



February 15, 2008

Office of the National Coordinator for Health Information Technology (ONC)  
Attention: Use Case Team  
Mary Switzer Building  
330 C Street, S.W. Suite 4090  
Washington, DC 20201

Dear PHC Use Case Team:

The American Health Information Management Association (AHIMA) welcomes the opportunity to comment on the Office of the National Coordinator's PHC Draft Detailed Use Case.

AHIMA is a not-for-profit professional association representing more than 51,000 health information management (HIM) professionals who work throughout the healthcare industry. AHIMA's HIM professionals are educated, trained, and certified to serve the healthcare industry and the public by managing, analyzing, reporting, and utilizing data vital for patient care, while making it accessible to healthcare providers and appropriate researchers when it is needed most.

AHIMA and its members participate in a variety of projects with other industry groups and Federal agencies related to the use of healthcare data for a variety of purposes including direct care, quality measurement, reimbursement, public health, patient safety, biosurveillance, and research.

We recognize the industry's need for a genetic/genomic test information methodology based on common standards that would allow for the incorporation of clinically useful, genetic, personal and family health history information, as well as the implementation of electronic health record (EHR) analytical functionality to support clinical decision-making. Yet identifying, capturing, indexing, extracting, and controlling data electronically from interfaced systems remains a challenging process because there are few broadly agreed-upon standards for the exchange of genetic/genomic test information. This climate of variation and confusion may well have a negative impact on the abilities of providers to customize treatment and management plans for patients based on their unique genetic makeup.

Our comments focus on those areas of particular interest to our members. We believe the use case is a good foundation; however, we have outlined some recommendations as ONC continues to expand the document.

Title of Use Case

AHIMA Comment:

“Personalized” may confuse stakeholders with the “personal health record”. The use case scenarios presented in the document describe “family history” and genetic/genomic” information.

Recommendation:

We recommend the Use Case be named given an alternate name to ensure it is differentiated from a Personal Health Record Use Case.

2.0 Introduction and Scope

AHIMA Comment:

No consideration is given to the lack of healthcare literacy among consumers and healthcare providers with regard to genetic testing and information. Also, creating and managing genetic/genomic databases will require trained staff, an information technology architecture and infrastructure, and standardized processes, system design, terminology, and nomenclature.

Recommendation:

The use case must consider the training, education, operating costs, staffing requirements, and standardization required to transition from the current state to the envisioned personalized healthcare information exchange environment. Consideration should be given to the fact that not all healthcare providers will have comparable literacy with regard to health information exchange, storage, retrieval, and security of healthcare data in databases or privacy implications for the patient or their family members. “Level setting” education and/or introduction is needed.

3.0 Use Case Stakeholders

AHIMA Comment:

Use Case does not attempt to provide a stakeholder access management model. We believe that only a limited number of stakeholders will have technical knowledge needed to understand and act on genetic and genomic testing information available.

Recommendation:

Consideration and awareness must be given to the varied backgrounds, training, education, and perspectives of the identified stakeholders. Not all stakeholders will possess the same backgrounds, training, education, and perspectives. There is a need to provide training and education to stakeholders so that they are prepared to make access management decisions. In addition model business processes, policies, and procedures will need to be developed to aid data stewards and stakeholders making access management decisions. Without proper training, education, standardized processes, policies, and procedures quality of care, patient safety, privacy, and security will be jeopardized.

#### 4.0 Issues and Obstacles

##### AHIMA Comment:

The use case makes the following statements with regard to confidentiality, privacy, and security.

##### *Confidentiality, privacy, and security*

“Consumers may require privacy controls for personal health information that govern how patient data is accessed, viewed, and communicated. Privacy controls and the means of restricting data access, which are available for paper-based records, are not currently available for electronic records.”

“Without permissions and controls, consumer participation in the act of electronic health information exchange may be limited.”

##### AHIMA Comment:

Because consumers lack experience, technical knowledge, and healthcare literacy regarding genetic and genomic testing they will most certainly be fearful of exchanging information beyond their primary provider. Consumers will most certainly want guaranteed privacy controls that govern how their data is accessed, viewed, and communicated.

The use case implies that paper-based records are more secure than currently available electronic records. We believe that properly implemented electronic records that adhere to accepted privacy and security standards are in fact more secure than present day paper records.

##### *Confidentiality, privacy, security and data access*

“Because EHRs are typically administered by healthcare providers, consumers may only have passive access to their medical record.”

“Without access to a personally controlled health record, the consumer may not be able to sufficiently restrict or grant access to sensitive information related to personalized healthcare.”

“The implementation of personalized healthcare may create additional risk of misuse of family history, disease risk, and predisposition.”

##### AHIMA Comment:

Without proper training, education regarding genetic and genomic testing and electronic health information exchange the consumer and healthcare stakeholders will not be knowledgeable enough to make appropriate privacy, security, and access management decisions.

*Family health history information interoperability and privacy*

“Family health history is typically obtained by interviewing the patient and/or other related individuals in an ad hoc and non-standardized manner. No industry guidelines exist to standardize this information or the manner in which it is gathered.”

“Without standards and consistent nomenclature, interoperable systems may be difficult to develop. These guidelines may facilitate information exchange between clinicians, between clinicians and patients, and between and among patients and authorized family members or other authorized consumers.”

We agree that data content standards must be developed to gather the appropriate information when capturing family history information. Further, efforts to develop such data content standards should begin immediately. When such data content standards are developed, standards for model document architecture formatting currently available from ASTM, HL7, IHE, and LOINC may be sufficient to support interoperability. These standards are continuously being refined and expanded upon. Stakeholder education about current state of model document architecture formatting is necessary. These existing standards can be readily expanded upon to support the family health history and personalized healthcare health information.

“Because of the sensitive nature of family health history information, several specific and unique issues related to privacy of patient information are of concern; particularly those related to the sharing of this information with authorized family members or other patient advocates. Currently, genetic information is treated as any other protected health information (PHI) under the Health Insurance Portability and Accountability Act (HIPAA).”

AHIMA Comment:

Treating genetic and genomic information the same as PHI under HIPAA, or other health information under mental health and substance abuse laws, provides sufficient privacy and confidentiality protection. As the recently published RTI Contracted “Privacy and Security Solutions for Interoperable Health Information Exchange: National Summary” (July 2007) points out, it is the nationwide inconsistencies in understanding and interpreting these laws that are the major concern. Genetic/genomic information/data is not more or less sensitive than mental health, substance abuse or other information such as HIV/AIDS or sexually transmitted disease information. A nationwide effort to educate stakeholders at all levels to address inconsistencies in interpreting HIPAA and other laws is needed now more than ever with genetic testing becoming more widespread.

*Genetic/Genomic data interoperability*

“The exchange of genetic/genomic information across systems, sites and settings of care is constrained by a fragmented nomenclature for ordering and reporting of tests and testing results.”

“The fragmented and unstructured nature of this information may lead to difficulties in the act of information exchange and put at risk the quality of care.”

AHIMA Comment:

The fragmented nomenclature for ordering and reporting of tests and testing results can be partially resolved by data content standards. Developing data content standards should begin immediately. Further, the fragmented and unstructured nature of genetic/genomic information also presents a privacy and security risk. If consumers and data users are unable to properly parse, sort, index, and rank the information they will be unable to appropriately make decisions regarding data access, use, and control. The result will be inappropriate access, use, and control decisions that will result in too much, too little, or inappropriate information exchange. Even “normal” results across various laboratory result providers are different regarding the unit of measure of what is normal. This lack of nomenclature standardization, especially related to genetic/genomic testing could provide great harm to the patient and/or their family.

Recommendation:

Consumer and stakeholder privacy, security, and access management controls education and training will be necessary to gain consumer support of personalized healthcare information exchange.

Model business processes, policies, and procedures must be developed to aid data stewards and stakeholders making privacy, security, and access management decisions. These standards and model business practices must be established before the implementation of personalized healthcare database systems is begun.

A review of current literature will reveal that electronic health records that adhere to the established standards regarding privacy and security administration are in fact more secure than paper-based records.

Standards of model document architecture formatting currently available from ASTM, HL7, IHE, and LOINC. These standards are continuously being refined and expanded. Continued support and funding is necessary to expand adoption of these existing document format standards.

**Figure 7-3: Clinical Assessment, Clinician Perspective.**

AHIMA Comment:

7.1.1.2 – Action: View consolidated available personal and family health history information. After information is gathered from multiple sources, the clinician views the information in a consolidated format to gain the most comprehensive view of the patient’s personal and family health history information.

Recommendation:

Policies, procedures, and workflow processes must be established to guide how health information is gathered, sorted, indexed, shared, and stored. Also, healthcare providers will need education and training on how to gather and consolidate information from various sources.

Without an established process there will be privacy and security risks to health information. When considering the volume of patients seen by providers, this becomes no small task. If staffing levels are not maintained at proper levels, privacy and security risks will increase.

AHIMA Comment:

7.1.1.3 – Action: Select personal and family health history information. After viewing the patient’s personal and family health history information, the clinician makes determinations regarding which information will be incorporated into the EHR.

Recommendation:

Policies, procedures, and workflow processes must be established to guide how health information is gathered, sorted, indexed, shared, and stored. Also, healthcare providers will need education and training on how to gather and consolidate information from various sources. Without an established process there will be privacy and security risks to health information. When considering the volume of patients seen by providers, and the wide variety of healthcare provider entities, it is clear to see that managing the process will be a challenge. If health information staffing levels and education/training are not sufficiently maintained, privacy and security risks will increase.

**Figure 8-3: Genetic Testing, Reporting, and Clinical Management, Clinical Perspective.**

AHIMA Comment:

8.1.3.1 – Action: Communicate results and additional interpretation from the testing laboratory to the next provider of care. This information can be incorporated into the clinician’s EHR.

Recommendation:

Standards, policies, procedures, and workflow processes will need to be established to guide how health information is gathered, sorted, indexed, shared, managed, controlled, and stored. Also, healthcare providers will need education and training on proper health information exchange. Appropriate staffing levels will need to be maintained. If these issues are left unaddressed then the privacy and security of the information will be compromised.

**Figure 8-4: Genetic Testing, Reporting, and Clinical Management, Testing Laboratory Perspective.**

AHIMA Comment:

8.2.2.1a – Alternative Action: Communicate with the ordering clinician to get clarification. The clinician responds to communication from the testing laboratory. This information exchange is likely to be of an ad hoc nature.

Recommendation:

Record management standards, policies, procedures, and workflow processes must be established to guide how health information is parsed, sorted, selected, shared, managed, controlled, and stored in an ad hoc communication environment. Healthcare providers must be educated and trained on proper health information exchange. Appropriate staffing levels will

need to be maintained. If these issues are left unaddressed then the privacy and security of the information will be compromised.

**Figure 8-5: Genetic Testing, Reporting, and Clinical Management, Consumer Perspective.**

AHIMA Comment:

8.3.1.1 – Action: Consumer receives laboratory results and clinical interpretation. The consumer receives available personal, family health, and/or genetic/genomic testing information via their PHR. Information in a standardized interoperable form would move through an information exchange and could be sent to other providers of care.

Recommendation:

Consumer healthcare literacy levels must be considered. What level of education and training would the consumer require before the consumer had the ability to understand and make choices based on the information received? A healthcare information access management model must be created to share information with other providers of care. What stakeholder would make the access and control decisions?

**Section 9.0 Information Exchange**

AHIMA Comment:

Figure 9-1. Personalized Healthcare Information Exchange Capabilities. 9.1 Data delivery, 9.2 Data retrieval, 9.3 Subject-data matching, 9.4 Support for personally controlled health records.

Recommendation:

In order for these information exchange capabilities to succeed; record management standards, policies, procedures, and workflow processes must be established. Staffing models, system design models, and indexing and coding models must be developed.

**Appendix A: Glossary – “Health Information Exchange”**

AHIMA Comment:

Definition from the AHIMA Practice Brief “HIM Principles in Health Information Exchange.” “HIE is the actual mobilization or movement of healthcare information electronically across organizations within a region or community...This term does not define the governance of the exchange model or the purpose of the information exchange. HIE provides the capability to electronically move clinical information between disparate health care information system while maintaining the accuracy of the information being exchanged.”

AHIMA agrees that a process that allows for the exchange of personalized healthcare information maintained in EHR systems would allow providers to customize treatment and management plans for patients based on their unique genetic makeup. AHIMA is an active developer and promoter of EHR record management practice standards. We also actively participate in the development of technical standards for PHR and EHR systems. We look forward to a day when interfaces between personal health records (PHRs) and EHRs, and

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health information exchange (HIE) accurately portrays a personal healthcare history that supports clinical assessment, evaluation, interpretation, and planning. AHIMA welcomes the opportunity to work with ONC and the healthcare industries to see that all these goals are met.

If AHIMA can provide any further information, or if there are any questions or concerns in regards to this letter and its recommendations, please contact Harry Rhodes, MBA, RHIA, CHPS, FAHIMA, AHIMA's director of practice leadership at (312) 233-1119 or [harry.rhodes@ahima.org](mailto:harry.rhodes@ahima.org) , or me at (312) 233-1135 or [donald.mon@ahima.org](mailto:donald.mon@ahima.org).

Sincerely,

A handwritten signature in cursive script that reads "Donald J. Mon".

Donald Mon, PhD  
Vice President, Practice Leadership

cc: Harry Rhodes, MBA, RHIA, CHPS, FAHIMA  
Allison Viola, MBA, RHIA