

Audits: pitfalls and good practice

Brian Hebron, clinical director of pharmacy at City and Sandwell Hospitals, Birmingham, suggests how trusts should approach audits

Currently trusts will be considering what has been learnt from the results of audits arising from the five National Patient Safety Agency alerts in the Safe Medication Practice Work programme for 2007/08. There have also been recent reaudits of the safe use of diamorphine and methotrexate.¹⁻³

Robust audits are ideal for gathering good evidence of practice but only if they are undertaken in a statistically valid manner. Furthermore, if the audit is not well designed it is a waste of time that could better be devoted to patient care. Discussing the audit with a trained statistician beforehand will prevent many pitfalls.

It might be more appropriate in future if audits are designed centrally with professional statistical advice that may not be easily available to many trusts. Perhaps pilot audits of the guidance might be undertaken first, to provide an evidence base for recommendations. Early implementer sites could provide estimates of the costs and future savings attributable to some of the audits.

Surveys and risk assessments may be more cost-effective undertaken at a regional or national level rather than duplicating this work in individual trusts. This is, perhaps, best illustrated with respect to the NPSA Alert 20 promoting safer use of injectable medicines. This requires a risk assessment to be undertaken on the selection, preparation and administration of injectables in all clinical areas. It partly involves assessing the risk of products. Pharmacies in different trusts have worked together to produce an agreed common categorisation of all injections into high, medium and mild risks,^{4,5} eliminating the requirement for each trust to develop its own.

Unlike guidance from the National Institute for Health and Clinical Excellence, NPSA audits do not come with a costing template. Trusts will have done what they can from existing resources, but without a common set of tools, they will differ in their approach, preventing pooling of data and duplicating the work across the nation. Perhaps a more serious consequence may be the temptation to cut corners and undertake a small survey, which would not produce reliable results.

When undertaking audits, it may seem appropriate that no breaches of practice should be found that threaten patient safety. This might be achievable if risks can be eliminated, such as dispensaries not holding stocks of methotrexate 10mg — stocking only 2.5mg tablets would eliminate potentially fatal errors caused by selecting the wrong strength. Auditing such compliance, however, presents difficulties. When a deviation of less than 5 is expected, no matter what the sample size, it is difficult to design a valid audit. In

these cases the sample size has to be 100 per cent or the advice of a statistician is essential.

Most audits are concerned with measuring good practice and 100 per cent compliance is unrealistic. Some idea of the expected result is needed before designing an audit. In many cases an idea of the results can be gained from the literature. For example, Cousins *et al* identified risks associated with intravenous drug preparation in a multicentre European audit.⁶ They observed 824 doses prepared and 798 administrations. The most common error observed was administering doses at the wrong rate (48 per cent in UK hospitals and 40 per cent overall). This error rate may be above what would be wished for at my trust, but we must check how we comply before altering procedures and reauditing. It might, therefore, be unrealistic to use a desired standard for the first audit. Where there are no data in the literature a proportion of 50 per cent should be assumed because this will require the largest sample size.

Precision

The precision required in the results must also be decided. The smaller the size of the sample audited, the greater is the possible spread of results and the observed value will be less precise. If a spread of + or -10 per cent is deemed acceptable, a smaller sample will be required than if + or -5 per cent is chosen. An estimate of how reliable the results are is also needed. Usually 95 per cent probability levels are chosen, meaning that, on average, in one in a series of 20 audits the true value lies outside the defined range.

Free statistical packages are now available through the internet, giving worked examples of how to calculate sample size. Unfortunately, the most user friendly ones are deep within the websites of universities. For example, sample size calculation D-8.1, from St George's University of London website, offers a more detailed explanation than presented in this article, but is under the heading of how to apply for grants (see Resources 1).

Once the audit is completed we should check the confidence interval chosen is what is attained. This is achieved by rearranging the formula in the website used above. Free web-based programs are again available, for example, CIPROPORTION, an Excel spreadsheet written by Robert Newcombe. This allows the spreadsheet data to be overwritten with local data to yield a confidence interval (see Resources 2).

Not only does the sample size have to be sufficient, but also the way the audit is conducted must be appropriate. For example, to ensure that high risk injectables are given appropriately, an audit of their use rather than the use of injectables in all clinical areas is required. Alert 21 ("Safer practice with epidural

injections and infusions") suggests a consecutive five-day audit. You may wish to ask why five and why days, rather than a proportion of the total epidural use. Trusts may wish to propose audits that examine these aspects as part of next year's plan.

Having gained a measure of performance the next step is to consider whether we should attempt to change practice — there are also risks associated with any change in an organisation or service. For example, there is a growing, strong base of evidence that patients are more likely to take their medicines if they are prescribed as once daily and taken at the same time each day, rather than several times during the day or on alternate days. It may also be preferable to provide whole dosage units, rather asking patients to halve tablets. The NPSA guidance that 0.5mg warfarin tablets should be made available should at first sight find support from the profession. However, some localities have standardised on only one strength (3mg) and use both alternate day administration and half tablet regimens to adjust clotting time. Where the people are used to this system, introduction of the full range of strengths could introduce other risks, such as confusing 0.5mg with 5mg tablets. As we do not have access to the evidence on which the recommendation to use all strengths of warfarin is based, a trust may decide to keep its current system. If this is the conclusion the trust will have to record in its risk register why it is not adhering to guidance. This decision should not be founded on isolated case reports from several years ago, but on sound evidence, provided by a robust audit of current practice.

References

- National Patient Safety Agency. Safe Medication Practice Work programme for 2007–2008. London: The Agency; 2007.
- National Patient Safety Agency. Safe Practice Notice ensuring safer practice with high dose ampoules of morphine and diamorphine. London: The Agency; 2006.
- National Patient Safety Agency. Improving compliance with oral methotrexate guidelines. London: The Agency; 2006.
- Beaney AM, Black A, Dobson CR, Williamson S, Robinson M. Development and application of a risk assessment tool to improve safety of patients receiving injectable medicines. *Hospital Pharmacist* 2005;12:150–4.
- Hardy L, Mellor L. Risk assessment of parenteral product presentation across secondary care acute trusts in the north of England. *Hospital Pharmacist* 2007;14:58–64.
- Cousins DH, Sabatier B, Begue D, Schmitt C and Hoppe-Tichy T. Medication errors in intravenous drug preparation and administration: a multicentre audit in the UK, Germany and France. *Quality and Safety in Health Care* 2005;14:190–5.

Resources

- www.sgul.ac.uk/depts/chs/discipline-groups/stat_guide/size.cfm
- www.cf.ac.uk/medic/aboutus/departments/primarycareandpublichealth/ourresearch/resources/confidenceintervals/index.html