

Initial Medical Devices Activity

Submission to PHARMAC

JUNE 14, 2013

Contact

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ABOUT THE NEW ZEALAND NURSES ORGANISATION

The New Zealand Nurses Organisation is the leading professional and industrial organisation for nurses in Aotearoa New Zealand, representing over 46,000 nurses, midwives, students, kaimahi hauora and health workers on a range of professional and employment-related issues. Te Runanga o Aotearoa comprises our Māori membership and is the arm through which our Te Tiriti o Waitangi partnership is articulated.

NZNO provides leadership, research and support for professional excellence in nursing, negotiates collective employment agreements on behalf of its members, and collaborates with government and other agencies throughout the health sector. Nurses are the largest group of health professionals comprising half the health workforce.

The NZNO vision is “Freed to care, Proud to nurse”. Our members enhance the health and wellbeing of all people of Aotearoa New Zealand and are united in their professional and industrial aspirations to achieve a safe, sustainable and accessible system of public health care for all New Zealanders.

INTRODUCTION

1. The New Zealand Nurses Organisation (NZNO) welcomes the opportunity to comment on the initial activity proposed in PHARMAC's development of a common system for procurement and management of medical devices used in DHB Hospitals.
2. NZNO has consulted its members and staff in the preparation of this submission, including members of Te Runanga, Colleges and Sections, regional councils, Te Poari and the Board, and professional nursing, policy and research advisers.
3. This submission builds on previous submissions relevant to the expansion of PHARMAC's responsibilities (March, 2013; April 2010), and collates feedback from individual nurses and Colleges and Sections which may also have been submitted separately.
4. NZNO trusts that PHARMAC's strong history in maintaining value for money in pharmaceuticals will realise similar success with the expansion of activities to medical devices, though both may be adversely affected by provisions in the Trans Pacific Partnership Agreement.
5. *In general*, nurses expressed strong support for most of the listed categories and offered suggestions for subsequent procurement activity.
6. Specific feedback for each category follows the discussion below which summarises nurses' observations, cautions and recommendations for efficient procurement.

7. The experience of consulting on such a large scale, on so many general and specific categories of relevance to NZNO's 46, 000 members and specialist colleges and sections, prompts our strong recommendation for face to face consultation with relevant nursing bodies prior to, during, and after procurement. Verbal communication with individual nurses and particularly NZNO's colleges and sections elicited a depth and breadth of detailed, highly relevant information, not covered in written feedback, which exposed the real nature of what happens with the procurement of resources, both within and across DHBs. It is only through this process that underlying and systemic issues that impact health outcomes, labour use and cost, can be fully understood, and we urge PHARMAC to consider this approach.
8. Nurses are "only half the health workforce" but they are the delivery agents of care in most cases, and manage the ordering and storage of supplies. Though they are well positioned through education, training and the nursing scope of practice to be able to evaluate the net effect of purchasing decisions from both a clinical and resource management base, many nurses report frustration and disengagement as their feedback is ignored and inappropriate decisions - both in terms of health outcomes and cost - are made with respect to resources which are thrust on them without engagement, training, or any process for evaluation that offers an avenue for feedback and/or reversing poor decisions.
9. Clearly, there needs to be more transparency and two-way communication: the rationale and evidence base for decisions must be accessible and robust and systematic evaluation must be embedded, to ensure, not only the most efficient use of resources, but the confidence and skills of the nursing workforce.

DISCUSSION

10. Nurses appreciate the collaborative and inclusive consultation and anticipate ongoing involvement as activity is rolled out. However, as anticipated, they are extremely busy and many have commented that there was more - alternative scenarios, other examples, suggestions, research etc. - to cover.
11. Nor did they feel confident or well informed about the respective roles and interrelationship between the agencies involved in developing procurement processes (and associated quality and health and safety processes) i.e. Health Benefits Limited (HBL), PHARMAC, the National Health Committee, and DHBs.
12. Confusion, and an appreciable disconnect between nurses who use medical devices and decision-makers purchasing them, is a significant

barrier to ensuring cost-effective procurement. Nurses, who comprise half the health workforce, must be fully engaged, listened to, and be able to influence outcomes.

13. In general, feedback indicated confidence in the potential for improved processes and outcomes from this national initiative, *as long as* appropriate allowance is made for substantial variations in supply and demand due to local circumstances, including demographic and location differences, and the currency of service design and development. We recommend avoiding duplication where service/product use has been recently reviewed.
14. The Infection Prevention and Control Nurses College, NZNO (IPCNC) proposed the following logical sequence for identifying potential issues with infection control and prevention and recommend that, as a general rule, every product should have a IPC sign off for suitability and safety:
 - Is the item sterile – if so what are the quality controls around the sterilising process used by the manufacturer? Does this meet AS/NZ Standard for sterilisation?
 - If not sterile – should it be sterile?
 - Does the device meet standards of care provision?
 - If not single use can the device undergo reprocessing that meets microbiological and IPC standards (cannot rely on manufacturer recommendations for reprocessing as these often do not meet international standards)
 - If single use is the device routinely reprocessed anyhow – e.g. electrophysiology catheters (will have high cost implications)
 - If single use can the item be recycled in our waste stream – with so much single use disposable devices we need to be responsible for our healthcare waste disposal
 - If item is to be reprocessed what is the recommendation for sterilisation/disinfection
 - Clearly stated recommended cleaning products with all equipment/consumables as there are many varied cleaning products now used.
 - Clear messaging about ability to reprocess and number of times for certain products e.g. anti-embolism stockings, compel drapes/gowns etc.
 - User acceptability – sterile gloves is a classic
 - Different organisations have different cultures and criteria for use of devices e.g. anti embolism stockings, thermometers
15. We assume from this that there is are no major concerns with the terms and conditions provided to DHBs by the National Procurement Taskforce, though no specific feedback was provided on this point.
16. Nurses particularly look forward to a rationalisation of medical devices where there are dozens of products on the market and ongoing

innovation, for example with hip joints. They are concerned that many devices are not tested well enough; that there are many risks with individual practitioners being able to select devices regardless of cost or context; and that little thought is given to the work entailed in accommodating multiple devices - the training, the storage, reciprocity with other devices, and/or the long term consequences.

17. Rigorous testing in multiple situations with comprehensive evaluation by end users was identified as one of the most important requirement for robust procurement, who cited many examples where the opposite has occurred. For example, nurses were asked to trial suction tubes which were found to be too short, too soft and generally unreliable - they collapsed and had to be replaced frequently and were thus dangerous and expensive in terms of time, cost and optimal care. Subsequently, without further communication, the same tubes were introduced, with nurses having to bear the additional work and stress associated with poor tubing and patients being exposed to higher risk. One nurse's observation that "Evaluation is *never* robust" was echoed by many.
18. Similar experiences have been quoted with the introduction of a variety of products - inco pads, drapes, saline ampoules, and sterilisation wrap, to name a few. A common complaint is that the quality of the new products is often so inferior that more of them have to be used; another is that changes are made without consultation before or after, even when new devices require new training. A process of continuous disengagement and *disimprovement* is unlikely to empower or inspire health practitioners.
19. In general, particular caution was expressed around:
 - precipitate implementation before appropriate trialling;
 - disproportionate emphasis on item cost above good function; and
 - a narrow, service/product-focused lens rather than a whole of health one.
20. Strong support was expressed for all the initial selection areas with the exception of the IPCNC, who have reservations about reviewing hand hygiene products and sterile gloves as most DHBs have done extensive consumer acceptability of the products they currently use.
21. Additional suggestions were made for consideration of:
 - continence products;
 - cleaning products;
 - diathermies;
 - consumables associated with drug and fluid delivery/removal systems - feeding tubes, blood tubes, IV tubes, catheters etc;
 - vital signs monitoring equipment;
 - disposable monitoring leads;

- Tubifast garments; and
- diagnostic testing equipment.

22. Nurses consistently recommended consideration of the following factors when purchasing medical devices:

- quality - efficacy and reliability;
- safety - note following point with regard to evidence;
- cost (including consideration of the high cost of ongoing consumables) coupled with good function;
- compatibility;
- security of service and supply (including in emergency) i.e. service history, company support systems, ability to service sizable contracts;
- sufficient range to enable appropriate choice;
- avoiding monopolies;
- comfort and ease of use;
- shelf life and stability;
- access to mentoring, training, professional development where appropriate;
- supply chain sustainability and waste minimisation (see c22); and
- local production.

23. Supply chain sustainability involves sourcing supplies from local suppliers where possible; minimising packaging and uses recycled materials where possible; streamlining orders to reduce frequency of deliveries; encouraging suppliers to use packaging exchange system such as polystyrene bins, and requests supply chain information from suppliers. Waste minimisation includes returning to reusable products which can be resterilised where possible.

24. Evidence for most of the above is dependent on collaboration with industry, expert opinion and consensus statements by relevant health professional bodies; it is qualitatively different from the high level of objective evidence normally demanded by PHARMAC. This difference needs to be factored in to all assessment and review processes to ensure rapid and equitable access to innovative products.

25. We note PHARMAC's current review of its decision criteria and welcome the potential of a more integrated and holistic approach to health interventions that extend beyond medicine, and towards optimising health.

26. Notwithstanding the foreshadowed, but as yet unconfirmed, actions arising from the Report by the Independent Taskforce on Workplace Health and Safety, NZNO is concerned with the poor level of awareness and mitigation of occupational health and safety risks in the health sector. These include known risks associated with medical devices, for

example, diathermy plumes, crate weights of sterilising and orthopaedic equipment, and wide range protective equipment - drapes, gloves, pads etc. In addition, innovative products by definition carry novel risks.

27. In the absence of evidence that a robust framework for monitoring and mitigating occupational health and safety risks in the health sector exists, NZNO strongly recommends that potential occupational health and safety risks be a mandatory part of the evaluation of all medical devices.
28. Finally, while not relating to the current selected categories, we take the opportunity to pass on feedback received on compatibility issues relating to what may potentially be procurement categories- enteral feeding tubes, and central venous lines.
29. *There are large numbers of children who are fed by enteral feeding tubes short, medium and long term. Percutaneous and nasogastric tubes are used in these instances. There is a safety issue with feeding tubes when they are used in hospitals. If the tubes fit IV syringes rather than oral syringes (which have a wider tip) there is a potential risk that someone will attach a syringe that has a food substance inadvertently to an IV line and give a bolus of food IV. I have read evidence of yoghurt (intended for the gastrostomy) being given by IV line by mistake with catastrophic results. Tubes come with a variety of ends. It would be a quality issue to make sure that feeding tubes had ends that were not compatible with IV syringe tips.*
30. *With central venous lines: Peripherally inserted central catheters are increasingly used for medium term venous access and blood sampling (PICC). There are different types of PICC lines on the market, some of which can be trimmed to suit children better. Some have centimetre increments marked up the length of the tube to help ascertain tube migration (a potentially fatal complication resulting in cardiac tamponade). Some PICCs have a tapered shape to prevent inward migration. These are all qualities that would be good to consistently see in a PICC line as they prevent harm.*

CATEGORIES

Anti-Embolism Stockings

31. This was identified as an important area of preventative health which would reduce costs overall.
32. The most important factor to consider is how easy they are to put on; a very wide range of sizes is necessary.

33. It must also be clear if they can be washed and remain effective. New Zealand Laundry standards would need to be met and consumers provided with very clear instructions.
34. It may be relevant to note in this context that nurses report that the use of tubifast garments is becoming more widespread in the treatment of eczema. Currently they can be individually purchased online - they are not always available in pharmacies - and are prohibitively expensive. Similarly Reynard disposable face cloths used for wet wrapping eczema children and babies. Better buying power would make these product lines cheaper for consumers and as these conditions can persist over many years the net savings would be considerable.

Disposable Sterile Instruments

35. Because of the high loss rate of reusable medical devices, there is a need to use disposable sterile instruments and this is mainly confined to a small group of specialities e.g. Delivery suite, Wards/Clinics and Emergency Departments. The cost of single use versus replacing quality surgical instruments is attractive. Theatres use high quality reusable instruments, but are tending towards disposables for fine lumened items such as small suction tubes which are exceptionally difficult to clean.
36. The primary problem with single use instruments is guaranteeing that they are of sufficient quality and strength to do the job they are required for. They need to be: fit for purpose; sturdy and with good action and grip; available in a range that includes finer instruments; available in a variety in the make-up of suture packs for individual EDs/DHBs; and, if possible, recyclable. The College of Emergency Department nurses note that currently some departments pass sterilised disposable instruments on to vets, or to sell as scrap metal.
37. To ensure that the correct grades of instruments are purchased, some DHBs ensure that all instrument purchases, reusable or single use, are approved prior to purchase by the manager of the Sterile Services Dept. This is reflected in the DHB policy and also in the intent of AS/NZS 4187:2003 :12:1 which states : *"Those responsible for reprocessing reusable instruments and equipment shall be involved in the selection process, prior to the purchase of instruments"*
38. Disposable instruments offered for sale in New Zealand should also bear the CE mark for the European Community and be processed under quality standards that meet the requirements of ISO 13485. Any national purchasing /tenders for supply of single use instruments should involve negotiation with the recognised experts in sterilising technology and instrument management and procurement. Members of the executive of the New Zealand Sterile Services Association should be invited to contribute to this process.

Hand Hygiene

39. This is regarded as a priority area because of its ubiquity, but the IPCNC cautions that a lot of work has already been done in this area which should not be duplicated. They stress the importance of consumer buy-in and the need for DHBs to make their own choices based on population and service needs and the epidemiology of regional microbiology - for example many DHBs would NOT favour a Chlorhexidine component in their product. The cost of a hospital acquired infection may outweigh potential savings of a nationwide product introduced and not accepted by staff.
40. Products that were cited included Microshield 4%; Chlorhexidine hand wash; Microshield hand gel; and Microshield moisturiser; and Sterigel. Distribution varies according to acuity, for example, from every bed side for high acuity beds, to each washstand in each room/ward, and in public locations, for example, hospital entrances.
41. While nurses assume there is an opportunity for cost saving due to economies of scale, they also noted potentially prohibitive costs associated with trying to standardise the vast array of containers in use. There may be an opportunity for PHARMAC to develop a purpose-designed container and holder.
42. The challenge for hand hygiene products in relation to dermatitis caused by frequent hand washing and allergic reactions is well known and that is to improve moisturisers in anti microbial hand gels whilst maintaining the anti microbial quality. Hand products need to be quick drying. It is essential to both evaluate products for their potential to cause skin sensitivity which increases the risk of cross infection, and to provide alternatives.
43. Another challenge is securing containers and holders without compromising ease of refill. Nurses are not infrequently sprayed and/or assaulted with bottles of hand wash that have been removed and theft is an issue in many facilities.
44. It is not unusual for patients to ingest hand gels, so low toxicity is another requirement.

Interventional Cardiology

45. Feedback in this area was very limited.
46. Nurses noted that this was a competitive area with private companies being very proactive in bringing information about technical advantages to clinicians' attention. However, the wide range of products can be problematic and there is potential to for cost savings by reducing the number of suppliers though care needs to be taken to ensure that this does not reduce the potential for innovation.

47. The IPCNC noted that there were issues around reprocessing single use catheters – e.g. electrophysiology catheters.

Mechanical Compression Devices and Consumables

48. The cost of consumables for these devices was also identified as an important factor to be taken into consideration.
49. There is a risk with some devices that are manufactured as single use items but appear to be robust enough to be able to be reprocessed; this can be dangerous for the patient.
50. IPCNC note that because of perceptions about waste, inappropriate reprocessing does occur. These considerations must be taken into account when considering single use items and the impacts of disposal.
51. Often the company provides the machines and the organisation, with Material Managements in-put, and consumables are bought at a contracted price. There are some reusable ones available. In some specialties the devices are used pre, intra and post-operatively and follow the patients. Other services use the devices only intra-operatively.
52. This is definitely seen as a growth area with prophylactic management of DVTs high on patient safety agenda for many organisations. In some DHBs each patient is risk assessed on admission.

Orthopaedic Implants – maximisation of suite of contracts

53. There are numerous challenges/opportunities in this area including the ability to:
- reduce inventory stock in the department;
 - rationalise training opportunities for staff - i.e. staff wouldn't have to learn multiple systems;
 - reduce costs increase competition therefore more opportunity to bring the cost down
 - increase the security of supply - note that with everyone using the same products, it will be a challenge to ensure there is enough stock on hand, however it will be easier to manage a smaller range.
54. As an example of the range of products being dealt with, some nurses report that they manage up to 63 different hip joints and dozens of 'stems' to service the personal preferences of around 17 surgeons. Most of these are not interchangeable and have specific requirements for other components such as hip cups. Similarly specialised equipment is required to insert implants much of which is loaned. This places a huge burden on management and storage systems, and on ongoing and essential education and training.

55. Nurses are also concerned that the outcomes of some new devices will not be known for many years and that later it may be difficult to access all the appropriate components and information. Nurses felt a more cautious approach was needed for the introduction of new devices and techniques. For example 'resurfacing' of hip joints was rapidly adopted in Australia a few years ago but problems are now emerging. A system adopted in some private hospitals is that a new device cannot be used unless at least three doctors agree and intend using it and nurses recommend that such an approach be adopted in the public system as a means of reducing wastage without substantially limiting choices.
56. A neglected consideration for these products and also the sterilising trays and equipment below is the way they are packaged and delivered and the lack of safe and consistent handling requirements. While 7kg is becoming the accepted international standard for crate weights, nurses are frequently expected to repeatedly lift loads of 15Kg or more over long periods when equipment arrives and is being prepared for theatres. The example shown in fig. 1 is not atypical, except that it does at least have a warning notice which is not altogether common. Contracts for provision of heavy products must include directions that protect the health and safety of those managing them. Please note that the Perioperative Nurses College, NZNO has undertaken extensive research with regard to crate weights.



Figure 1 delivery sticker, Orthopaedic supplies

Sterile Surgical Gloves

57. Meeting the needs of the various surgical specialities from the thickness required for protection e.g. Orthopaedic surgeon versus a thin and delicate glove for an ophthalmic surgeon, and reducing the risk of allergy (particularly latex allergy) and skin sensitivities are common themes raised by nurses.
58. NDICN notes that most DHBs have garnered very good contracts for surgical gloves and that it is very difficult to persuade surgeons to change their sterile glove preferences.
59. An agreed non latex surgical glove is a priority.
60. Other issues raised were:

- the need for robustness - latex gloves can be affected by the anti microbial hand gels;
- Security of supply - New Zealand currently has very limited resources to back fill supply if there is any interruption to overseas supply;
- Indicator gloves versus non indicator gloves are favoured by some specialties to highlight perforation detection to protect both staff and patients.
- Ease of use - some gloves stick together and are hard to put on without perforating.

Sterilisation Wrap, Tray Liners and Associated Consumables

61. Sterile wrap is one type of barrier product used in the sterilisation process of reusable medical devices; other products are reusable sterilisation containers and sterilisation pouches. The product used depends on the type of instrument and Sterile Services department preference, which must all conform to AS/NZS Standards.
62. Sterile Services are the largest user of sterile wrap. It is usually used in theatres, outpatient clinics, and endoscopy units only *after* the items have been wrapped and processed in sterile service units. The standard AS/NZS4187:2003 which guides practice in NZ sterile services already identifies what is required in a barrier fabric. The NZSSA as the specialists in this area should be consulted to develop national guidelines on the above; all products need to be evaluated in terms of use, waste management, and potential recycling.
63. One sterile wrap now in use was trialled by perioperative nurses and found to be far too thin to protect against cuts; a double layer is necessary with this product. The process by which feedback was sought, but ignored without further communication or reporting, was both disrespectful and unsafe; the roll out of the product without communication of prior learning as to its safe use in particular circumstances guarantees unnecessary 'trial and error' at the expense of staff and patients' health and safety. Procurement processes need to ensure advice and feedback on all areas is sought and encompassed.
64. While there are regional contracts in place regarding these products, there are wide variations in requirements and many factors to consider - one size does not fit all. The product must be validated against individual autoclaves and cycles and validated for different loads and weights. (Note comments above regarding crate weights). We note that there are costs involved in all validation processes.
65. The quality of the steam in an autoclave in Wellington will be different to that in Auckland and effect the product substantially. It is imperative that PHARMAC first meet and discuss this with the NZSSA and other relevant professional bodies, to gauge what is currently being undertaken and the effects of the changes to standard AS/NZS4187 in 2014.

Sutures

66. There were mixed opinions over whether there were distinct sub categories for sutures, with some noting that sutures can be linked in with the use of particular equipment from different companies, and others commenting on service use, for example, the use of thread in primary health care by general practitioners. An obvious distinction is between absorbable and non absorbable sutures.
67. Nurses did note that some sutures break easily, though that may be dependent on technique and strength, and that thread was particularly prone to creating irritation and the risk of infection. Though there is a lot of developmental work going on in this area, they felt that the results were not always well communicated and guidelines were needed to ensure practitioners needed were kept abreast of best practice.
68. The College of Emergency Nurses (New Zealand) (CENNZ-NZNO) suggested that a useful addition would be the availability of a cheaper option for teaching purposes as it is costly to use sterile sutures for teaching but there is no other option.
69. A further recommendation was made for an account manager to ensure the timely rotation of stock in each DHB, as, for example at Auckland City hospital, where the account manager rotates stock through different departments.

Thermometers

70. Thermometers types include:
- BD digital thermometers
 - Welch Allyn sure temp thermometers
 - Tyco digital thermometers
 - Mercury thermometers for neurosurgery,
71. The most common thermometers seem to be tympanic and oral digital. Both have their issues. Tympanic temperatures vary by user technique (ear canal straightened and pointed at tympanic membranes or not, and waxy, hairy ears). Oral digital thermometers are hard to keep against buccal membranes in frail older adults: they may breathe through their mouths, not understand or have lost sensation. Oral thermometers are often kept in nurses pockets which are not sanitary.
72. Thermometers are high risk as vectors of infection. All parts must withstand a sporicidal disinfectant. NDICN advise strongly against thermometers that have reusable parts that cannot be disinfected, or are single use but are likely to be reused.
73. Infra red thermometers that do not physically touch the patient are being

introduced in health and these have the potential to eliminate additional costs for covers for hygiene.

74. The most important quality needed in a thermometer is accuracy because wrong readings can lead to unnecessary interventions. For example, neonates' temperature is recorded by measuring axilla temperature. The target is between 36.7 degrees centigrade and 37.2 degrees centigrade. Temperature readings 0.2 below or above this range can be caused by the environment temperature *or* infection. Confusion can lead to an alteration in environmental temperature *or* a blood work-up for suspected sepsis. An inaccurate thermometer can thus cause unnecessary stress on a neonate and/or unnecessary costs. Tyco digital thermometers were introduced to one NICU without consultation and erroneous results were recorded, compared with BD digital and servo incubator temperature readings.
75. Some thermometers are designed to work in specific environments. For example a US diabetic ulceration thermometer trialled was designed for use in air conditioned offices which are not common in New Zealand. It is essential to be sure of the accuracy of the thermometer regardless of the ambient temperature.
76. Other factors that need to be considered are suitability for all age ranges; speed; durability; and security (i.e. they are often stolen so hand-held devices must have the capacity to be fixed to a large object).
77. Finding an alternative for mercury thermometers used on the sterile field is another challenge.
78. Any procurement of thermometers would require consultation with appropriate staff across a wide range of services since thermometers are a primary assessment tool.

Wound care

79. A range of opinions was expressed about subdividing this category which encompasses an almost limitless list of products with application to diverse health needs - "burns, plastics, silver, eyes" (Note the attached Chart of Primary Dressings document compiled NP Pip Rutherford).
80. Wound care overlaps many traditional boundaries of care, so there is a rationale for keeping the category as comprehensive as possible to allow a holistic perspective to inform decision-making. On the other hand there are significant differences between wounds from major and minor surgery, and cases done under local anaesthesia versus the ones performed under general anaesthesia.
81. Another suggestion is to follow the pan-pacific guidelines and have a group for leg ulcers and a combined or separate complex/chronic wound group which would comprise the older adult group for the most part. This could then be broken into product groups hydrocolloid, non adherent, absorptive,

alginate, foam etc

82. The major challenge with wound care is to ensure appropriate classification. Currently wound care is treated as a consumable cost rather than a treatment (DRG ICD10) and does not attract the appropriate case weight resourcing. For example, "consumables" is an inaccurate description of the wound care *treatments* used for total body surface burns, trauma, wounds secondary to dermatology, pressure treatments for diabetes, vasculitic wounds, and soft tissue infection, for example. Accurate recognition of cross functional treatments/products in wound care could be hugely beneficial in reducing costs and improving health outcomes, particularly in areas of escalating demand such as diabetes and infectious and skin diseases.
83. The Gerontology Nurse Section notes that wound healing is slower in the older adult population, which is growing. Wound healing in this group is as much about co-morbidity as it is about the wound care product, and this needs to be factored in when considering products. Incorrectly matching wound product and wound type causes patient harm and having a clinical advisory group is the right approach.
84. Wound care nurses and specialist/practitioners are key for the older age group as, for chronic wound management and conservative (non surgical) management of leg ulcers, their knowledge, skills and clinical exposure is extensive and beyond that normally encompassed by GPs. From a patient perspective, in practice there can be confusion between GPs/Dr and NP/CNS recommendations for wound care as there are so many products. In aged care the default answer is often to use "what causes us the least problem". Resources that identify the recommended product may be a platform to avoid such situations. Residential aged care facilities are substantial users of wound care products and for that reason it would be useful to have someone with a gerontology perspective on any clinical advisory group.
85. In this area as in others, we would caution about the risks of focusing only on the price of the product as an expensive dressing that stays on for five days is cost effective compared with alternative daily dressings, if the nursing time is factored in.
86. There is support for national standardisation of wound care as long as appropriate clinicians are involved in all processes. A standard catalogue could make easier to manage the products for wound care and when wounds are dressed consistently and appropriately, health outcomes are improved and wastage is reduced. There would be substantial benefits for out of town patients in being able to access the same products in their home district; it would make the patient journey more coherent through consistent teaching and reinforcement, and increase compliance in self wound care.
87. Sound education and training to optimise correct and consistent use of products would be required for experts and non experts alike. Nurses are

interested in being able to access clear guidelines/teaching tools/ support processes to help select and apply the right product for the right wound for example through online wound simulations modules. Access to such tools significantly impacts on cost and national procurement could provide an opportunity for developing national guidelines and reducing constant writing/reviewing of guidelines/procedure/tools/education etc duplicated in DHBs, aged care organisations, and district nursing teams.

88. NZNO notes that there are currently only three Nurse Practitioners specialising in wound care in Aotearoa and that comprehensive post graduate education, such as that at Monash University, Australia, is not available here. Industry is providing most of the education and support, and it is through these sources and the Australia Wound Management Association, the New Zealand Wound Care Society and the European equivalent that nurses have access to, and can contribute to innovation, research and expert consensus.
89. As noted previously, the evidence base for wound care necessarily differs from the double blind and randomised control trials which provide the evidence base for pharmaceuticals. For obvious reasons, it is not possible to have a placebo, and it is very difficult indeed to find comparison populations; yet, the high level of turnover and innovation demand qualitative assessment and timely updating and review to ensure the best care possible. The consensus statements of the aforementioned wound care bodies are current and based on expert knowledge, experience and practice. They provide appropriate standards for wound care and the Australasian bodies in particular need to be consulted on all aspects of wound care procurement. This is an areas where needs can differ markedly, not only between individuals but also between communities and locations. Appropriate treatment in cities may be impossible to deliver in rural locations, for example.
90. Wound care products need to be available in a wide variety of shapes suited to different ages and locations. Water gel dressings which are an important pain relieving measure in the initial management of burns, for example, must be available in both face and hand dressings.
91. Other factors that need to be considered in relation to products include shelf life, stability, cost of transport, access to mentoring, and professional support. An account manager to manage stock within and across the DHB would be useful.
92. While acknowledging the potential benefits from national procurement, the variables within this section are so wide, that nurses are concerned that access to potentially better treatments/ technologies/ products will be limited. Limitations of personal preferences where outcomes are not affected may be reasonably accommodated, but there are many situations where "choice" is clinically based. For instance, neonatal skin in infants below 31 weeks gestation is very immature in the first week of life, with only one layer of epidermis and it can take up to four weeks to mature to full thickness. Any loss of skin integrity can cause infection,

scarring and an increase in trans-epidermal water loss, all of which compromise the infant. It is essential that the product range matches the range of health needs. Where multiple choices exist within a particular service, a consensus may be required, but consensus in one service area must not be assumed to apply to other areas.

93. The IPCNC note that some DHBs have done a lot of work on wound care consumables and this should not be duplicated. As improvements have been made, staff trust in the latest wound care formulary, costs are controlled and DHBs have contracted suppliers. They also note that standardisation within a single DHB is extremely difficult, and may foreshadow significant problems with standardisation nationwide.

CONCLUSION

94. In conclusion, NZNO supports national procurement of these medical devices and recommends that you note in addition to the areas of concern, recommendations for alternative categories, and factors to be considered summarised in clauses 19-22, that you particularly note the need the following, less obvious requirements that need to be embedded in procurement processes, namely:

- Face to face consultation
- Sustainability;
- Evaluation;
- Two way communication
- Appropriate testing across a range of services; and
- Occupational health and safety

95. NZNO is in a position to solicit feedback from nurses in all health settings throughout Aotearoa and would like to be kept informed of PHARMAC's progress in all categories.

96. Members of our specialist Colleges and Sections in particular are interested and able to offer clinical opinion and we would be happy to facilitate this.

97. Finally, NZNO reiterates its support of PHARMAC's national procurement of medical devices, as well as its concern that the projected gains may be threatened by extended patent protections in the Trans Pacific Partnership Agreement, which may affect the cost of medical devices/treatments as well as pharmaceuticals.

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