



Promoting the Inclusion of Device Identifiers and the Global Unique Device Identification Database in MDEpiNet Demonstration Projects

RAPID UPDATE

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Many Peripheral Interventional Devices

- Angioplasty Balloons
 - Plain, drug coated, cutting, cryoplasty
- Stents
 - Bare metal
 - Self-expanding, balloon expandable
 - Covered
 - Drug-eluting
- Atherectomy devices
 - Laser, mechanical
- Total occlusion crossing devices
- Many not approved for peripheral arterial treatment



UDI Use in Registries

- Ultimate Goal:
 - Scan device for UDI number for direct entry into EHR
 - Derive necessary attributes (eg, diameter, length) from look up table populated from AccessGUDID.
- Current reality:
 - Without scanners, UDI number entry prone to errors
 - Need complex drop down menus for practical device entry
 - Huge number of ever changing devices makes maintenance of drop down menus difficult and expensive for registries



RAPID - Access GUDID Project

- Work with FDA and NLM to use APIs or other automated methods to periodically extract specific device data from Access GUDID to populate relevant registries.
- Assess usefulness of current PVI device categorization and suggest improvements as appropriate. Compare to Global Medical Device Nomenclature in GUDID.
- Issues:
 - Stents approved for coronary, biliary, trachea-bronchial applications are used off-label in peripheral vascular Rx
 - Current FDA product codes for vascular devices includes only those with specific indication
 - Developing categorization scheme to include all relevant devices is an early goal



RAPID - Access GUDID Project

- Progress:
 - Working group with society, industry, FDA, NLM representatives is established
 - First in person meeting today at MDEpiNet
- Next Steps:
 - Develop category list to include all RAPID devices
 - Distribute categories to registries, manufacturers
 - Develop automated extraction of devices in these categories and relevant device attributes from Access GUDID (e.g. diameter, length)
 - Use working group to 'road test' GUDID data
 - Encourage all manufacturers to update GUDID data regularly for new devices and alert relevant registries