Patient safety alerts: a balance between evidence and action

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A perspective on the article by Freer and Lyon (see page 327)

The scale of harm from health care has been documented for over 150 years, but only in the last decade has there been any sustained interest in systematically examining safety issues. The principal theme of the first major report on safety in the NHS, *An organisation with a memory*,¹ was that health care in general, and the NHS in particular, was extraordinarily poor at learning from mistakes and disasters. One of the most striking instances of this failure was that, between 1985 and 2000, there had been at least 13 documented instances of death from the spinal injection of cytotoxic drugs in the NHS. The circumstances were remarkably similar in all cases; warnings on labels and reports in the medical literature had been insufficient to avert this series of tragedies. We now know events of this kind are far from rare. Studies in several countries have generally found that about 8–12% of patients suffer some kind of adverse outcome from their health care.^{2–5} Many of these are slight, but a proportion are serious or even fatal.

Appreciating this background is key to understanding the role of the National Patient Safety Agency (NPSA), which in effect functions as the “safety memory” of the NHS. NPSA is a Special Health Authority created to allow learning from patient safety incidents occurring in the NHS through coordinated efforts of all those involved in health care.⁶ Reports of incidents and near misses are collected from staff at local level and entered into the NPSA’s national reporting and learning system for analysis and subsequent development of appropriate solutions. This can be in the form of clinical recommendations or practice alerts which are distributed to all relevant healthcare personnel. Robust evidence from the medical literature is important to support the recommendations, as is endorsement by the relevant professional bodies.

The paper in this issue by Freer and Lyon on nasogastric tube (NGT) placement in neonates raises several important patient safety issues. NGT placement is a regular and established clinical practice on neonatal units; thousands of NGTs are placed everyday,

mostly by midwives and neonatal nurses, as well as carers such as the babies’ parents. NPSA identified 11 serious incidents reported that were due to malpositioning of the NGT, including one death in which the malposition was undetected using litmus paper. No incidents were reported for neonates, but the actual incidence of problems is unknown. NGT insertion and reinsertion are not without risks, and the alert has important implications for the running of all neonatal units as well as for the training of the staff and carers.

The survey showed that the recommended changes in the alerts have not been fully adopted, although it did not reveal why this was the case. Adoption of the recommended practices may be even lower than reported, as the respondents are probably aware of the guidelines and may err on the side of compliance with the alerts when completing the questionnaire. Despite the collaboration and involvement of professional bodies in the compiling of the alert, it is remarkably difficult for NPSA or any other national body to bring about changes in front line practice, however desirable these might be. In this case, however, some aspects of the alert were met with resistance.

Freer and Lyon highlight and question two particular aspects of the changes recommended by the NPSA alert. Firstly, they question the change to using pH paper instead of blue litmus paper. They are not satisfied with the use of pH indicators, as the normal range of gastric pH in neonates is not established. In the absence of this information, not surprisingly there was a wide variation in pH values used to determine when it was safe to start feeding, with several units using variable levels and 19 units using a level of ≤ 6 as the cut off point rather than the ≤ 5.5 value recommended by the NPSA alert. However, the uncertainty about pH values does not mean that the use of litmus paper is necessarily better. Documenting the actual pH will always provide more useful information than simply stating that the aspirate is acidic or not; similarly recording the temperature in $^{\circ}\text{C}$ is always more helpful than

simply indicating the presence of fever. How the information is to be used and the accuracy of the pH measurement is a different issue. Indeed pH strips from different manufacturers can be slightly different, and standardisation of the method used across the country may be necessary.

The second aspect of the alert questioned by Freer and Lyon is the recommendation to discontinue the use of supplementary methods for ascertaining NGT tip position—for instance, by auscultation for the “whoosh” sound. The use of the supplementary tests as a primary method to determine NGT position obviously needs to be discouraged. However, their use to provide “supplementary” evidence to assist judgment and decision making cannot be discarded totally, as relying on pH measurement in isolation, especially when it is not clear how the measurement should be interpreted, is not safe and may lead to other risks. A study to investigate how the supplementary tests can predict the outcome and influence decision making would be useful in this respect.

The specific case of NGTs raises a number of general issues about the management of safety in the NHS. First, a clarification. The safety alerts released by the NPSA are not mandatory; they are, as the title suggests, alerts combined with recommendations. The NPSA is not a regulatory authority and is not empowered, or even designed, to compel clinicians to adopt particular practices. Health care, for all the plethora of regulatory bodies, does not have the equivalent of a Civil Aviation Authority with the power to actually mandate changes at the clinical level.

Secondly, in any safety issue, a balance has to be struck between evidence and action. Freer and Lyon argue, reasonably enough, for a more careful examination of the evidence for the precise procedures recommended. This is a genuinely difficult issue, and a balance always has to be struck between issuing an alert to prevent harm and waiting until sufficient evidence has accumulated to definitively establish best practice. Whereas removing dangerous drugs such as potassium chloride from wards would seem not to require a full clinical trial, there is certainly a case for a further examination of the proper approach to NGTs. However, until the NPSA alert, no one seems to have been troubled by the current uncertainty or carried out any studies to provide a more systematic set of guidelines and code of practice, all the more important as NGTs are often inserted by staff with comparatively little training. Focusing on the particular difficulties of the pH/

litmus and supplementary methods, although understandable, may distract us from the wider questions of the value of nationally coordinated alerts on key safety issues. In particular, the use of the alert as a starting point to encourage adverse incident reporting may have been lost.

A third, more subtle, issue emerges from this debate, which concerns the role of standardisation in safety. Standardisation of procedures, although only one aspect of safety, is an important basic tenet of reliability.^{7,8} Freer and Lyon imply that there is already an established clinical practice for NGTs, and that evidence is required to move away from this. Yet, the paper reports that, even after the NPSA alert, there was an extraordinary range and variability of current practice, including a wide range of pH values and about eight additional practices of varying practicality and validity. Although this partly reflects the genuine uncertainty about gastric acidity in neonates, it is also an example of the willingness of healthcare professionals to accept variability in practice as a pleasant eccentricity rather than as a threat to patient safety.

Although we accept that the NPSA guidelines are not ideal, the attempt to introduce guidelines of some kind is

surely a step in the right direction, and they have at the very least exposed the current confusion and uncertainty. The Department of Health has commissioned a group of researchers through the Patient Safety Research Programme to set guidelines for insertion of NGTs. The NPSA alert is not simply a "knee jerk" response to a series of incidents, but a considered response to prevent further adverse events from accumulating. This should not, however, blind us to the need for further research on the issues identified by Freer and Lyon and for continued monitoring of problems associated with NGT placement. As James Reason has pointed out,⁹ where safety is concerned there are no decisive victories. Each safety solution brings new hazards and questions in its wake, and safety is only achieved by a continual process of watchful monitoring and thoughtful adjustment of clinical practice in the light of the best evidence available at the time.

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High frequency oscillatory ventilation

High frequency oscillatory ventilation: is equivalence with conventional mechanical ventilation enough?

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A perspective on the article by Marlow *et al* (see page 320)

Several investigators have reported short term results of trials comparing high frequency ventilation with conventional mechanical ventilation in premature infants with respiratory distress syndrome. However, very few data are available on longer term outcomes in infants randomised to these two very different modes of mechanical ventilation.^{1,2} In this issue, Marlow *et al* for the United Kingdom Oscillation Study Group (UKOS) report 2 year respiratory and neurological outcomes for the study cohort in their randomised trial of high frequency oscillatory ventilation (HFOV) compared with conventional mechanical

ventilation. Although the prevalence of disability in their study cohort was high, they found no significant differences in neurodevelopmental scores or report of respiratory symptoms at 2 years of age between infants randomised to the two modes of ventilatory support.

The original report of the short term outcomes of their trial, published in 2002, showed no difference in the primary outcome (death or chronic lung disease at 36 weeks postmenstrual age) between the two ventilatory strategies.³ In addition, they found no differences in other complications of prematurity between the two groups, including cranial ultrasound

abnormalities or air leak. The strengths of their study design include the rapid assignment of mode of ventilation (within one hour), its large size (797 infants randomised), near universal use of antenatal glucocorticoids and postnatal surfactant, and enrolment of infants at 28 weeks gestation or less, who are at highest risk of developing chronic lung disease. The lack of differences in outcome at 2 years in their present study is encouraging for proponents of HFOV, and suggests that there are not deleterious effects of early use of HFOV on pulmonary and neurological function. The UKOS authors conclude that high frequency and conventional mechanical ventilation are equivalent in safety and efficacy for treatment of respiratory failure in premature newborns.

Why the great interest in using high frequency ventilation as a primary mode of respiratory support for premature infants with respiratory failure, and is equivalence with conventional ventilation enough to justify its wider spread use? Most infants born below 28 weeks gestation have respiratory failure caused by surfactant deficiency and require some form of assisted ventilation. However, lung injury induced by assisted ventilation contributes to the