High Risk Implant Work Group Charter

WORK GROUP TOPIC: Criteria for High Risk Implants

WORK GROUP LEADERS:

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PARTICIPATING MEMBERS:

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Joel	Weissman	PhD	Brigham and Women's Hospital	Deputy Director and Chief Scientific Officer
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CHARTER:

The charge of the High Risk Implants workgroup is to create a set of criteria for inclusion in an application program interface (API) for GUDID queries that returns to the user a high risk implantable device list.

The work group will take into consideration the efforts and potential impact of other LUC work groups focused on the quality of the data within the GUDID.

The High Risk Implant criteria will need to be reviewed on an intermittent basis to be determined by AHRMM and FDA.

BACKGROUND:

The current implantable device list posted at the AccessGUDID website (https://accessgudid.nlm.nih.gov/resources/developers/implant_list_api) is based upon an FDA product code query of the Global Unique Device Identification (GUDID) database. The query currently returns all devices that are cleared or approved with a product code that classifies the device as implantable. Some medical devices (e.g. instruments specific to implant) may be classified with their associated implantable devices (considered as a system) during the clearance/approval process and therefore assume the product classification of that implantable device. As a result, the FDA's current list of "implantable devices" contains devices that may be associated with implants but are not implants themselves. Another limitation of the FDA's list (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UCM382463.pdf) is that it is static and includes all implants. Stakeholders have expressed interest in having a list of "high risk implants".

This work group is charged with developing a set of search criteria to be run against AccessGUDID to return a list of High Risk Implants that correctly identifies high risk implantable devices. These criteria could be used in multiple ways to support documentation of implants in health IT.

The first phase of UDI adoption efforts is aimed at linking the UDI of implantable devices to the patients who have received those devices at the point of implant, and to document one or both portions (DI and PI) of the UDI in health IT systems. These efforts will support collection of RWE (Real World Evidence).

This workgroup will coordinate its efforts with the Device Categorization work group.

STAKEHOLDERS:

AHA, AHRMM, AORN, BUILD, Claims processors and coders, Clinicians, CMS, FDA, Informaticists, Health IT vendors, Health systems, Manufacturers, MDEpiNet participants, NEST participants, ONC-HIT, Patients, Providers, RAPID, Researchers, VA

DELIVERABLES:

Search criteria and suggestions to FDA/NLM on changes needed to the GUDID's public access APIs that would support an automated useful list of high risk implantable medical devices.

COMMUNICATION PLAN

TBD