IHE 2012-2013 Call for Proposals

IHE Brief Work Item Proposal

IHE Detailed Work Item Proposal

1. **Proposed Profile: Electrophysiology Report Content (EPRC)**

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   Domain: Cardiology

2. **The Problem**

   This proposal is targeted at the completion of the original 2011-2012 proposal for a cardiac electrophysiology report content profile. That original work item was not completed during the 2011-2012 development cycle.

   A CDA implementation guide for an EP procedure report will bring the benefits of structured reports to the EP lab. This is a critical first step to a profile that uses the EP procedure clinical report as pre-population data for submission to a registry

   The practice of clinical cardiac electrophysiology requires management of data obtained from multiple sources both shared with the practice of cardiology and unique to EP such as pacemakers, implantable cardioverter defibrillators, cardiac resynchronization devices, external and implantable loop recorders, intracardiac electrogram recording systems, three-dimensional intracardiac mapping systems and catheter ablation equipment.

   The Electrophysiology Report Content profile offers the capability to leverage industry standards that address both the structure and content of data used in the electrophysiology domain.

   The content provided by the Electrophysiology Report Content profile can be utilized by many domain groups and the following profile-specific use case illustrates a beginning use for which Electrophysiology Report Content can be served.

3. Key Use Cases

3.1 Use Case Scenario #1 – Office Encounter

Patient Betty Swoon is experiencing shortness of breath during mild exertion and schedules an appointment with her Family Practice physician, Dr. Eric.

On arriving for her appointment, Betty first meets with Dr. Eric's nurse, who records Betty's vital signs, takes an electrocardiogram, and draws blood work that is sent to the local diagnostics lab. She is then seen by Dr. Eric, who reviews with Betty the medical history in her EMR record for completeness, performs a physical exam, and reads the ECG. Betty Swoon reports having experienced shortness of breath during mild exertion. Dr Eric records a History and Physical (H&P) Exam Report for the encounter, and adds his interpretation of the ECG to the EMR.

Dr. Eric refers Betty to an Electrophysiologist, Dr. Ken, for an evaluation and possibly a procedure to implant a cardiac rhythm device. Dr. Eric sends a referral request, a Continuity of Care (medical summary) Document, the H&P report, and the ECG from his EMR via the regional Health Information Exchange to Dr. Ken at the nearest University Hospital.

After leaving the consultation with Dr. Eric, Betty again meets with Dr. Eric's nurse for pre-admission counseling. Dr. Eric's nurse discusses with Betty her recorded advanced directives, and Betty signs some updated directives, which Dr. Eric's nurse scans into the EMR system. The EMR system makes Betty's advanced directives available through the HIE.

3.2 Use Case Scenario #2 – EP lab workflow

Dr. Ken receives the referral, and reviews Betty's CCD, H&P report, ECG report, blood lab report, and advanced directives through the HIE, meets with Betty in an office encounter and orders additional testing. During a department meeting to consult with other team members and review the results of the additional testing, a decision is made to schedule a procedure to implant a cardiac rhythm device at the University Hospital EP Lab.

On the day of the device implantation procedure, Dr. Ken reviews Betty's documents on the workstation in his office, and then goes to the EP lab.

When Betty arrives in the admission suite or pre-operative holding area of the EP Lab, basic demographic information regarding the her encounters and the problem that is the reason for the EP Lab procedure, her diagnostic test results acquired during the encounter, arrhythmia history and risk factors are acquired and stored into an EMR, CVIS or other system.

Dr. Ken meets Betty in the EP Lab prep room, and discusses the procedure with her. Dr. Ken reviews the procedure informed consent with Betty, she signs the consent document, and the assisting nurse scans the signed document into the CVIS system.

After the EP Lab procedure has been completed, Betty is transferred to a postoperative setting and observed until discharge and additional data is entered into a discharge summary and stored in the patient's EMR, CVIS, or other system. Aggregated data from the EP Lab procedure is also stored within the patient's EMR, CVIS, or other system.

3.3 Use Case Scenario #3 - EP Lab procedure data acquired and saved as a CDA document

When a patient arrives in the admission suite or pre-operative holding area for an EP Lab procedure, basic demographic information regarding the patient's arrhythmia history and risk factors are acquired and recorded into an EMR, CVIS or other system.

During the EP Lab procedure, data related to the procedure is collected and stored in the EP Lab systems used during the procedure.

The EP Lab systems record data related the EP procedure.

The Case is completed in the EP Lab.

Aggregated data from the ICD procedure is also stored within the patient's EMR, CVIS, or other system.

After the ICD procedure has been completed, the patient is transferred to a postoperative setting and observed until discharge and additional data is entered into a discharge summary and stored in the patient's EMR, CVIS, or other system.

The physician performing the procedure validates the data related to the procedure. The physician user or the nurse assisting in the ICD procedure exports the procedure data to the patient's EMR, CVIS, or other system.

The EP Procedure Note becomes the basic document containing data related to the procedure in CDA R2 format. The aggregated data is stored within the patient's EMR, CVIS, or other system.

4. Standards & Systems

Standards:

CDA implementation guides – CRC, CIRC, and HL7 Consolidated CDA

IHE XDS

IHE – PCD IDCO Profile

DICOM SR – Templates 3800 Cath, 3500 Hemo, 3202 QVA, 3213 QAA, 10001 Dose

DICOM Supplement 129 IEEE definitions of key data elements required for monitoring of PM and ICD function

ACC/AHA/HRS 2006 Key Data Elements and Definitions for Electrophysiological Studies and Procedures

ACCF/AHA Key Data Elements and Definitions of a Base Cardiovascular Vocabulary for EHR

NCDR ICD Registry v2.1 Coder's Data Dictionary

Systems:

CVIS - DSS/OF, Information Source, Document Source (consent), Document Repository

Hemo/logging system – Acquisition Modality, Information Display, Document Consumer

5. Discussion

5.1 History

Note that some of this workflow was in the original IHE-Cardiology Cardiac Electrophysiology key data elements whitepaper.

This proposal is targeted at the completion of the original 2011-2012 proposal for a cardiac electrophysiology report content profile. That original work item was not completed during the 2011-2012 development cycle.

5.2 Scope

Electrophysiology Report Content (EPRC) will be a *content* profile – it is agnostic with respect to the workflow or data exchange mechanism in which the data is produced and handled. The workflow in the storyboard is informative; this is a content profile only.

Content Profiles define how the content used in a transaction is structured. The binding of the Content to an IHE transaction that is part of an IHE Workflow Profile specifies how this payload may influence the metadata or the behavior of the transaction. Content modules within the Content Profile then define the payloads. Content modules are transaction neutral, in that what they describe is independent of the transaction in which they are used, whereas content bindings explain how the payload influences the transaction metadata and/ or behavior.

The set of EP procedures that should be addressed include

- EP study
- Device implant/explant/replacement
- Lead implant/ extraction/revision
- Cardiac ablation
- Cardioversion

Much of the detailed header, section, and entry content modules should be identical to the CRC profile. The CRC profile will be the starting point for this work item. However, the following areas of additional work required have been identified – code/value sets, structural changes, and modeling.

5.2.1 Code / Value Set Extensions

The following codes/value sets in the CRC profile will have to be checked for additional needs specific for the EP procedures:

- Problems/concerns – table 1.3.6.1.4.1.19376.1.4.1.5.31
- Body site – table 1.3.6.1.4.1.19376.1.4.1.5.32
- Family history – table 1.3.6.1.4.1.19376.1.4.1.5.33
- Lab results – table 1.3.6.1.4.1.19376.1.4.1.5.35
- Vital sign observation – table 1.3.6.1.4.1.19376.1.4.1.5.36
- Procedure indications – table 1.3.6.1.4.1.19376.1.4.1.5.37

- Result observations/findings – table 1.3.6.1.4.1.19376.1.4.1.5.38
- ECG information as observation/findings – table 1.3.6.1.4.1.19376.1.4.1.5.38
- Conduction indication measurements as observations/findings – table 1.3.6.1.4.1.19376.1.4.1.5.38
- Arrhythmia indication measurements as observations/findings – table 1.3.6.1.4.1.19376.1.4.1.5.38
- Cardiac activity procedures – table 1.3.6.1.4.1.19376.1.4.1.5.40
- Finding types – table 1.3.6.1.4.1.19376.1.4.1.5.43
- Post procedure diagnoses – table 1.3.6.1.4.1.19376.1.4.1.5.44
- Complications – table 1.3.6.1.4.1.19376.1.4.1.5.46

In addition, it will need to be determined:

- If the ablation site codes can be mapped to the targetSiteCode values set.
- What the device/lead list of codes will be – possibly from UDDI?

5.2.2 Structural Changes

The following are work items related to the CRC CDA section and entry content module structure:

- Need to add the "approachSiteCode" to the Procedure Activity Procedure entry for the "insertion site"
- How should the recording of the ECG signal and/or measurements recorded from the ablation site be linked to the targetSiteCode?
- Need to allow references to external documents & reports at the Procedue Activity Procedure entry level and possibly other levels.

5.2.3 Modeling Extensions

The following are work items to address specific EP related requirements:

- Cardiac Ablation
    - need to get specific items to measure (see DICOM Supplement 129)
    - There are different types of ablation – RF, Cryo, etc. This will not include surgical ablation?
    - Are the ablation steps (as Procedure Activity Procedures) organized chronologically only?
- What is the granularity of the procedure? What information is included in the Procedure Description vs. the Procedure Activity Procedure?
    - Consider the insertion of catheters as Procedure Activity Procedures?
    - Consider need for nesting of Procedure Activity Procedures to address insertion of catheters, ablating, taking measurements, inserting additional catheters, etc.

- Determine how to model the ICD device and the relationship with leads. Are the leads separate devices?
    - How to represent the serial number for each device?
    - How to identify the state/status of the lead over time?
- Are there other graphics that need to be associated the procedure?
    - 3-D anatomical map, 12-lead ECG, ICE image, fluoro images for lead placement, echo, etc?

5.3 Synergy/Benefit

Ratings – High, Medium, Low

Alignment with internal responsibilities of IHE Cardio - **High**, since we are responsible for defining cardiology content.

Alignment with Government / National programs (DMP, ONC/MU, Infoway, etc) – **High**

The significance and urgency of the interoperability problem in the business of healthcare - **High**

Benefit to global community - **High** for the United States. **Medium** internationally (Snomed) with changes needed to account for variations in nomenclature.

Degree of expected adoption - **High** because defining cardiology content will allow portability of data.

Alignment with IHE development domains outside of IHE Card - **High**. We are potentially using content structures and standards from the PCC domain, ITI domain (e.g. RFD profile), and PCD domain (e.g. IDCO profile). This also requires alignment with the HL7 SDWG efforts for the "HL7 Implementation Guide for CDA R2 – IHE Health Story Consolidation" (a.k.a. CDA Consolidation) specifically for section and entry content module definitions.

6. Risks

Underlying specifications for EP nomenclature will change in a way to cause a need to revise this profile. Impact on implementations can be managed by versioning.

Technical Committee must monitor CDA Consolidation efforts that relate to this profile. Note that Consolidation CDA is US Realm specific and this EPRC profile will for the universal realm.

7. Open Issues

- Will this profile be an extension to the CRC profile or be a separate profile that is based on the CRC profile?
- What is the relationship between the EPRC profile and the IDCO profile? Does the IDCO content need to be included in these reports? IDCO includes device settings - are these needed for EPRC? IDCO defines HL7 v2.x messages but references IEEE 11073 10103 nomenclature. IDCO does not model device/leads explicitly. Confirm the classification of the primary procedure types:

    1- Device implant/explants/replacement

2- Lead implant/extraction/revision

3- EP study

4- Cardiac ablation

5- Cardioversion

- Confirm the following hypothesis: Device Implant and Ablation are the most often performed procedure types of this group.
- Does cardioversion need to be treated as a separate procedure or is it always a sub-procedure of one of the remaining primary procedure types?
- Data fields may have different meanings by registry and registry version.

8. Effort Estimates

The work effort for profiling this profile is high.