March 30, 2025

By email

devices@pharmac.govt.nz

Tēnā koe

Comprehensive List of Medical Devices

About the Australian and New Zealand College of Anaesthetists

ANZCA, which includes the Faculty of Pain Medicine (FPM) and Chapter of Perioperative Medicine is the leading authority on anaesthesia, pain medicine and perioperative medicine. It is the professional organisation responsible for postgraduate training programs of anaesthetists and specialist pain medicine physicians, and for setting the standards of clinical practice throughout Australia and New Zealand. Our combined membership comprises 9649 fellows, pain medicine specialists and trainees, of whom around 1300 work in Aotearoa New Zealand. ANZCA is committed to upholding Te Tiriti o Waitangi in the provision of competent, culturally safe care, and to promoting best practice and ongoing continuous improvement in a high-quality health system.

Submission

Executive summary

ANZCA welcomes the opportunity to provide feedback on the proposed comprehensive list of medical devices. This submission is informed by discussion and consultation with ANZCA members and committees, in particular, members and chairs of the ANZCA New Zealand National Committee (NZNC) and Faculty of Pain Medicine.

While there is some support for moving to a single national purchasing model for medical devices, we have also identified significant risks, that would need to be mitigated through careful and transparent management of the transition. We are not sanguine that this is possible within the proposed timeframe, given that there is no available resource and the inadequacy of the consultation and proposed lists. Members expressed dissatisfaction and frustration with the consultation process as they found the lists overwhelming, difficult to navigate (or even open in some cases) and they did not have the non-clinical time or resources to undertake even a partial audit. These time constraints are not likely to change in the period given for ensuring the lists are current, accurate and complete.

Our feedback on specific medical devices that are not on the list (Question 1) is limited and reflects the somewhat haphazard nature of the lists, where devices used in anaesthesia are only partly listed in the Critical Care - Anaesthesia section, with many listed under other specialties. The lists are a long way from being complete. One anaesthetist, for example, focused on four key items essential for regional anaesthesia or vascular access and found that only one was listed. Other significant omissions include the lack of description of anaesthesia machines, ultrasounds, disposable fibreoptic options, nerve stimulators and gaps in devices for airway management. Accordingly, we recommend ensuring:

- Robust processes for engagement and assessment of devices, including targeted consultations with clinical specialties, the equipment teams managing supply, and end users.
- Clear communication about potential changes to medical devices lists.
- Sufficient time to respond to proposals.

- A much-extended transition period, preferably with cross party support.

It will also be important to retain some degree of flexibility beyond the proposed timeframe for clinicians to have confidence that inadvertent omissions (which we suspect will be numerous) can be quickly addressed and that they will be able to access devices and/or get them approved quickly.

We have not identified any items that should not be listed (Question 2) but have taken this opportunity to recommend device(s) to remove nitrous oxide and to recommend automated low flow technologies that reduce the carbon footprint of anaesthesia, as consistent with ANZCA's Statements on Climate Change and the government's evidence-based policy and plans with regard to climate change and health services. ANZCA strongly advocates for sustainability of devices and equipment, including strategies to reduce greenhouse gas emissions, being a significant part of the assessment process.

National purchasing of medical devices

ANZCA recognises there are potential advantages of moving towards a single national purchasing model for medical devices, for example by reducing the differences in access to medical devices across the country. While some of these are understandably related to size and location, some are due to lack of awareness of/training on more up-to-date devices, new uses for existing devices, interruptions to supply chains, costs, stockpiling, and inadequate storage facilities. A monopsony for medical devices makes sense for a small country of 5.12 million people and, as with the pharmaceutical model in place, is likely to improve efficiency and cost effectiveness, *if* well-resourced and managed. Reducing duplication, waste, unnecessary variation and obsolete devices and supporting practitioners with information, training and reliable access to current and innovative medical devices regardless of location, will also enhance health equity and quality.

Risks

There are risks, however, including that any failure could expose the entire nation, as opposed to a few services, to significant risk - for example, in the event of a recall on a major device or issues with supply as seen in 2019-2020. Additionally, although small, our population and services are not homogeneous and have different and specific needs, which can be easily overlooked in a 'one size fits all' model. Standardisation should make it easier for clinicians and end users of devices when moving between services and locations, but control measures need to be in place to mitigate the increased risk with a sole supplier that a small error could have national consequences.

Decisions on the purchasing of devices need to keep pace with improvements and innovation, to ensure health practitioners have the means to constantly upskill and deliver timely, quality healthcare for all New Zealanders. A profoundly adverse potential unintended consequence, especially in view of the government's successive health system reforms, singular focus on specific health targets, and signalled move towards increasing use of private health providers, for example, would be if the quality and availability of medical equipment used in public hospitals and community health services were eroded over time in comparison to that used in the private health sector. A 'two tier' health system where there is a significant difference between the standard of health care able to be delivered in private as opposed to public hospitals is inherently inequitable and inefficient, as various reviews of the impacts of National Health Service reforms in England have found[i], [ii]. Consistent feedback from members suggests that what really matters to clinicians and services is – how easy is it to get an unlisted device/product on to the approved list and can this happen quickly? This process needs to be described and supported by Pharmac.

Removing obsolete or unnecessary devices poses a risk as rarely used devices that may be useful in rare circumstances for specific patients may be dropped off the list, in preference to those that are immediately needed, when they should be retained. Individual examination of 'outliers' of rarely used items, with appropriate clinical and end user input, is required. End users must be fully

consulted as there are very significant patient risks that occur when changing equipment used in clinical procedures. Muscle memory is highly relevant, and morbidity can occur. An example here is the rise in post dural puncture events seen after changing epidural providers because of subtle differences between brands. It is quite possible that the cost savings seen for the first few years were completely negated by increased admissions and length of stay, plus treatment procedures for those increased cases of PDPH (post dural puncture headache).

A comprehensive list is likely to present new challenges. It is relatively common for devices and equipment from one service to be adapted and/or used in another – ultrasound is an obvious example. These will be hard to identify from the current listed categories/clinical services. We suggest there needs to be some flexibility to ensure innovative uses of devices are not constricted by rigid classification of items only to be used for a set purpose/service. Similarly, it will be necessary to ensure devices are accurately and completely listed and that the lists are updated often to avoid confusion with new models, and names, as with the examples of the fluid meters given below. It is not clear what provision will be made for parts and servicing of existing machines which are still in use, but which may not be listed. We suggest Pharmac develops transparent protocols to clarify and distinguish additions/changes and recommend maintaining parts and services for devices still in use for as long as necessary until replacement.

For expensive items such as anaesthesia machines, wider aspects than simply cost and maintenance must be considered. We are particularly concerned that only two of many machines, Drager and Mindray, are listed. We trust that this is unintentional and that there is no intention to create a duopoly as this would render a whole cohort of machines unserviceable and would be "disastrous". We strongly advocate the need for Pharmac to develop agreed and comprehensive cost-benefit criteria for decision-making. The risks and costs of such a substantial change affecting all public services on top of extensive health system restructuring, may outweigh potential benefits. While not perfect, the current system is working, and we feel that precipitate changes to fundamental health system infrastructure adds considerably to the load on clinicians and could put patient safety at risk. We also urge you to consider significantly extending the time frame, and developing transparent, in-depth processes for constructing a comprehensive list of medical devices that clinicians and the public can have confidence in. Cross party and health sector support has been critical in offering a secure platform for Pharmac's undoubted success with cost effective purchase of medicines; we suggest that for medical devices the same, careful and collaborative approach will be necessary.

Reducing carbon footprint

We have not identified any items that should not be listed but have taken this opportunity to recommend device(s) to remove nitrous oxide, a potent greenhouse gas used in some facilities, mainly for pain relief in childbirth, to mitigate leakage from storage tanks. We note that the application of automated low flow technologies (partially effective in GE and Mindray and most efficient in Drager Zeus) improves task shedding for the clinician and minimises volatile gas usage. This saves pharmaceutical costs but also has an enormous impact on environmental pollution. We draw your attention to ANZCA's Position Statement on Climate Change and Joint Statement: Working together to achieve high quality care in a changing climate, (Australia) as well as Te Whatu Ora's "whole of government' response to climate change and the Ministry of Health's Health National Adaptation Plan 2024-2027,mandated by the Government Policy Statement (GPS) on Health 2024 – 2027. ANZCA strongly advocates for sustainability of devices and equipment being a significant part of the assessment process.

As indicated, to develop and maintain a comprehensive list of medical devices, it will be important to ensure robust processes for engagement with clinicians, including targeted consultations with specific clinical groups, transparent evaluation and reporting protocols, timely communication about potential changes to medical devices about to come off the list, and sufficient time to respond to proposals. Equipment officers and/or equipment groups including clinicians, appear to

work well, ensuring continuity of supply, current and upcoming technologies, changes of use, training needs etc. within each clinical/ service. We recommend these are developed and supported.

Question 1

Are there any medical devices used by public hospitals that are not on this list?

There are innumerable devices and anaesthetic machines that are not listed , including:

- The Edwards Lifesciences suite of patient monitoring equipment seems to be fully represented except the very new Acumen IQ Fluid Meter. The list does contain 'Edwards Acumen IQ' and the 'Edwards Acumen IQ Sensor' has been in use for some time. The 'Edwards Acumen IQ Fluid Meter' is new and is used in addition to the sensors.
- Introcan Safety Deep Access 64mm intravenous cannulae sizes 22G and 20G - supplier item code 4251621-01 and 4251622-01 (used for long-dwell deep access ultrasound-guided peripheral venous access in difficult intravenous access patients).
- 3M Carillon No Sting Barrier Film 1ml Wand 3343 - supplier item code MED309 (used as a sterile skin preparation to improve dressing adhesiveness for peripheral regional anaesthesia nerve catheters).
- BD Concentric Tip 30ml Syringe Hypodermic - supplier item code 301231 (used for peripheral regional anaesthesia to allow a 30ml total volume for 10ml of air for the compressed air injection technique to monitor injection pressure indirectly. NB: can be luer lock, doesn't need to be luer slip.
- There are several holes in the equipment listed for airway management. ROTEM is listed but not TEG.
- There are several anaesthetic machines, apart from Mindray and Drager that are not listed
- Nerve stimulators
- Ultrasound machines

We note the absence of any devices used to eliminate carbon dioxide leakage and recommend that you consider purchasing:

- MDU - Mobile Destruction Unit Medclair | Medclair.com
- CDU - Central Destruction Unit Medclair | Medclair.com
- Destruction - Medicvent

Conclusion

In conclusion, we are disappointed that the list, as presented, is incomplete, poorly laid out, and missing vital anaesthetic devices; we are apprehensive about the practicalities of transitioning to a monopsony model within the given timeframe, notwithstanding its potential value. We ask that you consider the risks outlined above and seek assurance and evidence of a demonstrable cost-benefit to the public health system responsible for delivering health equity. Accordingly, we **recommend** that you develop stringent and transparent assessment processes for the inclusion/ addition/deletion of any listed device that ensure:

- Appropriate clinical input within appropriate timeframes.
- Sufficient resourcing to enable clinicians to participate meaningfully in consultation, auditing and assessment processes. Ie clinicians not expected to be consulted, undertake audits, make recommendations, and assess devices outside of their clinical hours;
- Consultation with end-users and a process to facilitate end-users to audit their devices.
- Flexibility during the transition process *and beyond* to reduce the risk of disruption of supply, and ensure timely access to devices.
- Sustainability, and specifically reduction of greenhouse gas emissions, as a criterion.

- Continued development and support of equipment officer roles and equipment groups.

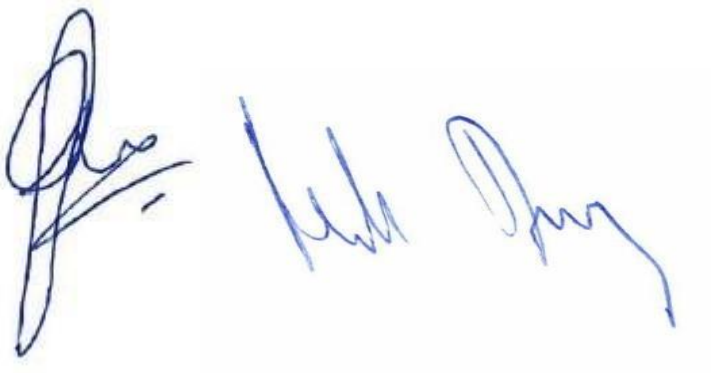
We reiterate our overriding concerns:

- There are insufficient resources within the public health system to undertake a nationwide restructure of the purchase of medical devices on top of the considerable restructuring that is already under way.
- The methodology and timeframe for such a substantial project is similarly lacking.
- There is real potential for public health services to be put under further pressure and possibly eroded.
- Where public health services are undermined, it is usually the most vulnerable that are impacted, so this is unlikely to improve health equity.
- Without widespread health sector, public and political understanding, the proposed purchasing model may fail.

Public health spending needs to be consistent with Te Tiriti o Waitangi principles and be table to improve health equity.

Again, we thank you for this opportunity to provide feedback on the comprehensive list of medical devices.

Nāku noa, nā



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References

[i]*The wrong medicine A review of the impacts of NHS reforms in England*. (n.d.). Retrieved March 30, 2025, from https://neweconomics.org/uploads/files/295a135f8d05864461_87m6iyt2s.pdf
ii Roderick P, Pollock AM. Dismantling the National Health Service in England. Int J Health Serv. 2022 Oct;52(4):470-479. doi: 10.1177/00207314221114540. Epub 2022 Jul 25. PMID: 35876348; PMCID: PMC9449439

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[i] *The wrong medicine A review of the impacts of NHS reforms in England*. (n.d.). Retrieved March 30, 2025, from https://neweconomics.org/uploads/files/295a135f8d05864461_87m6iyt2s.pdf
[ii] Roderick P, Pollock AM. Dismantling the National Health Service in England. Int J Health Serv. 2022 Oct;52(4):470-479. doi: 10.1177/00207314221114540. Epub 2022 Jul 25. PMID: 35876348; PMCID: PMC9449439