Australian Breast Device Registry - Information Overview

MONASH University
Medicine, Nursing and Health Sciences

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The ABDR is a national clinical quality register for high risk implantable breast devices; implants and tissue expanders. It provides a tracking system for breast devices and a structure for monitoring device performance and patient outcomes following breast surgery.

It is the first of its type internationally as it includes breast surgeons, plastic surgeons and cosmetic surgeons.

The ABDR is funded by the Commonwealth Government (Department of Health) and administered by Monash University, Department of Epidemiology & Preventive Medicine.

Aims

The ABDR aims to enhance the long term monitoring of implanted breast devices and improve patient safety.

Target Population

The ABDR utilises an opt-out approach. All patients having breast device surgery at a participating site are automatically included in the registry, unless they notify the registry coordinator they do not wish to participate (via a free-call phone no. or email address). Once they have opted-out, details of their procedure are removed from the registry database; name and date of birth are retained to ensure the patient is not contacted again in future.

Data Collection

The ABDR collects the following information at time of surgery via a paper data collection tool:

⇒ Patient name, Medicare no., Hospital Unique Reference no., date of birth;
⇒ Patient contact details, including address and telephone no.;
⇒ Treatment data, including device details, name of operating hospital and surgeon, date of operation and type of procedure;
⇒ Outcome data, including revision procedure details, adverse events and death.

To understand the medium to long-term outcomes associated with breast device surgery, patients will be followed-up 1, 2, 5 and 10 years post-procedure. The survey tool to be used for the purpose of follow-up is yet to be determined.

Use of data

The register will monitor safety and performance issues on an ongoing basis and statistical modelling will be used to detect aberrance at an early stage.

Data will be reported to key stakeholders on a regular basis; including hospitals, surgeons, and government regulators. The register will produce an Annual Report.

Under no circumstances will individually identifiable data, in respect of patients, contributing surgeons, or craft groups, be made available to parties other than the ABDR Steering Committee, authorised ABDR personnel, and members of working groups directed by and reporting to the Steering Committee.

Data Storage & Security

Data is stored securely within Monash University servers.

Database Security is maintained using data encryption, a managed and audited protocol for access, training and accreditation of personnel, role-based access and authentication of data. The ABDR database is ISO 27001 certified, incorporating the Privacy Act (1988) and Health Records Act (2001) within its Applicability Statement.

Data Access

Access to information collected and collated by the ABDR is guided by strict protocols and procedures to ensure that privacy and other ethical principles are maintained at all times. Patients may access their surgical information, and surgeons their patients' information, but researchers will have access only to de-identified information.

All publications will be reviewed by the ABDR Steering Committee prior to submission to ensure that no individual or identifying information will be reported in any publication, only aggregate data.

Registry Governance

A Steering Committee made up of representatives of key stakeholder groups oversees all project matters, liaising with the Management Committee, Technical Reference Group and Clinician Working Group.

The ABDR conforms to national operating principles for clinical quality registries (CQRs) as set out by the Australian Commission on Safety and Quality in Health Care (ACSQHC).

Ethics Approval

The ethical aspects of this research project have been approved by the Alfred Hospital Human Research Ethics Committee Project No. HREC/15/Alfred/61.

Australian Society of Plastic Surgeons

BreastSurgANZ

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Or log on to our website at www.abdr.org.au