Risk management on the labour ward

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Risk management describes a process whereby the risk of adverse events is eliminated or where the effects of those events are reduced as far as possible. This is particularly relevant to the labour ward setting with respect to intrapartum care.

Risk management was unveiled as a central tenet of clinical governance in the 1997 White Paper *A First Class Service* (Department of Health, 1998). The importance of risk management was further emphasized last year by the Chief Medical Officer's document *An Organisation With A Memory* (Department of Health, 2000a), leaving no doubt that risk management is here to stay.

A number of complex definitions for risk management exist but, simply put, risk management refers to a process that aims to eradicate risks that can be eliminated and to reduce the effects of risks that cannot be eliminated. Risk itself refers to an adverse incident whereby there is the potential for a patient to be harmed, either by unintentional medical error or by the inherent nature of the complication or procedure (Vincent et al, 1998).

Clinical risk management includes effective adverse event reporting, good and clinically relevant information systems which feed back to clinicians, well-constructed clinical audit, timely and evidence-based clinical guidance, and the belief in continuing education for all levels of clinical staff. This paper will outline the principles of risk management, focusing on clinical incident reporting, now known as adverse clinical events, and the implementation of a model for their recording and management onto a busy delivery suite.

DRIVERS FOR RISK MANAGEMENT

The impetus for the implementation of good risk management comes from several quarters, the most important of which is the inherent drive of front-line clinical staff to provide the best possible care to all patients. This is supported by the Department of Health; as early as 1994, the NHS Executive, in a document entitled *Risk Management in the NHS*, stated that 'risk management is no longer an optional extra' (NHS Executive, 1994). Last year, the Chief Medical Officer produced another document devoted entirely to risk management within the NHS (Department of Health, 2000a). Thus, risk management should now be firmly embedded in policy at trust level.

At this stage, it is perhaps worth illustrating the potential size of the problem facing the NHS. Studies in America and Australia have demonstrated that between 4 and 17% of inpatient episodes are associated with adverse events (Brennan et al, 1991; Wilson et al, 1995). Pilot data from the UK suggest that approximately 10% of inpatient episodes lead to a harmful adverse event (Woloshynowych et al, 2000). This has been extrapolated to show a potential 850 000 adverse events in England per annum, costing the NHS £2 billion in extra bed-days alone (Department of Health, 2000a).

Not only do these adverse events lead to extra direct costs to the NHS, but they may also lead to civil litigation. While the NHS bill for litigation in the year 1998–99 is probably less than the £400 million quoted in *An Organisation With A Memory* (Department of Health, 2000a), it is still in the region of £84 million per annum, an amount which is increasing by at least 7% each year (Fenn et al, 2000). Evidence that risk management can reduce litigation is limited (Localio et al, 1991; Mant and Gatherer, 1994; Mant et al, 1998), despite this being one of the primary aims for its introduction into the NHS. Nevertheless, risk management is positively promoted by the Clinical Negligence Scheme for Trusts, which gives low-priced insurance contributions for trusts who establish good risk management systems.

These figures conceal the human face of medical mistakes. Although intrapartum stillbirth rates have fallen in recent years to approximately 0.5/1000, three-quarters of these cases were considered to have had suboptimal care (the vast majority having grade 2 or 3 suboptimal care),

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suggesting that some of these deaths were avoidable. Subsequent enquiries focusing on breech delivery and the management of labour in women with a previous caesarean section have demonstrated similar failures (Confidential Enquiry in Stillbirths and Deaths in Infancy, 1997). Other examples appear regularly in the Confidential Enquiries into Maternal Deaths and include avoidable factors in deaths from thromboembolism, hypertension and haemorrhage (Department of Health, 2000b).

It is apparent that effective systems for incident investigation can lead to improved understanding of why things go wrong and identify methods of rectifying problem areas. Good clinical risk management will therefore facilitate improved quality of care for patients (Mant and Gatherer, 1994; Vincent et al, 2000) as well as allow doctors to follow that most basic of medical tenets – primum non nocere – first do no harm.

CRITICAL INCIDENT INVESTIGATION

Traditionally, investigations into adverse events within the NHS have focused only on events immediately surrounding the incident and have looked to apportion blame to the individuals directly concerned in the case. While it is occasionally true that adverse events can occur because of gross negligence or even criminal behaviour, the majority of serious failures involve organizational failures which stretch far beyond the actions of individuals.

Attention must be paid not only to psychological and human factors in the nature, mechanism and causes of error, but also to the fact that error is also strongly affected by the context and conditions of work (Leape, 1994). It is not useful to 'witch-hunt' the junior obstetrician who misinterprets the cardiotocographic trace, where no training has been provided and where the hours worked do not conform with working time agreements. Such an event will inevitably be repeated unless steps are taken to improve training and conditions of work. It is apparent, therefore, that a systematic approach to the investigation of adverse incidents is required, with less focus on the individual involved and more on pre-existing organizational factors that provide the conditions in which less than optimal practice can occur (Reason, 1990).

This so-called 'human factors' approach focuses on human components within complex sociotechnical systems. Such a systematic approach also allows identification and investigation of a serious incident that has been managed well and allows positive feedback to individuals and organizations. In acute specialities, serious events are common and most pass without serious harm. It is at least as important to congratulate staff for a job well done as to criticize for perceived failure.

Research into adverse incidents in settings such as the aviation and petrochemical industries have given rise to several models of the anatomy of adverse events. These have been used in the assessment of high profile disasters, such as the Piper Alpha oil platform explosion, the King's Cross underground fire, Chernobyl and the Marchioness tragedy. One of the most widely accepted models, developed by Reason (1990, 1995), has also been adapted for use in the health-care sector (Vincent et al, 1998).

REASON'S MODEL

This model examines the chain of events leading up to an adverse incident, considers the action of those involved and looks back at the conditions of work and the organizational factors at play at the time of the incident. The model presents the people directly involved as the inheritors rather than the instigators of an accident, although it does not necessarily imply that blame is merely shifted up the chain of command (Reason, 1995). The model identifies two groups of human decisions and actions that result in an adverse event: active failures and latent failures.

Active failures

These are unsafe acts or omissions committed by those whose actions may have immediate adverse consequences, i.e. workers at the 'coal face', such as labour ward midwives and medical staff. Active failures include:

Action failures: Inadvertently opening the bladder at caesarean section.

Cognitive failures: Memory lapses and mistakes through ignorance or misreading a situation, e.g. failure to appreciate the significance of epigastric pain in the pre-eclamptic patient.

Violations: Deviation from accepted safe practice. These are often associated with motivational or organizational problems, such as low morale or the failure to publicize and disseminate accepted best practice.

Latent failures

These occur because of erroneous decision-making by individuals not directly involved in the workplace, such as senior clinicians or managers. These failures lie 'dormant' within the system until they are exposed by a single or succession of active failures. They influence staff performance and may precipitate errors by

exposing staff to unsafe environments. Latent failures include:

- Inadequate supervision of staff, e.g. failure to provide a sufficiently experienced shift leader at night
- A stressful environment, e.g. insufficient staff to cover the workload or an atmosphere of antagonism and mistrust among the labour ward team
- Rapid change within a system, e.g. failure to stagger the introduction of new members of the medical staff because of rotations as attested by the higher number of intrapartum asphyxial deaths noted in Wales during July and August (Stewart et al, 1998)
- Incompatible goals, e.g. maintaining the same number of deliveries with reducing financial support
- Poor communication pathways, e.g. the hospital switchboard not knowing which consultant is on call
- Inadequate levels and/or poor maintenance of equipment, e.g. the ventouse equipment that fails at the vital moment.

Defences exist to guard against human error and prevent the sequelae of error affecting patients, e.g. the senior labour ward midwife contacting the consultant obstetrician when he/she is unhappy with a registrar's actions. Adverse incidents may occur, however, when these defences are breached (*Figure 1*).

ADAPTATIONS FOR USE IN MEDICINE

Alterations to the basic model have been suggested by Vincent et al (1998, 2000) to better suit the medical environment, where perhaps the organizational aspects are less well delineated than in the industry. A framework is therefore required to better understand the organizational influence in adverse events.

Patient factors

The complexity and seriousness of the patient's condition, their ability or willingness to communicate and social or personality factors, e.g. the violent cocaine-using woman with a pre-eclamptic crisis.

Task factors

The availability and clarity of test results and protocols or a poorly designed task, such as a breech extraction in a term singleton pregnancy.

Individual factors

Knowledge and skills, motivation, physical and mental health, personality, overconfidence or low levels of confidence.

Team factors

Communication within the team, supervision and the availability of help. For example, a directorate decision to abandon planned term vaginal breech delivery in the light of the multicentre trial (Hannah et al, 2000) not being disseminated to the night staff.

Work environment

Staffing levels and skill mix within shifts, workload and shift patterns, equipment, administrative support, e.g. no ancillary health-care worker being available when midwives are too busy to retrieve notes.

Organizational and management factors

Financial restraints, the need for policy standards and a safety culture rather than 'we do it that way because we usually get away with it'.

Institutional context

Economic and regulatory policies of the NHS Executive.

Using this framework allows an incident to be systematically investigated, starting with the labour ward staff and working up through the hierarchy of the team and the unit. Patient factors are particularly important; those with more severe conditions may be less forgiving of mistakes or omissions than those with milder conditions.

Investigations should follow a pre-defined pathway and must not be limited to examination of patient records. Prompt interviewing of members of staff directly involved by individuals well versed in risk management investigation should be the norm. Checklists for a systematic investigation can be a useful tool at this stage

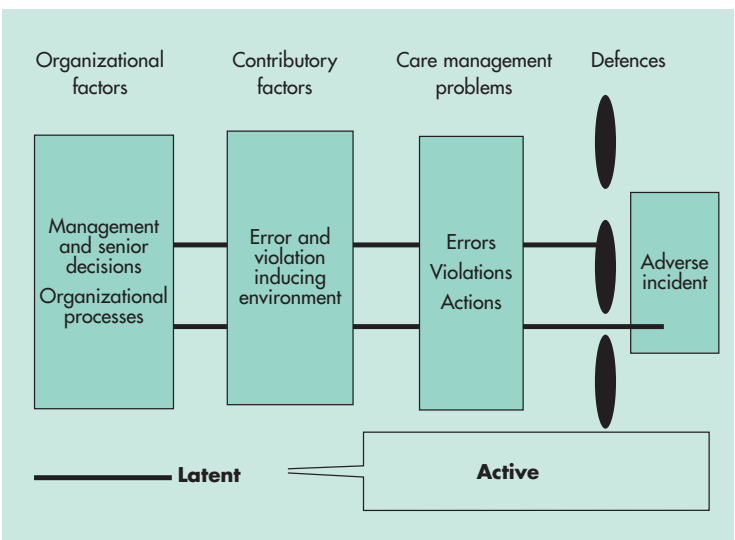

Figure 1. Schematic representation of Reason's model (Reason, 1990).

(Stanhope et al, 1997). After the interviews have been completed, a formal report should be produced illustrating the active and latent failures and giving suggestions for altering practice to reduce the likelihood of recurrence.

A MODEL FOR ADVERSE CLINICAL EVENT MANAGEMENT ON THE LABOUR WARD

One of the most difficult aspects of establishing a risk management system is ensuring that staff systematically report all adverse incidents because of fears about disciplinary measures and litigation (O'Connor, 1996). For a system to be effective universal, reporting is required – to achieve this, it is vital that staff are fully aware that the system is in place, primarily to improve patient care, but also to both protect and educate staff. Experience from previous models and attempts to implement systems suggested that ownership, simplicity and rapid evaluation and feedback are likely to be key factors in the success of any system. In addition, the system must be transparent and distinct from any disciplinary process. The entire emphasis of the system should be clearly educational.

It is helpful to establish a multidisciplinary team consisting of obstetricians, midwives, anaesthetists and paediatricians. This team can then set the goals and standards of the system as well as disseminate information to the staff. It is also useful, at an early stage, to liaise with the trust risk management team to define the remit of the labour ward system and its relationship to the trust-wide system.

TABLE 1.
Suggested trigger factors for delivery suite

Intrapartum/neonatal death	
Maternal death	
Amniotic fluid embolism	
Maternal cardiorespiratory arrest	
Transfers to intensive care unit	
Renal failure	
Pulmonary oedema	
Uterine rupture	
Caesarean hysterectomy	
Moderate/severe birth asphyxia (pH below 7.10, neonatal encephalopathy)	
Maternal disseminated intravascular coagulation	
Birth trauma	
Obstetric haemorrhage requiring transfusion	
Use of more than one instrument for delivery	
Cord prolapse	
Major placental abruption	
A birthweight unexpectedly below 2 kg at term	
Difficulties with resuscitation	
Failed intubation	
Total spinal blockade	
Staff unavailability	
Drug reaction	
Decision–operation time >30 minutes for emergency caesarean section	
Major protocol violation	
Additional trigger factors	Low apgar scores
	Caesarean section for fetal distress
	Difficulties on delivery suite
	Major equipment failure

Step 1: Establishing what is an 'adverse clinical event' in a clinical area

This should be established using both national guidance, e.g. issues of adverse drug reaction, and 'frontline' clinical staff to define what is important to them. So-called trigger factors are a useful tool to encourage reporting in the first instance (*Table 1*). The precise trigger factors to use can be decided at a local level. However, in the first instance, it is important to ensure a steady flow of incidents, therefore smaller units may wish to have more inclusive lists of trigger factors. There should be no confusion between what a trigger factor and a cause of a trigger factor might be. One of the suggested recorded events at national level was 'failure to document instructions'. However, if an issue was not documented, how was it to be identified as a trigger for event review? Failure to document instructions may be a reason for an adverse event; it is not an event in its own right.

Actual reporting should be simple and rapid: the 30 second form – to some extent based on the rapid reporting system used by the Confidential Enquiry in Stillbirths and Deaths in Infancy (1997) – is an ideal. This will enable staff to become rapidly accustomed to the system and to engender an atmosphere conducive to incident reporting. The system should encourage the reporting of all events in a particular category, not just those resulting in poor outcome. This holds several advantages: individuals involved are less likely to suffer from feelings of guilt and shame and others are less likely to apportion blame. Cases with good outcomes may demonstrate deficiencies in the organization or pattern of labour ward care before serious incidents occur (Stanhope et al, 1997).

Step 2: Rapid investigation of event

Investigation of incidents should be performed promptly, while memories are still fresh (*Figure 2*). While desirable, it would be impractical to subject each reported incident to the scrutiny of a full investigation. However, a basic investigation of whether an event was an active or latent failure can be performed quite quickly. This investigation should be carried out by a multidisciplinary group which includes different grades of staff. Ideally, it should also include the staff involved. The meeting should be an open forum to which all members of labour ward staff are invited. It should be non-threatening and should not look to blame individuals. The aim of the meeting should be educational, using the case as a basis for teaching on the subject of the event while evaluating the standard of care of the team involved.

Local investigation can be carried out using examination of the case sheets and informal discussion with members of staff involved, or, in selected cases, at a regular risk management meeting. Cases can be selected for detailed discussion because of the nature of the incident or to illustrate recurring themes. Rapid triage of cases allows selection of those requiring more formal review, as outlined below, or those which may fall within the trust's remit as a serious adverse incident. These incidents may require members of staff to be interviewed before the case is discussed at the open forum.

Step 3: Standard setting

Adverse event review is a peer-review process. If the review is open, then this allows free discussion, which is helpful in understanding events. However, at some point a view must be taken on whether the care provided was acceptable. This requires the group involved to have standards and for these standards to be transparent. In constructing any adverse event system, these standards need to be stated before implementation. For intrapartum events, these will generally be based on agreed guidelines or recommended practices within the unit. Some events may not fit neatly into an existing guideline, and therefore agreement must be reached on the standard expected before inclusion onto the trigger list.

Step 4: Feedback to clinicians

Feedback to staff is vital. If deficits are identified these should be approached positively, with joint recommendations for improving performance drawn up with the individual concerned. In the majority of incidents, staff will have responded appropriately, and it is vital that, under these circumstances, positive feedback is given. This will have the dual effect of raising morale and also encouraging incident reporting and development of a safety-conscious atmosphere. Consideration should be given to a formal feedback letter, which can potentially be filed in each clinician's personal development file.

Step 5: Actions

Once the event has been reviewed, then the peer-review group must formulate an action plan. There must be guidance on responsibilities for ensuring that these plans are put into practice, and the trust must be involved in formulating potential actions.

Closure of this final part of the loop may be the most troublesome because of busy schedules and staff working different shifts. Increasingly, trusts, if they wish to be taken seriously, are recognizing that they need to designate either sessional consultant time or senior management time within job plans to close this part of the system. Such an individual would also have some responsibility for integrating clinical audit with adverse event systems.

Step 6: Documentation

It is vital that the whole process is documented. A useful mechanism for this is to set up a computerized database to record the incidents and the results of the investigations along with any ensu-

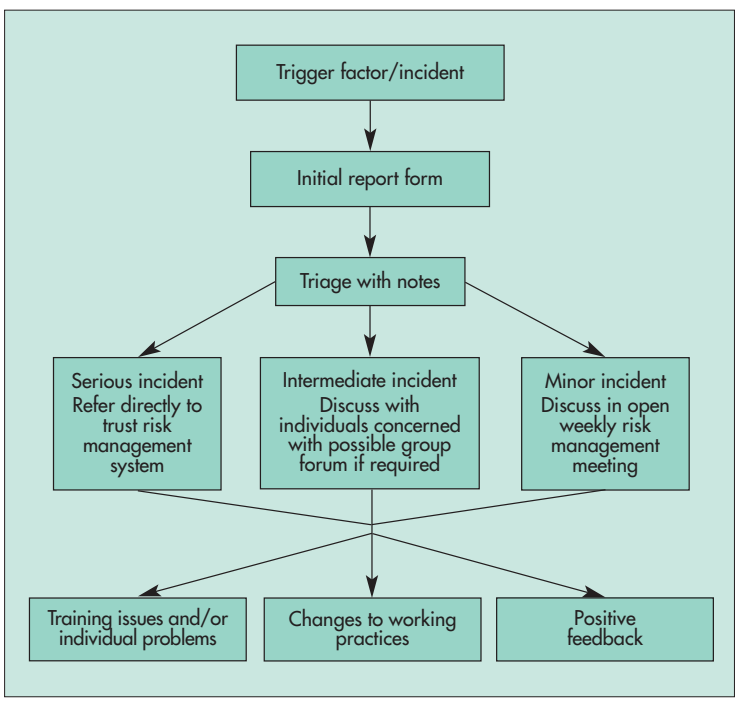

Figure 2. A suggested protocol for labour ward risk management.

ing recommendations. It should be made clear to staff that this documentation is separate from any future medicolegal or disciplinary processes.

Where a more formal review process has taken place, then a summary of this and any recommendations will be held by the clinical director. Depending on the trust's organization, these cases, on an individual basis, need to be shared with the clinical governance committee and trust senior risk management staff. In future, it is these cases in particular which may be and should be shared across the NHS.

FUTURE ISSUES

No system is fixed, and new issues appear. Human rights legislation emphasizes fairness. Adverse event reporting is a peer-review process, and given the paucity of robust evidence for much of obstetric practice, clinicians may disagree with the view of another group classifying care standards. The system must become capable of noting this.

There are no data on what constitutes an unacceptable number of poor care cases for varying grades of staff. Errors of judgment will always be made, even within the best systems. On what grounds would performance be judged 'poor' rather than 'unlucky'? The Liverpool Women's Hospital group have opted for educational review with the appropriate supervisor after three cases of poor care, irrespective of outcome. This will take place outside the adverse event action protocol and feed in formally to the education processes for midwives and medical staff.

CONCLUSIONS

Although risk management is unlikely to achieve the 25% reduction in the cost of medicolegal litigation in obstetrics and gynaecology over the next 5 years, as demanded by *An Organisation with A Memory* (Department of Health, 2000a), it has the potential to improve the quality of care provided for patients. To fully understand why errors occur, and therefore avoid them in future, it is necessary to systematically investigate incidents from both a human and organizational perspective. This approach has to be adopted and embraced by staff, who must see it as a non-threatening, valuable part of routine care. True openness can only be achieved by true involvement and ownership. HM

KEY POINTS

- Risk management involves a process which aims to eradicate risks that can be eliminated and to reduce the effects of risks that cannot be eliminated.
- Important lessons can be learned from adverse events with serious outcomes and those with near misses.
- Events have to be universally reported and investigated rapidly.
- Both human and organizational factors need to be addressed.
- The process must be transparent and seen as non-threatening and separate from disciplinary procedures.
- Documentation of investigations should be performed.
- The system at a local labour ward level should liaise closely with the trust risk management system.

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