MONASH University

Centre of Research Excellence in Patient Safety

School of Public Health and Preventive Medicine
Faculty of Medicine, Nursing and Health Sciences

Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

Monday, 23 April 2012

Dear Sir/Madam

Re: 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 Prostheses (PIP) breast implants

We suggest that there is an urgent need to establish a national clinical registry to monitor the performance of breast implants, regarded by the TGA as high risk implantable devices. The current method of voluntary reporting of device failure/rupture or contracture is inadequate because only a small number of clinicians take the trouble to report problems (and typically report only those the problems they are already recognised as a problem). In the case of the PIP device failure, voluntary reporting was found again found inadequate as it has been with most other device safety issues.. The reporting system could not provide accurate numerator or denominator data and was therefore of no value in scoping the extent of the problem.

A more effective means of monitoring the safety of high risk implantable devices is to use clinical registries. Clinical registries systematically collect health-related data on individuals. Their purpose is to monitor safety and quality of care and to provide early warning if safety problems are emerging. This is much preferable to being in the dark about a problem until it has become a scandal. .

Clinical registries collect a small but carefully chosen amount of key clinical data to enable risk adjusted outcomes to be monitored. They have high credibility amongst clinicians because they collect high quality data; pay close attention to gaining complete case ascertainment; and, in the assessment of outcomes analysis, they take into account factors which might explain variation but which are outside the control of the clinician.

The PIP breast implant issue has highlighted the need for government and industry investment in a registry to monitor outcomes. While a breast implant registry did exist in Australia prior to the PIP implant problem, it was funded by patients and had modest recruitment numbers at best. Only 4% of PIP implants used in Australia were captured by the registry.

In August 2011, Monash University successfully bid to develop a new, improved Breast Device Registry (BDR). The Australian Foundation of Plastic Surgeons provided seed funding to determine the minimum dataset, pilot test the methodology and establish outcome measures. The BDR is a population-based, opt out registry developed in collaboration with surgeons, epidemiologists and industry. The newly developed BDR must have a strong, functional and constructive relationship with the TGA. It should routinely report rate of revisions and major adverse events to the TGA.

The approach to registries adopted in Australia is more sustainable and effective than that adopted overseas. For example the failed US registry collected 26 pages of data rather than the carefully chosen key variables planned for the Australian registry. Extensive data collection of this type is unnecessary and will predictably compromise the sustainability of a registry.

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Monash University has a strong reputation in developing and maintaining clinical registries which has been built up over the previous decade. The School of Public Health and Preventive Medicine within Monash houses more than 16 clinical registries. It has a world class data management centre which is accredited to the highest standard in collecting patient level identifiable data. Monash has developed strong clinical ties and has a good reputation among the medical fraternity. Rather than attempting to replicate this infrastructure, the TGA would be best placed to help sponsor the BDR and provide expert advice and representation on the BDR Steering Committee.

Our recommendation to foster clinical registries to monitor device safety has been made more urgent by a series of major device failures affecting hip joint replacements, cochlear implants and cardiac pacemakers as wll as breast implants. The Australian Commission on Safety and Quality in Health Care has advocated for clinical registries to be developed in high risk areas of medicine. In November 2010, Australian Health Ministers endorsed national operating principles for clinical registries to advance this objective. In the US, the American Heart Association has strongly advocated for clinical registries to monitor device safety. In Sweden, registries monitor approximately 25% of all health expenditure.

In summary, we submit to the Senate Community Affairs Committee Inquiry that a national clinical registry should be rolled out to monitor breast device safety. The TGA should support the newly established BDR and assist it to achieve its goal for national coverage. The TGA should provide expert input on the BDR Steering Committee and provide a conduit to industry.

We would welcome an opportunity to discuss this further.

Kind regards

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Monash University

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