PROFESSIONALS *In* CARDIAC SCIENCES AUSTRALIA

PICSA

28/06/2023
The Hon. Mark Butler
Minister for Health and Aged Care
by email: Minister.Butler@health.gov.au

Dear Minister Butler,

I am writing on behalf of Professionals in Cardiac Sciences Australia (PiCSA) to draw your attention to critical issues affecting allied health professionals providing cardiac technical support services for cardiac implantable electronic devices (CIEDs) such as pacemakers and defibrillators.

PiCSA is very concerned about the present and future funding of CIED prostheses and follow-up services. This letter aims to bring to your attention certain information that may have been overlooked and omitted by the Prosthesis Industry. Furthermore, it includes a request for responses to five specific questions. Copies of this letter will also be sent to other political leaders and key stakeholders.

It is imperative that the government adopts a CIED funding model that does not preferentially favour industry employed personnel, nor adversely affect non-industry employed allied professionals and which enables patients to receive an appropriate unbiased international standard of care.

Why listen to PiCSA?

PiCSA plays a crucial role as a key stakeholder in the cardiac healthcare sector, representing the entire cardiac physiology workforce that is essential to ECG, Cath Lab, Echo, CIED, and Electrophysiology procedures. This workforce encompasses professionals working in public, private, and industry settings, and individual cardiac physiologists often transition between these distinct employment environments.

By advocating for the workers rather than the employers or manufacturers, PiCSA serves as a unique and essential voice. It is vital that decisions concerning funding related to CIEDs take into account the input and perspective of PiCSA.

Over-charging for prosthesis and technical support:

The funding of CIED prostheses and follow-up services directly impacts patient care and the taxpayer pocket. In Australia the cost of the prosthesis is currently exorbitant in comparison to other countries. There is also an issue regarding reimbursement of cardiac physiologist labour, particularly when industry employed cardiac physiologists (manufacturer representatives) are substituted for non-industry employed cardiac physiologists.

During a recent meeting with the Director of Prostheses Compliance and Assurance, Prostheses List Reform Taskforce, we were verbally informed of the following:

- A significant portion (40-50%) of the prostheses rebate for a CIED is to cover technical support provided on the day of implant.

- This implies that industry is charging $1,000 to $20,000 to assist with a procedure that typically takes less than 3 hours. (source: HealthDirect Australia - https://www.healthdirect.gov.au/pacemaker).
- Worse still, they are charging this price even if the implanting centre utilises their own cardiac physiologist for technical support during the implant without any industry staff present at all.

Lack of transparency:

We note that more recent correspondence from the Australian Government Department of Health and Aged Care *contradicts* the previous verbal advice we received: Labour on the day of implant is NOT included at all, and services to manage the device after implantation are listed instead [see PHI circular dated 10/05/2023 https://www.health.gov.au/news/phi-circulars/phi-2923-benefit-reductions-to-cardiac-implantable-electronic-devices]. Many patients transfer between public and private follow-up centres, and some private centres use non-industry employees for technical support. We also note that some patients do not live long enough to require much follow-up support, but the prosthesis benefit does not take that into account.

To examine the reimbursement structure more closely, we obtained a prosthesis rebate application for a defibrillator from a sponsor via a Freedom of Information request to the Department of Health and Aged Care. Surprisingly, this document only mentions the prosthesis and fails to identify any technical services component of the rebate price (whether on the day of implant or associated with subsequent support), leaving us highly concerned about transparency. The cost of remote monitoring equipment also appears to include a set lifetime fee for telecommunications and website costs, whether the patient uses their monitor for 1 year or 15 years or even at all. This fee may or may not include any industry labour costs (there is lack of clarity on this point) and may be charged even if the patient uses their personal mobile for the monitoring (paying for data transmission a second time via their phone contract).

Misallocation of labour and conflict of interest:

Labour substitution during CIED implant is only the beginning of the workforce issue. Many cardiac centres essentially use industry employed cardiac physiologists as “free labour” for ongoing CIED follow-up and support, despite their restricted scope of practice as manufacturer representatives. PiCSA strongly believes that the discussion around labour must consider the non-equivalency of an industry versus non-industry employed workforce.

For example :

- Industry employees are not allowed to access patient hospital records, or directly provide perioperative or periprocedural advice.
- They cannot recommend a competitor’s brand better suited to a patient’s unique clinical needs, and they cannot accommodate mixed brand clinics (which limits patient access to care).

- Blurred lines between a technical vs clinical vs sales role may prevent frank discussion re patient and CIED management and lead to imperfect programming.
- Cardiac physiologists who are being paid by the manufacturer may also have a conflict of interest when managing battery settings, recommending follow-up intervals, or discussing potential upgrade or replacement procedures.

We refer you to an article discussing conflict of interest in one area of workforce substitution [Article Link: https://www.mja.com.au/journal/2017/206/2/remote-monitoring-medical-devices-australia].

Going against guidelines:

International guidelines are developed with rigorous policies and methods to ensure that they are developed without bias or improper influence. These documents do not support labour substitution. Lindsay et al. stated in 2008 that it is not appropriate for company representatives to substitute for directly employed cardiac device specialists [Article Link: https://www.hrsonline.org/guidance/clinical-resources/2008-heart-rhythm-society-policy-statement-update-recommendations-role-industry-employed-allied]. More recently, a 2023 international position statement states that "although manufacturer representatives can play an important role in training clinic staff, it is not their role to perform, collect, or triage data on behalf of the clinic staff or be used as a staffing resource in lieu of local qualified personnel." [See sections 11 and 12 of the HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic, Article link: https://www.heartrhythmjournal.com/article/S1547-5271(23)02011-8/fulltext].

MSAC application 1724 intends to directly reimburse industry for labour substitution which is very likely to financially bias employers against utilising brand-independant staff. We have discovered that this application does not even acknowledge the limited scope of practice of industry employed cardiac physiologists or include any provisions for non-industry employed cardiac physiologists, who are the international standard for patient care. In our opinion, the estimated $102 million cost of the proposal [stated in the independent validation report by Klynveld Peat Marwick Goerdeler (KPMG)] is also significantly inflated. The estimate fails to consider patients receiving post-implant follow-up services from non-industry employed cardiac physiologists and falsely implies the presence of over 1,000 full-time industry field clinical support representatives in Australia, which is not the case.

Unregistered health professionals:

Whether in private or public healthcare settings, and regardless of who is paying the wages of the cardiac device physiologist, there is currently no government policy or legislation in place to protect patients against having their pacemaker technical support provided by someone who is unqualified, unregistered, or potentially incompetent.

PiCSA recommends that both employers and the Australian government should require the cardiac device workforce to be registered in the public registry of Australian Accredited Clinical Physiologists (accessible at www.accp.org.au). Registering with the ACCP demonstrates a dedication to upholding quality, safety, ethical standards, and continuous learning. In our view, reimbursement should be contingent upon participation in the ACCP register of accreditation.

Questions to answer:

On behalf of PiCSA, we request a response to the following 5 questions:

1. Is it acceptable for industry to receive reimbursement for labour that they do not necessarily provide, particularly when the prosthesis rebate does not publicly differentiate between the prosthesis and service components?

2. Where can we find the official written agreement that formally outlines the breakdown of technical support and prosthesis rebates? Access to this information is crucial for transparency and accountability within the system. What measures can be implemented to ensure this information is readily available?.

3. Instead of encouraging the substitution of labour by company representatives, shouldn't the funding system incentivise cardiac centres to comply with international staffing guidelines? What structures and legislation can be put in place to achieve this goal?

4. Shouldn't the discussion around labour consider the non-equivalency of an industry versus non-industry employed workforce, and acknowledge potential conflicts of interest that might adversely affect patient care?

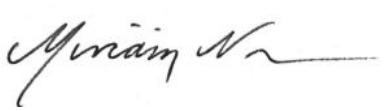
5. What measures does the government plan to implement in order to tackle the problem of an unregulated workforce?

PiCSA acknowledges the complexity of funding CIED prostheses and follow-up services. However, we firmly believe that the cost of the prosthesis should not remain inflated, and that reform measures should not inappropriately affect the labour model. Cardiologists must be able to choose to employ their own industry-independant staff without financial disadvantage. For further information, please refer to PiCSA's comprehensive response to the MSAC application 1724 consultation survey, available on our website at [Website Link: https://picsa.org.au/news/].

In conclusion, we strongly urge the government to prioritise patient welfare and adopt a funding model that upholds internationally accepted industry and non-industry workforce roles. It is vital that the government does not undermine the viability of 3rd party non-industry providers or the direct employment of cardiac physiologists. PiCSA is available to provide additional information in regard to this letter. We would welcome the opportunity to engage in a discussion with you or your representatives at your convenience.

Thank you for your attention to this matter, and we eagerly await your response.

Sincerely,



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