

FINAL DRAFT

Consolidated Health Informatics

Standards Adoption Recommendation

Multimedia Information in Patient Records

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Summary

Domain: Data from multiple media sources (e.g., images, photos, audios, videos, faxes, etc.)

**Standards Adoption Recommendation:
Digital Imaging Communications in Medicine (DICOM)**

SCOPE

The primary application of this standard is for combining data from multiple media (e.g., images, photos, audios, videos, faxes, etc.) into patient records with the objective of ensuring interoperability and information exchange among federal agencies. This standard is useful throughout the federal healthcare system which employs a wide variety of medical records and patient information systems.

RECOMMENDATION

This DICOM recommendation has two parts and encompasses storage and exchange of multimedia data.

OWNERSHIP

National Electrical Manufacturers Association (NEMA) owns the copyright to the standard. DICOM is a standards organization administered by the NEMA Diagnostic Imaging and Therapy Systems Division. NEMA is an ANSI-Accredited standards developing organization

APPROVALS AND ACCREDITATIONS

DICOM is not ANSI accredited, however the DICOM Standard is expected to become an ISO reference standard and has been a European Standards (EN) for years. DICOM also partners with Integrating the Healthcare Enterprise (IHE) and HL7.

ACQUISITION AND COST

Standards are available from <http://medical.nema.org> at a cost ranging from \$50.00 to \$700.00.

Part I – Team & Domain Scope Identification

Target Vocabulary Domain

Common name used to describe the clinical/medical domain or messaging standard requirement that has been examined.

Multimedia information including messaging format as a component of an electronic patient record.

Describe the specific purpose/primary use of this standard in the federal health care sector (100 words or less)

Multimedia Data:

The primary application of this standard is for combining data from multiple media (e.g., images, photos, audios, waveforms, videos, faxes, etc.) into patient records with the objective of ensuring interoperability and information exchange among federal agencies. This standard encompasses storage and exchange of multimedia data and is useful throughout the federal healthcare system which employs a wide variety of medical records and patient information systems.

Sub-domains *Identify/dissect the domain into sub-domains, if any. For each, indicate if standards recommendations are or are not included in the scope of this recommendation.*

Domain/Sub-domain	In-Scope (Y/N)
Incorporation of multimedia information into patient records:	Y
Images	Y
Audio information	Y
Waveform data	Y
Video information	Y
Telemedicine	N

Information Exchange Requirements (IERS) *Using the table at appendix A, list the IERS involved when using this vocabulary.*

Care Management Information
Improvement Strategy
Population Member Health Data
Body of Health Services Knowledge
Resource Availability

Team Members *Team members' names and agency names with phone numbers.*

Name	Agency/Department	Phone Number
William Heetderks, Co-Chair	Department of Health and Human Services, National Institutes of Health/NIBIB	301-496-9388
Richard Swaja, Co-Chair	Department of Health and Human Services, National Institutes of Health/NIBIB	301-451-4779
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Lewis Berman	Department of Health and Human Services, Centers for Disease Control	301-458-4096
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Work Period *Dates work began/ended*

Start

October 30, 2003

End

September 21, 2005

Part II – Standards Adoption Recommendation

Recommendation *Identify the solution recommended.*

This recommendation has two parts and encompasses storage and exchange of multimedia data.

Part 1 – Storing Multimedia Data in Patient Health Records

The Digital Imaging and Communications in Medicine (DICOM) Standard is recommended as the primary method for incorporating multimedia data into patient health records. In the development of this recommendation, the fundamental requirements considered for representing multimedia objects in electronic patient health records included (1) that the objects stored in the patient records are uniquely identifiable persistent entities and (2) that the objects contain patient study, study component, examination, equipment, unique identification, and other information (e.g., date, creator, body part, etc.) as attributes and metadata in addition to the objects themselves. DICOM satisfies these requirements.

To mitigate risks to patient safety, it is essential that patient health record metadata be integrated with patient multimedia data and communicated in a standard manner. DICOM supports these capabilities and is the preferred standard for multimedia because it records patient record metadata within the multimedia object, it provides a standard communication method for exchange of objects, and it provides a mechanism to define and validate interoperability conformance. Some specialties such as radiology heavily depend on DICOM as the standard without which interoperability would be severely compromised. Other specialties are in varying stages of adopting DICOM as the multimedia standard. Compatibility between specialties requires the use of the same standard to achieve interoperability. All multimedia specialty data must be interoperable as part of the electronic health record. DICOM is the most viable candidate for achieving interoperability across specialties within the electronic health record.

Specialties and devices that have not yet adopted DICOM for multimedia need an interim solution that incorporates the following requirements:

- Multimedia data and associated metadata shall be stored and transmitted in alternative format(s). These format(s) must be identified and their metadata content specified by some standards body in order to allow interoperability of systems. These formats must be easily convertible to DICOM for future compatibility. Particularly important is correct representation of patient and study identification information.
- There must be standard communication mechanisms for exchange of multimedia objects between systems.
- To allow validation of proper behavior of interfaced systems, conformance templates for interoperability must be developed and cited in procurements until

equivalent DICOM systems are available.

Part 2 – Exchange of Multimedia Data

The use of DICOM for electronic health record (EHR) information exchange is focused on the exchange of multimedia EHR content, instrument-produced structured reports, and the textual information necessary to properly identify the multimedia content/objects. All other textual EHR information (patient history, orders, progress notes, etc.) will be exchanged using the HL7 messaging standard already approved by the CHI.

There are multiple scenarios in which the exchange of multimedia EHR information must occur, each of which must be supported by information exchange protocols. Multimedia is an essential part of the overall EHR content. CHI has already adopted the HL7 messaging standard (version 2.3 and later) as the standard for exchanging textual EHR information. The exchange of multimedia EHR information should be as tightly integrated with the exchange of textual EHR information as possible.

The following six scenarios appear to cover all the possible information exchange permutations. The recommended exchange standards are listed after each scenario.

Scenario #1: Exchange of multimedia EHR information between two DICOM capable systems.
Recommended exchange standard: Use DICOM standard to exchange information.
Rationale: In this scenario, the primary purpose is to exchange multimedia EHR content. In this situation, the DICOM standard can be used as both the content formatting standard and the information exchange standard.
Scenario #2: Exchange of EHR information (including multimedia) between two EHR systems that are HL7 and DICOM capable.
Recommended exchange standards: Use DICOM for multimedia and associated

<p>metadata and HL7 for textual EHR information (patient history, orders, progress notes, etc.)</p>
<p>Rationale: In this scenario, the primary purpose is to exchange both multimedia and other EHR content. In this situation, the DICOM standard should be used for conveying the multimedia content including associated metadata and object-specific information, and HL7 should be used for exchange of other EHR textual information.</p>
<p>Scenario #3: Exchange of any type of EHR information between a sending HL7 and DICOM capable system and a receiving HL7 capable but non-DICOM capable system.</p>
<p>Recommended exchange standards: There are two alternatives. The first would be to remediate the receiving system to communicate using DICOM. The second alternative would be to use HL7 (preferably XML encoded) for textual information and Web-based standards (JPEG or MPEG) for multimedia, metadata, and object-specific information. This second alternative must integrate patient metadata with the multimedia data and transmit it in a standard manner.</p> <p>It is recognized that many systems will not be able to achieve either of these alternatives near-term. Hence, it is recommended that in those cases where either of the above solutions will not work, that the exchange occur using data formatted according to the IHE “Portable Data for Imaging” integration profile. This specification includes incorporating viewer software that allows the display of the DICOM objects. In places where electronic links exist between sites, the exchange may occur over a secure connection. For all other cases, the recommended form of exchange is through fixed media (CD or DVD depending on package size).</p>
<p>Rationale: In this scenario, the receiving system does not understand the DICOM standard; therefore, absent remediation, the DICOM standard could not be used. If interoperation is attempted without remediation, the HL7 standard should be used for textual information exchange and web based standards (JPEG or MPEG) should be used for formatting the multimedia content. All metadata required by DICOM for the multimedia object must be communicated between systems in a standard manner. In cases where the DICOM image is not compatible with the native software, IHE Portable Data for Imaging integration profile provides a standard means of allowing the images to be viewed on the receiving system until native viewing software can be implemented.</p>
<p>Scenario #4: Exchange of any type of EHR information between a sending HL7 capable but non-DICOM capable system and a receiving HL7 capable DICOM-capable system.</p>
<p>Recommended exchange standards: The sending system should use HL7 to send textual information and web based standards (JPEG or MPEG) to send multimedia metadata, and object-specific information. The receiving system should encapsulate this information into a DICOM object.</p>

<p>Rationale: DICOM Supplement 104 (now incorporated into DICOM 2004) addresses the need and ability to encapsulate information sent in PDF format from non-DICOM-capable imaging modalities. For multimedia information sent in non-PDF format, DICOM Secondary Capture (SC) is available. In either case, the resulting object is in DICOM format. All metadata required by DICOM for the multimedia object must be communicated between systems in a standard manner.</p>
<p>Scenario #5: Exchange of multimedia EHR information between a sending DICOM capable system and a receiving non-DICOM capable system. Neither system is HL7 capable.</p>
<p>Recommended exchange standards: There are two alternatives. One would be to remediate the receiving system to communicate using DICOM. The other would be to use CDs and DVDs formatted according to the IHE Portable Data for Imaging integration profile to transfer the data. This specification includes incorporation of viewer software that allows the display of the DICOM objects.</p>
<p>Rationale: In this scenario, the receiving system does not understand the DICOM standard; therefore, absent remediation, DICOM communications could not be used. The IHE Portable Data for Imaging integration profile provides a standard means of allowing the images to be viewed on the receiving system.</p>
<p>Scenario #6: Exchange of multimedia EHR information between a sending non-DICOM capable system and a receiving DICOM capable system. Neither system is HL7 capable.</p>
<p>Recommended exchange standards: There is only one option: remediate the sending system to communicate using DICOM.</p>
<p>Rationale: In this scenario, communication is possible only if the sending system understands the DICOM standard.</p>

Future Considerations:

The following items are recommended for future consideration and research support to address issues related to multimedia patient information:

1. Standards committee collaborations – As the standards continue to develop, it is recommended that the DICOM and HL7 committees (and others as appropriate) work together to harmonize their standards for healthcare applications. This is particularly desirable in the area of DICOM Structured Reports (SR) and HL7 Clinical Document Architecture (CDA) harmonization.

It is recommended that within the next year, HL7 and DICOM agree to a harmonization method for equivalent structures found in CDA and SR messages and maintain harmonization using an appropriate maintenance and management structure,

2. Time to incorporate industry standards – Consideration should be given to providing support for reducing the time between implementation of industry standards and incorporation into federal standards.
3. Long-term storage and retrieval of information – Consideration of problems associated with the “migration” of information among media bases, which are partly due to rapidly changing information technologies, is necessary.
4. Unique identifiers – Although assignment of unique identifiers is mature in the DICOM Standard, efforts should be supported in the ONCHIT initiatives to provide harmony with HL7 and other standards.
5. Computer system firewalls – For biomedical information exchange between agencies, issues of computer system security and firewalls are a larger hindrance to effortless communication than are the use of different data standards within agencies. Additional research is needed to develop secure data systems that remain open to exchange of large data sets from the outside.

Ownership Structure *Describe who “owns” the standard, how it is managed and controlled.*

DICOM is an international standard format for interchange of biomedical images and ancillary data. Development is coordinated by the National Electrical Manufacturers Association (NEMA) which provides a forum for standardization of electrical equipment that enables consumers to select from a range of safe, effective, and compatible electrical products. DICOM specifies a complete communications standard including a generic messaging service for exchange of imaging-related information between applications and the transfer of actual images.

Integrating the Healthcare Enterprise (IHE) is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care. Systems developed in accordance with IHE communicate with one another better, are easier to implement, and enable care providers to use information more effectively. Physicians, medical specialists, nurses, administrators and other care providers envision a day when vital information can be passed seamlessly from system to system within and across departments and made readily available at the point of care. IHE is designed to make their vision a reality by improving the state of systems integration and removing barriers to optimal patient care.

The World Wide Web Consortium (W3C) is an international consortium that primarily pursues its mission through the creation of Web standards and guidelines. W3C also engages in education and outreach, develops software, and serves as an open forum for discussion about the Web. In order for the Web to reach its full potential, the most fundamental Web technologies must be compatible with one another and allow any hardware and software used to access the Web to work together. W3C refers to this goal as “Web interoperability.” By publishing open (non-proprietary) standards for Web languages and protocols, W3C seeks to avoid market fragmentation and thus Web fragmentation.

Summary Basis for Recommendation *Summarize the team’s basis for making the recommendation (300 words or less).*

- Performed an initial comprehensive review of standards and activities dealing with various information media and eliminated any that did not consider the type of media associated with patient health records or were under development with a long-term deadline for completion.
- Developed a list of general data types and subtypes used for patient records in the federal healthcare system.
- Performed a comparison of each remaining standard against this checklist.
- Selected the standard that encompasses a large portion of applicable media types and identified gaps existing in the current standard.
- Developed recommendations for a standard. Also addressed issues that need to be considered for completeness, and options to accommodate gaps in the recommended standard until they can be addressed.
- Input solicited from CHI Image Messaging Workgroup to ensure compatibility among recommendations (intra-agency and inter-agency).

Conditional Recommendation *If this is a conditional recommendation, describe conditions upon which the recommendation is predicated.*

No conditions placed on recommendation. Please refer to the “Gaps” section in Part III of this report for additional Workgroup comments.

Approvals & Accreditations

Indicate the status of various accreditations and approvals:

Approvals & Accreditations	Yes/Approved	Applied	Not Approved
NEMA	Yes		
IHE	Yes		
W3C	Yes		

Options Considered *Inventory solution options considered and summarize the basis for not recommending the alternative(s). SNOMED must be specifically discussed.*

DICOM – Digital Imaging and Communications in Medicine (DICOM) is an evolving standard for exchange of medical information that is gaining worldwide acceptance. DICOM is a commercial, cooperative standard with basic goals of achieving intra-agency operability through negotiation and cooperation and improving workflow efficiency between imaging systems and other healthcare information systems. Although initially aimed at intra-agency applications, the standard has developed to where it is also appropriate for inter-agency applications.

Widely used to handle radiology images, the DICOM Standard added the ability to capture/store waveforms and related information in 1999. The initial work targeted waveforms in cardiology but then was expanded to ensure its application to a broad range of waveforms needed for the medical environment. DICOM Waveforms are persistent objects that not only capture the actual waveform data, but additional information such as Patient demographics, procedure context, instrumentation information, and linkage to images and other waveforms (if needed). These objects can be stored, queried and retrieved, and transmitted between various devices. The list of the currently defined waveforms is:

- 12-lead ECG Waveform Storage
- General ECG Waveform Storage
- Ambulatory ECG Waveform Storage
- Hemodynamic Waveform Storage
- Cardiac Electrophysiology Waveform Storage
- Basic Voice Audio Waveform Storage

This area is now beginning to be implemented extensively in the current standard. For example, IHE Cardiology is specifying DICOM for hemodynamic waveform storage.

SNOMED International deals with indexing images to patient records. The standard does not encompass the range of multimedia information (e.g.; imaging technologies, hardware, and software related to audio, video, imaging, etc.) required for this domain. However, the SNOMED Standard provides descriptive image information (or metadata) that might be required for multimedia database indexing.

DIG35 is a set of metadata standards being developed by the International Imaging Industry Association to allow efficient archiving, indexing, cataloging, reviewing, and retrieving of individual data sets from a large database. Existing imaging standards upon which the DIG35 initiative is based include JPEG, MPEG-7, and XML – all of which have been adopted as convention although the MPEG Standard continues to evolve. The intent of the 90-member association coordinating the DIG35 Standard is to develop and promote the adoption of open industry standards many of which encompass the media considered for this domain.

IEEE1073 – The IEEE1073 Standard is titled “Point of Care Medical Device Communication Standards” and is actually a family of standards developed to facilitate connectivity and

interoperability among bedside medical devices and the general hospital support environment. The standard is relevant to several aspects of the domain especially those dealing with the need to integrate the multiplicity of bedside medical devices from multiple vendors into the modern, computer-based hospital environment. The standard is under development and does not currently encompass the broad range of information required for this domain.

IHE – The Integrating the Healthcare Enterprise (IHE) initiatives have several working groups profiling standards, such as DICOM and HL7, for integrating and exchanging clinical and administrative data in healthcare. Areas being considered include radiology, cardiology, laboratory, pharmacy, and information technology infrastructure.

HL7 – Although intended primarily for text and coded data, the Health Level Seven (HL7) Standard enables transmission of certain waveform data. This is an emerging standard that has broad application in healthcare and research data.

Current Deployment

Summarize the degree of market penetration today; i.e., where is this solution installed today?

Although still evolving, since 1993 DICOM has expanded so that it is currently widely accepted in the radiology field. It is now also being used in ophthalmology, dentistry, endoscopy, and cardiology. As the usage of DICOM increases, it will displace non-standard approaches and make interoperability more easily possible.

What number or percentage of federal agencies have adopted the standard?

Those within the CHI group have adopted the standard for multimedia patient information.

Is the standard used in other countries?

Yes. Since 1999, DICOM has been an internationally-recognized standardization body with a Type A liaison to the International Standards Organization (ISO). This liaison is with ISO Technical Committee (TC) 215 on Health Formalities. ISO TC 215 has decided not to create an imaging workgroup but to rely solely on DICOM for biomedical imaging standards.

Are there other relevant indicators of market acceptance?

This standard is already widely accepted, and further development to incorporate multimedia concerns should pose no problems for market acceptance.

Virtually every radiology image acquisition device currently produced has the ability to support DICOM. There is an IHE initiative in cardiology that will use DICOM. In ophthalmology, the major manufacturers of retinal cameras are now using DICOM. There are standards activities in dentistry, endoscopy, and ophthalmology that will result

in further use of DICOM.

Technical efforts to develop a joint DICOM/ISO standard on “Web Access to DICOM Persistent Objects” (WADO) are nearing completion. This capability will enable Web access to all DICOM objects, although only if the viewing system knows the host system’s unique internal identifiers for each individual image.

Part III – Adoption & Deployment Information

Provide all information gathered in the course of making the recommendation that may assist with adoption of the standard in the federal health care sector. This information will support the work of an implementation team.

Existing Need & Use Environment

Measure the need for this standard and the extent of existing exchange among federal users. Provide information regarding federal departments and agencies use or non-use of this health information in paper or electronic form, summarize their primary reason for using the information, and indicate if they exchange the information internally or externally with other federal or non-federal entities.

- Column A: Agency or Department Identity (name)
- Column B: Use data in this domain today? (Y or N)
- Column C: Is use of data a core mission requirement? (Y or N)
- Column D: Exchange with others in federal sector now? (Y or N)
- Column E: Currently exchange paper or electronic (P, E, B (both), N/Ap)
- Column F: Name of paper/electronic vocabulary, if any (name)
- Column G: Basis/purposes for data use (research, patient care, benefits)

Department/Agency	B	C	D	E	F	G
Department of Veterans Affairs	Y and N	Y	Y	B		Patient care
Department of Defense	Y	Y	Y	B		
HHS Office of the Secretary						
Administration for Children and Families (ACF)						
Administration on Aging (AOA)						
Agency for Healthcare Research and Quality (AHRQ)						
Agency for Toxic Substances and Disease Registry (ATSDR)	Y	Y	Y	B		
Centers for Disease Control and Prevention (CDC)	Y	Y	Y	E	Evaluating several different vocabularies	Survey research and surveillance
Centers for Medicare	Y	Y	Y	B		Medicare and

and Medicaid Services (CMS)						Medicaid
Food and Drug Administration (FDA)	Y	Y	Y	E	N/A	Research
Health Resources and Services Administration (HRSA)						
Indian Health Service (IHS)						
National Institutes of Health (NIH)	Y	Y	Y	B		Research and patient care
Substance Abuse and Mental Health Services Administration (SAMHSA)						
Social Security Administration	N	N	N	N	N/A	N/A
Department of Agriculture	N	N	N	N	N/A	N/A
State Department	N	N	N	N	N/A	N/A
US Agency for International Development						
Justice Department	N	N	N	N	N/A	N/A
Treasury Department	N	N	N	N	N/A	N/A
Department of Education	N	N	N	N	N/A	N/A
General Services Administration	N	N	N	N	N/A	N/A
Environmental Protection Agency						
Department of Housing & Urban Development	N	N	N	N	N/A	N/A
Department of Transportation	N	N	N	N	N/A	N/A
Homeland Security	N	N	N	N	N/A	N/A

Number of Terms

Quantify the number of vocabulary terms, range of terms or other order of magnitude.

How often are terms updated?

Range of Coverage

Within the recommended vocabulary, what portions of the standard are complete and can be implemented now? (300 words or less)

Acquisition

How are the data sets/codes acquired and use licensed?

The DICOM Standard is available free on the Internet at <http://medical.nema.org>. The DICOM Committee can be reached by mail at 1300 N. 17th Street, Suite 1847, Rosslyn, VA 22209.

IHE specifications are available for free. The web address is <http://www.ihe.net/>.

W3C standards are available for free. The W3C headquarters in the US is located at MIT, 32 Vassar Street, Room 32-G515, Cambridge, MA 02139 USA. The web address is <http://www.w3.org/>.

Cost

What is the direct cost to obtain permission to use the data sets/codes? (licensure, acquisition, other external data sets required, training and education, updates and maintenance, etc.)

DICOM is available free on the Internet.

Systems Requirements

Is the standard associated with or limited to a specific hardware or software technology or other protocol?

No. DICOM is both vendor and platform neutral, and thus can be implemented into systems based on any technology.

Guidance

What public domain and implementation and user guides, implementation tools or other assistance is available and are they approved by the SDO?

DICOM is in widespread use and is accessible to the public.

Is a conformance standard specified? Are conformance tools available?

Yes - Part I of the DICOM Standard specifies a conformance standard.

Maintenance

How do you coordinate inclusion and maintenance with the standards developer/owners?
Voluntary upgrades through contacts with the DICOM Committee.

What is the process for adding new capabilities or fixes?

Continual review of multi-media requirements and standards, specific requests for upgrades and issues to be considered to the DICOM Committee.

What is the average time between versions?

Various.

What methods or tools are used to expedite the standards development cycle?

None. The DICOM Committee should be petitioned to consider specific items related to multimedia data.

How are local extensions, beyond the scope of the standard, supported if at all?

The DICOM Committee will decide the relevance of a request to the scope of the standard.

Customization

Describe known implementations that have been achieved without user customization, if any.

Within VHA medical facilities, approximately 250 different device models have been validated and implemented without requiring user customization. These devices are capturing approximately 500,000 images per day.

If user customization is needed or desirable, how is this achieved? (e.g, optional fields, interface engines, etc.)

Mapping Requirements

Describe the extent to which user agencies will likely need to perform mapping from internal codes to this standard.

Identify the tools available to user agencies to automate or otherwise simplify mapping from existing codes to this standard.

Compatibility

Identify the extent of off-the-shelf conformity with other standards and requirements:

Conformity with other Standards	Yes (100%)	No (0%)	Yes with exception
NEDSS requirements	X		
HIPAA standards	X		
HL7 2.4 and higher	X		

Implementation Timeframe

Estimate the number of months required to deploy this standard; identify unique considerations that will impact deployment schedules

Approval having been achieved for waveform, audio, 3D, 1-bit images, and security specification, the DICOM 2004 standard is complete with respect to multimedia applications. However, current systems may require time for re-engineering to comply with DICOM; interim exceptions will have to be made.

If some data sets/code sets are under development, what are the projected dates of completion/deployment?

Gaps

Identify the gaps in data, vocabulary or interoperability.

The following items are gaps related to multimedia data in the current DICOM standard that are being addressed and considered for future implementation:

1. **Three-dimensional (3D) data** – A DICOM proposal has been issued for registration and fusion of 3D data and should be approved during 2005.
2. **Security** – Some security-related issues are addressed in DICOM, but they need to be expanded to include (1) user identification and password, (2) information access restrictions, and (3) VPN issues.

Obstacles

What obstacles, if any, have slowed penetration of this standard? (technical, financial, and/or cultural)

Examples of issues that are considered but have not been yet been extensively implemented in DICOM include:

1. **Audio data** – An audio data standard is available in DICOM, but it hasn't been implemented by vendors at this time. The current MPEG standard is appropriate for patient audio data until the DICOM Standard is accepted.
2. **Video data** – A video standard is available in DICOM, but it has not been implemented at this time. The current MPEG standard is appropriate for patient video data until the DICOM Standard is accepted.
3. **Waveform data (e.g.; ECG, EEG, etc.)** – Although this area has not yet been extensively implemented in the current standard, DICOM is recommended for representing and storing all patient healthcare waveform data between systems. The ANSI-accredited HL7 Annotated ECG Waveform Data Standard is acceptable for use in clinical trials.

Appendix A

Information Exchange Requirements (IERs)

Information Exchange Requirement	Description of IER
Beneficiary Financial / Demographic Data	Beneficiary financial and demographic data used to support enrollment and eligibility into a Health Insurance Program.
Beneficiary Inquiry Information	Information relating to the inquiries made by beneficiaries as they relate to their interaction with the health organization.
Beneficiary Tracking Information	Information relating to the physical movement or potential movement of patients, beneficiaries, or active duty personnel due to changes in level of care or deployment, etc.
Body of Health Services Knowledge	Federal, state, professional association, or local policies and guidance regarding health services or any other health care information accessible to health care providers through research, journals, medical texts, on-line health care data bases, consultations, and provider expertise. This may include: (1) utilization management standards that monitor health care services and resources used in the delivery of health care to a customer; (2) case management guidelines; (3) clinical protocols based on forensic requirements; (4) clinical pathway guidelines; (5) uniform patient placement criteria, which are used to determine the level of risk for a customer and the level of mental disorders (6) standards set by health care oversight bodies such as the Joint Commission for Accreditation of Health Care Organizations (JCAHO) and Health Plan Employer Data and Information Set (HEDIS); (7) credentialing criteria; (8) privacy act standards; (9) Freedom of Information Act guidelines; and (10) the estimated time needed to perform health care procedures and services.
Care Management Information	Specific clinical information used to record and identify the stratification of Beneficiaries as they are assigned to varying levels of care.
Case Management Information	Specific clinical information used to record and manage the occurrences of high-risk level assignments of patients in the health delivery organization.
Clinical Guidelines	Treatment, screening, and clinical management guidelines used by clinicians in the decision-making processes for providing care and treatment of the beneficiary/patient.

Cost Accounting Information	All clinical and financial data collected for use in the calculation and assignment of costs in the health organization.
Customer Approved Care Plan	The plan of care (or set of intervention options) mutually selected by the provider and the customer (or responsible person).
Customer Demographic Data	Facts about the beneficiary population such as address, phone number, occupation, sex, age, race, mother's maiden name and SSN, father's name, and unit to which Service members are assigned
Customer Health Care Information	All information about customer health data, customer care information, and customer demographic data, and customer insurance information. Selected information is provided to both external and internal customers contingent upon confidentiality restrictions. Information provided includes immunization certifications and reports, birth information, and customer medical and dental readiness status
Customer Risk Factors	Factors in the environment or chemical, psychological, physiological, or genetic elements thought to predispose an individual to the development of a disease or injury. Includes occupational and lifestyle risk factors and risk of acquiring a disease due to travel to certain regions.
Encounter (Administrative) Data	Administrative and Financial data that is collected on patients as they move through the healthcare continuum. This information is largely used for administrative and financial activities such as reporting and billing.
Improvement Strategy	Approach for advancing or changing for the better the business rules or business functions of the health organization. Includes strategies for improving health organization employee performance (including training requirements), utilization management, workplace safety, and customer satisfaction.
Labor Productivity Information	Financial and clinical (acuity, etc.) data used to calculate and measure labor productivity of the workforce supporting the health organization.
Health Organization Direction	Goals, objectives, strategies, policies, plans, programs, and projects that control and direct health organization business function, including (1) direction derived from DoD policy and guidance and laws and regulations; and (2) health promotion programs.
Patient Satisfaction Information	Survey data gathered from beneficiaries that receive services from providers that the health organization wishes to use to measure satisfaction.

Patient Schedule	Scheduled procedure type, location, and date of service information related to scheduled interactions with the patient.
Population Member Health Data	Facts about the current and historical health conditions of the members of an organization. (Individuals' health data are grouped by the employing organization, with the expectation that the organization's operations pose similar health risks to all the organization's members.)
Population Risk Reduction Plan	Sets of actions proposed to an organization commander for his/her selection to reduce the effect of health risks on the organization's mission effectiveness and member health status. The proposed actions include: (1) resources required to carry out the actions, (2) expected mission impact, and (3) member's health status with and without the actions.
Provider Demographics	Specific demographic information relating to both internal and external providers associated with the health organization including location, credentialing, services, ratings, etc.
Provider Metrics	Key indicators that are used to measure performance of providers (internal and external) associated with the health organization.
Referral Information	Specific clinical and financial information necessary to refer beneficiaries to the appropriate services and level of care.
Resource Availability	The accessibility of all people, equipment, supplies, facilities, and automated systems needed to execute business activities.
Tailored Education Information	Approved TRICARE program education information / materials customized for distribution to existing beneficiaries to provide information on their selected health plan. Can also include risk factors, diseases, individual health care instructions, and driving instructions.