Unique Device Identification Webinar 15

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Agenda

Guest Speaker Dr Oliver Daly

Benefits and considerations for UDI in Healthcare

UDI Project Update

Questions and Answers

Dr Oliver Daly BSc(Hons) MBBS FRANZCOG CU CHIA

Dr Oliver Daly is a consultant Urogynaecologist/Obstetrician and among his many titles, he is also -

- Clinical lead for Urogynaecology
- Chief Medical Informatics Officer (Digital Applications)
  Western Health
- Clinical data lead, Australasian Pelvic Floor Procedure clinical quality Registry (APFPR)
  School of Public Health and Preventive Medicine at Monash University
- Clinical Informatics Associate
  University of Melbourne's Centre for Digital Transformation of Health.

Over the last 2 years, Oliver has been involved in writing the Australian Commission on Safety and Quality in Health Care (ACSHQC) business case to operationalise the AusUDID in Queensland, and the pilot recall process in Victoria, and co-chair for the Triggers Australian UDI Working Group.

Vital role of the TGA AusUDID as part of implantable device clinical safety and performance surveillance systems

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UROGYNAECOLOGIST AND OBSTETRICIAN, CMIO – WESTERN HEALTH
CLINICAL INFORMATICS ASSOCIATE – UNIVERSITY OF MELBOURNE
APFPR CLINICAL DATA LEAD – MONASH UNIVERSITY

Problem Statement

Until there is an Australian UDI System, no single universal identifier exists for devices implanted into patients

Limits capacity of health information system infrastructure or systematic processes in the Australian health system to –

- Record and document device information at the time of implantation in a patient
- Identify, collate, analyse and report implanted device usage and performance

A problem for patients, clinicians and health system regulators with limited ability to –

- Ascertain which patients have which device at a product and manufacturing detail level
- Provide feedback to clinicians about patient outcomes to inform clinical practice
- Determine incidence of adverse events and device performance effectiveness at a population level, in support of product safety and other evaluation processes

Problematic Device Examples

- Breast implant associated-anaplastic large cell lymphoma (BIA-ALCL) - Device outcomes that are unexpected, or may be difficult to assess in randomised control trials, or only evident at population level

- Metal-on-metal hip implants - changes in the design/composition of medical devices over time that may have an unexpected impact on performance or safety

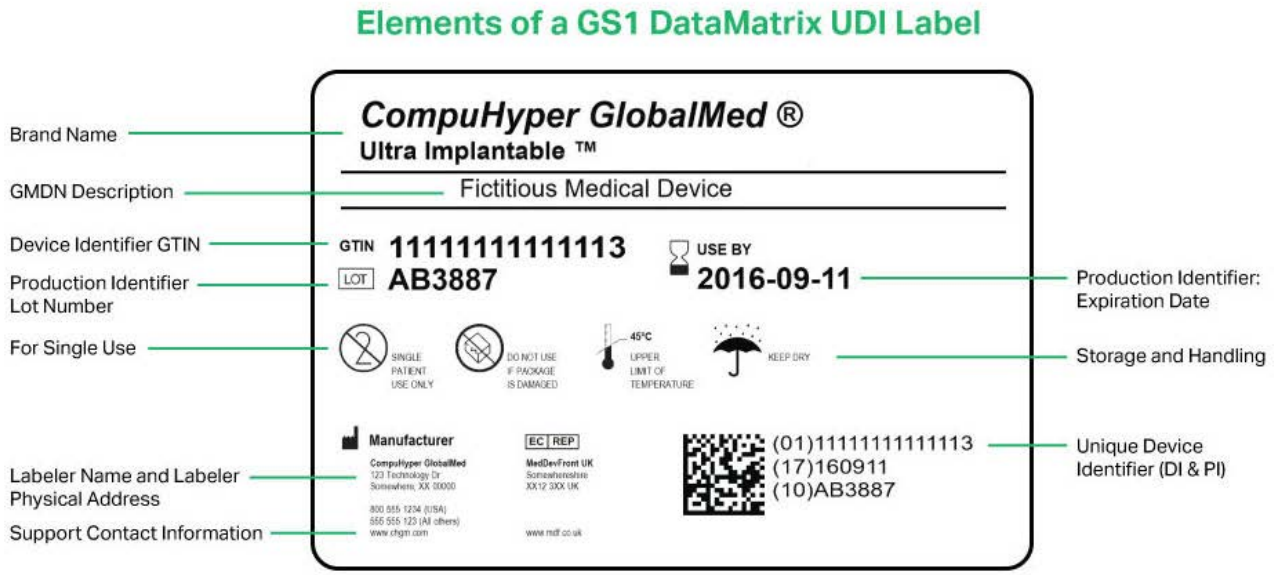
- Transvaginal mesh – delay in recognition of device-related complications and no means to determine the number of patients who have such implants, experiencing or at risk of complications

A UDI System Enables

- Systematic prospective recording of medical device implantation at a patient level including product and manufacturing information, at the time of implantation.
- Ascertainment of clinical denominators at all levels of the health system to monitor device usage, safety and performance.
- Analysis of changes in device safety and performance as they evolve over time.
- Linkage of device implantation with data in other health information systems, eg. procedure, diagnosis, complication and other clinical information, to enable analysis of outcomes at the time of implantation and longitudinally.
- Support for the role of other health authorities when medical device safety issues are investigated, confirmed and acted upon including the notification of patients with such devices, clinicians using devices and manufacturers/distributors providing devices.

How the UDI system enables this

- Standardisation of high-risk implantable device (HRID) product identification recorded by hospital staff
- A single unique identifier to design into Hospital Information Systems (HIS) and data collection processes
- Incorporation into jurisdictional administrative and clinical dataset reporting processes including clinical quality registries
- Incorporation into data-linkage and periodic reporting processes



Challenge One: Hospital Information Systems Incorporation

Considerations:

- Use in existing Operating Theatre Information, Patient administration and Electronic Medical Records (EMR) used by hospitals to record device information. Require accurate, routine and low effort capture at time of implantation
- Replacement of or use in conjunction with other device identifiers currently in use by hospital information systems for clinical, financial and stock control –
    - Other identifiers: Australian Register of Therapeutic Goods (ARTG) ID, Prosthesis list code, National Product Catalogue (NPC) code
- Updates hospital IT systems to include UDI to ensure current identifier is used via machine-to-machine integration or manual upload

Challenge Two: Storage, Extraction and Use

Implementing as part of health system regulatory, quality improvement and research activities.

Considerations:

- UDI recorded in patient record only at hospital level, need to support extraction as required for retrospective analysis
- Incorporation into My Health Record (MHR)
- Centralised storage in a specific register or dataset to support linkage activities
- Centralised storage in an existing datasets, eg. Jurisdictional administrative datasets like Victorian Admitted Episode Dataset (VAED) or National Hospital Morbidity Database (NHMD)

Challenge Three: Reporting and Data Linkage

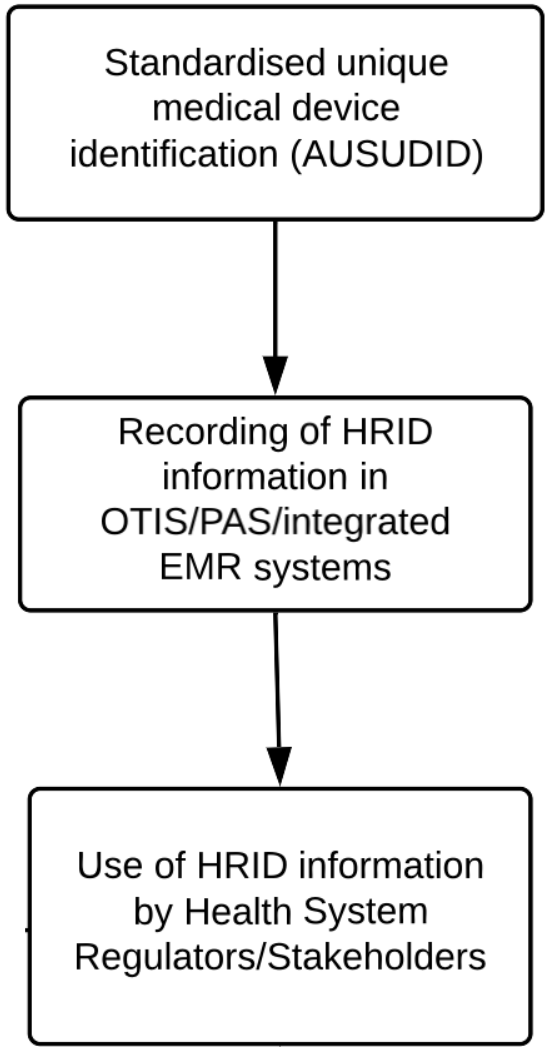
Considerations:

Support for using UDI for monitoring, assessment and reporting of device performance and patient outcome.

- UDI as part of minimum data sets for important adverse events related to each HRID type mapped to ICD-10AM* (diagnosis and complication) and Australian Classification of Health Interventions (ACHI) procedure codes.
- Use in data-linkage methodology and periodic reporting function
- Analysis and reporting requirements at hospital, jurisdictional and clinical quality registry level

*International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification

Figure 1
High-Risk Implantable Devices (HRID): Data Collection Components



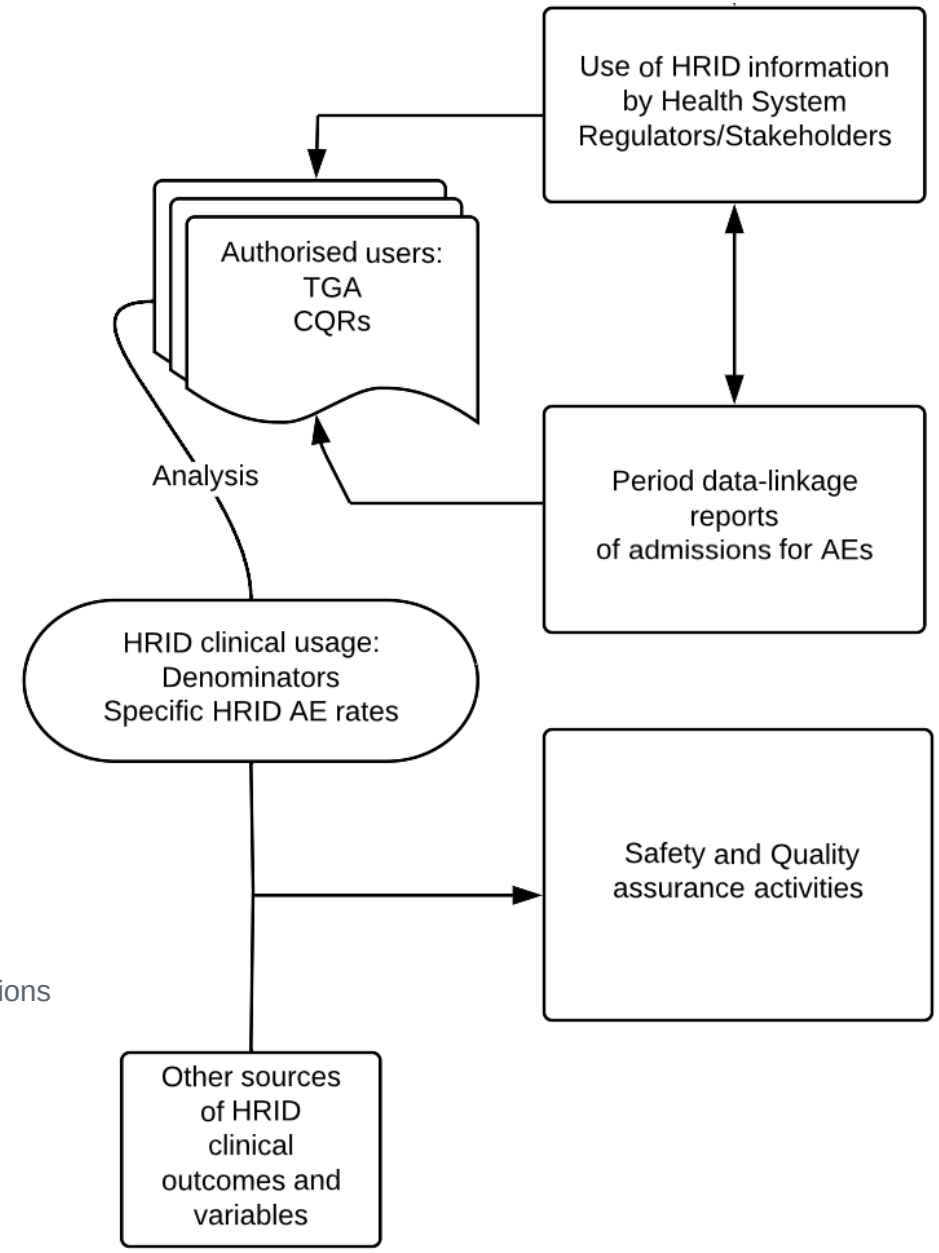
- Regulatory review
- HRID labelling
- Define HRID identifier minimum data
- Establish source of UDI information
- HIS storage of UDI information

- HIS current state assessment
- Device databases
- OTIS / PAS / EMRs
- Regulatory review
- Requirements for HRID usage documentation in HIS
- HIS system amendments +/- new tech
- HIS system HRID documentation compliance

- Review of dataset options for storing UDI
- Inclusion of HRID usage indicator and UDI

EMR – Electronic Medical Records
HIS – Hospital Information Systems
OTIS – Online Training and Information System
PAS – Patient Administration System

Figure 2
HRID RSS: Reporting and data-linkage components



- Review of dataset options for storing UDI
- Inclusion of HRID usage indicator and UDI

- Define HRID-specific AE minimum data set
- Mapping of AEs to ICD and ACHI codes
- Data linkage
- Define analysis and reporting requirements

ACHI - Australian Classification of Health Interventions
AE – Adverse Events
CQR – Clinical Quality Registry
ICD – International Classifications of Disease

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UDI Project Update

Questions and Answers

UDI Project Update

Gary Pascoe
UDI Product Manager TGA

UDI Project Update

- Registrations for Sandpit closed 31 January 2023
- AusUDID has moved into the Dept of Health environment for testing pre-production
- Aiming to release this version of AusUDID in March for testing by sponsors, manufacturers, healthcare providers and consumers
- Continuing to aim for Voluntary Compliance Release date mid 2023
- UDI policy remains in development and yet to be approved by the Australian Government
- Technical Working Groups will recommence 28 February
- Next UDI webinar will be 28 March

The UDI Sandpit Recap

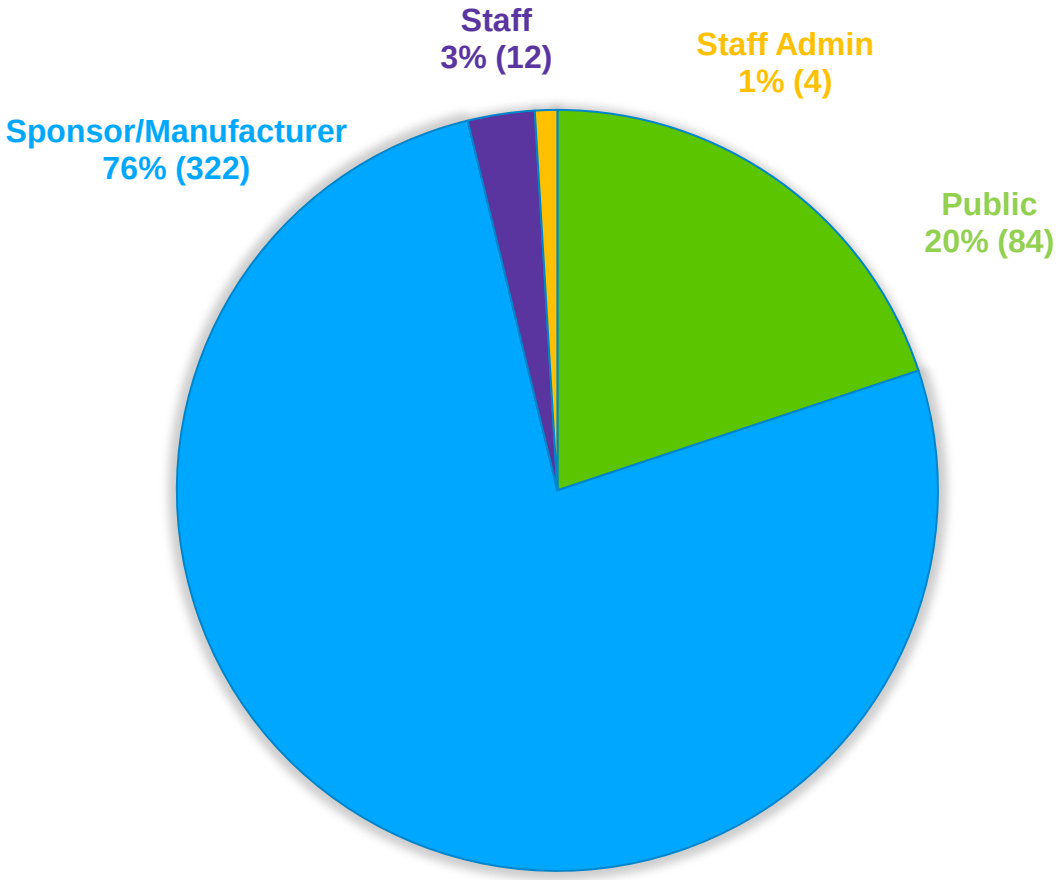
422 users registered

177 organisations

119 UDI records uploaded

Open from **4 July 2022** to **31 January 2023**

50 comments received via feedback tool - focusing on bulk upload, usability, and the AusUDID data dictionary



CATEGORIES OF SANDPIT USERS

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Website and link references

UDI hub	https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/unique-device-identification-udi-system
Third UDI consultation paper	https://www.tga.gov.au/resources/consultation/consultation-detailed-considerations-implementing-proposed-australian-medical-device-udi-regulatory-framework
Second UDI consultation paper	https://www.tga.gov.au/consultation/consultation-exploring-options-introduction-australian-unique-device-identification-udi-system
First UDI consultation paper	https://www.tga.gov.au/consultation/consultation-proposal-introduce-unique-device-identification-udi-system-medical-devices-australia
Previous webinars	https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/unique-device-identification-udi-system/unique-device-identification-system-communications-and-stakeholder-engagement

Contact us

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Questions

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More information

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TGA Linkedin	https://www.linkedin.com/company/therapeutic-goods-administration/
TGA Instagram	https://www.instagram.com/tgagovau/?hl=en

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration