

Reuse of single-use medical devices in sterile sites: how often does this still occur in Australia?

Peter J Collignon,* Dianne E Dreimanis,†
Wendy D Beckingham†

* Director, Infectious Diseases Unit and Microbiology Department; † Clinical Nurse Consultants, Infection Control; The Canberra Hospital, PO Box 11, Woden, ACT 2606
peter.collignon@act.gov.au

TO THE EDITOR: Single-use devices (SUDs) are in common use, and many are reprocessed.¹⁻⁷ When examined, these devices are frequently not clean and have residual biological material on or within them.^{2-4,6} This material may contain viruses or other infectious agents. SUDs are usually made from plastics or other heat-sensitive materials resulting in less effective means being used for sterilisation than can be used for more robust materials — chemical disinfectants can be ineffective in the presence of organic material, and have poor penetration compared with heat (eg, an autoclave).

In 1994 we found that, of 168 Australian hospitals reviewed, 68% were reprocessing SUDs used in sterile sites.¹ We repeated this survey (using a similar questionnaire) in 2001, in acute-care hospitals with more than 45 beds. The questionnaire was sent to 461 hospitals — 181 private hospitals (117 with fewer than 100 beds, 59 with 100–300 beds, and five with more than 300 beds) and 286 public hospitals (115 with fewer than 100 beds, 116 with 100–300 beds and 55 with more than 300 beds). Responses were received from 189 (see Box 1). Not all respondents answered all questions and many responded anonymously. Reuse of SUDs still occurred in all states and territories, but compared with 1994 the rate had

1: Number and types of hospitals reusing single-use medical devices

Type of hospital	Number reusing devices/Number respondents				Total respondents
	Bed numbers				
	Unknown	<100	100–300	>300	
Unknown	0/1	0/2	1/4	1/1	2/8 (25%)
Public	0/1	5/41	4/44	7/13	16/99 (16%)
Private		4/40	6/36	0/2	10/78 (13%)
Combined public and private		0/2	0/2		0/4
Total respondents	0/2	9/85 (11%)	11/86 (13%)	8/16 (50%)	28/189 (15%)

dropped to 15% (28 hospitals). Large hospitals reused more often than smaller hospitals (see Box 1). Reuse was slightly lower in private hospitals than in public hospitals (13% v 16%). Rural hospitals reused SUDs less often than metropolitan hospitals (12% v 16%).

The commonest SUDs reused were diathermy pencils. Given their low cost (\$5), the labour costs of reprocessing would exceed the cost of replacement. Diathermy pencils (Box 2) have spring-loaded buttons, which inevitably become contaminated with blood during surgical procedures. Thus, the potential exists to contaminate the surgeon's fingers during subsequent procedures. We believe that reusing such relatively inexpensive items is inappropriate from both financial and infection control perspectives. An Australian National Health and Medical Research Council (NHMRC) report stated that, after reprocessing and packaging in hospitals, almost all SUDs were contaminated with foreign material (including blood), and several pacing electrodes had damaged insulation.⁶ Other studies have shown that blood persists on cardiac ablation catheters when structural abnormali-

2: A diathermy pencil



ties (which occur frequently and early) are present.³ The reuse of these devices has been reviewed by the NHMRC and important changes have been recommended.⁶

Reuse of SUDs has been common in many countries. In the United States, reprocessing is frequent (eg, 2.5 million devices by one commercial reprocessor).⁵ In 2000, the US Food and Drug Administration issued a policy that, for practical purposes, should abolish the practice of reprocessing SUDs in hospitals.⁴ In Australia, the Therapeutic Goods Administration recently announced that reprocessing of SUDs will be regulated.⁷ This should have a similar effect.

As the methods and response rates of our two surveys were similar, we believe that the reuse rate has decreased. However, proportionately, fewer large public hospitals responded (only 13 of 55, or 24%, compared with 41% overall), even though they have the highest reuse rate (54%). Therefore, we are likely to have underestimated the actual rate of reuse. Also, those who are reusing may be less likely to admit to this practice, and thus less likely to respond.

Correspondents

We prefer to receive letters by email (editorial@ampco.com.au). Letters must be no longer than 400 words and must include a word count. All letters are subject to editing. Proofs will not normally be supplied. There should be no more than 4 authors per letter. Each author should provide current qualifications and position and full details of postal address, telephone and facsimile numbers.

There should be no more than 5 references. The reference list should not include anything that has not been published or accepted for publication. Reference details must be complete, including: names and initials for up to 4 authors, or 3 authors et al if there are more than 4 (see mja.com.au/public/information/uniform.html#refs for how to cite references other than journal articles).

Reuse of SUDs in sterile sites remains common practice in Australian hospitals (although the rate is lower than it was in 1994). Most SUDs appear to be unsuitable for reuse as they cannot be adequately cleaned and sterilised. We strongly advise against further reuse of these items.

1. Collignon PJ, Graham E, Dreimanis DE. Reuse in sterile sites of single-use medical devices: how common is this in Australia? *Med J Aust* 1996; 164: 533-536.
2. Heeg P, Roth K, Reichl R, et al. Decontaminated single-use devices: an oxymoron that may be placing patients at risk for cross-contamination. *Infect Control Hosp Epidemiol* 2001; 22: 542-549.
3. Avitall B, Khan M, Krum D, et al. Repeated use of ablation catheters: a prospective study. *J Am Coll Cardiol* 1993; 22: 1367-1372.
4. Favero MS. Requiem for reuse of single-use devices in US hospitals. *Infect Control Hosp Epidemiol* 2001; 22: 539-541.
5. Charatan F. Controversy erupts over reuse of "single use" medical devices. *BMJ* 1999; 319: 1320.
6. Report of the NHMRC expert panel on re-use of medical devices labelled as single use. Canberra: National Health and Medical Research Council, 1997. Available at: <http://www.health.gov.au/nhmrc/publications/pdf/ic8.pdf> (accessed Jun 2003).
7. Therapeutic goods (medical devices) regulations 2002 (Draft). Canberra: Therapeutic Goods Administration, 2002. Available at: <http://www.health.gov.au/tga/docs/pdf/devregdr.pdf> (accessed Jun 2003). □

Clifford F Hughes

Head, Department of Cardiothoracic Surgery,
Royal Prince Alfred Hospital, Suite 304,
100 Carillon Avenue, Newtown, NSW 2042
clifford.hughes@email.cs.nsw.gov.au

COMMENT: The letter by Collignon, Dreimanis and Beckingham about reuse of single-use medical devices (SUDs) in Australian hospitals again brings in to stark contrast the issue of safety and quality of medical devices and the pressing need to provide affordable services to the Australian public. Seven years ago, Collignon and colleagues showed an unacceptably high reuse of SUDs in Australia, especially in public healthcare institutions.¹ Since then, the National Health and Medical Research Council (NHMRC) has produced an expert panel report on these devices² and the Therapeutic Goods Administration has promulgated detailed device regulations.³ There has been continued debate in both the scientific literature and lay press, and the United States Food and Drug Administration has had extensive comments published on this matter.^{4,5}

Given the intensity of this debate, it is surprising that so few hospitals completed the questionnaire. It is also surprising that, despite the overall reduction in the reuse of SUDs, there has been no apparent reduction in their

use in large public institutions, 50% of which continue the practice. Collignon and colleagues have not investigated the quality control mechanisms in place in these hospitals. That could well be a subject for further research.

Not so obvious to the casual user is the effect of re-sterilisation on the materials of the device. The authors allude to the potential for degradation during sterilisation. There is inevitable pressure to use less effective (chemical) means for re-sterilisation.

On the other hand, the waste of an enormous resource that, if safe, could be readily reused must be recognised. The costs of devices are easy to quantify. The costs of re-sterilisation, not to mention quality control, less so. Collignon et al suggest one example of false economy in the reuse of a low budget but commonly used item — diathermy pencils.

They make a strong case for mandated reporting of re-sterilisation protocols for all single-use items. Informed consent must be a prerequisite. Tracking systems could well provide beneficial information on the safety and efficacy of procedures for particular devices. Furthermore, clinical audit would provide an early warning mechanism should re-sterilisation prove inadequate. These are among the main recommendations of the Report of the NHMRC Panel.²

Extensive regulations and controls have been applied to the use of biological products such as dura mater, heterograft and cardiac valves, among others. There is, however, reluctance to apply similar stringent controls to devices which may be contaminated by more pervasive but less obvious biological hazards.

There are only three options:

- cease this practice wherever a viable alternative is available until there is incontrovertible proof of the safety of reuse;
- mandate detailed protocols which include audit and surveillance mechanisms coupled with appropriate informed consent whenever SUDs are reused;² and
- develop a research and evidence base for improvements in design and material technology so that the “cost efficient

” of single-use devices could be translated to “non-disposable items”.

All three must be adopted.

Competing interests: Professor Hughes is a Member of the Australian Council on Safety and Quality in Health Care and was formerly Chairman of the Therapeutic Device Evaluation Committee for the federal government. He regularly consults with the device industry and is medical director of the Australia and New Zealand Heart Valve Registry, an independent but industry-sponsored device-tracking program.

1. Collignon PJ, Graham E, Dreimanis DE. Reuse in sterile sites of single-use medical devices: how common is this in Australia? *Med J Aust* 1996; 164: 533-536.
2. Report of the NHMRC expert panel on re-use of medical devices labelled as single use. Canberra: National Health and Medical Research Council, 1997. Available at: <http://www.health.gov.au/nhmrc/publications/pdf/ic8.pdf> (accessed Jun 2003).
3. Therapeutic goods (medical devices) regulations 2002 (Draft). Canberra: Therapeutic Goods Administration, 2002. Available at: <http://www.health.gov.au/tga/docs/pdf/devregdr.pdf> (accessed Jun 2003).
4. Lewis C. Re-using medical devices: ensuring safety the second time around. *FDA Consumer Magazine* Sep-Oct 2000. Available at: http://www.fda.gov/fdac/features/2000/500_reuse.html (accessed Jun 2003).
5. Re-using disposable medical devices. US Food and Drug Administration, Center for Devices and Radiological Health, 2000. Available at: <http://www.fda.gov/cdrh/Reuse/napsreusarticle.html> (accessed Jun 2003). □

An evaluation of a SAFE-style trachoma control program in central Australia

Graeme H Johnson,* Donna B Mak†

* Acting Public Health Medical Officer, † Former Public Health Medical Officer, Kimberley Population Health Unit, Derby, WA 6728.
graeme.johnson@health.wa.gov.au

TO THE EDITOR: In their study of a SAFE-style trachoma control program (which included *Antibiotic* treatment, *Facial* cleanliness, and *Environmental* improvement, but not *Surgery*) in a remote Australian community, Ewald et al suggest that no systematic SAFE trachoma control program exists in Australia.¹

In the Kimberley region of Western Australia, the Kimberley Public Health Unit (KPHU) has coordinated a trachoma control program since 1989. The World Health Organization SAFE strategy has been implemented since 1996, as described in the Kimberley regional trachoma control guidelines and a peer-reviewed publication.^{2,3}

The trachoma control program in the Kimberley has been delivered by a variety of environmental health, health promotion, community and clinical health professionals employed by State and local governments, and by community-controlled and other non-government organisations. We believe a coordinated