Problems with TGA transparency, says Australian study

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The Therapeutic Goods Administration's record on medical device regulation lacks transparency according to research led by the University of Sydney.

"The Therapeutic Goods Administration (TGA) has published no data on incidents involving medical devices on its website for over two years and it is unclear why — particularly as the number of serious injuries related to medical device incidents appeared to increase toward the end of 2009," said Dr Richard McGee, a PhD candidate from the Sydney School of Public Health at the University.

Dr. McGee is lead author of a retrospective analysis of the TGA, Australia's medical device regulator, published in the Medical Journal of Australia on 5 March.

The study investigated the frequency, characteristics and outcomes of reports of possible harms related to medical devices using publicly available data.

"There were several times during the January 2000 to December 2011 period covered by the study where data on medical device incidents was unavailable. This lack of transparency has the potential to undermine confidence in the TGA."

In addition to these gaps in reporting was the fact that while medical device incidents were increasing device recalls were not.

"In total, 295 deaths related to device incidents were reported, but there were only 12 'high risk' medical device recalls," Dr. McGee said.

Medical devices are common and range from low-risk devices such as toothbrushes and dressings to high-risk devices such as pacemakers and defibrillators.

"Surprisingly there is a disconnect between the number of complaints to the TGA - which has been rising - and the number of recalls, which has remained static."

Most device incidents (47.5 percent) were not investigated or, after initial investigation, no further action was taken (25 percent).

Another issue the research highlights is the lack of transparency about what class of devices are recalled by the TGA.

"Current product recalls describe the level of risk of an incident but not the risk classification of the device responsible," Dr. McGee said.

"So for example, a heat pack, which would be classified as a low-risk device, may have a fault that causes severe burns which would result in a high-risk recall. Currently the TGA would indicate that the recall was high-risk but not that the device was low risk.

"This means the public is not given details about how the device was originally approved. High risk recalls caused by devices which came through low risk pathways may not have been properly assessed and go on to cause significant problems."

Best practice as followed by the Food and Drug Administration, the TGA's equivalent in America provides a much greater level of detail about the device recall. In essence, there is much greater transparency,

something which is currently lacking in the Australian system.

"The data available to the public is incomplete, inconsistent and insufficient to assess the safety of medical devices and unless the transparency of the TGA is improved, public confidence in the system may be jeopardized."

Provided by University of Sydney