Unit"/>
      </act_procedure/>
    </pertinentInformation>
  </act_relationship>
</observation>
<observation V="LFT">
  <!-- liver function test items and results -->
</observation>
```

In the above example, ‘context_lock_ind’ is used to bind a set of interrelated tests (CBC – Complete Blood Count) together. This means that all test items (e.g., HGB – haemoglobin and PLT – platelet count) performed on this patient should

be read together. The 'act_relationship' indicates that all data bound within the <act_relationship> and <act_relationship/> tags is to be treated as a composite (COMP) data set and that the observations (blood test) CBC results were shown as a "manifestation" (MSFT) of the procedure of three units of blood transfusion given to the patient. Another test (observation) result with values equal to "LFT" (liver function tests) was also performed on this same patient. The test data lies outside the 'context_lock_ind', hence, the data ("LFT") are to be treated as independent from other test data ("CBC") shown in this example.

Likewise, a set of diagnostic tests and/or procedures can be linked in a similar way to one or more clinical problems or diagnosis. This will give the context (or reasons) under which the diagnostic tests or procedures are performed.

Recently the HL7 and openEHR⁶ communities began much closer collaboration in an attempt to more effectively address the context relationship representation problems. Archetype is defined as "a computable expression of a domain-level concept in the form of structured (with business rule) constraint statements, based on some reference information model"⁷. It is a formal definition of a specific clinical concept for potential inclusion in an EHR. Essentially an archetype is presented as a 'template' for clinicians to define the clinical concepts and organising relationships between the concepts. For example, an 'Asthma' archetype allows related observations and management to be linked together contextually (Figure 1). The openEHR archetype and HL7 clinical templates have

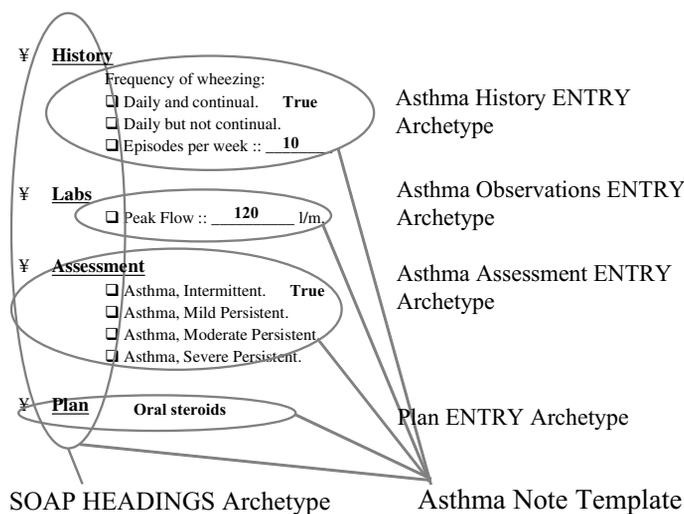


Figure 1. Example of an asthma archetype

The archetype is structured under Simple Object Access Protocol (SOAP) headings. For each heading the inputs can be defined by check boxes or numerical values. For numerical values an upper and lower range of values are set to help prevent accidental entry of wrong/inappropriate values e.g. a set of range (maximum and minimum) values for a peak flow rate appropriate to a patient's sex, age and size.

been proposed as the technical solution to provide the semantic inter-operability. The archetype, in particular, has been proposed as the effective structure for easily building and maintaining clinical data contextual relationships. Archetypes representing clinical concepts and their relationship can be included in HL7 messages for transmission from one system to another. Since each archetype conforms to the agreed standard, syntactic and semantic inter-operability at machine and human levels is ensured.

The 'Clinical Context Object Workgroup' (CCOW) Technical Workgroup is a technical group (within the HL7 community) that is set up to build a standard (used by a context manager) for establishing and maintaining common context between different or heterogeneous applications that present information about the same patient to users on their desktops⁸. CCOW is a technology and standard that complements HL7's traditional emphasis on data interchange and enterprise workflow. Using a technique known as context management, the clinical user's experience is one of interacting with a single system, when in fact he or she may be using multiple, independent applications from many different systems, each via its native user interface. By synchronising and coordinating applications so that they automatically follow the user's context, the CCOW standard serves as the basis for ensuring secure and consistent access to patient information from heterogeneous sources. The benefits include applications that are easier to use, increased utilisation of electronically available information, and an increase in patient safety.

Clinical guideline representation and decision support are two other technical workgroups within HL7 that seek to align their work with HL7. These groups, which include the Guideline Element Model group⁹ (from Yale University), the UK Clinical Practice Guideline Architecture group¹⁰, the Arden Syntax⁴, and the SAGE project¹¹ groups realise the importance of standards for data communications between decision support and clinical information management applications. Mappings of data structure from the various guideline representation works and the Arden Syntax to the HL7 RIM had identified a number of issues. The technical groups have started to investigate the use of the HL7 Development Framework as requirement analysis methodology and for identifying harmonisation requirements with the RIM classes.

This issue of the journal is based on papers presented at the *2nd Asia-Pacific and Cross-Strait HL7 Conference on Healthcare Information Standards* that was held in Taipei, Taiwan earlier this year. Papers presented at the conference demonstrated the variety of ways in which the development of HL7 standards is enabling healthcare organisations to achieve effective information transfer, and improve the healthcare process.

The keynote lecture was given by Professor Hammond, a past Chairman of the HL7 organisation. He elaborated on the role of health informatics in improving health and healthcare through the construction of electronic health records. He

pointed out that these could be used for a wide range of purposes including improving patient safety, treatment effectiveness, research and disease surveillance. As a consequence EHRs have the potential to improve care not only for individual patients but also for whole populations. He finished his lecture by emphasising the need for standards to create EHRs and highlighted the role of the HL7 organisation in providing these.

From the many excellent research papers presented at the meeting, three have been selected to illustrate how HL7 standards are being used to overcome the problem of data transfer between heterogeneous information systems and deliver some of the perceived benefits referred to by Professor Hammond in his paper.

The first research paper by Cheng and colleagues provides insight into the use of the HL7-Interface Engine (HL7-IE)/Gateway to facilitate successful information interchange between hospital information systems and laboratory/diagnostic (and imaging) systems. This enabled effective online ordering and results reporting. The success of the project was highlighted by the ability of the programming team to use different hardware platforms and application development environments such as COBOL, Visual Basic, JAVA, JSP, etc. to build the HL7-IE /Gateway solution and still make the various components work together well. The authors have provided a useful flow diagram to help personnel at other hospitals evaluate whether they need to implement an HL7 system to enable information transfer between their laboratory instruments and information systems.

The next paper by Long and colleagues also deals with the use of HL7 standards for laboratory systems. A major barrier identified to the implementation of HL7 in Taiwanese hospitals is the complexity of the HL7 interface and the expense of implementing it. The authors describe the use of intelligent HL7 agents to map data from a laboratory information system database schema to HL7 message format. This enables the easy generation of HL7-based laboratory messages for hospital information systems. As the authors point out, the use of the intelligent agent simplifies implementation, minimises customisation and saves both time and costs.

The third paper reports on the use of HL7 messages to facilitate automatic data transmission and reporting of infectious diseases from healthcare agencies to the Centre for Disease Control in Taiwan. Use of such a system facilitates more effective disease surveillance. The use of intelligent agents to autonomously and continuously monitor and report new cases of infectious diseases is described. The project again demonstrates the successful use of the HL7 messaging schema and the conceptual model for intelligent agent-based data monitoring and workflow management.

The research papers presented and ideas discussed at the conference confirmed that the healthcare industry considers the development of standards to be a critical success factor for machine and human inter-operability. A wealth of HL7 standards, development knowledge and experience exists within the international

HL7 community. It will be useful if extensive networking facilities can be established to enable cross-fertilisation of ideas and to assist the less experienced to overcome knowledge deficits and technical hurdles.

The successful development and implementation of HL7 standards in the Asian-Pacific countries affirms that HL7 is the international currency for health information interchange. HL7 represents an important and highly useful solution for achieving syntactic and semantic inter-operability that will enable the creation of EHRs, and the potential benefits associated with them.

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The Use of Health Informatics to Improve Health and Healthcare

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INTRODUCTION

Although some of the earliest applications of computers were in the healthcare arena, successes have been limited in the impact of computers in health. Widespread use has not occurred and the stability of commercialisation in the field has been unpredictable at best. We still await total acceptance of a proven value proposition for clinical use of computers. Over the half century since computers began to appear on the scene, the “holy grail” of the electronic medical or health record has yet to be realised.

In much of the world today, that situation is rapidly changing. Two publications by the Institute of Medicine have had a major impact on increasing awareness of the many stakeholders in health on the need for major improvements in the health system. *To Err is Human: Building a Safer Health System*¹ stated that approximately 98,000 deaths per year were attributed to medical errors making it the 5th leading cause of death in the United States. *Crossing the Quality Chasm: A New Health System for the 21st Century*² identified poor and inconsistent quality of care in the United States and called for a safer, timelier, efficient, effective, patient-centred and equitable health system. Added factors include the rising costs of healthcare, particularly drugs; the importance of effective management of chronic diseases; the move to evidence-based medicine in light of an exponentially increasing volume of knowledge in diagnosing and treating diseases; outbreaks of new diseases (e.g. SARS – Sudden Acute Respiratory Syndrome, West Nile virus, Monkey pox and AIDS – Acquired Immune Deficiency Syndrome); the threat of bioterrorism; and rising consumer interests in participating in their own health and healthcare. Finally, the aging of the “baby boomers” threatens to saturate the healthcare system with their needs and demands.

It has become increasingly clear that all of these concerns can only be addressed through the introduction of an integrated, computer-based healthcare system with connectivity at a national level. The National Committee on Vital and

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Health Statistics, the President's Information Technology Advisory Committee and the Institute of Medicine, have all emphasised the importance of a national health information infrastructure (NHII). This is deemed to be essential to improve patient safety and quality, rapidly detect bioterrorism and other health threats, and enhance the efficiency of the healthcare system. The recommendation stated, "*Recent events underscore that an effective NHII is not a luxury but a necessity; it is not a threat to our privacy but a vital set of resources for preventing and addressing personal and collective health threats.*" The recommendation also stresses that the initiative must be a public/private collaboration.

In March 2003 in an address to the American Medical Association, the Secretary of Health and Human Services, Tommy G. Thompson stated "*It is important for the federal government to lead by example by selecting and adopting these clinical data standards. With appropriate privacy protections for personal health information, consumers and patients will benefit when their health information is available to their doctors and other health care providers when it is needed, such as in the emergency room. But we cannot do it alone. The private sector will be crucial to the widespread diffusion of these standards.*" He endorsed the work of the federal government's Consolidated Health Initiative (CHI), a consortium of federal agencies with an interest in IT in health. The objective is improved patient safety and cost savings. Thompson recognised the need for a common coding system. The goal of this effort is to ensure that health information is available to the patient's doctors and other healthcare providers when it is needed. Thompson stated, "*Health technology is going to be the key driver of change for the 21st century.*" At the National Healthcare Information Infrastructure meeting "*Developing A National Action Agenda for NHII*" in July 2003, Secretary Thompson announced that the government had purchased a 5-year license for Systematized Nomenclature of Medicine (SNOMED) CT through the National Library of Medicine that would make SNOMED available for use in the U.S. at no cost. He also announced that the Institute of Medicine, working with the HL7 standardisation process, had been commissioned to create a standard specification for the required functionality of the Electronic Health Record. This technical specification will be the basis for a programme to act as an incentive for providers to use an EHR to increase quality and reduce medical errors.

A number of policy setting bills have been introduced in Congress, including bills for patient safety, improving quality, creating a national network and for adopting the EHR. Several important issues remain to be addressed. It is critical that the federal government takes the lead in establishing the infrastructure for the NHII. That infrastructure not only must define the leadership but also provide the funding and momentum to create the vision, the plans, and ultimately the physical connectivity to make this become a reality. The government should continue to support the adoption and implementation of existing standards and encourage through funding and other mechanisms other standards that will be

required for an NHII. The government should support certification of vendors to compliance of standards and create funding and processes to distribute and maintain standards and knowledge bases including terminology, clinical guidelines, clinical documents, clinical templates, master data registries, disease registries and other appropriate items. The government should support research in data mining, in health surveillance and in the analyses of the data in these nationally linked databases to improve our understanding of the:

- Occurrence of diseases
- Causes of diseases
- Differences in outcomes
- Treatment effectiveness
- Patient safety
- Clinical trials and other research
- New methods of surveillance

Much of the expenditure in research today is spent on establishing the infrastructure to collect the data, mix the data and create the databases. With an effective and efficient population dimension, much of that work will have been completed and the funding can be used more effectively for research.

This paper describes some background to set the stage for what is needed to effectively use information communications technology to improve the health-care systems to meet the needs of the 21st century.

BACKGROUND

The Electronic Health Record (EHR) has been the ultimate goal of the informatics industry from its beginning. In the United States today, only 5% of physicians have access to a true EHR. Researchers have worked on the development of this “thing” for almost 50 years. Yet, there is no commonly understood definition of what an EHR is or should be. Over the years “it” has been given many names, most chosen to keep up with the trends and what is deemed to be politically correct. It has been called the Automated Medical Record (AMR), the Computerised Patient Record (CPR), the Computer-based Medical Record (CMR), the Electronic Medical Record (EMR), the Electronic Health Care Record (EHCR), the Electronic Patient Record (EPR), the Person Medical Record Information (PMRI) and others.

Historically, the healthcare industry has largely focused on the inpatient environment and on Hospital Information Systems (HIS) for several reasons. First, the focus of the HIS has been the service components – Admission/Discharge/Transfer (ADT), and order management and result reporting. They are allied mainly to larger hospitals that can afford the substantial capital and yearly maintenance costs. Further, physicians in the hospital settings tend not to be as time constrained as physicians in the outpatient setting. As a result, the HIS dominates

the IT market in the inpatient setting. The HIS database is defined by the service functions, and the data is frequently available on-line for a limited time after discharge. With the advent of cheaper and larger storage, that situation is changing but provides little additional value as will be discussed later.

The most common computer systems in hospitals today are billing and accounting systems. In most cases, these systems are independent of the clinical HIS, if such systems exist. Data for accounting systems are still entered from paper and are optimised for maximum reimbursements by human experts, and more recently by expert computer systems. The database of most if not all HISs could not be called an EHR.

Department systems (laboratory, pharmacy, radiology, materials management) were for many years not linked to the HIS. Data were reported in paper form, even if the departments were computerised. A familiar sight in the 1960s and 1970s was two terminals sitting side by side, with a human operator transferring data from one system to another. In the 1980s, customised, expensive, one-of-a-kind interfaces were developed to permit the electronic transfer of data from the departmental systems to the HIS. Standard Developer Organisations (SDOs) were created in the late 1980s to create standards for the interchange of data, and again the initial focus was on the hospital information systems. Imaging standards for Picture Archiving and Communications Systems (PACS) and Radiology Information Systems were developed by different groups with an interest in imaging equipment.

Other computer applications in the healthcare settings are really subsets of the HIS and include what are now known as Computerised Physician Order Entry (CPOE) and ePrescribing Systems. Additional databases known as data repositories are used to distribute HIS data among the various clinical units.

Most hospitals in the United States currently support some form of computerisation of data. An estimated 13–15% of hospitals have some form of electronic prescribing; however, providers enter less than 25% of their orders electronically. Most systems serve administrative and financial requirements; in the clinical area, the functions are primarily service related. Paper is still the primary form for storage of data for patient care. In outpatient settings, the use of computers is predominately for patient management (administrative and financial). Less than 8% of providers in the United States use an electronic health record.

In the outpatient world, practice management systems have flourished and largely provide a billing function. Most outpatient systems were based in academic settings, and a few of these have been successful in the commercial arena. Outpatient systems must sell for a lower price and still have to deal with such issues as training, maintenance and development. Many speciality systems exist, focused on clinical specialities such as obstetrics, paediatrics, cardiology and others. Other systems address clinical purposes such as emergency departments, surgery systems, nursing homes and home care.

Finally research databases, data warehouses and data mining, and disease registries complicate the picture. The consequence of all of these disparate systems, driven by the health IT industry and based on what customers will buy is that few if any true EHRs exist in the world today.

In addition, what might be kindly referred to as EHRs today are further identified by site: inpatient and outpatient EHRs; by function: primary care, intensive care, emergency department, nursing, nursing home, billing/claims, research; and by disease: diabetes, oncology, coronary artery disease, myocardial infarction, hypertension, etc.

DEFINING THE EHR

As work continues to progress on the EHR, its definition and role must clearly satisfy multiple criteria based on site, purpose and function and view. It is important to note that the EHR serves, in any setting, multiple purposes. Clearly one important purpose is for patient care and the documenting of that care. It is the legal record for data, decisions, treatments and outcomes. It serves the purpose of billing. It is subject of audit for quality evaluation, accreditation, identifying medical errors and guaranteeing patient safety, creditation of health care providers, education, evaluation, research, reporting of various types and others.

The EHR is more than a data repository. How the data is stored, the EHR architecture, what data elements are stored and the data representation are very important, but those characteristics are only part of the story. The functionality and features are equally important in the management of workflow and information flow. Those characteristics also vary from location to location. What is required to support IT management in the inpatient setting is quite different to what is required in a primary care setting. A nursing home will require less data than an intensive care unit. Therefore, it is reasonable to believe that there will be more than one type of EHR – depending on setting and purpose. The site of care is one of the most important features for defining the EHR in that setting. The persistence of the data will also vary with site and purpose. However, the most important concept of the EHR is that it must be patient-centred and that requires a comprehensive, aggregated patient record. That aggregated patient record means that data must be shared and must be interoperable among all sites of care. Therefore, all types of the EHR must be interconnected and interoperable. This in turn means that a common set of data elements must be shared among all settings, and the different view of the EHR must be overlayable.

The EHR is not a clinical repository. Its purpose is to enhance and enable the care of the individual, and its contents are solely justified for that purpose. When data ceases to contribute to patient care, it should be removed from the EHR. The purpose of the data warehouse is to retain all data forever. The EHR documents the process of care, the gestalt of decision making, the data on which decision

making is based, expectations and goals, diagnostic and treatment process, quality measures, outcomes, and health and functional status. The EHR provides workflow and information flow management.

The linkages among the various EHRs will depend on operational factors. For example, in an oncology hospital, there is value in having a linked inpatient and outpatient EHR, since patients may move freely between those two settings, sometimes on the same day. As an example, a bone marrow transplant patient at Duke may move between an inpatient setting, the haematology clinic, the bone marrow transplant unit and the residential housing. Linkages support data flow as well as workflow among all the units. Enterprise systems need well-defined linkages among its participating bodies. A home care visit from a hospital staff member needs to be prompted by the inpatient or outpatient database and the results of the home care visit brought back into the system. A nursing home needs specifically defined information flows between various inpatient hospital settings, among primary care settings and among pharmacies.

We cannot afford to collect data multiple times. Data must be reusable and must serve all purposes. If decisions are made on data generated elsewhere, the integrity and the appropriateness of the data must be guaranteed. Research databases and claims databases must be derived from the clinical care database. Service processes must be integrated into the EHR and its functionality. Ideally, the reimbursement process will be integrated into the clinical systems and decisions made in real time as care is delivered.

Recognition that the quality of data required for clinical use and research is similar, and that the costs of recruiting patients for clinical trials and acquiring the research data independent of the clinical process is prohibitive, has led to models that perform both services as well as reporting for various purposes and reimbursement. An increasing interest on the part of the consumer in their health and in participating in informed decisions relating to their health and healthcare has introduced a new component to the traditional hospital-based, illness treatment model for healthcare. This new consumer interest has opened many new avenues for information management and information sharing including the concept of the personal health record and access to health-related information on the Internet with corresponding problems of quality control, authentication, appropriateness and understanding. Medical advice and prescribing on the Internet has raised many new issues in ethics and in legal issues including differing state laws regulating the use of these resources. The consumer interests have increased visibility in models for community healthcare, and includes nursing homes, home health, skilled nursing, rehabilitation, retirement communities, public kiosks for education, “*shopping mall health testing*” including MRIs and other imaging, cardiovascular testing, and a wide variety of other diagnostic testing. Continued emphasis on preventive care and healthy lifestyles has changed the focus in the United States from an electronic medical record to an electronic health record.

All of these factors have resulted in new views of what is required for the use and management of clinical and administrative data in health. The model includes three views of the EHR:

- An institutional/provider EHR that is similar to what most people recognise today as the medical record
- A population health record that is defined regionally and linked nationally
- A personal health record

For most institutions in the United States today, institutional/provider data exists primarily in paper form, and even if electronic, it is not linkable and shareable with other systems. The relationship of the EHR to the ordering process (CPOE and ePrescribing systems), the Hospital Information System, ADT systems, departmental systems, etc. as well as different settings (e.g. inpatient care, outpatient care, nursing homes, intensive care, emergency departments) must be considered. This record also serves the purposes of credentialing, billing, reporting and administrative management including staffing.

The “*population view*” serves the need for public health in health surveillance and monitoring for bioterrorist events. This population health record, a summary record derived from the multiple points of care, can also serve research purposes for the better understanding of prevalence of disease as a function of many environmental factors such as geography, weather, occupation, etc., and understanding differences in treatment and outcomes. The population record will also serve as a communicator, with the person’s permission, among all the providers involved in a person’s health. The consumer should be able to control and monitor access to this record.

The final view is the personal health record, which is growing in popularity in the United States. Throughout all of these views, the focus is patient-centric. Exactly what is meant by this term is still being discussed, but essentially it means the focus is on the patient. It means that data is independent of the source and input, the storage and the presentation. The data is accumulated and analysed to provide a current view of a person’s health status as well as a predictor for future events. With this focus on the patient, however, it is important to note that there are many other uses of the EHR including a provider-centric view.

Given these visions of the EHR, it is obvious that interoperability for the interchange and sharing of data and the necessary underlying infrastructure are fundamental requirements. It should also be obvious that the term EHR really implies an EHR system, not just a data repository, although that is an important component.

STANDARDS DEFINED TO PERMIT DATA SHARING AND INTEROPERABILITY

In order to create effective policies for interoperable IT healthcare systems, we must first create a shared, national vision that defines an operational framework

for accomplishing the goals of a comprehensive, person-centric EHR. It is clear that this vision must include a national infrastructure that will support the linking and sharing of data. Interoperability requires the creation, adoption and implementation of the necessary set of data standards. The *Connecting for Health Initiative* has just completed a nine month project focused on accelerating the rate of adoption of national clinical data standards throughout the nation's healthcare system in order to facilitate interoperability³. That report identifies operable standards, presents the value proposition, and addresses a migration strategy.

If data is to be aggregated across multiple sites of care for each individual, the most effective, error free method of linking the data is a unique personal identifier. This is a sensitive issue, but the public must be educated to understand the inherent value of such an identifier. It is also very important to establish levels of privacy and security and control of data that reduce the risk of misuse of such an identifier.

Today's electronic record systems have been developed in an evolutionary manner over many years. Technology has changed and concepts have changed. Systems were not designed with data sharing, integration and aggregation, and interoperability in mind, particularly beyond the institution. Standards are necessary for data sharing. Some have been developed; others are being developed; and others are yet to be developed. Operationally ready are the Health Level 7 (HL7) Reference Information Model, data types, and the HL7 V2.n and evolving V3 data interchange standards. In development are the Clinical Data Architecture, Clinical Templates, Clinical Guidelines and Decision Support Algorithms, and a functional model for the EHR for various clinical settings. Other operable standards include Digital Imaging and Communications in Medicine (DICOM) for imaging, the Accredited Standards Committee X.12 transactions standards as required by the Health Insurance Portability and Accountability Act, The National Council for Prescription Drug Programs' SCRIPT standard for electronic drug reimbursement, and the Institute of Electrical and Electronic Engineers (IEEE) x73 series of standards for medical device communication. The lack of a single integrated terminology standard remains a major barrier for the aggregation of data across multiple sources. Major progress is being made in this area with the U.S. Department of Health and Human Services/SNOMED agreement to include SNOMED CT in the National Library of Medicine's Unified Medical Language System (UMLS) and make it available without cost in the United States. Other terminologies include Logical Observation Identifiers Names and Codes (LOINC), International Classification of Diseases (ICD) 9 and 10 with clinical modification, Current Procedural Terminology, nursing terminologies and over 90 other terminologies. Efforts are now under way to map these various terminologies into a single, integrated terminology.

These required standards can be grouped into six major categories. The first category includes communication standards that are not specific to health and are

independent of application. The second category defines the data standards that are necessary clearly and unambiguously to define the full set of data elements along with their definitions and attributes. Those attributes include the data type and a valid terminology set. For complex data elements or data objects, a format standard or clinical template must be defined to create valid constructs and permit the decomposition of each complex data element into its composite parts. HL7 has produced or is developing standards for much of what is required in this area. Those standards, coupled with the creation of a single, integrated terminology using as sources SNOMED CT, LOINC, RxNorm for drugs, the various nursing terminologies, and others. The integrated terminology is likely to be a product of the NLM's UMLS. The HL7 standards include the Reference Information Model, data types, clinical templates, and clinical data architectures. HL7 also has begun work to identify the specific codes that would be available in a given data file to satisfy the terminology constraints. The third group is associated with the interchange of data among various organisations at institutional, enterprise, regional, state, national or international levels. Existing standards include HL7's version 2.n and the emerging version 3; DICOM for imaging, and IEEE x73 series for medical devices. The fourth category is associated with the electronic health record in its various roles as a function of site, purpose and view. As previously noted, the HL7 EHR SIG has started a process to create a technical specification for the levels of functionality required for the EHR. The fifth category of standards is related to knowledge representation and the use of knowledge in decision making. Again much work is being performed in HL7 by the Decision Support Technical Committee in this area. The sixth and final category is associated with application and includes such standards as disease registries.

THE FUTURE

Technology has finally exceeded the demand on what is required to make effective use of health informatics to improve health and healthcare. We now need a plan to rapidly involve all the stakeholders, to create and implement minimal systems in all settings – whether solo practices or small 35 bed hospitals. We must include the pharmacies, the nursing homes, home health, public health, employers, payers and government into an integrated information communication technology environment in which any provider always has at the point and time of care all appropriate data about the patient and the knowledge to use that data effectively. Access to both needs to respect the privacy and confidentiality of the person. Systems need to maximise the use of decision support to apply the knowledge. And finally, consumers need to become more active in the decision making process of healthcare and in sharing responsibility for their own wellbeing.

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Laboratory Data Exchange Using HL7-Interface Engine

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ABSTRACT

Objective: This paper discusses the necessity and decision to implement a Health Level Seven (HL7) standard to enable healthcare data exchange between hospital information systems (HIS), laboratory information systems (LIS), and automatic medical instruments (MIs).

Design: The major design challenge in developing intelligent laboratory information services is to enable distributed and heterogeneous medical instruments to be quickly, easily and cheaply connected to the LIS and the HIS.

Setting: University Hospital in Taiwan.

Methods: We followed the HL7 v.2.4 standard to define the related laboratory HL7 messages and to use the HL7 Interface Engine (IE) to communicate between heterogeneous systems and MIs. We used these to connect three Toshiba biochemistry machines to the LIS and HIS.

Results: Connections were accomplished in less than one week compared to a previous connection time of at least four weeks. The new system is able to process messages at more than twice the speed of the old system. It is currently running smoothly, handling almost 10,000 tests each day. Data exchange between the MIs, LIS and HIS is reliable, accurate and complete.

Conclusions: We have demonstrated that our approach is feasible and works in practice. We now plan to extend this approach to other medical instruments. Once we are assured of its reliability and applicability to a wide range of different MIs, we will promote our approach to other medical institutions. A flow chart is presented to aid other healthcare institutions decide if they should adopt HL7 to connect their medical instruments to their laboratory and hospital information systems.

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INTRODUCTION

Hospital software development is becoming increasingly complicated. Hospital system requirements for web-based, client/server and legacy applications, combined with support for multiple platforms, and sophisticated end-user functionalities have forced information system developers to pursue and adopt new approaches including integrated architectures, such as medical information exchange and medical application services^{1,2}

One of the major problems encountered with data exchange between different healthcare information systems is the lack of a uniformly accepted standard. Unlike standards used for general data exchange in businesses such as insurance and banking, these standards have to be directly designed for healthcare data exchange. As a consequence there are several popular data exchange standards in use around the world. Some of these and their developers are listed below:

- Arden Syntax from Columbia University and HL7³
- Clinical Context Object Working Group (CCOW) from HL7⁴
- Clinical Document Architecture (CDA) from HL7^{5,6}
- ASTM-E31 from the American Society for Testing and Material (ASTM)⁷
- DICOM-3 from the National Electrical Manufacturers Association (NEMA)⁸
- SNOMED from the College of American Pathologists (CAP)⁹
- LOINC from the Regenstrief Institute¹⁰
- CORBAmEd from the Object Management Group (OMG)¹¹
- ActiveX for healthcare from Microsoft¹²
- X12N from the Accredited Standards Committee (ASC)¹³

The choice of which standard to adopt requires careful consideration. Use of a well-defined and widely-acceptable medical data exchange standard is crucial to ensure both long-term use and to allow for the possibility of future development^{14,15}. HL7 has been specifically developed for transmitting text messages among healthcare information systems and is widely used around the world. This standard was thoroughly tested at the National Taiwan University Hospital (NTUH) before the decision to incorporate it as the standard for the hospital's information infrastructure was made¹⁶.

Careful consideration also needs to be given to the choice of interface used for connecting the laboratory information system to the heterogeneous medical instruments (MIs). We initially proposed using our own NTUH Laboratory Instrument Communication Interface (NTUH/LICI) standard for this purpose. This standard was developed over a 3-year period and implemented at NTUH in June 1999. As shown in Figure 1, it uses two file queues to handle the data exchange between the Laboratory Information System (LIS) and MIs. At NTUH it has been used to connect 40 MIs with our LIS. The process rate is about one message per second. The size of each command sent from a PC to an MI is approximately 130 bytes and the size of the result sent from the MI to the PC is

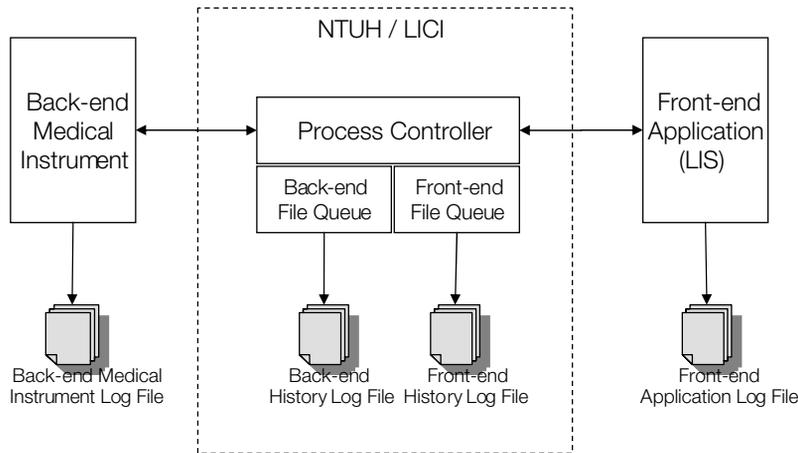


Figure 1. Laboratory Instrument Communication Interface (LICI) at National Taiwan University Hospital (NTUH)

This uses two file queues to handle the data exchange between the Laboratory Information System (LIS) and the Medical Instrument.

approximately 415 bytes. This file queue process mode is suitable for slow-speed MIs, but not for high-speed MI requirements. Our experience has also shown that each time a new MI is connected it takes at least one man month for planning, coding and testing. After careful consideration we decided that it would be better to use an internationally accepted interface. We felt that in the long-term this would offer significant advantages including simplifying and speeding up the connection process.

METHODS

In January 2003 our largest automatic biochemistry instrument, the Hitachi 7450, was replaced by three new Toshiba models (two TBA-200FR and one TBA-120FR). Using the accepted HL7 standard we managed to connect these three MIs to the LIS and HIS within one week. The connection pathways are shown in Figure 2, and technical details are given in Appendix A.

The steps involved in processing a sample can be summarised by the following four stages:

1. A doctor inputs laboratory orders into the HIS, and the HIS passes the message to the LIS.
2. When the specimen is received, a laboratory technician logs in the laboratory order entry in the HIS.
3. LIS transmits the information for a specific order to a specific MI which processes the specimen, generates a report and sends it back to the LIS.

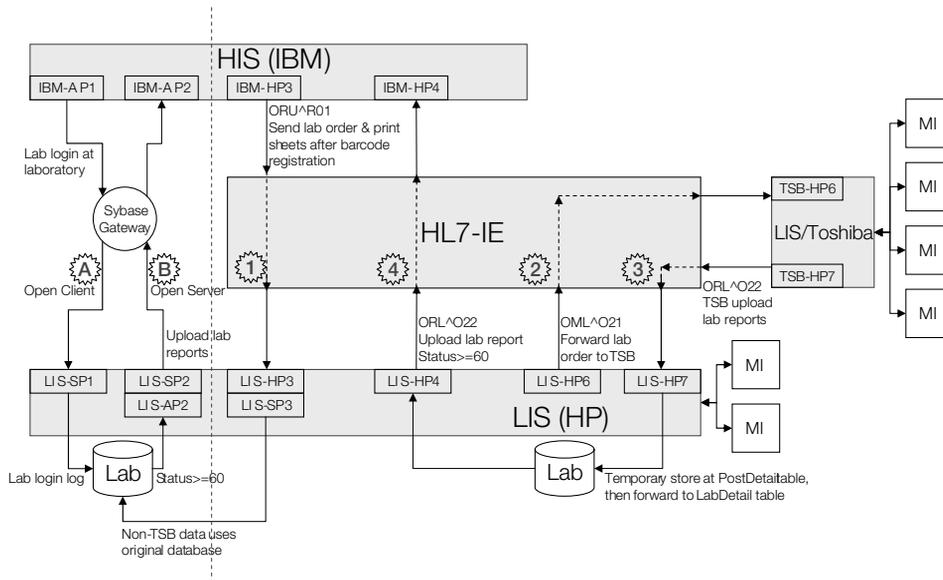


Figure 2. Detailed data exchange flow between the Hospital Information System (HIS), Laboratory Information System (LIS) and Medical Instruments (MIs)

The dashed vertical line delineates the use of two different solutions. The right-hand side uses the HL7-IE (Health Level 7-Interface Engine) gateway solution and the left-hand side uses the Sybase gateway solution. IBM-HPx: represents the use of HL7 programs at IBM (International Business Machines) mainframes; IBM-APx: represents the use of adapter programs at IBM mainframes; LIS-SPx: stored procedures at LIS; LIS-APx: adapter programs at LIS; LIS-HPx: the HL7 programs at LIS; and TSB-HPx: the HL7 programs for the Toshiba medical instrument system. Appendix B gives a table comparing the HL7-IE gateway and the Sybase gateway solutions.

4. The laboratory technician or doctor releases the laboratory report to the HIS.

Data exchange using the HL7-Interface Engine (HL7-IE) gateway solution between the HIS, LIS and Toshiba MIs was evaluated for 13 days in February and March 2003. The results are shown in Figures 3 and 4.

RESULTS

All three Toshiba MIs were connected to the LIS and HIS without difficulty within a one week period in February 2003. Since this connection was the first prototype attempt in Taiwan, the Toshiba MI connection interface implementations were provided free of charge by the vendors. However, due to the quicker connection time the new HL7 connection method should be cheaper than the old connection method which costs approximately US\$2,000 for each MI. Currently the system is working well handling an average of 31,267 tests per day for all laboratory orders and 9,725 tests per day for the Toshiba MIs. Data exchange between the MIs, LIS

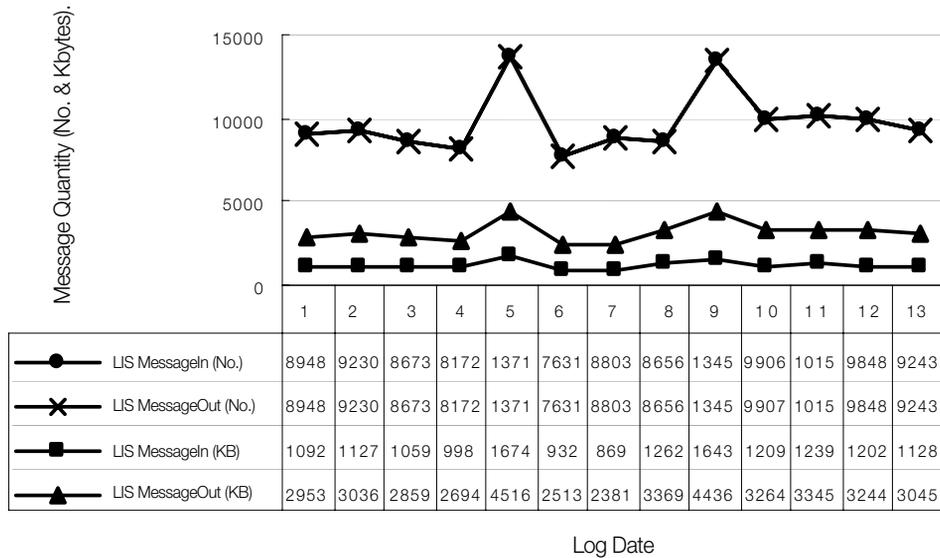


Figure 3. Data exchange using HL7-IE gateway for laboratory tests between the LIS and MIs

and HIS is reliable, accurate and complete.

Figure 3 shows the number and size of HL7 laboratory report messages passing between the LIS and Toshiba MIs on 13 individual days. The LIS MessageOut represents data passing from the Toshiba MIs to the LIS whereas the LIS MessageIn represents the corresponding acknowledgement message from the LIS to the Toshiba MIs. In the absence of errors or reject messages, the number of messages between these two systems should be exactly the same. The number of messages sent each day between these two systems is identical except for one day (day 10) where they differ by 1 message. There is, however, a notable difference in the size of the messages. Messages sent from the MIs to the LIS are approximately 2.7 times bigger than messages sent from the LIS to the MIs (337 bytes vs. 125 bytes respectively).

Figure 4 shows the number and size of HL7 laboratory order messages passing between the HIS and the LIS over the same 13 days. The HIS MessageIn represents laboratory order messages passing from the HIS to the LIS and the HIS MessageOut represents the corresponding acknowledgement message from the LIS to the HIS. There are small differences in the number of messages passing between these two systems on three days (days 5, 10 and 11). There is a much larger discrepancy of 23 messages on both days 7 and 8. However, it should be noted that there were more messages in than out on day 7, whereas on day 8 the converse is true. It is possible that this discrepancy is an artefact related to the timing of collection of data as the number of messages passing between these two systems is exactly the same for the two days combined. Each message passing from

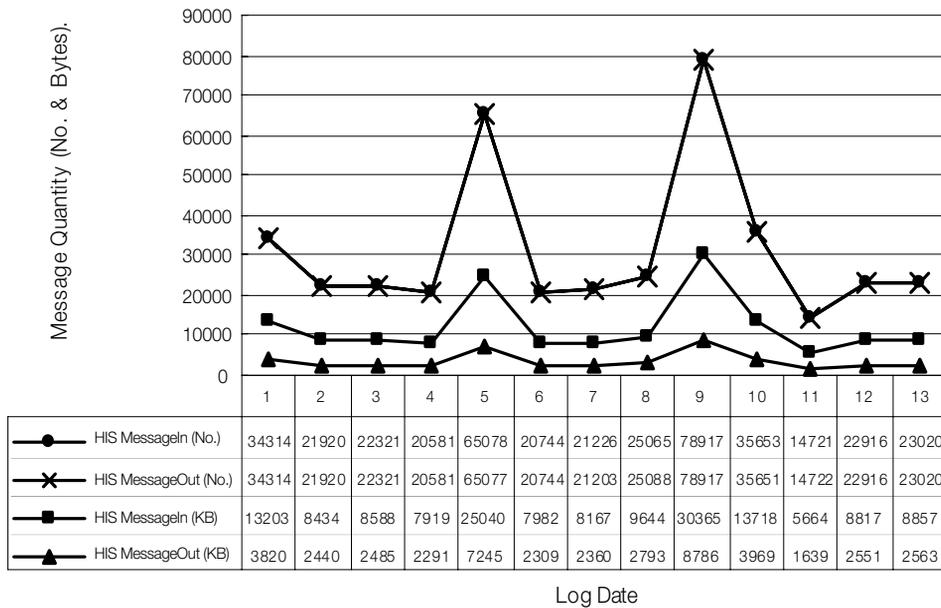


Figure 4. Data exchange using HL7-IE gateway for laboratory tests between the HIS and LIS

the HIS to the LIS is roughly 3.5 times the size of the message passing from the LIS to the HIS (394 bytes vs. 114 bytes respectively).

DISCUSSION

Automation of healthcare systems and processes within a hospital is desirable to improve the efficiency of healthcare. This is a major challenge due to a combination of disparate distributed systems, a wide variety of data both in text and image format and no universally accepted standards for data exchange. A fundamental first step in dealing with the problem is realising and dealing with the challenges of system selection, implementation and maintenance.

As mentioned earlier there are a number of different healthcare data transfer standards in use around the world. To connect a wide range of medical instruments it is necessary to choose standards that will allow data exchange in text format (e.g. biochemistry results), image format (e.g. x-rays) or a combination (e.g. electrocardiogram). In the healthcare setting, well recognised and widely used standards are HL7 for text transfer, and Digital Imaging and Communications in Medicine (DICOM) for image transfer.

Selection of the most appropriate standard is important to enable simplified, quick, and reliable connections to a wide range of heterogeneous instruments, e.g. laboratory, radiology, echocardiography, and electrocardiogram. The choice of

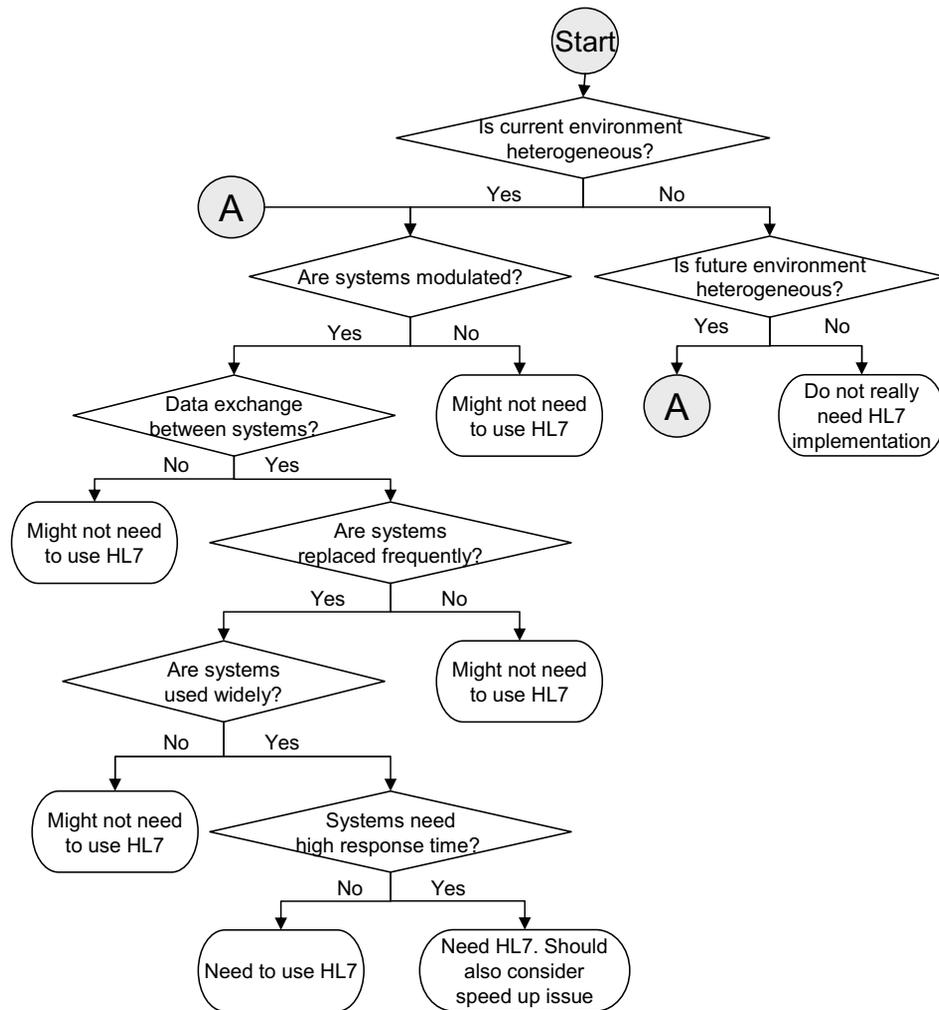


Figure 5. Decision tree to help decide if the HL7 standard should be used to connect medical instruments with laboratory and hospital information systems

The decision tree is based on our planning, decision and implementation experience with HL7 at NTUH.

standard should ideally be well-established, widely used, durable and allow for future expansion.

For the reasons given above we chose to use HL7 standards for data exchange, including replacing our own NTUH/LICI standard with the HL7-IE to manage and route messages. Using these standards we successfully managed to connect three automatic biochemistry machines to the LIS and HIS systems in our hospital. Currently, the system is running smoothly and we now plan to extend this approach to other heterogeneous medical instruments at NTUH. Based on our

experience we have produced a flow chart (Figure 5) to help chief information officers (CIOs) decide if they should implement HL7 to connect MIs to the LIS and HIS in their organisation.

The approach we have taken has worked well in our hospital with the three connected Toshiba instruments. However, before we can recommend other medical institutions adopt it, further work is required to establish its applicability and reliability with other heterogeneous MIs. Planned work includes:

1. Connection of other laboratory medical instruments.
2. Connection of other medical instruments, e.g. electrocardiogram, ultrasound, and x-ray machines.
3. Identification of the best HL7-IE gateway backup solution.
4. Improvement of the speed-up issue.
5. Implementation of a security module for Internet data exchange.
6. Introduction of a variable-length message passing method to replace the fixed-length one.

Finally we would like to quote Stanley Huff, a senior medical informaticist at International Health Care, Salt Lake City, Utah and the previous chairman of the board of directors of HL7: "If CIO's know how to implement standards, then they could reduce the costs and improve the speed of installation of electronic medical records systems."¹⁷ We believe the work in this paper confirms the value of this statement.

ACKNOWLEDGEMENT

This research result is part of the "Research for Deriving an Object-Oriented Electronic Health Record Data Processing Platform" project which is supported by the PhD Student Research Grant (NTUH.92-M014), National Taiwan University Hospital. The NTUH/LICI standard has been supported by XEVOX (Tai-Eo Lai and Ben-Kun Shu). The NTUH HL7-IE solution has been supported by the Information Systems Department (Jung-Lin Wu, Yu-Fang Wu, Chi-Hwa Chen, Mam-Chan Chang, Chun-Li Niu, Yu-Shiang Weng, Ming-Tsung Lai and Chia-Ping Tsai), Laboratory Department (Dr. Wen-Chen Cheng and Dr. K.S. Tsai), Toshiba Taiwan Co. (Joe Hong), TECO Inc. (Shih-Chan Fan), and Inqgen Co. (Bai-Hsiang Cheng, Shih-Hung Huang, Louisa Ho, Yu-Na Chiu, and Wei-Da Huang). The authors are grateful to all the above persons for their collaboration and contribution to this article.

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APPENDIX A

Technical details of the data exchange between MIs, LIS and HIS at NTUH.

1. A clinical doctor keys in laboratory orders from HIS at an IBM mainframe 3270 terminal. A laboratory technician confirms the specimen is received and logs in the laboratory order entry at HIS. HIS then calls the IBM-HP3 program to pre-process the order entries into an HL7 (ORU^R01) message and passes this message to LIS at HP-370D. LIS uses LIS-HP3, a PowerBuilder program, to receive this HL7 message automatically. After that, LIS-HP3 is called to retrieve the HL7 message, to parse it and to call another database stored procedure (LIS-SP3) to store the related information in our LIS database.
2. LIS transmits the information for a specific order item to a specific MI. For example, LIS can call a PowerBuilder program (LIS-HP6) to group the HL7 (OML^O21) message and send it to a Toshiba biochemistry instrument. This Toshiba biochemistry instrument will use a Visual Basic program (TSB-HP6) to receive and parse the HL7 message and pass it to corresponding medical instruments.
3. The specific MI processes the specimen, generates some reports, and then sends these reports to LIS. For example, the Toshiba biochemistry instrument will call a Visual Basic program (TSB-HP7) to create an HL7

(ORL^O22) message which contains the laboratory report and to send this message to LIS. Then LIS will use LIS-HP7, a PowerBuilder program, to receive and parse the HL7 message. Finally, LIS-HP7 will help to save related laboratory reports into the LIS database.

4. When a laboratory technician or a doctor wants to release the laboratory reports to HIS, LIS can call a PowerBuilder program (LIS-HP4) to collect the report, to group it into an HL7 (ORL^O22) message, and to send this message to HIS. HIS uses a corresponding IBM COBOL program, IBM-HP4, to receive and parse this HL7 message, then to save this report to the IBM IMS hierarchical database.

APPENDIX B

Comparison between the new HL7-IE gateway and the original Sybase gateway solution from the viewpoint of laboratory medical instrument connections

| | <i>Flow 1: Sybase gateway is used to support NTUH's own-defined data exchange messages and standard, LICI.</i> | <i>Flow 2: HL7-IE gateway is used to support HL7 and other world-wide standards.</i> |
|-----------------------------|---|--|
| HIS side (IBM mainframe) | <ol style="list-style-type: none"> 1. The COBOL programs for the Sybase OpenClient and OpenServer programs are hard to write. 2. The codes are hard to debug. | <ol style="list-style-type: none"> 1. The COBOL APPC programs for HL7-IE are easy to write. 2. The codes are neat. |
| LIS side | <ol style="list-style-type: none"> 1. The PowerBuilder programs and the other open system programming languages are almost the same at both solutions. 2. Have to write codes to group and parse the NTUH's own-defined data exchange messages. | <ol style="list-style-type: none"> 1. The PowerBuilder programs and the other open system programming languages are almost the same at both solutions. 2. Have to write codes to group and parse the HL7 messages. |
| MI side | <ol style="list-style-type: none"> 1. Use NTUH's own-defined LICI data exchange standards. 2. Limited speed. One message per second at most (60 per minute). | <ol style="list-style-type: none"> 1. High speed. Up to 150 messages per minute. Because of the different performance of the MI programs which are designed by different vendors, the program execution speed is limited by the MI receiving programs. Currently, the maximum throughput of the Toshiba MI side at NTUH is 150 messages per minute. |

We used several different programming languages to achieve our HL7-IE gateway solution. These were IBM COBOL, PowerBuilder, and Visual Basic. We also tried other programming languages to achieve system integration, including Java, and JavaServer Pages (JSP). We would recommend that newly created systems run in a Java platform.

APPENDIX C

APPC (Advanced Program-to-Program Communication) also called LU 6.2. It is a communication protocol and programming interface standard that operates in the presentation and session layers of the open systems interconnection communications model.

COBOL (Common Business Oriented Language) was the first widely-used high-level programming language for business applications. The language has been in use for thirty five years, and has been superseded by newer languages. Programs written in COBOL are viewed as legacy applications run in machines, such as IBM mainframes.

DICOM (Digital Imaging and Communications in Medicine) is an application layer network protocol for the transmission of medical images, waveforms and ancillary information. It supports a wide range of medical images across the fields of radiology, cardiology, pathology and dentistry.

IE (Interface Engine) is a gateway which can connect and communicate among application systems and acts as an integrating solution inside an enterprise. It serves to transform and route data.

IMS (Information Management System) is a transactional and hierarchical database management system for critical operational and e-business applications and data developed by International Business Machines (IBM). It enables information integration, management, and scalability.

Java is a programming language that is designed for use in the distributed environment of the Internet.

JSP (Java Server Page) is a technology for controlling the content or appearance of web pages through the use of servlets. These are small programs that are specified in the web page and run on the web server to modify the web page before it is sent to the user who requested it.

LIS (Laboratory Information Systems) process and manage laboratory specimens. LIS functionalities should include specimen registry, instrument alignment/connection, report submission, quality control/assurance, statistics reports, etc.

LICI (Laboratory Instrument Communication Interface) is the first and locally defined version of the laboratory instrument communication interface introduced in National Taiwan University Hospital in 1997.

OML is an HL7 laboratory order message that may be used for the communication of laboratory and other order messages and must be used for laboratory automation messages. Details can be found in section 4.4.6 of HL7 v2.4.

ORU is an HL7 unsolicited observation message that is designed to accommodate the laboratory processes of a laboratory automation system. The ORU message is fully supported by HL7 for transmitting laboratory results to other systems. Details can be found in section 7.3.1 of HL7 v2.4.

ORL is an HL7 general laboratory order response message. The function of this message is to respond to an OML message and serves as the application acknowledgment to an OML message. Details can be found in section 4.4.7 of HL7 v2.4.

PowerBuilder is a popular rapid application development tool for building object-oriented programming client/server applications.

SP (Stored Procedure) is a set of structured query language statements with an assigned name that is stored in the database in compiled form so that it can be shared by programs.

Visual Basic is a programming environment from Microsoft in which a programmer uses a graphical user interface to choose and modify the code which is written in BASIC programming language.



Synthesising the Technologies of Web Services and Intelligent Agents to Build an HL7/XML-Based Infectious Disease Reporting System

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ABSTRACT

Objective: To combine HL7/XML with the technologies of Web services and intelligent agents to implement a national infectious disease reporting system.

Design: Development of a system for automatically and directly reporting diagnosed infectious cases to a remote special authority.

Setting: The system was implemented in the Catholic Cardinal Tien Hospital in Taiwan, with reports being sent directly to the Center for Disease Control (CDC) also located in Taiwan.

Methods: The system utilises intelligent software agents and the World-Wide Web. Inside the hospital, the system is linked to the hospital's health information system in a loosely coupled manner that does not require any modification of the original hospital information system. The intelligent agents scan the hospital database for new cases of infectious diseases. When they find one they obtain specified information and prepare a report. The report is sent to the CDC via the Web exploiting the technologies of HL7/XML and intelligent agents. The whole process can be done automatically without the need for human intervention.

Results: We managed to successfully use the system to send daily reports to the CDC of infectious cases diagnosed at Catholic Cardinal Tien Hospital. The time from diagnosis of infectious cases to notification of the CDC was a few minutes. This is a significant improvement compared to the time taken with traditional manual reporting techniques using paper, telephone and facsimile machines.

Conclusions: We have demonstrated that the system can automatically perform surveillance and reporting of infectious diseases to the CDC with increased efficiency. A key feature of the system is that it reduces human workload as most of the work is done autonomously, including retrieval of data, preparation and sending of reports. With modification the system could be used for other healthcare data exchange purposes.

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INTRODUCTION

Taiwan is a subtropical country with a hot and humid climate predisposing to the spread of infectious diseases. In recognition of this and the potential threat to public health the government created a central authority, the Center for Disease Control (CDC) to prevent and control the spread of infectious diseases. Efficient and effective prevention of disease spread requires early identification and notification of infectious diseases. To aid this the Taiwanese Government has passed laws and regulations that require sanitary and public health institutions to immediately report to the county's public health bureau any suspected cases of infectious disease. Local healthcare personnel trace these cases and pass the relevant information to the CDC. The CDC has the task of analysing the data and if necessary implementing necessary measures to control and prevent the spread of infection.

Until now this reporting has been done by humans and the main media used for communication is the telephone or facsimile. This is not a very efficient system. It involves several personnel which may result in a significant delay before the information actually reaches the CDC. To prevent the spread of infectious diseases, action should be taken as soon as possible. The current system also requires re-entry of data which creates unnecessary work and introduces the possibility of transcription errors.

Developments in information technology offer the potential for improving the efficiency and reducing the workload for those involved in reporting and dealing with infectious diseases. In particular it offers the ability to produce a streamlined, integrated infectious disease reporting system. In this research project, we propose the development of a national, integrated system framework that will enable efficient and effective disease reporting in Taiwan. The system will enable information systems at hospitals and other healthcare institutions to communicate directly with the information system located at the CDC using a common message schema. The successful development of such a system could be adapted for the transfer of other inter-organisational healthcare messages, e.g. patient referrals or insurance fee claims.

The proposed project uses three main technologies:

- Workflow systems
- Intelligent agents
- Web services

The key features of these three technologies will be briefly described.

WORKFLOW MANAGEMENT

Workflow has been defined as "*The automation of a business process, in whole or part, during which documents, information or tasks are passed from one participant to another for action, according to a set of procedural rules*"

Workflow emphasises the coordination of tasks by highlighting their interdependence. Workflow management systems (WFMs) build upon traditional workflows. Their activation reduces human workload and gives great control over the workflow. WFMs can integrate resources dispersed throughout an organisation and also coordinate activities to achieve more efficient and cost-effective services.

Workflow management systems have several benefits². They:

- Prevent work being misplaced or stalled
- Allow managers to focus on staff and business issues, rather than routine tasks
- Ensure that procedures are formally documented and exactly followed. Consequently work is performed in a planned manner to meet business and regulatory requirements
- Select the best person (or machine) to do each task, and prioritise so that the most important tasks are assigned first
- Enable parallel processing, so that two or more tasks are performed concurrently. This is far more practical than a traditional, manual workflow

INTELLIGENT SOFTWARE AGENTS

Software agents usually bring great benefits in handling routine and repetitive tasks. The primary property of intelligent software agents is one of autonomy, i.e. they can continuously monitor and react to changes without the need for human intervention^{3,4}. Other critical properties of software agents are proactiveness, sociability and reaction⁵. Software agents exhibiting these abilities can be self-integrated, independently functioning or inter-coordinated to solve specific problems.

AGENT-BASED WORKFLOW MANAGEMENT

Figure 1 illustrates how intelligent agents are deployed in workflow management based on the And/Or concept⁶. To achieve an agent's goals, there is interdependency between Agent₁ and Agent₂ – they have to cooperate to complete some specific tasks. For example, G₁¹(Goal (1,1)) is the goal of Agent₁. To achieve this Agent₁ needs G_{1,1}¹ or G_{1,2}¹ to access the required resources represented by d₁¹.

Each agent has its own specific abilities, is assigned to a chosen task and plays a crucial role in solving specific organisational problems. In a dynamic inter-organisational workflow management system, four types of software agents are recognised:

- Process
- Service
- Monitor
- Discovery

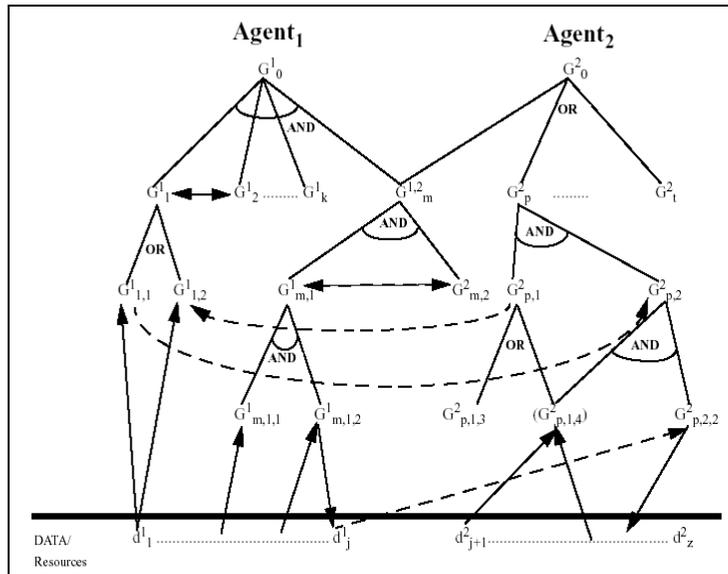


Figure 1. *And/Or goal structure*¹⁰

The process agent is responsible for designating tasks to service agents. Discovery agents are requested by process agents to search for appropriate service agents to perform specific tasks. Service agents possess specific abilities and are responsible for performing the tasks. Once a task has been performed, a return message corresponding to the status of execution is returned and received by a monitor agent.

WEB SERVICES

Web services are the paradigm shift of distributed object technology. Through the use of software components it is possible to loosely couple information systems effectively and rapidly, irrespective of their platform or language. The technology of Web services speeds up the integration of computer systems, both within and outside an enterprise, including incorporating legacy systems. Basically, Web services are a user-centred model, with users searching for services in accordance with their own needs. The service model is passive and user-driven.

Web services contain three participating roles, namely:

- Service provider
- Service registry
- Service requester

Service providers provide Web services and register them on a service registry. A service requester searches the registry for particular services and accesses them using defined protocols (e.g., Simple Object Access Protocol). These protocols

enable access without being blocked by firewalls. An explicit interface is provided using Web Service Description Language. This interface is based on XML and contains the return values, parameters, method names, protocols, and IP (Internet protocol) address for external programs to access the remote Web services⁷.

MATERIALS AND METHODS

HL7 standards⁸ have been created and released to enable medical and healthcare professionals to communicate with each other using a consistent and unique data format and message schema. The flow of data is the core process underlying the effectiveness of any communication. A fundamental issue is achieving rapid and effective data flow, both within an institution and between different institutions. In our research, we adopted the HL7 standard to act as a criteria of message exchange schema between the Catholic Cardinal Tien hospital and the CDC for the infectious disease reporting system.

Table 1 shows the message structure of ORU^R01 (Observation Reporting Unsolicited) used for this implementation. This was released as HL7 version 2.4 in the year 2000. Observation Reporting format regulates the process of sending

Table 1. ORU^R01 message structure

| MSH | Message Header |
|--------------|--|
| { | |
| [| |
| PID | Patient Identification |
| [PD1] | Additional Demographics |
| [[NTE]] | Notes and Comments |
| [PV1 | Patient Visit |
| [PV2]] | Patient Visit – Additional Info |
|] | |
| { | |
| [ORC] | Order Common |
| OBR | Observation Request |
| ZLR | Additional Info for Lab-Based Reporting |
| [[NTE]] | Notes and Comments |
| { | |
| [OBX] | Observation/Result |
| [[NTE]] | Notes and Comments |
| } | |
| [[CTI]] | Clinical Trial Identifier |
| } | |
| } | |
| [DSC] | Continuation Pointer |

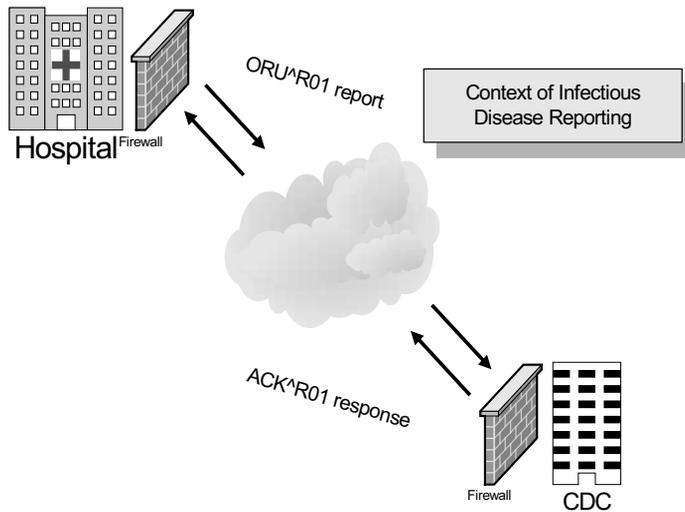


Figure 2. *ORU^R01 reporting context*

structured patient-oriented clinical data from one computer system to another⁸, in either the same or a separate medical institution. Observation Reporting Unsolicited mode is used primarily to transmit the values of new observations.

Figure 2 shows how a diagnosed infectious disease case in the hospital triggers ORU^R01 (Observation Reporting Unsolicited) to transmit a set of data to the Center for Disease Control (CDC). When the CDC receives the message, it returns an ACK^R01 (Acknowledgement) message with the structure shown in Table 2 to confirm receipt of the report.

The primary aim of the project was to achieve automation within the hospital by the use of an intelligent agent workflow management system within the hospital and Web services outside the hospital. The latter are essential to enable the automatic sending of the report to the CDC. Our automatic inter-organisational workflow architecture model is shown in Figure 3.

Inside the hospital, we used autonomous agents to establish active, unsolicited messaging. To achieve this goal, we created four kinds of agents, namely:

- Global Control Unit Agents (GCA)
- Delegation Agents (DA)

Table 2. *ACK^R01 message structure*

| | |
|---------|-------------------------|
| ACK^R01 | Acknowledgement |
| MSH | Message header |
| MSA | Message acknowledgement |

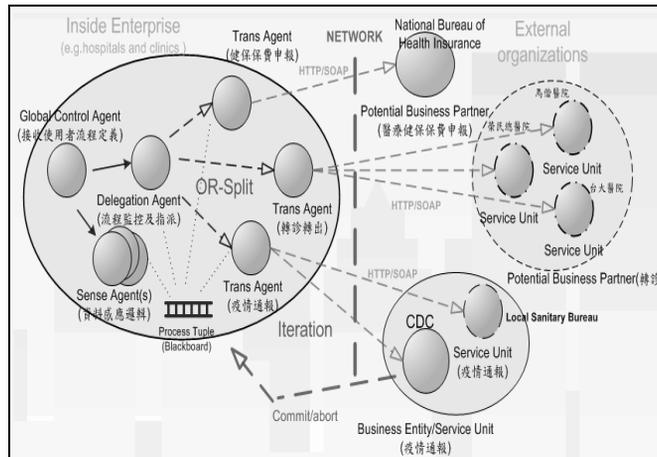


Figure 3. Conceptual model

- Sensing Agents (SA)
- Transmitting Agents (TA)

The Web Service component (WS) is located outside the hospital and provided by vendors and third parties. GCA retrieves the workflow specification given by the system administrator. According to the instructions given by the system administrator, the GCA assigns tasks to a DA and a SA. The SA is in charge of monitoring the target database. When it finds a new case it creates a new process tuple (an ordered set of values). DA judges the workflow pattern and produces the destination HL7/XML files. TA is responsible for the interactions with the remote WS, and confirms the completeness of the transmission flow, or in the failure to do so whether the process needs to be restarted or aborted. Through the combination of replaceable agents, enterprises have the flexibility to alter the way that messages are exchanged, the partners whom they cooperate with and also to adjust the contents of the message to individual specifications. In addition, through the help of the flexible-changed workflow specification it is possible to add or remove processes, cooperate with new agents or remote WSs. The system has the flexibility for changes to be made in response to developments, both in the internal and external environments.

Workflow specification may influence the execution of the process and result in different outcomes. Our workflow model is represented as a tuple W depicted below;

$$W = \{Type, DataSource, Priority, Destination, Local_service_name, Executable_Time, InnerConfirm, Directory, Url, Note \};$$

```

<?xml version="1.0" encoding="Big5" ?>
<Workflows>
- <Workflow>
  <type>Infectious_Disease</type>
  <datasource>InfectiousData</datasource>
  <priority>8</priority>
  <destination>CDC</destination>
  <local_service_name>TransORUThread</local_service_name>
  <executable_time>2</executable_time>
  <innerConfirm>0</innerConfirm>
  <directory>data</directory>
  <url>http://cyyang.adsltdns.org/axis/CDCService.jws</url>
  <note>呼叫CDC的webservice传递疫情资料</note>
</Workflow>
- <Workflow>
  <type>Health_Insurance</type>
  <datasource>Insurance</datasource>
  <priority>2</priority>
  <destination>BNHI</destination>
  <local_service_name>TransORUThread</local_service_name>
  <executable_time>10</executable_time>
  <innerConfirm>1</innerConfirm>
  <directory>data1</directory>
  <url>http://cyyang.adsltdns.org/axis/AdvancedService.jws</url>
  <note>a</note>
</Workflow>
+ <!-- -->
</Workflows>

```

| Item | Contents |
|--------------------|--|
| type | Inter-organisational flow types, such as infectious disease reporting, patient referral, insurance fee claims, etc. |
| datasource | Data source from the hospital's main database |
| priority | Priority of a certain flow (1(min)-10(max)) |
| destination | The destination where the data is to be transmitted to (e.g. CDC, another hospital, National Bureau of Health Insurance, etc.) |
| local_service_name | The class name of the transmitting agent, for the purpose of dynamic binding |
| executable_time | The allowance of executable times for a certain workflow |
| innerconfirm | Used to judge if the flow type is automatic type or requires human intervention |
| directory | The temporary directory for storing HL7/XML data |
| url | The Unique Resource Location of a remote Web service (endpoint) |
| note | Notes for conditions |

Figure 4. Example of workflow specification with table describing the elements in the workflow specification

RESULTS

To demonstrate the feasibility of our framework, we developed a system for reporting infectious diseases from Catholic Cardinal Tien Hospital to the CDC. The entire process and the agents involved in the reporting flow are illustrated in Figure 5.

The individual sequence steps to achieve the reporting process shown in Figure 5 are as follows:

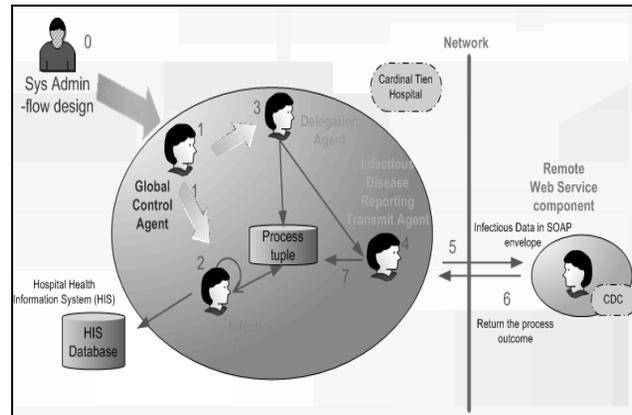


Figure 5. Process and agents involved in automatically reporting a case of infectious disease diagnosed in the Catholic Cardinal Tien Hospital to the Center for Disease Control (CDC).

SOAP= Simple Object Access Protocol.

0. The infectious disease reporting process is initiated by the system administrator editing the workflow specification to create, modify or delete the workflow processes.
1. & 2. The GCA designates tasks to the appropriate DA and SA. The SA senses any new cases of infectious disease reported in the HIS. If it finds one the SA creates a new process tuple, whose functionality is to enable communication between different agents. The executing status information is stored in the process tuple. The DA classifies the workflow into automatic or human intervention types depending on whether the data need human verification before being sent out. If this is not required, the flow type is automatic, and the DA creates a relative HL7/XML file automatically and transmits data autonomously.
3. & 4. The DA analyses the workflow type and decides which document to create, the destination for it and which TA to use to send it.
5. & 6. The selected TA is activated to carry out the task of sending the report (in HL7/XML format) to the CDC. At this stage, WSDL is a great help for dynamic binding to trigger the passive Web services located at the CDC. After the CDC receives and processes the message, it returns an acknowledgement message to the hospital. In response to the return message, the process tuple confirms completion of the reporting flow for this event. It is then reset to allow activation of the next reporting event.

Using the system we have been able to successfully report on a daily basis suspected infectious cases diagnosed by the doctors of Catholic Cardinal Tien Hospital to the CDC. All cases when they are diagnosed are written by the hospital's health information system into an intermediate database that is shared by the

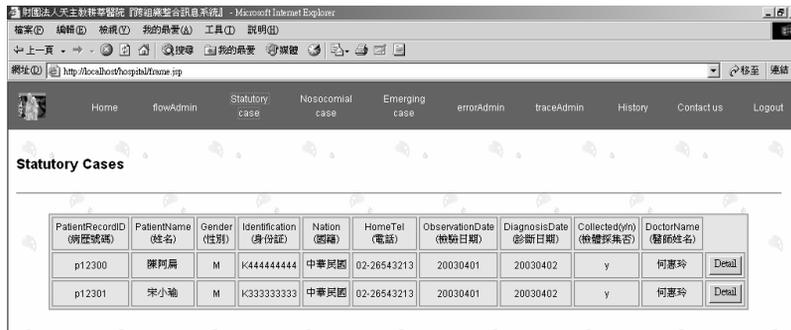


Figure 6. *The audit user interface*

reporting system. The reporting system is set periodically and automatically to pick up newly diagnosed infectious cases from the intermediate database. The reporting form and the message received by the CDC are illustrated in Appendix A (in Chinese). They are immediately manipulated by a peer system at the CDC side. The accuracy and completeness of the message is checked, and immediate action is taken by the CDC’s infectious disease controller who handles the case. Thus, this reporting process is effectively done with little human involvement and intervention, although the successful transmission and receipt of a message by the CDC should be confirmed by hospital staff examining the acknowledgement message. Cases sent can also be confirmed using the audit interface shown in Figure 6.

DISCUSSION

Infectious diseases are a constant threat to public health. The recent Sudden Acute Respiratory Syndrome (SARS) epidemic confirms this and also demonstrates the catastrophic human and financial consequences of delayed or ineffective initial action. To try to prevent or limit the effects of such epidemics it is essential that cases of infectious diseases are notified to the relevant authority as soon as possible. In Taiwan the Center for Disease Control is responsible for preventing and controlling the spread of infectious diseases.

Reporting to the CDC is currently done in an inefficient manner using telephones and facsimile machines. This method involves several personnel and also the re-entering of data. A more efficient system would enable data to be automatically sent to the CDC as soon as the diagnosis of an infectious disease is made.

We have demonstrated how this can be achieved in practice through a combination of intelligent agents and Web-based services. Our framework effectively integrates with the HIS inside a medical institution and communicates with external organisations. The model should be easily adoptable for use by other organisations as its design, including the use of HL7/XML standards, will overcome many of the problems of heterogeneous platforms, data types and coding

systems used by different institutions. The system also has the flexibility to be modified to the particular needs of an organisation. The framework could be used to model other kinds of medical message transferring applications such as insurance fee claims. We believe that the system has the ability to greatly improve the efficiency of healthcare data transfer but further evaluation of its benefits are required.

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APPENDIX

The Reporting Form (Figure A) with its HL7/XML ORU message.

傳染病個案(含疑似病例)報告單 - 病歷代號p12358

※ 註記『*』者為必填欄位！

| | | | |
|------------------------------|--|-------|----------------------------------|
| 醫院資料 | | | |
| 醫院/診所 | 財團法人天主教耕莘醫院 | *診斷醫師 | 阿惠玲 <必填> |
| *院所代碼 | 1231050017 <必填> | 電話 | 02-22193391 <格式: 02-12345678> |
| 院所地址 | 台北縣新店市中正路362號 | | |
| 簡單通報表 | | | |
| *疾病資料 | <input type="checkbox"/> 水痘(052) <input type="checkbox"/> 腮腺炎(072) <可複選, 必須有值> | | |
| *患者姓名 | <必填> | | |
| 病歷號碼 | <必填> | | |
| 疾病詳細通報表 <非上表所列> | | | |
| 患者資料 | | | |
| *患者姓名 | 陳金整 <必填> | | |
| *性別 | <input checked="" type="radio"/> 男 <input type="radio"/> 女 <必選> | | |
| *出生年月日 | 民國 44 年 11 月 05 日 <必填> | | |
| *身份資料 | 身分證字號 K77777777 <大小寫均可> 護照號碼 K77777777 <二選一, 必有一值> | | |
| 病歷與日期 | | | |
| 病歷號碼 | p12358 | | |
| *發病日期 | 民國 92 年 04 月 01 日 <必填> | | |
| *診斷日期 | 民國 92 年 04 月 02 日 <必填> | | |
| 主要症狀 | 高燒不退 <請以50中文字簡述之> | | |
| 住院情況 | <input checked="" type="radio"/> 是 <input type="radio"/> 否 <三選一> | | |
| 轉院 | <input type="radio"/> 轉院, 轉至 _____ 院所 | | |
| 檢體採檢 | <input checked="" type="radio"/> 有 <input type="radio"/> 否 | | |
| 疾病資料 <至少需有一值> | | | |
| 第一類 傳染病 | <input type="checkbox"/> 霍亂(001) <input type="checkbox"/> 鼠疫(020) <input type="checkbox"/> 黃熱病(060) <input type="checkbox"/> 狂犬病(071) <input type="checkbox"/> 伊波拉病毒出血熱(0788) | | |
| 第二類 傳染病 | <input type="checkbox"/> 白喉(032) <input type="checkbox"/> 炭疽病(022) <input type="checkbox"/> 流行性腦脊髓膜炎(0360) <input type="checkbox"/> 傷寒(002) <input type="checkbox"/> 副傷寒(002a) <input type="checkbox"/> 桿菌性痢疾(004) <input type="checkbox"/> 阿米巴性痢疾(006) 開放性肺結核 <input type="checkbox"/> 原發性結核感染肺結核病(010a) <input type="checkbox"/> 肺結核病(011a) <input type="checkbox"/> 其他呼吸道結核病(012a) <input type="checkbox"/> 粟狀結核病(018a) <input type="checkbox"/> 流行性斑疹傷寒(080) <input type="checkbox"/> 小兒麻痺症(045) <input type="checkbox"/> 急性無力肢體麻痺(045a) | | |

Figure A. The format of the Reporting Form (in Chinese)

```

C:\Documents and Settings\Administrator\My Documents\新資料夾\test.xml - Micros
檔案(F) 編輯(E) 檢視(V) 我的最愛(A) 工具(T) 說明(H)
← 上一頁 → 搜尋 我的最愛 記錄
網址(O) C:\Documents and Settings\Administrator\My Documents\新資料夾\test.xml
移至 連結

<?xml version="1.0" encoding="Big5" ?>
<ORU_R01>
  <MSH>
    <MSH.1>|</MSH.1>
    <MSH.2>^~^&</MSH.2>
    <MSH.7>20031021192033</MSH.7>
  </MSH>
  <MSH.9.1>ORU</MSH.9.1>
  <MSH.9.2>R01</MSH.9.2>
</MSH.9>
+ <MSH.11>
+ <MSH.12>
</MSH>
- <PID>
  <PID.3>
    <PID.3.1>K77777777</PID.3.1>
    <PID.3.4>
      <PID.3.4.1>TWNTUH(身份証字號)</PID.3.4.1>
    </PID.3.4>
    <PID.3.6>HL7_0363</PID.3.6>
  </PID.3>
+ <PID.3>
+ <PID.3>
- <PID.5>
  <PID.5.1>
    <PID.5.1.1>陳金整</PID.5.1.1>
  </PID.5.1>
</PID.5>
<PID.7>19551105</PID.7>
<PID.8>M</PID.8>
+ <PID.11>
+ <PID.13>
+ <PID.14>
+ <PID.16>
<PID.26>中華民國國民</PID.26>
<PID.28>中華民國</PID.28>
<PID.29 />
</PID>
+ <PV1>
+ <ORC>
- <OBR>
  <OBR.1>1</OBR.1>
  <OBR.4>CDC</OBR.4>
  <OBR.7>20030401</OBR.7>
  <OBR.9>N</OBR.9>
</OBR>
- <CTD>
  <CTD.2>
    <CTD.2.1>何惠玲</CTD.2.1>
    <CTD.2.5>Dr.</CTD.2.5>
  </CTD.2>
+ <CTD.3>
+ <CTD.5>
+ <CTD.5>
- <CTD.7>
  <CTD.7.1>1231050017</CTD.7.1>
  <CTD.7.3>財團法人天主教耕莘醫院</CTD.7.3>
</CTD.7>
</CTD>
+ <OBX>
- <FT1>
  <FT1.19>
    <FT1.19.1>123.1</FT1.19.1>
    <FT1.19.2>骨折</FT1.19.2>
    <FT1.19.3>ICD9</FT1.19.3>
  </FT1.19>
</FT1>
+ <ZRI>
</ORU_R01>

```

Figure B. HL7/XML ORU message corresponding to Figure A





An Open Source Intelligent HL7 Agent for Integrating Laboratory Information

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ABSTRACT

Objective: To provide an accessible platform to easily exchange data using HL7 standards.

Design: Developmental process.

Setting: Clinical laboratories of three hospitals in Taiwan.

Methods: An open source intelligent HL7 agent that utilises a graphical user interface was used to map and convert schema from a laboratory database to HL7 messages.

Results: We successfully managed to convert data from a laboratory database into HL7 messages using the intelligent agents.

Conclusion: We have shown that it is feasible to convert data from a laboratory database into HL7 messages using an intelligent agent. This process can be applied to other forms of data exchange. We recommend that, whenever possible, agents used for data exchange should be open sourced.

INTRODUCTION

In March 1995 the Taiwan government introduced the National Health Insurance Program (NHIP) which covers most medical services. One consequence of this is that if patients are not satisfied with the service or treatment they receive they have the right to change their doctor or hospital. This happens fairly commonly and creates the problem of ensuring that this action does not lead to a waste of medical resources or introduce a financial burden to the NHIP. This would occur if, for example, tests and investigations were unnecessarily repeated because the new doctor did not have access to the results of investigations performed by the previous doctor/hospital^{1,2}.

To prevent unnecessary repetition of tests and to effectively use existing medical resources it is necessary for healthcare providers and institutions to share patient data held in their medical records. This can be achieved most effectively and efficiently through the implementation of electronic medical records³.

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The Taiwan government is in the process of implementing electronic medical records in all healthcare settings. The project began in 2002 and is expected to take four years. A survey conducted in December 2002 showed that approximately 74% of primary care clinics and 90% of hospitals were computerised to some extent.

Having data in electronic format does not necessarily enable data to be exchanged between different healthcare providers. To achieve effective information exchange and to use the exchanged information among different computer systems, standardisation of medical data and communication protocols is required. The Health Level Seven (HL7) standards are designed to support system interoperability in the healthcare environment⁴. The standards cover, but are not limited to, the following applications:

- Admission/Discharge/Transfer (ADT)
- Financial management
- Patient care
- Patient orders
- Referrals

Currently more than 21 countries use the HL7 standard, confirming its acceptance as an international standard by both the healthcare industry and healthcare providers.

With respect to Taiwan, to date few hospitals have implemented the HL7 standard in their hospital information systems. A recent survey of over 600 hospitals in Taiwan found that only 10 hospitals (1.6%) had actually implemented HL7, with a further 22 (3.6%) being in the process of implementation and 106 (17.2%) planning to implement HL7. The vast majority (469 or 76.1%) were not planning to introduce HL7 in the near future. One of the reasons for this is that hospitals in Taiwan have a limited IT budget. Of the hospitals surveyed, 378 (61.4%) have an annual IT budget of less than US\$300,000 and less than five IT staff. Based on the experiences of implementing HL7 in other hospitals it is clear that two factors will be crucial to the successful implementation of HL7 in Taiwan:

- Simplifying the HL7 user interface
- Reducing the cost of installing the system

The main purpose of this study was to provide an accessible platform to exchange data via HL7 standards. We proposed to do this by using intelligent agent (IA) technology to implement a timesaving and cost-saving methodology. We envisage that if this is successful it will minimise customisation and simplify implementation. The use of intelligent agents reduces the need for knowledge about HL7 and interfaces, and thus reduces the barriers to entry for the introduction of HL7. We decided to implement this technology for laboratory results as they provide important objective information about a patient's medical condition.

METHODS

Our research explored the HL7 message structure, the data structure of laboratory information systems, the hierarchical relationship, schema-mapping (a schema is essentially a vocabulary defined to describe data), integration methods and the integration mechanism concerning the coding system. We proposed using OSIHA, an open source intelligent HL7 agent that utilises a graphical user interface (GUI) to map and convert the schema. OSIHA is designed to achieve a zero-line-programming or modification of the laboratory application while introducing HL7 standards.

Health Level Seven (HL7) standardises the format and protocol for the exchange of medical data. These can be used to transfer different types of information (including financial and patient related data, e.g. medical reports and laboratory tests) between different computer systems in healthcare environments. In Taiwan there are many commercial products available for HL7 and XML (extensible markup language). These include LINKTOOL⁵, Symphonia⁶, and Microsoft Biztalk⁷ with NEOTOOL Accelerator⁸. These products can achieve their intended purpose but suffer from the following drawbacks.

- They require the user to have basic knowledge of HL7
- They require XML and other system integration related knowledge
- The programs are not open sourced, i.e. it is not possible to study them. This can cause concerns about the integrity and security of the applications.

THE CONCEPT OF INTELLIGENT AGENTS

Software intelligent agents have been widely used in providing computer support for collaborative engineering. As an innovative technology, an intelligent agent has been defined as an agent that can learn, plan and reason. An agent can handle all messages defined by a protocol and also, depending on the protocol specifications, engage the service of other agents. For an agent, the message protocol to other agents is the interface for receiving messages. For users, the agent may be an application with a user-friendly interface and plenty of communicative functions.

OSIHA FRAMEWORK

The OSIHA framework is shown in Figure 1. The left OSIHA cube is the focus of this research. The HL7 intelligent agent adapts to the Laboratory Information System Database (LIS DB). It encapsulates the HL7 interface and possesses the ability to:

- Transform relational data format into HL7 messages
- Store in-bound HL7 messages
- Transform stored in-bound HL7 messages into the LIS database

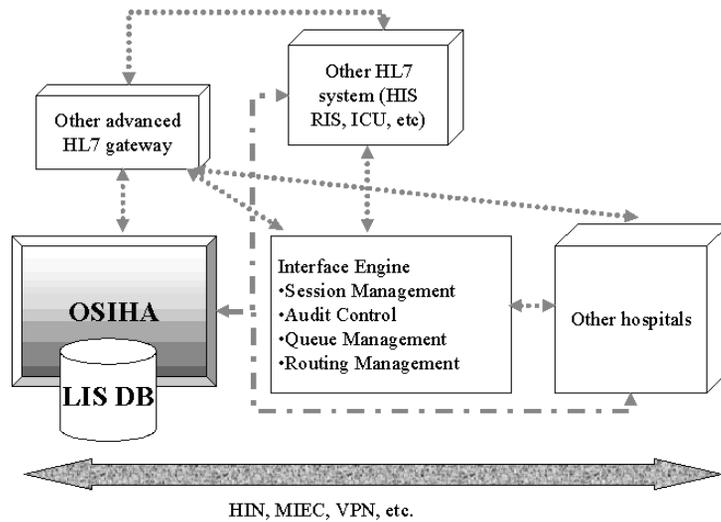


Figure 1. OSIHA architecture overview

After the implementation of an open source intelligent HL7 agent (OSIHA), the Laboratory Information System Database (LIS DB) can interact with other systems through the HL7 interface. HIS = Hospital Information System, ICU = Intensive Care Unit, RIS = Radiology Information System.

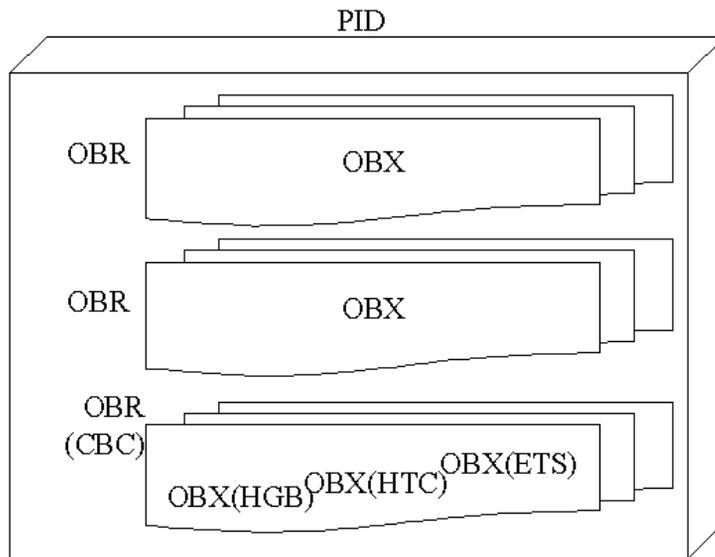


Figure 2. HL7 provides a one-to-many three level structure for laboratory information

Each patient can have one or multiple laboratory tests ordered by a physician and each laboratory test can have one or multiple results. For example a complete blood count (CBC) request will include values for the haemoglobin level (HGB), the haematocrit (HTC) and erythrocyte count (ETS). OBR = Observation Request Segment, OBX = Observation/Result Segment and PID = Patient Identification Segment.

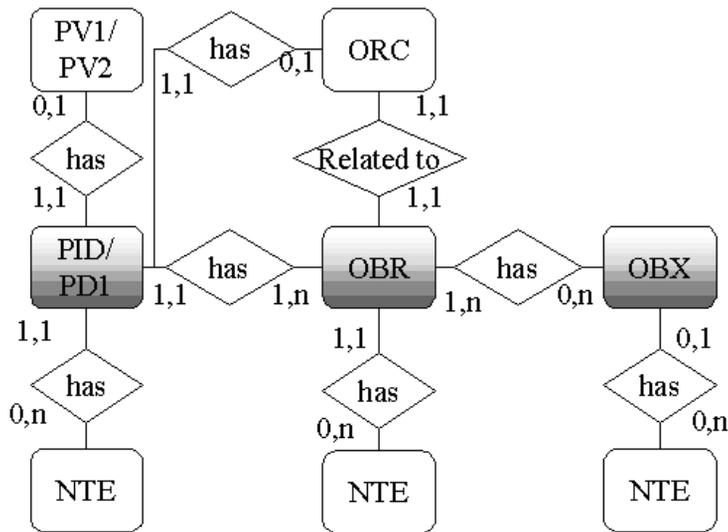


Figure 3. Entity relationship diagram for an unsolicited observation result (ORU) message

Segments PID/PD1, OBR and OBX represent the core data sets of laboratory information. Some specific scenarios might need PV1/PV2 to supplement PID/PD1 and ORC to supplement OBR. Each segment has an NTE for notes about information which cannot be encoded. In the diagram, the minimum and maximum of each entity have also been expressed, n means unlimited. PV1 = Patient Visit Segment, PV2 = Patient Visit – Additional information segment, ORC = Common Order Segment, PID = Patient Identification Segment, OBR = Observation Request Segment, OBX = Observation/Result Segment, NTE = Notes and Comments Segment.

HL7 AND LABORATORY INFORMATION DATABASE STRUCTURE

In HL7, the primary message for representing a laboratory data set is a three-level structure as shown in Figure 2. This consists of:

- PID (Patient Identification Segment) to present patient information
- OBR (Observation Request Segment) to present laboratory requests
- OBX (Observation/Result Segment) to present laboratory results

This design provides a one-to-many three-level structure, i.e. each patient can have one or multiple laboratory tests ordered by a physician and each laboratory test can have one or multiple results. For example, if a physician only orders an ESR (erythrocyte sedimentation rate) test, he will receive a single value. If he, however, also orders a CBC (complete blood count) test, he will, in addition, receive the several values that comprise a CBC result (see Figure 2).

The entity relationship diagram of an unsolicited observation result (ORU) message is shown in Figure 3. PV1 and PV2 represent patient visit information; ORC represents order information; NTE represents comment information.

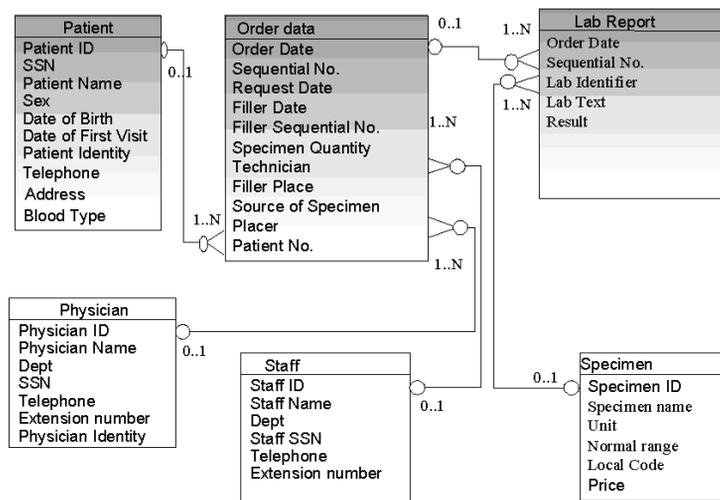


Figure 4. A typical entity relationship diagram for a laboratory information system

The tables of Patient Data, Order Data, and Laboratory Reports can have a one-to-many relationship. For example, the Order Data can link to the Patient table, Staff table, Physician table and Laboratory Results table through the Patient ID, Order Date, Sequential Number, Technician Identifier and Placer Identifier. Laboratory Results contains references to the Specimen table through a Specimen ID.

Combining Figure 2 and 3, we can generate Figure 4. This shows that the tables of Patient Data, Order Data, and Laboratory Report are generally comparable to PID, OBR, and OBX respectively.

DATA TYPE ANALYSIS

The data type in LIS tables is primarily composed of CHAR (Character), VARCHAR (variant Character), INTEGER, and DATETIME. These four data types are the most fundamental and cannot be further subdivided. The data types of messages in HL7 are more complex, with a total of 62 data types. The data types in OBR messages are shown in Figure 5 and 6.

AGENT MAPPING ALGORITHM

As the data type between the HL7 message and the relational database are quite different, OSIHA proposes an agential mapping algorithm to clarify the rules for transforming the relational data structure into HL7 messages.

1. Looking for the Terminal Data Element

In Figure 7, all data types starting with the * sign (*Value type, *Identifier, etc) are the terminal data elements. Generally speaking, the decision of the terminal data

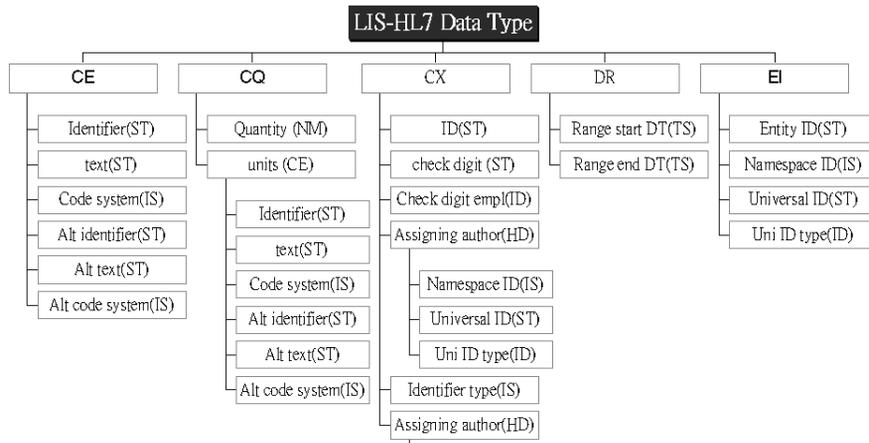


Figure 5. Important data types for HL7 messages in laboratory 1

There are three maximum sub-data types. The terminative sub-data type is always a string of numbers. CE = Coded Element, CQ = Composite Quantity with Units, CX = Extended Composite ID with check digit, DR = Date/Time Range, EI = Entity Identifier, ST = String, IS = Coded Value for User-Defined Tables, NM = Numeric, HD = Hierarchic Designator, TS = Time Stamp, ID = Coded Value for HL7-Defined Tables.

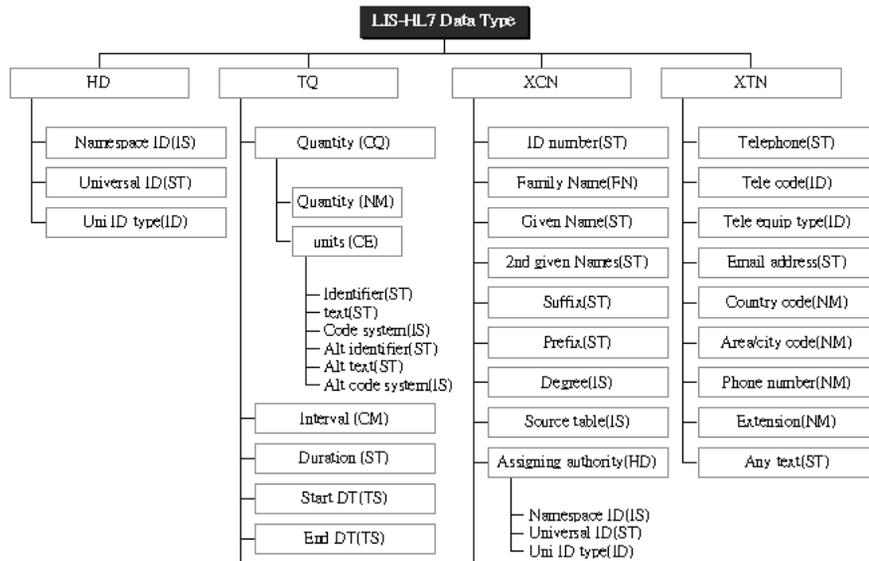


Figure 6. Important data types for HL7 messages in laboratory 2

The data type can be a sub-data type of another data type such as CE in this example. CM = Composite, FN = Family Name. For other abbreviations see legend to Figure 5.

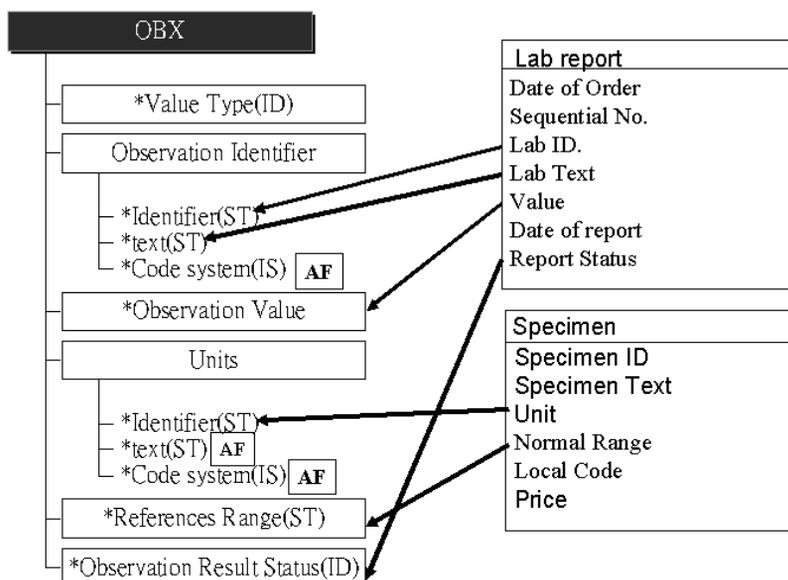


Figure 7. Example of a mapping algorithm from a relational table to a HL7 OBX segment

We cannot always find information to map to the data component, for example, the Assigning Field (AF) part sometimes needs to be assigned a regular value such as ICD9 (International Classification of Disease Version 9).

element depends on the completeness and comprehensibility of the source information.

2. Analysing Data Fields in LIS and Mapping to the Terminal Data Element

In Figure 7 we can see this step is usually difficult and ambiguous. Any given data element can contract with a dissimilar terminal data element from a different expert. The result, however, does not influence the encoding – expressing information efficiently based on correct syntax and common consensus is the key. A comprehensive way of coding can be found on the Web. For example, HL7 Taiwan provides several Chinese localisation guidelines on its official website⁹. This might help in reducing the variety of field conversions.

3. Data Format Transformation

This step maps and converts different formatted data fields from different sources using a different transformative approach. Laboratory information is relatively simple and stable. Consequently OSIHA proposed a series of data format transformative functions including separation, supplementation, truncation, replacement, concatenation and numerical conversion based on NoDoSE¹⁰ which is mainly applied to document transformation.

4. Assigning Coded Elements

Normally people use identifiers to represent complete long names in order to economise data storage and comprehensibility. The coded element (CE) provides a strict standard that requires the user to fill it in with the identifier, text of the laboratory item, the name of the coding system, alternate identifier, alternate text and name of the alternate coding system (see the AF mark in Figure 7). For example, the data element |530.0^Cough^ICD9| refers to the diagnosis of the common cold with the identifier in Version 9 of the International Coding of Diseases (ICD9) being 530.0. Other commonly used systems in medicine for providing coding include LOINC (Logical Observation Identifiers Names and Codes) and SNOMED (Systematized Nomenclature of Medicine). However, no field of names or coding systems are in common use for LIS. This could potentially result in confusion during information exchange. To prevent this, users can assign a constant value for the field and sometimes use the value “Z” to define the locally defined coding system.

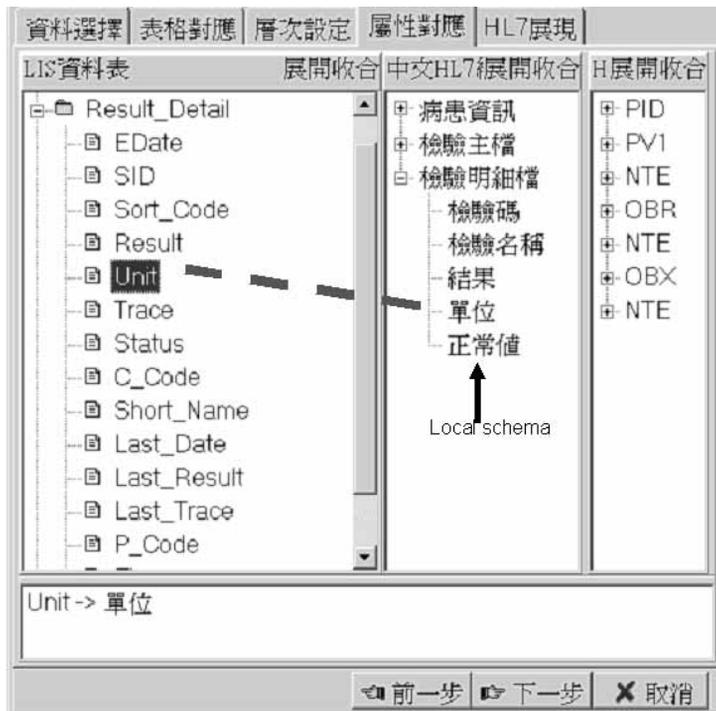


Figure 8. Source-and-destination selection wizard, that provides an alternative way of expression for HL7 in Chinese (middle part of the window), and a drag-and-drop way of schema mapping

The bottom part of the window shows the validated mapped fields.

RESULTS

OSIHA was created for a government sponsored project MIEC (Medical Information Exchange Center³) and introduced into the clinical laboratory of three hospitals located in Taiwan. OSIHA has been released as open source software and is being adopted by a growing community of users in hospitals on Source Forge (<http://sourceforge.net>) – the biggest open source community with a General Public License (GPL). The system begins with a source-and-destination selection process (Figure 8). The process can enable users to compare every data element via a drag and drop interface.

After selection of the source and destination process, a data transformative tool-window pops up and enables users to convert their data elements semantically (see Figure 9) with separation (see Figure 10), supplementation, truncation, replacement, concatenation (see Figure 11) and numerical conversion.

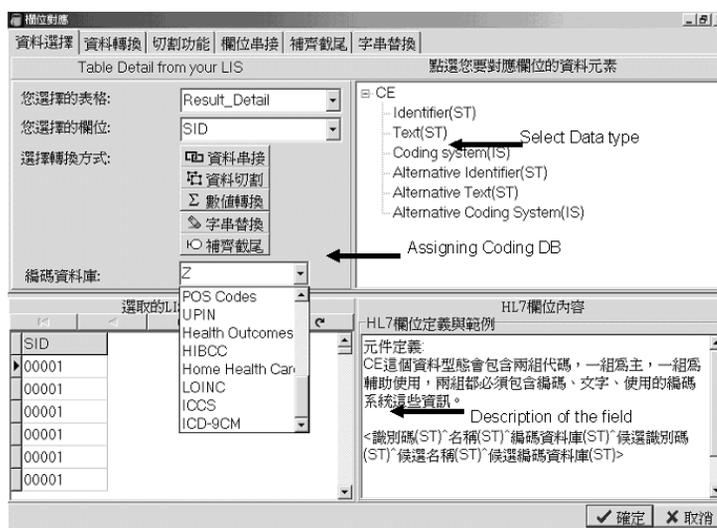


Figure 9. The data conversion main window



Figure 10. The separation function, allows the user to separate one field into several elements by setting a start position, an end position and a temporal alias name



Figure 11. The concatenate function

The large arrow designates the new alias name.

To generate the required HL7 message at an appropriate time, users must configure the occasion of the triggering event. There are two kinds of trigger event, one is external and one is internal. For example, OSIHA can wait for the external application to send out a query message and then search the database according to the patient identifier, physician identifier or data time range. It then generates the HL7 message in the external triggering status. In the internal triggering status, the user configures the scanning time interval to program OSIHA to scan the LIS database at the right time. After the configuration, OSIHA associates the related tables via the referential key and primary key that is designated by the user and generates the HL7 message in a semantically corrected form.

DISCUSSION

Independent projects are best built using freestanding components that leverage the power of freely available open source tools¹¹. An additional advantage of open source tools is that there is less concern about their integrity compared to using a commercial product. Open source tools can be downloaded and inspected by the user and publicly evaluated. In our opinion any national project on exchanging patient information should utilise open source tools.

OSIHA provides a customisable GUI data element transformative procedure that enables users to interface their application with HL7 in a zero-line-programming implementation. The method requires the user to have only a very basic knowledge of HL7 control and query and of the schema know-how for their application.

In this study we managed to successfully use OSIHA to convert data from a laboratory database into HL7 messages. Based on the results of our preliminary experience with OSIHA we now plan further work including:

- (i) Implementing the methodology into other clinical operating processes such as scheduling, admission, discharge and order entry

- (ii) Generating more schema mapping, transformative and other programmable tool sets
- (iii) Formalising the methodology and adding more graphical user interfaces to assist with data transformation.

If we are successful, it should be easier and cheaper to introduce HL7 standards into hospitals in Taiwan and consequently aid the process of implementing electronic patient records.

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Archetypes, GEHR, openEHR and Electronic Health Records

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ABSTRACT

HealthConnect, the proposed National Health Information Network for Australia (HINA), has centred the activity of health informatics in Australia around the establishment of a national electronic health record (EHR). In Australia, Good Electronic Health Record (GEHR), openEHR and their two level modelling and archetype approach are well regarded by experts on electronic health records. The two level modelling and archetype approach is a significant innovation in health information system design. The intention of adopting archetypes to empower domain experts to take the responsibility for domain knowledge modelling and updating is an important concept. The technology offers the promise of bridging the knowledge and skill base of both software developers and domain experts to achieve the goal of building a 'future-proof' electronic health record system. This gives promise for the construction of a user-centred health information system. Several projects have been sponsored by the Australian government to develop and test the technology. This article briefly reviews the initiation, development and current status of EHRs, archetypes and two level modelling technology. Issues of concern in archetype implementation are addressed and the direction for the development of openEHR is recommended.

INTRODUCTION

The Electronic Health Record Task Force¹ in Australia defines electronic health records (EHRs) as “*an electronic longitudinal collection of personal health information, usually based on the individual, entered or accepted by healthcare providers, which can be distributed over a number of sites or aggregated at a particular source. The information is organised primarily to support continuing, efficient and quality healthcare. The record is under the control of the consumer and is stored and transmitted securely.*” Any EHR system providing the above function should ideally maintain future-proof recorded information². The system should be built up of future-proof software and guarantee system interoperability at domain knowledge level. However, health information is characterised by huge volumes of domain concepts, for example, as numerous as 350,000 terms in SNOMED

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(Systematized Nomenclature of Medicine). The building blocks for EHR systems, such as domain knowledge, software and hardware technology are all subject to constant, rapid change with continuous introduction of new health concepts, treatment methodology and technology². In response to the dynamic and complicated challenge of both domain knowledge and the information systems that carry and manipulate the knowledge, two Australian health informatics modelling experts, Thomas Beale and Sam Heard, proposed a new concept ‘archetype’ and ‘two level modelling’ technology for EHR development. This two level modelling technology has been successfully implemented in two General Practice Computing Group (GPCG) funded projects: GP systems to GEHR transformation trial (GP to GEHR) and the OACIS-GEHR transformation project³.

This paper will briefly review the concepts of two level modelling, archetypes, GEHR and openEHR. The applicability of the technology in the current health information arena is discussed. Directions for the future development of openEHR and archetypes are recommended.

THE TWO LEVEL MODELLING AND REFERENCE MODEL

According to Beale *et al.*⁴, information is statements about specific entities. Knowledge is statements that apply to all entities of a class. The separation of information from domain knowledge is achieved through the use of two models:

- A reference model
- An archetype model⁵

Archetypes are used as part of a two level modelling methodology that aims to separate domain information from domain knowledge⁴. Systems are built from information models only and driven at runtime by knowledge-level concept definitions or “archetypes”⁶. The reference model comprises non-volatile concepts that apply across the entire domain⁴. It is the framework for building the information system. For example, the EHR Reference Model⁴, which is the building block for openEHR, has classes such as:

- EHR – Consists of Folders and Transactions.
- Folder – High-level organisation of the EHR, e.g. per episode, per clinical speciality⁷, etc.
- Transaction – Data from a particular clinical event (event transactions), or particular categories of clinical data that have long-lived significance, e.g. family history (persistent transactions).
- Organiser – Similar to a heading in a document. Consists of Organisers and Entries.
- Entry – Clinical “statements” about Observations, Evaluations, and Instructions⁷. It contains data structures (such as lists and tables) and data items (such as strings, booleans and codes from classification schemes).

The outer structure of an archetype is as follows⁴:

- Header_part – archetype identification, meta-data
- Body_part – archetype definition
- Terminology_part – terminology definitions and binding

To explain the concept of archetypes, Schloeffel⁸ has used an analogy with language. Sentences are created using words from a dictionary and according to grammatical rules. Archetypes are the rules for constructing meaningful sentences. Without such rules, we can construct an infinite number of grammatically correct but meaningless sentences e.g. ‘My English feels hungry’ or ‘Good food eats well’⁸.

ARCHETYPES

Archetypes are defined as “*domain concepts, expressed using constraints on instance structures of an underlying reference model*”⁵. Archetypes are basically constraints. They are, in simple terms, a set of rules that dictate how elements of the reference model can be organised into a meaningful form, and values that instances of the element can take. The purpose of an archetype approach is to let domain experts create and modify archetypes without the involvement of IT experts. The semantics of archetypes are defined in an archetype model corresponding to the reference model. According to Beale⁵, an unlimited number of archetypes can be derived from the archetype model. Each archetype should describe a distinct, complete clinical concept in an ontological space.

Bird *et al.*⁹ gave examples of a range of archetypes that could be used to constrain instances of the EHR Reference Model:

- Transaction level archetypes, such as patient contact, health summary and care plan
- Organiser (or document heading) level archetypes, such as problem lists, family history lists and discharge summary headings
- The archetype model may define that an observational content item owns a list of values
- Content item level archetypes, such as blood pressure, biochemistry and audiology test result

Figure 1 gives an example of a blood pressure archetype. Systolic and diastolic blood pressure are specialised types of general class blood pressure⁵. The first value in the “Proposition” list is “*Systolic*”. The value must be of type, quantity, with units “mmHg”. The minimum value is 40, and the maximum value is 300. The second value in the “Proposition” list is “*Diastolic*”. The value must be of type, quantity, with units “mmHg”. The minimum value is 40, and the maximum value is 300.

Archetypes should have a formal, well-defined internal addressing mechanism that allows intelligent querying. Relationships between archetypes can be dependent on composition or specialisation, similar to that in an object-oriented approach⁷. Archetypes can be updated and revised.

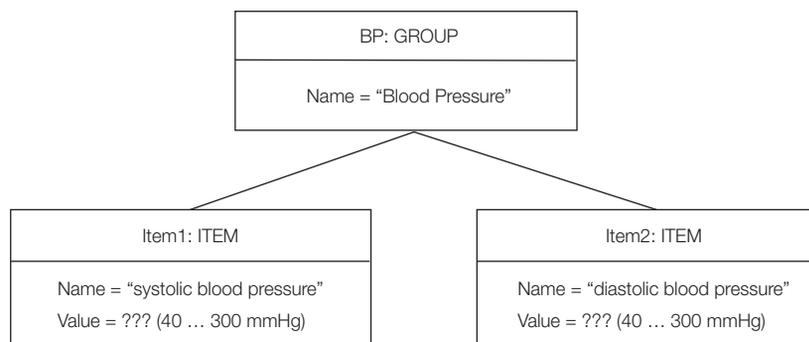


Figure 1. Blood pressure instance in archetype approach (adopted from Bird et al.⁹)

GEHR AND OPENEHR

Good European Health Record (GEHR) was a three year project started in 1991, funded by the European Union's Advanced Informatics in Medicine (AIM) initiative¹⁰. The GEHR consortium comprised 21 participating organisations in eight European countries. The project delivered a large body of work, including a comprehensive EHR architecture. It has significantly influenced the development of European standards. In 1998 Good European Health Record (GEHR) was renamed as the Good Electronic Health Record (GEHR). Two of the participants in the original GEHR project (Sam Heard and Thomas Beale) subsequently working on the development of EHRs in Australia proposed the concept of two level modelling, and the use of archetypes to separate information and knowledge⁴.

In 1999 the openEHR Foundation was established between Australian and European teams to encourage harmonisation and collaboration¹¹. This has led to active development of standards for an electronic health record throughout Europe and Australia. In 2002, the openEHR foundation began revising the GEHR model. The majority of concepts remain unchanged, but the GEHR is now referred to as the openEHR model. The *openEHR*, therefore, actually originated from the Good Electronic Health Record¹¹.

OPENEHR IN AUSTRALIA

In 1997, the IBM Consulting Group was contracted by the Commonwealth Department of Health and Family Services (DH&FS) General Practice Branch (GPB) to report on the issues surrounding the adoption and use of General Practice Computer Systems (GPCS) by Australian practitioners, and to develop a functional requirements specification and technical framework that would lead to widespread application.

The “Functional Requirements Specification Report”¹³ identified eight critical standards to form a Standards Framework. Regarding the category of Electronic Health Record Architecture, the report concluded: “*In order to ensure optimal data management and interoperation between GPCS applications/functional components, it is vitally important that the GPCS is based on a standard electronic health record architecture. From extensive research, the IBM Consulting Group has concluded that the Good European Health Record (GEHR) Architecture is the most appropriate and comprehensive health record architecture currently in existence.*”

As a consequence of the report, the General Practice Computing Group (GPCG) funded preliminary implementation trials for Good European Health Record. Further discussions and the outcomes of these trials can be found at: <http://www.gehr.org/gpcg/index.htm>.

In November 1999, the Australian Federal Government formed the National Electronic Health Records Taskforce to coordinate a national approach to the development of electronic health records. Their report, “A Health Information Network for Australia (HINA)”, was released, and endorsed by the health minister in July 2000¹⁴.

With respect to the standards to be used for the structure of the stored record, the Taskforce agreed that a standard format for data should be adopted, but accepted that there was no consensus as to the choice of standard. After much deliberation they proposed that GEHR be adopted. “*The GEHR (Good Electronic Health Record) appears to have the best prospects and is the subject of a trial within Australian general practices through the General Practice Computing Group (GPCG) at present. The Taskforce therefore proposes that further work proceed in this area, building on developments to date.*” As explained earlier GEHR is now known as openEHR.

A critical aspect of the openEHR framework is the concept of two level modelling through incorporating archetypes. Currently, openEHR is in the process of conducting implementation trials through the Software Development and Clinical Trials Phase of HealthConnect’s openEHR work program, commissioned by the Department of Health and Ageing. The project is continuing.

THE ABILITY OF OPENEHR TO WORK WITH LEGACY AND SOURCE SYSTEMS

Trials funded by the Australian General Computing Group have demonstrated the feasibility and benefits of adopting GEHR. The OACIS-GEHR project¹⁵ proved that data could be extracted from a large clinical database and used with a GEHR system. The conversion of data was achieved in two steps using a process that was specifically developed for the OACIS-GEHR project:

1. A pre-processing phase involving the extraction of rows from the database in plain text and conversion of this text to Extensible Markup Language (XML).

This was followed by mapping of the database 'fields' to the GEHR archetype 'fields'.

2. A generic phase, (which might be applicable to other systems), using the mapping tables produced in phase 1, XML technology and Extensible Stylesheet Language (XSLT). These processes automatically converted the database entries into the appropriate archetype format.

This data conversion involved a large amount of manual effort, and was not performed in a run-time situation. Nevertheless, the trial demonstrated the feasibility of achieving the conversion using current technology.

Another project, the GP-GEHR transmission project, used a conversion tool created by Distributed Systems Technology Center (DSTC)¹⁶. This conversion tool enabled the extraction of GEHR event summaries from the two dominant GP software packages in Australia, Medical Director and Locum Script, and exported the extracted data to a GEHR-compliant EHR server.

In both experiments, the key success factor was the capability of mapping between the fields. If the system-specific pre-processing stage can be simplified, for example, through improved mapping tools, then the whole process will be feasible. Tools to aid in this process are planned for development in 2003–2004⁹.

APPLICATION OF ARCHETYPES IN THE OACIS-GEHR AND GP-GEHR PROJECTS

In openEHR, archetypes are expressed in XML format. Domain experts, in this case healthcare professionals, are given the convenience of creating and editing archetypes without the need for knowledge of either software development or XML knowledge. A prototype archetype editor, Clinical Model Builder, developed in Visual Basic by the Project Titanium team at the DSTC, has developed this tool^{5,7}.

Archetypes should be stored in online repositories, easily accessible by the archetype editor. Systems are responsible for organising, searching and accessing archetypes, and their numerous versions created by multiple authors. Validator, a software component, is in charge of using archetypes for creating and manipulating the content of the EHR. Information is retrieved at runtime from the online repository. A validator is any component that works with archetypes to ensure that the content is valid against both the reference model and the archetypes⁵. For example, the creation of EHR content at clinical source systems (such as a patient event) would require data validation, through either a kernel within the source system, or in a data extraction/conversion tool. Similarly, a server storing EHR information would validate data upon receiving or sending extracts of the EHR (such as a patient event)¹⁷.

SOFTWARE IMPLEMENTATION

The exact mechanism for the implementation of the openEHR architecture is continuing to evolve, particularly through the planned stages of the Software Development and Clinical Trials Phase of HealthConnect's openEHR work program OACIS-GEHR and GP-GEHR project.

A mechanism for validating archetypes has been outlined by Bird *et al.*⁹. First, archetypes are specified in XML in a specific Archetype Constraint Language. An EHR extract is first checked against the reference model, using XML Schema. Then the extract is checked for conformance with the relevant archetypes by an XSLT processor, which uses a common XSLT script to retrieve archetypes from the online repository. Any errors in the EHR extract are then reported.

THE ROLE OF THE KERNEL

A kernel is a software component that implements the GEHR Object Model (GOM). It is responsible for loading archetype documents dynamically from a clinical knowledge server. The Reference Model and the set of stored archetype definitions are used to validate any clinical data placed inside a locally-created EHR, or sent from another EHR system as an EHR extract¹⁸.

THE IMPACT OF ARCHETYPES ON SOFTWARE DEVELOPMENT

The introduction of archetypes into health information system modelling is a significant innovation in software development. There are many software development models and although some of them emphasise the importance of user participation in software development, none of them empowers the user (or domain experts) with the authority of designing and manipulating components of the software. The intention of the archetype approach is to pass the task of archetype maintenance and evolution to domain experts. The domain experts are expected to add archetypes to the data model when new concepts arise. It is also the domain expert's responsibility to delete, revise or update an existing archetype.

THE ADVANTAGE OF THE ARCHETYPE APPROACH

The separation of a knowledge model (archetype) from a reference model reduces the size of the information system that has to be designed and implemented by software developers. It empowers users in a domain to formally define and implement their concepts in the information system. The system guides and validates user input at runtime to ensure that information 'instances' conform to domain requirements⁶. This is a significant innovation in software development. The

archetype approach provides a number of advantages in the maintenance, interoperability and future applications of the final software system⁶.

PROBLEMS WITH OPENEHR AND THE ARCHETYPE APPROACH

Tun *et al.*¹⁷ pointed out that the problem with the two level modelling approach is that important clinical semantics may be lost. They gave an example of a blood pressure test that has to be represented by systolic and diastolic values, with each in a decimal number. “An EHR system using this approach would have to allow users to set both their own field names and values, which may result in data that is inconsistent and impossible to use.”

Classes in reference models are highly generic, and have no real meaning by themselves. As Bird *et al.*⁹ states, users can organise these classes and limit their instances in an *ad hoc* manner to express the components of an EHR system. Without a strict standardisation process, inconsistency and poor interoperability between systems would result.

The Transformation of Data Automatically from non-GEHR Legacy Systems into GEHR XML Format and Vice Versa

This function is required to enable existing EHR systems to exchange data with each other. This may be achieved through using a common record architecture (namely GEHR) to enable interoperability among varieties of systems¹⁷.

How to Automatically Configure Interface Terminology to Reflect the Change of Archetypes?

A significant amount of domain terms are actually built into the interfaces of various gadgets and widgets such as buttons, text definitions for check boxes, radio buttons and text fields, etc. The problem of developing dynamic user interfaces, which can automatically configure themselves in response to the creation and changing of archetypes, has yet to be addressed.

The Separation of Knowledge and Information Levels Significantly Increases the Information Content of the Application

If the two levels are stored in different locations in a distributed environment, an always-on Internet connection is a prerequisite for the proper functioning of the system. Compared with a normal information system, a two level system significantly increases the overheads of the information system and the load of the network traffic. Further investigations are needed to discover how much extra storage space and operating speed the model will need compared with the normal one-level approach, and whether current technology and the distributed environment can handle this flow of information content?

The Construction of a Comprehensive Set of Archetypes at the Start of the System Development is Required for the Success of an Archetype-driven EHR

This requirement however diminishes the benefit of flexibility, adaptability and extensibility of archetypes. It could lead to the selection of the traditional single-level model as the most rational decision because of the simplicity of design and the popularity of the methodology in software industry.

THE FEASIBILITY OF ARCHETYPE CREATION AND MANAGEMENT

The question of whether domain experts have enough expertise and experience to handle the task of designing archetypes needs to be addressed. Bird *et al.*⁹ realised that the success of the archetype approach relies largely on the capability of domain experts to understand and create archetypes. An archetype editor application removes the need for programming when creating archetypes, but a good understanding of data modelling is still required.

The domain experts involved in the two GPCG funded projects: GP-GEHR and OACIS-GEHR are all GPs with a special interest in computer technology. They are enthusiastic IT advocates and keen on technology. Despite this, Bird *et al.*⁹ reported that domain experts had difficulty in constructing complicated archetypes even with the help of Clinical Model Builder, a GUI- (Graphical User Interface) based archetype creation tool that was used to simplify the archetype creation process. DSTC is continuing to develop new application tools to make archetype creating more manageable for domain experts.

Deficiency in the skills of domain experts can be addressed through training and practice. However, this raises issues about the number of domain experts that would need to be trained, the cost of the training and the source of funding. Given the diversity of healthcare domains, many of which are very specialised, the number of domain experts required to effectively conduct the task of creating and maintaining archetypes may be substantial.

Skill expectations are particularly relevant in health sectors where the penetration of information and communication technology is varied. A large proportion of domain experts involved in care of the elderly in Australia do not have sufficient computer knowledge to handle archetypes. Although well-trained experts could create the majority of archetypes for use at a state or even national level, the benefit of flexibility and extensibility that archetypes offer would be diminished if smaller organisations are incapable of creating customised archetypes.

The scenario for the successful implementation of a normal 'one level' EHR approach is that a uniform vocabulary and terminology set have to be adopted by the whole healthcare industry nationwide. This is the prerequisite for achieving interoperability and exchangeability in EHRs. In this scenario, even though the health information system adopts a normal big 'one level' data model, the terminology used in different systems should be consistent. If HL7 compatibility is

built into the system, the interoperability is achievable in an Internet-based Web application. The vocabulary and terminology may change from time to time. For system developers, this is a matter of searching and replacing the old terms with new ones. Medical Director, an electronic desktop prescription system, has been adopted by more than 80% of General Practitioners, and has been continuously updated in response to feedback from GPs. New functions are added, obsolete functions removed, problematic decision support functions modified, etc. Every year a new version of Medical Director is released. The success of Medical Director suggests that health information system can be effectively maintained by developers in close consultation with domain experts. Domain experts may have no knowledge of the software development process or the concept of an object oriented approach. Handing the task of creating and editing archetypes to domain experts will therefore be a significant challenge.

CONCLUSIONS

Both traditional modelling and the two level modelling approaches present potential problems. A single-level model requires a substantial, essentially centralised effort, through drawing on work from various domain models. It may be prone to inefficiency and misunderstandings of domain concepts.

An archetype approach offers the advantage of dividing the responsibility between software developers and domain experts. However, the availability of experts for the creation of the individual archetypes could be a problem. Possible issues in an archetype approach are: disputes over archetype suitability; redundancy of effort by separate creators; inappropriate archetypes and the risk of gaps in the knowledge required for the various domains.

As an innovative new idea and modelling approach, openEHR, two level modelling and archetypes are still in the infancy stage from the point of view of technology maturity. A lot of theoretical investigation and practical implementation has to be conducted to improve the technology. The syntax for archetype construction is yet to be defined in a concrete, concise, easy-to-read plain language. Education and capacity building of domain experts with enough knowledge and skill base is a critical factor determining the success of the openEHR and archetype approach. Building easy to use tools to facilitate archetype edition is an important action yet to be taken. How to dynamically update the domain term built into an interface corresponding to the change of relevant archetypes is a technical issue yet to be solved.

The establishment of Electronic Health Records is a substantial research and development endeavour that is defined by legislation, standards, culture and practices of healthcare in different countries. It requires the collaborative approach from health informatics researchers, government agents and domain experts all over the world. The current development of EHR functional specification by the

HL7 EHR special interest group is a further step toward acquiring complete evidence for the establishment of EHR. The design of EHR model and the consequent implementation is an important experiment yet to be taken. The feasibility of openEHR and the archetype approach has been tested by the two implementations mentioned in this paper. However, openEHR and the archetype approach is yet to be improved. This requires a collaborative approach from experts all over the world.

ACKNOWLEDGEMENT

The author is grateful for the research assistance provided by Stephen Trembath.

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