

## Upcoming seminar

### Strategies for improving medication safety in hospitals: The way forward

**About the seminar:** Medication errors are one of the most common types of adverse events reported in the hospital system. It is estimated that around 2-3% of admissions to hospital have an adverse medication event; in some populations it is estimated to be as high as 30%. Half of these errors are deemed to be potentially preventable.

A priority area for peak quality and safety bodies at an international, national and jurisdictional level has been to identify areas where additional patient safety activity could enhance patient safety. Investment is needed in assessing gaps in care, improving product safety, developing medication management systems and education and competency assessment.

Various efforts have been directed at understanding and reducing medication errors and improving safety at the system level and also at the practitioner level.

This seminar aims to share information about strategies that have been successfully implemented to reduce medication errors and thereby improve patient safety.

**Who should attend:** This seminar should be attended by all health professionals with an interest in medication safety including hospital pharmacists, clinicians, clinical governance staff and managers, nurses, allied health professionals and health service executives from both private and public hospitals.

It will be conducted by the NHMRC Centre of Research Excellence in Patient Safety (CRE-PS) in collaboration with the Australian Commission on Safety and Quality in Healthcare and the Safe Medication Management Unit, Medication Services Queensland, Queensland Health.

**Venue:** Edwin Tooth Tiered Auditorium, Education Centre, Royal Brisbane and Women's Hospital, Butterfield Street, Herston, Queensland, 4029.

**Seminar date:** Friday 30th October, 2009

**Seminar time:** 9:00am - 4:40pm  
(Registration opens at 8:30am)

**Cost:** \$250 per person (incl. of GST)

Further venue details, accommodation and parking information can be found on our website at: [www.crepatientsafety.org.au](http://www.crepatientsafety.org.au).

Enquiries to Catherine Pound on 03 9903 0891 or [catherine.pound@med.monash.edu.au](mailto:catherine.pound@med.monash.edu.au).



Centre of  
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 Health care 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 Health, Monash University Department of General Practice, Clinical Excellence Commission, Melbourne Pathology, Peter MacCallum Cancer Centre, Princess Alexandra Hospital, Boston University (US), Veterans' Affairs (US), Imperial College School of Medicine (UK), Bergen University (Norway).

## Registries for robust evidence



Dreyer NA, Garner S. *Registries for Robust Evidence JAMA. 2009;302(7):790-791.*

This commentary outlines the advantages and limitations of registries, which can be used to fill critical gaps in evidence and assess the safety and effectiveness of interventions used across a diverse array of patients and settings. The US Agency for Healthcare Research and Quality defines a patient registry for evaluating outcomes as ‘an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves a predetermined scientific, clinical, or policy purpose’. Registries are often referred to as ‘real world data’ and more attention is being focused on them to build an evidence base when randomised trials are not feasible or appropriate. They are also used to contribute to understanding how trial results can be applied in practice.

Registries can be organized around diseases, conditions or exposures; a health care service such as a procedure; or products, drugs or devices. They can address questions ranging from treatment effectiveness and safety to the quality of care delivered. Registries vary in complexity from simply recording product use as a requirement for reimbursement, to more systematic efforts to collect prospective data on many types of treatment, risk factors, and clinical events in a defined population. Follow-up can be retrospective, prospective, or a combination of both.

The commentary outlines examples of how registries have been used in the US to change practices. For example safety data from the Acyclovir Pregnancy Registry was used to inform the Food and Drug Administration (FDA) of the safety of the drug in pregnancy. The registry findings did not show an increase in the number of birth defects identified among the prospective reports when compared with those expected in the general population. There was also no pattern of defects among prospective and retrospective reports. In response the pregnancy labeling category for the drug was changed from category C (risk cannot be ruled out) to category B (no evidence of risk in humans).

The limitations of registries are also discussed and highlight how results require careful interpretation, taking into account the characteristics of the patients (disease severity, past treatments, comorbidities), the clinician (specialty, practice setting, training), and the terms of health insurance coverage or national guidelines. Selection biases are especially important, for example, when sicker patients are treated with newer treatments and when these patients have worse outcomes due to their underlying disease, this can be misinterpreted as a treatment effect.

**Take home message:** There is increasing recognition that randomized controlled trials may not always be appropriate and feasible to determine, in a timely manner, the safety and effectiveness of certain interventions. Registries can be used to fill the gaps in evidence and to enhance the evidence base. Understanding the potential sources of bias is important and the value of registries can be enhanced by providing a quantitative assessment of the extent to which bias may have affected the results.

## Do educational interventions improve prescribing?

Ross S, Loke YK. *Do educational interventions improve prescribing by medical students and junior doctors? A systematic review. Br J Clin Pharmacol. 2009;67(6):662-70.*

Prescribing is a complex and challenging task and there is evidence that poor prescribing practices influence preventable medication errors. Poor prescribing includes under, over and inappropriate prescribing. It is unclear to what extent educational interventions improve prescribing performance. The aim of this article was to review whether educational interventions improved prescribing skills in medical students and junior doctors.

The authors conducted a systematic review of the literature published in English from 1990 onwards. Studies were included if the population was medical students or junior doctors and the intervention was a structured educational activity for prescribing. Studies were excluded from the systematic review if they included educational activities aimed at increasing theoretical knowledge of pharmacology and therapeutics. Each study was reviewed by the two investigators using a pre-determined set of criteria.

**Results:** Of the 3189 publications initially identified, only 22 met the inclusion criteria and were selected for data extraction. From the 22 there were seven interventions that did not report any assessment results. The results of 11 controlled trials and 4 ‘before and after’ studies were used in the analysis. The studies addressed three types of questions: prescribing as a whole; dose calculation and administration; and prescribing errors. The majority of the interventions were based on the WHO Good Prescribing Guide. Ten of the controlled trials showed improvements in the scores of the intervention group on written scenarios or clinical examination stations but one study showed no effect on prescribing errors. All the ‘before and after’ studies reported significant improvements in written tests or clinical stations. The major limitation was that the outcome measures examined written case scenarios rather than actual prescribing in a clinical setting. The majority of the studies were small in size with significant methodological limitations. Therefore, the conclusions about the impact of educational intervention, is tentative at best.

**Take home message:** Very little is known about the impact of educational interventions to improve prescribing. More information and research is required to improve practice and to guide medical schools about the most effective approach to teach medical students and junior doctors.

## What 'patient-centered' should mean

Berwick DM. *What 'patient-centered' should mean: confessions of an extremist. Health Aff (Millwood). 2009;28(4):w555-65. Epub 2009 May 19.*

Healthcare performance is usually measured in the following six areas: safety, effectiveness, 'patient-centeredness', timeliness, efficiency, and equity. In this commentary, Berwick argues for a radical transfer of power and a bolder meaning of 'patient-centred care', in hospitals and healthcare centres. He asserts that 'patient-centeredness' is a dimension of health care quality in its own right, and not just because of its connection with other desired aims, like safety and effectiveness. There is growing evidence that 'patient centred care' has a positive relationship to health status outcomes.

His proposed definition of 'patient-centred care' is: 'The experience (to the extent the informed, individual patient desires it) of transparency, individualization, recognition, respect, dignity, and choice in all matters, without exception, related to one's person, circumstances, and relationships in health care'.

Some examples of what 'patient centred' care should look like include:

- Hospitals would have no restrictions on visiting—no restrictions of place or time or person, except restrictions chosen by and under the control of each individual patient.
- Patients would determine what food they eat and what clothes they wear in hospitals (to the extent that health status allows).
- Patients and family members would participate in rounds.
- Patients and families would participate in the design of health care processes and services.
- Medical records would belong to patients. Clinicians, rather than patients, would need to have permission to gain access to them.
- Shared decision-making technologies would be used universally.
- Operating room schedules would conform to ideal queuing theory designs aimed at minimizing waiting time, rather than to the convenience of clinicians.
- Patients physically capable of self-care would, in all situations, have the option to do it.

Berwick warns that the incorporation of 'patient centred care' into new health care designs will involve some radical, unfamiliar, and disruptive shifts in control and power, out of the hands of those who give care (doctors, nurses, technicians) and into the hands of those who receive it (patients and their loved ones). Such a consumerist view of the quality of care, itself, has important differences from the more classical, professionally dominated definitions of 'quality'. He anticipates three major objections from health care professionals. The first that evidence based medicine will be overlooked, secondly, that this type of care is socially irresponsible and lastly that it will ignore the clinicians' own needs and wants.

He concludes by suggesting ways in which the health system can be redesigned to include 'patient centeredness' as a quality dimension in its own right. Firstly, this includes asking patients for their feedback at the end of every interaction. Secondly,

allow patients and families control over decisions about care in all aspects and only take over control when permission is firmly granted. Thirdly, extend transparency into all aspects of care including science, costs, outcomes processes and errors. Fourthly, include flexible systems which can be adapted to meet the needs and circumstances of individual patients, and fifthly train all young healthcare professionals in 'patient centred care'.

**Take home message:** Health care is currently fragmented and not focused on the needs of the patient. There is growing evidence that 'patient centred care' has a positive relationship on health status outcomes and this commentary suggests some radical changes in the way health systems are designed and delivered in order to achieve patient centeredness in health care. This includes shifts in control and power, out of the hands of those who give care (doctors, nurses, technicians) and into the hands of those who receive it (patients and their loved ones).

## Effectiveness of thigh-length graduated compression stockings to reduce the risk of deep vein thrombosis after stroke

CLOTS Trials Collaboration, Dennis M, Sandercock PA, Reid J, Graham C, Murray G, Venables G, Rudd A, Bowler G. *Effectiveness of thigh-length graduated compression stockings to reduce the risk of deep vein thrombosis after stroke (CLOTS trial 1): a multicentre, randomised controlled trial. Lancet. 2009;373(9679):1958-65.*



Deep vein thrombosis (DVT) and pulmonary embolism are common complications after stroke. Measures to reduce deaths from these complications include the use of graduated compression stockings (GCS), intermittent pneumatic compression and anticoagulation therapy. Most national stroke guidelines (including those in the UK, France, Italy, Australia and New Zealand) recommend the use of GCS for patients with stroke, however most of the trials regarding effectiveness of GCS have been conducted in surgical patients. The CLOTS (Clots in Legs Or sTockings after Stroke) trials are three multicentre randomised controlled trials that use the same randomisation, data collection, and follow-up systems and that aim to assess the balance of risk and benefit of external compression in patients with acute stroke. All three trials test the effect of the addition of different compression strategies to routine care. CLOTS trial 1, which is the subject of this article, tested thigh-length GCS versus avoidance of GCS for reducing DVT after stroke. The CLOTS trials 2 and 3 are in progress and are testing thigh-length GCS versus below-knee GCS, and intermittent pneumatic compression versus avoidance of intermittent pneumatic compression, respectively.

A total of 2518 patients who were admitted to hospital within one week of an acute stroke and who were immobile were enrolled from 64 centres in the UK, Italy, and Australia. Patients were allocated via a central randomisation system to routine care plus thigh-length GCS (n=1256) or to routine care plus avoidance of GCS (n=1262). A technician who was blinded to treatment allocation undertook compression Doppler ultrasound of both legs

at about 7–10 days and, when practical, again at 25–30 days after enrolment. The primary outcome was the occurrence of symptomatic or asymptomatic DVT in the popliteal or femoral veins. Analyses were by intention to treat.

**Results:** DVT occurred in 126 (10.0%) patients allocated to thigh-length GCS and in 133 (10.5%) allocated to avoid GCS, resulting in a non-significant absolute reduction in risk of 0.5% (95% CI –1.9% to 2.9%). However, side effects, including skin breaks, ulcers, blisters, and skin necrosis were significantly more common in patients allocated to GCS than in those allocated to avoid their use (64 vs 16; odds ratio 4.18, 95% CI 2.40–7.27).

The advantages of this trial were its randomised multicentre design and also that all patients randomised were included in the analyses. One limitation was that only 73.1% of the intervention group were compliant and wore GCS for the full 30 day trial period, so incorrect use and poor compliance may have reduced their effectiveness.

**Take home message:** Thigh length graduated compression stockings are not clinically effective at reducing the risk of proximal DVT after stroke and are associated with side effects. National guidelines for stroke may need to be revised on the basis of these findings.

## Effectiveness and safety of nicotine replacement therapy assisted reduction to stop smoking



Moore D, Aveyard P, Connock M, Wang D, Fry-Smith A, Barton P. Effectiveness and safety of nicotine replacement therapy assisted reduction to stop smoking: systematic review and meta-analysis. *BMJ*. 2009;338:b1024.

Smoking is an important cause of illness and premature death in both developed and developing countries. Although many smokers try to quit each year the success rate is very low (2–3% in a study of smokers in the UK). Nicotine replacement therapies, including gum, inhalers, patches and lozenges, allow for the gradual reduction of nicotine as an aid to ceasing smoking. The objective of this systematic review is to determine the effectiveness and safety of nicotine replacement therapy for the cessation of smoking.

Inclusion criteria for the review were all randomised controlled trials that enrolled smokers who declared no intention to quit smoking in the short term, and compared nicotine replacement therapy with placebo, no treatment, other pharmacological therapy, or motivational support, and reported quit rates. Two reviewers independently applied eligibility criteria. One reviewer assessed study quality and extracted data and these processes were checked by a second reviewer. The primary outcome was six months sustained abstinence from smoking beginning during treatment, and other outcomes were cessation and reduction at end of the follow-up period, and adverse events.

**Results:** Seven randomised controlled trials studies met the inclusion criteria. Four trials used gum for the treatment group, two trials used inhalers and in one trial the participants were free to use gum, inhaler or patches. In all studies the populations had similar personal characteristics with potential participants excluded if they had heart disease, were pregnant or lactating, taking psychiatric drugs or had other drug problems. Behavioural support was provided in all the studies with participants provided with written information on how to use the treatments with clinical staff providing additional support if necessary. The behavioural support was repeated for 5 or more times for at least a year, in some cases it was up to 24 months.

A total of 1384 smokers were treated with nicotine replacement for six to eighteen months and 1383 were treated with a placebo. The numbers of participants who stopped smoking was low in both arms however the rates of sustained abstinence from smoking for at least 6 months were 6.75% in the treatment groups compared with 3.28% in the placebo group. The number needed to treat was 29. Successful reduction of smoking was more common in treatment group with 21.8% reducing consumption by half compared with 16.8% of the placebo group. The type of replacement therapy used did not seem to impact on the success of the intervention. Discontinuation due to adverse events was rare in these studies with 1.7% in the treatment groups and 1.3% in the placebo groups. Nausea was used as an indicator of potential nicotine overdose and rates were higher in the treatment groups (8.6%), compared to the placebo groups (5.3%). Four deaths were seen in each of the treatment and placebo groups.

**Take home message:** Nicotine replacement therapy is an effective intervention in achieving sustained smoking abstinence for smokers who have no intention or are unable to attempt an abrupt quit. Most of the trials included in this systematic review had regular behavioural support and monitoring and it is unclear whether using nicotine replacement therapy alone would be as effective.

## Exploring the harmful effects of health care

Kilo CM, Larson EB. Exploring the harmful effects of health care. *JAMA*. 2009;302(1):89-91.

Presently, precise data related to the magnitude of harm resulting from delivery of health services is scarce and it is unclear whether the aggregate harms from health care outweigh the benefits. In this commentary, potential harms from health care are discussed and the authors suggest a taxonomy for health care harm. They emphasise that investigators should start addressing the different types of harm to ensure that health care services are allocated so that they result in the greatest benefits.

Harm can occur as either a direct or indirect consequence of health care. Direct harm can be categorised as adverse physical or emotional effects, generally on individuals, as a by product of health care delivery. Physical harm resulting from routine care is an accepted risk of many treatments and most forms of physical harm can be avoided if treatments which have sufficient evidence of effectiveness and safety are used. Both health care professionals and patients tend to embrace new technology before adequate risk assessment is made, and this high intensity care may not improve survival. Unnecessary care results in emotional harm and this can include anxiety from testing or treatment and from creating inappropriate expectations. Although

this form of harm is less well studied, it also has important effects on patient well-being.

Indirect harm is usually related to costs and can result when health care expenditures are excessive or of low clinical value. For example, when financial resources are limited, expensive interventions of marginal value to a small group of patients may deprive the majority of less expensive care that is more effective. Although the magnitude of indirect harm may outweigh direct harm, the effects are less apparent to both those it affects and those who create it. Health care may cause indirect harm by diverting resources from other determinants of health such as education, environmental quality, jobs and income.

**Take home message:** Although health care's objective should be to improve health, its primary emphasis has been on producing services. Health care lacks adequate measures to evaluate its influence - either positive or negative - at the individual and community level. Better measurements of both direct (physical and emotional) and indirect harm are required, looking at duration and quality of life, in order to ensure appropriate distribution of resources relative to other health-producing investments.

## Do financial disincentives improve inpatient safety?

Milstein A. *Ending Extra Payment for "Never Events" – Stronger Incentives for Patient's Safety.* *NEJM* 2009; 360(23):2388-90.

Inouye SK, Brown CJ, Tinetti ME. *Medicare Nonpayment, Hospital Falls, and Unintended Consequences.* *NEJM* 2009; 360(23):2390-3.

The June 4 2009 issue of the New England Journal of Medicine published two perspectives about hospital reimbursement initiatives designed to improve patient safety.

Milstein, a member of the USA Medicare Payment Advisory Commission, outlines the case for not reimbursing hospitals for cost consequences arising from "never events". These are serious medical errors, as deemed by the National Quality Forum (NQF) that should not occur in safe hospitals. Examples of "never events" include foreign objects left after surgery, pressure ulcers, catheter-related urinary tract infections, incompatible blood infusions, and certain falls and trauma, amongst others. NQF is a private sector standard-setting organisation working to improve the quality of health care through the evaluation and endorsement of standardised performance measurement.

Milstein supports the decision of Congress to reduce payments to hospitals in the event of the occurrence of "reasonably preventable" hospital-acquired complications, as this encourages increased accountability for the financial consequences, thereby motivating hospitals to pro-actively facilitate patient safety improvements. This payment reform was implemented by Medicare in September 2008, with numerous commercial health plans and state Medicaid plans now following suit.

In the second article Inouye and colleagues express their concern that this policy has potential to cause unintended harm in the case of falls. Up to 20% of patients are reported to fall during a hospital stay, signifying a major patient safety issue. However falls do not necessarily reflect poor care, with

the authors quoting a recent systematic review reporting that only 20% of hospital falls are preventable. Inouye et al. also raise the potential consequence of hospitals reacting by introducing physical restraints in an attempt to reduce their falls risk, when the focus should be on maintenance of mobility. Such interventions not only reduce patient mobility, but are associated with additional complications including functional loss, delirium, agitation, and pressure sores. Such strategies may also increase costs.

**Take home message:** Financial disincentives for preventable "never events" have the potential to motivate hospitals to review their service delivery and facilitate proactive quality and safety practice. However, targeting falls, which are largely not preventable, could have unintended safety and financial repercussions.

## Effects of resident duty hour reform on surgical and procedural patient safety indicators

Rosen AK, Loveland SA, Romano PS, Itani KM, Silber JH, Even-Shoshan OO, Halenar MJ, Teng Y, Zhu J, Volpp KG. *Effects of resident duty hour reform on surgical and procedural patient safety indicators among hospitalized Veterans Health Administration and Medicare patients.* *Med Care.* 2009;47(7):723-31.

The Accreditation Council for Graduate Medical Education (ACGME) considered the lowering of resident doctor's duty hours as a possible way to improve patient safety in the hospital setting. Duty hour regulations were implemented by ACGME on July 1, 2003. At the time there was little evidence whether improvements in patient safety would be achieved due to a decrease in resident fatigue or if the reverse would occur, a decrease in patient safety due to discontinuity of care.

An observational study was conducted in order to measure the effect of decreasing duty hours on patient safety levels by measuring the change in reported patient safety events in more versus less teaching intensive hospitals. Teaching intensity was measured using a resident to bed ratio calculated as the number of interns and residents divided by the mean number of operational beds. Major teaching hospitals had a resident-to-bed ratio of greater than 0.25. The authors looked retrospectively at patients admitted to Veterans Health administration (VA) (N=826,047) and Medicare (N=13,367,273) acute care hospitals from July 1, 2000 to June 30, 2005 and compared patient safety events occurring before and after the duty hour reform took place. Statistical analysis included conditional logistic regression, adjusting for patient age, gender, co morbidities, secular trends, baseline severity, and hospital site. Patient Safety Indicators (PSI's) as measured by the Agency for Healthcare Research and Quality (AHRQ) were used to measure potentially preventable events that compromise patient safety. They were grouped into three categories; 'Continuity of Care', 'Technical Care' and 'Other' for purposes of evaluation. It was generally hypothesised that rates of PSIs related to 'Continuity of Care' may increase and the rates of PSIs related 'Technical Care' may decrease.

**Results:** The results were analysed using a multiple time series research design also known as difference-in-differences, to examine whether the changes in duty hour rates were associated with a change in the underlying trend in patient outcomes in teaching hospitals. This method reduces potential bias from unmeasured variables. In the VA dataset there was no significant difference in odds of PSI events for the composites 'Continuity of Care' or 'Technical Care' regardless of teaching intensity or time after reforms. The 'Other' care composite the rates increased in the second year following the reforms in more versus less teaching intensive hospitals (odds ratio, 1.63; 95% CI; 1.10-2.41). There was no significant difference in VA for this measure for the first year after reforms. In Medicare there was no significant difference in odds of PSI events for the composites 'Continuity of Care' or 'Other Care' regardless of teaching intensity or time after reforms. However, the odds of a 'Technical Care' PSI event in more versus less teaching intensive hospitals in the first year after reforms was 1.12 (95% CI; 1.01-1.25) although this difference was no longer significant in the second year after reforms. The study concluded that duty reform had no systematic impact on PSI rates. Where a statistically significant result was found the magnitude was deemed too small to be clinically meaningful.

**Take home message:** This study identifies the importance of assessing initiatives once implemented to ensure they are improving clinical practice and patient safety standards. In this case duty hour reform had no impact on patient safety indicators.

## Hospital quality and intensity of spending: Is there an association?



Yasaitis L, Fisher ES, Skinner JS, Chandra A. Hospital quality and intensity of spending: is there an association? *Health Aff (Millwood)*. 2009;28(4):w566-72.

In this paper the authors extend previous literature that has examined the relationship between quality and spending at a regional level to an investigation of the relationship at the level of individual hospitals. Previous studies report that higher spending is associated with high intensity care but lower quality of care, as defined by process of care measures.

This study used data (2004-2007) from a public (Centres for Medicare and Medicaid services)–private organisation collaboration and focused on three conditions for which there are high level evidence recommendations supporting specific processes of care; acute myocardial infarction (AMI), pneumonia and chronic heart failure (CHF). Evidence based measures were only included where a majority of hospitals reported at least 25 observations for the measure in 2004. A total of 11 process of care measures formed the basis for defining the construct 'quality of care'. Of note, none of these related to thrombolysis or reperfusion interventions. The scores were summarised by condition and as a composite score of all conditions. Percentile rankings were assigned to each hospital for overall and condition related quality.

The costing method was based on end of life spending performance by each organisation and included hospital utilisation, high dependency unit utilisation and ratio of specialist to primary care physician visits. Hospitals were then categorised into 5 quintiles of spending.

The analysis considered all hospital data and separation for academic medical centres (AMC) and appropriately considered adjustment for geographical region and other factors (fixed effects analysis). Regression analysis was used to report the association between quality quintile scores and spending.

**Results:** Almost half AMCs reporting adequate data were in the top spending quintiles. There were negative relationships between performance for AMI, pneumonia and overall quality scores but not for CHF. For AMCs there was a negative relationship only for spending and AMI performance. Some of the differences are mediated by geographical difference in intensity of care, but the relationship between performance for pneumonia and spending remained strong. There is wide variation within regions on spending and quality.

Limitations of the study include; inadequate definition of quality of care due to limited number of process measures, especially for AMI which might explain the findings within AMCs. In addition process measures are only proxy measures of outcomes. There is possible bias due to poorly performing organisations providing lower quality data. There may be inadequate adjustment of casemix factors, for instance for sicker patients receiving more intensive care.

**Take home message:** Overall the study reinforces the difficulties in measuring quality of care and associated costs, but adds some further support to the presence of within, and between, regional variation.

## Application of AHRQ patient safety indicators to English hospital data

Bottle A, Aylin P. Application of AHRQ patient safety indicators to English hospital data. *Qual Saf Health Care*. 2009;18(4):303-308.

Patient Safety Indicators (PSIs) have been used in the US for some time to monitor quality of care. These indicators are derived from administrative data. This paper describes how researchers translated the indicators from the coding used in the US (ICD 9) to the coding used in the UK (ICD 10) and then applied the indicators to UK data. It then describes the views of hospital administrators who received and were asked to interpret the data.

A retrospective cohort study was undertaken following translation of the following 9 PSIs:

- Death in low mortality Healthcare Resource Groups (HRGs). In Australia we refer to these as Diagnostic Related Groups (DRGs)
- Decubitus ulcers
- Foreign body left in during a procedure
- Selected infections due to medical care
- Post operative hip fracture
- Post operative sepsis
- Obstetric trauma, third and fourth degrees lacerations
  - o Vaginal without instrument
  - o Caesarean section

Reports providing results reported by financial year were fed back to 170 trusts. Included in the report were data relating to how many patients “flagged” (calculated by assessing rates of those with a PSI over a denominator of those at risk) and whether there were differences in hospitalisation rates, in-hospital death and unplanned admissions between those who did and did not flag. Following this quantitative analysis, a qualitative study was undertaken to determine the opinion of trusts on the figures and the way in which they were presented, the codes used and the potential utility of the indicators for driving quality improvement.

**Results:** A total of 0.26% of admissions flagged as having a potential adverse event using the 9 PSIs. Those admissions which flagged with a PSI were more likely to have a longer median length of stay and in-hospital death compared to those who did not flag. People with a decubitus ulcer were 5 times more likely to die in hospital and more than twice as likely to have an extended hospitalisation compared to those who did not have a documented decubitus ulcer. There was wide variation between trusts for all indicators, even after adjusting for age and gender.

A total of 21% of trusts replied to the survey. Concerns were expressed about the choices of coding, that data both within their own trust and also in other trusts were inaccurate (particularly the secondary diagnosis fields), that further case-mix adjustment was needed and that those with high rates would be concerned about how they would be perceived if data were published. Some which had undertaken audit against medical records add that rates were lower than that captured by the respective PSI.

**Take home message:** This mixed methods study highlights the difficulties in using administrative data to report on quality of care. In such studies it is often the quality of the data that is called into question more than the quality of the findings. Until validation work is undertaken it is unlikely that these findings will have any measurable impact on changing clinician behaviour.

## Methodological variability in detecting prescribing errors



Franklin BD, Birch S, Savage I, Wong I, Woloshynowych M, Jacklin A, Barber N. Methodological variability in detecting prescribing errors and consequences for the evaluation of interventions. *Pharmacoepidemiol Drug Saf.* 2009 E Pub Jul 24.

The aim of this study was to compare four methods of detecting prescribing errors in the same cohort of patients, both before and after introducing an intervention-computerized physician order entry (CPOE), and to determine whether the impact of CPOE was identified consistently by all methods.

The study was conducted in a 28 bed general surgery ward in a London teaching hospital, during two 4 week periods. The methods used to identify prescribing errors included: 1) prospective data collection and detection by the ward pharmacist during prescription monitoring, 2) retrospective health record review (RR) focusing on medication and including all medication errors regardless of outcome, 3) retrospective use of a US trigger tool adapted for UK use, and 4) spontaneous reporting using an established medication incident reporting system. Prior to the introduction of CPOE, medication orders were paper based and medication was stored in drug trolleys and stock cupboards. The new system incorporated CPOE, ward based automated dispensing, barcode patient identification and electronic medication administration records. The pharmacist providing the ward service remained the same during the study. Only those patients whose health records were available for RR were included in the comparison. A research pharmacist completed the RR form for each patient in the study and applied the trigger tool after the RR. The principal investigator checked for prescribing errors once a week in addition to those identified by the ward pharmacist.

**Results:** Ninety-three patients were reviewed pre-CPOE and 114 post-CPOE. Using all four methods, there were 135 prescribing errors identified pre-CPOE (10.7% of all medication orders), and 127 (7.9%) post-CPOE. There was little overlap in prescribing error detection by the different methods. RR revealed 93 (69%) pre- and 105 (83%) post-CPOE. Only 5–7% of all prescribing errors were identified by both the ward pharmacist and RR. Spontaneous reporting and the trigger tool each identified less than 1% of all errors. The key findings from the study were that the observed incidence of prescribing error is extremely dependent on the method of detection. Prospective evaluation of CPOE underestimates the incidence of prescribing error and overestimates the true effect of the intervention. A combination of methods may be required to understand the true effectiveness of different interventions.

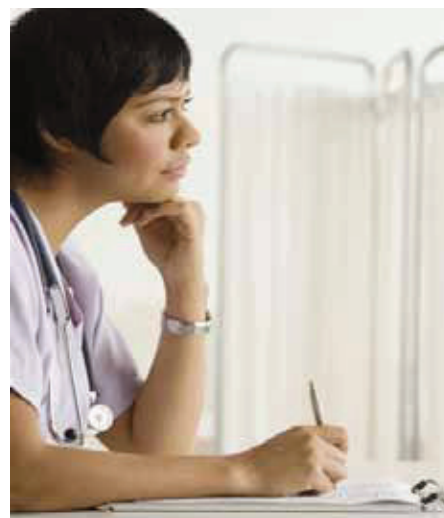
Key limitations to this study were that the authors were not able to ascertain whether the incidence of prescribing errors was reduced due to the introduction of CPOE alone or because of the “new system” which included additional processes. Because the study was a small pilot study based in one hospital and only involved surgical patients it cannot be generalized to other practice settings. It is also not made clear in the paper when the study took place.

**Take home message:** The observed incidence of prescribing errors is dependent on the method used for detection. A combination of methods will be required to measure the true effect of an intervention to reduce prescribing errors.

## How to critically appraise a research study

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Patient safety and quality improvement research can include a diverse range of study types, settings and interventions which can also vary in complexity. A practical approach to understanding the implications of this research is to develop critical appraisal skills. Critical appraisal is the process of systematically examining research to judge the relevance and validity of the results. It is important in order to gain a balanced assessment of the strengths of the research against its limitations. Listed below are some of the key questions to ask when critically appraising an article.



### Did the researchers use an appropriate study design to answer their question?

Different questions require different study designs. Generally, the best study design for evaluating the effectiveness of an intervention or treatment is a randomised controlled trial (RCT), however RCTs are not always ethical or feasible. Before and after studies are often used in quality and safety research, but it is recommended that several measurements are taken before and after to enable analysis of system change over time, independent of the intervention.

### Are the results of the study valid?

The presence of bias and confounding can distort the results of a study. Bias occurs when there is a systematic error in the results of the study because of the way it has been conducted, analysed or reported. Common types of bias include selection bias and measurement bias. A confounder is a factor that is linked to the outcome of interest and is unevenly distributed between the study groups, for example age. A factor is not a confounder if it lies on the causal pathway between the variables of interest. When critically appraising research it is important to systematically check that the researchers have done all they can to minimise bias and confounding.

### What are the results and are they clinically relevant?

Results can be expressed in various ways depending on the outcome of interest and can include prevalence or incidence change, odds ratios, relative risks, risk differences, sensitivity, specificity or number needed to treat. Sometimes an emphasis is placed on statistically significant findings which are not clinically relevant; alternatively, some researchers may dismiss potentially clinically important differences between groups that are not statistically significant, often because the sample sizes are too small.

In addition to thinking about these questions, there are a number of documents available to guide the process of critical appraisal. The Consolidated Standards of Reporting Trials (or CONSORT Statement) is an evidence-based minimum set of recommendations for reporting RCTs and comprises a checklist and flow diagram<sup>1</sup>. The Scottish Intercollegiate Guidelines Network<sup>2</sup> (SIGN) and the Centre for Evidence Based Medicine<sup>3</sup> (CEBM) also have checklists and other resources which can be used to appraise studies.

1 Consolidated Standards of Reporting Trials Statement available at: [www.consort-statement.org/consort-statement](http://www.consort-statement.org/consort-statement)

2 Scottish Intercollegiate Guidelines Network Critical Appraisal checklists available at [www.sign.ac.uk/methodology/checklists](http://www.sign.ac.uk/methodology/checklists)

3 Centre for Evidence Based Medicine – Critical Appraisal sheets available at [www.cebm.net](http://www.cebm.net)

#### Other useful references:

- Guyatt GH, Sackett DL, Cook DJ. Users' guides to the medical literature. II. How to use an article about therapy or prevention. Are the results of the study valid? Evidence-Based Medicine Working Group. *JAMA*. 1993;270(21):2598-601.
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- Brown C, Hofer T, Johal A, Thomson R, Nicholl J, Franklin BD, Lilford RJ. An epistemology of patient safety research: a framework for study design and interpretation. Part 2. Study design. *Qual Saf Health Care*. 2008;17(3):163-9.