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Response to the Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia

Bupa Health Insurance Pty Ltd (Bupa) welcomes the TGA discussion paper on potential changes to mandatory reporting of medical device adverse events as part of the government's reform program to improve the safety, performance, and quality of medical devices in Australia and improve health outcomes for patients.

Bupa supports the introduction of mandatory reporting requirements for healthcare facilities in order to strengthen the ability of the TGA to monitor the safety and performance of medical devices, more rapidly identify threats to patient safety and take meaningful action to protect consumers from harm.

The rationale for our support of mandatory reporting of medical device related adverse events for healthcare facilities or providers are provided through our response topics below:

1. Safety and efficacy are not well established prior to or during pre-market assessment and approval processes
2. The potential for substantial and sustained harm to patients is high
3. To balance risks with benefits and minimise harm, active safety and performance monitoring is essential and requires shared responsibility.

Bupa Response

1. Safety and efficacy are not well established prior to or during pre-market assessment and approval processes

As identified in the Review of Medicines and Medical Devices Regulation's final report on the *Regulatory Framework for Medicines and Medical Devices*, most medical devices are approved based on their design and the manufacturer's compliance with quality standards, rather than the detailed clinical trial results that are required for medicines.[1]

This is because implanted devices cannot usually be ethically trialled in animals or healthy volunteer subjects and because new devices (or new uses for existing devices) can be approved by demonstrating substantial equivalence to a device or devices already on the market (predicate devices). Where clinical studies are carried out, they may also be too small and too short to detect problems for premarket approval purposes.[2]

[1] March (2015) available at https://www1.health.gov.au/internet/main/publishing.nsf/content/expert-review-of-medicines-and-medical-devices-regulation#report1

[2] UK Medicines and Healthcare Products Regulatory Agency (MHRA) quoted in Cohen, D. 'Out of Joint' *BMJ* 2011;342:d2905

For example, transvaginal mesh devices were not initially classified as high-risk because they had previously been used to treat hernias[3] and the first randomised control trial (RCT) data on their use for the treatment of pelvic organ prolapse were not published until five to seven years after the devices were in widespread use. Similarly, the articular surface replacement (ASR) hip prostheses were classed as medium-high risk and didn't need to be tested in patients before entering the market, only laboratory testing on simulators to evaluate how the device wears over time, the materials used and device strength.[4] However, research suggests that simulators do not really represent the biological environment[5] and experts such as Professor Stephen Graves, an orthopaedic surgeon and Director of the Australian National Joint Replacement Registry suggest simulator testing should not be relied on to establish how a device will function when used in a person.[6]

International research has also revealed significant concerns in the US and Europe about the number of devices approved without scientific data, particularly clinical data, to support their claims of substantial equivalence.[7] One US study using a sample of 50 medical devices cleared through FDA processes between 2008 and 2012 found that scientific data to support the claim of substantial equivalence was available for only 8 of the 50 newly cleared implants (16%) and only 31 of their 1105 listed predicates (3%). Most of the evidence was nonclinical data.[8] An investigation by the International Consortium of Investigative Journalists (ICIJ) that combined safety data, including more than 5 million "adverse event" reports, to create a global picture of medical devices revealed regulators in the EU have no clinical data on 90 per cent of highest risk devices because they were assessed as sufficiently similar to existing products.[9]

This combined with the increasing diversity and complexity of medical devices, the learning curve associated with adopting these new technologies, and the short lifecycle of medical devices make it even more essential to closely monitor the performance of medical devices in the real world. An effective regulatory system must be able to identify emerging safety and performance issues and take remedial actions as early as possible. [10]

2. The potential for substantial and sustained harm is high

Medical devices and implants can save lives and provide many quality-of-life benefits when they function as intended. However, when they malfunction, are poorly designed or poorly implanted, used off label or in unintended ways, they may cause substantial harm to individual patients, and their families.

In 2018, a major international investigation found 170 Australians have died and more than 8,500 Australians had been injured in the previous decade due to potentially dangerous medical devices.[11]

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[3] Mesh Working Group, Interim Report (December 2015) *NHS England* available at https://www.england.nhs.uk/wp-content/uploads/2015/12/mesh-wg-interim-rep.pdf

[4] Cohen, D. 'Out of Joint' *BMJ* 2011;342:d2905

[5] Kamali A, Hussain A, Li C, Pamu J, Daniel J, Ziaee H, et al. Tribiological performance of various CoCr microstructures in metal-on-metal bearings: the development of a more physiological protocol in vitro. *J Bone Joint Surg Br* 2010;92:717-25.

[6] Cohen, D. 'Out of Joint' *BMJ* 2011;342:d2905

[7] Zuckerman D., et. al. (2014, Nov 1), 'Lack of publicly available scientific evidence on the safety and effectiveness of implanted medical devices' in *JAMA Internal Medicine,* 174(11):1781-7 Published online September 29, 2014. Abstract available at: http://archinte.jamanetwork.com/article.aspx?articleid=1910556

[8] Zuckerman D., et. al. (2014, Nov 1), 'Lack of publicly available scientific evidence on the safety and effectiveness of implanted medical devices' in *JAMA Internal Medicine,* 174(11):1781-7 Published online September 29, 2014. Abstract available at: http://archinte.jamanetwork.com/article.aspx?articleid=1910556

[9] Christodouloum M; Branley, A; Scott, S; Ting, I; Mann, A. 'The Implant Files: Deadly devices' *ABC Online* Published 26 November 2018. Available at: https://www.abc.net.au/news/2018-11-26/implant-files-shine-light-on-medical-device-industry/10521480?nw=0&r=HtmlFragment

[10] Center for Devices and Radiological Health, (2013, April) *Strengthening our national system for medical device postmarket surveillance. Update and next steps,* US Food and Drug Administration, Silver Spring, p. 3. Available at: http://www.fda.gov/downloads/MedicalDevices/Safety/CDRHPostmarketSurveillance/UCM348845.pdf

[11] Christodouloum M; Branley, A; Scott, S; Ting, I; Mann, A. 'The Implant Files: Deadly devices' *ABC Online* Published 26 November 2018. Available at: https://www.abc.net.au/news/2018-11-26/implant-files-shine-light-on-medical-device-industry/10521480?nw=0&r=HtmlFragment

Examples including breast implant associated anaplastic large cell lymphoma (BIA-ALCL), transvaginal mesh, hip replacement implants, pacemakers, heart valves and implantable drug delivery pumps demonstrate the huge amount of pain and suffering that results from device failures and safety issues.[12]

The impact of unsafe medical devices also goes further than the pain, suffering and adverse quality of life experienced by individuals. The often-ongoing remedial care required is borne by the health system, public and private, contributing to rising costs. As noted by Jeffrey Shuren, Director of the US Food and Drug Administration Centre for Devices during congressional hearings in 2011, "Patients can get a device that's ineffective when they had alternative effective treatments. As a result, they put their health at risk, and the health care system winds up paying for it".[13]

In Australia, key drivers of rising healthcare costs and the subsequent increases in health insurance premiums and public health expenditure include new technology, rising chronic health conditions, utilisation or volume growth and increasing underlying complexity of services delivered.[14] Medical devices and the adverse events and outcomes related to them contribute significantly to each of these drivers.

For example, rates of joint replacement surgery have been rapidly increasing for many years and are anticipated to continue doing so.[15] More than 85,000 hip and knee replacements are undertaken each year in Australia. While joint replacements produce considerable success in alleviating pain and disability, the outcomes of such procedures are highly variable.

A comprehensive study published in 2020[16] examined Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) data from September 1999 to December 2017 to compare the survivorship of prostheses free from revision over nearly 20 years in procedures where a new design model was introduced to replace a prior knee system from the same manufacturer. The study found that of the 11 total knee arthroplasty (TKA) implants in the Australian registry that underwent design modifications during the period, five delivered implant survivorship that was either no different from or inferior to the design they replaced.[17] It also found that revisions for instability have not decreased in any new system, despite changing concepts of femoral curvature, introduction of technology to improve the precision of component placement such as computer navigation or image-derived instrumentation, the addition of single millimetre increment increases in polyethylene insert thickness, and more choices of polyethylene shape.[18]

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[12] Australian Commission on Safety and Quality in Healthcare submission to House of Representatives Standing Committee on Health, Aged Care and Sport Inquiry into approval processes for new drugs and novel medical technologies in Australia available at: Sub207 - Australian Commission on Safety and Quality in Health Care.pdf; Scott, S and Sadler, R 'Rules designed to protect patients from faulty medical devices delayed until next year' ABC Online published 21 June 2020. Available at: https://www.abc.net.au/news/2020-06-21/tga-rules-to-provide-more-oversight-medical-devices-delayed/12373290

[13] Christodouloum M; Branley, A; Scott, S; Ting, I; Mann, A. 'The Implant Files: Deadly devices' *ABC Online* Published 26 November 2018. Available at: https://www.abc.net.au/news/2018-11-26/implant-files-shine-light-on-medical-device-industry/10521480?nw=0&r=HtmlFragment

[14] Medicare Benefits Schedule Review Taskforce. 2020 *Final Report: An MBS for the 21st Century: Recommendations, Learnings and Ideas for the Future.* Commonwealth of Australia Department of Health.

[15] Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) website accessed December 2021: https://aoanjrr.sahmri.com/background

[16] Lewis PL, Graves SE, de Steiger RN, et al. Does Knee Prosthesis Survivorship Improve When Implant Designs Change? Findings from the Australian Orthopaedic Association National Joint Replacement Registry. *Clin Orthop Relat Res*. 2020;478(6):1156-1172. doi:10.1097/CORR.0000000000001229 Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7319368/

[17] As above

[18] Leopopld, S Take 5 Interview with Peter L. Lewis MBBS, FRACS(Orth), FAOrthA first author of "Does Knee Prosthesis Survivorship Improve When Implant Designs Change? Findings from the Australian Orthopaedic Association National Joint Replacement Registry" Clin Orthop Relat Res. 2020 Jun; 478(6): 1152–1155. Published online 2020 Apr 8. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7319384/

An international comparison of total hip arthroplasty (THA) patients, implants, techniques, and survivorship in Sweden, Australia, and the United States also demonstrated that Australia has the lowest five- and 10-year implant survival rates of the three countries.[19] The expert study authors identified the higher degree of variation in implant selection in Australia as the most likely reason for this difference. Sweden and the US used a limited number of implants while in Australia over 2,000 cup and stem combinations were used including 78 different THA acetabular cups and stem model combinations with 10-year follow-up and cumulative percentage revision rates ranging from 2% to 46%. Only 35% of these combinations had a 10-year cumulative percentage revision rate of less than 5% (AOANJRR 2017). In comparison, 6 stems and 15 cups accounted for over 90% of the implant usage in Sweden with lower revision rates than both Australia the US.[20]

Joint replacement revisions are not straightforward. As well as exposure to the risks of general anaesthetic, revisions also have a higher rate of failure,[21] and are associated with significant patient morbidity and high costs.[22] One study using cumulative percent revision from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) to calculate and compare the net present value (NPV) of revision total knee procedures by prosthesis found statistically significant differences in cumulative percent revision of a well performing implant system and that of other implant systems at 6 years. The NPV (inflation adjusted) of revision TKA cost for a 6-year time horizon was as high as 5,302,709 AUD (with 0% well performing implant system usage) and as low as 3,304,866 AUD (with 100% well performing implant system usage).[23]

When a patient experiences an adverse event or outcome from a medical device, the remedy will almost always involve further hospital care. Many also result in chronic conditions with complex ongoing care needs. This may include multiple remedial surgeries as well as rehabilitation, chronic pain management, mental health treatment and other health services.

Reviews of transvaginal mesh surgery found that women who underwent the operation had high rates of needing repeat surgery due to mesh exposure, bladder injury and urinary incontinence.[24] Complications could be severe and catastrophic and were not limited to pain, impaired mobility, incontinence/frequent urination as well as related relationship/marriage difficulties, sexual difficulty, loneliness/social withdrawal, recurring infection, lethargy and depression. Physical symptoms were closely linked with psychological symptoms and could be lifelong and irreversible in some cases.[25]

Post-operative depression is a common outcome when surgery involves an adverse event that has health consequences or the need for further medical intervention. There can be a variety of factors contributing to this including pain and discomfort, a lack of mobility, and increased dependency on others. For patients who have had an organ or body part removed, a feeling of loss can also play a role.[26]

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[19] Elizabeth W Paxton, Guy Cafri, Szilard Nemes, Michelle Lorimer, Johan Kärrholm, Henrik Malchau, Stephen E Graves, Robert S Namba & Ola Rolfson (2019) An international comparison of THA patients, implants, techniques, and survivorship in Sweden, Australia, and the United States, *Acta Orthopaedica*, 90:2, 148-152, DOI: 10.1080/17453674.2019.1574395. Available at: https://www.tandfonline.com/doi/full/10.1080/17453674.2019.1574395?src=recsys

[20] As above

[21] Grammatopolous G, Pandit H, Kwon YM, Gundle R, McLardy-Smith P, Beard DJ, et al. Hip resurfacings revised for inflammatory pseudotumour have a poor outcome. *J Bone Joint Surg Br* 2009;91:1019-24.

[22] A. Naidu-Helm, S. Dunlop, R. Ditto; 'PMD14 Economic Analysis to Evaluate IMPACT of Prostheses Choice in Primary Total Knee Arthroplasty' (2020) *Value in Health Regional Issues*, Vol 22, S61, September 2020. DOI:https://doi.org/10.1016/j.vhri.2020.07.320. Available at: https://www.valuehealthregionalissues.com/article/S2212-1099(20)30369-1/fulltext#relatedArticles

[23] As above

[24] C Maher et al, "Transvaginal Mesh or Grafts Compared with Native Tissue Repair for Vaginal Prolapse" (2016) 2 *Cochrane Database of Systematic Reviews* 10.

[25] Scottish Independent Review, *The Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women, Interim Report* (2 October 2015) 14. Available at www.gov.scot/resource/0048/00486661.pdf also Prof Picone, Committee Hansard, 3 August 2017, p. 39.

[26] Pinto A, Faiz O, Davis R, et al. Surgical complications and their impact on patients' psychosocial well-being: a systematic review and meta-analysis. *BMJ Open* 2016;6:e007224. doi: 10.1136/bmjopen-2014-007224 Available at: https://bmjopen.bmj.com/content/6/2/e007224.info

A 2016 systematic review and meta-analysis of 50 studies found that patients who suffered surgical complications had significantly worse postoperative psychosocial outcomes even after controlling for preoperative psychosocial outcomes, clinical and demographic factors. Half of the studies with significant findings reported significant adverse effects of complications on patient psychosocial outcomes at 12 months (or more) post-surgery.[27]

Bupa examples of device adverse events

Bupa's expenditure for all claims classified as adverse events or repair from 2018 to 30 June 2021 is increasing. The tables below highlight the number of episodes Bupa covered.

Total episodes and costs for device related adverse events by specialty

Device adverse events by specialty	2018	2019	2020	2021*
Cardiac and vascular episodes	2,776	2,737	2,808	1,406
Orthopedic episodes	5,847	6,124	5,613	3,147
Other episodes	5,484	5,077	4,980	2,585
Total episodes	**14,107**	**13,938**	**13,401**	**7,135**

*Data for 2021 reflects the first half of the year (to 30 June 2021) only due to normal lags in receiving and processing claims.

Bupa data on complications specific to cardiac devices are further outlined in the tables below. We experienced 275 admissions in 2020 due to mechanical complications from cardiac devices, with a total of over $4 million in benefits paid (including hospital/medical and additional prosthesis). Growth is around 5% per annum since 2018.

Adverse outcomes from Cardiac devices (Pacemakers and DeFibrillators)

Diagnostic Description	Episode Count					
	2018	2019	2020	2021*	2018-19 % change	2019-20 % change
Infection and inflammatory reaction due to electronic cardiac device	171	132	130	87	-23%	-2%
Mechanical complication of cardiac electronic device	258	270	275	136	5%	2%
Other specified complications of cardiac and vascular prosthetic devices, implants and grafts	408	371	398	168	-9%	7%
Pain following insertion of cardiac and vascular prosthetic devices, implants and grafts	35	38	52	34	9%	37%
Unspecified complication of cardiac and vascular prosthetic device, implant and graft	21	33	18	8	57%	-45%
Total	**893**	**844**	**873**	**433**	**-5%**	**3%**

*Data for 2021 reflects the first half of the year (to 30 June 2021) only due to normal lags in receiving and processing claims.

Annual episodes by principal procedure for cardiac admissions with adverse outcomes

Principal procedure for admissions with adverse events	Episodes by discharge year			
	2018	2019	2020	*2021
Insertion of cardiac pacemaker generator	42	49	49	17
Allied health intervention, physiotherapy	44	30	46	14
2 dimensional real time transoesophageal ultrasound of heart	16	57	30	43
Replacement of cardiac pacemaker generator	33	43	29	25
Replacement of permanent transvenous electrode of other heart chamber(s) for cardiac pacemaker	34	33	25	14
Allied health intervention, pharmacy	13	11	24	10
Removal of cardiac pacemaker generator	15	20	23	10
Adjustment of transvenous electrode for cardiac pacemaker	14	19	19	9
Replacement of cardiac defibrillator generator	19	21	18	12

[27] Pinto A, Faiz O, Davis R, et al. Surgical complications and their impact on patients' psychosocial well-being: a systematic review and meta-analysis. *BMJ Open* 2016;6:e007224. doi: 10.1136/bmjopen-2014-007224 Available at: https://bmjopen.bmj.com/content/6/2/e007224.info

Percutaneous transluminal balloon angioplasty	15	16	18	6
Testing of other cardiac pacemaker	20	29	18	7
Removal of cardiac defibrillator generator	32	13	17	7
Coronary angiography with left heart catheterisation	23	16	17	5
None listed	91	70	74	37
Total	**893**	**844**	**873**	**433**

*Data for 2021 reflects the first half of the year (to 30 June 2021) only due to normal lags in receiving and processing claims.

3. Shared responsibility for active safety and performance monitoring is essential to balance risks with benefits and minimise harm

Active and passive systems to detect problems with new and existing technologies are paramount to maintaining patient safety. Continuing evidence-based assessments of the clinical, ethical, social and economic effects of the devices and technologies being used in the healthcare system are also imperative to ensure they are safe, effective and delivering value.[28]

Bupa agrees that signals relating to medical device safety and performance are either going undetected or are taking too long to identify in Australia.[29] A more active surveillance system incorporating multiple sources of data from multiple participants would allow emerging safety signals and issues to be identified and acted upon earlier, preventing unnecessary harm to patients. Unfortunately, this is not occurring under the current voluntary reporting approach.

Qualitative research in the UK, Australia and Canada suggests the culture of non-reporting is attributable to healthcare professional factors (fear of blame, belief that errors were inevitable and it was pointless to report them, avoidance of bureaucracy, time constraints, lack of knowledge about what to report and how,) and organisational factors (inadequate feedback, lack of processes and reporting systems).[30] The Department of Health estimates only 0.5 per cent of medical device adverse events are reported to the TGA. A case study on ventilators found fewer than 0.4 per cent of failures were reported, leaving the Health Department's medical devices branch "unable to determine the proportion of all failures that resulted, or may have resulted in patient harm". This is concerning for life-support equipment, where any swap-out during use or reduced service availability may have a serious impact on patients.[31]

Reform of our regulatory frameworks is therefore needed to make active surveillance a shared responsibility and ensure accountability for it through mandatory reporting requirements. Importantly, healthcare providers hold a unique viewpoint of the healthcare journey that enables them to identify problems much more quickly than others within the health system, unlike Private Health Insurers (PHIs) who only know about issues at the point of a claim.

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[28] Mytton OT, Velazquez A, Banken R, *et al* Introducing new technology safely *BMJ Quality & Safety* 2010;19:i9-i14. Available at: https://qualitysafety.bmj.com/content/19/Suppl_2/i9

[29] TGA (2021) Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia Discussion Paper; Martin J and Lucas C, Reporting adverse drug events to the Therapeutic Goods Administration *Aust Prescr* 2021;44:2–3 https://doi.org/10.18773/austprescr.2020.077

[30] Gagliardi AR, Ducey A, Lehoux P, et al. Factors influencing the reporting of adverse medical device events: qualitative interviews with physicians about higher risk implantable devices. *BMJ Qual Saf*. 2018;27(3):190-198. doi:10.1136/bmjqs-2017-006481. Craig A, O'Meley P, Carter P, The Need for Greater Reporting of Medical Device Incidents *EMJ Innov*. 2019;3[1]:56-63. Available at: https://www.emjreviews.com/innovations/article/the-need-for-greater-reporting-of-medical-device-incidents/

[31] Craig A, O'Meley P, Carter P, The Need for Greater Reporting of Medical Device Incidents *EMJ Innov*. 2019;3[1]:56-63. Available at: https://www.emjreviews.com/innovations/article/the-need-for-greater-reporting-of-medical-device-incidents/

Medical practitioners are accustomed to mandatory reporting requirements in other important areas such as child abuse and notifiable infectious diseases and mandatory reporting of medical device adverse events is aligned to the professional responsibilities found in the Australian Medical Council *Guidelines on Good Medical Practice*[32] for example.

Existing accountability systems already require serious mishaps be reported and provide disincentives to unsafe care. Both the National Safety and Quality Health Service (NSQHS) Standards and the National Safety and Quality Primary and Community Healthcare (NSQPCH) Standards require healthcare services to have processes for reporting all suspected adverse drug reactions (ADRs) experienced by patients to the TGA[33] as well as documenting them in the healthcare record and an organisational incident reporting system.[34]

Both drug and device related adverse events have the potential to cause serious harm, the risk of which can be prevented and minimised through participation in active surveillance. Therefore, Bupa believes the same requirements for recording and reporting adverse events and failures should apply to both drugs and devices. This would utilise at least one existing framework to ensure accountability and ongoing participation by facilities in meeting their reporting obligations and failure to comply with standards could be addressed in this context.

International best practice

International best practice supports a mandatory reporting approach. For example, the World Health Organisation reports:

- Canada's Medical Devices Regulations (SOR/98-282) require hospitals to report adverse events; any doubt cast on a device will trigger instant removal from the approved devices list until an investigation is made.[35]
- In Slovenia, a brief description of an adverse event must be sent to the Ministry of Health within 48 hours, and 45 days later a satisfactory analysis with corrective actions must be submitted or else a follow-up consultation with the Ministry occurs.
- The Czech Republic has reporting requirements that follow from their accreditation standards.
- The Netherlands has a two-tiered process. The Health Care Inspectorate, the agency accountable for taking actions against substandard performance, mandates hospitals to report adverse events that have led to death or permanent impairment. Other adverse events are reported voluntarily. There is interest in moving towards a more uniform blame-free reporting system to aggregate events nationally.
- Multiple jurisdictions in the United States have reporting systems that require hospitals or other providers to report certain types of serious, usually preventable events, to the FDA,[36] and the US National Electronic Injury Surveillance System – Cooperative Adverse Drug Event Surveillance (NEISS-CADES) system in hospital emergency departments has proven more efficient than a system of voluntary reporting.[37]
- The Danish Health Care System passed an Act on Patient Safety that requires health-care providers to report adverse events so information can be shared and aggregated for quality improvement.[38]

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[32] https://www.medicalboard.gov.au/codes-guidelines-policies/code-of-conduct.aspx

[33] Action 4.09 in Australian Commission on Safety and Quality in Health Care. *National Safety and Quality Health Service Standards*. 2nd ed. – version 2. Sydney: ACSQHC; 2021 p39; Australian Commission on Safety and Quality in Health Care. *National Safety and Quality Primary and Community Healthcare Standards*. Sydney: ACSQHC; 2021 pp34-35.

[34] Action 4.08 in Australian Commission on Safety and Quality in Health Care. *National Safety and Quality Health Service Standards*. 2nd ed. – version 2. Sydney: ACSQHC; 2021 p39; Australian Commission on Safety and Quality in Health Care. *National Safety and Quality Primary and Community Healthcare Standards*. Sydney: ACSQHC; 2021 pp34-35.

[35] Medical Devices Regulations (justice.gc.ca)

[36] Overview of Device Regulation | FDA

[37] Wiktorowicz ME, Lexchin J, Paterson M, Mintzes B, Metge C, Light D, et al. (2008) *Research networks involved in post-market pharmacosurveillance in the United States, United Kingdom, France, New Zealand, Australia, Norway and European Union: lessons for Canada*. Edmonton (AB): Canadian Patient Safety Institute.

[38] WHO Draft Guidelines for Adverse Event Reporting and Learning Systems, 2005

Bupa recommends the TGA aligns Australia's requirements for healthcare practitioners and facilities to international counterparts by mandating the reporting of faulty devices. International post-market vigilance exchanges should also continue to be supported.

A registry must be created to track device safety and patient outcomes

Accountability systems can (and should) be learning systems if investigations are carried out and if the lessons learned are disseminated to other system participants. We know that mature registries can deliver good quality long-term outcome data using measures that matter to patients. They give unparalleled opportunities for research and audit, enabling policy makers, regulators, health care providers and clinicians to monitor long term outcomes and report on whether health care is safe and effective.[39] As outlined in the *National Clinical Quality Registry and Virtual Registry Strategy*[40] clinical quality registries are internationally recognised as key vehicles for improving survival and quality of life after treatment for patients and contributing to health system sustainability through avoided treatment costs.[41]

However, Australia does not currently have a comprehensive registry covering all high-risk medical devices and unfortunately the specific registries that have been established, such as those for pelvic floor procedures, cardiac devices, joint replacements, and breast implants have been prompted by catastrophe.[42]

Bupa strongly supports the establishment of a registry or registries for all high risk and implantable devices, as recommended by multiple inquiries and reviews including the Review of Medicines and Medical Devices Regulation's final report on the *Regulatory Framework for Medicines and Medical Devices*.[43]

Along with the implementation of a globally harmonised Unique Device Identifier (UDI) system, this would allow long-term follow up of patients and provide information on both device safety and patient reported outcomes, including those that only become apparent after several years. It would also facilitate new approaches to generating clinical evidence such as nested clinical trials. Registry nested trials can answer more directed or specific questions more effectively and less expensively than current approaches.[44]

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[39] Cumberlege J. First Do No Harm. The Report of the Independent Medicines and Medical Devices Safety Review. July 8, 2020. London, England, Crown Copyright. Available at: https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf

[40] Commonwealth of Australia (Department of Health) 2020

[41] ACSQHC (2016) *Economic Evaluation of Clinical Quality Registries Final Report*. Available at: https://www.safetyandquality.gov.au/sites/default/files/migrated/Economic-evaluation-of-clinical-quality-registries-Final-report-Nov-2016.pdf

[42] Australian Senate Community Affairs References Committee, Final Report on Number of Women in Australia Who Had Transvaginal Mesh Implants https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/Report; Australian Senate Community Affairs References Committee, Final Report on The role of the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prothese (PIP) breast implants https://www.aph.gov.au/parliamentary_business/committees/senate/community_affairs/completed_inquiries/2010-13/implants2012/report/~/media/wopapub/senate/committee/clac_ctte/completed_inquiries/2010-13/implants_2012/report/report.ashx; Branley, Alison 'Patients report pacemaker 'electrical storms' as advocates predict device registry failure' *ABC Online*. 22 January 2020. Available at: https://www.abc.net.au/news/2020-01-22/pacemaker-defibrillator-device-registry-will-not-work,-advocates/11882880;

[43] Recommendation 22, March (2015) available at https://www1.health.gov.au/internet/main/publishing.nsf/content/expert-review-of-medicines-and-medical-devices-regulation#report1

[44] Leopopld, S Take 5 Interview with Peter L. Lewis MBBS, FRACS(Orth), FAOrthA first author of "Does Knee Prosthesis Survivorship Improve When Implant Designs Change? Findings from the Australian Orthopaedic Association National Joint Replacement Registry" Clin Orthop Relat Res. 2020 Jun; 478(6): 1152–1155. Published online 2020 Apr 8. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7319384/

The strengthening of Australia's post-market monitoring of medical devices can also be greatly facilitated by digital technology and big data[45] including the ability to access and interrogate linked data from the UDI system, device and procedure specific registries, as well as Pharmaceutical Benefits Scheme (PBS) and Medical Benefits Scheme (MBS) data.[46]

Conclusion

Innovation in medical care, drugs and devices has saved and improved many lives but where safety and efficacy cannot be well established prior to or during pre-market assessment, it can also cause harm.

Crucial opportunities to learn about what works well, what does not, what needs special measures put around its use, and what should be withdrawn because the risks over time outweigh the benefits are being lost in Australia's current post-marketing surveillance systems and lack of long-term outcome monitoring. A stronger, more active system of safety and performance monitoring will benefit everybody by ensuring patients are not exposed unnecessarily to risk and that manufacturers and others are not exposed to undue liabilities.

Bupa would welcome the opportunity to discuss any of the issues raised in this submission with the TGA on request.

[45] Cumberlege J. *First Do No Harm. The Report of the Independent Medicines and Medical Devices Safety Review*. July 8, 2020. London, England, Crown Copyright. Available at: https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf

[46] *National Clinical Quality Registry and Virtual Registry Strategy* (2020) Commonwealth of Australia (Department of Health); Leopopld, S Take 5 Interview with Peter L. Lewis MBBS, FRACS(Orth), FAOrthA first author of "Does Knee Prosthesis Survivorship Improve When Implant Designs Change? Findings from the Australian Orthopaedic Association National Joint Replacement Registry" Clin Orthop Relat Res. 2020 Jun; 478(6): 1152–1155. Published online 2020 Apr 8. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7319384/