Integrating the Healthcare Enterprise

IHE Patient Care Coordination

White Paper

Waveform Tracings

Public Comment

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This is a white paper from the IHE Patient Care Coordination Technical Committee.

It is submitted for Public Comment between June 1, 2009 and July 1, 2009.

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Details about the IHE Patient Care Coordination may be found at:
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Details about the structure of IHE Technical Frameworks and Supplements may be found at: http://www.ihe.net/About/process.cfm and http://www.ihe.net/profiles/index.cfm

The current version of the IHE Patient Care Coordination Technical Framework may be found at:. http://www.ihe.net/Technical_Framework/index.cfm

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Introduction

People of a certain age may remember the 1970s TV action drama “Emergency!”, where emergency providers could review wave tracing information being transmitted electronically from a field-based ECG device to an emergency room in near real-time. The ability of healthcare providers to access general wave tracing data from locations separate from where wave tracings are captured falls far short of what was shown in that series more than 35 years ago. This white paper discusses two approaches to the exchange of this sort of information using existing work done by two different IHE domains.

White Paper Abstract

This white paper discusses the use of the IHE DEC, SPD and XDS-SD profiles to exchange waveform tracings. Two use cases are examined, for concurrent (near real-time) review, and for post-factum review.

Open Issues and Questions

1. Need discussion of “what is a waveform” to address issues in PCD Scope.

Closed Issues

1. Address issues of Patient Identity Reconcilliation, where patient identity information is possibly not present. Patient identity issues are not within the scope of this white paper.
2. Address issues around anonymization/pseudonymization, once a rendering is produced, we may no longer be able to anonymize/pseudonymize the results. Anonymization/Pseudonymization are not within the scope of this white paper. The use cases for these two seem to be more related to research.
3. Need to coordinate this activity with PCD. Information was exchanged with PCD committee members and all feedback received was incorporated into this white paper.

Waveform Tracings

1 Scoping Statement

Wave tracings are used by a variety of medical specialties for diagnostic purposes. Waveforms are used in Electrocardiograms (ECG), Fetal Heart Traces, Perioperative Reporting, Electroencephalograms (EEG), Electromyograms (EMG), Pulmonary Function Tests, Cystometrograms, et cetera. The waveforms produced by these studies often need to be exchanged or shared to provide care to a patient.

A variety of standards already exist dealing with special purposes, for example, synchronized audio and video waveforms for various ultrasound and endoscopy applications using the DICOM standard. Furthermore, IHE has already profiled the use of the Portable Document Format for exchanging information from scanned images of clinical data in the XDS-SD profile developed by the IT Infrastructure technical committee. The XDS-SD profile could be used to scan wave tracings and exchange data. However, the use of scanned versions of wave tracings is limited in its utility, as it suffers from degradation of information from the scanning process.

This presents a gap in available mechanisms for exchanging wave tracings for general clinical use. The purpose of this white paper is to describe two approaches using IHE Profiles to support the exchange of wave tracing information. IHE Cardiology has already defined the Retrieve ECG for Display profile to provide access throughout the enterprise to ECG documents for review purposes. This white paper is consistent with, and borrows heavily from that profile with respect to rendering and generation of waveform output. The IHE Patient Care Devices domain has also described several HL7 messages that could be utilized to exchange wave tracing data.

Two use cases that can be addressed by the use of existing IHE profiles are described in further detail below.

1.1 Concurrent Review

In the concurrent review use case, a consulting provider is reviewing the waveform results concurrently with those results being gathered. In this use case, the consulting provider may want to review prior portions of the waveforms, annotate the waveform, or locate significant events at different time locations.

1.2 Post-factum Review

In the post-factum review use case, the consulting provider reviews the waveform results after they have been gathered. In this use case, the consulting provider may want to review prior portions of the waveforms, or possibly add annotations to the waveform.

2 Rendering Requirements

Both use cases have a set of requirements for the rendering of the output in common and these are provided in further detail below. These requirements draw heavily from the IHE ECG profile and have been generalized for the broader cases in the scope of this white paper. The output must state when the waveforms were recorded from the patient and shall include the date and time (to the resolution recorded by the device) of the recording. It is assumed the date/time is local to wherever the recording was made, unless specific timezone information is provided. Output that includes waveforms shall encode those waveforms at diagnostic quality.

Waveforms shall include an indication of the measured quantity and time scale. For example, for ECG by usage of standard calibration pulse (1 mV high, 200 ms wide), and a nominal 1 mm grid. The output should contain statements about the conversion scale used for rendering. For example, for ECG, statements about scale such as mm per unit time and mm per mV such as “25 mm/s 10 mm/mV”; or for Fetal Heart Rate, scales such as “3 cm / minute” and “20 bpm / cm” would be reported.

When measuring electrical signals, if different leads have different gains (e.g., precordial chest leads at half gain), sufficient information must be given to determine the gain of each lead. The actual size of the displayed output is under control of the user at the display client, thus, the information source cannot control that the nominal 1 mm squares on the background grid is always displayed as a 1 mm square on the screen of the display device.

The aspect ratio shall be fixed, so that a unit square in the rendered output appears as a square on the display, not as a rectangle; a change in aspect ratio may make the waveform interpretation difficult for those accustomed to reading at the standard scale.

The output shall conform to diagnostic standards for the monitoring device for rendering scale markings and output. For example, for ECG, there should be major axes every 5 mm in both dimensions drawn with darker or thicker lines, corresponding to 200 ms and 500 uV when the report scaling is 25mm/s and 10 mm/mV. The minor axes at 1 mm intervals (at 40 ms and 100 uV when the report scaling is 25 mm/s and 10 mm/mV) may be drawn using fainter or thinner lines, or by using small “dots”.

The rendering shall identify the input traces and the method of collection (e.g., Fetal ECG Scalp Lead, Tocodynometer, Doppler). The rendered waveform shall include an indication denoting the transition from one input trace to the next in a waveform “line”.

The representation shall allow multiple input traces to be shown, possibly for multiple subjects (e.g., for monitoring in multiple gestation), (e.g., each input trace on an ECG, or in Fetal Heart Tracings, the contractions, O2 Saturation, and Fetal Heart Rate), in a way that allows the measurements to be compared. Waveforms shall include statement of frequency content, e.g. “0.05 – 150 Hz”.

The output may include timed annotations recording other monitored data, or arbitrary annotations created by the user. The output may also include interpretations generated by the user. If the interpretation statements are included, the document shall also include a statement as to whether the report is preliminary vs. signed, and the document should clearly note its status.

To meet the waveform quality requirements, the rendering system shall use vector graphics to minimize aliasing effects. This means the renderer shall generate rendered “content” (i.e., vector drawing commands) to be rendered on the display device, versus generating a bitmap image. To do this, the rendered needs to generate the output using vector-drawing commands. The various wave forms described above shall be represented as a graph of the measured data over time.

3 Concurrent Review

The ideal review scenario would allow providers to review data concurrent with the capture of the waveform data, or to select a time range of data to be reviewed. The data would be accessible in the most accurate manner possible in near real time. The data could then be optimally formated by the appropriate actor for a specific destination device, such as a cell-phone, PDA, laptop, monitor or other device. Where devices have existing formatting capability, the formatting could be performed at the destination device (e.g., an iPhone or laptop display). In other cases (such as a cell-phone), the data may be formatted as a a preformatted raster image.

The IHE Subscribe to Patient Data profile (SPD) defined by the PCD Domain specifies a mechanism by which a Device Observation Consumer (the reviewer's workstation), can query for a snapshot of patient data for rendering from the Device Observation Filter actor communicating with the system maintaining or storing the observation data. This profile allows for the time range of samples and the reporting frequency to be specified in a query for information. The Device Observation Filter can then communicate appropriate data. With appropriate use of the messages specified in this profile, the units of measure and measurement scaling can be provided in the incoming messages to support communication of the data using the original measured values communicated by the device, preserving the fidelity of the information exchange.

Using the SPD profile, the Device Observation Consumer can request concurrent data and receive it in near real-time for review and consulation, or the provider can request prior data samples to receive recently measured values.

The Device Enterprise Communication (DEC) also from the Patient Care Devices domain can be used to support the exchange of time stamped anotations from the reviewer workstation to the repository of device observations. To meet this requirement, the role of Device Observation Communicator and the Device Observation Reporter switches. The reviewer workstation now becomes a reporter of observations, and the system which maintains device observations now becomes the consumer of observations generated by the reviewer.

4 Post-factum Review

A commonly accepted single standard for waveform data does not yet exist. There are numerous standards in use for waveform communication worldwide. The IHE Cardiology domain profiled the use of the Portable Document Format/Archive standard to exchange ECG tracings in the Retrieve ECG for Display profile.

To support review of waveform recordings after the fact, we recommend use of the IHE XDS-SD profile, using the PDF option. The output waveforms shall be rendered in the PDF as required above under rendering requirements. The resulting document may be stored in an XDS Repository, or exchanged using the XDR or XDM profiles.

5 Conclusions and Next Steps

In the near term, the XDS-SD profile seems to be the most readily available technology for storage of waveform data in a readily rendered format. The Cardiology ECG profile has been used as a mechanism of exchange of ECG wave tracing data for long term storage within enterprises; the extension of that profile's requirements to waveforms beyond ECGs needs further review by relevant domain experts. The IHE XDS-SD profile has been shown to be an effective way to communicate data that is generated natively in the Portable Document Format without an intermediate scanning stage, ensuring full fidelity in data rendering. The combination of these two IHE profiles into a content profile that supports the exchange of waveform tracings seems to be a viable mechanism for a near term solution. This might be developed as a separate IHE profile, as an option on the XDS-SD profile, or might simply published as a white paper by IHE.

The existing SPD and DEC profiles developed by the Patient Care Devices domain may be used in the fashion described in this paper to support concurrent review. The current profiles are designed for intra-enterprise use, and may not be suited for cross-enterprise exchange of waveform data across enterprises. In addition to security, issues of bandwidth and quality of service issues may also need to be addressed. Additional profiling or grouping with additional IHE profiles may be necessary to make these solutions suitable for cross enterprise exchange. A complete protocol for the communication of waveform data for concurrent review has not yet been profiled by the IHE Patient Care Devices domain. However, a proposal has been presented to generate a Waveform Communication Management profile that could fill some of the gaps for concurrent review.

In the longer term, the lack of a commonly accepted long term storage format for waveform data remains an obstacle. A long term archival format for waveform data would be usefull not just for concurrent and post-factum review, but could also be used to develop archives of waveforms for research use. There are several standards available for the communication of multi-channel waveforms that might be applied to this problem by the respective standards bodies. The problem in this case seems to be selection and adoption of one standard from the many available.

