OPTIONAL DESCRIPTOR

RAPID WORKING GROUP

ABBOTT VASCULAR PERSPECTIVE ON UTILITY OF RAPID CORE DATA SET

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RAPID GOALS

- Standardize core data elements that could serve as a global case report form for both pre- and post-market assessment of peripheral arterial interventional devices
  - PHASE 1: Identify minimal set of core data elements for registry assessment of infrainguinal arterial devices from existing peripheral arterial registries and industry case report forms used for pivotal device approvals (2016)
  - PHASE 2: Develop data extraction interoperability across peripheral registries (SVS VQI and ACC NCDR) and selected hospital EHRs that provide patient level data for core data elements (2016)
  - PHASE 3: Apply coordinated registries network to a prospective clinical trial supporting a priority area of peripheral artery disease clinical research and/or a regulatory decision (2017)

STANDARDIZED CORE DATA ELEMENTS

POTENTIAL VALUE

- Provides minimal/standard data elements for peripheral vascular procedures, in-hospital outcomes and follow-up
- Creates common definitions (eg. peripheral anatomy/clinical presentation)
- Simplifies clinical studies for sites
  - Standard data elements collected, and data entered just 1 time
  - Reduced "study specific" eCRF data entry
- Facilitates data review by FDA due to similar data across studies
- Reduces the cost of conducting clinical studies
- Streamlines safety surveillance
  - Real-world data more consistent and accessible
- Needs to have ability to link to CMS data for longer term outcomes

OPPORTUNITIES TO USE RAPID CORE DATA ELEMENTS

- Performance goal (PG) refinement or development with larger, more robust, real-world data

- Superficial femoral /popliteal artery PG refinement
  - Is the current PG reflective of real SFA/popliteal stenting outcomes? Should it be updated?
    - VIVA PG for safety and effectiveness developed by Rocha-Singh, et al. in 2007 based on 116 PTA pts from FDA studies and 191 pts from literature
    - Goal for effectiveness for metallic self-expanding stents set at 2x PTA patency (66%)
    - Does this reflect real outcomes? Should it be modified?

OPPORTUNITIES TO USE RAPID CORE DATA ELEMENTS

- Performance goal (PG) refinement or development with larger, more robust, real-world data
- Infrapopliteal arteries
  - Do the suggested OPGs developed by Conte et al. for catheter based treatment of CLI patients work in the current regulatory enrivonment?
  - Do follow-up angiograms that evaluate patency in CLI patients add unnecessary risk?
    - Development of a PG for tibial artery lesion patency based on RB Class or WIfI classification using non-invasive (eg. duplex) methods
    - Development of a PG related to wound healing in CLI patients or develop standardized method to assess wound healing

OPPORTUNITIES TO USE RAPID CORE DATA ELEMENTS

- Comparison of two existing PAD treatment modalities for SFA
  - Utilization of concurrent control rather than RCT or historical treatment

- Comparison of a new device type for PAD treatment of the SFA, popliteal, or infrapopliteal arteries
  - Utilization of concurrent control rather than RCT or historical treatment
  - Combined approach – use of registry data, supplemented as needed, with collection of additional data elements related to new device

OPPORTUNITIES TO USE RAPID CORE DATA ELEMENTS

- Randomized Controlled Trial
  - –What will be needed to demonstrate cost effectiveness?
  - –Comparison of two existing PAD treatment modalities for patients with claudication and SFA/popliteal disease to evaluate clinical outcomes, cost effectiveness, and QoL in real-world patients

    - Revascularization with different devices or surgery
    - Revascularization with different devices plus optimal medical therapy and exercise, versus optimal medical therapy and exercise alone

STANDARDIZED CORE DATA ELEMENTS

POTENTIAL CHALLENGES TO BE ADDRESSED

- Adoption of registry models by hospitals, physicians and industry
  - –The benefit of participating needs to outweigh the cost
  - –Patient records need to be complete and support eCRF
- Adoption of data elements across societies and specialties (eg. WIfI)
- Education required for staff entering the patient information
- Ability to secure high level long-term follow-up, if required
- Use of registry models for RCTs – how to ensure blinding is maintained
- Resolution of informed consent requirements for data supporting RA submissions
- Keeping the data elements and definitions current
- Data ownership and publication rights, especially with new technologies

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