



The Editor
The Age / SMH

By email

28th February 2022

Dear Editor,

## RE: To hell and back: Devices meant to ease pain are causing trauma, Liam Mannix, February 5, 2022, The Age and SMH

From a medical perspective, the recent article "To hell and back" is concerning in terms of the inaccuracies and the lack of disclosure by the journalist [1]. We believe this is not a balanced piece of journalism, which the public has come to expect from a reputable newspaper such as yours (The Age and SMH).

When Mr. Mannix interviewed the authors of a recent scientific study, he did not disclose to your readership that he was, also one of those authors [2]. This information was withheld and there is no capacity for your readers to determine what degree of conflict or bias this constitutes when the journalist is both scientific author and independent opinion writer. We note that this is the only publication by Mr Liam Mannix on pubmed.gov and as such he would be required to disclose potential conflicts of interests. This begs the question whether there are any other potential conflicts of interest that need to be disclosed for the current or past newspaper articles related to pain.

Separately the newspaper article has errors, incorrect suppositions and is, we believe, alarmist in nature. It states there were 5 deaths associated with the device (spinal cord stimulator) yet did not state that three of these were unrelated to the device i.e., one patient died of cancer, one died of a pulmonary embolus caused by a deep vein thrombosis (DVT) and one where the "death was not related to the device". We also note that the study explicitly states, "Because of the limitations of the data, we cannot comment on whether the deaths were directly attributable to the device or implantation procedure." [2].

When an implantable device battery has come to end of charge life it is removed (explanted) and a new one implanted (to continue therapy) yet the study Mr. Mannix referenced counted this as device removed (when it was not i.e., the device was replaced). The conclusions inferred, cannot be relied upon when the underlying methodology is not sound. There are many other inaccuracies of this study that will be addressed directly with the Journal Editorial board directly, as per usual medical practice.

The study shows 520 adverse events out of 26,786 devices implanted, which equates to an adverse rate of 1.94%. In medical fields this is considered low adverse event incidence, in terms of other surgical complications. To put this into perspective, surgeries such as spine surgery, hip & knee surgery have much higher rates of adverse events.

We are presuming that your readers would expect these adverse events to be described in relative terms. To put this into relative terms, a brief literature search on Pubmed revealed a recent publication on cardiac pacemaker complications from a French National Hospital Database [3]. This study looked at 65,553 patients and found that overall, 618 patients (5.3%) had a record of pacemaker





complications during follow-up, of which 89% were related to the lead and pocket [3]. The authors concluded that major complications associated with the lead and pocket of conventional pacemaker systems are still common.

Rather than tabloid alarmist articles it would have been preferable to seek a balanced input from the accredited medical bodies who practice in this area of medicine, namely the Faculty of Pain Medicine (FPM) and the Royal Australian College of Surgeons (RACS).

Australia has what is considered a world-class health system. Part of the reason that we have a world-class health service is rigorous and exceptional oversight of practice Australia from both the Therapeutic Goods Administration (TGA), Commonwealth and State Health Departments as we as our medical governing body Australian Health Practitioner Regulation Agency (AHPRA).

Australians can and should trust in our world class system and its regulatory bodies.

As part of our commitment to the field of medicine, NSANZ, has been calling for the establishment of a national registry of implant devices, like The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) and we remain committed to the development of such a registry, with a full data capture which can be used in conjunction with the TGA data.

NSANZ would like to extend a personal invitation to the SMH/The Age medical correspondents to attend our 15th Annual Scientific Meeting (NSANZ 2022), which will be held in Melbourne in August 2022, where we highlight both local and international experts in this field of medicine in a forum where we rigorously appraise, debate, and discuss scientific evidence in this field of medicine [4].

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Rachel Whipp Pain Management Nurse Committee Chair

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Megan Hannah Clinical Nurse Consultant Committee Chair

On behalf of the NSANZ membership

## References

- 1. To hell and back: Devices meant to ease pain are causing trauma, Liam Mannix, February 5, 2022, The Age and SMH
- 2. <u>Jones CMP, Shaheed CA, Ferreira G, Mannix L, Harris IA, Buchbinder R, Maher CG. Spinal Cord Stimulators: An Analysis of the Adverse Events Reported to the Australian Therapeutic Goods Administration. J Patient Saf. 2022 Jan 21.</u>
- 3. Clémenty N, Fernandes J, Carion PL, de Léotoing L, Lamarsalle L, Wilquin-Bequet F, Wolff C, Verhees KJP, Nicolle E, Deharo JC. Pacemaker complications and costs: a nationwide economic study. J Med Econ. 2019 Nov;22(11):1171-1178.
- 4. <a href="https://www.dcconferences.com.au/nsanz2022/">https://www.dcconferences.com.au/nsanz2022/</a>

## Copies to

- A/Professor Michael Vagg, Dean Faculty of Pain Medicine (FPM)
- A/Professor Dean White, Dean Royal Australasian College of Surgeons (RACS)
- Rachel David CEO Private Healthcare Australia
- Paul Dale Director, Policy Medical Technology Association of Australia (MTAA)