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Re: Consultation Paper on Bundling Arrangements for General Use Items on the Prostheses List

1. *Introduction*

RACS is the leading advocate for surgical standards, professionalism and surgical education in Australia and New Zealand.

Our Fellows' focus is on ensuring that their patients have the best possible outcomes. This is only achievable if clinicians have access to medical devices best suited to their patients' particular clinical circumstances.

2. *Concerns about the removal from the Prostheses List of items classified as General Use*

RACS is supportive of reforms to the Prostheses List (PL) which improve the long-term sustainability and cost efficiency of healthcare. However, RACS is concerned about the removal from the PL of those items described as 'General Use' - a 'reform' which is due to take place in July 2023.

If opinions about the removal of items classified as 'General Use' are not strictly within the scope of this consultation RACS would nevertheless appreciate it if they are detailed in IHACPA's report.

Because the funding of items classified as 'General Use' will not be mandatory, it seems inevitable that there will be instances of clinicians having reduced access to items which they believe are the most appropriate for their patients.

Whatever advice IHACPA provides in relation to bundling arrangements for General Use Items, this is likely to be the case.

When the funding of specific items is not mandatory, variability in private hospital size, market share and negotiating power may mean those items will not always be available. Decisions about whether clinicians have access to specific general use items may depend on whether hospitals and insurers have reached agreements on the funding of those items.

Reforms should not result in a contravention of the principle that decisions about the use of particular devices are the domain of clinicians, and their patients.

3. *Concerns about availability in emergency situations*

Inadvertent and unforeseen damage to vessels can occur during elective cases. Although rare, such damage can occur during orthopaedic surgery, spinal surgery, general surgery, urological, renal, dialysis access procedures, invasive interventional cardiology procedures (including the increasing prevalence of TAVI), electrophysiological procedures, biopsies and insertion of lines, catheters and ports in intensive care units and oncology settings.

In such emergency situations the availability of 'General Use' items such as surgical sealants, haemostatic devices and closure devices can be a matter of life and death.

RACS is concerned that the lack of remuneration for such items may have the consequence of a reduced inclination by smaller private facilities to order and keep a critical stock of them.

A lack of such items could result in prolonged attempts at salvage, increased blood loss, limb or organ loss, emergency interhospital transfers and (potentially preventable) deaths.

An additional concern that applies to emergency and other surgical situations is that if specific items are less available there will be less frequent utilisation of those items. Less staff familiarity inevitably means that they will be less effectively employed.

4. Concerns about specific items scheduled for removal

RACS would like to note concerns that some items scheduled for removal are not correctly classified as 'General Use'. RACS notes in particular concerns expressed by the Australian and New Zealand Society for Vascular Surgery (ANZSVS) in relation to the inclusion of arterial closure devices among General Use items. In ANZSVS' view these are highly specific, clinically efficacious devices that are not comparable to general use items.

RACS endorses ANZSVS' views.

RACS also notes the views of General Surgeons Australia (GSA). GSA has said that the removal of items in the General Miscellaneous Category does not recognise their essential nature in specialised General Surgery. GSA has argued for these items to be categorised into a new listing 'Product Category 14 - Specialist General Surgery' to reflect more accurately their specialised nature, and to make them distinct from items such as topical adhesive that are designed for 'general use'.

Some examples of the specific use of devices include:

- Laparoscopic cholecystectomy:
  - requires laparoscopic ligation devices for securing the cystic artery and duct
  - requires laparoscopic delivery bag to avoid contamination of the abdominal wall

- Incisional hernia:
  - requires tackers, staples, and ligation devices to perform the surgery correctly

- Colorectal and small bowel surgery:
  - requires staple devices to join the bowel back together - rectal surgery cannot be performed without this equipment
  - many patients would require a permanent colostomy without the stapling device

- The use of LigaSure devices to cauterise bleeding is standard of care in all major surgery, and reduces operating time and post operative bleeding by 20%.

- Liver and Pancreas Surgery safety has been revolutionised by the use of stapling and energy devices, to remove sections of liver and pancreas.

- Pharmaceutical beads are the mainstay of treatment of hepatocellular carcinoma and deliver a cure rate from unresectable cancer of up to 20%. These beads also hold the disease at bay while the patient is waiting for a liver transplant.

RACS endorses GSA's views.

Other items which are considered general use but which are specifically required as part of an operative procedure include for example, stents in pyeloscopic/ureteroscopic procedures, and laparoscopic ports for any robotic or laparoscopic procedure

The department needs to work on the principle that any equipment that is an integral part of an operation should not be classified as general use but rather funded as part of the operative procedure.

5. Other alternatives to the planned reforms

RACS is of the view that a mechanism which guarantees access to all items which clinicians believe are best suited to their patients should be put in place. This could be through the addition of a category/categories to the Prostheses List similar to the suggestion by GSA, or by other means.

Yet RACS recognises that there are likely to be clinicians who regularly use unnecessary types or amounts of items classified as 'General Use'. Given this likelihood, and to ensure the continued viability of all components of the private health system, RACS acknowledges that reforms should be undertaken to prevent misuse/overuse of items classified as 'General Use'.

An appropriate reform would be to increase clinicians' focus on *choosing wisely* in relation to such items, and prosthetic devices more generally.

In principle RACS would be willing to work with regulators to educate surgeons and other clinicians about best practice in the use of such items and even provide opinions about different general use items and other disposables & prosthetics.

6. *Responses to specific consultation questions*

In the event that the reforms continue as planned, RACS contributes the following views in relation to 'bundling design'.

Regarding 'data sources', those proposed in the consultation paper appear appropriate. RACS can suggest no other appropriate sources.

Regarding the quality and utility of the data, it is fair to say that many general items can easily be overlooked and as such billing code data may underrepresent actual usage. Underreporting may also result from the use of multi-pack type items, however RACS can provide no evidence beyond anecdote.

Regarding classification, the use of ICD-10-AM/ACHI/ACS is appropriate as a universal classification system. MBS tends to be used to classify episodes of patient care in the private sector, and DRGs are used in the public sector.

RACS can contribute no evidence to indicate whether COVID-19 has impacted on the use of items classified as General Use among episodes in which these items are used.

7. *Need for monitoring of reforms*

Finally, if the reforms continue as planned, RACS believes it would be appropriate for access to, and use of, devices removed from the PL to be independently monitored. Monitoring should be based on the views of clinicians. Should monitoring find that clinicians believe their clinical choices have been significantly impacted, then the changes should be revisited.

This RACS submission is supported by General Surgeons Australia, the Australian and New Zealand Society for Vascular Surgery, and the Urological Society of Australia and New Zealand.

SIGNED

Prof Mark Frydenberg

RACS Councillor

Chair, RACS Health Policy and Advocacy