Registry Assessment of Peripheral Interventional Devices (RAPID)

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RAPID Partners

- **3 Major U.S. Societies / Registries**
  - American College of Cardiology (**ACC**)
    - National Cardiovascular Disease Registry (**NCDR**)
  - Society of Interventional Radiology (**SIR**)
    - National Interventional Radiology Quality Registry (**NIRQR**)
  - Society for Vascular Surgery (**SVS**)
    - Vascular Quality Initiative (**VQI**)

- **5 International Partners**
  - Japan's Pharmaceuticals and Medical Devices Agency **(PMDA)**
  - Global Medical Device Nomenclature Agency **(GMDNA)**
  - Australian Vascular Audit
  - German Vascular Society
  - Northern German Association for Vascular Medicine

RAPID Partners

- **7 U.S. Agencies**
  - FDA (**CDRH** pre- and post-market, and **CEDR**)
  - Agency for Healthcare Research and Quality **(AHRQ)**
  - Centers for Medicare and Medicaid Services (**CMS**)
  - Department of Defense **(DOD)** Healthcare Resources
  - Office of the National Coordinator (**ONC**)
  - National Heart, Lung and Blood Institute **(NHLBI)**
  - National Library of Medicine **(NLM)**
- **6 EHR / Registry / Clinical Research Companies**
  - Epic
  - M2S
  - MedStreaming
  - Healthjump
  - Boston Biomedical Assoc.
  - Novella Clinical, Quintiles

RAPID Partners

- **12 Vascular Device Manufacturers**
  - Abbott
  - Aortic Medical Inc.
  - Avinger
  - Boston Scientific
  - Cardiovascular Systems Inc.
  - Cook Medical
  - CR Bard
  - Medtronic
  - Spectranetics Corp
  - Terumo
  - Volcano Corp/Phillips Health Technology
  - WL Gore

RAPID Goals

- Phase I: Identify minimal set of core data elements for registry assessment of lower extremity arterial devices, including methods to identify specific devices being used

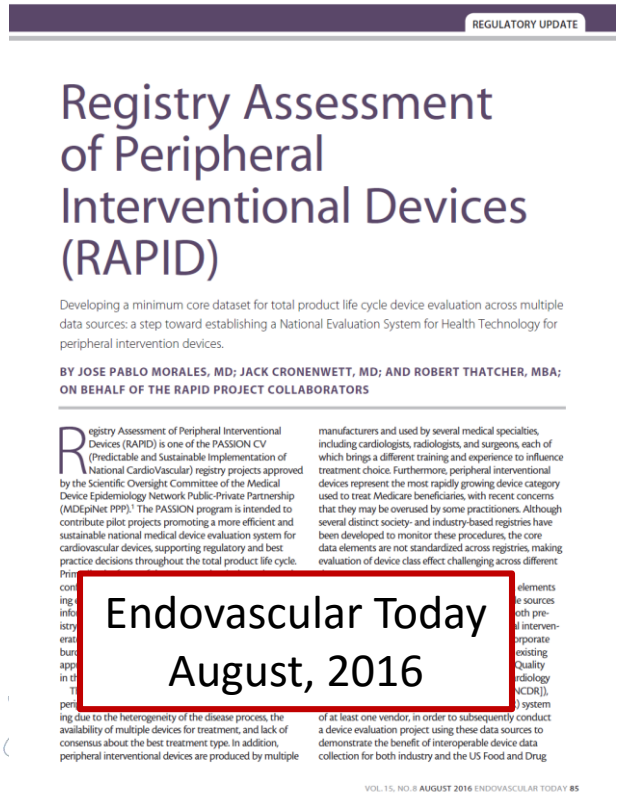
- Phase II: Demonstrate the feasibility of data extraction interoperability across registries and hospital EHRs that provide patient-level data for core data elements.

- Phase III: Use a coordinated registries network (CRN) for studies supporting a regulatory decision.

RAPID Goals

- Phase I: Id… …ts for registry assessmer… …rial devices, including methods to… …specific devices being used

Completed! August, 2016



REGULATORY UPDATE

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

Registry Assessment of Peripheral Interventional Devices (RAPID) is one of the PASSION CV (Predictable and Sustainable Implementation of National CardioVascular) registry projects approved by the Scientific Oversight Committee of the Medical Device Epidemiology Network Public-Private Partnership (MDEpiNet PPP).[1] The PASSION program is intended to contribute pilot projects promoting a more efficient and sustainable national medical device evaluation system for cardiovascular devices, supporting regulatory and best practice decisions throughout the total product life cycle.

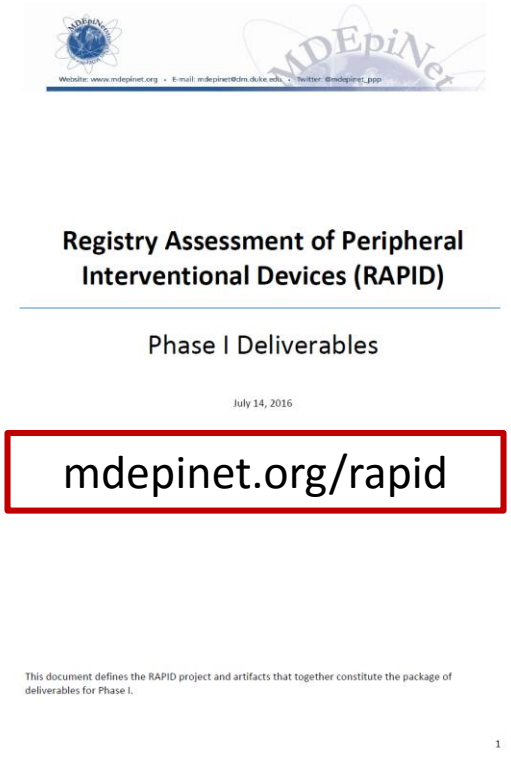
manufacturers and used by several medical specialties, including cardiologists, radiologists, and surgeons, each of which brings a different training and experience to influence treatment choice. Furthermore, peripheral interventional devices represent the most rapidly growing device category used to treat Medicare beneficiaries, with recent concerns that they may be overused by some practitioners. Although several distinct society- and industry-based registries have been developed to monitor these procedures, the core data elements are not standardized across registries, making evaluation of device class effect challenging across different

…elements …e sources …both pre- …l interven- …orporate …existing …Quality …rdiology …NCDR]), …) system

ing due to the heterogeneity of the disease process, the availability of multiple devices for treatment, and lack of consensus about the best treatment type. In addition, peripheral interventional devices are produced by multiple

of at least one vendor, in order to subsequently conduct a device evaluation project using these data sources to demonstrate the benefit of interoperable device data collection for both industry and the US Food and Drug

Endovascular Today
August, 2016



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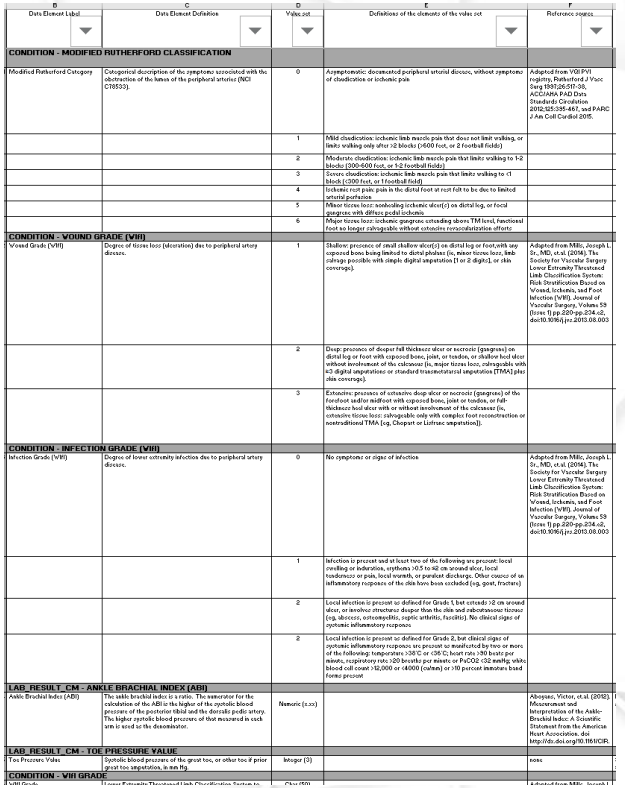
Registry Assessment of Peripheral Interventional Devices (RAPID)

Phase I Deliverables

July 14, 2016

mdepinet.org/rapid

This document defines the RAPID project and artifacts that together constitute the package of deliverables for Phase I.



B Data Element Label	C Data Element Definition	D Value set	E Definitions of the elements of the value set	F Reference sources
CONDITION - MODIFIED RUTHERFORD CLASSIFICATION				
Modified Rutherford Category	Categorical description of the symptoms associated with the obstruction of the lumen of the peripheral arteries (NCI C78553).	0	Asymptomatic: documented peripheral arterial disease, without symptoms of claudication or ischemic pain	Adapted from: Vol PVI registry; Rutherford J Vasc Surg 1997;26:517-38; ACC/AHA PAD Duts 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	
CONDITION - WOUND GRADE (WIfI)				
Wound Grade (WIfI)	Degree of tissue loss (ulceration) due to peripheral artery disease.	1	Shallow: presence of small shallow ulcer(s) on distal leg or foot, with any exposed bone being limited to distal phalanx (ie, minor tissue loss; limb salvage possible with simple digital amputation [1 or 2 digits], or skin coverage).	Adapted from: Mills, Joseph L. Sr., MD, et al. (2014). The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk Stratification Based on Wound, Ischemia, and Foot Infection (WIfI). Journal of Vascular Surgery, Volume 59 (Issue 1) pp 220-pp 234-e2, doi:10.1016/j.jvs.2013.08.003
		2	Deep: presence of deeper full thickness ulcer or necrosis (gangrene) on distal leg or foot with exposed bone, joint, or tendon, or shallow heel ulcer without involvement of the calcaneus (ie, major tissue loss; salvageable with ≤3 digital amputations or standard transmetatarsal amputation [TMA] plus skin coverage).	
		3	Extensive: presence of extensive deep ulcer or necrotic (gangrene) of the forefoot and/or midfoot with exposed bone, joint or tendon, or full-thickness heel ulcer with or without involvement of the calcaneus (ie, extensive tissue loss: salvageable only with complex foot reconstruction or nontraditional TMA [eg, Chopart or Lisfranc amputation]).	
CONDITION - INFECTION GRADE (WIfI)				
Infection Grade (WIfI)	Degree of lower extremity infection due to peripheral artery disease.	0	No symptoms or signs of infection	Adapted from: Mills, Joseph L. Sr., MD, et al. (2014). The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk Stratification Based on Wound, Ischemia, and Foot Infection (WIfI). Journal of Vascular Surgery, Volume 59 (Issue 1) pp 220-pp 234-e2, doi:10.1016/j.jvs.2013.08.003
		1	Infection is present and at least two of the following are present: local swelling or induration, erythema (>0.5 to ≤2 cm around ulcer, local tenderness or pain, local warmth, or purulent discharge). Other causes of an inflammatory response of the skin have been excluded (eg, gout, fracture)	
		2	Local infection is present as defined for Grade 1, but extends >2 cm around ulcer, or involves structures deeper than the skin and subcutaneous tissues (eg, abscess, osteomyelitis, septic arthritis, fasciitis). No clinical signs of systemic inflammatory response	
		2	Local infection is present as defined for Grade 2, but clinical signs of systemic inflammatory response are present as manifested by two or more of the following: temperature >38°C or <36°C; heart rate >90 beats per minute; respiratory rate >20 breaths per minute or PaCO2 <32 mmHg; white blood cell count >12,000 or <4000 (cells/mm) or >10 percent immature band forms present	
LAB_RESULT_CM - ANKLE BRACHIAL INDEX (ABI)				
Ankle Brachial Index (ABI)	The ankle brachial index is a ratio. The numerator for the calculation of the ABI is the higher of the systolic blood pressures of the posterior tibial and the dorsalis pedis artery. The higher systolic blood pressures of that measured in each arm is used as the denominator.	Numeric (x.xx)		Aboyans, Victor, et al. (2012). Measurement and Interpretation of the Ankle-Brachial Index: A Scientific Statement from the American Heart Association. doi: http://dx.doi.org/10.1161/CIR.
LAB_RESULT_CM - TOE PRESSURE VALUE				
Toe Pressure Value	Systolic blood pressure of the great toe, or other toe if prior great toe amputation, in mm Hg	Integer (3)		none
CONDITION - WIfI GRADE				
WIfI Grade	Lower Extremity Threatened Limb Classification System to	Char (50)		Adapted from: Mills, Joseph L.

RAPID Progress

Phase I: Started June, 2015 – Completed, August 1, 2016

- DCRI Informatics Team –Anne Heath, Mary Williams
- 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
- Analyzed 3,904 data elements
- Selected and organized 2,021 variables that were specific to peripheral arterial device evaluation

RAPID Progress

Phase I: Started June, 2015 – Completed, August 1, 2016

- Work Groups (many conference calls, face-to-face meeting)
  - Clinical – Schuyler Jones, MD
    - Selected 100 core data elements for PVI device evaluation
  - Informatics – James Tcheng, MD
    - Developed technical specifications to support interoperability
  - UDI – Terrie Reed, MSIE
    - Developed method to incorporate GUDID data into core data set

RAPID Phase I: Delivered

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

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

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- Phase I: Identify minimal set of core data elements for registry assessment of lower extremity arterial devices, including methods to identify specific devices being used

- Phase II: D n interoperab at provide pat

- Phase III: U for studies supporting a regulatory decision.

Combine Phase II and III, by launching a device evaluation project NOW, that can be incrementally joined by registries and EMR systems as they are able to integrate RAPID core data elements.

RAPID Phase II/III Combination Benefits

- Pilot Project to start the RAPID pipeline!
- Not just proof of concept, but actual deliverables:
  - Contemporary objective performance goals for classes of devices used in PVI treatment
  - Device-specific data for companies that may wish to expand indications for use of current devices
  - Expanded opportunities for a more “rapid” pace and additional projects as more registries and EMR systems are able to contribute data over time

RAPID Agenda May 25, 2017

- Learn from other national models
  - SENTINEL, PCORnet, BUILD. LOINC
- Discuss the initial RAPID Phase II/III Project
- Methods for data / UDI capture, integration, management
  - Successes and challenges from registries, EHRs, industry
- Funding RAPID Phase II/III
  - Industry, VQI, NEST perspectives
- Methods for data sharing with industry and FDA
  - -VQI, SENTINEL, BUILD, International perspectives
- Multi-stakeholder benefits of RAPID:
  - FDA, CMS, Industry
- Planning next steps