IHE Brief Work Item Proposal

1. Proposed Work Item: Registry Data Submission Profile for NCDR Peripheral Revascularization Procedures

Proposal Editors:

Author:

Nichole Kallas
2400 N Street NW
Washington DC, 20037
202 375-6415
nkallas@acc.org

Editors:

Michael Simanowith
2400 N Street NW
Washington DC, 20037
202 375-6227
msimanowith@acc.org

Nandan Shanbhag
2400 N Street NW
Washington DC, 20037
202 375-6367
nshanbha@acc.org

Contacts:

Nandan Shanbhag
Nichole Kallas

Submitted: September 19, 2012
Version: 1.0
Domain: Cardiology Domain
Sponsored by the American College of Cardiology

2. The Organization

The American College of Cardiology Foundation (ACCF) is a nonprofit medical professional society and teaching institution dedicated to fostering optimal cardiovascular care and disease prevention through professional education, promotion of research, and leadership in the development of standards and formulation of health care policy.

The NCDR® is the most comprehensive, outcomes-based quality improvement program in the United States, encompassing both hospital-based registries and a practice-based program. As a trusted, patient-centered resource, the NCDR is uniquely positioned to help participating facilities and other medical

professionals identify and close gaps in quality of care; reduce wasteful and inefficient care variations; and implement effective, continuous quality improvement processes.

3. The Problem

This document provides the reader with information supporting the need for an IHE profile for describing the processes and outcomes related to patients undergoing a peripheral revascularization procedure. The specific procedures that have been targeted for inclusion in the registry include carotid artery endarterectomy, carotid artery stenting, and lower-extremity vascular interventions (atherectomies, balloon angioplasty and vascular stenting). Development of an IHE profile is needed to support standardized medical documentation in an electronic format, improve cross-platform transfer of data from equipment used to acquire or record procedure data into the electronic health record (EHR), facilitate compliance with existing and future registries, and to facilitate measurement for quality improvement programs, including tools for performance measure.

Data management for peripheral revascularization is dependent on data obtained from multiple sources such as cardiovascular information systems, hospital registration systems, laboratory information systems, electronic medical record systems, pharmacy systems, device libraries, and potentially other systems within and outside of the hospital setting. Currently, the process of acquiring all of the necessary data elements from these disparate systems into a single document which complies with the submission requirements of the Peripheral Revascularization Registry is a time consuming, manual process that is prone to error and inefficiencies. There is a need to be able to extract these data elements from the medical record (and other source systems mentioned above) in an automated, objective manor that can operate in a cross-platform environment across multiple systems regardless of source system vendor.

In addition to being able to collect data from multiple source systems within one registry (the Peripheral Revascularization Registry for this request) the NCDR intends to create an integrated platform for data collection by creating a single data model which incorporates multiple procedure types. This will facilitate interoperability and streamline the development of future registries based on a uniform data model.

The goal of this proposal submission is to define an IHE profile for submitting Peripheral Revascularization Registry version 1.0 data to the NCDR.

4. Key Use Case

NCDR Peripheral Revascularization Registry version 1.0 Registry Form – CEA/CAS/PVI Procedure-Types

The following use case describes the high level workflow of collecting Peripheral Revascularization Registry data, and concludes with a further detail on how the IHE profile would likely provide added value.

When a patient arrives at the facility or pre-operative holding area for a carotid artery or lower-extremity revascularization procedure, basic demographic information regarding the patient, their history, and

associated risk factors are acquired and recorded in a portion of the medical record. Depending upon the institution, this may or may not be in an EMR/EHR. This initial patient intake process corresponds to three separate phase areas of the Peripheral Revascularization Registry Form– designated as 'Demographics', 'Episode of Care', and 'History (Prior and Of Present Illness)'.

Once the patient has been registered and/or admitted, the patient will likely receive a routine set of pre-procedure tests which are recorded in the 'NonInvasive Testing' section of the form. They will then be prepped for the specific procedure.

After prep for the procedure is complete, the patient is introduced into the location within the facility where the procedure will be performed, typically a "Catheterization Lab" or surgery suite. The Peripheral Revascularization Registry focuses on three main procedure types – carotid artery stenting, carotid artery endarterectomy, and lower-extremity vascular interventions. The purpose of each is to improve blood flow to an area of the body that has been compromised due to lesion within the vessel supplying it. The 'Procedure', 'Lesion Descriptor', 'Labs' and 'Procedure Totals' (with Medications) sections are documented as part of the routine procedure reporting and documentation process. Data elements within each of these sections vary depending on the procedure performed but fall into these broad sections regardless of procedure type. While uncommon, it is possible for a patient to have more than one procedure (two lower-extremity procedures—one on each leg, for example) performed during the same 'Episode of Care'. An 'Episode of Care' is synonymous with an 'admission' or 'hospitalization', and covers the period of time between arrival at the facility performing the procedure and the discharge/departure of the patient, and is independent of the 'inpatient' or 'outpatient' status of the patient.

The patient is then transferred to a post-procedure setting and observed until discharge. In this setting, the remaining data elements pertaining to the hospital admission are recorded in the medical record and used to complete the remaining sections of the procedure-specific Peripheral Registry Form--'Intra/Post Procedure Events' and 'Discharge'.

After hospitalization, the patient may receive follow-up care in the outpatient setting to track his/her response to treatment and disease progression. Completion of the 'Follow-up' section of the form is currently related back to the in-patient hospitalization by Patient ID and the Procedure Date. Completion of this section concludes the data collection process for one hospitalization

This describes the overall user story for collecting and populating the Peripheral Registry Form. Presently, this process is completed manually by a trained individual who reviews the entire medical record and must identify, retrospectively, all components requested by the Registry. This spans multiple phases of the hospital visit, systems within the hospital, and potentially the outpatient setting as described above. This is often a time consuming process and is prone to error. An IHE profile, which could be

leveraged to transmit all Peripheral Registry data elements from any source system and vendor, would dramatically reduce the human resource expense required to complete this process, will improve overall registry data quality and ultimately improve patient outcomes via research/reporting performed on the resulting data.

In addition to the 'registry-specific' benefits, the IHE profile will be extremely beneficial across procedure types. Under the current NCDR data model, only the patient demographics data section is truly shared across all registries through use of a universal NCDR Patient Record. Episode of Care information (data collected once during the 'hospitalization', such as History of Present Illness and Discharge) is essentially mirrored across all registries with a high level of interoperability. Beyond the Episode of Care, data which could potentially be shared across registries is limited by 'siloed' definitions, timeframes of interest, or coding rules. A universal specification defining how to record the cardiovascular data of interest will reduce resources required to record the same information in multiple registries and improve the accuracy of this data across registries.

Finally, the creation of an IHE profile to systemize reporting systems like the Peripheral Registry data elements will provide a standard format that would enable CRM vendors and EHR vendors to identify the requested data element fields in all parts of the medical record (e.g. pre-operative notes, operative notes and post-operative notes). This new lexicon will permit automated extraction of clinical terminology in a standard, shareable and interoperable format which should promote standardized data collection and overall accuracy.

5. Standards & Systems

Standards & References that may be of assistance for completion of this profile include:

1) Universally accepted standards as determined by the Cardiology Domain
2) Peripheral Revascularization Registry v 1.0 Data Set. Please see attached draft data set and data model

6. Discussion

IHE profiles provide a collaborative forum in which clinicians and vendors can agree on a standards-based approach to solving critical patient safety concerns using existing technology. This in turn creates a more efficient process for health care delivery. Products with IHE Profile compliance are already available and in clinical use.

Vendors that support and comply with the IHE Profile would gain a competitive advantage and become more attractive in the marketplace as physicians and their institutions will request and decide to purchase integration capability when selecting a CRM device to implant, and when selecting an EHR system to purchase.

The following challenges and constraints need to be considered for the submission:

1. The profile design must complement with NCDR's ongoing internal project to define a uniform data model. This work is expected to be complete November 23rd, 2012.
2. This proposal is being submitted along with a sister-proposal for the NCDR CathPCI Registry. NCDR would like to publish profiles for both the registries in parallel.
3. The totality of the scope requested by NCDR via these proposals should be considered in the response and NCDR would appreciate the following items covered in the proposal response, if selected:
    a. A task list /time line of the proposed profile creation
    b. Mandatory NCDR participation task items
    c. Optional NCDR participation task items to reduce timeline.
4. Our current process stipulates that vendors need nine months from receipt of vendor specifications to develop interfaces to submit data to the NCDR. The ideal timeline for this proposal would be:
    a. Proposal decision: Nov 2012
    b. Draft Profile: June 2013
    c. Vendor Specifications released to current NCDR vendors by June 2013
    d. Vendor In-house development: Dec 2013
    e. Peripheral Registry 1.0 Connect-a-thon: Jan 2014
    f. Production Go-Live: March 1st 2014