

## Clinical governance in action

# Finding the hidden risks with medical devices: a risk profile tool

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### ABSTRACT

There is an increasing interest in the risk management of medical devices in the UK to comply with Controls Assurance standards. Controls assurance and clinical governance share a common thread with risk pooling in risk management. This paper gives a brief outline describing the development and thought processes for designing a risk register tool. It illustrates one method of determining the risk rating number based on the New Zealand model for calculating risk. The tool is universal in that it can be

used across any medical device; we have chosen to assess risk using generic device types such as defibrillators, infusion pumps, or a pair of crutches, but it could be used for a specific model equally well. This tool will work across the healthcare sector and it is envisaged that, with some modification, it can be used to inform procurement decisions.

**Keywords:** controls assurance, medical devices, risk management, standards

### Introduction

Risk management is becoming an increasingly important topic in healthcare throughout Britain and more so with the standards with which primary care trusts (PCTs) and NHS hospital trusts need to comply. Recent advances in medical technology have made it difficult for health professionals, including nursing staff and clinicians, to understand and properly operate new medical equipment.<sup>1</sup> The Medicines and Healthcare products Regulatory Agency MHRA (formerly the Medical Devices Agency) summarises that: 'almost 9000 incidents were reported to the agency during 2002, a rise of 11% over the previous year. These incidents involved medical devices of all kinds, from simple laboratory equipment to highly sophisticated MR [magnetic resonance] and CT [computed tomography] scanners'.<sup>2</sup> Risks involving medical devices can impact on and affect staff, patients, family members and healthcare professionals as well as the organisation.

Medical devices have started to feature in risk assessments particularly in respect of Controls Assurance and the Clinical Negligence Standards for Trusts (CNST).<sup>3,4</sup> Risk, according to Bamber, reflects both

the likelihood that harm will occur and its potential severity.<sup>5</sup> Hence both the consequences (outcomes) and probability (frequency) need to feature in any risk-profiling tool. There is a pleasing trend in how organisations deal with risk with a shift away from the blame culture to one of insight and how to create defence systems or error-tolerant systems. The ethos now appears to be 'how can we learn from this incident or near miss risk to prevent it from recurring or minimise its impact?'

### The project

The risks associated with healthcare are being highlighted and hospital trusts are taking steps to manage these through risk assessment. A project was developed to assess the risks associated with medical devices across all specialties in the acute trust distributed geographically over three sites, although it is equally valid in the primary care sector. National and local presentations have produced considerable interest from other hospital trusts and PCTs. From this risk profiling it was required to identify those

devices within generic categories that have the highest risk. The medical devices would then be added to the risk register and an action plan drawn up to manage the identified risks. The remit was to produce a simple-to-use tool that is flexible enough to work across all specialties, ward/department structures and all medical devices. Such a remit precluded detailed device-specific assessments while providing the flexibility to encompass all generic device groups. Examples might include a nebuliser or a pair of crutches that can be used in a hospital setting or by a patient at home for continued treatment.

## Methodology: developing a risk-profiling tool

There are obviously many factors that may contribute to risk and these can be divided into human factors and system factors.<sup>6</sup> These factors have been taken from a University College London (UCL/Association of Litigation and Risk Managers) protocol published in a Department of Health/National Patient Safety Agency (DOH/NPSA) document as a causal analysis checklist.<sup>7</sup> In the hospital context, human factors can be subdivided further into patient, staff and team issues. Knowledge and understanding of medical devices are prerequisite for efficient and safe use.<sup>8</sup> It must also be recognised that patients frequently take medical devices home for continuing care. The role of the healthcare staff is thus; as users of equipment, selectors of appropriate devices and trainers of patients in using devices in their home competently. System factors can similarly be divided into task, work environment, and organisation and management. Again the risks associated with a device in one environment may not necessarily transfer to another environment or a different task.

To counterbalance the contributing factors, organisations put in place a number of control measures. Hence the risk rating previously alluded to as consequences and probability can now be expressed as the product of the contributing factors and control measures.<sup>9</sup> In risk assessment our aim is to identify the contributing factors and either overcome them through changes in practice or manage them by introducing added control measures.

To identify risks we have developed a series of questions that 'measure' human/system factors and any control measures already in place. All of the questions were assessed for clarity from a panel comprising a risk manager, clinician (nurse consultant) and a medical physics head of department.

In total 38 questions were posed, divided equally between contributing factors and control measures. Examples of questions are shown in Box 1.

### Box 1 Examples of questions asked

#### Contributory factors

- Was the device formally 'accepted' before use?
- Is the device suitable for the purpose and environment?
- Are staff who use this device assessed for competence?

#### Control measures

- Is routine calibration or maintenance carried out where necessary?
- Are NHS/trust protocols/procedures in place for this device?
- Is all communication relating to this device clear and concise?

These questions were phrased as closed questions requiring a yes/not applicable (n/a) or no answer by the respondent. For clarity the questions were grouped under familiar headings: device maintenance, device operation and use, staff – skills and knowledge, patient profile, device suitability, dealing with errors, supervision, communications and organisational culture. The respondents were identified as people responsible for the equipment, usually the head of department, ward manager or 'nominated person'. It is recognised that the individual user also has a responsibility and duty of care in this instance.

The respondent answers were coded such that a 'yes or n/a' response scored 1, whereas a 'no' response scored 2. The product of all of the contributing factor answers produced a value for risk outcomes. The control measures were handled in a similar manner producing a value of 'likelihood'. The New Zealand model for risk classification is a methodical approach that is being increasingly adopted in the UK. Using the New Zealand model AS/NZS4360, the consequences were graded into five groups labelled: insignificant, minor, moderate, major and catastrophic.<sup>9</sup> The likelihood scores were also divided into five groups, namely: rare, unlikely, possible, likely and almost certain. The scorings attributed to each of the grades were factors of two based on the number of questions.

This produces a grading of risk outcomes and of likelihood. The final calculation is to multiply the two values together to produce a risk rating number (RRN). Once more the RRN is divided into four levels: high, medium, low and very low similar to that in the New Zealand model.<sup>9</sup> The Australian/New Zealand model is now widely accepted as the standard risk rating matrix for many NHS organisations and has also been adopted by the NPSA. A graphical matrix for the risk rating is given in Appendix 1.

Hence from the above process we can deduce a risk rating for a medical device used in a particular environment. This matrix does not identify a rating for a specific risk but provides an overall assessment for all risk factors.

To develop the usefulness of this tool further, the questions were grouped into six categories and a scoring of greater than half the number of questions answering 'no' flagged up the category for additional control measures. The categories are: staff training/skills and knowledge, supervision and support, device technical support, environmental improvements, resources and, finally, procedure/policy changes. Thus the tool not only produces a risk rating for a device in a particular setting but also identifies areas where added control measures need to be considered. It is recognised that this tool does not identify specific risks but indicates general areas that need to be revisited and the risks managed more effectively. In managing risks, the concept would be to first address identified 'high' risk aspects and then through a continued quality improvement programme look at the lower risk aspects.

To make the system manageable, the tool was developed into an Access® database program and installed on a laptop computer for portability. The program facilitates searching of the data under many fields that include: hospital, directorate, ward/department, device type or risk rating. A feature was provided to download the data onto a server in Excel® format at the touch of a button. If necessary the data can then be exported to, say SPSS® for statistical analysis. Facilities are provided to add new device categories and new wards as the tool is used in practice.

## Outcomes

The main operating theatres were chosen for the pilot study as they provided a wide spread of device types and staff groups in a stressful and difficult working environment. The pilot has provided an opportunity to refine the risk register tool and amend the action levels for added control measures. It has also given an opportunity to provide feedback from a practical situation by the clinical staff likely to use it. The tool has also been used recently to assess the risks prior to a clinical trial, on devices used by patients at home and single use devices. It has also been used following incidents and root cause analysis to inform the way forward. The eventual aim is that this tool will be available to all departments on a county-wide basis

over the hospital internet to allow all hospitals to conduct their own risk assessments; interest has also been expressed in using this as an aid to procurement decisions.

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## FURTHER READING

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## CONFLICTS OF INTEREST

None.

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## Appendix 1

### Risk rating matrix

	<b>Rare</b>	<b>Unlikely</b>	<b>Possible</b>	<b>Likely</b>	<b>Almost certain</b>
<b>Insignificant</b>	Very low	Very low	Very low	Very low	Very low
<b>Minor</b>	Very low	Very low	Very low	Low	Low
<b>Moderate</b>	Very low	Very low	Low	Medium	Medium
<b>Major</b>	Very low	Low	Medium	High	High
<b>Catastrophic</b>	Very low	Low	Medium	High	High