Learning UDI Community Summary Statement

WORK GROUP TOPIC: Define Criteria to Identify High Risk Implants

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 database. The query currently returns all devices that are cleared or approved with a product code that classifies the device as implantable. Since product codes are based upon device approval and not device use, the list includes implants and associated medical devices (e.g. instruments) that are together classified as an implant for device approval. This work group is being charged with developing a more user-based set of search criteria that would be run against AccessGUDID and return a search result to document implants in health IT – including those working with the automated billing process – and to be shared publicly.

WHY THIS TOPIC IS IMPORTANT:

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 the implant Device Identifier (DI) of the UDI for billing purposes. The UDI adoption community seeks to develop processes and tools that reduce the barriers to making this link by creating a more narrow set of criteria returning a high risk implantable device list that can be used to improve documenting device use. Rather than employing the criteria used to develop the implantable device list currently posted at the AccessGUDID website, the LUC will provide input to create search criteria resulting in a more refined high risk implantable device list that is useful to those who are documenting and exchanging implantable device information.

AFFECTED/REQUIRED STAKEHOLDERS: (who are the critical participants that are affected/need to be included in this proposed work group, e.g., manufacturers, providers, technology companies, clinicians, etc.*)*

Laurie Burkhardt, George Arges (AHA), Behnaz Minaei, Jove Graham, VA and other clinicians and Informaticians, researchers who would use the implantable list.

BRIEFLY DESCRIBE, IF APPLICABLE, ANY WORK THAT HAS BEEN DONE ON THIS ISSUE PREVIOUSLY:

See above. This work was specifically requested by AHA members.

EXPECTED OUTCOMES/DELIVERABLES OF THE WORK GROUP: (guidance, case studies)

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

PROPOSED TIMEFRAME TO DELIVERABLES:

6 months from start of project.

INDIVIDUALS PROPOSING TOPIC:

Mike Schiller, AHRMM