NSW Health – response to TGA's call for consultation - Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia

Q 1. Do you agree with our proposal to establish the UDI System in Australia, taking the IMDRF UDI Guidance (when it is finalised) as the basis for informing Australia's regulatory and legislative requirements?
NSW Health agrees with, and supports the TGA's proposal to establish the UDI system in Australia and the timeframes proposed. National implementation of a single, globally harmonized medical device identification and classification system is anticipated to support standardisation and consistency in a number of areas in the health system related to medical devices. Use of the UDI system, if mandated and regulated, could support practices for lifecycle management of medical assets (e.g. biomedical equipment, diagnostic medical imaging equipment, etc) through: o Supporting standardisation of asset naming convention o being a source of truth for referencing medical device details such as model name, model number, brand name etc. o supporting interoperability and data exchange between disparate systems (e.g. asset management systems, medical device recall systems and medical equipment traceability)
Q 2. The Australian UDI System will apply to all devices placed on the market except custom-made devices and certain other devices. For example, in Australia some products are regulated as devices while the same groups of products are not considered to be medical devices in some other jurisdictions. Also should UDI in Australia apply to Class I medical devices, particularly those other than Class Im (with measuring function) and/or Class Is (supplied sterile)? While it is highly desirable to align internationally, do you have proposals for possible exemptions from UDI requirements?
It is the view of NSW Health that the UDI apply to all maintainable medical assets - biomedical equipment including custom-made biomedical equipment and major medical devices (e.g. Diagnostic Medical Imaging equipment),
Q 3. It is proposed to have the power to accredit one or more Issuing Agencies. What requirements should this accreditation be subject to?
No comment
Q 4. Sponsors will be required to have an agreement with the device manufacturer to legally enter the required information into the AusUDID - what should be taken into account when making the legislative amendments to clarify these responsibilities? For example, where more than one sponsor has pre-market authorisation for the device?
No comment
Q 5. It is proposed that the TGA establish and manage the AusUDID. Are there any concerns with this proposal? Are there alternative organisations that could establish and manage the AusUDID? What are the advantages and disadvantages of these alternatives?
There are no concerns with the proposal for the TGA to establish and manage the AusUDID. Consultation with jurisdictions is suggested to ensure robust governance and processes are in place to support administration and output of the AusUDID.
Q 6. What core data elements and other relevant information should be entered into AusUDID?
For the purpose of medical asset management, NSW Health considers the following as minimal data entry requirements that should be provided by the manufacturer/Australian sponsor, and entered into the AusUDID: • Model Name • Model Number • ARTG Number • Brand name

- Basic UDI-DI
- The manner in which production of the device is controlled e.g. Manufacturing date and Serial Number
- Name and address of the manufacturer
- Global Medical Device Nomenclature code, description and hierarchy
- Sponsor name – as per ABN
- Sponsor trade name
- Name and address of the authorized representative, if possible
- Additional trade names of the device, if possible
- Manufacturer warranty period, if possible
- URLs for additional information such as:
    - Technical service manuals, if possible
    - Operation manuals, if possible
- The Manufacturer's minimum preventative maintenance and performance testing requirements to meet the AS/NZS 3551 standard, if possible
- Status of the device (on the market, no longer placed on the market, recalled, field safety corrective action initiated etc where applicable), if possible

Q 7. How should we link the ARTG and the UDI database? What information should they share?

- Model Name
- Model Number
- ARTG Number
- Brand name
- Basic UDI-DI
- Global Medical Device Nomenclature code, description and hierarchy
- Sponsor name – as per ABN
- Sponsor trade name

The ability to link ARTG information to AusUDID to pre-populate fields will be helpful to reduce impact of data entry on health staff and improve reliability of information

Q 8. Should different transitional arrangements be implemented for different classes and categories of devices? Is the alignment with EU transitional times appropriate?

No comment

Q 9. What impacts (including unintended impacts) do you anticipate for you and other stakeholders?

- If implemented effectively across jurisdictions, mandated use of UDI system has the potential to impact medical equipment asset management practices, including:
    - System-wide or jurisdiction-wide monitoring of corrective maintenance, preventative maintenance and performance verification testing, to identify trends in medical equipment performance (e.g. the performance trends of X equipment by supplier Y on verification testing)
    - Supporting identification and tracking of medical equipment prescribed to patients through interoperability with electronic medical record or digital health solutions (e.g. eMR or My Health Record) to track patients on certain equipment, or devices reused between patients (such as domiciliary equipment loaned between patients by funding agencies).
    - More robust Hazard Alert & Recall tracking

- A national UDI system could mean that local, disparate systems with equipment information (e.g. asset management systems) currently applying different equipment identification and naming convention.

- Jurisdictions may incorporate the UDI to complement, but not necessarily replace existing asset management system information. This will require additional effort locally to cleanse and map existing data sets to incorporate the UDI.

- Where devices are upgraded, or go through a change of Sponsor, the identification details on

the physical labelling/packaging do not change, does this require access to the system (e.g. ARTG, AusUDID) to determine the modification status and the meaning of the UDI? What are the local process implications of this?

Q 10. Are there any other issues and questions we need to consider when implementing this change?

- Opportunities for linkages/interoperability with:
    - Interoperability with Medicare Benefits Scheme item numbers for relevant diagnostic imaging modality Capital Sensitivity measures
    - Environmental Protection Authority (EPA) licencing for medical radiation imaging
    - Interoperability/data sharing of the AusUDID with jurisdictional Asset Management systems to support asset management practices through:
        - Consistency and standardization of nomenclature and terminology between local asset management systems and the AusUDID, suppoing identification and monitoring of medical devices in use by jurisdictions
        - collection and monitoring of information pertaining to the conduct of corrective maintenance, preventative maintenance, performance verification testing and decommissioning/disposal
        - Dynamic or near-life updates to data jurisdictional asset management systems when there is a change in the AusUDID/ARTG e.g. change in TGA sponsor
    - National Product Catalogue
    - Jurisdiction Incident Management systems

Considerations:

- What are the process implications of the proposed models e.g. scenario where devices are upgraded do not have their number changed – to see the modification status we would need to view the system e.g. AFMO to see the meaning of the UDI.

- Where a medical device is brought in from overseas, and has a UDI from an overseas regulator – will these devices require a UDI through an Australian issuing/entity (i.e. be registered in the AusUDID) with the respective e.g. European notified body-issued Conformity Assessment Certificate.