Welcome to New Members

The first APLA Membership Directory has been circulated to members. Updates for the directory will be produced on a regular basis. The following are the members who have joined since the release of the directory:

Mr Adrian Meegan, SA
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Mr Matthew Mitchell, NSW
Mr Len Levy, Barrister, NSW
Mr Sukwant Singh, WA
Mr Ian Walker, UK
Mr Steve Churches, SA
Mr Sergio Bacchetti, VIC
Ms Dianna Prosser, ACT
Mr Stephen Roche,QLD
Mr Hugh Dalton,QLD
Mr Michael Cope, QLD
Mr Mark Bolster, NSW
Mr Allan Warnick, QLD

Mr Rodney Parker QC, NSW

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Re-Use of "Single Use " Devices - Hospital Liability and the Nurse's Dilemma.

Angela Sdrinis,[Accredited Personal Injuries Specialist], Partner, Ryan Carlisle Thomas, VIC

Over recent months there has been an increasing level of concern over the prevalence of the practice of reuse of devices that have been designated as single use only by the manufacturers.

Unfortunately, the whole debate has been muddied by what appears to be a lack of research, particularly on the part of the hospitals, as well as the clearly conflicting economic interests which are involved. That is, it is clearly in the manufacturers' interests to designate devices as single use only whereas the hospitals have an interest in re-using devices as often as possible.

Further, in the midst of the debate are the patients, who, more often than not, are completely ignorant of the situation, and nurses, who are in the difficult position of being expected to follow a hospital policy which many fear will lead to serious infection and/or death.

In terms of legal liability, hospitals are certainly at risk, both at common law and under the <u>Trade Practices Act</u> 1974 [Cth], if they allow, or indeed enforce a re-use policy without proper research and justification.

In other words the fact of the designation of an item as single use only by the manufacturer is not of itself conclusive evidence that an item cannot be safely reused. Certainly, in terms of medical negligence claims against a hospital, if the hospital could establish that there had been adequate research which had established that re-use was "safe" a potential plaintiff might have real causation problems. ("Re-use of Single Use Devices. Beware the Legal Pitfalls" Suzie Laufer, [1993] 2 HLB)

Putting aside the <u>Trade Practices Act</u> 1974 [Cth] where different considerations apply, the real problem for hospitals at the moment is that very little research appears to have been done.





Indeed whereas there have been demonstrated risks such as infection due to inadequate sterilisation, reduced efficiency of the device and a risk of toxic reaction caused by residual proteins from the sterilising agent, little has been done to put hospitals in a position where they can call evidence that certain items can be re-used once, twice or indefinitely despite the single use only tag.

Further, some hospitals in an attempt to appear to be protecting their patients have developed policies which are completely self serving and which basically place the entire responsibility of re-use on the user, usually a nurse.

These policies basically state that items should not be re-used unless the user can guarantee the "integrity of the item"! To be able to do this a nurse would have to also moonlight as a materials engineer and have access to testing equipment which is not available in most hospitals.

The other consideration in medical negligence claims is the patient's right to know and be advised of risks associated with certain procedures. Whilst Rogers v Whittaker [1993] 67 ALJR 47 does not actually impose an obligation on health providers to obtain informed consent, it is clear that failure to warn of risks can form the basis for liability.

The <u>Trade Practices Act</u> also provides fertile ground for legal liability in this area. Sections 52 to 55 which prohibit misleading or deceptive conduct would certainly be relevant. In particular, many nurses complain that some private hospitals re-use single use devices but charge the patients as for new ones.

Sections 71 to 74 deal with warranties and s75AA deals with "defective" products. All of these sections include the processing of goods. To this extent there is little doubt that hospitals could therefore be regarded as "manufacturers" for the purposes of the Act. Further, in the case of "E" v Australian Red Cross Society and Ors.[1991] ATPR 41-085, it was determined that hospitals can be regarded as "trading corporations" and similarly the Act would therefore apply.

Accordingly, given the "right set of facts" there is little doubt that hospitals could be held liable if injury did occur. This however does not give much joy to nurses who are in the unenviable position of having to enforce policies that they believe are putting their patients at risk.

Questions arise therefore as to a nurse's [or indeed any other health professional's] position where they disobey a "lawful order".

Clearly, there is no requirement to obey an unlawful order. In this connection, hospital policies could not currently be regarded as "unlawful" although it could be argued that in re-using single use items, hospitals are in breach of the Therapeutic Goods Act 1974 [Cth] which requires compliance with the Code of Good Manufacturing Practice for Sterile Medical Devices. Whilst clause 6.5 does allow for reprocessing, query whether this would include "single use devices".

Assuming however that re-use is "lawful" what is the nurse's position? It is often said that an employee must obey all such instructions that are reasonable. By implication, a refusal to follow such direction as is unreasonable is permissible.

This area of law is not entirely satisfactory and it is not possible to say on current case law that a nurse in these circumstances would be justified in refusing to reuse a single use device. Unfortunately, the courts have not really grappled with the question of a conflict of duties where an employee clearly owes a duty to his/her employer but also owes a duty to his/her patients.

Having said that, it would be a brave employer indeed who would sack a nurse for refusing to follow a reuse policy particularly given the current community concern in relation to the transmission of the HIV virus and Hepatitis C.

Membership

Membership currently stands at 144
If you have colleagues who should join
APLA please call Anne Purcell,
Co-ordiniator
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APLA needs your

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