

## Clinical governance in action

# Assessing risk by analysing significant events in primary care

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### ABSTRACT

Risk assessment in one local healthcare co-operative (LHCC) was conducted by applying a national incident grading matrix (CNORIS) to 56 significant event analyses (SEAs) undertaken by 32/39 (82%) general practitioners (GPs) as a voluntary and educational activity.

Analysis demonstrated a ratio of 'near miss' to actual adverse event of 1:6 and a wide range and combination of categories. In 40% of incidents reported, the severity was assessed to be 'major' or 'catastrophic'. In 78% of incidents, the risk of recurrence was considered 'possible', 'likely' or 'almost certain'. Risk assessment for recurrence of

incidents was described as 'high' in 25%, 'moderate' in 31% and 'low' in 44% of cases.

The study demonstrates that GPs can work within a national framework for risk assessment. However, the process identified a need for consistency in terms of definitions and coding, dedicated software, a managed reporting system, practical guidance and possibly incentives for GPs.

**Keywords:** diagnostic errors, general practice, medical errors, medication errors, risk assessment, risk factors

## Introduction

Risk management is an essential component of all healthcare systems that wish to maintain their function and protect their users and reputation. Following the creation of the National Patient Safety Agency (NPSA), it is proposed general practitioners (GPs) will have to report all incidents in which a patient was or could have been seriously harmed. The NPSA reporting system sets out ten local requirements 'for managing, reporting, analysing and learning from adverse incidents involving NHS patients'.<sup>1</sup>

Significant event analysis (SEA) is a powerful learning tool with the potential to improve patient care.<sup>2</sup> Its applicability to primary care has been demonstrated.<sup>3</sup> However, it is estimated that only around 20% of practices in the UK are using SEAs for this purpose.<sup>4</sup>

In Scotland, the Management Executive has made explicit to NHS trusts that critical event reporting will be used to monitor and improve existing

practice.<sup>5</sup> By the same token, Royal College of General Practitioners (RCGP) Practice Accreditation has included completion of SEAs as an 'essential' criterion in its Scottish pilot.<sup>6</sup> The importance of SEAs is reflected in their inclusion in the appraisal and revalidation process for GPs.<sup>7</sup> It is therefore anticipated that at national, local and individual levels, studying adverse events will lead to quality improvement and proactive risk management in primary care, whilst averting complaints and claims.

Systems for incident grading have been adopted by NHS trusts complying with the national standards proposed by the Clinical Negligence and Other Risks Indemnity Scheme (CNORIS). Launched, in Scotland, on 1 April 2000 membership is mandatory for all health bodies including primary care trusts (PCTs).<sup>8</sup> While GPs do not subscribe to the CNORIS scheme, its categorisation for risk management can be applied to adverse events and 'near misses', which occur in primary care.

The aim of this work was to determine whether, by applying a national incident grading matrix such as CNORIS to SEAs, this voluntary educational activity

could contribute to risk assessment in one local healthcare co-operative (LHCC). The potential uses of this process were to identify barriers to and opportunities for the development of an integrated reporting system in primary care.

## Method

The framework for clinical governance in primary care in Lanarkshire is provided by the PCT which developed a prescriptive and incentive-based clinical governance 'pack' for local implementation in all practices between October 2000 and April 2002. The 'pack' which included audit and SEAs was linked to external peer review by the regional department of postgraduate medical education, which awarded GPs one postgraduate educational session for the successful completion of an SEA.

Topics for analysis were selected entirely at the GPs' discretion to ensure the broadest possible range of problems. The West of Scotland Deanery provided a structural framework and evaluation schedule for the satisfactory completion and external peer review of the SEA providing consistency and a degree of quality control (Murray Lough, personal communication). Evaluation was judged by the following:

- a clear description of why the event happened and its importance to practice life
- how the event happened
- lessons learned as a result
- changes, if any, implemented, if none, an explanation provided.

In Lanarkshire, associate advisers for continuing professional development (CPD) were engaged to assist GPs. In addition, a clinical governance co-ordinator visited every practice within Clydesdale LHCC and collected documentation including copies of SEAs throughout the 18-month period.

An explanatory letter outlining the purpose of the study and seeking consent for inclusion of their analyses was sent to all GPs in April 2002. There were no objections. A final draft of the paper was also circulated for approval.

Two independent researchers, a GP associate adviser and PCT risk management facilitator categorised and coded reports, discussing individual SEAs until consensus was reached. A random sample of six (10%) SEAs were read, categorised and coded independently by an acknowledged authority in risk management formerly employed by CNORIS.

Codes were based on established criteria for risk analysis:

- risk categories

- severity of the outcome of the significant event
- likelihood of recurrence of the event
- assessment of risk of recurrence.

Assessed risk or risk exposure rating was represented by a single numerical value (range 1 to 25) calculated by multiplying the severity of the outcome by the likelihood of recurrence. The risk was then assessed as 'low', 'moderate' or 'high' using a risk assessment table adapted from the NPSA matrix.

## Results

In the 18-month period, 56 SEAs were undertaken by 32/39 (82%) GPs from all ten practices. GPs in Clydesdale were representative of general practice as a whole in terms of sex (male 64%; female 36%). Of the 39 GPs, 37 were unrestricted principals and two non-principals. Twenty-eight GPs were full-time and 11 part-time. Of the seven GPs who did not complete an SEA, six were part-time (five female, one male) and one was full-time (one male).

Excluding one 'celebratory' SEA, 55 were considered suitable for categorisation using the above matrix. The SEAs analysed demonstrated a ratio of 'near miss' (8/15%) to actual adverse incident (47/85%) reporting of 1:6.

### Categories of risk

A wide range and combination of categories is shown in Table 1. The largest risk categories identified were 'operational' (44%) and 'clinical' (36%) with some risks overlapping in categories, dependent on the nature of the incident. 'Strategic' risks occurred in 16% of cases, the most common example involving information management. 'Human resources' (4%), 'political' (2%) and 'legislative' (2%) incidents were rare and none was reported to have had a financial cause.

### Severity or impact

In almost half of cases (47%), the severity of impact was considered 'insignificant', i.e. there was no injury, no financial loss and no interest to the press (Table 2). In general, these outcomes resulted in a breakdown in the doctor-patient relationship, inefficiency or suboptimal care, for example giving a harmless but wrong vaccination.

In 40% of incidents reported, the severity or impact was assessed to be 'major' or 'catastrophic', for example, preventable death from drug misuse and dissecting aortic aneurysm. Severe disability arising

**Table 1** Risk categories

Risk category	<i>n</i> (%) ( <i>n</i> = 55)	Examples
Human resources	2 (4)	Staff dismissal (irregular leave) Inadequate training (limited knowledge)
Strategic	9 (16)	Failure of emergency planning Unsafe out-of-hours service
Operational	24 (44)	Breach of security and confidentiality of patient information Inadequate systems for reporting results, repeat prescribing and referral Dispensing errors, immunisation errors
Political	1 (2)	Ineffective joint working with local authority Restrictive cross-boundary policies
Legislative	1 (2)	Inadequate procedures for controlled drugs
Major change	0 (0)	
Financial	0 (0)	
Clinical	20 (36)	Delayed diagnosis, diagnostic error, delayed treatment, medication error Breakdown in doctor–patient relationship Anaphylaxis
Environmental	3 (5)	Patient absconds from hospital undetected
Project	0 (0)	
Combination, e.g.		
Operational/clinical	2 (4)	Haemorrhagic complications of warfarin arising from inadequate monitoring
Strategic/political/environmental	1 (2)	Inclement weather isolates hospital from services
Environmental/human resource	1 (2)	Practice design, security and safety of staff

**Table 2** Severity of the outcome of the significant event

Impact	<i>n</i> (%) ( <i>n</i> = 55)	Impact
Insignificant	26 (47)	No obvious harm/injury, e.g. wrong vaccine
Minor	5 (9)	First aid treatment required
Moderate	2 (4)	Medical treatment required
Major	10 (18)	Disabling injury, e.g. missed ectopic pregnancy, blindness
Catastrophic	12 (22)	Death from drug misuse, aortic aneurysm, pressure sores

from the haemorrhagic complications of anti-coagulation resulted in visual loss, subdural haemorrhage and carpal tunnel syndrome.

## Risk of recurrence

Each situation was assessed for the risk of recurrence in the absence of any controls for example the risk of a patient accessing confidential information from a computer without a screensaver made the risk almost certain to recur (Table 3). In over three-quarters (78%) of incidents, the risk of recurrence was considered 'possible', 'likely' or 'almost certain'. In the minority of cases where the risk of recurrence was considered 'rare', if the event did occur the outcome was potentially catastrophic, for example the stabbing of a GP.

## Risk assessment

Informed by the 'likelihood' and 'severity' scores, the risk assessment for recurrence of the incidents was described as 'high' in 25%, 'moderate' in 31% and 'low' in 44% of cases (Table 4).

## Discussion

This paper provides evidence of the existence of serious risk in primary care. It also demonstrates that by conducting an SEA, GPs can work within a national framework such as that proposed by CNORIS. However, problems in implementing such a system have been identified and in so doing, the process has provided valuable information to support the development of a learning culture at both team and individual levels in primary care.

As most circumstances are multifactorial, overlap

is perhaps inevitable. The combination of factors made apparent by undertaking the analysis indicates a need for a more detailed taxonomy of categorisation of risks in general practice, such as that proposed by Makeham and colleagues.<sup>9</sup> The study supports the need for a robust coding procedure and a dedicated software system. This should enable a further subcategorisation of the 'clinical' and 'non-clinical' groups to, for example 'health and safety', 'breach of confidentiality' or 'failure of systems'.

The proportion of those described by CNORIS as 'major' or 'catastrophic' events (40%) can be accounted for by the selection of fatal incidents for reporting by GPs. In three-quarters of cases the adverse event was considered 'possible', 'likely' or 'almost certain' to recur, giving a risk assessment score of 'high' in 25% and 'moderate' in 31% of cases. This is comparable with larger studies in which 27% of incidents in general practice had the potential for severe harm.<sup>10</sup>

More importantly, this work exemplifies the complexity of applying a predefined matrix to a subjective and consequently biased account of an incident. Strengths of the study include the concordance of GPs, structured responses, the educational value of the activity and acceptability of the clinical governance 'pack'. Additional advantages in the design were multiple ratings by three researchers from different professional backgrounds and a criterion-based tool for measurement.

Important weaknesses in the study are the identification of a false positive in a 'celebratory' SEA, self-selected and limited reporting by GPs and a variation in the quality of submissions. A 'celebratory' SEA while unavoidable is, in the context of this study, inappropriate. Its inclusion reflects the discordance between SEA for educational and quality improvement and the incidents that the NPSA aims to identify in order to improve patient safety.

As an educational activity, Pringle has described

**Table 3** Likelihood of recurrence of the event

Risk of recurrence	<i>n</i> (%) ( <i>n</i> = 55)	Examples
Rare	4 (7)	Attempted murder of GP
Unlikely	8 (15)	Wrong directions to locus from police
Possible	35 (64)	Wrong medication, wrong vaccine
Likely	6 (11)	Missed aortic aneurysm, meningitis, astrocytoma
Almost certain	2 (4)	Patient accessing information from computer without screen saver

**Table 4** Assessment of risk of recurrence

Risk exposure	<i>n</i> (%) ( <i>n</i> = 55)
Low	24 (44)
Moderate	17 (31)
High	14 (25)

significant events as ‘any event thought by any member of the primary care team to be significant in terms of patient care or the conduct of the practice’.<sup>11</sup> An alternative perspective is that which restricts the definition to adverse events, specifically, ‘instances which indicate or may indicate that a patient has received poor quality care’.<sup>12</sup> At the other extreme, and more explicitly damaging, is the current NPSA definition, which is ‘one that could have or did lead to unintended or unexpected harm, loss or damage’.<sup>1</sup>

A minority of events were not caused by the healthcare process, for example the stabbing of a GP and drug-related deaths. However, in his 1998 paper, Pringle describes how even these apparently unrelated cases help improve the quality of care.<sup>11</sup>

The first requirement for risk management in primary care is consistency by limiting analyses to events which fulfil three key characteristics, namely ‘negativity’, ‘patient involvement’ and ‘causation’, where the event is a result of the healthcare process.<sup>13</sup> While this negative view might be considered restrictive, in order to apply a risk grading system such as CNORIS, it is necessary to separate SEAs into those that fit the definition of adverse events and ‘near misses’ and those that do not, before undertaking research.

Quantitative analysis was not undertaken because of the nature of the investigation and the non-random sample. Therefore, consistent with other authors,<sup>10,14</sup> this snapshot of data cannot indicate the prevalence of adverse incidents and is considered to be non-generalisable.

Individual judgement and professional perspective also influence the grading process and outcome. While agreement was achieved in all cases, the process of reaching consensus could have benefited from a more detailed purpose-designed reporting form with additional fixed-response questions including the age and sex of the patient, the presence of chronic disease and the estimated frequency of the error in the practice.

Events categorised as ‘insignificant’ are not necessarily inconsequential. Errors with no discernible

effects can still put patients at risk and probably underestimate the impact in terms of the distress caused by the action. For example, while damage to the doctor–patient relationship may be ‘insignificant’, most complaints against doctors concern attitudinal and behavioural problems rather than clinical incompetence.<sup>15</sup> At practice level, these errors lead to discontent and a waste of time and money.

The minority of ‘near misses’ is important in that, while harm may have been averted, the potential for harm could still remain. An assessment of ‘preventability’ has the potential to contribute to the planning of preventative procedures.

Acknowledging that the CNORIS standards can apply to independent practitioners such as GPs there will need to be detailed discussions within PCTs in order to develop integrated systems for receiving incident reports, providing feedback on trends and a mechanism for sharing lessons learned. The challenge is for GPs, primary care teams and all practice staff to increase reporting of all incidents, including ‘near misses’, fostering a culture of openness and honesty when things do go wrong. Only then can data be aggregated and reliably converted into rates to inform local and corporate risk registers.

Research has shown that GPs believe that the status of general practice will improve as a result of a central reporting mechanism.<sup>16</sup> However, for them to participate fully in an integrated reporting system, GPs should feel ownership of the system.

In Lanarkshire GPs were facilitated and supported by an incentive-based clinical governance programme. Factors influencing participation including part-time status, anonymous reporting and resource implications need to be explored.

## Conclusions

The delivery of effective, efficient and safe healthcare is underpinned by adverse incident reporting. GPs in this study have demonstrated the willingness and the capacity to report adverse events. SEA, as an educational activity, is an appropriate method to support the process.

For this to become mainstream, as it is within other areas of the NHS, GPs will benefit from access to practical guidance and support within an established framework. CNORIS provides one such framework, which assesses risk by analysing significant events.

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