

Australian Patient Safety Bulletin

Newsletter of the NHMRC Centre of Research Excellence in Patient Safety

July 2007 Issue 6

The Australian Patient Safety Bulletin has been developed to enable clinicians to keep abreast of current literature in the field of quality and safety. A few articles from the many hundred published each month which relate to quality and safety are selected for inclusion in the Bulletin. A panel of academics reviews the articles for inclusion in the Bulletin against the following criteria:

1. that the articles must demonstrate good methodology;
2. that the articles should come from a high quality peer-reviewed journal;
3. that the articles must discuss an issue which has relevance to or is likely to be of interest to clinicians working in the Australian healthcare sector; and
4. that the articles must have been published in the previous six month period.

The NHMRC Centre of Research Excellence in Patient Safety is housed within the Department of Epidemiology and Preventive Medicine at Monash University. The research agenda for the Centre is governed by a Management Committee and is informed by a Reference Group comprising people from health and non-health related backgrounds. Details of our management structure, can be found on our website at <<http://www.crepatientsafety.org.au>>.

Our next seminar, titled **Incident Management**, is to be held on July 26th 2007 in Sydney. We will hear presentations from people using and improving reporting systems in Australia. In addition, Professor Richard Thompson from the National Patient Safety Agency in the United Kingdom will join us by videoconference to discuss changes being made to the UK National Learning and Reporting System (NLRS).

You should also mark the 6th of December in your diary. On this date we will be running a seminar in Melbourne on "How human factors can provide opportunities for patient safety." At this seminar, internationally recognized expert Sidney Dekker will be our keynote speaker. Sidney is Professor, of Human Factors and Systems Safety at the University of Lund in Sweden. He will talk about the old and new views of human error, how to build resilience and on human factor investigation techniques. This will be followed by a workshop on 7th December looking at issues of accountability in healthcare with health and non-health related experts.

Incident Management Seminar:

Thursday July 26th 2007
Kerry Packer Auditorium (Kerry Packer Education Centre)
Royal Prince Alfred Hospital, Camperdown, NSW
Cost: \$165 per person (incl. of GST)

This seminar aims to: (a) identify positive outcomes from incident management; (b) discuss the role of incident reporting in relation to the wider safety and quality framework; and (c) identify ways in which to enhance incident management systems.

Further information and registration forms can be found on our web site at: <www.CREpatientsafety.org.au>



Centre for
Research Excellence
in Patient Safety

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The CRE in Patient Safety is funded by the Australian Commission on Safety and Quality in Healthcare and designated as a NHMRC Centre of Research Excellence. The CRE is based in the Department of Epidemiology & Preventive Medicine, Monash University, Alfred Hospital.

Collaborating institutions include: Bayside Health, University of Queensland, Melbourne Health, Southern Health, Wimmera Healthcare Group, ACT Health, ANU Centre for Health Stewardship, Victorian Institute of Forensic Medicine, CSIRO, Medical Defence Association of Victoria, Peninsula Health, Queensland Health, Australian Centre for Health Innovation, South Australian Department of Health, Western Australian Department of Health, Australian Institute for Health and Welfare (AIHW), Commonwealth Department of Health and Ageing, Australian Council for Healthcare Standards (ACHS), Victorian Department of Human Services, Monash University Department of General Practice, Clinical Excellence Commission, Melbourne Pathology, Peter MacCallum Cancer Centre and Princess Alexandra Hospital.

Complication rates on weekends in US hospitals

Bendavid E, Kaganova Y, Needleman J, Gruenberg L, Weissman JS. Complication rates on weekends and weekdays in us hospitals. Am J Med 2007; 120(5):422-8.

There is often a claim that more adverse events occur on the weekend compared to weekdays because more patients are admitted through the emergency department, fewer patients are discharged and fewer services are provided on weekends compared to weekdays. Studies exist both supporting and refuting this claim.

The objective of this particular study was to determine whether complication rates in hospitals were higher on weekends than weekdays.

Complications were assessed using data from inpatient databases which collect standardized data on hospital admissions (including ICD codes for diagnoses and procedures obtained from providers) from nonfederal hospitals in three US states.

Eight types of complications were assessed: complications of anaesthesia, retained foreign body, postoperative haemorrhage, accidental laceration during a procedure, birth trauma, obstetric trauma during vaginal delivery with and without instrumentation, and obstetric trauma during caesarean section. Analysis was adjusted for case-mix, (demographic characteristics and co-morbidities) and controlled for route and type of admission.

Results: Nearly five million patient admissions of at-risk patients were assessed. Patients admitted on weekends constituted nearly 15% of the total number of admissions and were more likely to be younger and non-white. Of those admitted to hospital 2.3% were associated with a complication, of which about two-thirds related to obstetric trauma and nearly 30% were surgical complications.

Complications relating to anaesthesia were less likely to occur on the weekend. Patients undergoing vascular surgery were more likely to have complications on weekends (OR =1.46). Complication rates for birth trauma and two of the three obstetric trauma indicators were also significantly higher on the weekend. There were no differences associated with accidental laceration or retained foreign bodies.

Take home message: There were small but significantly increased rates of several types of complications on weekends for surgical, newborn and obstetric patients which are independent of casemix or triage status. Reasons are unclear but suggest that differences may be due to staffing and skill mix on the weekend. This study raises the question: how do we compare in Australia?



Pharmacist intervention to improve medication adherence on heart failure



Murray MD, Young J, Hoke S et al. Pharmacist intervention to improve medication adherence in heart failure: a randomized trial. Ann Intern Med 2007; 146(10):714-25

Studies indicate that 50% of patients with chronic illnesses do not take their medication as prescribed. This randomised controlled trial was developed to identify whether having a pharmacist providing ongoing advice and support to patients suffering heart failure improves adherence to prescription medication compared with usual care.

A total of 314 low-income patients aged over 50 years were randomly assigned to a pharmacist intervention or usual care. The pharmacist assessed the patient's current knowledge and provided verbal and written instructions on how to take their medication. An easy to follow timeline was also provided to remind patients when to take their tablets. Pharmacists also monitored study participants' medication use, healthcare encounters and body weight.

Adherence to medication was measured using electronic monitors over the nine-month intervention period and three-month post-intervention period. The study also assessed whether the intervention impacted on admissions to hospital and emergency department presentations for cardiac-related problems, self-reported compliance, satisfaction with pharmacy services and total direct health costs in the two groups.

Results: Medication adherence was significantly higher in the intervention group compared to the usual care group during the nine month intervention period (78.8% vs 67.9%) however this dropped to almost the same level at the end of the three-month post-intervention period (70.6% vs 66.7% respectively). Individual medication adherence is also reported in the article. The intervention group had 19% fewer hospital admissions or ED presentations for cardiac related events compared to the control units.

The intervention cost US\$205 per patient. Savings resulting from fewer hospital encounters in the intervention group meant that overall the intervention had a cost saving of US\$2960 per patient.

Take home message: The pharmacist improved adherence to cardiovascular medication. This quite likely resulted in fewer hospital presentations and cost savings to the health sector. However, the effect was not sustained. As soon as the pharmacist stopped providing assistance, people's adherence rapidly dropped off. The question is whether we should continue to support these programs on an on-going basis. While on face value it appears to be a costly exercise in the short-term, it can provide saving benefits in the long-term.

Evaluation of an intervention to improve voluntary incident reporting

Evans SM, Smith BJ, Esterman A et al. Evaluation of an intervention aimed at improving voluntary incident reporting in hospitals. *Quality & Safety in Health Care* 2007; 16(3):169-5.

This study aimed to improve incident reporting in public hospitals. Twenty clinical areas spread across two regional and four metropolitan hospitals in South Australia participated in the study. Half the hospitals continued with normal practice while the other half received an intervention which comprised:

1. intense education of reportable events and the reporting process (including privilege afforded to incident reporting);
2. a change to the reporting process such that all reports in the first instance went directly to the Quality Manager and the either the Nurse Unit Manager (for nurse-initiated reports) or the Medical Head of Unit (medically-initiated reports); and
3. regular feedback to staff via departmental meetings and newsletters. Staff could report using a one-page form or a telephone reporting service which operated 24 hours a day, 7 days a week.

Results: The intervention resulted in an absolute increase of 60 reports/10,000 occupied bed days (OBDs) in inpatient areas and an increase of 28 reports per 10,000 Emergency Department (ED) attendances. An additional 20 anonymous reports were generated per 10,000 OBDs and ED attendances combined. The majority of reports were lodged on a one-page report form (79%). The call centre was used by 21% of reporters. There was a greater spread of incident types reported during the intervention period compared to baseline and to the control units.

At departmental level, units improving the most had the following features:

- medical Heads of Units attended root cause analysis training designed to teach systems approach to error management;
- the initial education captured most doctors;
- departmental education and feedback sessions were held at least every 10 weeks, with discussion of incidents lasting at least 20 minutes;
- feedback provided clinically relevant incidents for discussion;
- posters and manuals clearly visible in the ward area;
- on-line reporting was not offered.

Take home message: Improving incident reporting requires support from clinical leaders/champions. There needs to be a genuine commitment to discussing incidents. Reporting improved most in units where leaders attended the workshop. This might indicate a greater commitment at the outset or that techniques learned at the workshop were beneficial in fostering a reporting culture.

Cost-benefit analysis of a hospital pharmacy bar code solution

Maviglia SM, Yoo JY, Franz C et al. Cost-benefit analysis of a hospital pharmacy bar code solution. *Arch Intern Med* 2007; 167(8):788-94.



Medication errors are one of the most common causes of unintentional harm and are prevalent across healthcare systems.

Additionally, medical errors and adverse drug events (ADE) carry a high financial burden. Hospitals incur substantial costs per ADE. In America, ADEs cost approximately \$US2 billion per year.

This article focuses on the use of bar coding in order to reduce hospital pharmacy dispensing errors. It attempts to demonstrate that the cost of implementing a pharmacy bar coding system is outweighed by the benefits to patients and additionally that it can produce a return on investment over a period of time.

To test this hypothesis, cost-benefit analysis was performed on a code-assisted medication dispensing system. This was completed within a large, not-for-profit tertiary care hospital pharmacy and was implemented prospectively for the next five years.

There were two main outcomes. The primary outcome looked at the net financial cost versus the total benefit after five years of implementing the bar coding system. The secondary outcome was the time taken until benefits equaled costs.

Results: The research findings showed that primary benefit was a decrease in adverse drug events from dispensing error. The total costs over five years totalled \$US2.24 million. These costs took into consideration inflation and time value adjustments.

Furthermore, the annual savings were \$US 2.20 million with a net benefit after five years being \$US3.49 million. The break-even point of the hospital's investment occurred within a year of implementation.

Take home message: The aim of the article was to determine if bar coding would substantially decrease ADEs and these benefits would justify the costs involved. After clearly identifying both outcomes it is evident that in the long term bar coding does reduce drug dispensing errors and is cost effective. Additionally, the break-even point for hospitals is easily manageable. Bar coding not only decreases adverse events but has a positive financial return.

Use of administrative data or clinical databases as predictors of risk of death in hospital: Comparison of models

Aylin P, Bottle A, Majeed A. *Use of administrative data or clinical databases as predictors of risk of death in hospital: comparison of models. BMJ 2007; 334(7602):1044.*

The use of routine administrative databases for monitoring the performance of health systems is becoming increasingly popular in the United States, the United Kingdom and Australia. The perception that such databases lack important clinical content which influences their ability to provide sound, risk adjusted information has encouraged the development of more expensive clinical databases for specific diagnoses and/or procedures.

This study aimed to compare the ability of mortality risk prediction models developed from the Hospital Episode Statistics (HES) database with those from clinical databases for three index procedures: isolated coronary artery bypass graft (CABG), abdominal aortic aneurysm repair (AAA), and colectomy for bowel cancer.

The most accurate published mortality models from the National Cardiac Surgical Database, the National Vascular Database and the Colorectal Cancer Study were compared to those developed for the listed conditions from HES.

The ability of the models to discriminate between risk of death for those who died and those who survived was examined through analysis of Receiver Operating Characteristic (ROC) curves (examination of the c statistic). Values less than 0.7 are generally thought of as having low discrimination, 0.7- 0.8 as reasonable, and greater than 0.8 as having good discrimination. In addition, the goodness of fit of the models was assessed using the Hosmer-Lemeshow statistic (which is influenced by sample size) as well as analysis of standardised residuals.

Results: For analysis of isolated CABG surgery, the HES data included 152 523 cases (3247 deaths), AAA (ruptured) 12 781 cases (5987 deaths), AAA (un-ruptured) 31 705 cases (3246 deaths) and colorectal excisions 144 370 cases (10 424 deaths). For each index procedure, a simple, intermediate and complex model was developed which included progressively more variables. The c statistics for the HES complex models demonstrated that for AAA repairs and colorectal excision surgeries, the HES model had greater discrimination than the model developed from a clinical database. The model developed from the HES for isolated CABG had a similar c statistic to that developed from the national cardiac surgical database (0.768 and 0.783 respectively). The Hosmer-Lemeshow statistics suggests that there was a significant difference in the HES model for repair of AAAs compared to the clinical database model.

The authors suggest that the large sample size used in this study may have resulted in a significant difference in the final models. When residuals were examined for influential points, all complex models were found to have good fits.

The authors concluded that routine administrative data can be used to develop mortality prediction models which are comparable to those obtained from clinical databases for three

common procedures. Rich data sources such as administrative databases can therefore be viewed as useful tools for risk prediction and case mix adjustment as well as adjuncts to clinical databases for monitoring system performance.

Take home message: Routinely collected administrative data can provide good risk prediction models which are comparable to those developed from more resource intensive clinical databases. Such models enable these databases to be useful when assessing and monitoring provider performance and may support analyses from clinical databases.

Comparing survival outcomes for patients with colorectal cancer treated in public and private hospitals.



Morris M, Iacopetta B, Platell C. *Comparing survival outcomes for patients with colorectal cancer treated in public and private hospitals. MJA. 2007; 186(6): 296-300.*

This retrospective, population-based study of tertiary care hospitals is one of the few articles in which systems of healthcare are compared directly with each other as an independent quality healthcare indicator.

The study population were patients diagnosed with colorectal cancer in Western Australia between 1993 and 2003 (N=3809 treated cases).

This data was obtained from:

- Retrospective review of pathology records from the four hospital pathology departments in Western Australia with cross-referencing with data from the Western Australian Cancer Registry
- Tumour stage and site determined from pathology reports with cross referencing with admission and procedure record data
- Treatment as determined from patient records and cross-checked with the Western Australia Linked Database
- Individual case reviews of mortality data from the state death registry. Postoperative mortality is defined as death within 30 days of a surgical procedure
- Index of socio-economic advantage / disadvantage determined for each patient based on the 2001 Australian Bureau of Statistics report on Socio-Economic Indices for Areas

Results: Within the study period, 5809 patients were treated in Western Australia for colorectal cancer. In this population, 26% were managed in the private healthcare sector.

Colorectal patients managed in the public sector were more likely than those treated in the private sector to (1) be older; (2) have a lower index of Relative socioeconomic advantage/disadvantage, economic resources (P=0.0001) and level of education and occupation; and (3) have a higher 30-day post-operative mortality rate (5% vs 2.5%, P=0.001).

In comparing private and public health sectors, more colorectal patients managed in the private sector had unknown staging of their disease and the proportion of patients with Stage 1V cancer was higher in the public health sector (12% vs 9%, P=0.048). There were no differences in the stage of disease at presentation or the 30-day postoperative mortality rate.

Patients treated in private hospitals had significantly better five year overall survival and cancer specific survival for all stages of colorectal cancer as compared to those in the public healthcare sector (P=0.0001).

Logistic regression showed the following significant independent predictors of receiving treatment in a private hospital (regardless of the type of socio-economic index used for the calculation):

- Younger age at diagnosis
- Male gender
- Cancer of the colon
- Higher index of relative socioeconomic advantage/ disadvantage

Independent predictors of improved overall survival were found to include:

- Treatment in a private hospital
- Diagnosis at a younger age
- Female gender
- Cancer Stage

These same independent predictors were seen for cancer-specific survival (excluding the influence of gender of the patient).

Take home message: Treatment in a private hospital is a significant independent indicator for overall and specific survival outcomes for colorectal carcinoma in this study population. Reasons for the improved survival outcomes need to be further studied. This has serious implications regarding the equity and access to treatment if the observed improvements are the result of superior treatment and not just patient selection.

A new approach to clinical governance in Queensland

S J Duckett. *A new approach to clinical governance in Queensland. Australian Health Review. 31 Suppl 1:S16-9, 2007 Apr Australian Health Review; April 2007; 31 suppl 1*

This short article describes the key reforms to clinical governance underway in Queensland Health. The imperative for the reforms were external reviews including the Bundaberg Hospital Inquiry.

The major rationale for the reform effort is to change the culture in Queensland Health to enhance clinician, patient involvement and a just & open approach to managing adverse events.

Results: The four areas for change include:

1. developing a culture that supports improvement in patient safety;
2. attraction and retention of good staff;
3. working in teams; and
4. effective organisational systems.

Examples of changes in each of the areas include altering the governance structure to include establishing a new Patient Safety and Quality Board to guide policy and specific training for 5100 managers (including clinical leaders and supervisors). New enhancement to staff pay and conditions along with new credentialing and privileges process was another significant change.

The importance of teamwork is highlighted by implementing culture / climate survey across all Queensland Health staff.

The most dramatic changes appear in the area of organisational systems where they have implemented measurement of 27 separate indicators, a feedback tool and a system to facilitate reporting and learning from clinical incidents.

Take home message: These changes are still being implemented and it is too soon to evaluate the impact on Queensland Health.

Supporting patients in making decisions about treatments

Thomson RG, Eccles MP, Steen IN, Greenaway J, Stobart L, Murtagh MJ, May CT. *A patient decision aid to support shared decision-making on anti-thrombotic treatment of patients with atrial fibrillation: randomised controlled trial. Qual.Saf.Health-care 2007;16:216-223.*

Medical care today increasingly aims to encourage patients to make informed choices about treatment options based on the evidence of potential benefits and risks.

This exploratory randomised controlled trial set out to determine whether use of a computerised decision aid in a shared decision-making consultation with their doctor, was as effective as conventional doctor-led advice based on clinical guidelines.

Decision conflict (or 'state of uncertainty about a course of action'), was measured in general practice settings in the North-Eastern region of the United Kingdom, amongst patients with atrial fibrillation and who chose whether to take warfarin or aspirin therapy to reduce the risk of stroke. In addition, anxiety, comprehension and decision-making preferences were measured. All outcome measures were validated tools.

Results: Decision conflict was significantly less in the group of patients seen in the shared decision-making consultation, utilising the computerised decision aid.

Both groups of patients however experienced a reduction in anxiety and an increased understanding about treatment options.

Interestingly, in this project, patients in the shared decision making group (also utilising the computerised decision aid) were less likely to choose warfarin as a treatment option, as they had an increased understanding of the potential risks associated with this medication.

Take home message: Decision aids used in shared decision-making consultations with doctors, have the potential to enhance patient comprehension, enabling them to balance the benefits and risks of treatment options. This empowers patients to make an informed choices.

Getting the right tools for the job: Evaluating teamwork in simulation



Morgan PJ, Pittini R, Regehr G, Marrs C, Haley MF. Evaluating teamwork in a simulated obstetric environment. *Anesthesiology* 2007; 106: 907-15.

High-risk industries, such as healthcare, have long been interested in the topic of teamwork and how we can establish competencies required for effective team performance under pressure.

Team training has increasingly moved from a pure focus on technical skills, such as knowledge and clinical expertise, to those non-technical requirements, such as communication, teamwork, leadership and decision-making. Consequently, the field of human factors has become an important part of attempts to evaluate team performance, both in practice and in simulation.

This article presents a US study which uses high-fidelity simulation to present obstetric scenarios for team assessment. It sought to determine whether two different human factors rating scales could be used to reliably assess obstetric team performance.

The first is the Human Factors Rating Scale (HFRS) which is an adaptation of the Operating Room Management Attitudes' Questionnaire (ORMAQ). The HFRS was created to assess general teamwork, communication, stress recognition, and safety concerns of teams and had demonstrated reasonable internal consistency. It contains 45 items. The second tool is the Global Rating Scale (GRS). The GRS uses a fairly simple 5-point rating scale with anchored descriptors to give an overall view of team performance.

Teams were composed of obstetric nurses, physicians and resident physicians (34 in total) who were assigned to teams of five and six, each team managing one to four 20-minute scenarios. Nine healthcare professionals (a mixture of both obstetric and human factors experts) then independently evaluated the 12 videotaped team performances using the HFRS and GRS. Self-assessed team scores by simulation participants were also collected in this study.

Results: When assessing overall team performance using global ratings, the two different methods produced similar findings. However, the GRS, whether produced by external examiners or self-ratings, was better able to differentiate team performances, was better able to distinguish between scenarios of differing difficulty, and did not demonstrate differences between raters' self-assessments as a function of the rater's profession. The GRS was also able to demonstrate moderate to good reliability while the HFRS was considerably less reliable.

This study does not support the use of the HFRS for assessment of obstetric teams. The GRS appears to have potential as a summative but not a formative assessment tool. However, overall, this research points to the need to develop a domain specific behavioural marking system for obstetric teams.

Take home message: Currently there is no consensus on how to measure teamwork, with a lack of empirical data to validate measures. This is especially true in healthcare and although simulation provides opportunities to develop and test tools it seems clear that we can not transfer these directly from other contexts into the medical domain. Moreover, it appears that transfer from one medical domain to another could also be inappropriate. The authors of this paper suggest that obstetric crisis management may be sufficiently unique to require a domain specific evaluation tool.

Clearly, we must engage with professionals, throughout the hierarchy of healthcare, in order to develop the most appropriate human factors tools rather than attempting to impose methods which have had (often limited) success in other domains.

Disclosing medical error

Gallagher T, Studdert D, Levinson W. Disclosing harmful medical errors to patients. *New Eng J Med* 2007; 356:2713-9.

When errors occur, there is an expectation by patients that they will be promptly informed about it. However, there is a divide between this expectation and actual practice.

Despite the fact that healthcare workers are reluctant to disclose errors for fear of litigation, there is some evidence that disclosure can reduce exposure to malpractice litigation. This article provides some examples of the impact of disclosure on claim payouts. However, the lack of proper evaluation means that the real effect of disclosure is not known and it is unlikely that it will be known for some years to come.

In the US, standards, programs and laws have been introduced to encourage disclosure in some areas of the health system. There has been almost a doubling in the number of hospitals with disclosure policies over the past three years. Last year the Harvard hospital group released a consensus statement on disclosure of unanticipated outcomes to patients. Guidelines for disclosure were last year endorsed by the National Quality Forum outlining:

- the need to incorporate disclosure as a core component of high-quality healthcare;
- the need to ensure that clinicians are properly trained in how to disclose information;
- the need to monitor its effect on outcomes.

These are voluntary guidelines. Australia and the UK both have introduced disclosure programs however, to date no results have been published outlining the effect of these programs.

On the legal front, a bill was introduced into Congress (but not passed) proposing enhancement of disclosure processes. Seven states have introduced legislation mandating the disclosure of medical errors to patients.

At least 34 states have introduced “apology laws”, however, there are many problems with this approach. There is little way of enforcing these laws. In the majority of the apology laws, there is simply a requirement to express regret, not to comment on causality. Only one state has introduced sanctions for non-compliance. There is no ongoing monitoring of whether disclosure occurs or the quality of it.

The greatest chance of seeing open disclosure work is having it embraced locally. For this reason, there is a need to use quality improvement techniques within institutions to track, test, and refine disclosure techniques.

In progressing this work there is a need to better understand how patients want disclosure carried out, how education should best be delivered, and how disclosure affects patient satisfaction and claiming behaviour in the longer term.

In the short term, the authors suggest that to optimize the likelihood of uptake, voluntary standards and linking disclosure with pay-for-performance should be introduced across the health sector.

Take home message: Open disclosure was introduced in Australia in 2003. It is fair to say that its uptake has been sporadic although it has been highlighted as a priority area by the Australian Commission and most health departments. We need to evaluate these programs at a variety of levels as a matter of urgency.

Although there is a tendency to look at claims as the principal indicator of effectiveness of open disclosure, it could be argued that the mental health effects of disclosure on both patients and clinicians is a more valid measure of its worth.

The hidden risks of information technology in healthcare



de Wildt SN, Verzijden R, van der Anker JN, de Hoog M. Information technology cannot guarantee patient safety. BMJ 2007; 334: 851-852.

This short BMJ practice article demystifies the idea that information technology (IT) and automation in healthcare is a simple answer to solve some current patient safety concerns.

It focuses on the issue of using IT tools when calculating drug doses and infusion rates, highlighting a case study example where errors were exacerbated as a result of a new handheld assistant within paediatric resuscitations rather than the use of traditional drug dose charts.

A case study is highlighted where a 3 month old infant received a sevenfold higher dose of noradrenaline than intended for at least two hours. This was a result of a software flaw which meant that formulae cells on the PocketExcel sheet were not locked, enabling the medical practitioner to overwrite the concentration of noradrenaline for infusion with the patient's weight.

The article goes on to develop the case from a doctor and an information technologist's point of view and comes to the conclusion that since handheld computers are increasingly being used for important calculations, healthcare institutions should at least “increase awareness of the possible pitfalls.” However, how to achieve this is not discussed.

Take home message: Rigorous risk assessments need to be carried out both pre- and post- implementing new technologies and / or automating existing manual processes in healthcare.

In this way, we may be able to both better prepare for and design out risk or, in the worst case scenarios, retrospectively adapt systems to alleviate any unintentional risk that a new technology brings.

Doing good quality research: Part 2

STEP 2: Choosing a study design

The first thing you need to determine when deciding on the research design is whether you are simply observing a group of people/ a disease/ practice (i.e. an observational study) or whether you are putting into place an intervention (i.e. an interventional study). Observational studies are often undertaken to determine why something happens. In observational studies you are not assigning any exposure or treatment. Observational studies can be simply describing something or they can be used to understand why something has happened (analytic). Figure 1 below shows the different types of analytic observational studies that can be done. If you gather a group and follow them forward in time, then you have a cohort study. An example of this might be following all patients who have undergone surgery to look at adverse event rates. If you want to look retrospectively (back) at something to work out why it occurred then you might chose a case control study. Cross sectional studies are designed to get a snapshot of something. An example might be looking at the prevalence of pressure ulcers in hospitals on a targeted day each year. The relative value of each of these three types of analytic studies is shown in Figure 2.

Interventional or experimental studies involve implementing some change and measuring its impact. There are various types of interventional studies. The gold standard of research is the double blinded randomised controlled clinical trial (RCT). This involves putting into place an intervention where neither the people participating in the study nor those evaluating its outcome are aware of what treatment is being received. For example, a study investigating whether antibiotic-coated central venous catheters (CVCs) are more effective at preventing bloodstream infections than non-coated CVCs would be double blinded if neither those inserting the catheter nor those assessing the outcome (infection) are aware of what type of catheter has been used in the patient. These types of studies are rarely feasible to do in clinical practice. Provided that objective outcomes are used to measure the effectiveness of the intervention, whether the study is blinded or not is not of major importance.

A common approach to doing interventional studies in clinical settings involves using a continuous quality improvement (CQI) model known as the Deming Cycle (Figure 3). A central concept of CQI is process improvement using measurement to monitor progress towards defined outcomes as different changes are applied. This methodology has been applied in Clinical Practice Improvement projects and those implemented as part of the *Safer System Safer Lives* campaign. While many studies have demonstrated that CQI can improve clinical practice, there is little understanding of why variation in outcomes exists among organisations applying CQI methodology and whether improvements achieve long term sustainability.¹

1. Counte M, Meurer S. Issues in the assessment of continuous quality improvement implementation in health care organizations. *Int J Qual Health Care* 2001; 13(3):197-207.

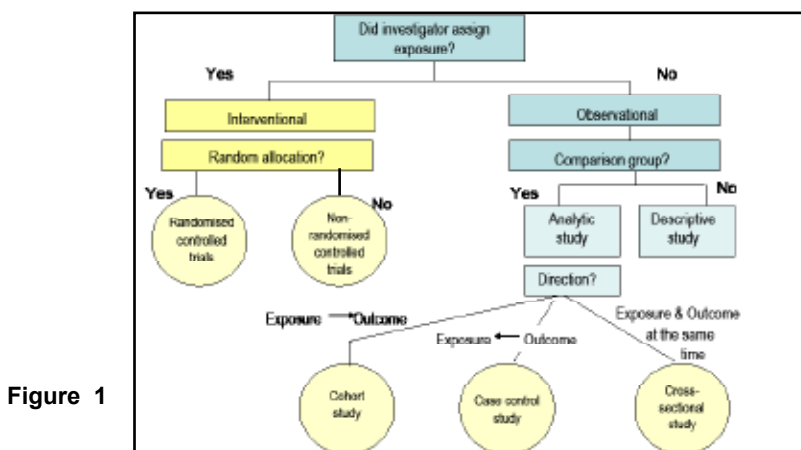


Figure 1

	Cohort study	Case control study	Cross-sectional study
Cost	Expensive	Cheap	Cheap
Time	Longer	Shorter	Shortest
Size	Larger	Smaller	Smaller
Perceived quality of the research	★★★	★★	★★
Rare problem	Efficient	Inefficient	
Lag time b/n exposure & outcome	Inefficient	Efficient	

Figure 2

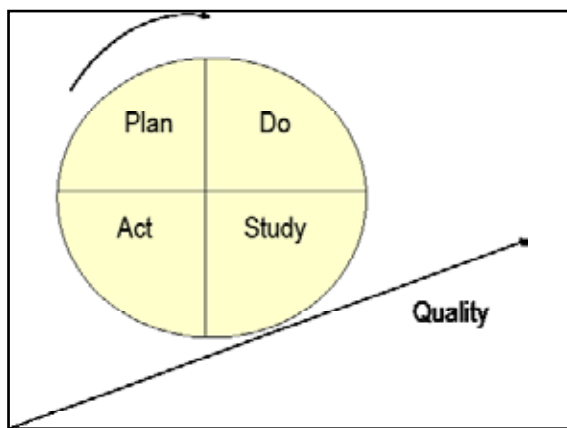


Figure 3