Registry Assessment of Peripheral Interventional Devices (**RAPID**)

Rational

&

Intended Uses

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Current Challenge = Heterogeneity

Devices Heterogeneity

- Multiple devices used at a given intervention
- Different technologies
  - Angioplasty Balloons
    - Plain, drug coated, cutting, cryoplasty
  - Atherectomy devices
    - Laser, mechanical
  - Total occlusion crossing devices
  - Stents
    - Bare metal
      - » Self-expanding, balloon expandable
    - Covered
    - Drug-eluting

Patient and Disease Heterogeneity

- Age, gender, diabetes influence outcomes
- Disease Severity
  - Claudication (life style) vs. Critical Ischemia (limb threat)
  - Differing lesion length, occlusion vs. narrowing, calcification
- Disease Location
  - Large (iliac),
  - Medium (SFA, popliteal),
  - Small (tibial) Arteries

Provider Heterogeneity

- Variable Physician Specialty, Training, Experience
  - Cardiologists, radiologists, surgeons
- Variable Treatment Options
  - Numerous device types, on- and off-label use in practice

Most Important = Standardization and Homogeneity

- Global case report form
  - Same variable, same definitions and same measuring scales
- EHR adoption to allow for dissemination and real world application

What could be done with RAPID?

- Leads to ability to analyze large amount of data to allow for safety and effectiveness:
  - Device specific analysis
  - Device class specific analysis: Performance Goal development

Deliverables?

- Global CRF with respective definitions should lower the reviewer regulatory burden as well as decrease cost to sponsors.
- GUDID / NLM should allow for device specific outcomes searches

Take home message

- Registries are here to stay and if we develop them together they can work on our behalf

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