Private Healthcare Australia
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Prostheses List Post-listing review of Urogynaecological mesh (mid-urethral slings)

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About Private Healthcare Australia

Private Healthcare Australia (PHA) is the Australian private health insurance industry's peak representative body. We have over 20 registered health funds throughout Australia as members and collectively represent 98% of people covered by private health insurance. PHA member funds provide healthcare benefits for more than 14 million Australians.

Response

PHA and our CEO, Dr Rachel David, have been vocal on the lack of oversight of pelvic mesh use, including insufficient checks and balances such as registries that should have identified early problems. PHA recognise that the majority of issues related to mesh used in Pelvic Organ Prolapse (POP) and not Urogynaecological mesh (mid-urethral slings) used for Stress Urinary Incontinence (SUI).

PHA are aware that pelvic floor mesh was approved without proper clinical studies, instead fast tracked through 510(K) equivalence which was shown to be woefully insufficient to assess the risks for patients of these devices.

PHA are not in a position to provide superior or unique evidence around the use of mid-urethral slings beyond what would be expected from the external consultant, the various retrospective papers and analysis presented by the learned Colleges or the recommended position from the Australian Commission on Safety and Quality in Health Care.

However, there is a systemic response needed for proper release management of technologies such as this. The introduction of novel devices should be included in a formal post market surveillance tool or registry. Had such a registry existed for pelvic mesh, complications would have been identified sooner, and more women would have been spared the debilitating consequences of this treatment. Where the use of technology is high risk/reward, formal training programs should be in place from the respective clinical college with certification/accreditation provided on competency. Clear guidelines on use and contraindications also clearly specified and available to patients as well as to clinicians.

PHA are also engaged in the implementation process around Unique Device Identification (UDI) for high-risk devices. Clinical consultants identify pelvic mesh as a device category that would have been flagged as being of concern sooner had UDI controls been in place. We support the government's objective to include UDI information in multiple points of patient records including detail held by health insurers on behalf of members.

It is paramount that patients are provided complete transparency and disclosure of the options available to them in treatment, and active informed consent for any device used. While it is possible to stop taking a medication, removing a device is often difficult, or in the case of pelvic mesh, impossible.

Many women whose lives were impacted from the failures of pelvic mesh were not even aware that a Prolene (polypropylene) mesh had been implanted in their body by their doctor. In addition to UDI tracking and an appropriate registry, we expect all patients to receive an implant card with details on

devices implanted, the material composition and tracking references should a later recall or post market review be established.

When a device is subject to a recall notice, the cost to address this is not born by the manufacturer, instead it is carried by insurers, taxpayers and public hospitals for the revision costs, and by consumers for the potentially life changing impact of a failed device.