

Global Interoperability and Archetype-Based Clinical Information Systems

By

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Abstract

The story of Health Information Technology (IT) interoperability can be compared to the proverbial Tower of Babel, wherein all people originally spoke one language. The medical record, historically a paper document used to record health care data, was interoperable within the confines of technology. It could be written, mailed, copied, faxed, even more recently, scanned and sent as an email attachment. However, as electronic health IT systems have evolved and proliferated with their own unique framework, they have become increasingly isolated and non-interoperable. This review examines the fundamental requirements for and global implications of health IT interoperability.

Lack of system interoperability is a significant barrier to the implementation of health IT globally. This prevents health IT from fully realizing its potential as a tool to improve overall healthcare quality and medical research, increase surveillance for pandemics and other public health concerns, and from serving as a 'rising tide' that raises the level of health systems worldwide. On a more pragmatic level, lack of global health IT interoperability has significant impact on all who travel, work, and live abroad.

This paper is based on a review of the recent literature regarding health IT interoperability. It explores the present status of specific nations to implement interoperable solutions within their existing health IT systems. The benefits of interoperability are examined in depth, along with the many barriers that stand in the way. Finally, solutions to these barriers are reviewed, as are the requirements for implementation. These solutions are crucial for health IT to deliver the many societal benefits it promises to bring to global health.

Introduction

Terms and Definitions

What defines “interoperability” from the health IT perspective? Some have broadly characterized it as “healthcare’s holy grail.”¹ At a high level, Freedman² defines interoperability as the ability for “data to be transferred or shared in a meaningful way—typically in conjunction with other data.” Adding to this, Hufnagel³ states that “interoperability is the ability of an IT system component to work with other IT system components without special effort on the part of the user.” Others take this one step further, adding that not only must information be transferrable between systems, it also must be usable. For instance, Kun⁴ defines interoperability as the “ability of two or more systems or components to exchange information and to use the information that has been exchanged.” Dr. Robert Mathews⁵, an interoperability expert at the Center for Strategic Advancement of Telematics and Informatics, defines it as “that ability for people to interact with each other, between organizations, across domains of influence and geographical boundaries—supported by the proper decisioning tools and services—to achieve a goal/objective/decision....”

With regards to interoperability in the arena of health IT, Jerome and Wong⁶ classify it as follows:

- Technical interoperability - connecting computer systems to exchange information
- Functional interoperability - combining the information and processing it in a meaningful manner
- Semantic interoperability – ensuring precision in meaning as information is exchanged so that it is understandable by any person or application receiving the data

Similarly, Wozak et al.⁷ provide the following criteria are core components of interoperability:

- Interfaces: Has a common structure of interfaces been agreed on?
- Semantics: Are data interpreted identically on systems of different vendors?
- Legal: Are local legal and organizational requirements correctly considered?
- Security: Must the security level of a system to be decreased for the sake of interoperability?

Interoperability can also be viewed from a framework perspective. For example, researchers in England used qualitative methods to assess the impact of health IT interoperability across a highly integrated

healthcare network. Using Diffusion of Innovation theory as a framework, they found that interoperability must occur fundamentally at 3 levels: ⁸

- The Micro-level by the material properties of the technology, individual's attitudes and concerns, and interpersonal influence.
- The Meso-level by organizational antecedents, readiness, and operational aspects of implementation.
- The Macro-level by institutional and socio-political forces.

All of these definitions and frameworks share a common thread—health IT interoperability is ultimately defined by the ability to exchange electronic health information in a meaningful way.

A Global Perspective

The paper medical record has been used to record healthcare data for decades, and in virtually every country. As noted, it affords basic interoperability in many ways. It is easily transferred between providers or healthcare organizations, and once transferred, is readily interpreted and re-used, language and cultural barriers notwithstanding. In fact, one could argue that the recent evolution of healthcare information from paper to electronic format has created, or at least compounded, the issue of interoperability. This is in contrast to financial and other industries, which have experienced increased interoperability when implementing electronic information technology.⁹

When examined from a global perspective, one quickly realizes the complexity of issues surrounding health IT interoperability. System standards are much more varied, as are messaging protocols. And barriers are not simply technical, but also legal and regulatory, since policies and laws governing privacy and confidentiality vary widely from country to country. Even a relatively unified organization such as the European Union lacks a standardized legal framework regarding health information technology.¹⁰ Finally, as with the paper record, the issue of language remains, although one may argue that English is the de facto “lingua franca” of medicine world-wide.

From this general overview, the following is a brief regional and country-specific look at interoperability:

Asia

In Japan, as in the US, lack of interoperability is seen as a significant barrier to wider adoption of computerized medical record systems within its hospital system. One study showed an adoption rate of 10 % for such systems as of February 2007, well below the Japanese government's target of 60 %.¹¹ Although healthcare organizations in Japan also cite financial constraints as a leading barrier to health IT adoption, this study's conclusion that "the communication between EMR systems should be further standardized to secure functional and semantic interoperability in Japan" underscores the importance of interoperability there as well.

China's health IT infrastructure is relatively new. Nonetheless, Chinese healthcare leaders and policy makers recognize the important role that semantic interoperability will play to improve healthcare quality in China.¹² The nearby island nation of Taiwan does not face the same geographic and ethnic diversity challenges as China, yet also grapples with interoperability. In their paper, Jian and colleagues¹³ describe the development of the Taiwan Electronic Medical Record Template, designed to provide a standardized solution to the lack of an interoperable electronic health record (EHR) in Taiwan.

Europe

Healthcare organizational structure in Europe is shaped by the European Union (EU), yet with large national variance. The health IT infrastructure in many EU nations is sophisticated and mature. That stated, every nation within the EU faces issues associated with lack of health IT interoperability. The goal of a highly integrated health IT network throughout Europe has encountered a variety of technical and legal challenges.^{10,14,15} Two recent studies by the European Commission found that improving the semantic interoperability of member nation health IT systems is essential if they are to improve healthcare quality individually, and collectively.^{16,17} In many ways Europe's experience serves as a harbinger of the issues other nations in the global community will face as they attempt move forward with health IT interoperability.

Canada

Infoway, an independent, non-profit organization funded by the Canadian government, has taken the lead in efforts to both increase the adoption and interoperability of electronic health records in Canada. Infoway's stated goal is to have 50 % of Canadians covered by a fully interoperable EMR in 2010, and 100 % covered by 2016. As of March 2010, 38 % of Canadians are covered, and \$2.1 Billion invested.¹⁸ Although a key objective is to connect the many EHR systems within Canada using HL7 v3 messaging standards, progress has been hampered by a lack of ability to enforce adoption of this or other standards. In Ontario, for example, there are at least 20 separate EHR systems in use, and most of these are not interoperable due to differing messaging and semantic standards.¹⁹

Africa

Health IT projects, including telemedicine and electronic medical record implementations, are occurring on a limited basis in Africa, most notably in Kenya, South Africa, Rwanda, Uganda, Nigeria and Mozambique.²⁰ Most of these are relatively modest projects, funded by non-governmental organizations (NGOs), and staffed by volunteers. Although some have enjoyed remarkable success on a local level, such as Malawi's Baobab EMR project, there has been little progress made, or even attention paid, to health IT interoperability between these nations or even within their systems.²¹

Australia

According to Sprivulis' group²³, Australia's healthcare system could realize additional benefits from greater interoperability, even though health IT adoption there is relatively high.²² Recognizing this, Australia created the National E-Health Transition Authority (NEHTA) and a national e-Health strategy plan with the main objective of advancing health IT interoperability, chiefly by defining national standards.²⁴ A key initiative of NEHTA is to implement a nationwide unique patient identifier system in Australia. This effort has encountered significant resistance and is now far behind schedule, despite its promise to enhance information exchange between EHR systems and thus improve efficiency and reduce medical errors.²⁵

USA

In the US, lack of health IT interoperability is a significant problem with many causes. Healthcare organizations, under increasing pressure to remain financially viable, are threatened by the prospect of sharing their patient-specific data with competing entities. Vendors with much invested in product research and development see little benefit from open standards and software coding. Even providers are often reluctant to share data, citing patient privacy concerns.

Another issue is that of ownership. In the US, there are four major regulatory bodies for which health IT interoperability is a significant focus: the American Health Information Community (AHIC), the Health Information Technology Standards Panel (HITSP), the Nationwide Health Information Network (NHIN), and the Certification Commission for Health Information Technology (CCHIT). Many more entities have at least a partial role in developing interoperability standards. The Office of the National Coordinator for Health Information Technology (ONC) was created in 2004, in part to address this “balkanization” of standards.²⁶

In 2004, President Bush issued Executive Order 13335, mandating that all federal organizations delivering healthcare have interoperable information systems by 2014. President Obama recently expanded the scope of this mandate to include the use of a certified EHR for each person in the United States by 2014. However, at present there is a lack of interoperability even among federal organizations that share patients and objectives, such as Department of Defense and Veterans Administration. Their EHR systems (AHLTA and Vista, respectively), despite a common development ancestry and billions of dollars invested, are not functionally interoperable at this time. Although they planned an information exchange using the NHIN CONNECT framework in early 2010, it has not yet occurred.²⁷

In a recent interview, David Blumenthal, head of the ONC, was asked about the global challenges to health IT interoperability. He noted that it will require a “cross national standardization of information exchange (and) convergence across borders to common standards...”²⁸ However, he readily acknowledged that interoperability of the US health IT system is the ONC’s present focus, not the global environment. According to Dr. Blumenthal, the US faces particular interoperability challenges due to its large size and diversity. He further noted the particularly high cultural value Americans place on individual autonomy also raises barriers by creating privacy and security constraints not found in Europe or elsewhere.

Benefits of Global Interoperability

Why all this interest in global health IT interoperability? To date, the benefits of health IT have proven difficult to document and quantify.²⁹ Indeed, there is concern that health IT solutions may even increase some medical errors, or at the very least, have unintended consequences.³⁰ In light of these, the value that interoperability will bring to as yet unproven technology requires insight and vision.

Healthcare Quality

Although there are few documented improvements in healthcare quality resulting from health IT, interoperability will magnify any future improvements generated. In 2001, the Institute of Medicine (IOM) cited lost information, lack of coordinated care, and information silos as leading contributors to the “quality chasm” facing healthcare.³¹ Fragmented healthcare results in poor healthcare quality.^{32,33} Interoperable systems decrease this fragmentation, and reduce (medical) errors of omission and commission by providing real-time exchange of vital patient information.³⁴ Conway and Clancy³⁵ emphasize the importance of this, stating that “interoperability between systems and exchange of health information is essential to enable coordinated care.” They further note that “important patient health information that is difficult or impossible to locate should become the exception instead of the norm.”

Biomedical Research

The primary use of the electronic health record is to document patient care. Increasingly, its secondary use as a valuable research tool is being realized.³⁶ Although legal issues pertaining to privacy and confidentiality need to be addressed, the aggregate power that many interoperable electronic health record systems would provide the clinical researcher such as those in the fields of genetics and translational bioinformatics is readily apparent. Halamka³⁷ cites clinical research as one of the key benefits of interoperable EHRs. Kun⁴ states that if health IT systems were globally interoperable “discoveries relating to the prevention or curing of a disease in one part of the world would be “known” everywhere else instantaneously.” Optimism notwithstanding, interoperable health IT systems could rapidly disseminate and incorporate the latest clinical research in the form of clinical decision support for clinician end-users.³⁸

Public Health Surveillance

The past decade has witnessed the emergence of new or rapidly evolving infections on the international stage: Severe Acute Respiratory Syndrome (SARS), Avian Influenza, H1N1, and others have captured headlines worldwide. While a truly global pandemic has not occurred, public health experts insist it is only a matter of time.³⁹ Although initially seen as a valuable tool for monitoring bioterrorism and other hostile acts, interoperable health information systems are now touted as front-line agents in real-time outbreak surveillance. Hufnagel⁴⁰ cites global syndromic surveillance as a prime use case for global health IT interoperability, while acknowledging that issues of privacy exist – for example, when data is used for this purpose, when must it be de-identified data? Clearly the answer depends on many factors, not the least of which are the privacy laws and regulations of the host nation. This is a classic case of the law not having caught up with the technology, insofar as most nations have yet to issue guidance as to what constitutes acceptable use of identifiable patient information for a greater public good. Nonetheless, the value that a fully interoperable global health IT system brings to syndromic surveillance cannot be denied.

Global Health Systems Improvement

Improving biomedical research and biosurveillance through global health IT interoperability would also have direct beneficial impact on global health systems. Kun⁴ states that “interoperability will help improve the quality of our healthcare and public health systems while significantly reducing expenses...” On a personal level, he comments that an “individual's life may be saved a few times by having the right information in the right place at the right time. The quality of life may improve, and ... personal genetic information will allow us to move into true disease prevention.” Interoperability means sharing information, and will require that the technological “haves” share with the “have-nots.”⁴ This is already occurring, as noted by Blaya et al.⁴¹

Healthcare Cost Savings

Lack of interoperability also leads to significant waste and inefficiency within the healthcare system. A detailed analysis by Walker et al.⁴² found that implementing full interoperability within the US healthcare system could generate savings of at least \$77 billion annually. Sprivulis et al.²³ estimated a net return on investment of over \$2 billion annually from increasing health IT interoperability in Australia. Both groups found that savings would be realized by decreasing redundant testing and other

medical evaluations, and by improved administrative efficiency within their healthcare systems. In this age of skyrocketing healthcare costs, savings of this magnitude are clearly a worthy goal. As noted by these authors, the improvements in healthcare quality generated would render these cost savings a tremendous value, regardless of their magnitude.

Adoption of Health IT

Finally, it is worth noting that the *lack* of interoperability impedes the further adoption of health IT technology. In fact, this lack of interoperability is cited as one of the primary reasons why US clinicians have not embraced health IT technology.⁴³ There are several reasons for this. First, since health IT systems are not interoperable, users must often enter demographic and other data manually, even though it exists in a digital format elsewhere. Second, laboratory and other clinical data are often not available real-time at the point of care, thus decreasing the value of health IT to the busy clinician. Finally, clinicians increasingly practice in more than one organizational setting (privileges in two or more hospitals for example), and most interact with many different insurance providers, yet have no functional information interoperability between them.

Specific Use Cases for Global Interoperability

In addition to the high level benefits of improving healthcare quality, medical research, syndromic surveillance, and raising standards of healthcare while lowering its cost, interoperability has practical uses. For example, consider the following specific use case scenarios:

Tourist Traveler

Tourism is a leading industry worldwide. It can also be dangerous, with travelers facing a host of exotic diseases and increased risk of trauma. Obtaining healthcare in a foreign environment is challenging at best, and providing that care when the patient's past history is unknown only adds to the risk. Few travelers take their medical record with them when they travel, and fewer return home with any record of the care they received abroad.

Expatriate

It is estimated that 8 million Americans are presently living outside the US, and this number is only predicted to increase.⁴⁴ Access to relatively inexpensive medical care is cited as a leading factor by many expatriates when asked why they live abroad, as any Google search quickly reveals. As with the tourist traveler, these individuals face issues related to incomplete medical record documentation while abroad, and if they return to their native country.

Diplomatic Community

The US State Department provides care for over 50,000 US government employees and their families assigned to US embassies overseas. These individuals are representative of the global diplomatic community: they move frequently, as part of posting assignments, and although the State Department has a modest medical program overseas, many of these individuals receive healthcare “on the local economy.” Much of this care goes undocumented, because it is often paper-based, or if electronic, is documented by systems that are not interoperable with those of US clinicians.

Military

According to Hufnagel,³ 80 % of veterans and 50 % of military personnel receive care from the private sector, as well as all of the Reserve and National Guard members who are not on active duty. Additionally, emergency care of active duty members stationed outside the US is often provided by healthcare providers in host nations. The EHR system of the Department of Defense (and subsequently, the Veterans Administration) presently captures little, if any, of this data in a structured format.

Multi-National Corporations

It is estimated that three percent of the world's workforce is deployed abroad by multi-national corporations (MNCs) at any given time.⁴⁵ As with diplomatic and military personnel, many of these individuals receive healthcare while abroad, and most MNCs provision for this through local healthcare systems. In addition to the risks inherent to living abroad, some of these workers also sustain occupational injuries and conditions, about which neither clinicians in their host country or those at home when they return, may be aware.

All of these "use cases" have common elements: patients are increasingly receiving care in foreign countries from foreign healthcare providers, most of whom provide this care without access to a longitudinal patient record. Many of these patients eventually return home without salient historical details of the care they received abroad. Their care is fragmented, incomplete, repetitive and haphazard as a result. A globally accessible electronic health record system would address these issues, to the benefit of their employers, their governments, and most importantly, the patient.

A Final Comment

This comment from David Blumenthal captures the role globally interoperable health IT systems should have:

"... all of us—every country in the world, including those that are far more advanced than we are in adoption—all of us face the challenge of using the power of information technology to change practice patterns, to change the flow of work in physician offices and in health care facilities, to hold ourselves accountable for improved performance, to systematically use the power of that information to make human beings more successful."²⁸

Barriers to Global Interoperability

Just as there are many benefits to be gained from health IT interoperability, there are also many barriers standing in the way. According to the ONC, these can be generally categorized as a lack of standards for transmitting the data, and the lack of a network on which to transmit the data.¹ Indeed, Hufnagel⁴⁰ notes that interoperability becomes “a quality of increasing importance for information technology products as the concept that “the network is the computer” becomes a reality.”

From a global perspective the situation is again complex. Using a framework approach, Wozak’s group⁷ defined several core components of health IT systems that constitute barriers to interoperability on a global scale: among them are the user interface, data semantics, and their legal and security requirements.⁷ From this high-level framework, several specific barriers merit further comment given the particularly significant role they play in preventing health IT interoperability.

Standards

Standards are the technical specifications that define how data are stored in systems, and transmitted between them, and are a crucial component for interoperability. Without them, systems are functionally illiterate, akin to traveling to Paris and not speaking a word of French. Ironically, the problem facing health IT is not a paucity of standards, but rather an over abundance of them, with resultant redundancy and incompatibility. For example, there are over 150 different sets of terminology standards alone, most of which do not readily map to each other.²⁰ Also, data transmission standards are not consistently applied or recognized. Systems sharing semantic interoperability standards cannot exchange information if they do not share transmission standards.

Unique Patient Identifiers

There is little benefit for health IT systems to share transmission and semantic interoperability standards if they cannot correctly identify the patient. Patient misidentification creates both false positive (matching different patients) and false negative (not matching the same patient) errors, both of which can lead to medical errors. Most countries, including the US, do not have a unique patient identifier (UPI) system in place, due to privacy concerns.⁴⁶ Australia’s plan to implement a UPI system has encountered stiff political resistance generated by privacy advocates, and is now behind

schedule.²⁵ Although several nations in Europe have instituted UPI systems, a unified solution that enhances inter-European interoperability has not been agreed upon to date.⁴⁷

Absent a UPI system, statistical matching algorithms are used to match records, as process called disambiguation. Unfortunately, disambiguation has several issues: it is inefficient, relatively expensive, and most importantly, it creates errors. These errors occur at relatively high rate, approximately 8 %, and thus create a significant source of medical errors.⁴⁶ Indeed, some believe that an excessive preoccupation with privacy results in decreased healthcare quality as a consequence.⁴⁸

Technology

There is little to be gained from having semantic and transmission standards aligned and patients uniquely identified if the technology infrastructure cannot support the functional and technical requirements that interoperability demands. This is not to say that complex solutions are necessary, especially in the developing world, which arguably stands the most to gain from health IT interoperability. For example, Malawi's Baobab EMR, the only fully electronic point of care EMR system in Africa, is successful *because* of its simplicity.²¹ This reflects that the technology deployed must be scalable and realistic for the conditions where it will be used. Moreover, it should be rigorously evaluated to ensure it works.⁴⁰

Funding

An often overlooked question is how the changes necessary to bring true interoperability to the healthcare system will be funded.⁴⁹ Restated, who will pay for the technology and infrastructure changes necessary for interoperability to occur? Although this is an obvious issue in the developing world, it also impacts developed nations. In the US, there is often an uncoupling of incentives, in that the cost of instituting health IT solutions is typically borne by the patients and their clinicians, who benefit from them the least, rather than insurers and equivalent entities.⁵⁰ This uncoupling will undoubtedly be an even greater issue as interoperable health IT solutions are sought for the developing world.

Workforce

Designing, implementing, and maintaining health IT systems requires expertise, and there is a growing awareness that health informatics specialists are needed to provide this expertise.⁵¹ It takes people with special skills to develop, implement and maintain health IT systems. And not just IT specialists, but also clinician specialists, health information management professionals, as well as health science librarians.⁵² Expanding this, the ONC has now identified 12 specific health IT workforce roles needed to meet healthcare delivery requirements in the US.²⁶ Unfortunately, similar workforce analyses do not exist for nations in the developing world. Just as “all politics is local,” so is healthcare, and the workforce roles defined in the US cannot be assumed to extrapolate to other nations, especially in the developing world. This makes it difficult to structure training and other workforce development programs abroad.⁵³

In addition to defining the workforce roles required in health IT, it is also important to assess how many workers are required, both now and in the future. According to a recent survey of the health IT marketplace, the push to reform healthcare in the US will add at least an additional 50,000 health IT professionals to the workforce by 2015.⁵⁴ What is not known is how many will be required to sustain this surge long term. Moreover, the number of professionals needed to implement realistic health IT solutions in the developing world is not known, yet it is clear the need in “low resource” countries is especially acute.⁵³ Again, it is difficult to propose and implement solutions without solid projections however.

Medico-Legal and Cultural Differences

The policies and laws that regulate the content and use of electronic health information also vary widely between nations, and create a significant barrier to interoperability. Nowhere is this more evident than in Europe, with its high density of nations and widespread adoption of health information technology.^{10,55} The solutions to the legal barriers facing European nations may serve as templates for others in the global community as they in move forward with interoperability.

A subtle but nonetheless important barrier to interoperability is the social milieu in which the health IT system functions. For example, what serves as a standard of medical care in one country may seem outlandish in another. There is growing recognition that “local culture, languages and indigenous

medicine is critical for successful e-Health implementation and interoperability”, according to a consensus of experts at the Rockefeller Foundation’s Bellagio Center conference.⁵⁶ In light of this, creating standards which are semantically interoperable for every use case may not always be practical, desirable, or even necessary.

National & Financial Interests

Nations often perceive a need to withhold public health information, be it for fear of causing economic downturn or civil unrest, or harming national security, or even civic pride. Witness the initial delayed reporting of the SARS outbreak by the Chinese government.⁵⁷ Health IT interoperability poses a potential threat from this perspective. Similarly, for-profit business enterprises may view the sharing and cooperation implicit in interoperability as anathema to their business models, and at times, a direct threat to their survival. It should therefore come as little surprise that some in government and private enterprise have been lukewarm in their support of interoperability.⁵⁸

Solutions

The following solutions, although by no means exhaustive, would collectively make global health IT interoperability not only attainable, but sustainable.

Uniform Standards

Although not as numerous as the many standards for transmitting and storing health IT data, there are multiple, autonomous organizations that play a role in developing and managing these standards. A listing of these reads like an alphabet soup of acronyms: IHE, ANSI, CDSIC, IHTSDO, DICOM, CEN, CCR, HL7, and ISO. There are many more, each with a particular functional, domain, or geographic focus for standards development. They are now working collaboratively to define ownership of standards, resolve conflicts between existing standards, and set policy for developing standards.⁵⁹

Although a case can be made for a single organization with ultimate authority to set standards, that is unlikely in an increasingly “flat” global economy.⁶⁰ Hence, the present emphasis on global collaboration and partnership regarding standards development, rather than unilateral mandate and fiat, must be encouraged, as progress is gradually being made.⁵⁹

Patient identifier systems

Recognizing the value that a UPI system brings to interoperability, many are now calling for its implementation. The multinational attendees at the Rockefeller Foundation’s recent *Path to Interoperability* conference agreed unequivocally that “successful exchange of information and the use of eHealth will require unique patient identifiers.” Hammond et al.²⁰ likewise identify the development of a global UPI as one of the five priority areas for health IT interoperability.

Hillestad and colleagues⁴⁶ address several of the concerns against UPIs raised by privacy advocates in a Rand Monograph. First, they note that a UPI, which is only used for healthcare purposes, is in essence “firewalled” off from the patient’s other sensitive information, such as financial records. Second, in the event of a breach, a new UPI is easily generated, unlike the patient’s other demographic information presently used for disambiguation purposes. Third, although not ideal, a UPI system could be optional, at least initially, which would encourage acceptance and consumer buy-in. They postulate that most would opt in as the clear cut advantages of the system become evident. Finally, Hillestad’s group⁴⁶ acknowledges that implementation costs for a UPI system are significant, up to \$11 billion. However, this is offset by the estimated \$77 Billion yearly savings (in the US alone) that a widely implemented and interoperable EHR system would generate.⁶¹

Other unique solutions may be necessary to placate privacy advocates. For example, a system of federal insurance, similar to the FDIC depositor guarantee for personal bank accounts, may be warranted. In the event of a privacy breach resulting in financial harm, this system would guarantee an individual’s losses, up to certain limits. Such a system could easily be funded within the present US health insurance system structure. Innovative solutions such as this may ultimately be necessary to obtain public acceptance of a UPI system.

Health IT Education

As noted, a shortage of qualified professionals in the workforce is a significant barrier to health IT interoperability and implementation. In the US, innovative programs such as AMIA 10x10 (“ten by ten”), developed by the American Medical Informatics Association (AMIA) in partnership with Oregon Health & Science University (OHSU), have been established to address this need. The goal of AMIA 10x10 is to train 10,000 professionals in medical informatics by the end of 2010.⁵⁴ Recently, the Health Information Technology for Economic and Clinical Health (HITECH) Act, part of the American Recovery and Reinvestment Act (ARRA), has committed significant funding to health IT workforce development in the US. One immediate result of this: the ONC has allocated \$84 million in grants to US educational institutions to develop training programs for the 12 specific health IT workforce roles it recently identified.²⁶

In the developing world, novel approaches to training health IT professionals are especially needed, such as those being used concurrently with the deployment of the OpenMRS EHR in Africa. OpenMRS implementers provide education and training within the local populace, and thus create an IT workforce that remains in place and provides longitudinal support for health IT, a key component for future interoperability in Africa.⁶²

Other collaborative initiatives focused on global health informatics education and training are in progress. In August 2008, AMIA sponsored an international conference on global e-health capacity. AMIA is now offering i10x10, an international adaptation of the 10x10 program, based on feedback from this conference. AMIA has also launched the Global Partnership Program, funded by the Bill and Melinda Gates Foundation, which established a Fellowship Program for health informatics education, training, and mentoring in the developing world. The Fogarty International Center of the National Institutes of Health in the US has set up a similar program, the Informatics Training for Global Health Programs, which funds partnerships between US and international informatics training programs, with an emphasis on programs in the developing world.⁵³ These and other programs are a start, but what is most acutely needed is research to define the type and number of health IT specialists required in the workforce of the developing world.⁵³

Meaningful Use

Halamka⁶³ believes that the push to make health IT systems fully interoperable in the US will receive a significant boost from Meaningful Use, to be implemented as part of the HITECH Act. Others concur.^{64,65} Although Meaningful Use criteria are presently being finalized, it is evident that US healthcare providers will be required to exchange information—and thus have interoperable systems—in several core areas. Notable among them are electronic prescribing, submissions of public health surveillance data, interface with immunization registries, transfer of care documentation, and reporting of quality measures.

New Frameworks & Models

Personal Health Records

Just as the technology and standards necessary to drive health IT interoperability continue to evolve, so do architecture frameworks and models. One approach that has been touted as a solution to interoperability is the Personal Health Record (PHR), typically either a standalone, web-based commercial application (such as Google Health and Microsoft's HealthVault) or integrated within an existing EHR.^{66,67} The data in the PHR is managed and maintained by the patient, who also has direct control who accesses it. This overcomes issues of privacy, and thus enhances interoperability. Although seamless exchange of information exchange between PHRs and EHRs does not yet occur, this is gradually being addressed with the growing use of both of these systems.

Service Oriented Architecture

Recently, a new architecture model for EHR development has been promoted, because it enhances interoperability between systems. Termed service-oriented architecture (SOA), it is predicated on a distributed, component-based model that is successfully used in many other business domains. In addition to promoting interoperability, another advantage of an SOA approach is its flexibility, in that it allows deployment in controlled stages.⁶⁸ A core set of generic components has been proposed within the SOA framework.⁶⁹ Interoperability is promoted by the SOA model because core components are not omitted, and it “takes a data agnostic approach to data access and transfer”.^{20,70}

Archetypes

Finally, there is significant interest in the role archetype-based solutions can play to foster interoperability.^{62,71,72} A prime example of this is openEHR, which originated in Australia but has recently received significant development work in Europe. Built with open source coding, and based on the unique architectural model of archetypes, openEHR uses these synergistically to enhance its interoperability.⁷³ A closer look at archetype-based health IT systems, and how they facilitate interoperability, is found in the appendix.

Leadership

The Role of Government, NGOs and Foundations

Clearly many government organizations foster health IT interoperability by creating public policies, procedures, and regulations that mandate, or at least promote it. Other quasi-governmental organizations play a role, notably the United Nations, World Health Organization, and HL7. Non-governmental organizations also have a unique, and crucial, contribution however. Since they lack many of the political constraints facing governments, they are seen as impartial entities without an agenda other than to promote communication and cooperation. The Rockefeller Foundation, by sponsoring its “Making the eHealth Connection: Global Partnerships, Local Solutions” conference series, is a prime example of one such organization.

Interoperable Use Cases Solutions

These solutions can be applied to the use cases outlined earlier. There are other solutions to these use cases, and indeed, many other use cases, but the following hypothetical scenarios illustrate that global interoperability brings tangible solutions to real life health information issues.

The Tourist Traveler

Scenario

Sue Jones, on safari in Tanzania, becomes acutely ill in the bush and immediately returns to Dar es Salaam where she is hospitalized for several days with “fever of unknown origin.” Her blood smear is negative for malaria, although she had been taken prophylactic mefloquine briefly. She stopped

taking it after a few doses due to disturbing dreams. No clear diagnosis is made, and her fever abates. She returns to US but does not take the presumptive anti-relapse therapy (primaquine) prescribed, since she feels well and fears side-effects. Three months later she is febrile again. She consults her clinician, and informs him that although she was ill during her trip to Tanzania, no diagnosis was made and she has no other recall or record of the healthcare she received. However, she does have a business card of the attending physician in Dar, which includes his email address. He is contacted by email, and responds within the hour.

Solution: a Continuity of Care Document

The hospital in Tanzania recently installed an EHR system with the help of an NGO-supported grant; this system is capable of creating a Continuity of Care Document (CCD) in extensible markup language (XML) HL7 format standards. The patient's clinician in the US also has an XML/HL7 compatible EHR system, and requests the hospitalization and discharge information from the Tanzanian hospital be electronically sent to him. In less than 5 minutes he has the CCD with all salient details of her recent illness available to him—including concern about malaria, but blood smears negative. He notes the recommendation that she take primaquine and be re-tested for relapsing malaria should unexplained fevers recur is noted. Her US clinician learns that she did not take primaquine as advised. A thick and thin smear test for malaria is immediately obtained, confirming diagnosis of *Plasmodium ovale*. Appropriate therapy with malarone is initiated, and Ms. Jones makes uneventful complete recovery.

The Expatriate

Scenario

John and Mary Smith have decided to “take the plunge” and move their family to Laos. They have dreamed of combining teaching, their avocation, with travel, a favorite pastime. In addition, they view this as an excellent opportunity to expand the horizons of their two children, ages 7 and 9. In the chaos of packing and moving abroad, they delay seeking travel medicine advice until the last minute. When they do, their clinician informs them that she does not have some of the travel vaccines they need. They are advised to obtain them from a reputable travel medicine clinic as soon as they arrive in Laos. Upon arrival in Vientiane, John and Mary report to the Australian Medical Clinic, where they've been informed they can receive reliable vaccines at a reasonable cost.

Unfortunately, they discover their entire family's vaccine records are still in shipment to Laos, and their clinician's office in the US is closed, since it is 1 am there. Alas, they are scheduled to depart Vientiane for their new home "up country" first thing in the morning.

Solution: a Bi-directional Immunization Registry

Fortunately for them, the Australian Clinic has recently installed a state of the art EHR. Not only does it access an up-to-date travel medicine database, providing a complete listing of all of the vaccines they need based on their itinerary, it also has Clinical Decision Support; this alerts the clinician the new vaccine for Japanese encephalitis has not been proven safe or effective for children under 17. John and Mary are astounded when the clinician assures them that the missing immunization records are not an issue. The Clinic's EHR system is bi-directionally interoperable with most immunization registries in the Australia, Europe, even the US, and within minutes he has the entire family's immunization history at his disposal. He sees that John needs a rabies booster, Mary needs a second hepatitis A vaccine, and the children need some routine childhood immunizations. The next morning finds the family on a ferry heading up the Mekong to their new life in Southeast Asia, a bit sore from the numerous vaccines just received, but happy to know they won't have to make the arduous trip back to Vientiane anytime soon.

The Diplomatic Community

Scenario

Henry Harrison, a harried, high ranking US diplomat, arrives at UN headquarters in Geneva, only to find his luggage is lost, and unfortunately, it contains his diabetes and heart medications. Even though he will only be in Geneva for a few days, he knows he cannot go without these critical medications for even a day. Not knowing what to do, Ambassador Harrison consults with the medical clinic at UN Headquarters. He cannot recall the names of his medications, but fortunately has the card for his health insurance, which includes his unique patient identifier (UPI) and Pharmacy Benefit Manager account information.

Solution: an Archetype Model EHR

Recently, the UN Medical Clinic's internal analysis revealed that replacing lost or expired medications is its most common workflow. To this end, the Clinic realized it needed a clinical IT system capable of operating in various pharmacopeia and language environments, as well as interfacing with clinical IT systems from other nations to fullest extent possible. In fact, In light of this, the clinic selected a recently developed EHR based on an archetype model (see appendix). This system enjoys widespread usage throughout greater Europe, and more importantly, readily functions in many different languages. It is "terminology neutral", and interfaces with different electronic prescribing standards, including RxNorm of the Unified Medical Language System compendium. The staff of the UN Clinic enters Ambassador Harrison's UPI and other account information into their system, and once the biometric fingerprint scan confirms his identity, his medication regimen is immediately reconstructed. The system has translated his prescriptions into French (and German), and also generated the local equivalents and dosing to his US medications. The diplomat receives his replacement medications within the hour and is able to the keynote address to the afternoon's plenary session on nuclear arms reduction as scheduled.

The Military

Scenario

Col. Joe Johnson is concerned. He is the medical officer in charge of syndromic surveillance for PACOM, the United States military's Pacific Command, and has been tasked to monitor the prevalence of influenza-like illness (ILI) in his region, since this is thought to serve as an early warning marker for predicting the next pandemic influenza. Although he is able to query the database of AHLTA, the EHR used by the Defense Department, he realizes that this database is incomplete, insofar as some military personnel receive care "on the local economy." This is especially common in Asia, a likely source for the next global pandemic, and a region where many US military personnel generally do not have access to military healthcare facilities. Compounding the problem, most of the local healthcare systems in Asia do not yet have electronic health information systems, and those that do are not interoperable with other systems.

Solution: an m-Health Application

While pondering this dilemma, Col. Johnson receives mobile phone text message from his daughter, who attends an international school in Jakarta, where he is presently stationed. She sends him a Short Message Service (SMS) text message, reminding him that she is auditioning for the school play and will be home late. Reading her message, Dr. Johnson realizes a solution to his problem is literally in hand. What if military troops were instructed to send a short SMS should they or their family members develop influenza-like symptoms? In his office the next day, Col. Johnson reads about FrontlineSMS, open source software that can be used anywhere that has mobile phone network coverage.⁷⁴ This software system creates an interoperable, bi-directional messaging system on a standard mobile phone – no EHR or even internet connection is needed. It allows the user to easily create a contact “send to” list for a pre-configured message, and the user can be sent regular “check in” reminders. It is also easily configured to keywords, such as “flu” or “fever” and can even be programmed to automatically map to the Google Maps application. Aware that virtually all of military personnel in Asia have mobile phones, Col. Johnson recognizes that “m-health” – using mobile telecommunications as a health application– provides the ideal solution he has been looking for.

Multi-National Corporations

Scenario

Larry Largent is Chief of Occupational Medicine at Ginormous AG, a multi-national agriculture conglomerate with offices in over 200 countries world-wide. Recently, there has been concern at Ginormous headquarters regarding the skyrocketing cost of providing healthcare to its overseas workforce. The Ginormous workforce has an epidemic of hypertension, cardiac disease, stroke and diabetes. Corporate management is concerned that this could represent an adverse effect of the company’s new fertilizer product, and fear that a surge of worker compensation claims will soon follow. This has reached the CEO’s desk, and he is asking for an innovative and proactive approach to the issue. Dr. Largent and his team have researched the scientific literature, and queried their limited clinical database. They are confident that the workforce is suffering from nothing more ominous than the sequelae of the world-wide epidemic of obesity. To prove their point, and combat the problem, they plan an ambitious, company-wide wellness program. They are constrained, however, by a lack of data about their globally dispersed workforce.

Solution: an Integrated PHR

After researching various options, Dr. Largent convinces Ginormous management to implement a Personal Health Record (PHR) system that interfaces with its existing EHR system. This so-called “integrated PHR” has several advantages over a standalone PHR system, including enhanced capability to capture home monitoring data, synchronous communication for interactive guidance, access to health knowledge resource bases, and accessibility via the Internet.^{75,76} All of these factors encourage employees to regularly download preventative and other health data on it. Each employee is issued a unique username and password, thus authenticating access to the web-based system. In addition to capturing data from home monitoring devices such as blood pressure devices, weight scales, glucometers, and pedometers, the PHR’s Services Oriented Architecture also allows the patient to enter medications, access online health information, even connect with other employees through Web 2.0 applications such as instant messaging and community forums. Interoperability is achieved using Portable Document Format-Healthcare (PDF/H), a new use case of Adobe’s existing Open Source, ISO-approved and internationally recognized PDF standard.⁷⁷ PDF/H functions as a secure and portable “container” allowing bi-directional exchange of structured and unstructured data between PHRs and EHRs. It is not a new standard per se, but rather supports the use of existing CCR and HL7 CDA standards.

Dr. Largent and his Occupational Health team are now able to capture disease management and wellness information from their patients, regardless of where they are deployed in the world. Although the quantity of data received from the company’s large workforce is enormous, integration into the EHR permits meaningful data summary, query and analysis. Using this information, Dr. Largent documents to company management that Ginormous employees are not in the throes of some unknown toxic exposure, but rather suffering from the same adverse effects of obesity as 1 billion others world-wide. More importantly, he and his wellness team are able to develop a comprehensive company wellness program that is individually-tailored, longitudinal, and provides direct feedback to the individual’s PHR. Now, the healthcare needs of the company workforce are no longer neglected because of lack of global interoperability, regardless of where they work or travel.

Conclusion: A Synthesis

My organization, the US State Department's Office of Medical Services (MED), faces many of the same barriers to global health information interoperability as other healthcare organizations, and stands to gain the same benefits from it, if not more. Hence, the following look at where MED is, its vision for the future, and an agenda for achieving that vision, is instructive.

The Present

How does MED presently conduct operations? In size, MED is a relatively small medical organization, with approximately 200 clinicians practicing in health units at US embassies world-wide. MED's scope of practice is large, however, with a highly mobile patient panel (Foreign Service Officers and families) residing in almost every nation world-wide. Our practice is minimally electronic; most of our medical records are paper, although we have recently started to implement electronic prescribing. We administer routine and complex travel vaccine protocols based on written and occasionally incomplete or missing vaccination records. Our consultations are often telephonic, and consultant notes generally mailed or faxed. Our providers do not have access to clinical decision support or other electronic practice aids. MED clinicians have no way to compare their practice skills with their US or MED peers. Similarly, our patients have no way to assess the competence of their MED provider and have little input or even access to their medical records. Back in Washington, MED management has scant information regarding practice quality metrics, and what is available is of dubious value. Outbreaks of febrile illness and other potentially valuable biosurveillance markers are not captured. In short, MED's present system of healthcare record management is not interoperable, and contributes to a healthcare system that is fragmented, incomplete, inefficient and unmonitored.

A vision

So where does MED need to be? MED clinicians need real-time access to their patient records, regardless of where they are in the world. These records must be up-to-date and accurate. Patient immunization data must be synchronized with a central database, and globally accessible. MED providers must be able to prescribe electronically, and receive clinical decision support when they do so. Since Foreign Service (FS) personnel obtain medical care in foreign healthcare systems, MED providers must be able to access this information in a usable electronic format. Our patients must also be empowered to input, and indeed manage, aspects of their medical record as they travel the world. MED management needs to receive real-time data input that allows for biosurveillance analysis, in addition to

standard quality improvement measures. They must ensure that MED providers adhere to US standards of care and have access to evidence-based medicine guidelines. The clinical culture of MED must shift from one of evaluation and treatment to one of prevention and wellness. Treatment that is rendered must be based on documented outcomes data, not anecdote and established workflow patterns.

An Agenda

So how does MED get there? Virtually all of the activities called for in this vision statement require health IT that interoperates on a global scale. Here are some solutions: First and foremost, MED must implement an EHR satisfying HITSP & Meaningful Use interoperability criteria. A system based on service-oriented or perhaps even archetype architecture will provide the scalability, adaptability, and functionality that the global operating environment demands. This system must include an integrated PHR. It must bi-directionally interface with an immunization registry, preferably one centrally managed by the CDC or other similar organization. This system must also integrate real-time electronic prescribing, and provide concurrent, patient-specific clinical decision support. Laboratory and imaging data must be readily incorporated into this EHR. It must provide MED management with data query tools that reflect the varied and dynamic nature of global healthcare systems. It must also allow MED to share its vast global health experience and surveillance capabilities with other federal and public health communities. Initiatives such as NHIN CONNECT afford just such a vehicle, and MED's IT systems must therefore be interoperable with it. MED must also leverage advances in technology that permit telemedicine to deliver synchronous medical consultations to even the most remote locales. Finally, MED must use its "bully pulpit", including direct access to the Secretary of State and others in the power structure of the US government, to lobby for health policies that promote global interoperability. Encouraging the US's greater role in health IT education in the developing world, such as with a USAID-sponsored program, is just one such example.

Although the specific details may differ, MED's journey is shared by almost every health care organization. Clearly some are further along, yet all face ongoing challenges of local, regional and global information exchange, and all stand to gain great benefit from it. Interoperability requires standards, technology and investment. Ultimately this will take leadership – hence the crucial role that the ONC, the EU and US government, the Rockefeller, Gates and other Foundations, and many individual leaders in the health IT community must play to achieve true global interoperability. The "pay-off" of reduced healthcare cost, improved healthcare quality, and greater patient safety and satisfaction demands nothing less.

Summary

Global interoperability is a vital part of the larger picture to make healthcare IT function as a rising tide that raises the quality of healthcare, and an ebb tide that lowers its cost. There are other benefits to be gained from global health IT interoperability, notably the positive impact it would have on biomedical research, syndromic surveillance and increasing the greater adoption of health IT. Global interoperability would also directly benefit the expatriate living or working abroad, those serving their national military or diplomatic corps, indeed anyone who travels beyond the confines of their local healthcare system—in other words, virtually everyone.

Many barriers stand in the way of achieving interoperability, especially on a global scale. Overcoming them will require harnessing technology, harmonizing standards, bridging legal and cultural differences, assuaging privacy concerns, and developing a robust global health IT workforce. All of these must be based on principles of affordability, scalability and sustainability, as well as respect of cultural differences. Finding the innovations needed to achieve global interoperability will require the collaboration and investment of governments, international organizations, the scientific and medical communities, and groups such as Rockefeller Foundation. In light of the many benefits to be gained, the only remaining question is not who, but how.

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APPENDIX: Archetype Models and Global Health IT Interoperability

Overview

This appendix provides a closer look at archetype-based health information systems, a new and unique paradigm for creating highly interoperable health information technology (IT) solutions. Since clinical archetypes transcend language, most standards, and many technology barriers, proponents cite global interoperability as a major benefit of their use. This appendix is based on a review of the recent literature, as well as web-based documentation from the openEHR Foundation, the leading proponent of clinical archetype-based systems. In addition to reviewing pertinent studies regarding clinical archetype systems, openEHR's archetype system is detailed, and benefits and barriers of the archetype model are discussed.

Introduction

An archetype is broadly defined as “something that serves as a model or a basis for making copies.”¹ In medical computing, the use of archetypes is derived from initial framework logic analysis by Kifer, Lausen and Wu², and then expanded by Beale.³ The first group to propose using the archetype model in the health IT setting was Australia's Good Electronic Health Record (GEHR) project, although the electronic record itself was never built.⁴ Since then, an international consortium of healthcare informaticians and clinicians has formed the non-profit openEHR Foundation, which has taken the lead advancing the archetype model as a key component of an interoperable electronic health record solution.⁵

In the context of information technology (IT), an archetype refers to a formal, re-useable model of a domain concept.⁵ The main benefit of archetype models in computing is that they permit separation of the domain models from the information models. They also allow for creation of parent-child relationships. These qualities are similar to those seen in object-oriented programming languages, and have similar benefits. In fact, archetypes function as clinical knowledge objects in the openEHR framework.⁵ One key attribute of archetype models is re-usability. Another is adaptability. The more they are used, the more applicable and adaptable they become. These and other attributes make the archetype model versatile, scalable, and functionally interoperable.⁶

Clinical Archetype Systems

Archetype-based health information systems have a two-tier architecture structure: the Reference Model (RM) and the Archetype Model (AM). The RM is an object-oriented entity which contains the data schema used in the EHR.⁷ Functionally, the RM serves as a robust record management tool and provides the infrastructure for managing the many archetypes within it, thereby creating a “firewall” between technical and clinical domains.⁸ The RM does not need to be re-coded as the clinical data of the system changes, since the archetypes provide this functionality.

As noted, archetypes in the AM are clinical knowledge objects and are based on one of the Reference Model objects, similar to parent-child or one-to-many relationships, with the associated benefit of inheritance.⁹ Archetypes bring standardization to the model because they model clinical data in standard ways. They are also readily re-usable, and adaptable, without compromising their interoperability. Archetypes are readily combined to create new archetypes (while leaving the original intact) with different use cases, similar to the polymorphism of object-oriented programming systems. They also provide data query functionality and are useful to create templates and forms used in clinical care.¹⁰

Archetypes in openEHR

For the past 15 years, groups in Australia and Europe have worked to define the specifications, create standards, and perform validation on the clinical archetypes to be used in openEHR. The openEHR paradigm is based on the following principles: Open Source, vendor independent, patient-centered, internationally accessible and operable, and thus, interoperable. The non-profit openEHR Foundation now provides development and governance for the openEHR initiative, although it does not develop an actual EHR.

Health IT applications based on openEHR archetypes are starting to appear in the commercial realm (<http://www.openehr.org/shared-resources/usage/commercial.html>). In the US, two commercial health IT systems presently use openEHR archetypes, PatientOS (<http://www.patientos.com/#2>) and Ethidium. Launched in 2008, PatientOS is designed to provide an enterprise level EMR solution, whereas Ethidium’s Evolution EMR is designed for a small ambulatory medical practice (<http://www.evolutionemr.com/index.html>).

Programming Tools

The Archetype Definition Language (ADL v1.4) syntax is used by openEHR to create each archetype as a text file.¹¹ ADL was developed specifically for the clinical archetype use case, and has the following advantages:⁵

- It is both human and machine readable
- It represents a formal way of representing architecture
- It supports describing a system at a higher level than previously possible
- It permits analysis of architectures – completeness, consistency, ambiguity, and performance
- It supports automatic generation of software systems
- It is a graphical syntax with a textual form and thus ideal for modeling distributed systems

In addition to ADL, there are other programming tools for viewing and editing archetypes, including a Windows Clinical Archetype tool and Java Archetype Editor available in the Eclipse platform. As noted, data query functionality is provided at the archetype level. This is done using Archetype Query Language (AQL), a database language based on SQL.¹² The following data call, requesting all BMI values greater than 30 kg/m² for a patient, is from openEHR sample documentation¹¹:

```
SELECT o/[at0000]/data[at0001]/events[at0002]/data[at0003]/item[0004]/value
```

```
FROM EHR [uid=@ehrUid]
```

```
CONTAINS COMPOSITION c [openEHR-EHR-COMPOSITION.report.v1]
```

```
CONTAINS OBSERVATION o[openEHR-EHR-OBSERVATION.body_mass_index.v1]
```

```
WHERE o/[at0000]/data[at0001]/events[at0002]/data[at0003]/item[0004]/value >
```

```
30
```

Architecture

The openEHR architecture is based on the archetype model described above, with further refinement. It uses the Reference Model to provide structure, including archetype identification and support. It uses a wiki-like platform called the Clinical Knowledge Manager to develop and disseminate the archetypes.⁵ It also adds a Service Model, which functions as a bridge between the RM and archetypes by controlling data access between them.¹³

[Figure 1: openEHR Architecture](#)

Hierarchical Structure

Table 1 shows the basic hierarchical structure of the archetypes in openEHR¹¹:

[Table 1: Hierarchical Archetype Structure in openEHR](#)

As shown in Table 1, the following classes of archetypes are found within the openEHR Reference Model: Composition, Section, Entry, Structure, Cluster, Element, and Demographics. Each of these inherent specific attributes or constraints from their “parent” Reference Model, and in turn, pass these on to their “child” subclass archetypes. Subclasses of archetypes are then further characterized. For example, these clinical archetype subclasses are within the Entry class: Observation, Evaluation, Instruction and Action.

Note that each individual archetype typically consists of the following core components:¹³

- Header--contains the archetype names and the specialization information
- Description--contains authoring information, lifecycle status, and archetype purpose
- Definition--the clinical concepts represented, described in terms of the Reference Model
- Ontology--contains links to terminologies and bindings

Screenshots from openEHR⁵

Figure 2 shows openEHR screenshots from the blood pressure measurement archetype, found in the Observation subclass of the Entry class. Note the numerous iterations, and multi-language translations of the archetype.

[Figure 2: Blood Pressure Archetype](#)

Figure 3 shows screen shots for the “Problem List – Diagnosis” Archetype in the Evaluation subclass, including an ADL coding segment example and corresponding Mindmap.

[Figure 3: Problem List Archetype](#)

Figure 4 shows representative screenshots from a segment of the medication prescribing archetype of the Instruction subclass.

[Figure 4: Prescribing Archetype](#)

Finally, Figure 5 shows the archetype for creating patient Follow-up instructions, found in the Action subclass.

[Figure 5: Patient Instruction Archetype](#)

Additional examples are detailed in openEHR’s Clinical Knowledge Manager at:

<http://www.openehr.org/knowledge/>

Benefits of Archetype-based Health IT Systems

Interoperability

The inherent promotion of interoperability that archetype-based systems bring to health IT is arguably their greatest benefit. The archetype model facilitates interoperability at several levels. Archetype systems readily share data content, and thus have knowledge-level interoperability.^{10,14} They are also

“terminology-neutral”, and readily link to external terminologies link SNOMED and LOINC.⁸ The stability and inheritance qualities of the RM also foster interoperability. Since the archetypes are easily constrained or combined, they adapt readily to change. With proper governance, data structure and meaning is preserved, thus they add to semantic interoperability.^{15,16} Archetypes themselves are highly standardized; ISO 13606 is now recognized as the international standard for archetypes.^{17,18}

Clinical Decision Support

Since the data in an archetype-based system is highly structured and standardized, it promotes the system’s use of clinical decision support. Barretto et al.¹⁹ found that an archetype-based EHR readily incorporates evidence-based medicine guidelines. Others state that “archetypes enable better access and reliable use of patient data by a decision support system, mainly because they are designed to consistently link patient data with terminological systems and metadata.”²⁰

Legacy Data

Moner et al.¹⁷ found that an archetype-based system could be configured to automatically standardize legacy healthcare data (discharge summaries), making it much easier to integrate with a new EHR system. Chen’s group²¹ recently showed that semantic mapping between the archetype-based openEHR and a proprietary EHR (COSMIC) could be performed. They then used this to conduct automated bi-directional conversion between openEHR archetypes and COSMIC templates. In addition to enhancing interoperability, this functionality may have practical application as EHRs are adopted and evolve in the coming years.

International & Open Source

Although the concept of archetype-based health IT systems originated in Australia, it is now clearly an international movement, especially in Europe, where active development is ongoing. As such, it transcends national borders and interests, adding to its potential value as a globally interoperable HIT solution. Many of the archetype’s documents and coding has been translated into several languages, and work is continuing on others. This makes them much more accessible to clinicians who are not fluent in English. The openEHR Foundation Website makes all archetype information transparently available to the world-wide healthcare community. The fact that it is Open Source only adds to its accessibility, adaptability, and affordability.

Issues

Archetype-based systems are still in their relative infancy, and need further development and validation before widespread adoption can be considered.²² Although clinicians must play an active role in the content development of archetypes, a suitable mechanism for this has yet to be defined.¹⁶ Archetype systems are still largely theoretical, and must overcome significant adoption inertia in the crowded and rapidly evolving HIT systems arena.⁶ Finally, like other Open Source applications, clinical archetype systems challenge an entrenched industry with a large financial stake in maintaining the status quo.

Summary

Clinical archetype systems are a new paradigm for health IT system architecture. They have many characteristics that enhance interoperability, and bring additional significant benefits to the global health information community. Although the openEHR Foundation has made significant progress towards developing an Open Source archetype-based EHR framework, widespread adoption and implementation has not occurred to date. Only time will tell if archetype-based EHRs are a solution to the global interoperability conundrum.

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TABLES and FIGURES

Table 1: Hierarchical Structure of the Archetypes in openEHR

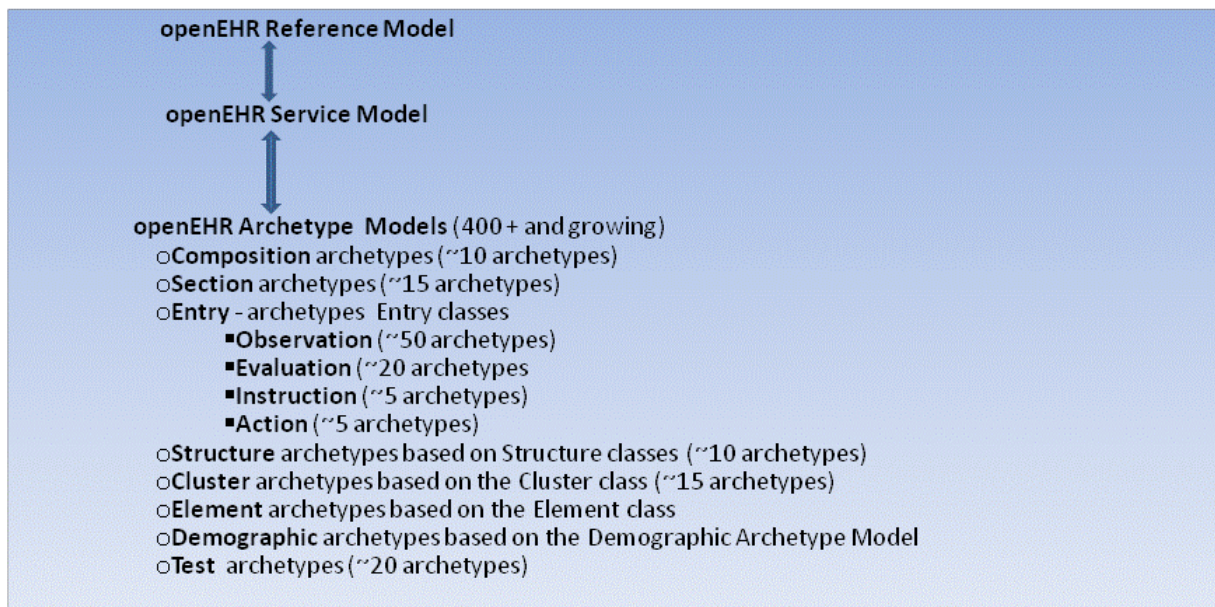
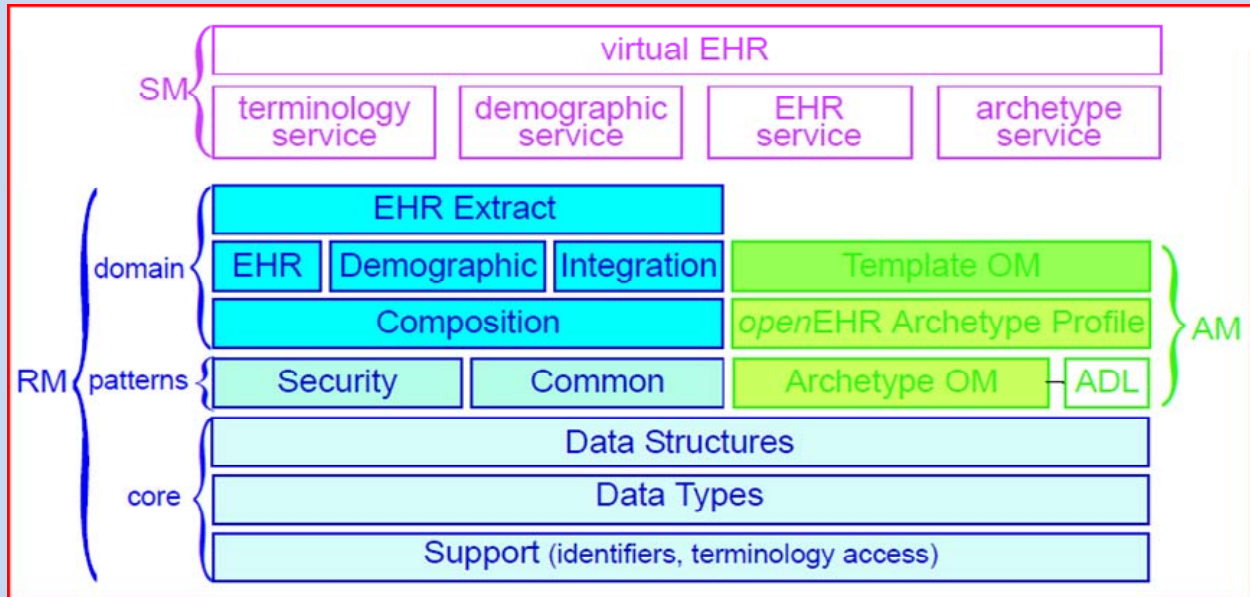


Figure 1: The openEHR Architecture



From: <http://www.openehr.org/releases/1.0.1/architecture/overview.pdf>

Figure 2: Blood Pressure Archetype

Blood Pressure

Archetype: Blood Pressure (openEHR-EHR-OBSERVATION.blood_pressure.v1)

Structure: Tree
 Occurrences: 1..1 (mandatory)
 Cardinality: 0..* (optional, repeating, unordered)

T Position Coded Text Occurrences: 0..1 (optional)	The position of the subject at the time of measurement.	<ul style="list-style-type: none"> Standing [Standing at the time of blood pressure measurement.] Sitting [Sitting (for example on bed or chair) at the time of blood pressure measurement.] Reclining [Reclining at the time of blood pressure measurement.] Lying [Lying flat at the time of blood pressure measurement.] Lying with tilt to left [Lying flat with some lateral tilt, usually angled towards the left side. Commonly required in the last trimester of pregnancy to relieve aortocaval compression.] Assumed value: Sitting Free or coded text
T Confounding factors Text Occurrences: 0..1 (optional)	Comment on and record other incidental factors that may be contributing to the blood pressure measurement. For example, level of anxiety or 'white coat syndrome'; pain or fever; changes in atmospheric pressure etc.	Details about physical activity undertaken at the time of blood pressure measurement.
A Exertion Slot (Cluster) Occurrences: 0..1 (optional)		Include: openEHR-EHR-CLUSTER.level_of_exertion.v1 and specialisations
T Sleep status Coded Text Occurrences: 0..1 (optional)	Sleep status - supports interpretation of 24 hour ambulatory blood pressure records.	<ul style="list-style-type: none"> Alert & awake [Subject is fully conscious.]

Blood Pressure

Archetype: Blood Pressure (openEHR-EHR-OBSERVATION.blood_pressure.v1)

Structure: Tree
 Occurrences: 1..1 (mandatory)
 Cardinality: 0..* (optional, repeating, unordered)

Q Systolic Quantity Occurrences: 0..1 (optional) [SNOMED-CT(2003)::163030003] (On examination - Systolic BP reading (finding))	Peak systemic arterial blood pressure - measured in systolic or contraction phase of the heart cycle.	Property: Pressure Units: • 0.0..<1000.0 mm[Hg] Limit decimal places: 0
Q Diastolic Quantity Occurrences: 0..1 (optional) [SNOMED-CT(2003)::163031004] (On examination - Diastolic blood pressure reading (finding))	Minimum systemic arterial blood pressure - measured in the diastolic or relaxation phase of the heart cycle.	Property: Pressure Units: • 0.0..<1000.0 mm[Hg] Limit decimal places: 0
Q Mean Arterial Pressure Quantity Occurrences: 0..1 (optional)	The average arterial pressure that occurs over the entire course of the heart contraction and relaxation cycle.	Property: Pressure Units: • 0.0..<1000.0 mm[Hg] Limit decimal places: 0
Q Pulse Pressure Quantity Occurrences: 0..1 (optional)	The difference between the systolic and diastolic pressure.	Property: Pressure Units: • 0.0..<1000.0 mm[Hg] Limit decimal places: 0
T Comment Text Occurrences: 0..1 (optional)	Comment on blood pressure measurement.	Free or coded text

openEHR Clinical Knowledge Manager

Figure 3: Problem List Archetype

Archetypes Templates Reports About

Find Resources Problem Diagnosis

Diagnosis (v1)

```

definition
  EVALUATION[at0000.1] matches { -- Diagnosis
    data matches {
      ITEM_TREE[at0001] matches { -- structure
        items cardinality matches {1..*}; ordered matches {
          ELEMENT[at0002.1] matches { -- Diagnosis
            value matches {
              DV_CODED_TEXT matches {
                defining_code matches {[ac0.1]} -- Any term that 'is_a' diagnosis
              }
            }
          }
          ELEMENT[at0.32] occurrences matches {0..1} matches { -- Status
            value matches {
              DV_CODED_TEXT matches {
                defining_code matches {
                  [local:
                    at0.33 -- provisional
                    at0.34 -- working
                  ]
                }
            }
          }
          ELEMENT[at0003] occurrences matches {0..1} matches { -- Date of initial onset
            value matches {
              DV_DATE matches {*}
            }
          }
          ELEMENT[at0004] occurrences matches {0..1} matches { -- Age at initial onset
            value matches {
              DV_DURATION matches {*}
            }
          }
        }
      }
    }
  }
  
```

MDS Hash: 72775741a1fb1d1728f957e3671fe60a

openEHR Clinical Knowledge Manager

Username Password Sign in Forgot your password? Sign up

Archetypes Templates Reports About

Find Resources Problem Diagnosis

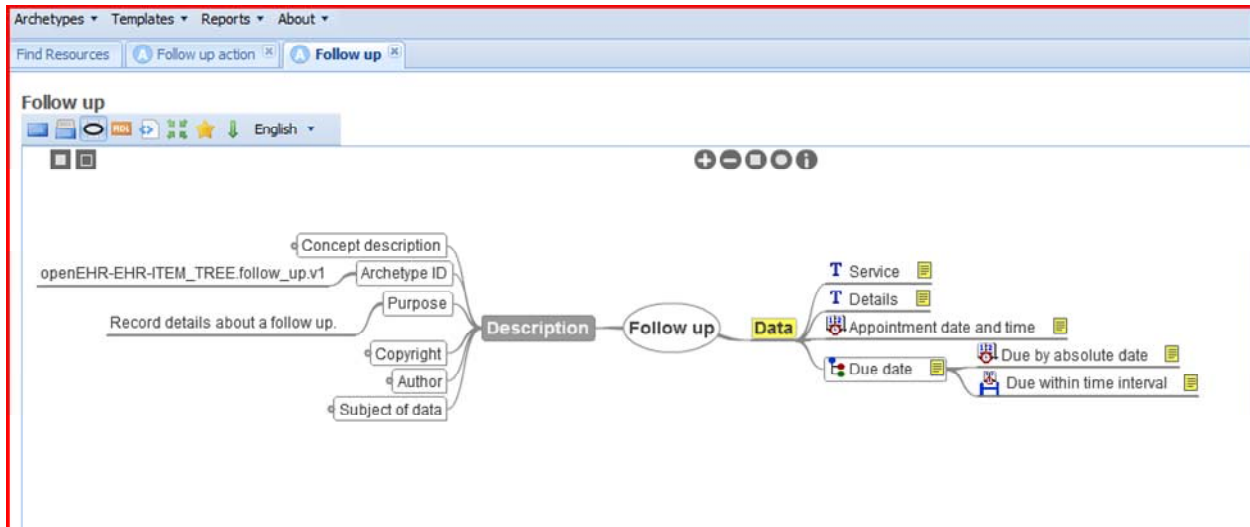
Diagnosis (v1)

Figure 4: Prescribing Archetype

The screenshot displays the openEHR Clinical Knowledge Manager interface. The main content area shows the 'Medication description' archetype with the following table of properties:

Property Name	Description	Value/Constraint
Name of medication	The name of the intervention - which may be coded	Free or coded text
(Generic name)	The generic name of the drug which is an alternative name to the name of medication	Free or coded text Runtime name constraint: =Generic name OR Brand name [*]
Strength per dose unit	The strength of the medication	Choice of: <ul style="list-style-type: none"> Quantity Property: Mass Units: <ul style="list-style-type: none"> >=0.0 pg >=0.0 µg >=0.0 mg >=0.0 gm Quantity Property: Mass (IU) Units: <ul style="list-style-type: none"> >=0.0 IU >=0.0 mIU Quantity Property: Mass (Units) Units: <ul style="list-style-type: none"> >=0.0 mJ >=0.0 U

Figure 5: Patient Instruction Archetype



The screenshot shows the openEHR Clinical Knowledge Manager interface. The left sidebar displays a tree of archetypes under the 'Action' category, with 'Follow up instruction (v1)' selected. The main panel displays the 'Follow up' archetype structure, including a table of data elements with their types, descriptions, and cardinalities.

Icon	Element Name	Description	Cardinality
T	Service	The name of a service	Free or coded text
T	Details	Details of the service	Free or coded text
1 1 2	Appointment date and time	The current active appointment date and time	Full Date and Time
1 1 2	Due date	*	Cluster
1 1 2	Due by absolute date	Date due by	Date/Time
1 1 2	Due within time interval	Due within a time interval eg 'X' weeks	Interval of Date/Time

