RESPONSIVENESS TO THE CHLORHEXIDINE EPIDURAL TRAGEDY: A MENTAL BLOCK?

Paralysis following an epidural anaesthetic is a rare event. The mechanism usually involves accidental injection of skin antiseptic instead of local anaesthetic. Two recent cases, one involving paralysis, the other a “near-miss”, are described. The first case resulted in an extensive root cause analysis and an admission of liability by the hospital. The response of the anaesthetic community and the New South Wales Department of Health was swift but failed to produce uniform protocols across the region. Furthermore, the requirement of medical staff to double check medications with a second person before their administration was not addressed. Abandoning a more effective but neurotoxic antiseptic solution in favour of a solution with weaker antiseptic properties, as had previously occurred in one Sydney hospital, could incur higher risks of epidural infection. Defensive medical practice can lead to unwanted negative consequences.

INTRODUCTION

On 26 June 2010 a 32-year-old primigravida, Mrs Grace Wang, requested an epidural analgesic to control labour pain in the delivery suite at The St George Hospital in Sydney. Instead of injecting local anaesthetic, the anaesthetist mistakenly injected 8 ml of an alcoholic solution of chlorhexidine, the skin antiseptic used to clean the skin prior to inserting the epidural needle. The patient developed spinal paralysis and cerebrospinal fluid obstruction and secondary hydrocephaly that required a shunt to be surgically inserted. Mrs Wang was still unable to walk, sit or breastfeed her baby two months after the accident. By March 2011 Mrs Wang still required a mechanical hoist to move in and out of bed and was subject to uncontrollable spasms of her legs. She was still unable to hold her son, Alexander. The patient faces the possibility of remaining permanently paraplegic as a result of this accident. The hospital has admitted liability and is already providing extensive rehabilitation care to the patient and child care for her son.

THE ROOT CAUSE ANALYSIS

Under freedom of information legislation, the root cause analysis was obtained by the Sydney Morning Herald in March 2011. The accident was the result of mistaken identification of the clear fluids in two
identical metal containers which were used in the procedure of inserting a needle into the patient’s epidural space external to the spinal cord. In this case the two solutions were an antiseptic (chlorhexidine in alcohol, both highly neurotoxic) and saline, which is used in a syringe attached to the end of the Tuohy’s needle to detect loss of resistance when the epidural space is entered. Instead of these two solutions being checked by the anaesthetist from labelled packs or ampoules, the nursing staff had decanted the solutions into two identical metal “galley pots”. The colour of the antiseptic solution had recently been made lighter because the concentration of the chlorhexidine had been increased to improve bacterial antisepsis. The first entry into the epidural space resulted in aspiration of blood and so the needle was withdrawn. During a second pass of the needle, light pink fluid was obtained on aspiration. This was wrongly interpreted as blood contamination and the full 8 ml of fluid (now known to be chlorhexidine in alcohol) was erroneously injected into the epidural space.

In its recommendations the root cause analysis committee recommended to the New South Wales Department of Health that it consider using coloured syringe plungers, different-sized syringes or sterile labels to distinguish fluids. It also recommended that the Department consider using antiseptics that were more visually distinctive than chlorhexidine, as well as impregnated swabs instead of liquid antiseptic.7

This author is aware of a near miss with an epidural insertion involving injection of chlorhexidine at a Sydney obstetric unit. This incident happened approximately three to four weeks before the Wang case in June 2010. Just as it was in the case at St George Hospital, two galley pots holding de-identified solutions – one containing a highly neurotoxic antiseptic solution and the other containing harmless saline – were laid out on the equipment tray by the anaesthetist before insertion of the Tuohy needle. Fortunately for the patient, the anaesthetist failed to locate the epidural space and the chlorhexidine was injected more peripherally in the subcutaneous tissues of the woman’s back, producing only local backache.

**THE NEW SOUTH WALES DEPARTMENT OF HEALTH RESPONSE**

On 25 August 2010 the New South Wales Department of Health released *Safety Notice 010/10* entitled “Correct Identification of Medication and Solutions for Epidural Anaesthesia and Analgesia”.8 The Notice set out steps to be followed in the skin antisepsis and insertion of the epidural needle. These included skin preparation with an antiseptic solution (unspecified) followed by removal of that solution and associated swabs from the sterile pack. Then the anaesthetist was to personally select, prepare, administer and make record of the administration. Where a nurse or midwife was required to prepare a medicine dose for administration by a prescriber in a sterile set-up, the prescriber was to act as the second person and check the medicine before he or she administers it to the patient.9 These recommendations echoed the Position Statement of the Australian and New Zealand College of Anaesthetists released in August 2010.10

**RESPONSES OF SYDNEY OBSTETRIC HOSPITALS**

One Sydney hospital had already abandoned chlorhexidine before this incident because of a previous complication arising from ignition of an alcoholic antiseptic solution. It now provides only Betadine™ skin preparation for insertion of epidural anaesthetics. Of the teaching hospitals surveyed by the author in November 2011, none appears to have formalised the requirement for doctors to check medications with a second person before administration, although this is customary. Galley pots are still being utilised at another Sydney hospital but not in the sterile set-up. At St George Hospital the

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7 Robotham, n 6.
2% chlorhexidine in 70% alcohol antiseptic solution has been retained but it is used on disposable swab sticks which are discarded before inserting the epidural needle. Table 1 summarises the epidural practice at five Sydney teaching hospitals surveyed.

### TABLE 1 Epidural practice at five Sydney teaching hospitals, November 2011

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Using chlorhexidine skin prep</th>
<th>Concentration of chlorhexidine (if used)</th>
<th>Still using galley pots</th>
<th>Discarding antiseptic and syringes before needle insertion</th>
<th>Nurses involved in medication preparation</th>
<th>Dr required to check medication with second person</th>
</tr>
</thead>
<tbody>
<tr>
<td>The St George Hospital*</td>
<td>Yes</td>
<td>2%</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Not formalised but customary</td>
</tr>
<tr>
<td>Royal Hospital for Women, Randwick**</td>
<td>Yes</td>
<td>0.5%</td>
<td>Yes, but not in sterile set-up</td>
<td>Yes</td>
<td>Yes</td>
<td>Not formalised but customary</td>
</tr>
<tr>
<td>Westmead Adults Hospital***</td>
<td>Yes</td>
<td>0.5%</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Not formalised but customary</td>
</tr>
<tr>
<td>Royal North Shore Hospital†</td>
<td>No</td>
<td>Betadine™ only</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Not formalised but customary</td>
</tr>
<tr>
<td>Royal Prince Alfred Hospital††</td>
<td>Yes</td>
<td>0.5%</td>
<td>No</td>
<td>Antiseptic not in sterile set-up</td>
<td>Yes</td>
<td>Not formalised but customary</td>
</tr>
</tbody>
</table>

* Personal communication: Dr Sheyin Ng, 1 November 2011.
** Personal communication: Dr Steven Katz, 1 November 2011.
*** Personal communication: Dr Sheyin Ng, 1 November 2011.
† Personal communication: Dr Gavin Pattullo, 1 November 2011.
†† Personal communication: Dr Ian Douglas, 1 November 2011.

**PREVIOUS EPIDURAL ANAESTHETIC ACCIDENTS INVOLVING ANTISEPTICS**

### Phenol contamination of anaesthetic solutions

In 1957 Cecil Roe and Albert Woolley suffered permanent neurological damage as a result of administration of an spinal anaesthetic solution contaminated with phenol (carbolic acid). The ampoules of nupericaine were stored in the phenol solution as a sterility measure. Both men had surgery on the same day (13 October 1947) at the Chesterfield Royal Hospital. Minute cracks in the glass ampoules of nupericaine had allowed phenol to contaminate the anaesthetic solution. In Roe v Minister of Health [1954] 1 WLR 128 at 135, McNair J found that the anaesthetist, Dr Graham, and the hospital were not negligent on the grounds that the anaesthetist had checked each ampoule for cracks before aspirating the nupericaine for spinal injection:

> The truth is that Dr Graham, believing, in common with other competent anaesthetists in 1947, that there was no danger of percolation except through cracks which would be visible under a proper theatre examination, was not relying upon colour except as an additional precaution in the case of ampoules visibly cracked.

In my judgment, on the standard of reasonably competent anaesthetists in 1947, he cannot be blamed for so acting.12

An appeal was also dismissed unanimously. In Roe v Minister of Health [1953] 2 QB 66, Denning LJ opined (at 86-87):

These two men have suffered such terrible consequences that there is a natural feeling that they should be compensated. But we should be doing a disservice to the community at large if we were to impose liability on hospitals and doctors for everything that happens to go wrong. Doctors would be led to think more of their own safety than of the good of their patients. Initiative would be stifled and confidence shaken. A proper sense of proportion requires us to have regard to the conditions in which hospitals and doctors have to work. We must insist on due care for the patient at every point, but we must not condemn as negligence that which is only a misadventure.

Public confidence in the safety of spinal anaesthesia was set back for the subsequent two decades.13

Chlorhexidine contamination of obstetric epidural

In 2001 Angelique Sutcliffe received an obstetric epidural for a caesarean section with her daughter, Abigail, at University Hospital in Aintree, Liverpool, United Kingdom. She developed paraplegia. At trial in Sutcliffe v Aintree Hospitals NHS Trust [2007] EWHC 3545, the judge found the arachnoiditis14 was caused by contamination of the spinal anaesthetic (bupivacaine) with a cleaning agent (chlorhexidine). The judge concluded that this could only have occurred as result of liquid-to-liquid contact when the syringe and needle were prepared for delivery of the anaesthetic. Furthermore (at [59]), there had been a breach of duty of one of the two relevant clinicians who “normally operated to a very high standard”:15 The trial judge held that the hospital was negligent because the anaesthetic solution was contaminated with chlorhexidine: a small splash of the liquid may have contaminated the syringe prior to the epidural being administered.16

On appeal, the Trust did not contest that antiseptic contamination had occurred but argued:

It is unreasonable to put a clinician under a duty to notice any spillage, when it is as small as one ten-thousandth of a litre.17

The appellant further argued that, when analysing the claimant’s expert evidence, the only mechanism that would result in contamination of such a damaging degree would be substantial spillage or dropping the needle into the chlorhexidine. This was inconsistent with the judge’s assessment of the two clinicians operating “to a very high standard”. Further, the defendant argued that the judge’s findings could not be supported by the evidence given by the expert prior to the trial.18

The appeal to the Court of Appeal in Sutcliffe v Aintree Hospitals NHS Trust [2008] EWCA Civ 179 (Buxton LJ, Latham LJ, and Longmore LJ) was dismissed on 21 February 2008. The judge had clearly based his findings upon answers given by the claimant’s expert to the judge’s own questions at

12 Cope, n 11 at 270.
14 Adhesive arachnoiditis is an incurable inflammatory condition affecting the middle (arachnoid) layer of the meninges (which are the membranes surrounding the spinal cord): see Smith S, Adhesive Arachnoiditis, http://www.cofwa.org/Arachnoiditis.htm viewed 1 November 2011.
17 As quoted in Narain, n 16.
18 Sayers and Menjou, n 15.
trial. The judge was entitled to accept that evidence even when clearly different from views expressed before trial.\textsuperscript{19} Ms Sutcliffe received approximately £6 million.

**Accidental epidural chlorhexidine injection for Achilles tendon repair**

A 34-year-old European woman received an epidural anaesthetic for an Achilles tendon repair in 1997.\textsuperscript{20} Because she was allergic to the normal antiseptic solution, Isobetadine,\textsuperscript{21} a colourless solution of alcoholic chlorhexidine was used as a replacement antiseptic. Just prior to this accident, the hospital had rendered these alcoholic solutions of chlorhexidine colourless to increase their shelf life. After identifying the epidural space with a loss of resistance method, alcoholic chlorhexidine was accidentally drawn up into a syringe instead of local anaesthetic. The antiseptic was then injected into the epidural space. The woman became tetraplegic\textsuperscript{22} and unable to swallow, requiring constant care for three years until she died. At trial, the hospital was found negligent and ordered to pay £6,000 per month for nursing care. Baele commented that “[d]eparting from usual procedures removed an essential element of safety (colour) of which the operator had not been conscious before”.\textsuperscript{23}

**MEDICATION ERRORS IN ANAESTHESIA**

A Canadian study\textsuperscript{24} of over 2,000 anaesthetists found that of the 30% (687) who responded, 85% had made a medication error at least once in their career. The majority of these errors (98%) were minor; however, four deaths had resulted. Most errors were “syringe swaps” where a muscle relaxant was given instead of a reversal agent. Ninety-seven per cent of the anaesthetists read the label on the ampoule “most of the time” before administering a drug to the patient and regarded the colour on a label as an important secondary cue.\textsuperscript{25} In the same Journal, Fasting and Gisvold reported a study of anaesthetic errors in more than 55,000 procedures over three years. They reported that “[s]yringe swaps occurred most often between syringes of equal size, and were not eliminated by colour coding of labels”.\textsuperscript{26} In Australia, 896 anaesthetic errors were analysed in 2005.\textsuperscript{27} Approximately 50% of the reported incidents were either drug preparation or syringe errors, with 20% due to selection of the wrong ampoule or drug labelling errors: “Each drug administration can be associated with up to 40 component steps; therefore it is not surprising that errors can and do occur.”\textsuperscript{28}

Although these anaesthetic error rates are very small in relation to the number of intravenous drug injections performed by anaesthetists, medication errors in hospitals are a major cause of preventable

\textsuperscript{19} Sayers and Menjou, n 15.
\textsuperscript{21} Isobetadine™ contains povidone-iodine.
\textsuperscript{22} “Tetraplegia: paralysis of the arms, legs, and trunk of the body below the level of an associated injury to the spinal cord … Signs and symptoms commonly include flaccidity of the arms and the legs and the loss of power and sensation below the level of the injury, Cardiovascular complications also may develop from any injury that damages the spinal cord above the fifth cervical vertebra because of an associated block of the sympathetic nervous system. A major cause of death from such injury is respiratory failure. Other symptoms may include low body temperature, bradycardia, impaired peristalsis, and autonomic dysreflexia”; see The Free Dictionary, Tetraplegia, \url{http://www.medical-dictionary.thefreedictionary.com/tetraplegia} viewed 1 November 2011.
\textsuperscript{23} Baele, n 20 at 206.
\textsuperscript{25} Orser, Chen and Yee, n 24.
\textsuperscript{27} Abeysekera A, Bergman JJ and Kluger MT, “Drug Error in Anaesthetic Practice: A Review of 896 Reports from the Australian Incident Monitoring Study Database” (2005) 60 Anaesthesia 220.
\textsuperscript{28} Abeysekera, Bergman and Kluger, n 27.
patient morbidity and mortality. The Harvard Study of Medical Practice found that iatrogenic injury to hospitalised patients occurred in 3.7% while a similar Australian study found a rate of 18.9%. 29

ANALYSIS OF THE SYDNEY RESPONSE TO THE WANG CASE

Reliable antisepsis

The maternity unit which has abandoned all use of chlorhexidine as a skin preparation prior to epidural blockade may increase its exposure to the risk of epidural abscess, 30 a risk far more likely than contamination of an epidural with chlorhexidine and just as catastrophic. 31 However, Scott et al reported only one spinal abscess in a series of 505,000 epidural blocks. 32 Unless aqueous iodophor (Betadine™) is left on the skin for at least two minutes before insertion of an epidural catheter, bacterial contamination is possible. The American Society of Regional Anesthesia and Pain Medicine recommends the routine use of antisepctic solutions with an alcohol base for skin disinfection before peripheral regional techniques and this recommendation reflects the superior results of alcoholic chlorhexidine in a paediatric study by Kinirons et al. 33 Weinstein et al support the use of chlorhexidine skin preparation before insertion of epidural catheters because of its high antibacterial activity although they do mention work in rats showing destruction of adrenergic nerves by application of chlorhexidine. 34

Physical separation of antiseptic solutions from the epidural sterile tray

This strategy has been widely adopted since June 2010 and does improve safety by reducing the likelihood that antiseptic solution will be injected instead of local anaesthetic solution.

Use of multiple galley pots

It is clear that the use of multiple receptacles containing de-identified solutions was a major contributor to the two recent Sydney cases of accidental injections of chlorhexidine instead of saline during epidural needle insertion. One Director of Anaesthesia opined that any maternity unit which continued to provide multiple identical galley pots to hold antiseptic solutions and normal saline for epidural insertions was “just one protocol violation away from a critical incident”. 35 Where a single galley pot is used for an intensely brown coloured antiseptic solution such as Betadine, this risk may be lessened. St George Hospital has developed its own internal guideline which has prohibited the use of galley pots completely. 36

35 Personal communication with Director of Anaesthesia at St George Hospital, Sydney, 30 October 2011.
“Dry” techniques for needle insertion

One strategy which has not been canvassed is to abandon the technique which employs the loss of resistance to saline for identification of the epidural space. Many anaesthetists use loss of resistance to an air-filled syringe instead. The use of air may not, however, be risk-free: paraparesis has been reported, the rate of dural puncture may be higher and air embolus is also a possibility. Other techniques for needle insertion such as a compression of a small air bubble in saline, hanging drop, pop off feeling, nerve stimulation and ultrasonic identification of the epidural space are all alternatives, the last three of which do not require liquid to be injected into the epidural space. Where saline is to be used for needle insertion, at least three Sydney units draw the saline from sterile marked ampoules or packs directly into the syringe once its identity has been checked by the anaesthetist and the midwife assistant.

Uniform practice

As can be seen from Table 1, subtle differences occur in the epidural technique being used at a variety of obstetric units in Sydney. As visiting and staff anaesthetists often service several Sydney obstetric units, it would seem that a common protocol for all obstetric units in the region would enhance safety.

Safety design technology

Design engineering applications such as colour coding, size alterations in syringes, sterile packs which separate skin preparation from epidural injection can all play a part in safety enhancement. However, all such methods can fail, as can be seen from the European case where a well-meaning pharmacist abandoned the colouring of alcoholic chlorhexidine solution to prolong its shelf life. A change in the colour of the antiseptic solution was also a factor in the Wang case. Recent promising developments designed to improve safety in administering anaesthetic medications include the use of prefilled bar-coded syringes with colour-coded labels.

Double-checking medications

Conspicuous by its absence in these responses is a concentration on the one key factor which protects patients from medication errors: drugs must be checked and cross-checked by any person who administers them to a patient. The New South Wales Health Department Safety Notice requires this of nurses but not seemingly of the administering doctor. None of the obstetric units surveyed in Table 1 appears to have formally required doctors to have medications checked by a second person before administration, even though this is customary at all hospitals. It is of concern that studies of anaesthetists’ use of medications reveal that checking labels of drugs is not universal. The practice of a doctor and a nurse together checking details of a patient and her or his intended therapeutic procedure is well established before a surgical procedure is carried out or a blood transfusion is administered.

38 Temporary paresis of a leg has been reported just from injection of air into the epidural space: Nay P, Milaszkiewicz R and Jothilingam S, “Extradural Air as a Cause of Paraplegia Following Lumbar Analgesia” (1993) 48 Anaesthesia 402.
41 New South Wales Health, Safety Notice, n 8.
42 Orser, Chen and Yee, n 24.
CONCLUDING REMARKS

Catastrophic errors in medicine are frequently the result of multiple errors. In the two Sydney cases and in the Achilles tendon case, decolourised solutions of chlorhexidine in alcohol made recognition of the mistake more difficult. In both Sydney cases the use of identical galley pots containing de-identified solutions, one highly neurotoxic, the other harmless, was a critical source of confusion.

Improved safety in medicine comes from a careful, freely available analysis of avoidable factors in accidents and misadventure. Near-misses such as that described above add weight to the need for enhanced safety measures for obstetric epidural practice. Uniformity of practice across a region should also add safety. Medical negligence litigation may not always have the desired effect of improving future patient safety. This is particularly so if modified procedures incur greater risks of other complications such as infection, dural perforation or air embolus. Legal scrutiny of medical practice can and has increased the standardisation of care. Evidence-based College-sponsored guidelines and protocols are of great assistance to clinicians and administrators alike. A broad-based understanding of “best practice” by hospital staff is also a useful “brake” on unsafe procedures.

The inescapable truth is that meticulous checking of any medication before it is administered is the prime means of preventing drug errors. Any practitioner, be they anaesthetist, midwife or pharmacist, should be required to double check the medication with another health professional before it is given.

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