Medical Device Interoperability for Patient Safety: Driving Procurement Changes	October 2008

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This paper discusses the requirements for medical device interoperability in the modern healthcare environment. These requirements are changing the way in which we procure medical devices. An appendix provides shareable RFP and contract language examples.

Background

Medical devices, essential for the practice of modern medicine, have been traditionally designed to operate independently using proprietary protocols and interfaces for system integration. With the increasing complexity of the healthcare environment, stand-alone, proprietary devices and systems no longer provide an acceptable solution. Medical devices and systems must easily integrate with other vendors' equipment, software and systems in order to improve patient safety.

Essential improvements in patient safety and healthcare efficiency in high-acuity clinical settings require system solutions that can be implemented using standardized, interoperable medical devices and systems.[1] Clinical societies and the FDA now endorse the potential of medical device interoperability to lead to "improvements in patient safety and clinical efficiency". [2][3]

Our collaboration through the Medical Device Plug-and-Play (MD PnP) program over the last four years leads us to conclude that Healthcare Delivery Organizations (HDOs) must lead a nationwide call to action for interoperability of medical devices and systems. One way that HDOs can effect this change is by including medical device interoperability as an essential element in the procurement process and in vendor selection criteria.

We HDOs wish to adopt interoperability standards for medical device interconnectivity. We also recognize that the necessary standards are not yet fully developed or widely implemented by medical equipment vendors. However, we believe that adoption of standards-compliant interoperable devices and systems will enable the development of innovative approaches to improve patient safety, healthcare quality, and provider efficiency for patient care; will improve the quality of medical devices; will increase the rate of adoption of new clinical technology and corresponding improvements in patient care; will release HDO resources now used to maintain customized interfaces; and will enable the acquisition and analysis of more complete and more accurate patient and device data, which will support individual, institutional, and national goals for improved healthcare quality and outcomes. Our goal is to document the clinical demand and to strongly encourage the development and adoption of medical device interoperability standards and related technologies.

Medical Device Free Interoperability Requirements for the Enterprise (MD FIRE)

Clinical Context

Why is medical device interoperability necessary to improve patient safety? As an example, when taking an x-ray in the Intensive Care Unit, the ability to synchronize the x-ray with the patient's breathing cycle has been demonstrated to improve image quality. [4] Unfortunately, the capability of interconnecting and synchronizing these devices is not available today. Similarly, a safety interlock that would stop the flow of opioid pain medication from an infusion pump and call the nurse if a patient showed signs of respiratory distress could save lives.[5] There are numerous other examples whereby medical device interoperability and medical system integration, if available, will improve patient safety.[6],[7]

Standards-based medical device interoperability can provide real-time comprehensive population of the electronic medical record (EMR), and in the future will permit the creation of integrated error-resistant medical systems that will support advanced capabilities such as automated system readiness assessment; physiologic closed loop control of medication delivery, ventilation, and fluid delivery; decision support; safety interlocks; monitoring of device performance; plug-and-play modularity to support "hot swapping" of replacement devices and selection of "best of breed" components from competitive sources; and other innovations to improve patient safety, treatment efficacy, and workflow efficiency.[6]

Recommendations

We strongly encourage HDOs to adopt medical device interoperability as an essential element of their procurement process.

We have drafted sample medical device interoperability requirements and would encourage HDOs and vendors to use such requirements in their procurement process, including their requests for proposals (RFPs) and contracts. You can find the sample language attached as an Appendix to this document and available at http://www.mdpnp.org/MD_FIRE.html. We expect that the sample requirements and contracting language will evolve over time based on use.

We believe that changing the way in which we procure medical devices to integrate requirements for interoperability will provide a way for us to ensure patient safety, improve healthcare quality, reduce healthcare costs, and provide for more comprehensive and secure management of health information.

References:

[1] Getting Connected for Patient Safety: How Medical Device "Plug-and-Play" Interoperability Can Make a Difference. Patient Safety & Quality Healthcare 5:1, Jan-Feb 2008. (http://mdpnp.org/Publications.html#PSQ)
[2] http://mdpnp.org/Endorsements_of_Interop.html
[3] "FDA Perspective," 2007 Joint Workshop on High Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (HCMDSS-MD PnP 2007), pp xii-xiii, 2007 (http://tinyurl.com/mdpnpfda)
[4] Synchronization of Radiograph Film Exposure with the Inspiratory Pause Effect on the Appearance of Bedside Chest Radiographs in Mechanically Ventilated Patients. American J of Resp and Crit Care Med, V160, p2067, 1999.
[5] Dangers of Postoperative Opioids. APSF Newsletter, V21, No4, Winter 2006-2007 (http://tinyurl.com/apsfpca)
[6] ASTM F29.21 draft standard on the Integrated Clinical Environment, Annex B: "Clinical Context and Clinical Scenarios"
[7] Plug and Play OR Edges Closer to Reality. Anesthesiology News, V33, No1, January 2007, p1,15. (http://mdpnp.org/Publications.html)

Medical Device Free Interoperability Requirements for the Enterprise (MD FIRE)

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Medical Device Free Interoperability Requirements for the Enterprise (MD FIRE)

RFP AND CONTRACT LANGUAGE EXAMPLES (6 pages)

<u>**MD FIRE: RFP EXAMPLES**</u>

Note: This is language to be used in an RFP or RFI to select vendors in a competitive process. Include in the RFP the contract terms, i.e. the contract language examples below, if it is the intention of the Customer to utilize them for the contract. Each of the sections below may be included in any combination.

RFP Example A: Request for Specific Functionality and Interoperability Capabilities
Note: Requests a complete description of specific functionality and interoperability capabilities. The text shown is an example only, and should be greatly expanded by the HDO. This may be used if the HDO knows what interoperability capabilities it is seeking, what product functions support that interoperability, and which standards are to be implemented.

- Current Interoperability Functionality: Devices must have the following capabilities:
    - Pulse oximeter sends % oxygen saturation and pulse rate data to other clinical systems using standard [XXXXX].
    - Etc.
- Future Interoperability Functionality: Device must have the following capabilities within [18 months] [of standard XXXXX being approved] [of these functions being included in HITSP interoperability standards]:
    - Pulse oximeter sends clinical and technical (equipment) alarms, and upper and lower oxygen saturation and pulse rate alarm settings to other clinical systems using standard [XXXXX].
    - Pulse oximeter interfaces with clinical systems and accepts data and control to set alarm limits (and averaging time and sensitivity mode, if applicable).
    - Etc.
- Performance testing: All requirements will be verified in the Customer's own test environment and operational environment.
- Support: All functions must be included in the regular maintenance and support agreement.

RFP Example B: Description of All Interoperability Capabilities and Related Functionality
Note: Requests a complete description of the Product interoperability, but does not call for any particular function or standard.

Please include in your response to the proposal your company's approach and plans for interoperability of your Products, specifically:

- All interoperable interface standards, technology standards, terminology standards, communication standards, and design guidelines that the Products will implement and comply with (including but not limited to USB, WiFi, ZigBee, Bluetooth, HL7, Continua). For each standard and guideline, describe:
    - The current and proposed scope of compliance with each standard and guideline, including but not limited to the exact specifications and guideline versions.
    - A description of the current and proposed Product functions that are interoperable and supported by the standards and guidelines.

- An estimate of the [NTE, time and materials, estimated] cost and schedule to implement the proposed capabilities and standards listed above. If updates or compliance are included in the regular maintenance agreement, please describe those terms.
  "Current" means functions, features, and compliance that are currently marketed by your company and in use by your customers.

- Your company's process for demonstration, acceptance testing, and certification and validation of interoperability for the standards listed above. If you propose to provide independent validation and verification of capability, the full price of that effort should be described.

- A description of your company's processes for maintenance and upgrades to accommodate new interface technology, new interface standards, updated interface standards, or new Product functionality.

- All supported proprietary, customized, standards-based, and interoperable interfaces, electronic data interfaces, and data transfer functions supported by the Product.

- A description of the Product's current and proposed functions that are available or fully functional only when the system is interfacing with your company's Products or your company's partner's products.

- A list of the Product's current and proposed interfaces that are only fully supported when interoperating with your company's Products or your company's partner's products.

For all of the above items, please describe all the resources required from the Customer and third parties. Include costs and dependencies if known.

RFP Example C: Description of Technology Supporting Interoperability
Note: Requests a complete description of the Product technology. This should be used only if the Customer intends to evaluate the Product's technology and implementation.

Please describe in your response to the proposal your company's implementation of technology relevant to interoperability, including:

- Description of the current and proposed system architecture, including interfaces.

- Description of the current and proposed software architecture, including interfaces.

- Description of the current and proposed hardware architecture, including interfaces.

- Description of the current and proposed application architecture, including interfaces.

RFP Example D: Description of Vendor's Past Support for Interoperability
Note: Requests a complete description of the vendor's corporate activities related to interoperability but not directly related to the Product itself. This should be used only if the Customer intends to evaluate vendors' past commitment and contributions to interoperability.

Please describe in your response to the proposal the efforts and contributions your company has made to achieving medical device interoperability for your products in particular or the industry in general. The response may take any form, but as an example it could include:

- Your company's participation in interoperability standards consortiums, societies, or other similar organizations developing or promoting interoperability.

- Any relevant public demonstrations, plug-fests, or product implementations that show the interoperability of your company's products.

MD FIRE: CONTRACT TERMS EXAMPLES

Option 1: Complete Interoperability
Note: The purpose of this section is to provide an example of terms for complete interoperability. Language in square brackets [this or that] should be selected as appropriate by the Healthcare Delivery Organization (referred to herein as "Customer" or "HDO").

1. Supplier shall list all external interfaces for each Product, including interface and communication standards and terminology definitions (referred to collectively herein as "interfaces"). This includes listing any interface standards for a Product which Supplier does not intend to implement or conform to. For each of these interfaces, Supplier shall describe:
   a. The unique identifier or name for the interface
   b. The applicable standard or the Supplier's own name for the interface. Examples include but are not limited to ANSI, ASTM, NEMA, ISO DICOM, IEEE, IHE, USB, WiFi, ZigBee, Bluetooth, HL7, and Continua
   c. The standard name and version if applicable, e.g. HL7 2.3
   d. The domain, subset, and profile of the interface as applicable, e.g. IHE Radiology Profile
   e. Whether its classification is "proprietary & closed", "proprietary & open", "standard" (i.e. HL7 or DICOM), "standard with a third party implementation guideline or profile" (e.g. IHE Radiology) or "standard with a third party implementation guideline and third party certification" (e.g. Continua or USB or WiFi)
   f. Whether it is currently in operational use at customer sites, developed but not in use, in development, or planned for development
   g. Product implementation and support plans for the interface – include implementation or discontinuation plans, as applicable
   h. References to the interface's specification – these could be external links to Standards Development Organizations, or the Supplier's own documentation as applicable
   i. A description of the Product functions supported by the interface

   A table illustrating the information required above is shown at the end of the Appendix.

2. During the Term of the Agreement and any subsequent period during which Customer is purchasing support and maintenance services from Supplier for Products, Supplier will implement federally ratified interoperability standards and interoperability specifications for all interfaces described in paragraph 1 above as follows:
   - Applicable specifications published by the Health IT Standards Panel (HITSP)
   - Applicable certification criteria published by the Certification Commission for Health IT (CCHIT)

- Applicable specifications recognized by the Secretary of US Health and Human Services and required under the federal contracting provisions of US Executive Order 13410
- Other interoperability standards and specifications recognized or required in applicable laws, rules, regulations, and legislation from the federal government and states and districts where HDO operates

Supplier will implement these standards and specifications [before the US Government and its agencies mandate compliance for any final specification] in accordance with HDO project timeline in Exhibit XXX.

3. As part of the Customer's acceptance testing process, Supplier shall demonstrate in the Customer's own test and operational environments that the Products successfully interoperate with Customer's third party equipment and systems in accordance with the requirements in this Exhibit and with the use cases [described in this Agreement, mutually agreed upon by the parties].

4. For any proprietary interfaces, Supplier shall provide to Customer and designated third party suppliers the information necessary for them to understand and test the Product's interface specifications that are in use by Customer and, where needed, a royalty-free license to use these proprietary interfaces with third party products that interoperate with Products in use by Customer.

5. In the event the Product fails to interoperate with third party products and systems in accordance with the Product's integration and interoperability specifications set forth in this Agreement, then Supplier shall remediate the problem at Supplier's cost and shall reimburse Customer for its reasonable costs and expenses resulting from re-work, re-testing, re-certification, and re-validation of the product.

6. For all of these terms, Supplier shall specify whether the capability is available in the proposed Product without a maintenance agreement. If any capability is only available with a maintenance or development agreement, the terms of that agreement shall be fully disclosed and described.

Option 2: Independent lab testing of interfaces

Supplier agrees to have each interface tested and verified by an independent lab approved by Supplier and Customer.[1] All costs from the Supplier and other third parties for independent lab testing and certification shall be listed separately [and paid by Supplier]. Supplier also agrees to obtain any applicable consortia certification for Product interfaces, including without limitation, USB, WiFi, ZigBee, Bluetooth, HL7 and Continua.

Option 3: Connectivity by Clinical Domain
Note: This section provides a means to add requirements by clinical domain. Customer should consider selecting a specific domain if needed.

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[1] Such as the Medical Device Plug-and-Play Lab at the Center for Integration of Medicine and Innovative Technology (CIMIT) or the Kaiser Garfield Center

Product and all subsequent releases and replacement Products shall comply with applicable interoperability standards, guidelines, and certifications in the following domains:
- Acute Care Documentation
- physiological monitors
- ventilators
- patient care beds
- etc.

Option 4: Request for Conformance to Specific Standards
Note: This section provides a means to add conformance to specific standards if not required by other sections.

Product and all subsequent releases and replacement Products shall comply with the following standard:
- (e.g. ASTM xxxx 200x)

Option 5: Commitment to Work towards Interoperability
Purpose: This section is to be used when the Supplier is expected to make a best effort to achieve interoperability, and at the same time to inform the Customer of any issues, barriers, or problems with the current set of standards.

At every release of Product software, either for implementation or maintenance, Supplier shall use best efforts to implement applicable [federally ratified] interoperability standards. Supplier and Customer shall meet quarterly [in-person or by teleconference by mutual agreement] to discuss Supplier's progress towards implementing and conforming to applicable standards. At each meeting, Supplier shall provide the following information:
1. For each interface, a description of the progress and accomplishments made towards conformance with standards
2. For each interface, a list of issues, objections, and problems encountered with the Supplier's Products, third party products, and the Customer's or standards' specifications that prevent or delay conformance

Option 6: Customer Requirements-Gathering Example

Exhibit XXX

This is a placeholder for the Customer to define its program/project timeline with respect to gathering requirements for interoperable interfaces. It is referenced in the Agreement terms. To support this Agreement language, this Exhibit should at a minimum specify:
- When requirements will be delivered from the Customer to the Supplier
- When the Supplier is expected to complete development of interfaces
- When the Supplier is expected to complete testing, validation, and certification of interoperable interfaces

The actual content of this exhibit should be created by the Customer's legal team.

Sample Language Appendix

This table contains examples of the expected level of detail to be provided
by Supplier for its external interfaces.

Example Interface Standard Table								
Interface Name	**Standard**	**Domain**	**Type**	**In use?**	**Scope of Conformance**	**Plans**	**Reference to interface specification**	**Functions supported**
Patient demographics	HL7 2.3	Demographics	Open standard, not validated	In operational use	Partial implementation	No plans to discontinue	www.hl7.org	Receiving and displaying patient demographic data
Patient lab data	Proprietary	Laboratory	Proprietary, open	In operational use	Full	Will be maintained for existing products, but eventually replaced by HITSP standard interface	www.vendorname.com/productsupport/interfacess	Sending patient lab data
Patient lab data	TBD	Laboratory	Open standard, CCHIT validation	Planned for development	Planned to be lab data	Will replace lab data interface within 12 months of ratification of the specification and adoption by the US government	www.hitsp.org	Sending patient lab data to the EMR
Patient weight	IEEE XXX, Continua V1 Guidelines	Disease Management	Open validated standard, Continua guidelines, Continua validation	No	Full & Certified	Planned for delivery in 2009 Q2 products	www.continuaalliance.org	Receiving CHF patient's weight
Contrast injectors	CIA425, Part 2: Injector	CAN-Open Application Profile for Medical Diagnostic, Add-on Modules, Part 2: Injectors	Standard	Yes	Full	No plans to change	http://www.can-cia.org	Connect injectors to CANOpen network for X-ray contrast injections
Pulse Oximeter	IEEE P11073-10404(sm)	Pulse Oximeter	Standard	Yes	Full	No plans to change	https://development.standards.ieee.org/pub/active-pars?n=12	Acquires Pulse Oximeter data
Integrated Clinical Environment (ICE) Data Logger	ASTM F29.21 ICE Part II	ICE system data logging	In process	No	N/A	Will conform within 12 months of publication	www.sdo.org	Continuously log data from patient-centric devices in the ICE
Disease Taxonomy	ICD-11	All	Standard	No	None	Will implement within 18 months of ratification and publication by WHO	http://www.who.int/classifications/icd/ICDRevision/en	All functions supporting clinical documentation