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**INTRODUCTION: THE EVOLUTION OF 'SAFETY'**

The 'patient safety' movement has come about through an appreciation that the techniques and approaches used to improve safety in other industries can be applied to healthcare [1]. Anaesthesiology has long been at the forefront of this movement, particularly in the field of critical incident reporting [2], and while this is a cause for celebration, it also brings temptation! It is easy to allow ourselves to feel that the battle for safety has been won. Of course, this is not true. Not only has our work become more complex, but new risks also appear and there is always the danger that we forget the old ones. Also, although many anaesthesiologists understand the idea that what they do is part of a system, many do not behave in practice as though they understand it, preferring to stick to a model of medical professionalism which prioritises the clinical freedom of the individual over the safety needs of the system. The actions of anaesthesiologists can influence safety in the hospital more widely than we might realise [3].

Reason's model of accident causation is widely used [4-6]. This suggests that there are many potential accidents, and many factors potentially contributing to them, but that most are prevented from becoming actual accidents by a series of controls or *barriers*. When the controls fail, the accident that has been 'waiting to happen' can occur.

Contributing factors can arise from the following sources: the patient, an individual staff member, the team, a task, communications, education and training, equipment and resources, working conditions and organisational and strategic issues. They may act as influencing or causal factors. Generally speaking, removing the influencing factor might not have prevented the accident, but it should improve the safety of care generally.

Barriers may be of four types:

- *Physical barriers*, e.g. keypad-controlled doors.
- *Natural barriers*, that is, barriers of distance, time or location e.g. the procedure for diagnosing brainstem death, where independent review by two doctors is repeated a number of hours later.
- *Human action barriers* e.g. checking the temperature of a bath before immersing an elderly patient.
- *Administrative barriers* e.g. protocols and procedures.

Physical barriers are the most reliable in terms of providing failsafe solutions to safety problems. Natural barriers, whilst less effective, generally provide a more robust solution than human action and administrative barriers. However, in healthcare there is a predisposition to rely on human action and administrative type barriers as solutions to problems.

In the United Kingdom, patient safety has been given further impetus by the creation of the National Patient Safety Agency (NPSA) in 2001. As well as running the UK's National Reporting and Learning Scheme for sharing lessons learned from adverse events, the staff of the Agency (who include human factors specialists and risk management experts as well as clinical staff) also work on identifying risks in healthcare and trying to find solutions. The underlying assumptions in the Agency's work, as in 'safety science' generally, are that systematic scrutiny and analysis of problems using rigorous methods can bring benefits.

**ROOT CAUSE ANALYSIS**

Root cause analysis (RCA) is a technique used to explore incidents and help gain the best understanding of how accidents are caused, so that future ones can be prevented [7-10]. It is a structured methodology that enables you to ask the questions:

- What happened?
- How did it happen?
- Why did it happen?

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A successful RCA needs a team approach. The RCA team will normally consist of a facilitator together with people from a range of professions. It is important to be clear about the skills and attributes needed within the team. Sometimes it is recommended that the team is independent of anyone involved in the incident, but this may not be necessary or indeed possible. Support at senior levels of the organisation is also important, to ensure the co-operation and attendance of those who may be less willing to take part!

As the RCA can be quite time-consuming, often extending over a number of months, it is important to choose which incidents to investigate. Serious ones – those leading to the death of a patient – should take priority. However, smaller-scale investigations into incidents that arise from normal clinical activity are also likely to yield useful information for continuous quality improvement.

The most important task – which usually takes up about two-thirds of the total investigation time – is collecting all the relevant data. The data will come from a number of sources: interviews with, or statements from, staff and patients, the preservation of any equipment involved, site visits, and review of policies, training records, and minutes of meetings. It is a good idea to get hold of information which is readily accessible as quickly as possible. People forget details and events quite rapidly and their accounts should be obtained as soon after the incident as possible. Once you have established what data you have, it also becomes easier to identify the gaps to guide your later search, and frame questions for later interviews.

### **BOX 1 TOOLS AND TECHNIQUES USED IN ANALYSIS OF INCIDENTS**

#### **BRAINSTORMING AND BRAINWRITING**

Brainstorming is a way of generating as many ideas as possible from a group of people on a given subject. It can be *unstructured* - where everyone can freely produce ideas – or *structured* - where each participant in turn produces an idea. A facilitator records the ideas on a flip chart or white board. They are not discussed, developed, criticised or evaluated as they come up. When no new ideas are produced, that part of the session stops and the ideas can then be grouped and clarified. Brainwriting is essentially the same, but each participant writes his/her ideas down instead of calling them out. It is useful when the anonymity of participants needs to be protected, or when some people might dominate an oral brainstorming process.

#### **TIMELINES**

A timeline is produced by mapping and tracking the chronological chain of events involved in the incident. It allows the investigator(s) to identify information gaps and also to identify critical problems that arose during the process of care delivery.

A timeline should either begin at the point at which the chain of events leading to the incident started, or at the point of incident occurrence and work backwards to the agreed start point. It is useful to do this before an RCA meeting, and also can help clarify events when many different specialties are involved or there may have been more than one ‘failure’ in the lead-up to the event.

#### **TIME-PERSON GRIDS**

A time person grid is a tabular mapping tool that enables you to track the movements of people (staff, patients, visitors, contractors) before, during and after an incident, therefore enabling the investigator to clarify where all persons were at key points in the incident. A table is created on paper or in a suitable computer program comparing staff and times. It is particularly useful for short time frames when a lot seems to be going on and many people are involved in the delivery of care. It can be mapped onto a short section of a timeline.

#### **5 ‘WHYS’**

The main purpose of this technique therefore is to repeatedly ask ‘*Why?*’ through the various layers of cause, thus progressing towards the true root cause of the identified problem or issue. For each primary cause, the group is asked ‘*Why is this a cause of the original problem?*’. This should generate further and deeper reasons as to why the problem exists. This process is repeated until no new answers arise.

#### **FISHBONE DIAGRAM**

This is a useful way of representing contributory factor information. Draw a horizontal arrow on a large sheet of paper: at its head is the problem to be explored. Spines are added to each side of the arrow to form a fishbone shape. Each spine is given a contributory factor (see list in *Introduction* above) and the influencing factors within this category are written along the spine.

#### **BARRIER ANALYSIS**

This focuses on exploring the role of barriers in the system. Starting from the event to be analysed, we ask (1) what barriers were in place (2) did the barrier/control work? (3) if not, how much did this contribute to the event? This allows investigators to focus on how existing barriers might be made stronger.

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Once the data are complete, the team works through them, using one or more of the tools and techniques shown in Box 1 to establish the root causes of the incident. Generally, the contributory factors identified during the incident analysis are the root causes or fundamental issues you are looking for. In addition to finding root causes that are specific to the incident under investigation, some undesirable general, perhaps long-standing, features of the ward, hospital or unit may be uncovered which can then be improved for the future.

## PROSPECTIVE HAZARD ANALYSIS

RCA is an effective technique and can prevent repetition of a given event but is obviously a reactive process taking place after harm has been done [11]. New working practices, new equipment, collective forgetting and the pure capriciousness of chance all mean that the potential for new problems is always with us. Prospective methods of risk identification complement the retrospective approach by attempting to tackle as yet unforeseen hazards. A number of methods have been used in other industries, ranging from the simple to the complex [12,13] (see Box 2).

### BOX 2 TECHNIQUES OF PROSPECTIVE HAZARD ANALYSIS

#### QUALITATIVE:

- Brainstorming
- Use of checklists
- ‘What if..?’ techniques, including SWIFT (structured ‘what if’ checklist)
- Scenario analysis
- Human error analysis (HEA)
- Hazard and operability studies (HAZOP)
- Failure Mode and Effect Analysis (FMEA), with its variant, Failure Modes Effects and Criticality Analysis (FMECA)
- Hazard Analysis and Critical Control Points

#### QUANTITATIVE:

- Fault tree analysis (FTA)
- Event tree analysis (ETA)
- Cause-consequence analysis (CCA)
- Quantified Risk Assessment (QRA)
- Reliability simulation
- Cost-benefit analysis

However, a commonly-used framework for analysis is to assess the *effect* (or severity) of the risk, its *likelihood*, and what *controls or barriers* exist to reduce it (see above). The choice of method depends on a number of factors, including the level of perceived risk and possibility of its mitigation, capabilities of staff, availability of data and type of system – some are best used for ‘hardware’ systems, others where human factors come into play. Further, different techniques may be applicable at different stages of the same project, with more structured tools becoming necessary as a project progresses.

Techniques within both groups can be classified into those with a ‘top down’ approach – that is, those that start with hazardous outcomes and work backwards to analyse possible contributory factors – and those with a ‘bottom up’ approach, which start with processes or potential causes and try to predict the potential hazards which could arise from them. These techniques vary considerably in complexity, the need for training in their use, degree of structure and quantification and so on.

More recently, there has been discussion about how such prospective methods might be applied to healthcare. Failure mode and effects analysis (FMEA) is probably the most widely known and has been tested in practice, with apparently successful results [14-16]. In the United States, the Joint Commission on Accreditation of Healthcare Organizations expects institutions to perform at least one proactive risk assessment annually. However, it is far from clear that FMEA is the most appropriate tool, and others have been suggested [17].

Despite the distinction implied in the title of this article, some techniques can be used both retrospectively or prospectively. For instance, a prospective barrier analysis may be useful. The team would identify a potential failure then identify all the control measures currently in place which tend to prevent it. They would consider how important each of these is to practice and how far they could be said to be ‘failsafe’. If more than two failsafe (i.e. physical) barriers are present, then the systems are reasonably robust. If not, the team would need to consider other ways of supporting existing, or creating additional barriers to improve system safety.

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## AN EXAMPLE: A SWIFT (*STRUCTURED ‘WHAT IF?’ TECHNIQUE*) ANALYSIS APPLIED TO THE PERIOPERATIVE PERIOD

This was co-ordinated by the UK NPSA in 2004. The aim of the exercise was to try to identify the non-operative risks associated with elective surgery under general anaesthesia in adults.

First, the stages through which the surgical patient passes were mapped. Second, a working group was convened with clinical staff from primary and secondary care, members of relevant professional organisations and governmental agencies, and patient representatives. The working sessions were facilitated by a trained risk analyst and discussions were transcribed electronically by a recorder with knowledge both of anaesthesia and human factors. The sessions ran over 5 days, typically for 6 hours per day. The group's first task was to split up the perioperative period into blocks (*pre-assessment, admission until induction of anaesthesia, induction, moving into theatre, maintenance* etc). Then the group identified the current controls within each group. Participants were prompted to create 'what if' questions to help them think about these issues, for instance, 'What if the wrong premedication were given?'. Members of the group were then asked to grade each risk they had identified according to its likelihood and severity and these were incorporated into a risk matrix. This was used to rank the risks in order of importance. For further prioritisation, Agency staff with expert knowledge of anaesthesia analysed the results, considering:

1. The *speed* with which the recommendations could be acted upon
2. The *cost* of adopting each of the group's recommendations
3. How *effective* the recommendations would be at reducing the risk.

The final list of recommendations could be ordered to reflect each of these three factors.

The areas offering the greatest potential safety gains were:

- Removing unrelated distractions from the operating theatre.
- Improving equipment and practice relating to airway management.
- Developing and enhancing standards for theatre staff, including encouraging flexible working.
- Improving communication about pre-operative assessment.
- Encouraging the use of peripheral nerve stimulators to monitor neuromuscular blockade.
- Protecting patients during positioning and movement.
- Standardisation of equipment within hospitals e.g. infusion devices.
- Prevention of inadvertent intraoperative hypothermia.

The process clearly extends beyond anaesthesia in the operating theatre. This reflects the political need for the Agency to be seen to be involving a wide range of staff and other individuals, but also makes sense in that we know that many factors which can cause problems during anaesthesia have been apparent preoperatively [18]. A further finding is that many risk reductions, including some with great potential, were estimated to be quite cheap to implement. This all-embracing approach yields more useful systems data than work driven by the desire to explore single risks e.g. preventing wrong site surgery. Further analysis is required to see how the results from this prospective exercise compare with the findings of published retrospective analyses of critical incidents.

The main drawback of the technique is the time required. In many safety-critical industries, it is mandatory for staff to take part in such exercises and time is made available. In healthcare, if clinical staff are taken away from clinical practice, there may be some loss of patient care activity. There is a risk that such short-term economic considerations prevent proper engagement with long-term safety goals. Also, it was necessary to make a number of assumptions about severity and cost. Nevertheless this appears to be the first prospective hazard analysis relevant to anaesthesia.

## CONCLUSION: RISK AND INCIDENT ANALYSIS IN THE HEALTHCARE WORKPLACE

Although many of the techniques described above are simple, the need for training in risk analysis techniques must be acknowledged. Clearly a cadre of individuals who can undertake hazard analysis is required but these should not only be managers. Taking part in the processes of analysis has a beneficial effect on clinical and support staff. In practice, as incidents worthy of analysis do not often occur (2 or 3 per year in our hospital), there may be limited opportunities to use and practise these skills. Although there are differences between industry and healthcare [19], the use of such risk and incident analysis methods is justified. It is important that we use systematic methods to improve safety and this article has outlined how this can be done.

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