What factors should you focus on to provide meaningful risk assessments?

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In preparation for changes to the regulation of pharmacists, the Royal Pharmaceutical Society has commissioned a series of studies to look at ways in which regulation might be carried out in the future. This includes the use of revalidation; that is, a periodic reassessment of pharmacists' fitness to practise. One question that the Society (and its regulator, successor, the General Pharmaceutical Council) wishes to consider is how to develop a revalidation system that is proportionate to the level of risk involved in different types of practice but no more onerous than is necessary to manage this risk. On the face of it, there appears to be a straightforward and non-contentious matter. However, consider what “risk” means to you, whether you are engaged in pharmacy work or in activities outside the pharmacy. Is the risk to you, to other people, or to both? Who — or what — creates the risk? And who decides that it is a risk?

Such questions have occupied academics and practitioners of risk management in a range of industries. We are currently involved in a study for the Society to investigate how the concept of risk translates to the pharmacy setting, and especially to the regulation and revalidation of pharmacy practitioners. Here, we would like to put forward some ideas of our own, but also encourage practitioners and service users to share their views.

One approach that is often used to characterise risk factors is the Swiss Cheese model, developed by James Reason at the University of Cambridge. This model, illustrated in the Figure, depicts an organisation as consisting of five “layers”, namely:

- Decision makers — designers and high-level managers of the organisation who are responsible both for setting goals and determining how the goals will be met
- Line management — groups (eg, optometry boards or pharmacy accreditation boards) who implement the decision-makers’ strategies
- Preconditions — features that need to be in place in order to allow successful work activity (eg, reliable equipment, skilled and motivated workforce, procedures, environmental conditions)
- Productive activities — activities carried out by people and machines in order to achieve tasks
- Defences — safeguards put in place to protect individuals and machines from hazards associated with their activities

Reason’s Swiss Cheese model

Ideally, each of these layers would be strong, but in practice each of them can have a weakness of some sort. Under certain conditions, a hazard can exploit a weakness in every layer, and as a result propagate through the work system. In simple terms, a critical incident can arise from the culmination of both personal factors and features of the work setting. Which, then, should be the focus of risk control measures?

A number of US and UK studies have sought to identify the characteristics of healthcare professionals (nurses, doctors and dentists) who have either faced disciplinary action by their registration boards or, in the UK, been referred to the National Clinical Assessment Service (NCAS). Some of the key issues identified by these studies include:

- Particular specialties or sectors (most notably, general practice, surgery, obstetrics and gynaecology, and psychiatry) being at greater risk of disciplinary action or NCAS referral
- The age of the practitioner and the length of time in practice sometimes led to the greater risk, whereas in other cases it was a greater number of years
- In the UK, GPs working alone being at increased risk
- Male practitioners, non-white practitioners and overseas-trained practitioners trained overseas being at increased risk

Findings such as these indicate that the focus of a risk assessment should be on individual practitioners. However, to take the last set of findings as an example, is there something intrinsic to male practitioners, ethnic minority practitioners and overseas-trained practitioners that places them at increased risk of disciplinary action? Is it possible that these findings reflect process variables, for example difficulty in establishing a rapport with service users. (By way of illustration, research by Maxine Papadakis and colleagues at the University of California has found that, among US physicians, previous poor performance or unprofessional conduct is a predictor of subsequent behaviour resulting in disciplinary action.) Given the retrospective nature of these studies, it is difficult to rule out a bias in the reporting or referral patterns of practitioners in the first place. In any case, the NCAS data suggest that the relationship between practitioner variables is more complex than might first appear: the National Patient Safety Agency reports that non-white UK-qualified and white non-UK qualified doctors are at lower risk of referral than white UK-qualified doctors, while non-white non-UK qualified doctors are at the highest risk.

Other research in pharmacy highlights the importance of considering contextual factors as well as personal characteristics. For example, a 2005 study by one of us found that, in a sample of UK community pharmacies, a number of errors and near-misses were reported to have occurred in the presence of increased workload, reduced staffing or distractions. A follow-on study highlighted the influence of organisational culture on a pharmacy’s ability to develop safe practice. For example, there appears to be a tendency to under-report medication incidents for a number of reasons, which deprives pharmacies of opportunities to learn from critical incidents.

So, what message can be drawn from the work discussed here? Almost by definition, the agenda of professional regulation implies a focus on the risk posed by individual practitioners. Yet, as we have illustrated, risk can be seen as a product not just of a practitioner himself or herself, but also of the physical and cultural context within which a practitioner works. It is though, one thing to recognize the multiplicity of risk factors but another to incorporate them all adequately into a risk assessment. Through our current work, we hope to be able to suggest ways of doing so that are acceptable to all stakeholders — regulators, service users, service providers, and practitioners alike.