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Registry Assessment of Peripheral Interventional Devices (RAPID)

Developing a minimum core dataset for total product life cycle device evaluation across multiple data sources: a step toward establishing a National Evaluation System for Health Technology for peripheral intervention devices.

BY JOSE PABLO MORALES, MD; JACK CRONENWETT, MD; AND ROBERT THATCHER, MBA; ON BEHALF OF THE RAPID PROJECT COLLABORATORS

Phase 1: Core data elements needed for device evaluation

Phase 2: Real-world data extraction from multiple sources

Phase 3: Use of same core data for all PAD treatment evaluation

RAPID Stakeholder Participants

- Multiple Medical Specialty Registries
  - SVS VQI, ACC NCDR, SIR NIRQR
- Agencies – US and International
  - FDA, CMS, ONC, NLM, AHRQ, NHLBI, DOD
  - GMDNA, Japanese PMDA
- Device Manufacturers
  - Abbott, Aortic Medical Inc, Avinger, Boston Scientific, Cardiovascular Systems Inc, Cook, CR Bard, Medtronic, Spectranetics, Terumo, Volcano/Phillips, WL Gore
- EHR/Registry Companies
  - Boston Biomedical, Epic, Healthjump, M2S, Medstreaming, Novella Clinical, Quintiles

RAPID Phase 1: Core Data Elements

Started June, 2015 – Completed, August 1, 2016

- Received and anonymized data elements from:
  - 6 Society-based registry data forms
    - 3 Major US Registries: ACC NCDR, SIR NIRQR, SVS VQI
    - 3 International Registries: Australia, Germany, Japan
  - 7 Device manufacturer case report forms
    - Bard, Boston Scientific, CSI, Cook, Gore, Medtronic, Terumo
- DCRI Informatics staff analyzed 3,904 data elements
- Selected and organized 2,021 variables that were specific to peripheral arterial device evaluation

RAPID Phase 1: Core Data Elements

- Work Groups comprised of all stakeholders:
  - Multiple conference calls, face-face meetings
- Clinical
  - Select 100 core data elements most central to PVI device evaluation from the initial 2000 possible elements
- Informatics
  - Develop technical specifications and meta data for each data element to support interoperability
- Device Identification
  - Develop methods to incorporate global unique device identifier (GUDID) data into the core data set

RAPID Phase I Deliverables

- Core Data Elements
  - Main elements, FDA device problem codes, medications, device categories central to PVI device evaluation
- Use Cases for Core Data Elements
  - Pre- and post-market and randomized clinical trials
- Workflow Diagrams
  - Point of care, total product lifecycle and registry-based clinical trials
- GUDID Project Summary
  - Key learnings about use of GUDID data useful to other projects

Download at: mdepinet.org/rapid

RAPID Data Elements – Example

Data Element Label	Data Element Definition	Value set	Definitions of the elements of the value set	Reference source
CONDITION - MODIFIED RUTHERFORD CLASSIFICATION				
Modified Rutherford Category	Categorical description of the symptoms associated with the obstruction of the lumen of the peripheral arteries (NCI C78533).	0	Asymptomatic: documented peripheral arterial disease, without symptoms of claudication or ischemic pain	Adapted from VQI PVI registry, Rutherford J Vasc Surg 1997;26:517-38, ACC/AHA PAD Data Standards Circulation 2012;125:395-467, and PARC J Am Coll Cardiol 2015.
		1	Mild claudication: ischemic limb muscle pain that does not limit walking, or limits walking only after >2 blocks (>600 feet, or 2 football fields)	
		2	Moderate claudication: ischemic limb muscle pain that limits walking to 1-2 blocks (300-600 feet, or 1-2 football fields)	
		3	Severe claudication: ischemic limb muscle pain that limits walking to <1 block (<300 feet, or 1 football field)	
		4	Ischemic rest pain: pain in the distal foot at rest felt to be due to limited arterial perfusion	
		5	Minor tissue loss: nonhealing ischemic ulcer(s) on distal leg, or focal gangrene with diffuse pedal ischemia	
		6	Major tissue loss: ischemic gangrene extending above TM level, functional foot no longer salvageable without extensive revascularization efforts	

Clinical Data Element Highlights

- Updated Rutherford Classification to include definitions of claudication distance
- Adopted WIfI system for wound, infection grading
- Patient functional status classification
- Lesion calcification grading system
- Detailed anatomic, lesion, device classification

- Download data elements: www.mdepinet.org/rapid

RAPID Phase 2-3 Progress

- VQI has incorporated all RAPID core elements into its new PVI registry, including device identifier lookup with link to Access GUDID in NLM
- Medstreaming has incorporated RAPID core data elements into its Vascular EMR system
- This readies VQI for participation in interoperable data extraction for total life cycle PVI device evaluation
- Other registries, EMR systems in progress

- Potential for international device evaluation