

Proposal to introduce a unique device identification (UDI) system for medical devices in Australia
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Response from the Centre for Big Data Research in Health, University of NSW, Sydney

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?

We support the development and implementation of a single, globally harmonised system in Australia.

Without patient-level data on medical devices, and the capacity to link it to administrative datasets, it is not possible to know the incidence of adverse events or whether the events are specific to one or more device subtypes. A current example of this is *breast implant associated anaplastic large cell lymphoma (BIA-ALCL)*.

For several decades it has been possible to reliably track parcels and car components (e.g. airbags). It is therefore not reasonable that medical devices implanted or surgically inserted in humans cannot be similarly traced. The AusUDID should be considered a priority to enable comprehensive monitoring of devices nationally. Particularly as many sponsors and manufacturers will already be developing or have systems that allow them to comply with the IMDRF UDI Guidance, the US FDA legislation and the EU Regulations.

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?

We do not agree that custom-made medical devices that are implanted or surgically inserted in humans should be exempt from inclusion in the AusUDID. There are likely to be unintended consequences of such exemptions, placing patients at risk of harm.

We do not believe that the UDI in Australia should apply to Class I medical devices (e.g. elastic bandages, tongue depressors, cervical collars, slings and non-sterile dressings). We do not propose any other specific exemptions; UDI in Australia should apply to all Class II and above medical devices.

It is proposed to have the power to accredit one or more Issuing Agencies. What requirements should this accreditation be subject to?

No comment.

Sponsors will be required to have an agreement with the device manufacturer to legally enter the required UDI 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.

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?

The AusUDID could be established and maintained by the TGA who could link it to the Australian Register of Therapeutic Goods (ARTG). The advantage is that the TGA has significant domain expertise and will be responsible for enforcing compliance.

Alternatively, the AusUDID could be managed by multiple organisations. Key principles for the governance and design of the AusUDID include existing IT infrastructure and experience in the management and analysis of large, complex, real-time databases that can be readily integrated with other administrative databases that capture key outcomes, such as readmissions, complications, re-operations, incident cancers and mortality, and thereby enable efficient and effective surveillance. Agencies with such expertise include the ABS and the AIHW.

Key features of an effective surveillance system to maximise the utility of the AusUDID for public benefit will include:

1. Streamlined data governance
2. Timely construction of the linked dataset to allow rapid identification of potential safety issues
3. Use of high-performance cloud computing and related infrastructure to permit interoperable, modular, cost-effective and secure database construction and access
4. A longitudinal linked dataset fit for sophisticated analyses at the level of a medical device (e.g. breast implant) and medical device model (e.g. brand X, textured breast implant)
5. A funded program of analyses to monitor outcomes and identify safety signals using state-of-the art methods for large-scale observational data
6. A funded program of rapid in-depth targeted analyses to explore potential safety issues identified through this monitoring and other sources (e.g. public, industry and clinician-generated reports, international reports), again using state-of-the art methods for observational data, including methods for causal inference.

What core data elements and other relevant information should be entered into AusUDID?

Identifying information about the patient (full name, address, sex, date of birth), the date of use, date of removal (as relevant, e.g. implanted device), an identifier for the responsible

clinician, and an identifier for the health care institution. This would mirror the data elements currently collected for dispensed medicines in Australia.

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

The ARTG and UDI databases should be linked by medical device (model). The shared information should be adequate to enable monitoring, surveillance and research purposes.

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

Yes, the implementation should be transitional, with the highest risk devices implemented first. Alignment with EU transitional times is appropriate.

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

Patient safety must be the primary objective and concern. The AusUDID is long-overdue and negative and positive impacts can be expected across the industry.

As noted above, we do not agree that custom-made medical devices that are implanted or surgically inserted in humans should be exempt from inclusion in the AusUDID. There are likely to be unintended consequences of such exemptions, such as increased use, placing patients at increased risk of harm.

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

No comment.