RAPID – Registry Assessment of Peripheral Interventional Devices

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11:30 am - 12:30pm

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Disclosures

James Tcheng – none
Carrie Bosela – none
Randomized Controlled Trials (RCT)

Gold standard to:
• Evaluate effectiveness of new (or established) therapies
• Account for effects of unmeasured confounders, selection bias

Issues:
• Increasingly complex
• Expensive
• Lengthy enrollment
• Not ‘real-world’

“This randomized, double-blind trial involving over 20,000 patients was conducted over a 10 year period. Unfortunately we’ve forgotten why.”
Randomized Registry Trials

Basic Principles for Registry Success

• Developing uniform, harmonized definitions specific to a particular area
• Defining relevant questions
• Establishing quality by design principles to ensure data quality and ability of registry to pass audit
• Addressing relevant informed consent issues
• Developing incentives for sustainability of the registry
Peripheral Arterial Disease

- Registry Assessment of Peripheral Interventional Devices (RAPID)
  - Launched June 5, 2015
- Goal
  - Develop standardize core data elements for a harmonized foundation for both pre- and post-market assessment of peripheral arterial interventional devices
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 CDER)
  - 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 Association
  - Novella Clinical / Quintiles
RAPID Partners

• 12 Device Manufacturers
  • Abbott
  • Aortic Medical Inc.
  • Avinger
  • Boston Scientific
  • Cardiovascular Systems Inc
  • Cook Medical
  • CR Bard
  • Medtronic
  • Spectranetics Corp
  • Terumo
  • Volcano Corp / Philips
  • WL Gore

RAPID Leadership

Co-Chairs
• Pablo Morales
  • Food and Drug Administration (FDA)
• Robert Thatcher
  • Cardiovascular Systems, Inc. (CSI)
• Jack Cronenwett
  • Society for Vascular Surgery (SVS)

Project Leader
• Rebecca Wilgus
  • Duke Clinical Research Institute (DCRI)

MDEpiNet Key Advisors
• Mitchell Krucoff, DCRI
• Danica Marinac-Dabic, FDA
Why RAPID?

Current Challenge = Heterogeneity of PVD

- Devices
- Patient and disease characteristics
- Provider specialties managing PVD
- Treatment options
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
- Vessel size, disease location
  - Large (iliac),
  - Medium (SFA, popliteal),
  - Small (tibial) arteries
Provider Heterogeneity

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

• Phase I: Identify **minimal set of core data elements**
  • Obtain data elements from existing registries and industry case report forms used for pivotal device approvals
  • Develop structured comparison report of all relevant data elements to allow selection based on clinical expertise
  • Select core data elements, develop technical specifications for each element and a method to integrate Unique Device Identifier (UDI) data for precise device specification
  • Duke Clinical Research Center (DCRI) Informatics Team: Anne Heath, Mary Williams
RAPID Project Plan

- Phase II: Demonstrate data element interoperability from EHR to peripheral vascular registries (patient-level data using core data elements)
  - ACC, SIR and SVS peripheral intervention registries to incorporate the core data elements
  - EHR manufacturers to develop data representations for the data elements of the core data set
  - Core data set to be provided to other national registries, such as the International Consortium of Vascular Registries (ICVR)
RAPID Project Plan

• Phase III: Use a coordinated registries network (CRN) for clinical trials supporting a regulatory decision
  • Projects would extract minimal core data from different registries or other data sources, such as centers using the same EHR
  • Individual projects could need supplementary data
    • Prospective clinical trial, pre-market study
    • Post-market study, surveillance
    • Development of objective performance criteria
• Goal: Total Product Life Cycle evaluation of devices in real world practice
RAPID Progress

Timetable

• Phase I:
  • July 2015: finalized core data element selection
  • Dec 2015: finalized meta-data specification
  • Ongoing: developing terminology as a data standard

• Phase II:
  • 2016-2017: incorporation core data elements into registries, EHR systems

• Phase III:
  • 2017: initiation of device evaluation clinical trial(s)
Deliverables

- RAPID should facilitate standardization and homogeneity
- Global CRF should lower the reviewer regulatory burden and decrease cost to sponsors
- Work will facilitate international device evaluation
- Public availability of GUDID will allow:
  - Model-specific outcomes searches
  - Lower cost for device data entry
  - Auto-population and improved accuracy of device data
Implementing RAPID Core Data Elements: VQI PVI Registry Review

Carrie Bosela, VQI Administrative Director
18 Regional Quality Groups
VQI Registries

- Carotid Artery Stent
- Carotid Endarterectomy
- Endovascular AAA Repair
- Hemodialysis Access
- Infra-Inguinal Bypass
- IVC Filter
- Lower Extremity Amputations
- Open AAA Repair
- **Peripheral Vascular Intervention: 118,000 procedures**
- Supra-Inguinal Bypass
- Thoracic and Complex EVAR
- Varicose Vein
GMDN

• Pull Devices based on “stent” in GMDN Collective Terms description
### Explorer

**Browse device definitions by group.**

#### CT145: Cardiovascular devices
- CT1704: Angioscopes
- CT1705: Arterioscopes
- CT520: Cardiac catheters and associated devices
- CT1864: Cardiac pacemakers and associated devices
- CT1010: Cardiac physiology/mapping devices
- CT1910: Cardiac resuscitators
- CT2510: Cardiovascular guidewires
- CT1678: Cardiovascular monitors/monitoring systems
- CT752: Cardiovascular prostheses and associated devices
  - CT2566: Haemodynamic-modulation vessel repair devices
  - CT300: Heart valve prostheses and associated devices
  - CT2402: Heart ventricle spatial modification implants
- CT485: Vascular stents
  - CT2250: Aortic stents
  - CT2137: Bioabsorbable vascular stents
  - CT1102: Coronary artery stents
  - CT2269: Drug-eluting vascular stents
  - CT2270: Endovascular stent-grafts
  - CT2249: Intracranial vascular stents
- **CT2067: Peripheral artery stents**
  - CT836: Cardiovascular surgical devices
  - CT2486: Circulatory assist devices
  - CT1147: Defibrillators and associated devices
  - CT1113: Peripheral artery grafts
  - CT2567: Venous stents

#### 11 term(s)
- Bare-metal carotid artery stent
- Bare-metal renal artery stent
- Drug-eluting carotid artery stent
- Drug-eluting femoral artery stent
- Drug-eluting infrapopliteal artery stent
- Drug-eluting renal artery stent
- Iliac artery stent, bare-metal
- Iliofemoral artery endovascular stent-graft
- Mesh-sleeve carotid artery stent
- Multiple peripheral artery stent, bare-metal
- Multiple peripheral artery stent, bioabsorbable

#### 1884 product(s)
- 09717648176310 - ABBOTT VASCULAR INC. - Absolute Pro
- 09717648176392 - ABBOTT VASCULAR INC. - Absolute Pro
- 09717648176296 - ABBOTT VASCULAR INC. - Absolute Pro
- 09717648176259 - ABBOTT VASCULAR INC. - Absolute Pro
- 09717648175272 - ABBOTT VASCULAR INC. - Absolute Pro
- 09717648175255 - ABBOTT VASCULAR INC. - Absolute Pro
- 09717648175258 - ABBOTT VASCULAR INC. - Absolute Pro
- 09717648175241 - ABBOTT VASCULAR INC. - Absolute Pro
- 09717648175234 - ABBOTT VASCULAR INC. - Absolute Pro
- 09717648175227 - ABBOTT VASCULAR INC. - Absolute Pro
- 09717648175210 - ABBOTT VASCULAR INC. - Absolute Pro
SNOMED CT

- Agreement with GMDN share terminology
- Same search capabilities
- 30 Member Countries
- Over 14,000 implantable devices
Plain Balloon, Special Balloon, Stent, Stent Graft, Atherectomy, Bailout Stent, Bailout Stent Graft

Manufacturer

By device name

Diameter and length

(free text or pulled from GUDID website)
GUDID Integration in VQI

Three ways to enter stents/stent grafts:
1. Manufacturer
2. Product number
3. Device Identifier (DI)
## Procedure Information

### Access
- Number Access Sites: 2

### Site 1
- **Site**: Femoral Retrograde
- **Side**: Right
- **Access Guidance**: U/S
- **Largest Sheath Size**: 6
- **Closure Device Type**: None
- **Hemostatic Skin Patch**: InsituSeal

### Site 2
- **Site**: Femoral Retrograde
- **Side**: Left
- **Access Guidance**: U/S
- **Largest Sheath Size**: 8
- **Closure Device Type**: Perclose

### Procedure
- **Fluoro Time**: 30 minutes
- **DAP**: 60 Gy.cm²
- **Contrast Volume**: 75 ml
- **CIN Prophylaxis**: Bicarb

### Treatment Details
- **Number of Arteries Treated**: 1

### Artery 1
- **Indication**: Occlusive Disease
- **Artery Treated**: SFA
- **Side**: Left
- **Site of Prior Treatment**: No
- **TASC Grade**: B
- **Total Treated Length**: 2 cm
- **Total Occlusion Length**: 1 cm
- **Calcification**: Mild
## Product Number

<table>
<thead>
<tr>
<th>Device 1</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment Type</strong></td>
</tr>
<tr>
<td><strong>Product Number or Device Identification Number (DI)</strong></td>
</tr>
<tr>
<td><strong>Manufacturer</strong></td>
</tr>
<tr>
<td><strong>Type</strong></td>
</tr>
<tr>
<td><strong>GUDID Diameter</strong></td>
</tr>
<tr>
<td><strong>GUDID Length</strong></td>
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</tbody>
</table>
Device 1

Treatment Type: Stent Graft

Product Number or DI: VBC050502 DI:00733132614394

Manufacturer: W. L. Gore & Associates, Inc.

Type: GORE VIABAHN Endoprosthesis

GUDID Diameter: 5 Millimeter

GUDID Length: 5 Centimeter
Manufacturer

Device 1

- Treatment Type: Stent
- Product Number or DI:
- Manufacturer: Covidien LP
- Type: Select
- GUDID Diameter: Select
- GUDID Length: Select
Device Type

Device 1
- Treatment Type: Stent
- Product Number or DI
- Manufacturer: Covidien LP
- Type: PROTE’GE™ EverFlex™
- GUDID Diameter: Select
- GUDID Length: Select
Diameter

Device 1

Treatment Type: Stent

Product Number or DI:

Manufacturer: Covidien LP

Type: PROTE‘GE’™ EverFlex™

GUDID Diameter: Unavailable

Diameter: 5 mm

GUDID Length: Select
Length

There are multiple devices which match your selection. Please choose the specific device which was used for this treatment by clicking on the radio button.

<table>
<thead>
<tr>
<th>Primary DI: 00821684068526</th>
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<tbody>
<tr>
<td>Description: STENT PRB35-05-030-120 PROTEGE EF V08</td>
</tr>
<tr>
<td>Model or Version: PRB35-05-030-120</td>
</tr>
<tr>
<td>Catalog Number: null</td>
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<tr>
<td>Brand: PROTE GE ™ EverFlex™</td>
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<tr>
<td>Device Sizes:</td>
</tr>
<tr>
<td>&quot;sizeType&quot;:&quot;Catheter Gauge&quot;,&quot;size&quot;:{&quot;unit&quot;:&quot;French&quot;,&quot;value&quot;:&quot;6.0&quot;},&quot;sizeText&quot;:null</td>
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<tr>
<td>&quot;sizeType&quot;:&quot;Length&quot;,&quot;size&quot;:{&quot;unit&quot;:&quot;Millimeter&quot;,&quot;value&quot;:&quot;30.0&quot;},&quot;sizeText&quot;:null</td>
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</tbody>
</table>

<table>
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<th>Primary DI: 00821684068519</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description: STENT PRB35-05-030-080 PROTEGE EF V08</td>
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<tr>
<td>Model or Version: PRB35-05-030-080</td>
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<td>Catalog Number: null</td>
</tr>
<tr>
<td>Brand: PROTE GE ™ EverFlex™</td>
</tr>
<tr>
<td>Device Sizes:</td>
</tr>
<tr>
<td>&quot;sizeType&quot;:&quot;Length&quot;,&quot;size&quot;:{&quot;unit&quot;:&quot;Millimeter&quot;,&quot;value&quot;:&quot;30.0&quot;},&quot;sizeText&quot;:null</td>
</tr>
<tr>
<td>&quot;sizeType&quot;:&quot;Catheter Gauge&quot;,&quot;size&quot;:{&quot;unit&quot;:&quot;French&quot;,&quot;value&quot;:&quot;6.0&quot;},&quot;sizeText&quot;:null</td>
</tr>
</tbody>
</table>
Auto Populates Product # and DI:

Device 1

- Treatment Type: Stent
- Product Number or DI: PRB35-05-030-120 DI: 00821684068526
- Manufacturer: Covidien LP
- Type: PROTE`GE`™ EverFlex™
- GUDID Diameter: Unavailable
- Diameter: 5 mm
- GUDID Length: 30.0 Millimeter
DI (GUDID)
Device 1

- **Treatment Type**: Stent
- **Product Number or DI**: EV06181CD DI:00801741000652
- **Manufacturer**: Bard Peripheral Vascular, Inc.
- **Type**: Valeo® Balloon Expandable Biliary Stent
- **GUDID Diameter**: Unavailable
- **Diameter**: __mm__
- **GUDID Length**: Unavailable
- **Length**: __mm__
GUDID website: Text entry

<table>
<thead>
<tr>
<th>Size Type Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Size Text, specify: Delivery Catheter, Shaft Length, 120 Centimeters</td>
</tr>
<tr>
<td>Device Size Text, specify: Inner Diameter, 6 Millimeter</td>
</tr>
<tr>
<td>Device Size Text, specify: Stent Length, 18 Millimeter</td>
</tr>
</tbody>
</table>
GUDID Clinically Relevant Size (CRS) Workgroup

**Problem Statement**
- Medical devices are produced in multiple sizes
- Device dimensions key for selecting specific devices for specific patients
- Dimension parameters are on packaging and / or IFU
- Dimension parameters are NOT available as systematic data anywhere

**Desired State**
- UDI-specific query of GUDID returns a consistent payload of CRS data
- CRS attributes to be determined by SME (clinicians + manufacturer)
- GUDID CRS data payload will facilitate data interchange
In the **GUDID today**, a set of 4 fields captures the components of device size. The set of size fields can be repeated as many times as necessary per UDI.

- Size Type (dimension – e.g., diameter, length)
- Unit (UCUM)
- Value (numeric measurement)
- SizeText (optional)

Inspection of data in the GUDID shows that size data has been entered inconsistently and incompletely.
CRS Workgroup Report Recommendations

- Update GUDID data structures to more effectively and intuitively capture CRS data
- Update FDA reference materials to provide examples, improve clarity of instructions
- Establish value set authority to manage allowed values in SizeType (dimension) and Unit (units of measure) fields
- Create a series of SME workgroups about high-value classes of implantable devices
- Coordinate with other LUC groups (esp. device classification) to prioritize device classes for GUDID data “clean up”