Risk Assessment in Pharmacy Practice

Executive Summary

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Background and methods
In line with proposals made by the Department of Health, the Royal Pharmaceutical Society of Great Britain (RPSGB) and its regulatory successor, the General Pharmaceutical Council (GPhC) intend to introduce revalidation of registered pharmacists and technicians – that is, a periodic reassessment of their fitness to practise. One expectation for the scheme is that the degree of scrutiny applied to a given registrant should be proportionate to the level of risk that he or she poses. However, this raises the question of how “risk” should be defined and assessed for the purposes of revalidation.

The aim of this study, commissioned by the RPSGB, was to advise the pharmacy regulator on the assessment and management of risk in pharmacy practice to underpin the development of revalidation standards and processes. The specific objectives were to:

i) Develop a definition of risk in the context of pharmacy practice;
ii) Identify areas of high risk in pharmacy practice, using existing datasets;
iii) Identify how stakeholders distinguish “high risk” and “low risk” practice;
iv) Develop a framework for assessing risk;
v) Suggest ways in which revalidation could be undertaken in order to manage the risk of individual registrants’ practice.

In order to meet these objectives, a number of research methods have been employed. A literature review was conducted, using literature in human factors, management and safety science. This review provided a basis for conceptualising risk in pharmacy, identifying markers of risk, and developing models of risk-based revalidation. In order to provide empirical data from a pharmacy setting, a retrospective record review of the RPSGB’s disciplinary
records was conducted, in which the characteristics of pharmacists who had been referred to the Disciplinary Committee were compared with the characteristics of those who had not been referred. A set of interviews was carried out with pharmacy staff, managers and service users in order to understand how they distinguish between “high-risk” and “low-risk” practitioners. Finally, focus groups were conducted with subject matter experts in pharmacy risk management in order to obtain feedback on a revalidation model and risk assessment criteria proposed by the researchers.

**What is “risk” in pharmacy practice?**

While risk is a ubiquitous concept, there are varying views as to how it should be defined in practice. In the context of pharmacy work, risk can be viewed purely in technical terms – for example, the probability of an adverse event combined with an assessment of severity. However, it can also be viewed in terms of the relationship between the pharmacist and the various stakeholders who are involved in his or her work. From the latter view, it becomes important to consider what risk means to these different stakeholders. In the current study, the interviews were used to obtain views from stakeholders (hospital and community pharmacists, their managers, and a limited selection of service users) about what constitutes pharmacist risk. Interview data, in addition to data from previous studies, were used to devise a conceptual model of pharmacist risk, that was further refined during the focus groups. This model gave rise to a working definition of risk: *the potential for harm to occur to the pharmacy workforce, their organisations or the recipients of their services, as a result of pharmacists’ activities.*

**What are the indicators of “high risk” and “low risk” practice, and how do stakeholders distinguish between the two?**

The literature review included a number of studies that examined factors influencing healthcare practitioners’ risk of being sanctioned by a professional regulator. These studies identified a number of individual characteristics, for example age, gender, ethnicity and country of training. In addition, though, other studies were identified that point to the role of organisational factors, such as staffing and workload, in the occurrence of medication errors. Taken
together, these studies suggest that both the pharmacist and the pharmacy need to be taken into account; a point that was reinforced by the qualitative data collected as part of this study.

The retrospective record review found that, from four potential predictors (age, ethnicity, sector, country of training), only the pharmacist’s sector was a statistically significant predictor of his or her likelihood of being referred to the disciplinary committee. Specifically, community pharmacists were significantly more likely to be referred than were pharmacists in a non patient-facing role, while there was also a non-significant trend for hospital pharmacists to be more likely than non patient-facing pharmacists to be referred. There were also non-significant trends for non-UK trained and non-White pharmacists being more likely to be referred. Descriptive analysis of the data identified some additional patterns in the data; for example, approximately one-fifth of pharmacists referred to the disciplinary committee had been sanctioned by the RPSGB previously. However, it should be noted that the sample used this study, and the data available from the sample, were quite limited when compared to the population of pharmacists who are subject to investigation by the regulatory body.

The interview data identified factors that were perceived by participants to be associated with practitioner risk. A range of characteristics were cited, for example training overseas and changing sectors. Generally, a pharmacist who was unfamiliar with his or her current working environment and practices was deemed to be of higher risk than one who was not. Pharmacists with sound knowledge and skill, and appropriate attitudes to dealing with risk, were considered to be of lower risk. While the record review suggested the possibility that particular sectors of practice might engender greater risk, there was no clear evidence to suggest that specific sectors or areas of practice, such as advanced and specialist practice (as opposed to characteristics of individual pharmacies and practitioners) were necessarily more risky than others, when differences in risk management processes and their relative frequency of occurrence in the population were taken into account.
Developing a framework for assessing risk and ways in which revalidation should be undertaken to manage risk

From the literature review and empirical data, a set of criteria were generated which potentially can be used to distinguish between high and low risk practitioners. From these criteria, eight specific criteria (length of practice; English proficiency; overseas training; change of sector; career break; patient-facing role; previous sanctions; solo practice) have been identified as being easily assessed and having some evidence to link them to risk. They are presented in this report as the basis for pharmacist risk assessment, subject to further empirical validation. In addition, further criteria (health and stress; engagement with continuing professional development; knowledge, skill and attitude), are suggested, as are “contextual” factors that influence pharmacist risk but do not necessarily lie within the scope of individual revalidation (for example workload, staffing and organisational culture).

The literature review identified a number of models and approaches that could be used for risk-based revalidation. Based on these, the researchers proposed a model, which comprises CPD and competency-based assessment and is implemented in conjunction with the risk criteria. The latter are used to select registrants who will be subjected to a more intensive revalidation regime; it is suggested that, subject to it being cost-effective, five years for low risk pharmacists and three years for high risk pharmacists is a sensible interval. This model was presented to the focus groups and refined accordingly. Both the focus group participants, and those in the interviews, highlighted a number of issues to be taken into account when implementing a revalidation scheme. Essentially, these express a concern that such a scheme should, whatever form it takes, be applicable and equitable across the different sectors and roles of the pharmacy profession.

Conclusions and recommendations

This study has examined the use of risk assessment in pharmacist revalidation, and in doing so has offered a definition of risk, a set of criteria for assessing risk and a model for risk-based revalidation. It is recommended that these are used as the basis of a revalidation process. Further work to
develop revalidation should focus on a number of key areas. Firstly, to validate the risk assessment criteria (both those that have been included in the current model and those that have been identified for potential inclusion). Secondly, to investigate the use of additional methods (for example, in-house risk controls, and training interventions) and to consider the integration of pharmacist assessment with assessment of the pharmacist's work setting. In addition, it is recommended that a more extensive analysis of the Society’s disciplinary records be carried out, supported by the routine collection of further data from registrants.