Public Health Association
AUSTRALIA

Public Health Association of Australia submission on Alignment with European medical device regulatory framework: Up-classification of surgical mesh & Patient implant cards

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Introduction

The Public Health Association of Australia

The Public Health Association of Australia (PHAA) is recognised as the principal non-government organisation for public health in Australia working to promote the health and well-being of all Australians. It is the pre-eminent voice for the public's health in Australia. The PHAA works to ensure that the public's health is improved through sustained and determined efforts of the Board, the National Office, the State and Territory Branches, the Special Interest Groups and members.

The efforts of the PHAA are enhanced by our vision for a healthy Australia and by engaging with like-minded stakeholders in order to build coalitions of interest that influence public opinion, the media, political parties and governments.

Health is a human right, a vital resource for everyday life, and key factor in sustainability. Health equity and inequity do not exist in isolation from the conditions that underpin people's health. The health status of all people is impacted by the social, cultural, political, environmental and economic determinants of health. Specific focus on these determinants is necessary to reduce the unfair and unjust effects of conditions of living that cause poor health and disease. These determinants underpin the strategic direction of the Association.

All members of the Association are committed to better health outcomes based on these principles.

Vision for a healthy population

A healthy region, a healthy nation, healthy people: living in an equitable society underpinned by a well-functioning ecosystem and a healthy environment, improving and promoting health for all.

Mission for the Public Health Association of Australia

As the leading national peak body for public health representation and advocacy, to drive better health outcomes through increased knowledge, better access and equity, evidence informed policy and effective population-based practice in public health.

Preamble

PHAA welcomes the opportunity to provide input to the consultation on the alignment with European medical device regulatory frameworks for surgical mesh. The reduction of social and health inequities should be an over-arching goal of national policy and recognised as a key measure of our progress as a society. The Australian Government, in collaboration with the States/Territories, should outline a comprehensive national cross-government framework on promoting a healthy ecosystem and reducing social and health inequities. All public health activities and related government policy should be directed towards reducing social and health inequity nationally and, where possible, internationally.

PHAA Response to the consultation paper

Up-classification of surgical meshes

Are there any unintended consequences that may arise out of this change?

There is a need to clearly separate the smaller risks associated with stress urinary incontinence sling surgery from those of pelvic organ prolapse mesh surgery. The up-classification of mesh may result in doctors and women being more cautious and possibly less likely to consider urethral slings for stress incontinence. However, urethral slings for stress incontinence have been found to be effective and the associated surgery safe.[1] These concerns may reduce surgical options for women.

If there are issues, provide suggestions for mitigating them?

A certification system for specialists could be introduced based on existing international guidelines. Doctors must be encouraged to undertake professional education and training as offered by the Urogynaecology Society of Australia and the Australian College of Obstetricians and Gynaecologists. This, together with clear clinical practice guidelines and patient education, will ensure evidence based decision making and confidence in mid-urethral slings used for stress incontinence, and that highly trained specialists carefully evaluate and perform surgery without the need for transvaginal mesh in the case of pelvic organ prolapse.

Patient implant cards

Do you have any suggestions about effective ways to ensure that the patient ID card reaches the patient?

The patient ID cards must be associated with unique code given to mesh implant itself and issued to women upon implantation along with patient education materials. The codes should be immediately entered into an online national database linked to the Australian Register of Therapeutic Goods upon implementation. The unique identifiers should agree with existing standard international codes with regulators abroad, including Canada, the European Union, and Japan.

Do you have any comments or suggestions on alternative or additional strategies to promote the provision of the implant card to the patient?

Extensive piloting of the patient card must be undertaken including track and trace mechanisms. Without such systems the card will be ineffective. Clinical champions and consumer bodies should be involved in these processes including the promotion of the ID card. These efforts should be aligned with co-ordinated multi-centered studies to investigate the safety profile of mesh. Financial mechanisms also need to be in place to ensure patients are compensated in case of harm.

Are there any issues or unintended consequences that may arise out of this change?

Women may be concerned about privacy and confidentiality and doctors may be concerned about the additional burden of the associated administrative and data collection work.

If there are issues, provide suggestions for mitigating them?

Women, doctors and their professional associations must be involved in all steps of the development, implementation and evaluation stages to ensure the translation of this into policy and practice.

[1] Ward KL, Hilton P. A prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: two-year follow-up. American journal of obstetrics and gynecology. 2004 Feb 29;190(2):324-31.

Conclusion

PHAA supports the broad directions of the up-classification of mesh and patient implant cards. However, we are keen to ensure adequate consultation in line with this submission. We are particularly keen that the following points are highlighted:

- a certification system for specialists should be mandatory
- patient ID cards must have a unique code entered into a national online database
- patient ID cards must be piloted with women, doctors and professional associations involved at all stages

The PHAA appreciates the opportunity to make this submission and the opportunity to comment on the up-classification of surgical mesh implants and patient implant cards. Further information regarding PHAA's position on transvaginal mesh implants is contained within our submission to the Senate Standing Committee on Community Affairs Inquiry into the number of women in Australia who have had transvaginal mesh implants and related matters, available from www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/Submissions (Submission number 20).

Please do not hesitate to contact me should you require additional information or have any queries in relation to this submission.

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