REPORT FROM THE CLINICAL WORKING GROUP

RAPID Face-to-Face
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Disclosures

- Research Grants:
  - Agency for Healthcare Research and Quality
  - American Heart Association
  - AstraZeneca
  - Bristol Myers Squibb
  - Daiichi Sankyo
  - Doris Duke Charitable Foundation
  - Patient-Centered Outcomes Research Institute
- Honoraria:
  - American College of Radiology
  - Mondopoint

Outline

- Data Sources
- Process
- Core Data Elements

RAPID Progress

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

Based on intense effort by:

- DCRI Informatics Team –Anne Heath, Mary Williams
- Clinical Working Group members
- 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 PAD device evaluation

Domains

- Condition
- Test
- Procedure
- Device
- Outcomes

Final, thin set of 100 core data elements
Multiple teleconferences and face-to-face meetings

Data Elements

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	

Data Elements

Data Element Label	Data Element Definition	Value set	Definitions of the elements of the value set
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).
		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 necrosis (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
		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 (cu/mm) or >10 percent immature band forms present

Lesion Characteristics

CONDITION - LESION CHARACTERISTICS			
Lesion Length	The length of the target lesion is inclusive of the arterial section treated with the study device (e.g., a stent) and the 10 mm proximal and 10 mm distal to the treated section. (CV endpoints)	Integer 3	
Degree of Stenosis	The quality or state of being open or unobstructed; the relative absence of blockage, measured in percent. (adapted from Merriam-Webster's Medical Dictionary)	Occluded	Complete closure of the normally patent lumen of the blood vessels (adapted from C35318)
		< 50%	Less than 50% closure of the normally patent lumen of the blood vessels.
		>= 50%	50% or greater closure of the normally patent lumen of the blood vessels.
Degree of Lesion Calcification	Vascular calcification is a pathologic response to toxic stimuli involving metabolic substances and/or inflammatory cells [1,3,8,15,16]. (Rocha-Singh, Krishna J., MD, et al., Peripheral Arterial Calcification: Prevalence, Mechanism, Detection, and Clinical Implications, Catheterization and Cardiovascular Interventions 00:00–00 (2014))	Focal	<180 (1 side of vessel) and less than one-half of the total lesion length
		Mild	<180 and greater than one-half of the total lesion length
		Moderate	≥180 (both sides of vessel at same location) and less than one-half of the total lesion length
		Severe	>180 (both sides of the vessel at the same location) and greater than one-half of the total lesion length

Other Key Concepts

- How to name/track target lesions
- How to document access site location, direction, and sheath size
- Whether to track longitudinal cardiovascular outcomes

Device Information

Term/Concept (e.g., label on a CRF)	Data Element Label (e.g., on a CRF)	Data Element Definition	Value set (i.e., permissible values)	Definitions of the elements of the value set
Primary DI Number		An identifier that is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use. The primary DI number will be located on the base package, which is the lowest package level of a medical device containing a full UDI. For medical devices without packaging, the primary DI number and full UDI may be on the device itself.	Type: Num. or Alphanum. Length: min-6, max-23* *defined by Issuing Agency structure.	Enter the Device Identifier (DI) Number. Data type and field length are determined by the individual Issuing Agency structure. GS1: Numeric (Num.), with 14 digits HIBCC: Alphanumeric (Alphanum.), with 6-23 characters ICCBBA: Alphanumeric, with 10 or 16 characters
Company Name		Company name associated with the labeler DUNS Number entered in the DI Record.		Auto populated based on the Labeler DUNS Number The labeler company name submitted to the GUDID should match the company name on the device label.
Brand Name	Brand Name	The Proprietary/Trade/Brand name of the medical device as used in device labeling or in the catalog. This information may 1) be on a label attached to a durable device, 2) be on a package of a disposable device, or 3) appear in labeling materials of an implantable device. The brand name is the name that is typically registered with USPTO and have the ® and/or TM symbol.	Type: Alphanum. Length: 80	Only symbols, ® and ™ will be supported for the current production release of GUDID. NOTE: per Edit Rules, you will not be able to change ® or ™ (if entered) after the Grace Period. Enter NA if the device does not have a Brand Name.
Catalog Number	Catalog Number	The catalog, reference, or product number found on the device label or accompanying packaging to identify a particular product.	Type: Alphanum. Length: 80	Enter the Catalog or Reference Number. Catalog/Reference number can also serve as Version/Model if it represents the devices that have specifications, performance, size, and composition within limits set by the labeler.

Thanks