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Dear Dr Holland

Inquiry into the role of Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Protheses (PIP) breast implants

The National Heart Foundation of Australia (Heart Foundation) welcomes the opportunity to make a submission to the Senate Community Affairs Committee inquiry into the role of Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Protheses (PIP) breast implants.

We recognise the Terms of Reference being considered, however we would like to see stents and pacemakers, as medical devices, included as part of this inquiry. In addition, we would like to encourage the Committee to also consider the urgent need for a cardiac procedures register.

In Australia there is an increased use of such devices as stents and pacemakers due to technical advances, and the increased need due to an aging population and survival from acute myocardial infarction.

A recent study in the Journal of the American Medical Association found that, of the patients with endocarditis (inflammation of the inside lining of the heart chambers and heart valves), 6.4% were in those with an implantable cardiac device and from this there was a higher rate of hospital acquired infections, high rate of valve infection and high mortality rate.¹

Heart Foundation calls for:

1. A National implantable cardiac device registry. This could be the first stage of a National cardiovascular procedures registry. This is a vital part of quality monitoring of the health system.
2. A concerted effort needs to be maintained on the prevention of hospital acquired infections – as per the Quality Commission's guidance.
3. Prior to the insertion of implantable cardiac devices there is a need for attention to the provision of appropriate care;

¹ Athan, E. et al; *Clinical Characteristics and Outcome of Infective Endocarditis Involving Implantable Cardiac Devices*, Journal of the American Medical Association, April 25, 2012, Vol 307, No. 16

- Attention to the predisposing patient based risk factors – diabetes, age, nutrition status, drug usage (in particular steroids and other immuno-modulators), skin infections.
- Attention to the patient's clinical status and clinical need – a risk-benefit appraisal with fully informed consent. NB: infective endocarditis is a serious condition.
- The occurrence or need for other invasive procedures – for example this age group has an increased likelihood for joint replacements.

National Cardiac Procedures Register

Australia needs a National Cardiac Procedures Register to help save lives and improve outcomes for patients with heart disease.

While the quality of care received by patients with cardiovascular disease in Australia is generally good, it could be even better if there was a systematic way of measuring outcomes and feeding this information back to doctors.

With more than 300,000 cardiovascular procedures performed in public hospitals and 250,000 in private hospitals each year, the need for a register is clear.

The register would work in a similar way to the national joints register by gathering data on outcomes of various cardiac procedures including angioplasty with stent implantation and coronary artery bypass grafts.

The information on outcomes for each procedure, including mortality rates, infection rates and other complications, can then be compiled and analysed.

This information can then be provided to cardiologists and cardiothoracic surgeons, who can then make decisions about what procedure or what device is best suited to the specific circumstances of each patient based on the very best evidence available.

The result is better informed doctors, better clinical decisions and - most importantly - better outcomes for patients.

Better informed evidence-based treatment will lead to fewer complications and hospital readmissions, improving outcomes for patients while helping to keep a lid on health costs for governments.

A National Cardiac Procedures Register would: ²

1. Improve data collection. An integrated national database would overcome the currently fragmented approach and ensure use of a common set of indicators while accommodating more specific local data collection and analysis.
2. Support appropriate application of practice guidelines, resulting in improved patient management.
3. Provide better information to assist patients in decisions related to their treatment.
4. Enable clinicians and service planners to compare clinical outcomes with national and international standards to improve procedures and practices and assess emerging therapies.

² Tonkin, A, *Why Australia Needs a Cardiac Procedures Database*, Heart, Lung and Circulation 2001; 10 (suppl.)

5. Support efficiencies within the healthcare system, with better planning of services and infrastructure, and sounder economic management.

The final report of the National Health and Hospitals Reform Commission in 2009 made two recommendations supporting a National Cardiac Procedures Register: ³

- a) To support quality improvement, data on safety and quality should be collated, compared and provided back to hospitals, clinical units and clinicians in a timely fashion; and
- b) Support the health workforce by providing timely relevant data on comparative clinical performance and latest practice knowledge to support best practice and continuous quality improvement.

Please find attached supporting information including an article published in the Medical Journal of Australia (MJA) in 2001, by Andrew M. Tonkin, *Why Australia Needs a Cardiac Procedures Database* and the recent Journal of the American Medical Association (JAMA) article, *Clinical Characteristics and Outcome of Infective Endocarditis Involving Implantable Cardiac Devices*.

We wish you well with your deliberations and would be keen to assist with any inquiries you may have.

Yours sincerely

Dr Lyn Roberts AM
Chief Executive Officer – National

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³ National Health and Hospitals Reform Commission, *A healthier future for all Australians - Final Report*, June 2009