ORIGINAL ARTICLE

Risk management, or just a different risk?

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Background: National reporting of adverse incidents has resulted in a number of clinical alerts being issued. Despite a lack of evidence, these alerts are often accompanied by a mandatory requirement to alter practice. There is likely to be clinician resistance to such a method of change management, particularly where evidence of safety is missing.

Aim: To determine the level of implementation within neonatal units of an alert requiring the change from litmus to pH paper to test nasogastric tube position.

Method: A questionnaire sent to all neonatal units in the United Kingdom with more than 12 cots.

Results: From the 207 questionnaires sent, there were 165 (80%) responses. Fifty five percent of units were still using litmus. All continued to use supplementary tests not recommended in best practice statements issued at the time of the alert. There was considerable variation in the pH value at which it was considered safe to feed.

Conclusions: Nine months after the alert, more than half the units had not changed to pH paper, and supplementary methods of testing were still being used. The wide range of pH values highlights the uncertainty about the "normal" gastric pH in the newborn. The evidence that, in neonatal units, changing to pH paper is safer than the long established use of litmus is lacking. Recommendations for change in practice must be based on good information and not seen just as a "knee jerk" response to adverse incidents.

Providing quality care is a core principle of modern health care. One definition of quality is doing "the right thing, at the right time, in the right way, for the right person—and having the best possible results".¹ This means that healthcare providers have a duty to examine their practice and, where appropriate, implement change.

There are many drivers for change. Practice should be the result of ongoing critical assessment against data from good quality, relevant literature.

The development of national reporting systems has resulted in a number of alerts being issued following adverse events.² The process for investigating incidents and developing action plans is not always made explicit. There may follow a mandatory requirement to change practice, often before good evidence is available.

Where national guidelines exist, even if based on good data, there can still be much variation in the way these are applied and adhered to.³⁻⁵ Improvements in health care may not follow unless the right people are involved in an active process of change. Clinical resistance to alterations in practice may be increased further if the driver for change is seen as a "knee jerk" response to a series of incidents, rather than based on a reasoned, evidence based argument.

The use of alerts as a method of implementing change has potential consequences in all areas of health care.

In 2004 the Medicines and Healthcare Regulatory Agency (MHRA)⁶ in England and Wales, and the Scottish Healthcare Supplies (SHS)⁷ issued alert warnings about the use of litmus paper for testing the position of gastric tubes in all patient groups. In the alert, MHRA and SHS stated that they were aware of one incident where the decreased sensitivity of litmus paper contributed to a patient's death.

The actions required by the alert were a review of local protocols for testing tube position, the withdrawal of blue litmus paper in favour of pH paper, and a training programme on the use of pH paper. There was no guidance on the pH range to be used or the type of pH paper. There was reference to other literature on "best practice" which recommended that supplementary methods of testing such

as auscultation, aspirate consistency, and observing bubbling at the end of the tube be no longer used.

It was clear that, in the initial alert, the specific requirements of the neonatal population had not been considered, despite this being the largest patient group in whom these tubes are used. There was also no information on the pH ranges that should be used in the newborn baby, with an assumption that these would be the same as in adults. The status of these alerts, however, was such that all neonatal units should change to pH paper.

Following on from the alert, the National Patient Safety Agency (NPSA) were tasked with producing guidelines for testing nasogastric tube (NGT) position. NPSA were aware of a number of other incidents reported in adults and older children, but none in the newborn.

The aim of this survey was to determine the level of implementation in neonatal units in the United Kingdom of the required actions of the alert, and to explore if any supplementary methods were being used to assess NGT position.

METHOD

A simple nine question survey instrument was designed. The questions were structured to elicit a yes/no response—for example, do you document the length of NGT—or to enable the respondent to describe their unit's guidelines—for example, do you use other methods to help assess NGT position (please describe). No preferences or opinions about the alert or its recommendations were sought.

Units providing intensive care or who had more than 12 cots were identified from the *Neonatal nurse handbook*. The clinical manager/senior nurse was asked to complete an online questionnaire. If a response was not received within four weeks, the unit was contacted by telephone.

As this was a survey of unit practice and did not involve any patient information, it was not necessary to obtain local ethics committee approval for the questionnaire.

Abbreviations: MHRA, Medicines and Healthcare Regulatory Agency; NPSA, National Patient Safety Agency; NGT, nasogastric tube

Table 1 pH value used to determine safety for feeding down the nasogastric tube

pH value	Number of units
≤3	9
≤4	21
≤5	23
≤6	19
No agreed value	3

RESULTS

A total of 207 letters were posted, and 165 responses (80%) were received. Of those responding, 37 units (23%) were level 1, 80 units (48%) level 2, and 48 units (29%) level 3.

Aspirate testing method

Seventy five (45%) of the units were using pH paper to test aspirates. Ten units were using both litmus and pH paper/strip.

For those who had changed to pH paper, table 1 shows the pH values that were used to determine if it was safe to feed down the nasogastric tube.

Tube position assessment

All units stated that they did not remove a tube automatically if there was no change in litmus colour, or the pH value was outside their guidance range for administering feeds. Consideration was given to maturity of the infant, prescribed drugs, and frequency of feeding when making decisions about continuing to use the NGT.

Table 2 shows the number of units that use other methods to assess tube position. It compares units still using litmus paper with those who had changed to pH paper.

If the litmus/pH paper value was outside the accepted range, or if no aspirate could be obtained from the tube, several interventions were carried out. These included: offering a small oral feed, changing baby's position, checking NGT length, adjusting NGT position, inserting some air, inserting some water. On completion of one or all of these activities, the tube was aspirated. One unit reported using "air bubbling" as a technique for excluding the position of the tube in the major airways.

DISCUSSION

This was a national survey with a good response rate. Despite units being aware of the recommendations, nine months after the publication of the alert less than half of the respondents had changed to pH paper. Few units had implemented the recommendations in the "best practice" statements referred to in the alert.

There was wide variation in the pH value used to determine safety for feeding. However, no unit removed the NGT because the litmus paper did not change colour, or the pH value was outside the specified range. The use of gastric pH was only one of a number of assessment strategies used for testing NGT tip position.

In adults, a gastric aspirate pH of 4 or below is used to indicate that the tube is in the stomach. In the newborn the

gastric pH can be influenced by a number of factors including immaturity,⁸ age,⁹ frequency of milk feedings,¹⁰ and use of histamine 2 receptor blockers.¹¹ The range of pH values used by units in this survey highlights the uncertainty in the neonatal literature about gastric pH under varying conditions. Litmus paper registers a colour change at any pH<7. It is not influenced by any of these other factors, and one could speculate that perhaps it is this simplicity that has made it a widely accepted diagnostic test.

If units relied only on an aspirate pH of 4 or less to show that a nasogastric tube was in the stomach, it is possible that many more tubes would need to be replaced. Inserting a nasogastric tube in a baby is not without risk and often adds to the distress experienced by infants.¹² It may trigger a bradycardia and/or apnoeic episode, particularly in the unstable or fragile infant. Such events can cause blood pressure surges and these may be important causative factors in newborn brain injury.^{13 14} Oesophageal tears and intracranial placement are rare but well documented complications during NGT insertion.^{15 16} It is interesting that no unit made the decision to change a tube on the value of the aspirate pH alone.

This survey showed that supplementary testing techniques, such as auscultation and aspirate consistency, were still being used, even in units that had changed to pH paper. In studies of older children and adults, these methods are described as being unreliable.¹⁷ There is no reason why they would be more reliable in the newborn population. However, they are seldom the primary method for determining tube position, but, where there is difficulty in interpreting the colour change of the litmus/pH paper or no aspirate is obtained, staff find them helpful.

Clinical guidelines need, where possible, to be based on good evidence.¹⁸ Where there is no strong evidence base, we have no way of knowing whether changes are actually going to be safer than clinical practice that has been established over many years. The adverse consequences of uncontrolled oxygen administration (retrolental fibroplasia) and the use of steroids in the management of chronic lung disease (increased risk of cerebral palsy) are two examples in neonatology where it was thought we knew what was best practice before there was any good evidence for efficacy or safety. The use of litmus paper for determining the position of nasogastric tubes has never been tested in a randomised controlled trial. However, in neonatology, this technique has become, over decades, a well accepted method of testing. This clinical experience, along with the apparent rarity of adverse events in neonates, makes it important that there is a good evidence base to support any change in practice.

Following four cases of cardiac tamponade associated with central venous lines in newborn babies, a recommendation was made, by the Department of Health in the United Kingdom, not to position the tip of the line within the cardiac shadow on radiographs.¹⁹ It was acknowledged at the time that there were few good data to support this recommendation, but it became accepted practice. Making sure the line is outside the cardiac shadow will have increased the number of x ray investigations performed, and the number of times the line needs to be repositioned after initial insertion. Increased handling may be an important factor in the risk of line infection. The Department of Health recommended that there be a prospective audit of all such lines. No resources were made available, and this audit has not been implemented. Further reports have since questioned the recommendation,²⁰ but this remains accepted practice in United Kingdom.

So why is it that the recommended changes to practice have not been adopted by many neonatal units? The questionnaire did not ask specifically why a unit had not adopted the new policy and so possible reasons must remain speculative.

Table 2 Mechanisms used to determine tube position

Mechanism	Litmus paper	pH paper/strip
Auscultation over stomach	53/73 (73)	35/65 (54)
Radiograph of tube	9/57 (16)	13/55 (24)
Aspirate characteristics	59/74 (80)	59/67 (88)

Values in parentheses are percentages. The denominator is the number of respondents answering the question.

According to Rogers²¹ there are five elements to an innovation that will determine whether it will be adopted: relative advantage, compatibility, complexity, trialability, and observability. These can be expanded in relation to the change to pH paper for the testing of NGTs.

- Relative advantage: how important is the required change? There is no evidence in the literature that pH paper has any advantage over litmus in neonatal care. However, it could be argued that knowing the aspirate pH value strengthens the certainty of NGT position.
- Compatibility: how does the innovation sit with current thinking? No adverse outcome in relation to premature or sick infants has been reported, although this may be due to under-reporting. Neonatal nurses/midwives are probably the most skilled and knowledgeable users of this feeding method and one could speculate that they do not believe that any problem has been identified.
- Complexity: what should be the content of the guideline? The alert has no apparent relevance for the neonatal intensive care population. The particular characteristics of, and management of enteral feeding in, premature or sick infants were not considered. It was assumed that the pH values used in adults could be applied to the newborn infant. In the United Kingdom there is no clinical precedent for the use of pH paper in testing NGTs in neonatal units.
- Trialability: what is the potential to evaluate and modify the innovation? The MHRA alert appears regulatory; there is no apparent mechanism for testing the acceptability or usability of the instruction. However, given the degree of concern from individual clinicians and professional bodies, the guidance, as applied to the neonatal population, has been modified through the NPSA, working with the British Association of Perinatal Medicine, in the United Kingdom.
- Observability: to what extent is the guideline being implemented? A new way of working is much more likely to occur if there are obvious, respected champions for the change. Less than half the units had made the change, and there was no strong professional support for the recommendation.

Improvement in clinical care and outcome results when data support an active process of planned change in the delivery of care.²² The evidence supporting the change from litmus paper to pH paper, and withdrawal of supplemental assessment methods to determine tube tip position, in the newborn population is limited. New practice guidelines must be grounded in relevant evidence and be practicable to implement. Given the evidence from the available literature and our survey, it would seem that clinicians may not "buy into" this required change to practice. It is important that adverse events are recorded and acted on, but care must be taken in making sure that recommendations for change in practice are based on good information and are not just "knee jerk" responses. They must be seen by all as a sensible way forward. If there is no strong evidence base, then, at the very least, implementation must be accompanied by the resources for a prospective audit of the impact of such changes in practice.

Following comment from individuals and professional bodies, such as the British Association of Perinatal Medicine, the NPSA have developed a guideline for the use of pH testing in the newborn.²³ The evidence for the pH values adopted is still lacking, and clinical judgment is required where there is uncertainty in the pH measurement or no aspirate is obtained.

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What is already known on this topic

- Implementation of national guidelines can be very variable
- Practice is being changed by alerts issued after adverse events

What this study adds

- There is resistance to implementing change where evidence is lacking and no need for change is perceived
- Where evidence is lacking, forced changes in practice could just replace one risk with another

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