ACHIEVING SYSTEMS CHANGE – REDUCING DRUG ERRORS

Alan Merry

Auckland City Hospital and the University of Auckland,
Auckland

A well-publicised medication error in a major hospital earlier this year provided a timely reminder of the importance to patients of reliability in the administration of drugs. Unfortunately this event was not as rare as one would expect from a high quality health service. Studies overseas have provided estimated rates of adverse drug events (ADEs – defined as injuries resulting from medical interventions related to a drug[1]) of 2.4,[2] 2.5[3] and 6.5[4] per 100 admissions overall, and with various estimates in specific areas. For example, in the context of intensive care, 19 preventable and potential events were identified per 1,000 patient days[5] and a study in the paediatric, neonatal intensive care unit and postnatal wards at Dunedin Hospital over a 12 week period in 2002 found a rate of 12.9 ADEs per 100 admissions, or 22.1 per 1000 patient days, or 2.1 per prescription episode. In the New Zealand Quality of Healthcare Study, 12.9% of public hospital admissions were associated with an adverse event, of which half occurred in hospital and were considered preventable; of these, 7.5% were associated with pharmacological treatment – approximately one ADE per 200 admissions (0.5 per 100 admissions).[6,7] In New Zealand's annual report of serious and sentinel events occurring in hospitals there are typically 15-20 ADEs each year. For example, in 2009/10 there were 17 ADEs, accounting for 5% of all adverse events and 1% of all deaths included in the report.[8] For the same year, 998,390 people were treated and discharged by hospital staff – 391,265 day patients and 607,125 inpatients (there were also over 1.7 million outpatient discharges). Rounding to one million inpatient discharges, this gives a rate of serious ADE of about 1 per 60,000 admissions, but it should be remembered that the threshold for reporting in this category is high, and that there is almost certainly a substantial degree of under-reporting – these are the so called "never events" which absolutely should not have happened, but have.

In 2007 the New Zealand Pharmacovigilance Centre received 61 reports of ADEs, of which 65.5% involved harm to patients. Several studies have shown that ADEs increase the length of hospital stay with estimates varying from one or two days to over a week.[2,9,10] Obviously, ADEs are associated with increased cost, but the extent of this is difficult to work out precisely. The estimate for the paediatric service in Dunedin in 2002 was NZ$ 235,214 per annum.[11] Overseas figures vary considerably. In NZ, one million inpatient discharges per year and one ADE per 100 discharges would give 10,000 ADEs per year. Estimating the cost of hospitalisation at NZ$ 1,000 per day, this translates to an annual cost of between $10 million and $75 million (depending on which estimate of prolongation of stay is used; the Health Quality and Safety Commission's estimate, using essentially similar assumptions, was that reducing these errors had the potential to save DHBs NZ$ 62 million per year).

In anaesthesia the best estimates come from facilitated incident reporting in which a form is returned for every anaesthetic. This approach has provided estimates of one drug administration error per 135 anaesthetics in New Zealand, 1 per 150 in the US, and 1 in 274 in the Republic of South Africa. It is plausible that 1 in 100 of these errors results in an ADE.[1] On this basis, one in every 13,500 to 27,000 patients is harmed (approximately) – so one in 20,000 is probably a reasonable figure for the purposes of discussion. This would imply that most practising anaesthetists seriously harm a patient at least once in their career from this cause (many anaesthetists administer drugs more than a quarter of a million times over their working life – New Zealand data suggests that, on average, there are 10 IV drug administrations per anaesthetic.[12] It would not be unusual to anaesthetise twenty patients a week, forty weeks a year, for forty years, and this works out at 320,000 without counting gases, vapours and ward prescriptions). Although only 12.5% of anaesthetists surveyed some years ago admitting to having harmed a patient from a drug administration error,[13] many respondents would only have been part way into their career. Furthermore, it is often the case that practitioners making drug errors do not even know they have occurred. This point is illustrated by the frequency of failure to administer prophylactic antibiotics in the correct time frame (the one hour preceding incision). In the New Zealand part of the study of the use of the WHO Safe Surgery Checklist, failures in timely administration of antibiotics occurred in 12% of cases – even after the introduction of this checklist.[14] There is a strong link between such failures and the likelihood of postoperative infections. A review of 81 cases of awareness from the Australian Incident Monitoring Study identified drug error as the cause in half of these events.[15] Taking all of this into account, I believe that the proposition that one in 20,000 patients undergoing anaesthesia will suffer an ADE attributable to a drug administration error is conservative.

Recent Guidelines and Standards

Several recent guidelines or standards have been published which deal with the safe administration of drugs and are of relevance to anaesthetists (as well as other practitioners).

In 2008, the International Organization for Standardization (ISO) published ISO 26825:2008(E) – "Anaesthetic and respiratory equipment – User-applied labels for syringes containing drugs used during anaesthesia – colours, design and performance" ("ISO Standard").[16] As the most recent relevant standard this replaces the very similar AS/NZS 4375:1996 – "User-applied labels for use on syringes containing drugs used during anaesthesia,"[17] and other similar international equivalents.[18,19] In the same year, in the UK, the National Patient Safety Agency promulgated "Design for patient safety. A guide to labelling and packaging of injectable medicines. Edition 1."[20]

In 2009, the Australian and New Zealand College of Anaesthetists (ANZCA) produced a new Professional Document dealing specifically with the administration of drugs in anaesthesia, PS51 – "Guidelines for the Safe Administration of Injectable Drugs in Anaesthesia" ("PS 51").[21]

In 2010, the Australian Commission on Safety and Quality in Health Care developed a new guideline for labelling, of more general applicability, but still of considerable relevance to anaesthetists – "National Recommendations for User-Applied Labelling of Injectable Medicines, Fluids and Lines" ("Labelling Recommendations").[22]

The Labelling Recommendations have no official standing in New Zealand, but were developed with New Zealand input (see disclaimer) and consultation with relevant international organisations including ANZCA. These recommendations apply to healthcare in general, and the ISO Standards take precedent for syringes used by anaesthetists in the operating room. Provisions related to drugs used in sterile fields are of particular relevance to anaesthetists, and if followed might possibly have prevented a recent tragedy involving the injection of chlorhexidine into the CSF of a patient in Australia. PS 51 is more concise, but broader in scope. This document goes beyond labelling to the wider issues of medication safety in anaesthesia. It provides a clear definition of the aims of safe administration of injectable drugs in anaesthesia (Box 1).

> ***Box 1.*** The aims of safe administration of injectable drugs in anaesthesia (from PS51).[21]
>
> 1. To give the correct drug for the correct patient in the correct dose by the correct route at the correct time
> 2. To record accurately this information in the anaesthetic record
> 3. To be able to demonstrate that 1 and 2 have been accomplished reliably

It emphasises the importance of understanding the pharmacology of the drugs administered, and of knowing the relevant medical information about the patient to which they are being given. It provides guidance on systems-related matters such as the purchase and storage of drugs, as well as on the technicalities of how drugs should be drawn up, the syringes labelled, and the medications injected. Although PS51 was published before the recent revision of the process by which ANZCA's professional documents are compiled and reviewed,[23] its development took some years and extensive consultation, including review by all of ANZCA's regional committees and the New Zealand National Committee (where it actually began – Vaughan Laurenson and Paule Smeele should be acknowledged for this). It seems reasonable to expect that all anaesthetists practising in Australia and New Zealand should at least read PS51.

Anesthesia Patient Safety Foundation – Time for a New Paradigm

In January 2010, at Phoenix Arizona, Robert K. Stoelting MD, the current president of the Anesthesia Patient Safety Foundation (APSF; a US organisation whose vision is "that no patient shall be harmed by anesthesia"[24]) held an invitation only meeting of approximately 100 experts entitled "Medication Safety in the Operating Room – Time for a New Paradigm."[25] The main recommendations emerging from this meeting are encapsulated in the four elements of a "new paradigm" for medication safety in anaesthesia (Box 2).[25]

Box 2. A "new paradigm" for medication safety in anesthesia (reproduced from the agenda for the meeting "Medication Safety in the Operating Room – Time for a New Paradigm" held in Phoenix, Arizona, in January 2010).[25]

- Standardization (drugs, concentrations, equipment)
- Technology (drug identification and delivery, automated information systems)
- Pharmacy (satellite pharmacy, premixed solutions and prefilled syringes whenever possible)
- Culture (recognition and reporting of drug errors to reduce recurrences)

Interesting aspects of the recommendations include a strong emphasis on the value of pre-filled, pre-labelled syringes, not as an isolated initiative, but as part of a systematic approach to systems re-design, on standardisation, and on the use of technology for drug identification.

The Auckland Initiatives – Recent Data

The Department of Anaesthesiology at the University of Auckland has an established programme of research, the overarching hypothesis of which is –

> *"Harm from human error in anaesthesia can be reduced through systematic analysis of its causes and implementation of appropriate strategies."*

Some (not all) of this research has focussed on drug administration. This has depended on support from clinical colleagues, mainly at Green Lane and Auckland City Hospitals, but also from Wellington and Christchurch Hospitals. In association with this research there have been progressive and cumulative changes in practice at Auckland City Hospital, North Shore Hospital, Mercy Ascot Hospital, Brightside Hospital, Gillies Southern Cross Hospital, and The Mobile Surgical Bus which have improved the safety of drug administration in anaesthesia. These changes have centred on the partial adoption of a novel integrated system of drug administration and recording for anaesthetists (the Safer Sleep System, also known as the IDAS,[26] see disclaimer). A recent analysis of 74,478 facilitated incident reports demonstrated a 35% relative reduction in parenteral drug errors in association with using the new system ($P = 0.002$) and a trend towards a reduction in harm ($P = 0.055$). The report of a recent observer-based, prospective, randomised trial of the system, involving over 1,000 patients, carried out with the assistance of 89 anaesthetists, has been provisionally accepted by a major peer reviewed journal. I hope to be able to present these (presently embargoed) data at AQUA.

Achieving Systems Change – Campaigning for Safety

Information appears to be relatively ineffective in generating change in practice. The Institute for Healthcare Improvement (IHI) has developed a reputation for the effective promotion of improvements in patient safety. The following explanation of what it is and does is to be found on its website –

> *"An independent not-for profit-organization based in Cambridge, Massachusetts, IHI focuses on motivating and building the will for change; identifying and testing new models of care in partnership with both patients and health care professionals; and ensuring the broadest possible adoption of best practices and effective innovations."*
>
> (www.ihi.org/about/pages/default.aspx)

The IHI has recently been responsible for two major campaigns to improve patient safety in the US. The first was the "100,000 Lives Campaign"; the second is the "5 Million Lives Campaign."[27]

The practices promoted by these campaigns (Box 3) have high face validity. It will be noted that one of these interventions aims to prevent adverse drug events.

Box 3. The interventions promoted in the 100,000 lives campaign.[27]

- Deploy rapid response teams to patients at risk of cardiac or respiratory arrest
- Deliver reliable, evidence based care for acute myocardial infarction
- Prevent adverse drug events through drug reconciliation (reliable documentation of changes in drug orders)
- Prevent central line infections
- Prevent surgical site infections
- Prevent ventilator associated pneumonia

The framework for the campaign (Box 4) provides a useful guide for those who seek to improve the system.

Box 4. Essential components identified by the Institute for Healthcare Improvement for spreading a healthcare initiative.[27]

- Ensuring leadership commitment
- Setting clear aims (including changes to be spread, target level of performance, target population, and time frame)
- Identifying and packaging proved ideas and practices
- Developing and executing a plan to communicate and implement the ideas
- Creating a system for measuring progress
- Establishing a process for refining the plan in response to learning during implementation

Measurement is a key element of quality improvement,[28] and it is very important that the measurements used are meaningful to those whose practices one seeks to change, easy to obtain, and objective. It is debatable whether the concept of "lives saved" (used in these IHI campaigns) meets these criteria,[29] but there is, nevertheless, much that can be learned from the IHI in relation to system improvement. Ideally these lessons should be amalgamated with emerging concepts of evaluating quality improvement initiatives in healthcare.[30]

National Commissions to Promote the Quality and Safety of Healthcare

In New Zealand and Australia, Governments have recently invested in Commissions (www.safetyandquality.gov.au and www.hqsc.govt.nz) to promote the quality and safety of healthcare (safety being one of the elements of quality – and see disclaimer).[31] This investment in quality reflects recognition of the potential financial benefits inherent in doing things better in constrained economic times. The Health Quality and Safety Commission in New Zealand has adopted a modification of the Triple Aim developed by the IHI.[32] The New Zealand version of the Triple Aim is the simultaneous pursuit of three aims –

- Improved quality, safety and experience of care
- Improved health and equity for all populations
- Best value from public health system resources

The Commission is pursuing two main projects to address medication safety. One is the introduction of a standardised, well-designed medication prescribing chart for all adult inpatients. The second is the introduction of reconciliation of patients' medications on admission to and discharge from hospital. In addition, work is being done on improving medication safety in aged care settings. The Commission has also been working to accelerate initiatives begun by the former Quality Improvement Committee and subsequently taken over by the National Health IT Board and others to promote a series of integrated electronic initiatives to provide the infrastructure for a major improvement in patient safety. It is important to recognise that computerised solutions facilitate the human processes that create safe practice, and do not usually replace these. The system improvements involved in the paper based initiatives form the foundation for the electronic investments still to come (and for those hospital who wish to move directly to electronic solutions, the only impediment is financial).

Achieving Change in Your Own Practice

In the end, the culture of any healthcare organisation is the sum of the attitudes of the practitioners and others who work within it.[31] Given that anaesthetists administer medications every day of their working life it seems reasonable to expect that they will devote time to mastering the elements of doing this safely. This implies developing a reasonable understanding of the epidemiology of medication error, and of the behavioural science[31] and the emerging standards related to reducing harm to patients from this problem. Considerable consensus exists on the core elements of safe medication administration in anaesthesia.[21,33] Typically, anaesthetists are expert pharmacologists. The challenge is to match that expertise with an equal expertise in deceptively simple, but in reality very challenging task of administering drugs safely.

Conflict of Interest

Alan Merry has financial interests in Safer Sleep LLC (see www.safersleep.com); he chairs the Board of the Health Quality & Safety Commission (see www.hqsc.govt.nz); he is a councillor of the Australian and New Zealand College of Anaesthetists; he chaired the committee which oversaw the production of the Labelling Recommendations.

References

1. Bates DW, Boyle DL, Vander Vliet MB, Schneider J, Leape L. Relationship between medication errors and adverse drug events. J Gen Intern Med 1995;10:199-205
2. Classen DC, Pestotnik SL, Evans RS et al. Adverse drug events in hospitalized patients. Excess length of stay, extra costs, and attributable mortality. JAMA. 1997 Jan 22-29; 277(4): 301-6
3. Runciman WB, Roughead EE, Semple SJ, Adams RJ. Adverse drug events and medication errors in Australia. Int J Qual Health Care 2003; 15: i49-59
4. Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, Servi D, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. JAMA 1995; 274: 29-34
5. Cullen DJ, Sweitzer BJ, Bates DW, Burdick E, Edmondson A, Leape LL. Preventable adverse drug events in hospitalized patients: a comparative study of intensive care and general care units. Crit Care Med 1997; 25: 1289-97
6. Davis P, Lay-Yee R, Briant R, Ali W, Scott A, Schug S. Adverse events in New Zealand public hospitals I: occurrence and impact. N Z Med J 2002; 115: U271
7. Davis P, Lay-Yee R, Briant R. Adverse events in New Zealand public hospitals. II: preventability and clinical context. NZ Med J. 2003. Accessed Apr 2011. URL: http://www.nzma.org.nz/journal/116-1183/624
8. Heath Quality & Safety Commission. Making our Hospitals Safer: Serious and Sentinel Events 2009-2010. Wellington: Health Quality & Safety Commission, 2010
9. Davis P, Lay-Yee R, Schug S, Briant R, Scott A, Johnson S, et al. Adverse events in New Zealand public hospitals: principal findings from a national survey. Occasional paper. Wellington: Ministry of Health, 2001
10. Bates DW, Spell N, Cullen DJ, Burdick E, Laird N, Petersen LA, et al. The costs of adverse drug events in hospitalized patients. JAMA 1997; 277: 307-11
11. Kunac D, x00E, Kennedy J, Austin N, Reith D. Incidence, preventability, and impact of Adverse Drug Events (ADEs) and potential ADEs in hospitalized children in New Zealand: a prospective observational cohort study. Paediatric Drugs 2009; 11: 153-60
12. Webster CS, Larsson L, Frampton CM, Weller J, McKenzie A, Cumin D, et al. Clinical assessment of a new anaesthetic drug administration system: a prospective, controlled, longitudinal incident monitoring study. Anaesthesia 2010; 65: 490-9
13. Merry AF, Peck DJ. Anaesthetists, errors in drug administration and the law. N Z Med J 1995; 108: 185-7
14. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med 2009; 360: 491-9
15. Bergman IJ, Kluger MT, Short TG. Awareness during general anaesthesia: a review of 81 cases from the Anaesthetic Incident Monitoring Study. Anaesthesia 2002; 57: 549-56
16. Anaesthetic and respiratory equipment - User-applied labels for syringes containing drugs used during anaesthesia - Colours, design and performance (ISO 26825:2008): International Organization for Standardization, 2008

17. User-applied labels for use on syringes containing drugs used during anaesthesia (AS/NZS 4375:1996). Wellington: Standards New Zealand, 1996
18. Standard for user-applied drug labels in anaesthesia and critical care (Z264.3-98). Etobicoke, Canada: Canadian Standards Association, 1998
19. Standard specification for user applied drug labels in anesthesiology (D4774-94). Philadelphia: American Society for Testing and Materials, 1995
20. National Patient Safety Agency. Design for patient safety. A guide to labelling and packaging of injectable medicines. Edition 1. London: The Agency, 2008
21. Australian and New Zealand College of Anaesthetists. Guidelines For The Safe Administration Of Injectable Drugs In Anaesthesia (Policy Document PS 51). Melbourne: The College, 2009
22. Australian Commission on Safety and Quality in Health Care. National Recommendations for User-Applied Labelling of Injectable Medicines, Fluids and Lines. Sydney: AQSQH, 2010
23. Australian and New Zealand College of Anaesthetists. Professional documents (ADP1). Melbourne: The College, 2009
24. Eichhorn J. The APSF at 25: pioneering success in safety but challenges remain. APSF Newsletter 2010; 25: 1, 23-4, 35-9
25. Eichhorn J. APSF hosts medication safety conference: consensus group defines challenges and opportunities for improved practice. APSF Newsletter 2010; 25: 1-7
26. Merry AF, Webster CS, Mathew DJ. A new, safety-oriented, integrated drug administration and automated anesthesia record system. Anesth Analg 2001; 93: 385-90
27. McCannon CJ, Schall MW, Calkins DR, Nazem AG. Saving 100,000 lives in US hospitals. BMJ 2006; 332: 1328-30
28. Donabedian A. An Introduction to Quality Assurance in Health Care. New York: Oxford University Press, 2003
29. Wachter RM, Pronovost PJ. The 100,000 Lives Campaign: A scientific and policy review. Joint Commission Journal on Quality & Patient Safety 2006; 32: 621-7
30. Shekelle PG, Pronovost PJ, Wachter RM, Taylor SL, Dy SM, Foy R, et al. Advancing the science of patient safety. Ann Intern Med 2011; 154: 693-6
31. Runciman B, Merry A, Walton M. Safety and Ethics in Healthcare: A Guide to Getting it Right. Aldershot: Ashgate, 2007
32. Berwick DM, Nolan TW, Whittington J. The triple aim: care, health, and cost. Health Aff (Millwood) 2008; 27: 759-69
33. Jensen LS, Merry AF, Webster CS, Weller J, Larsson L. Evidence-based strategies for preventing drug administration errors during anaesthesia. Anaesthesia 2004; 59: 493-504