Risk Assessment in Pharmacy Practice
Final Report, Version 2

December 2010

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## Document history

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<thead>
<tr>
<th>Version</th>
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</tr>
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<tr>
<td>1</td>
<td>September 2010</td>
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</tr>
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Risk Assessment in Pharmacy Practice

Executive summary

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.

Acknowledgements

The authors would like to acknowledge the following:

- The Department of Health for funding this study;
- The RPSGB’s Revalidation Research Steering Committee for its guidance during the course of the study;
- The RPSGB’s Membership Department for providing access to pharmacist data for the record review;
- The National Clinical Assessment Service for allowing the researchers the use of its office space;
- The various individuals and agencies who agreed to take part in an interview or focus group;
- The overseas-based pharmacists (who are identified at the appropriate points in the main text) who provided the researchers with information about assessment and revalidation in their respective countries.
1. Introduction

1.1 Background

The Department of Health’s White Paper, “Trust, Assurance and Safety: the regulation of health professionals” (Department of Health, 2007), proposed that all statutorily regulated health care professions have arrangements in place for the revalidation of their members’ fitness to practise. It suggests a number of principles that should underpin revalidation regimes, one of which is that they should be proportionate to the practice risks they address and the benefit they bring. The Royal Pharmaceutical Society of Great Britain (RPSGB) has reiterated the principle of proportionality in the regulation of pharmacy practice (Royal Pharmaceutical Society of Great Britain, 2009a). The Society’s aspiration for revalidation is that it is limited to what is necessary to minimise the risk of pharmacy practice without placing unnecessary burdens on practitioners or others involved in the process (Noyce, 2006). In order to inform the decision making of the Society’s regulatory successor, the General Pharmaceutical Council, about a suitable revalidation regime, the RPSGB commissioned a study by the School of Pharmacy and Pharmaceutical Sciences at the University of Manchester. The aim of the study was to provide the RPSGB with advice on the assessment and management of risk in pharmacy practice to underpin the development of revalidation standards and processes.

Risk assessment has long formed a cornerstone of safety management systems (SMS) in industry, where it has served to reduce the potential for harm by identifying hazards and ways of preventing their impact on work activities (Glendon, Clarke, & McKenna, 2006; Makin & Winder, 2008). Typically, an SMS examines not just the practitioner, but also the nature of the tasks that he or she undertakes and the characteristics of the work system within which the tasks are carried out; hence, any or all of these can be the subject of a risk assessment (Glendon et al., 2006). In the context of healthcare, the publication of “An Organisation with a Memory” (Department
of Health, 2000) has led to an increased interest in risk management. According to Kohn, Corrigan & Donaldson (2000), there is a need for healthcare to shift its focus from loss control to the prevention of incidents; the latter activity would, in principle, lend itself to the use of risk assessment. The National Patient Safety Agency (NPSA, 2006) has proposed a general framework for risk management, which described steps for identifying, assessing and minimizing risk. Against the backdrop of the NPSA’s framework, the focus of the current study was on identifying specific risk factors in pharmacy practice and considering ways of assessing and monitoring these risks.

The specific research objectives were as follows:

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.

1.2 Research methods used

1.2.1 Literature review

The literature review had three aims:

i. generate ideas from the practice of cognate professions about how risk could be conceptualised and assessed in pharmacy;

ii. identify characteristics of individuals, tasks and organisational context that have been associated with adverse events in pharmacy;

iii. consider different models of professional regulation and their relative strengths and weaknesses from a risk management point of view.

The general strategy was to identify and review relevant literature in human factors, management and safety science, and where appropriate,

In addition to the search of academic databases, public domain repositories (for example, government and NHS websites, and relevant professional organisations) were consulted. Also, the reference lists of retrieved articles were consulted for relevant material. In order to supplement the academic literature on overseas practice in revalidation, the researchers consulted directly with colleagues based in Australia, Denmark, Germany, Holland, Canada, New Zealand and the United States.
<table>
<thead>
<tr>
<th>Topic</th>
<th>Keywords</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk management in:</td>
<td>Safety management systems, risk management systems, quality management systems</td>
</tr>
<tr>
<td>i) pharmacy in the UK and overseas;</td>
<td></td>
</tr>
<tr>
<td>ii) healthcare professions with a similar educational and contractual arrangement to pharmacy in the UK and overseas (e.g. medicine; dentistry);</td>
<td></td>
</tr>
<tr>
<td>iii) “high hazard” industries in the UK only (nuclear, process control, petrochemical, aviation, rail)</td>
<td></td>
</tr>
<tr>
<td>iv) financial organisations in the UK only (insurance and credit control)</td>
<td></td>
</tr>
<tr>
<td>Factors that are associated with malpractice or adverse events in healthcare practice, particularly those with relevance to pharmacy practice</td>
<td>Pharmacy error(s), pharmacy accident(s), pharmacy risk(s), dispensing error(s), drug error(s), medication error(s), drug misadventure(s), near miss(es), risk factor(s), malpractice</td>
</tr>
<tr>
<td>Regulation and revalidation of healthcare practitioners</td>
<td>Professional regulation, professional (re)validation, accreditation, credentialing</td>
</tr>
</tbody>
</table>
1.2.2 Record review

The aim of the record review was to obtain empirical data about pharmacist risk, based on the assumption that an objective measure of risk is a pharmacist’s likelihood of being disciplined by the professional regulator (see Section 2). The study used a case-control design, in which pharmacists who had undergone a disciplinary hearing were compared to matched control cases (pharmacists who had not undergone a hearing but were matched the disciplined pharmacists in terms of gender, country of residence and year of registration). In order to identify pharmacists who had undergone a hearing, the researchers used the repository of fitness to practise records published on the RPSGB’s website. These records provide particulars of cases that have been heard by the Society’s Disciplinary Committee (DC) following an allegation of poor performance or misconduct. The criteria for including a DC case in the sampling frame was that it was registered by the RPSGB after 1 April 2007 (on which date a new disciplinary framework was introduced) and that it was a new disciplinary case, rather than an application for restoration to the register following a period of suspension. This ensured that all cases had been reviewed against the same standards of practice. In all, 117 pharmacists who met the criteria for inclusion in the study were identified in the online repository as of December 2009 (when data extraction was carried out); all of these were included in the study. In addition to these disciplined pharmacists, a stratified sample of 580 non-disciplined pharmacists was obtained from the RPSGB’s membership database, comprising the control group. This latter sample comprised five non-disciplined pharmacists per disciplined pharmacist, who were matched on the criteria described earlier. The choice of five control cases for each case in the sample provides a sample size that is sufficiently large for a multivariate analysis (Tabachnick & Fidell, 2001), whilst being cautious to avoid masking any effects because of too high a ratio of control cases. Hence the total sample comprised 697 pharmacists. Details of this sample are shown in Table 1.2.

For each pharmacist in the sample, demographic details (date of birth; ethnicity; sector; whether qualified in the UK or abroad; whether qualified as a
prescriber) were recorded. For pharmacists in the disciplined group, details of the case (source of the complaint; nature of the complaint; outcome of any hearing; whether the pharmacist had previously been the subject of disciplinary action) were also recorded. This allowed the characteristics of pharmacists in both groups to be compared. The researchers obtained their data either from the information that was published on the website or from the RPSGB’s membership database.

All data were entered into SPSS Version 15.0 and anonymised prior to analysis. A multiway frequency analysis and a logistic regression analysis were carried out, with sector, qualification, ethnicity and age as the predictors and allocation to the disciplined or control (non-disciplined) group as the dependent variable. Due to low cell frequencies within the sector, ethnicity and qualification variables, these were recoded prior to analysis (Sector: hospital; community; other. Ethnicity: white; non-white. Qualification: UK; non-UK). Registration as a prescriber was removed from the predictors due to the outcome groups being perfectly separated on this variable, leading to large values of standard error. Because the frequency analysis uses categorical data, age was categorised for the purpose of this particular analysis. The categories, which are shown in Table 1.2, were chosen arbitrarily to provide an even spread of cases in each in each category. In the logistic regression, age was used in its continuous form. Prior to each run of the regression analysis, cases with missing data on the independent variable(s) were removed using listwise deletion.
Table 1.2 Demographic characteristics of the sample

<table>
<thead>
<tr>
<th>Group</th>
<th>Disciplined</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong>*</td>
<td>Male</td>
<td>92 (78.6%)</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>25 (21.4%)</td>
</tr>
<tr>
<td><strong>Country</strong>*</td>
<td>England</td>
<td>100 (85.5%)</td>
</tr>
<tr>
<td></td>
<td>Scotland</td>
<td>8 (6.8%)</td>
</tr>
<tr>
<td></td>
<td>Wales</td>
<td>4 (3.4%)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>5 (4.3%)</td>
</tr>
<tr>
<td><strong>Sector</strong></td>
<td>Hospital</td>
<td>8 (6.8%)</td>
</tr>
<tr>
<td></td>
<td>Community</td>
<td>89 (76.1%)</td>
</tr>
<tr>
<td></td>
<td>PCT</td>
<td>2 (1.7%)</td>
</tr>
<tr>
<td></td>
<td>Industry</td>
<td>1 (0.9%)</td>
</tr>
<tr>
<td></td>
<td>Academia</td>
<td>2 (1.7%)</td>
</tr>
<tr>
<td></td>
<td>Wholesale</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Other pharmaceutical</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Non-paid</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Non-pharmaceutical</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>No information available</td>
<td>15 (12.8%)</td>
</tr>
<tr>
<td><strong>Qualification</strong></td>
<td>Adjudication / OSPAP***</td>
<td>7 (6.0%)</td>
</tr>
<tr>
<td></td>
<td>Reciprocal***</td>
<td>5 (4.3%)</td>
</tr>
<tr>
<td></td>
<td>European</td>
<td>4 (3.4%)</td>
</tr>
<tr>
<td></td>
<td>UK</td>
<td>101 (86.3%)</td>
</tr>
<tr>
<td><strong>Registered prescriber?</strong></td>
<td>Yes</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>117 (100%)</td>
</tr>
</tbody>
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Continued on next page
Table 1.2 Demographic characteristics of the sample (continued)

<table>
<thead>
<tr>
<th></th>
<th>Disciplined</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
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<tr>
<td>White British</td>
<td>38 (32.5%)</td>
<td>295 (50.9%)</td>
</tr>
<tr>
<td>White Irish</td>
<td>1 (0.9%)</td>
<td>9 (1.6%)</td>
</tr>
<tr>
<td>White Other</td>
<td>8 (6.8%)</td>
<td>22 (3.8%)</td>
</tr>
<tr>
<td>Black Caribbean</td>
<td>None</td>
<td>2 (0.3%)</td>
</tr>
<tr>
<td>Black African</td>
<td>6 (5.1%)</td>
<td>15 (2.6%)</td>
</tr>
<tr>
<td>White and Black African</td>
<td>None</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>White and Asian</td>
<td>None</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Mixed Other</td>
<td>None</td>
<td>3 (0.5%)</td>
</tr>
<tr>
<td>Indian</td>
<td>19 (16.2%)</td>
<td>96 (16.6%)</td>
</tr>
<tr>
<td>Pakistani</td>
<td>7 (6.0%)</td>
<td>26 (4.5%)</td>
</tr>
<tr>
<td>Bangladeshi</td>
<td>None</td>
<td>3 (0.5%)</td>
</tr>
<tr>
<td>Asian Other</td>
<td>2 (1.7%)</td>
<td>7 (1.2%)</td>
</tr>
<tr>
<td>Chinese</td>
<td>3 (2.6%)</td>
<td>14 (2.4%)</td>
</tr>
<tr>
<td>Other ethnic group</td>
<td>None</td>
<td>4 (0.7%)</td>
</tr>
<tr>
<td>Declined to answer</td>
<td>1 (0.9%)</td>
<td>6 (1.0%)</td>
</tr>
<tr>
<td>Did not return census form</td>
<td>29 (24.8%)</td>
<td>76 (13.1%)</td>
</tr>
<tr>
<td>No information available</td>
<td>3 (2.6%)</td>
<td>None</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25-34 years</td>
<td>19 (16.2%)</td>
<td>108 (18.6%)</td>
</tr>
<tr>
<td>35-44 years</td>
<td>20 (17.1%)</td>
<td>100 (17.2%)</td>
</tr>
<tr>
<td>45-54 years</td>
<td>36 (30.8%)</td>
<td>184 (31.7%)</td>
</tr>
<tr>
<td>55-64 years</td>
<td>33 (28.2%)</td>
<td>165 (28.4%)</td>
</tr>
<tr>
<td>65+ years</td>
<td>6 (5.1%)</td>
<td>23 (4.0%)</td>
</tr>
<tr>
<td>No information available</td>
<td>3 (2.6%)</td>
<td>None</td>
</tr>
<tr>
<td>Mean, standard deviation</td>
<td>48.7, 11.3</td>
<td>48.0, 11.4</td>
</tr>
</tbody>
</table>

**Year of registration (median, range)** 1984, 59 1984, 59

**Year of birth (median, range)** 1959, 51 1960, 64

Note: * indicates a variable that was used to match participants in either group. 
* Adjudication / OSPAP qualifications are those that were obtained outside the EU and subsequently validate in the UK via a post-qualification diploma. Reciprocal qualifications are those that are obtained outside the UK but considered equivalent by virtue of a reciprocal agreement.
between the respective countries. Historically this included Australia and New Zealand, but now applies to Northern Ireland only.

1.2.3 Interviews

The aim of the interviews was to elicit stakeholder views about the nature and sources of risk in pharmacy practice. Thirty-two participants were recruited from several locations in England; these participants were identified through purposive sampling in order to represent a range of pharmacy stakeholders. The composition of the sample is shown in Table 1.3. Each interview was carried out by researcher DLP on a one-to-one basis, and was audio recorded for subsequent transcription, with the consent of the participant. Three participants did not consent to being recorded; instead, the interviewer took handwritten notes from these interviews. Each interview lasted for approximately 1 hour, and consisted of two parts:

i) A semi-structured interview schedule, covering the following main points:
   a. What can go wrong in pharmacy practice?
   b. What makes a pharmacist “high-risk”?
   c. What makes a pharmacist “low risk”?

ii) A repertory grid exercise. The repertory grid approach was developed by Kelly (1955) to investigate the ways in which a person conceptualises a particular issue. It does so by presenting the person with a number of “elements” (people or objects) that are related to the issue and asking the person to compare and contrast these elements. In doing so, the person identifies the “constructs” (schemata) that he or she uses to organise the elements. Traditionally, a repertory grid elicits the constructs entirely from the participant. However, for the purposes of this study the researchers used an adaptation of Fransella & Bannister’s (1977) rank order grid method, in which participants are presented with all of the elements (the twelve fictitious pharmacists listed in Table 1.4) and asked to rank order them along the general construct of “least risky” to “most risky”. In each element, the pharmacist has started a new job, but the elements vary in terms of the pharmacist’s sector
(hospital or community), employment status (employed in the same sector as previously, employed in a new sector, or working as a locum) and training (overseas or UK-based). These characteristics were chosen on the basis of the initial literature reviews and discussion amongst the research team; the aim being to cover a range of supposed risk factors whilst keeping the number of cards to be sorted to a manageable number. Following the rank ordering, the participant was invited to compare and contrast the pharmacists described in the elements with a real-life pharmacist with whom he or she was familiar; hence, the participant had an opportunity to bring into the exercise characteristics that were considered to be relevant to risk but not included in the elements provided. The intended outcome of the exercise was the elicitation of constructs that participants use to determine the relative risk of pharmacists.
Table 1.3 Participants in the interview study

<table>
<thead>
<tr>
<th>Sector / Organisation</th>
<th>Participants [N in brackets]</th>
</tr>
</thead>
<tbody>
<tr>
<td>General teaching hospital 1</td>
<td>Director of pharmacy [1]; Pharmacists [3]</td>
</tr>
<tr>
<td>(North-West England)</td>
<td></td>
</tr>
<tr>
<td>General teaching hospital 2</td>
<td>Consultant pharmacist [1]; Technician [1]</td>
</tr>
<tr>
<td>(North-West England)</td>
<td></td>
</tr>
<tr>
<td>General teaching hospital 3</td>
<td>Director of pharmacy [1]; Principal pharmacist [1]; Technician [1]</td>
</tr>
<tr>
<td>(North-West England)</td>
<td></td>
</tr>
<tr>
<td>Specialist hospital</td>
<td>Consultant pharmacist [1]; Pharmacist [1];</td>
</tr>
<tr>
<td>(North-West England)</td>
<td>Senior technician [1]; Technicians [2]</td>
</tr>
<tr>
<td>PCT 1</td>
<td>Senior primary care pharmacist [1]</td>
</tr>
<tr>
<td>(North-West England)</td>
<td></td>
</tr>
<tr>
<td>PCT 2</td>
<td>Practice pharmacist [1]</td>
</tr>
<tr>
<td>(North-West England)</td>
<td></td>
</tr>
<tr>
<td>PCT 3</td>
<td>Head of medicines management [1]</td>
</tr>
<tr>
<td>(West Midlands)</td>
<td></td>
</tr>
<tr>
<td>Large pharmacy chain 1</td>
<td>Superintendent pharmacist [1]</td>
</tr>
<tr>
<td>(North-West England)</td>
<td></td>
</tr>
<tr>
<td>Large pharmacy chain 2</td>
<td>Superintendent pharmacist [1]</td>
</tr>
<tr>
<td>(North-West England)</td>
<td></td>
</tr>
<tr>
<td>Independent pharmacy</td>
<td>Pharmacy proprietor [1]; Technician [1]; Counter assistant [1]</td>
</tr>
<tr>
<td>(West Midlands)</td>
<td></td>
</tr>
<tr>
<td>Supermarket-based pharmacy</td>
<td>Pharmacy manager [1]; Pharmacist [1]; Technicians [2]</td>
</tr>
<tr>
<td>(South-West England)</td>
<td></td>
</tr>
<tr>
<td>School of Pharmacy</td>
<td>Teaching Fellow / Locum community pharmacist [1]</td>
</tr>
<tr>
<td>(North-West England)</td>
<td></td>
</tr>
<tr>
<td>Police force</td>
<td>Controlled drugs liaison officer [1]</td>
</tr>
<tr>
<td>(North-West England)</td>
<td></td>
</tr>
<tr>
<td>NPSA</td>
<td>National Clinical Assessment Service pharmacist [1]</td>
</tr>
<tr>
<td>(North-West England)</td>
<td></td>
</tr>
<tr>
<td>Members of the public</td>
<td>Attendees at a parent and toddler group [2];</td>
</tr>
<tr>
<td>(North-West England)</td>
<td>Hospital PALS representative [1]</td>
</tr>
<tr>
<td>Element</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
</tr>
<tr>
<td>1</td>
<td>“This pharmacist has recently started work at a hospital pharmacy. Previously, the pharmacist was working in a community pharmacy. The pharmacist was trained in the UK.”</td>
</tr>
<tr>
<td>2</td>
<td>“This pharmacist has recently started work at a hospital pharmacy. Previously, the pharmacist was working in another hospital pharmacy. The pharmacist was trained in the UK.”</td>
</tr>
<tr>
<td>3</td>
<td>“This pharmacist has recently started work in a hospital pharmacy. The pharmacist is a locum worker, and was trained in the UK.”</td>
</tr>
<tr>
<td>4</td>
<td>“This pharmacist has recently started work in a hospital pharmacy. Previously, the pharmacist was working in a community pharmacy. The pharmacist was trained overseas before moving to the UK.”</td>
</tr>
<tr>
<td>5</td>
<td>“This pharmacist has recently started work in a hospital pharmacy. Previously, the pharmacist was working in another hospital pharmacy. The pharmacist was trained overseas before moving to the UK.”</td>
</tr>
<tr>
<td>6</td>
<td>“This pharmacist has recently started work in a hospital pharmacy. The pharmacist is a locum, and was trained overseas before moving to the UK.”</td>
</tr>
<tr>
<td>7</td>
<td>“This pharmacist has recently started work at a community pharmacy. Previously, the pharmacist was working in a hospital pharmacy. The pharmacist was trained in the UK.”</td>
</tr>
<tr>
<td>8</td>
<td>“This pharmacist has recently started work in a community pharmacy. Previously, the pharmacist was working in another community pharmacy. The pharmacist was trained in the UK.”</td>
</tr>
<tr>
<td>9</td>
<td>“This pharmacist has recently started work in a community pharmacy. The pharmacist is a locum, and was trained in the UK.”</td>
</tr>
<tr>
<td>10</td>
<td>“This pharmacist has recently started work in a community pharmacy. Previously, the pharmacist was working in a hospital pharmacy. The pharmacist was trained overseas before moving to the UK.”</td>
</tr>
<tr>
<td>11</td>
<td>“This pharmacist has recently started work in a community pharmacy. Previously, the pharmacist was working in another community pharmacy. The pharmacist was trained overseas before moving to the UK.”</td>
</tr>
<tr>
<td>12</td>
<td>“This pharmacist has recently started work in a community pharmacy. The pharmacist is a locum, and was trained overseas before moving to the UK.”</td>
</tr>
</tbody>
</table>
The interview data was analysed using template analysis (Crabtree and Miller, 1992; King, 1998). Template analysis is an inductive process that involves the analyst reading through the data and creating a “template” consisting of the general themes that emerge from this reading. The template is then modified and extended through successive readings until it provides sufficient coverage of the data. In the current study, the initial template comprised four superordinate themes based on the literature review: the nature of risk in pharmacy; pharmacist characteristics that indicate level of risk; task characteristics indicating risk; and organisational characteristics indicating risk. These were used as a framework to categorise the data from each interviewee, following which each theme was developed by identifying subordinate themes in the data assigned to it. Version 7 of NVivo was used to document the analysis, which continued until the analysts had identified as many themes as possible from the data. The analysis was carried out by DLP. The final template, consisting of the superordinate and subordinate themes, was reviewed by PRN and DMA to confirm the relevance of the themes to pharmacist risk.

1.2.4 Focus groups

The aim of the focus groups was twofold: firstly, to review the findings of the foregoing empirical work with subject matter experts in pharmacy practice and pharmacy risk management; secondly, to elicit these experts’ views about the practical implementation of the study’s findings. Three focus groups were conducted. Two of these – one that was held in Manchester and another in London – involved consultant pharmacists (one with specialise expertise in medication safety), fitness to practice panel members, pharmacy educators and members of an advisory body on healthcare professional performance management. A third focus group in Doncaster involved community pharmacists and pharmacy managers. The participants, therefore, represented both staff who are involved in managing the risk of other pharmacists or dealing with fitness to practice allegations, and pharmacists who would themselves be subjected to risk management and risk-based revalidation. The composition of each focus group is shown in Table 1.5.
Table 1.5 Participants in the focus groups

<table>
<thead>
<tr>
<th>Focus group</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>1: London</td>
<td>Hospital pharmacy technician / RPSGB Fitness to Practice panel member</td>
</tr>
<tr>
<td></td>
<td>Hospital consultant pharmacist (safe medication practice)</td>
</tr>
<tr>
<td></td>
<td>Pharmacist adviser to NCAS</td>
</tr>
<tr>
<td></td>
<td>Revalidation researcher at NCAS</td>
</tr>
<tr>
<td></td>
<td>DLP (Facilitator)</td>
</tr>
<tr>
<td></td>
<td>PRN (Facilitator)</td>
</tr>
<tr>
<td>2: Manchester</td>
<td>Hospital consultant pharmacist</td>
</tr>
<tr>
<td></td>
<td>Locum pharmacist / RPSGB Fitness to practise panel member</td>
</tr>
<tr>
<td></td>
<td>Pharmacy CPD course director</td>
</tr>
<tr>
<td></td>
<td>DLP (Facilitator)</td>
</tr>
<tr>
<td></td>
<td>DMA (Facilitator)</td>
</tr>
<tr>
<td>3: Doncaster</td>
<td>Head Office Pharmacist, Medium Chain 1</td>
</tr>
<tr>
<td></td>
<td>Head Office Pharmacist, Medium Chain 1</td>
</tr>
<tr>
<td></td>
<td>Area Support Pharmacist, Medium Chain 1</td>
</tr>
<tr>
<td></td>
<td>Branch Pharmacist, Medium Chain 1</td>
</tr>
<tr>
<td></td>
<td>Branch Pharmacist, Medium Chain 1</td>
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<tr>
<td></td>
<td>Branch Pharmacist, Medium Chain 1</td>
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<td></td>
<td>Branch Pharmacist, Medium Chain 1</td>
</tr>
<tr>
<td></td>
<td>Branch Pharmacist, Medium Chain 1</td>
</tr>
<tr>
<td></td>
<td>Branch Pharmacist, Medium Chain 2</td>
</tr>
<tr>
<td></td>
<td>DLP (Facilitator)</td>
</tr>
</tbody>
</table>

All focus groups were facilitated by DLP, with assistance from DMA and PRN, and were audio recorded for subsequent transcription with the consent of the participants. Three exercises were carried out at each focus group:

1. Refining a definition of “risk” in pharmacy practice, derived from the literature review and interviews;
2. Reviewing a set of criteria for assessing pharmacist risk, derived from the literature review, record review and interviews;
3. Discussing potential models for carrying out risk-based revalidation of pharmacists.

These exercises, and their outcomes, are described in more detail in the following chapters.

1.2.5 Ethics

All of the studies conducted as part of this project received ethical approval from the University of Manchester Senate Committee and from North West 11 Research Ethics Committee [NRES reference: 10/H1016/71].

1.3 Structure of the report

The remainder of the report is structured as follows:
- Section 2 examines the definition of risk in pharmacy practice [Research objective (i)]
- Section 3 identifies potential indicators of risk in pharmacy practice, focusing on ways of identifying high-risk and low-risk practitioners [Research objectives (ii), (iii) and (iv)]
- Section 4 discusses ways of implementing risk-based revalidation [Research objective (v)]
- Section 5 provides a series of recommendations for policy development and implementation.
2. What is “risk” in pharmacy practice?

2.1 Introduction

Many people recognise that risk is in some way relevant to both their personal lives and their work activity (Beck, 1992; Furedi, 2006). However, while it is commonly agreed that there is such a thing as “risk”, there is less agreement about what is meant by this term, let alone what it means to assess it. This issue has been the subject of extensive discussion in the academic literature, where it is generally acknowledged that there are different ways of conceptualising risk. Pidgeon (1998) and Slovic (1999) note that it has been common practice to express risk in probabilistic terms; for example, in a medical context, one might refer to the probability of a treatment leading to a specified patient outcome. According to Pidgeon and Slovic, this approach embodies an assumption that risks can be defined and quantified in an objective manner, and hence has found appeal as the basis of an expert (as opposed to lay) risk analysis.

However, Pidgeon and Slovic both argue that there is more to risk analysis than the measurement of supposedly natural processes or entities. Toft (1996) notes that the quantification of risk embodies a number of assumptions: that they refer to objectively defined objects; that modelling risk is an objective activity; that an exhaustive set of failure modes can be defined; that reliable data is available to calculate risk probabilities; that the complexity of human behaviour can be reduced to a quantitative representation; and that a work system will continue to act in the same way as it always has done. Toft argues that these assumptions may be problematic in practice, given the technical complexity and social embeddedness of modern organisations. Risk appraisal, whether on the part of a single person or a group of people, embodies a combination of the objective “real world” and one’s perception of it (Hansson, 2010; Furedi, 2006; Rosa, 1998; Hale & Glendon, 1987). For example, Peters & Slovic (1996) found that support for nuclear power was influenced by respondents’ worldviews (that is, their generalized attitudes
towards the world: “fatalist”; “individualist”; “egalitarian”). In this view, risk assessment can be seen as an exercise in power, inasmuch as it favours the beliefs and values of those who define and assess risk in a given situation. In the words of Ball & Boehmer-Christiansen (2002):

“Ultimately, risk management decisions are based on some form of prejudice or preference for one choice over another. Such preferences should be open to inspection and malleable in the face of convincing arguments.” (p. vi).

Hence, there is a need to consider not just the technical knowledge that contributes to a risk assessment, but also the social and political views that are represented within it (Walker, Simmons, Wynne, & Irwin, 1998; Ben-Ari & Or-Chen, 2009). Within the healthcare context, a study of operating theatre staff by McDonald, Waring, & Harrison (2006) found that “risk” had a different meaning to nurses than it did to doctors. Nurses saw risk as being an event or action that interfered with their execution of nursing duties, with risk management being a matter of strictly adhering to protocols and policies. Doctors, however, saw risk as an intrinsic feature of their task as opposed to something that results directly from the way in which they carry out their activities; hence, it is something which should be accepted rather than controlled. Both perspectives differed from the notion of “objective” risk, with its emphasis on the identification and measurement of specific hazards¹ that are separate from, but mediated by, the activities of healthcare professionals. The latter approach is, according to McDonald et al., likely to inform managerial policies on patient safety, but on the basis of their findings, possibly at odds with the way in which nurses and doctors consider risk should be conceptualised in their everyday practice.

While McDonald et al.’s study identified differing views about the source of risk, McLaughlin (2007) suggests that regulatory control of social work embodies a number of assumptions about the object of risk. In the most

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¹ “Hazard” is used here to refer to a specific agent that potentially has an adverse effect within a work system, and hence can be considered a source of risk (Hale & Glendon, 1987).
common view, social workers are risk assessors – that is, they are responsible for identifying and controlling hazards to society. Simultaneously, though, regulatory policy implicitly views social workers as being themselves at risk (that is, vulnerable to stress, violence or harassment) and a risk (that is, capable of abusing others). In practice, the latter has been further assumed to include generally engaging in “disreputable” behaviour whether on- or off-duty.

In pharmacy, as in industry, healthcare and social services, there could be a variety of views between stakeholders about what is involved in risk assessment. Issues that need to be clarified might include:

- **What is the risk to be managed?** Is it a risk of adverse events, of harm to the practitioner, of bringing the profession into disrepute, or all of these? Does it come from the task itself, from the practitioner, from the setting, or from all of these?

- **Who creates the risk and who is subject to it?** Pharmacy staff, service users, other healthcare professionals, managers and policy makers, or the general public?

- **Who defines and controls the risk?** Are they stakeholders in the pharmacy process? How much awareness do they have of the process? What perspective(s) and assumption(s) do they bring to the assessment?

### 2.2 What approaches are available for assessing risk?

Klinke & Renn (2001; 2002) described three broad approaches for managing risk. The *risk-based approach* emphasises the use of quantitative data, for example probability ratings, severity ratings, and exposure limits. Secondly, the *precaution-based* approach is based on the principle that, in the event of uncertainty about the quantitative data, the emphasis should then be placed on making the work system more adaptive to unexpected events, for example by identification, monitoring and containment of potential adverse outcomes. Thirdly, where there is ambiguity about what constitutes risk in a given setting, the *discourse-based* approach may be adopted, wherein the emphasis is on
attaining a shared understanding of the nature of the risk and how it should be managed. This approach includes activities such as mediation, knowledge elicitation, and stakeholder consultation.

There are several risk-based or precaution-based methods available, most of which originate from safety-critical industries such as process control and aviation but some of which have also been used or suggested for use in healthcare settings (Lyons, Adams, Woloshynowycz & Vincent, 2004). Examples include root cause analysis (RCA), failure modes effects analysis (FMEA), hazard and operability studies (HAZOP), and the systematic human error reduction and prediction approach (SHERPA). Typically, these involve either examining a process (such as dispensing a medication item) and considering points in the process at which failures may occur, or examining an adverse event (such as a medication error) and identifying the activities that led to that event. Sometimes, a general distinction is made between risk indicators that occur before an accident or near miss (“proactive” indicators) and risk indicators that occur afterwards (“reactive” indicators); the implication is that it would be of benefit to ensure both are taken into account (Korvers & Sonnemans, 2008; Health and Safety Executive, 2006). How these two types of indicator translate to actual assessment criteria, if it is indeed necessary to make a distinction at all, depends on the nature of the work setting (Hopkins, 2009). Given that revalidation is largely a proactive exercise, the emphasis is likely to be on proactive indicators. Table 2.1 lists some indicators that might apply to pharmacists.
Table 2.1 Examples of risk indicators that could be incorporated into an assessment of pharmacist practice

<table>
<thead>
<tr>
<th>Proactive indicators</th>
<th>Reactive indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nature of clinical practice (e.g. sector; frequency of particular medications or patient care services(^2))</td>
<td>Rate of dispensing errors in the pharmacy</td>
</tr>
<tr>
<td>Practitioner characteristics (e.g. time since registration; training; performance record)</td>
<td>Rate of near-misses in the pharmacy</td>
</tr>
<tr>
<td>Pharmacy characteristics (e.g. use of automation)</td>
<td>Incident reporting by the pharmacy</td>
</tr>
<tr>
<td>Staffing levels</td>
<td>Complaints against the pharmacist</td>
</tr>
<tr>
<td>Prescription throughput</td>
<td></td>
</tr>
</tbody>
</table>

These methods are sometimes used in a purely qualitative manner, in which the focus is on providing descriptive information about a work system. For example, Lane, Stanton, & Harrison (2006) demonstrated the use of SHERPA to identify the human errors that could occur during the administration of drugs by nurses, while Adachi & Lodolce (2005) applied FMEA to intravenous drug administration; the information from both methods can be used both to anticipate the most risk-prone parts of the activity and to suggest way of preventing or ameliorating any errors. Other applications of risk analysis methods incorporate qualitative data into a quantitative methodology – usually probabilistic risk assessment (PRA) – with the aim being to provide an “objective” risk analysis of the type alluded to earlier. Quantitative analyses are more commonly found in industries such as nuclear power generation, where efforts have already been made to generate and validate probabilistic

\(^2\) Examples of the latter include medicine use reviews and advanced/specialist practice in the United Kingdom, medication therapy management services in the United States, and pharmaceutical opinions in Canada.
data for specified hazards (Kirwan, Kennedy, Taylor-Adams & Lambert, 1997; Kirwan, 1996; Embrey, 1992). However, Marx & Slonim (2003), Battles, Dixon, Borotkanics, Rabin-Fastmen & Kaplan (2006) and Eidesen, Sollid & Aven (2009) suggest that a combination of qualitative and quantitative methods can also be used to facilitate risk analysis in health settings. One issue for the use of methods from industrial settings is the ease with which they can be applied to healthcare activities. In practice, task activities and probabilistic or weighting values may be context-dependent (Joice, Hanna & Cuschieri, 1998; Phipps, Meakin, Beatty, Nsoedo & Parker, 2008). Shebl, Franklin & Barber (2009) found that, while FMEA was a useful exercise insofar as it facilitated a systematic inquiry into processes of medicine administration, there was poor inter-rater reliability in the identification and prioritisation of failures. They recommend further investigation to determine the circumstances under which it is most effective in healthcare settings.

One risk analysis method that has been applied to hospital pharmacy employs the “Bow Tie” model (Guchelaar, Colen, Kalmeijer, Hudson & Teepe-Twiss, 2005; Hudson & Guchelaar, 2003; Wierenga et al., 2009). This method, illustrated in Figure 2.1, identifies a “top event” (a specific undesirable event with the potential to cause harm) and links it to antecedent hazard(s) and harmful consequence(s). Finally, it indicates any potential barriers that might prevent the top event or mitigate its effects. The Bow Tie is of particular value in that it incorporates concepts from a number of risk analysis methods (including RCA and FMEA), as well as from the Swiss Cheese model of accident causation, described in the next section.
These methods involve a systematic examination of the processes involved in completing a set of tasks. This in itself makes a worthy contribution to risk management by identifying those aspects of work activity that should be the focus of a safety management system (Trbojevic & Carr, 2000; Kennedy & Kirwan, 1998; Cacciabue, 2000). However, in the context of healthcare practice, their grounding in the technical process of service delivery means that they are more sensitive to failures in clinical care than they are to general, unprofessional behaviour such as dishonesty or sexual misconduct. Also, professional regulation focuses on the certification of individual practitioners; hence, it is necessary to consider how individuals can be incorporated into a risk assessment. The Department of Health (DoH, 2006) suggests the use of a “risk rating” approach, in which practitioners are evaluated against a set of criteria that allow “high risk” and “low risk” practitioners to be distinguished. Criteria suggested by the DoH include type of work, time since registration, level of supervision available and current performance record. While risk rating would be a relatively new approach within healthcare regulation in the UK, some Canadian provinces already use risk factors (age and pattern of activity) to identify doctors for performance assessment (Allsop & Jones, 2006). There is also a precedent from work in other fields, most notably
financial credit rating. Hand & Henley (1997) note that a range of statistical methods has been developed in order to evaluate credit risk, usually based on regression or discriminant function analysis. Typically, these also take as predictor variables applicant characteristics such as current address, age and occupation. Wong, Pitfield, Caves, & Appleyard (2009a,b) have used similar methods to determine the contribution of airport characteristics to the risk of aviation accidents, while there is a tradition within occupational psychology of using biographical markers (“biodata”) as predictors of future employee behaviour (Becton, Matthews, Hartley & Whitaker, 2009; Breaugh, 2009). The latter line of application, however, has shown a potential conceptual and practical problem with the use of risk ratings. Biodata are often focussed on what predicts a particular outcome rather than how or why the predictors have been found to lead to the outcome. While this makes them good predictors of behavioural outcome, it is possible that this predictive ability comes at the cost of disadvantaging people belonging to a particular gender, ethnic or age group, or with a particular disability (Breaugh, 2009). This is not inevitable, and it may or may not be acceptable to an organisation and its stakeholders, but it is an issue that needs to be borne in mind when interpreting data from such studies. Specifically, there is a need to consider whether risk is intrinsic to particular types of individual or whether it is an artefact of the interaction between a person and the circumstances under which he or she works. This is a matter that will be expanded on in the next section.

While the methods discussed so far have typically been used within a risk-based or precaution-based approach, there is also scope for adopting a discourse-based approach. Indeed, as the studies cited earlier in this section (e.g. Hale, 1987; McDonald et al., 2006; McLaughlin, 2007) suggest, it would be apposite to consider the range of perspectives through which risk in pharmacy practice might be viewed. While there are fewer examples of such an approach in a pharmacy setting, one study that is of relevance is Morecroft, Cantrill & Tully’s (2005) examination of patients’ and GPs’ preferences for hypertension management. This found that the two groups differed with regard to what they considered to be the most appropriate form of treatment; in addition there were differences in opinion between individual
patients. This study suggests that there is merit in exploring similarities and differences in stakeholders’ perceptions of healthcare practice.

2.3 Pharmacy risk as a “soft system”

As the foregoing discussion indicates, there are a number of perspectives that can be taken on risk in pharmacy, and these are informed by social as well as technical concerns; crucially, pharmacy could be viewed in terms of a complex system that comprises more than just a collection of technical procedures (e.g. Toft, 1996). Hence, it would appear to lend itself to analysis using soft systems methodology (SSM; Checkland & Scholes, 1999). This approach proposes that a work setting can be interpreted in a number of ways – that is, it can be seen to serve different purposes depending on the perspective from which it is viewed. The aim of SSM is to elicit the different perspectives that might be held by people involved in the setting, and use these to develop understanding of its dynamics, problems that may arise and potential solutions to these problems. The general process of SSM is illustrated in Figure 2.2. For the current study, the “problematic situation” was defined as pharmacist risk. The literature review, record review and interviews were used as ways to express the situation; the researchers used the information from these to develop a model of the situation. The focus groups were used to refine this model, compare it with the situation at hand and identify ways to improve it. However, these latter stages were also informed by the literature.

![Figure 2.2 A simplified representation of the SSM process (adapted from Checkland & Scholes, 1999)](image-url)
review and interviews.

2.4 Interview data

From the interview data, five subordinate themes were identified under the general theme of “nature of risk in pharmacy”. These are: clinical risk to patients; dishonesty and fraud; violations of law; risk to healthcare professionals; and unprofessional conduct.

Clinical risk to patients. Given that the main purpose of pharmacy is to manage the use of medicines, a key risk identified by participants is that of causing clinical harm to a patient. Some participants felt this to be the primary concern from a risk point of view:

I think what kind of things can go wrong to the patient or to the person who the consequences will happen to, I think that’s an important thing to remember, it’s not necessarily about “Oh yeah I’m going to get struck off, and that’s it!” it’s not about that or it’s about actually, what’s going to happen to the patient and worse case scenario they’re going to die. [Lead pharmacist, Teaching hospital 1]

As regards to the patient behaviour on medical care…well the worst case scenario is the patient getting the wrong medication or the wrong dose of medication isn’t it? [Technician, Teaching hospital 3]

[In] the pharmacy cases I’ve dealt with [...] clinical issues do come to the fore increasingly but they probably haven’t historically been identified as those, I think they’ve been identified as poor business practice [...] but actually patients are not getting good advice, they might be having the wrong medicines dispensed so there are errors, there’s no real sort of scrutiny of prescriptions going on and the use of over the counter medicines has you know probably not been properly supervised and so on. [NCAS pharmacist]

Violations of law. Pharmacy is governed to a considerable extent by legislation (for example, the Misuse of Drugs Act and the Medicines Act). Hence, a particular risk of pharmacy practice is that it may break the law.
If you’re working as I do in the ‘back office’ as it were, not meeting customers, we have risks about “Are we interpreting legislation correctly?” and developing SOP’s correctly, are those…are the SOPs written in a way that minimises risk as far as possible so there’s…I mean you have to acknowledge that there is going to be risk but how do you minimise it? [Superintendent, Large chain 2]

[If medics misuse controlled drugs then the pharmacist could face legal action]. Pharmacists don’t realise that they are [taking on the risk of medics], but they are. It’s okay when things go fine, but when something goes wrong they could end up in trouble. [Technician, Specialist Hospital]

*Risk to the pharmacist.* While patients were seen as the primary “recipient” of risk, some interviewees identified a number of ways in which pharmacists themselves could be harmed by pharmacy practice.

Access to [controlled drugs] in the shop, [which] they start taking themselves which is not uncommon…you know abusing them drugs themselves […] and they become addicted. [Controlled Drugs Liaison Officer]

There are you know Cytotoxics […] that have to be handled and so there needs to be good processes in place to make sure […] that they are handled appropriately as well, as well as other drugs. But certainly in terms of the ones that are administered, you know, the injectable ones that are being prepared perhaps in a hospital pharmacy then […] I do think that, that sort of role, that specialist role in the […] hospital sector in itself poses a risk as well. [Pharmacist, PCT 1]

*Fraud and theft.* Another way in which pharmacist can cause harm is to either employers, or the general public, through dishonest practice. Examples of dishonesty include a pharmacist submitting a fraudulent claim for remuneration or removing drugs from a pharmacy.

Sometimes there’s an opportunity for pharmacists in terms of potential to abuse their position in terms of either the money that’s in the till or the drugs that are lying around. Yes you can say well moneywise there’s nothing here but yes but there are plenty of drugs they could use if they’re in hospitals but usually there’s, there’s plenty
of checks to say that stuff isn’t disappearing you know. [Pharmacist, Specialist hospital]

I would have thought [that in hospital pharmacy] the more likely thing [...] would be from either something that had happened out of pharmacy and it wasn’t declared, conviction, or not disclosing information, yeah, or lying on a CRB [...] I think it would more likely to be those kind of things rather than stealing. I know stealing goes on but I would have thought it’d be those kind of things rather than anything other than what you see in [community pharmacy] cos we don’t make...we don’t falsify documentation to make money [Technician, Teaching hospital 2]

I think maybe about twenty years ago it used to be very common to always say, “I’ve given the branded thing of this” and give the generic and then get paid money for the thing that’s expensive and then people would pocket the difference. [...] And I think that still goes on in other, kind of, I don’t know, fraudulent dealings. [Pharmacist, Teaching hospital 1]

Unprofessional conduct. A perhaps more subjective risk than fraud, but nevertheless one that was identified by some participants, is a pharmacist’s behaviour undermining his or her own, or the profession’s, standing in the eyes of colleagues and the public.

What [the pharmacist] was doing was managing to cream off a little bit of the Methadone powder, went out into her car at lunchtime when the pharmacy was shut with like a spoon and a cigarette and snorting Methadone powder. Now that's...she was seen by members of the public, you know now if it’s that bad that you’re seen by members of the public [...] you’re not fit to run a business and barely able to run the shop bearing in mind you’ve only been doing it for six months as it is. [Controlled drugs liaison officer]

I do think behaviour is a really important thing actually because, we are a profession and you know, just because you’re competent it doesn’t mean to say that you’re a good pharmacist [...] if you’re competent but then your behaviour is atrocious, that is not you know, a good pharmacist. I do think that you know, people should be brought to task if their behaviour is, is not as it should be [...] and certainly you know
there are different grades of behaviour […] so that in itself is difficult to comment on
but if it’s quite clear cut that people are just being rude to patients, who are just acting
completely unprofessional with other healthcare professionals then that is brought to
their attention, or brought to somebody’s attention and it’s actually dealt with.
[Pharmacist, PCT 1]

Summary. These subthemes indicate that a range of stakeholders might be
harmed by pharmacists – not just patients, but also pharmacists’ employer,
the public at large and even the pharmacists themselves. In some cases the
pharmacist actively creates the risk, for example by committing fraud. In other
cases the risk comes from elsewhere but is, or could be, amplified by the
pharmacist’s practice – for example, an order that is accompanied by an
incorrect script or no script at all. While the most obvious risks are clinical,
there appear to be other risks that need to be considered, such as those to
professional standing.

2.5 Focus group data

Drawing from the literature review and interview data, as well as a previous
qualitative study of pharmacy practice (Phipps, Noyce, Parker & Ashcroft,
2009), the researchers created a “rich picture” of pharmacist risk. A rich
picture is a method used in soft systems methodology to represent the
dynamics of a situation; in the current study, it was used to represent the
stakeholders of pharmacy and the ways in which they can be harmed. This
rich picture was presented to participants in the focus group, who were invited
to comment on its coverage of pharmacist risks. The final diagram, following
refinement, is shown in Figure 2.3.
Figure 2.3 A representation of harm in pharmacy practice
Incidentally, while the diagram implies that all stakeholders are equal, some participants saw a hierarchy of stakeholders. The most obvious candidate for the top of this hierarchy (that is, the one considered to be the most important) was the patient and/or the general public. However, pharmacists’ employers, and the profession as a whole, were also singled out. This, perhaps, reflects a legacy of previous fitness to practise reviews; prior to the 2007 reforms, these focused on misconduct rather than clinical competence, the latter lying outside the remit of the RPSGB’s disciplinary procedures.

All of the examples of risks you’ve given […] each of those is a risk to the patient, you know delivering substandard primary care to a patient is a risk to the patient. I accept that there’s a sort of risk back upstream if you like for the prescriber and things, but […] it has to be about first and foremost patient and the public but then there’s the integrity of the service […] If you view revalidation as a purely regulatory function then it has to be. [Focus group 1]

I suppose we’re caught in this kind of transition period isn’t it, the, you know, the policy direction is a risk based regulation about protecting the public, but you know the historical kind of legacy of for instance the disciplinary committee of the society, it’s all really been about conduct and standing of the profession, but should our definition capture both aspects? [Focus group 2]

I mean we would regard theft as a behavioural aberration within the misconduct framework […] and for some strange reason we regard theft from an employer as much worse than theft from anywhere else. [Focus group 2]

An additional consideration expressed by the participants was that the definition of risk was applicable to pharmacists in all roles. These included community, hospital and academic pharmacists and their managers (who were well represented amongst the focus group participants) and industrial pharmacists (who were not as well represented).
The principles are very much the same [for industrial pharmacists]. The behaviours that mean you’re breaching if you like, those principles might manifest different ways under a different setting, but the principles broadly, will be the same. [Focus group 1]

Participant 1: I wondered [about non patient-facing] sectors or other locations of work […] I’d written here what about industry and things like that, would that…I’m assuming someone, you know, someone who did a QA job in industry who had been to the party the night before, been a bit tired at work and signed off a batch of tablets which you know shouldn’t have been or does…is that type of risk reflecting you know if they are the pharmacist, you know? […]

Participant 2: Well there’s a lot of those that probably fit in and it almost…in my view the bit where it’s got from the pharmacists to the prescriber, either directly or sort of indirectly, so you can almost see sort of from an industry point of view, giving information on behalf of a company to a prescriber could then potentially lead to sort of harm, sort of that way. And then I suppose from academia there is something potentially about those who are partially responsible for training some of the pharmacists and actually giving them either incorrect knowledge or skills or something like that, then could have a direct effect on patients either directly all the information they give to prescribers I think. [Focus group 2]

Having used a rich picture to “map out” the situation at hand, the researchers were then in a position develop a model of pharmacist risk using the SSM process. One or more models can be devised to account for a particular situation, with each model reflecting a given interpretation of the situation. For the purposes of this study a single model will be used, which represents the researchers’ interpretation of pharmacist risk. In SSM, this model is expressed in terms of a root definition, which is shown in Table 2.2.
Table 2.2 A “root definition” of pharmacist risk

| “Customers” | Pharmacy staff; employers; other healthcare professionals; patients and public; the profession; the regulator |
| “Actors” | A pharmacist |
| “Transformation” | A stakeholder becomes harmed |
| “Worldview” | Certain actions by the pharmacist are considered to be capable of having an undesirable effect on one or more of the stakeholders |
| “Owner” | Pharmacy staff; employers; other healthcare professionals; patients and public; the profession; the regulator |
| “Environment” | The influence of the immediate work environment (that is, the design and operation of the pharmacy) and the wider organisation (for example, company or NHS trust policies and practices) on the pharmacist’s behaviour |

The root definition provides the basis for a working definition of risk in pharmacy practice. For the purposes of this study, the definition offered is the potential for harm to occur to the pharmacy workforce, their organisations or the recipients of their services, as a result of pharmacists’ activities.

Incidentally, it should be noted that one source of risk was identified in the interview study that lies outside the scope of this definition: that of aggression towards pharmacy staff from people outside of the pharmacy, such as service users. While this is considered to lie outside the scope of pharmacist risk, as it is not primarily a result of the pharmacist’s activities, it was considered to be
an issue worthy of separate attention, and so is expanded on in Appendix A to this report.

2.6 Section Summary

Defining risk in many settings is a less than straightforward matter, and pharmacy practice is no exception. This section began with a literature review that provided a basic conceptual framework for understanding the nature of risk; essentially it can be understood both in technical terms (the likelihood and cost of failures in a pharmacist's performance) and in social and organisational terms (the impact of the pharmacist's behaviour on various pharmacy stakeholders). This socio-technical view of risk was elaborated upon during the interviews and focus groups, which identified a range of ways in which a pharmacist might inflict harm on stakeholders. While the primary concern is of clinical harm to patients, other risks were identified, such as unprofessional conduct, harm to the profession and harm to oneself. Hence, any risk management intervention needs to be capable of dealing with these various hazards. Having suggested what “risk” in pharmacy entails, this report will, in the next section, examine ways of determining which pharmacists are likely to require most attention from risk-based revalidation.
3. What are the indicators of “high risk” and “low risk” practice?

3.1 Introduction

A general conceptual framework for identifying risk factors is Reason’s (1990; 1997) Swiss Cheese model. This model, illustrated in Figure 3.1, depicts an organisation as consisting of five “layers”, namely:

1. **Decision makers**: these are the designers and high-level managers of the organisation, and are responsible both for setting goals and determining how the goals will be met;

2. **Line management**: these are specialist groups (for example: operations; finance; procurement; personnel) who implement the decision-makers’ strategies;

3. **Preconditions**: these are features that need to be in place in order that organisational activities are successful (for example: reliable equipment; skilled and motivated workforce; procedures; environmental conditions);

4. **Productive activities**: the activities carried out by people and machines in order to achieve the tasks;

5. **Defences**: the safeguards put in place to protect individuals and machines from hazards associated with the work.
Ideally, each of these layers would be solid, but in practice it is likely that each of them has a weakness of some sort (fallible decisions; line management deficiencies; precursors of unsafe acts; unsafe acts themselves; and inadequate defences). Under certain conditions, a hazard can exploit a weakness in every barrier, and as a result propagate through the work system leading to an adverse event (as represented by the thick arrow in Figure 2).

The Swiss Cheese model forms the basis of a protocol for analysing adverse events in clinical settings (Taylor-Adams, Vincent, & Stanhope, 1999; Vincent et al., 2000). The key message of this model, and the clinical investigation

**Figure 3.1** The Swiss Cheese model of accident causation (adapted from Reason, 1990)
protocol derived from it, is that an adverse event can arise from a culmination of both person-specific factors and contextual factors.

3.2 What is the empirical evidence for pharmacy risk factors?

A number of studies in the United States and United Kingdom 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). The causes of disciplinary action varied: some involved negligence or incompetence; others involved inappropriate behaviour such as fraud or sexual misconduct; yet others involved being mentally or physically impaired. A general picture can be drawn from these studies:

- particular specialties or sectors (most notably, general practice, surgery, obstetrics and gynaecology, and psychiatry) are at greater risk of disciplinary action or NCAS referral (Dehlendorf & Wolfe, 1998; Khaliq, Dimassi, Huang, Narine & Smego, 2005; Morrison & Wickersham, 1998; National Patient Safety Agency, 2009);
- the length of practice was connected to the risk of disciplinary action. However, while fewer years led to increased risk amongst Ohio physicians (Clay & Conatser, 2003), more years led to increased risk in California physicians (Morrison & Wickersham, 1998). Amongst Colorado and Texas nurses, fewer years in the current post increased risk (Green, Crismon, Waddill & Fitzpatrick, 1995);
- amongst US physicians, greater age led to increased risk of being disciplined for sexual misconduct (Dehlendorf & Wolfe, 1998), while amongst Colorado and Texas nurses the 40-44 age group were at greatest risk of disciplinary action (Green et al., 1995);
- in the UK, general practitioners working alone are at increased risk of disciplinary action (Watts, 2009);
- male practitioners were at increased risk (National Patient Safety Agency, 2009; Morrison & Wickersham, 1998; Khaliq et al., 2005; Green et al., 1995; Clay & Conatser, 2003);
- non-white practitioners were at increased risk (National Patient Safety Agency, 2009; Khaliq et al., 2005);
- practitioners trained overseas were at increased risk (National Patient Safety Agency, 2009; Morrison & Wickersham, 1998; Khaliq et al., 2005).

Findings such as these imply that the focus of a risk assessment should be on individual practitioners. The last three findings are of particular interest with regard to the discussion in the previous section about the use of risk ratings. Is there something intrinsic to male practitioners, ethnic minority practitioners and overseas-trained practitioners that places them at increased risk of disciplinary action? It is possible that these findings reflect process variables, for example difficulty in establishing a rapport with service users. However, 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 suggests that the relationship between practitioner variables is more complex than might first appear; the NPSA (2009) 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. Furthermore, Papadakis and colleagues (Papadakis et al., 2005; Papadakis, Arnold, Blank, Holmboe & Lipner, 2008) point to the need to consider behavioural indicators as well as demographic variables; they found that amongst US physicians, previous poor performance or unprofessional conduct, both at medical school and during training, is a predictor of subsequent behaviour resulting in disciplinary action.

Other research in the pharmacy setting highlights the importance of considering circumstantial factors as well as personal characteristics (James et al., 2009). Malone et al. (2007) surveyed a sample of US-based community pharmacy managers on characteristics of their work activity, and found that high workload and particular types of automated dispensing systems increased the risk of potential drug-drug interactions being dispensed. In the United Kingdom, Ashcroft, Quinlan, & Blenkinsopp (2005) examined self-reported dispensing errors in a sample of community pharmacies. They found
that a number of errors and near-misses were reported to have occurred in the presence of increased workload, reduced staffing or distractions; in addition, they were attributed to a number of causes, including drug selection, prescription reading, and order assembly. Within secondary care settings, Fogarty & McKeon (2006) have found evidence to suggest a range of causal factors in medication errors, both individual (for example, fatigue and poor training) and organisational (for example, inadequate staffing and organisational climate). Finally, Ashcroft, Morecroft, Parker & Noyce’s (2005) study of community pharmacy places risk in the context of organisational practices and norms. For example, they note that the skill mix of pharmacy staff, and the use of standard operating procedures (SOPs) can enhance or mitigate the effect of workload on medication safety. In addition, they point to the influence of organisational culture on a pharmacy’s ability to develop safe practice; most notably in this regard, there appears a tendency to under-report medication incidents for a number of reasons, which deprives pharmacies of opportunities to learn from patient safety incidents. Incidentally, Nieva & Sorra (2003) argue that another learning mechanism that depends on a supportive culture is the use of risk analyses such as RCA and FMEA.

Malone et al.’s and Ashcroft et al.’s studies are not easily compared with the previously cited studies. The other studies make use of a different outcome variable; that is, disciplinary action against an individual practitioner (either for poor clinical practice or for unprofessional conduct) as opposed to a process failure (which may or may not reflect substandard practice on the part of a particular person). Furthermore, the former set of studies are based on empirically verifiable data; for example, whether or not the practitioner has been disciplined. Hence, the extent to which the causative or predictive factors are transferable between the different studies is unclear. However, there remains the possibility that contextual factors need to be considered alongside person-specific factors within risk regulation; that this is so is suggested by the presence of both types of factor, plus managerial practice, in industrial safety audits (Chang & Wang, 2010; Costella, Saurin, & Guimares, 2009; Guldenmund, Hale, Goossens, Betten, & Duijm, 2006). A similar argument has been made by the European Union of Medical Specialists with
regard to the use of quality assurance systems in medical care (Borman, 2004).

3.3 Record review findings

3.3.1 Do demographic factors predict a pharmacist being referred to the Disciplinary Committee?

As described in Section 1.2.2, a sample of pharmacists was obtained from the RPSGB, comprising a group who have been referred to the Disciplinary Committee since 2007 and a group who have not been referred. These groups were compared using multiway frequency analysis and multiple regression.

From the frequency analysis, the most parsimonious model was identified through stepwise selection by deletion of effects. This model contained only sector as a predictor. The likelihood ratio \(\chi^2 (57) = 30.588, p = 0.998\), indicating a good fit between observed frequencies and the expected frequencies generated by the model. The proportion of community pharmacists in the disciplined group is greater than that in the control group. However, inspection of the descriptive statistics in Table 1.2 indicates that the modal sector in both groups is community pharmacy. It is possible that, while the pharmacist’s sector appears to be the best indicator of whether he or she becomes the subject of disciplinary action, this could be due in part to the lower representation of non-patient facing sectors (that is, PCT, industry, academia, wholesale, other pharmaceutical, non-paid and non-pharmaceutical) within the disciplined pharmacists’ group. That said, it is interesting to note that approximately twice the proportion of non-disciplined pharmacists as that of disciplined pharmacists is hospital-based; this observation will be discussed in more detail later.

The regression analysis found a good model fit on the basis of all four predictors \([\chi^2 (5, N = 514) = 12.591, p = 0.028]\), indicating that the predictors, as a set, reliably distinguished between disciplined and non-disciplined pharmacists. However, the variance in outcome accounted for by the model
is rather modest [Cox & Snell R-Square = 0.024; Nagelkerke R-Square = 0.043].

Table 3.1 shows the Exp-b odds ratios and their 95% confidence intervals for each of the four predictors. According to the Wald criterion, only the pharmacist’s sector has a statistically significant effect on the classification. Specifically, pharmacists working in community pharmacy were at increased risk of being disciplined when compared to pharmacists in non patient-facing roles. In addition, a relatively high but statistically non-significant odds ratio was obtained when comparing community pharmacists to hospital pharmacists (odds ratio = 2.302, p = 0.088). With the exception of the pharmacist’s age (which is very highly correlated with the matching variable of years since registration: Pearson’s r = 0.929, N = 694, p < 0.001), the other predictors also show odds ratios greater than 1, although none of these reach statistical significance. The univariate odds ratios for overseas training and non-White ethnicity come close to being statistically significant (with p values of 0.068 and 0.094 respectively), although in the multivariate model these predictors are no longer close to significance (p values increase to 0.489 and 0.570 respectively).
Table 3.1 Results from the regression of group allocation onto the demographic predictors

<table>
<thead>
<tr>
<th></th>
<th>Univariate</th>
<th></th>
<th></th>
<th></th>
<th>Multivariate</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR</td>
<td>95% CI</td>
<td>p</td>
<td>OR</td>
<td>95% CI</td>
<td>p</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sector:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital (vs</td>
<td>1.461</td>
<td>0.454,</td>
<td>0.525</td>
<td>1.531</td>
<td>0.347, 6.745</td>
<td>0.574</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other)</td>
<td></td>
<td>4.699</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Community (vs</td>
<td>2.959*</td>
<td>1.156,</td>
<td>0.024</td>
<td>3.523*</td>
<td>1.056, 11.753</td>
<td>0.041</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other)</td>
<td></td>
<td>7.570</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Qualification:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-UK (vs UK)</td>
<td>1.756</td>
<td>0.959,</td>
<td>0.068</td>
<td>1.343</td>
<td>0.582, 3.101</td>
<td>0.489</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-White (vs</td>
<td>1.492</td>
<td>0.934,</td>
<td>0.094</td>
<td>1.166</td>
<td>0.685, 1.985</td>
<td>0.570</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White)</td>
<td></td>
<td>2.384</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>1.005</td>
<td>0.988,</td>
<td>0.572</td>
<td>1.019</td>
<td>0.995, 1.044</td>
<td>0.117</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Key: OR: Odds Ratio. * Wald statistic p < 0.05. For the Sector predictor, df = 2. For the other predictors, df = 1.

3.3.2 What are the other characteristics of disciplinary referrals?

Table 3.2 provides further descriptive statistics about the disciplined pharmacists and the circumstances surrounding their being reported to the RPSGB. As the table shows, misconduct (violation of standards; dishonesty; behaviour) is cited more frequently than clinical malpractice (dispensing errors; controlled drug errors). It should be noted, though, that in 28 of the cases, two or more reasons were given for referral. That said, the same pattern is observed even amongst those pharmacists who were reported against one category only; indeed, the difference between misconduct and clinical malpractice frequencies becomes even larger (72 versus 16 citations respectively). It is also possible that the reason for the pharmacist being reported in the first place may be different from that given on referral to the DC; it appears from a review of the publicly available DC cases that in some of them, the particulars as described in the determination are not consistent with the reason given in the database. By way of illustration, examples of the two types of complaint are shown in Table 3.3.
### Table 3.2 Characteristics of disciplinary cases

<table>
<thead>
<tr>
<th>Reason for investigation:*</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Violation of professional / legal standards</td>
<td>52</td>
<td>-</td>
</tr>
<tr>
<td>Dishonesty</td>
<td>38</td>
<td>-</td>
</tr>
<tr>
<td>Controlled drug errors</td>
<td>17</td>
<td>-</td>
</tr>
<tr>
<td>Dispensing error: strength and dosage</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>Dispensing error: incorrect medication</td>
<td>10</td>
<td>-</td>
</tr>
<tr>
<td>Behaviour towards customers and colleagues</td>
<td>11</td>
<td>-</td>
</tr>
<tr>
<td>Dispensing error: labelling</td>
<td>7</td>
<td>-</td>
</tr>
<tr>
<td>Dispensing error: out of date supply</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>Health problem: drugs</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>Conviction / caution</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>Health problem: alcohol</td>
<td>1</td>
<td>-</td>
</tr>
</tbody>
</table>

Subject of previous disciplinary action by the RPSGB?

<table>
<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>22</td>
<td>18.8</td>
</tr>
<tr>
<td>No</td>
<td>95</td>
<td>81.2</td>
</tr>
</tbody>
</table>

Source of complaint:

<table>
<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employer</td>
<td>23</td>
<td>19.7</td>
</tr>
<tr>
<td>Primary care organisation</td>
<td>20</td>
<td>17.1</td>
</tr>
<tr>
<td>Police</td>
<td>20</td>
<td>17.1</td>
</tr>
<tr>
<td>Inspector / Society</td>
<td>15</td>
<td>12.8</td>
</tr>
<tr>
<td>Member of public</td>
<td>12</td>
<td>10.3</td>
</tr>
<tr>
<td>CFSMS°</td>
<td>10</td>
<td>8.5</td>
</tr>
<tr>
<td>Self-referral</td>
<td>6</td>
<td>5.1</td>
</tr>
<tr>
<td>Another Society member</td>
<td>4</td>
<td>3.4</td>
</tr>
<tr>
<td>Another healthcare professional</td>
<td>4</td>
<td>3.4</td>
</tr>
<tr>
<td>Co-worker</td>
<td>2</td>
<td>1.7</td>
</tr>
<tr>
<td>Other enforcement agency</td>
<td>1</td>
<td>0.9</td>
</tr>
</tbody>
</table>

Continued on next page
Table 3.2 Characteristics of disciplinary cases (continued)

<table>
<thead>
<tr>
<th>Pharmacist’s role:*</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proprietor / owner</td>
<td>18</td>
<td>15.4</td>
</tr>
<tr>
<td>Employed pharmacist</td>
<td>11</td>
<td>9.4</td>
</tr>
<tr>
<td>Locum pharmacist</td>
<td>10</td>
<td>8.5</td>
</tr>
<tr>
<td>Manager</td>
<td>8</td>
<td>6.8</td>
</tr>
<tr>
<td>Superintendent</td>
<td>6</td>
<td>5.1</td>
</tr>
<tr>
<td>Other</td>
<td>4</td>
<td>3.4</td>
</tr>
<tr>
<td>Unknown</td>
<td>60</td>
<td>51.3</td>
</tr>
</tbody>
</table>

Notes: * This data was collected from a variety of sources, some of which may not relate to the time at which the incident occurred. † Percentage figures are not provided as 28 pharmacists were reported for more than one of these reasons. ® Counter Fraud and Security Management Service.
<table>
<thead>
<tr>
<th>Type</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Violation of professional / legal standards</td>
<td>Taking controlled drugs from patient returns and dispensary stock for own use</td>
</tr>
<tr>
<td>Dishonesty</td>
<td>Committing tax fraud</td>
</tr>
<tr>
<td>Behaviour towards customers and colleagues</td>
<td>Inappropriate or dismissive remarks made to a colleague about a work matter</td>
</tr>
<tr>
<td>Controlled drug errors</td>
<td>Failing to properly dispose of patient-returned controlled drugs</td>
</tr>
<tr>
<td>Dispensing error: strength and dosage</td>
<td>Repeatedly dispensing a different strength of medication to that described on the prescription and/or label</td>
</tr>
<tr>
<td>Dispensing error: incorrect medication</td>
<td>Repeatedly dispensing different medicines to those described on the prescription and/or label</td>
</tr>
<tr>
<td>Dispensing error: labelling</td>
<td>Dispensing methadone mixture against prescriptions for dexamphetamine elixir</td>
</tr>
<tr>
<td>Dispensing error: out of date supply</td>
<td>Allowing out-of-date medicines to be mixed with in-date stock and dispensed</td>
</tr>
<tr>
<td>Conviction / caution</td>
<td>Being convicted of driving under the influence of alcohol</td>
</tr>
<tr>
<td>Health problem: drugs</td>
<td>Having a drug dependency</td>
</tr>
<tr>
<td>Health problem: alcohol</td>
<td>Having an alcohol dependency</td>
</tr>
</tbody>
</table>
The most frequent source of complaints is from someone who is in a position of oversight of the pharmacist – for example, the employer, the primary care organisation or a Society inspector. However, there are a range of other routes by which a pharmacist can be brought to the attention of the Society: approximately seventeen percent of referrals are triggered by the police, ten percent by a member of the public, and yet others by peer- or self-referral.

Of those pharmacists who were referred to the DC, approximately one fifth had previously been the subject of disciplinary action by the Society. This is particularly noteworthy given that, in any one year, the proportion of pharmacists on the entire RPSGB database who is referred to the Investigating Committee is approximately 1% (Royal Pharmaceutical Society of Great Britain, 2008, 2009b); it is possible that previous disciplinary action may indeed be a predictor of future disciplinary action, although no data from the case controls was available for the current study, so this hypothesis could not be tested. Also, no data was available about sanctions by other bodies, or previous criminal convictions. At the time of data collection, the role of the pharmacist at the time of the incident was not routinely recorded. The frequency data listed here for pharmacist roles have been collated from the information available in DC determinations or on the membership database, and may not pertain to the pharmacist’s role at the time of the incident. These caveats in mind, it would appear that the most frequently occurring role is proprietor or owner, with employed (non-manager) pharmacists and locum pharmacists the next most frequent roles.

3.3.3 Discussion of record review

As described earlier in this section, previous studies of healthcare professionals have found that age, ethnicity, occupation and country of training predict the likelihood of being the subject of disciplinary action. The current study has found some support for the proposition that these characteristics might also predispose a pharmacist to become the subject of disciplinary action. However, here the predictive factors appear to be limited to the pharmacist’s sector; specifically, whether the pharmacist is working in community pharmacy, and possibly also whether the pharmacist is working in
a patient-facing role. In addition, there is a noticeable but statistically non-
significant effect of the pharmacist’s location of training and his or her
ethnicity. The latter finding is consistent with a previous study, which
suggested that a disproportionate number of ethnic minority pharmacists were
being referred to disciplinary tribunal (Hassell, 1996).

The reason for these patterns, however, is not clear. Are ethnic minority
pharmacists or those trained outside the UK inherently more risky, or are
there other factors at play? One might surmise, for example, that while some
pharmacists are able to resolve problems informally without recourse to any
disciplinary framework (Phipps et al., 2009), it may be less easy for a
pharmacist to do so if there exists a cultural or linguistic barrier between the
pharmacist and colleagues or patients. It appears apposite to explore the
issues surrounding non-UK trained pharmacists in future research (Ziaei,
Schafheutle & Hassell, 2010). Incidentally, as suggested earlier, the finding
that age was unrelated to the risk of being disciplined may represent either a
genuine effect in the population or an artefact of the sampling strategy used
for this study.

The finding that community pharmacists are more likely than hospital
pharmacists to end up facing disciplinary action could be an artefact of there
being greater numbers of the former; alternatively, it may reflect a genuine
difference between the two sectors in terms of risk. For example, the greater
prevalence of sole practitioners in community pharmacy might make it
intrinsically riskier than hospital pharmacy, in which the pharmacist is more
likely to be engaged in collaborative work. However, by way of a caveat this
finding should be put into the context of differences between the two sectors.
Anecdotal and empirical evidence suggests that some healthcare
organisations are more inclined or able than others to deal with disciplinary
matters “in-house” without referral to an external body (Allsop & Jones, 2006).
In the United Kingdom, many hospital pharmacists are employed by NHS
trusts, which are likely to have their own disciplinary processes. This may
also be the case in the larger community pharmacy chains, where a
hierarchical “command structure” is often present. However the smaller
community pharmacies (particularly those where the pharmacist is also the superintendent and/or sole proprietor) may not have a structure in place for addressing fitness to practise concerns, and hence those who wish to raise such concerns would need to involve the regulatory body. Of the 89 community pharmacists who were in the disciplined group in the current study, details about the type of pharmacy were available only for 30. Eleven of these were in independent pharmacies, 8 were in a small or medium chain, a further 8 in a large chain, and 3 in a supermarket. In addition, as indicated in the previous section, pharmacy owners appear relatively frequently amongst disciplined pharmacists; however, there does not appear to be any particular type of disciplinary offence that is more attributable to these pharmacists than to others. It is difficult to draw any clear conclusions on this matter with the limited data available, but these issues are worthy of exploring further in future work as more data accumulates.

Evidence from previous studies suggests that referrals of healthcare professionals are triggered more often by particular sources – namely, colleagues and patients – than by others (Cox & Holden, 2009). However, the current study suggests that, while referrals are triggered by a variety of sources, the employer or primary care organisation is the most frequent source, although a sizeable proportion of referrals also came from the police, RPSGB inspectors and members of the public.

Finally, it is noteworthy that approximately one-fifth of pharmacists in the disciplined group have been the subject of previous disciplinary action. As mentioned in the introduction section, there is evidence to suggest that previous concerns about conduct can predict the likelihood of subsequent disciplinary action. However, the data used in the current study pertains only to previous disciplinary action by the RPSGB; it may be worth collecting data in the future about disciplinary action by other professional bodies, by the School in which a pharmacist trained, or his or her being the subject of criminal or civil action.
While the study has been able to identify some patterns within the data, some limitations need to be considered. Firstly, it should be noted that the Disciplinary Committee represents the end stage of a process that begins with a review of the case by the Investigating Committee (IC). The most serious cases will be referred from the IC to either the DC or the Health Committee (HC), but a substantial proportion of the cases are dealt with by the IC themselves. The RPSGB (2009b) reports that, between 1 April 2008 and 31 March 2009, the IC reviewed 636 cases, of which only 77 were referred to the DC; a similar proportion were also referred during the previous year (RPSGB, 2008). A case will be referred from the IC to the DC if there is believed to be an impairment of fitness to practise that is not due to health impairment and either: (a) it cannot be resolved by words of advice from the Society (for example, because of the gravity of the offence or because the registrant has failed to comply with a previously agreed undertaking); (b) the participant does not accept that his or her fitness to practise is impaired (HMSO, 2007). Hence, the data used in this study represents a small subset of the population of investigated pharmacists. Unfortunately, after consultation with legal advisors, it was decided that the RPSGB could not make details of cases heard only by the IC (which are not released into the public domain) available for use in the current study because of concerns about data protection. It does, though, remain highly desirable for this dataset to be included in subsequent studies if possible.

Secondly, it should be noted that the study involves retrospective analysis of records that were not initially designed to elucidate risk factors. As has been indicated in the foregoing text, some data was not fully available to the researchers. Furthermore, it is possible that other items of information, not currently collected from pharmacy practitioners on a routine basis, could be used as risk factors. Examples include: hours worked per week; length of time in current job; whether the practitioner has recently changed sectors; whether he or she is working as an advanced or specialist practitioner, and whether he or she is working alone. In the context of tailoring revalidation regimes, indicators such as these also have the advantage of being more
transparent, and possibly more defensible, than are demographic factors such as socio-economic status and ethnicity.

Thirdly, the time window represented by the cases in this study is quite limited. It is insightful to view the findings in the context of the demographic trends identified by Seston & Hassell (2010). They note that between 2002 and 2009, amongst other demographic changes, there has been an increase in the proportion of members who are non-white and, amongst those pharmacists who were trained outside the UK, an increase in the proportion that are accredited via the European route. In addition, there has been an increase in the number of pharmacists who are qualified as independent prescribers. Given the odds ratios reported earlier, it is possible that, as more data accumulates from disciplinary hearings, other statistically significant risk factors could emerge.

3.4 Interview study

The interview data clustered around three main themes of pharmacist risk: pharmacist characteristics; task characteristics; and organisational characteristics.

3.4.1 Pharmacist characteristics

Knowledge, skill and attitude. For many participants, a key attribute distinguishing between high-risk and low-risk pharmacists is the perceived level of the pharmacist’s competence. At face value, competence might be thought of in terms of technical knowledge. However, the participants saw it as more than this; it also encompassed the pharmacist’s ability to recognise and work within the limits of his or her expertise. In addition, some participants referred to a quality that could best be labelled “conscientiousness”: more specifically, a desire to do one’s job thoroughly and in accordance with ethical and professional standards.

I would say the things which make a pharmacist high risk are their competencies and abilities, their motivation to keep up to date, or their motivation to self develop and motivation to continue to improve. I think there are some inherent things within an
individual’s character which might make a pharmacist high risk, lack of self awareness would be a big factor and that can be manifested a number of ways […] an individual can be over confident about their abilities, an individual can be not prepared or not able to see their own deficiencies and where they are getting to the end of their understanding and the end of their knowledge. [Pharmacy manager, Teaching hospital 1]

“[When I spot minor but frequent mistakes], that shows that the pharmacist hasn’t got to grips with what needs to be done. If I’m picking these up then what’s the bigger picture?” [Technician, Specialist hospital]

Well you can tell the ones that practice by the book, you know, and follow the law and ethics and all the rest of it that we’re supposed to follow, and you can tell, you know, from working with them their respect for the medicines and things that they’re working around and that kind of thing, so yes I think you definitely get a good idea from working with somebody about whether they have good work ethic and whether they’re doing what they supposed to be doing and not taking risks with things or cutting corners or you know that kind of thing. Making records and keeping on top of entries for things, that kind of thing, so yes you can definitely pick up vibes from other pharmacists as to whether you would regard them as high or low risk. [Locum pharmacist]

As reflected in the quote from the technician, those pharmacists who are believed to have appropriate knowledge, skill and attitude are more likely to inspire confidence in coworkers and patients. However, while technical knowledge and skill is relatively straightforward to conceptualise and assess, the non-technical aspects, and attitudes, are slightly less so. The quotes provided here allude to some of the ways in which the latter might be conceptualised: wanting to attain and maintain a high standard of practice; being aware of one’s own limitations and wanting to avoid working beyond them; an aversion to taking unnecessary risks.

*Employment history.* A number of interviewees referred to aspects of the pharmacist’s “track record”. In general, a pharmacist was considered to be lowest risk when he or she had a been established in a particular role or
sector for a period of time; those pharmacists who changed sector or employer, or who took a career break, were judged to have a higher risk if there were significant differences between the pharmacist’s previous and new work systems. However, some interviewees suggested that the technical knowledge acquired from previous work roles might in fact be of benefit in future roles.

You tend to look at whether the… the frequency of them moving jobs so if they’ve moved jobs a lot that might be an indicator that you know they’re, they’re a problem employee or you, you know they, they don’t stick around. If there’s gaps in their employment history which are unexplained then that might give you some indication as well so those sort of things you’d look for in terms of their history [Pharmacy manager, Teaching hospital 1]

Another [pharmacist] I referred to [the RPSGB], […] I had concerns very quickly and spoke to the Inspectors, and she’d worked for various other companies who I think had dismissed her, but not informed them about her. She’d kind of been working her way around different companies, now I think; they felt if other companies took things as seriously as probably we do […] some of these people would have been picked up sooner, so I think if we’ve got concerns that they’re not capable to fit, work in our company, then it’s really important that the Society are told about it. [Superintendent pharmacist, Large chain 1]

If you come from a small district general hospital to somewhere like here, and I think here is very, very complex as we’ve got children’s…well a tertiary centre for children and most people won’t have seen that so…I’ve been here for three years, and I’ve always worked across sites, but I still really struggle with all of the unusual children’s things that you see in dispensary, and it makes me feel really uncomfortable. We’ve got specialist haematology, so we’ve got medications you need to have special procedures that you phone up and make sure the patient’s undergone all the necessary checks before having them, and there’s specialist clinics, loads of unusual, kind of…although…ways of working that no one really tells you about, so I think that’s a quite hard environment to come to [Pharmacist, Teaching hospital 1]

Well I think that, that the issue is that if you were trained in community and you were working in community then you’re more comfortable with your surroundings, if you
train in hospital and you work in hospital you’re more comfortable with your surroundings. For any community that go to hospital then there’s a…there’s much more risk I would say. At the start of your career, I mean obviously ultimately you will relax, relax into it but I think the…where you were trained and what sector you’re working in, if it’s the same then it reduces the risk [Superintendent pharmacist, Large chain 2]

[With career breaks]…it depends what the break is to be honest, getting back up to speed and, and that sort of stuff. It also depends what you did on the break. I took a break myself and went and spent two years overseas with VSO and when I came back to the UK, EHC had been introduced…so that was completely new to me, there’d been some minor changes to the structure of the contract, the drug tariff had changed, there was new drugs on the market that hadn’t been there two years previously, so that, all that was a real steep learning curve to come back to. Having said that I was quite heavily involved in pharmacy in my two years off because I was working as a Pharmacist, but overseas. If you’d gone and spent two years travelling around the world on a sort of extended gap year as it were the you’re not going to be practicing as a Pharmacist so you’ve perhaps have forgotten a significant chunk of that because if you’re not using it, you tend to forget it as a rule. [Superintendent pharmacist, Large chain 2]

Most of [the delegates on a return-to-practice course] had lost confidence and were very much more concerned about being a risk than they probably would have been in practice. So the sense of being out of touch and being isolated and having lost sort of knowledge and skills was much stronger than when we actually did return to practice programmes it turned out to be the case. […] If people recognise they need a reintegration programme then I’d call them low risk. If people just think they can come back in and, and again we’ve got experience of this now with doctors who have perhaps been suspended and generally if they’ve been suspended more than six months we say they need a, a reintegration programme because they’ve been out of clinical practice for six months. There are some who think they don’t need that and they would worry me far more than the ones that say, “Yes you know that would be extremely helpful” so again it’s about how the level of insight isn’t it to sort of help them. [NCAS pharmacist]
The quotes provided here describe a number of situations that may arise in a pharmacist's career: changing jobs within the same sector (either through choice or due to being managed out of a previous job); moving between community and hospital sectors; and taking a career break. The key concern in all of these circumstances appears to be whether the pharmacist has sufficient technical knowledge for the job into which he or she is moving. This risk might be exacerbated by failure to recognise the limits of one's own knowledge but, by the same token, mitigated by taking action to familiarise oneself with the tasks conducted in the new job. Two of the quotes also indicate the importance of pharmacies taking steps to manage the integration of new or returning pharmacists, possibly with support from the professional associations.

Engagement in continuing professional development (CPD). One indicator of a pharmacist’s commitment to maintaining knowledge and skill is the level of engagement in CPD. Some participants referred to lack of CPD engagement as a potential risk indicator.

We have got courses from CPPE [the Centre for Pharmacy Postgraduate Education] that we attend which are very useful to me because it keeps you up to date but obviously there are some pharmacists who just do not attend, and if you don’t tend to keep up to date you are going to lag behind with experience and knowledge […] so especially now in this day and age, you’ve got to keep up to date with development of new drugs and so on, so it is a good idea to attend courses [Pharmacy proprietor]

Pharmacists who have a willingness to develop themselves and have a good track record in terms of continuing professional development are professionally engaged and, and you know self motivated to, to continue to show an interest in, in their profession, in their patients and their area of work so I think they would be my low risk individuals [Pharmacy manager, Teaching hospital 1]

Again, this risk factor appears to reflect the level of knowledge that a pharmacist can bring to bear on his or her work, as well as the pharmacist’s willingness to keep his or her knowledge up to date. In effect, it might be
considered a manifestation of the “knowledge, skill and attitude” factor described earlier.

*Health and lifestyle.* A pharmacist’s level of heath, as well as the presence or absence of life stressors, can amplify or reduce the effects of work pressures on job performance. Also, in addition to poor decision making in general, a stressed or unhealthy pharmacist is possibly more prone to one of the specific risks mentioned in the previous section; that is, abuse of pharmacy resources.

You know, it’s home/work type balance. And you have to recognise that and see that people are always gonna have different times in their life that things are going pear-shaped, either at work or at home, might be with a young family, might be sleepless nights due to a baby, and it’s recognising all those types of things, so that if someone’s having particular problems, it’s having a look at their working practice and doing something as a department to try and support that person. Especially if it’s something that’s out of character and it’s usually a really good, squeaky clean pharmacist that doesn’t make errors, and then their error rate increases… [Technician, Specialist hospital]

It’s probably more to do with the situation or the mental state of the pharmacist […] if you were of the mind that you wanted to abuse medicines then any pharmacist could potentially do that because the medicines are around you. […] You’ve got a CD cupboard, so I would say its probably more to do with personal situations of the practitioner rather than, you know, environment or anything. Although it’s true to say that you would be more stressed if you were having a hard, I mean a very busy pharmacy with lots of stuff going on. [Locum pharmacist]

Taken together, these quotes suggest that the pharmacist and his or her managers are jointly responsible for managing any risks that arise from the pharmacist’s health and lifestyle. To be more specific, the effects of psychological or physical ill health on pharmacist risk can be moderated by the pharmacist’s own coping style and the ability of pharmacy managers to support their staff through periods of ill health. Another issue to be considered is the support that pharmacists perceive to be provided by the regulator in cases of ill health, as discussed in Section 4.2 of this report.
Communication skills. An issue that was commonly mentioned by participants was the pharmacist’s ability to communicate with colleagues and service users. A salient aspect of communication is command of the local language; however, an understanding of cultural norms for interpersonal communication was also considered to be important. It is possible that the effect of language and communication is not necessarily on actual risk, but on perceived risk from the perspective of colleagues and customers.

I’ve got to say the majority of pharmacists that I’ve come across in practice have good English skills and good language skills and so […] for me that hasn’t been an issue. I can see how it could be…going way back to an experience I had […] one [foreign] pharmacist [who] struggled to understand the […] idioms and expressions used normally in English…understood English perfectly well but it was the nullities of English that […] that individual struggled with and did actually cause them some problems in their, in their practice. And so, yes, I can see how language would be a barrier to developing and coaching an individual who had performance problems. [Pharmacy manager, Teaching hospital 1]

I don’t know whether [a language barrier] necessarily makes it riskier or whether it just makes everything much harder work because it certainly can cause huge problems if you’re not able to communicate with a patient and you’re not able to communicate with other health care professionals, that can be a big problem and certainly you might say that somebody who has a slight language barrier might have the potential to read things slightly wrong or, you know, hear the wrong drug if they’re not familiar with the names, then that potentially could be a risk I suppose [Locum pharmacist]

We openly tell [overseas trained pharmacists] that [cultural norms] will be an issue for them, to think about how they’re talking to people and that generally speaking Brits don’t like abruptness in the way that they’re spoken to. We had one situation where a customer was talking to the pharmacist, and [she] just went “Of course!” and what she really meant was “Yes, of course.” […] It just came across really abrupt and dismissive, and the patient took great offence at that, [but] that’s not what [the pharmacist] intended at all… [Superintendent, Large chain 2]
Very often we have complaints about communication and, and very often its people who have been trained here, who are from here who just have no social skills whatsoever. And those are people who actually should know better because they, they...it’s not a cultural thing with them its, its just a complete lack of manners [...] sometimes with people it’s a cultural thing. [PALS representative]

As these quotes indicate, there are several facets of communication that can impact on perceived risk. These range from the obvious, such as misunderstanding others or being misunderstood oneself, to the more subtle, such as inviting attributions about one’s credibility based on “peripheral cues” such as speaker accent (e.g. Lev-Ari & Keysar, 2010). As the superintendent indicates, being understood is not just a matter of using the correct language; it is also a matter of using appropriate paralinguistic cues, including inflection and non-verbal language. To be sure, the comment by the PALS representative is worthy of emphasis – difficulties in communication are not the sole, nor inevitable, preserve of pharmacists from overseas (see also Section 3.4.5).

Length of service. Two risk groups were suggested by participants. One group is newly-qualified pharmacists who were believed to have relatively less experience. The other group are long-serving pharmacists who were believed to be in danger of becoming less interested in professional development due to their becoming “settled” or approaching the end of their careers.

If someone’s well trained, if someone has been a pharmacist for twenty years they’re going to have an awful lot of experience and it wouldn’t matter which area they’ve worked in they would still have the skills to be able to work in community in hospital, you know, so those risks are a lot lower than a newly qualified and it wouldn’t matter whether it was a newly qualified from community or hospital transferring or staying in the same area they’re still going to have the same high risk. [Technician, Specialist hospital].

I’d met [pharmacist X] while he was a pre-reg. Unfortunately he worked in a shop that didn’t do Methadone at all, never come across it, never come across these
addicts and then […] he went working in a shop where he was the sole pharmacist as soon as he’d qualified had a lot of addicts and he was making mistakes […] My view is he should never have been the sole pharmacist in a busy pharmacy like that, second pharmacist, yes, until he knew what he were doing but he didn’t and he was making quite a lot of mistakes. [Controlled drugs liaison officer]

Older pharmacists have…not exclusively [a higher risk, but] sometimes it’s about older pharmacists who are settled into a way of working and they just do ward visits and they’re not really sort of scrutinising the scripts as they should. [NCAS pharmacist]

People coming to perhaps towards the end of their career that tends to be where, the point at which people give up on CPD I would say…and perhaps don’t do as many CPPE packs as they should or record as much CPD as they should. They might also only be working two days a week and again that means you’ve slowed up a bit so that the days that you do go into work you’re perhaps not at the same speed as you were and the same…perhaps not have the same thought process as you have been five years earlier when you were working full time. A bit of sweeping generalisation but that, that tends to be what we find and as you get you know we do have the odd Pharmacists at sort of over seventy and you think “Oh, well actually maybe now’s the time to think about giving up.” [Superintendent, Large chain 2]

That both newly-established pharmacists and long-serving pharmacists are both perceived to be higher risk than pharmacists who are midway through their careers is an interesting finding. In effect, there appears to be a “U-shaped” relationship between length of service and risk – this is consistent with the previous studies of practitioner risk cited in Section 3.2, where the direction of the linear relationship between length of service and risk varied between studies. However, what is not so clear is the interdependency between length of service and age.

Relationship to colleagues or patients. In keeping with the notion that pharmacists operate in a social as well as a technical environment, some comments from interviewees referred to how well-established the relationship was between the pharmacist and his or her colleagues and patients. This,
though, could well be less an indicator of actual risk, and more an indicator of how much trust pharmacy stakeholders hold in someone unknown to them.

I know they know what they’re doing […] If you know somebody has good work ethic then you trust their ability. [Locum pharmacist]

A pharmacist is low risk if they’re working for a reputable company who the Society, probably the Inspectors, know of, and know that they… I mean, use us as an example, so if a pharmacist is working for us, the Inspectors do know as well, we have an annual meeting with the Inspectors where we go through our procedures, and the way we do things and we know they’re happy with how we do things in our pharmacies, PCTs know as well, they know how we, how we do things [Superintendent, Large chain 1]

I mean most of our pharmacies are proper community pharmacies and what we tend to find is that the pharmacists and the staff have been there since the year dot and patients go in because they know the pharmacist or they know the members of staff and they trust them and they’ve got that relationship with them and so most of our pharmacists I suppose have been in the same place for quite a number of years, and as a consequence I think most of them become fairly low risk because they know Mrs Jones is always on Atenolol hundred milligrams, and if she suddenly changed to fifty milligrams they’d want to know why and so they’d be having a conversation finding out…why there’d been a change for example, so there’d be lots of elements that you would be able to identify that would reduce the risk, but knowing your patients being the key one [Superintendent, Large chain 2]

These quotes suggest that underlying the attributions of risk to pharmacists based on familiarity is a judgement about their perceived competence. Hence, the effect of familiarity on perceived risk might be to provide the person making the judgement with a more sound basis for making inferences about knowledge, skill and attitude. However, it may also be that being familiar with a pharmacist is in itself a risk-mitigating factor because the pharmacist will also have a good understanding of the service user’s needs, as implied in the superintendent’s quote.
Advanced and specialist practitioners. There were mixed views with regard to whether being an advanced or specialist practitioner (for example, a consultant or prescribing pharmacist) had an influence on risk. On the one hand, there was thought to be lower risk due to these pharmacists possessing greater technical expertise in those areas in which they specialise; on the other hand, though, the potential for their work to go beyond the boundaries of standard pharmacy practice was suggested to be a source of risk in itself.

By the nature of the fact that they are advanced and specialist practitioners working in that area of practice they should have advanced and specialist skills and competences and knowledge to go with that. And so the danger would be putting a non-trained, non-advanced, non-specialist member of staff to cover those clinical areas of practice because they wouldn’t have that level of competence and knowledge. […] We do have some very specialist practitioners whose knowledge is unique to them in some cases. Now they’re not here seven days a week, fifty two weeks a year so we do have to cover their duties. [Pharmacy manager, Teaching hospital 1]

I think the risk is ever increasing because I think we are a) asked to do more, b) we want to do more and we’re pushing the boundary, you know if you think in the last few years there’s more supplementary than now independent prescribers, we are you know, pharmacists are becoming much more kind of practice based and therefore their level of risk or perception might be perceptively be increased even though they are you know kind of experienced and skilled people you know practitioners, its just kind of more risky. Yes I think the higher we go or the further away from the pharmacy we go sometimes to dip into new areas, I think that its kind of fraught with risk, but the key is actually how that risk is managed rather than saying it’s more risky. [Pharmacist, Specialist hospital]

Both of these quotes allude to a potential complication in managing the risk of advanced and specialist practice: the uniqueness of such roles means that some risk factors could emerge that are specific to each role. That said, the variance in risk factors between advanced, specialist and general practice is likely to be more technical than person-specific. Hence, for the purposes of professional registration adequate coverage of risk might be provided by the
other personal characteristics considered here, such as length of service, knowledge and skill. It is possible, though, that being an advanced or specialist practitioner enhances or mitigates the effect of these characteristics on risk; for example, a pharmacist in a specialist post who does not keep his or her knowledge up to date could be a greater risk than one in a generalist post who falls behind on knowledge.

Summary. A range of personal characteristics was identified in the interviews. Unlike some of the more generic characteristics suggested in previous studies of disciplinary records – for example, gender and ethnicity – the characteristics described here appear to have a clearer conceptual link to risk. Hence, they potentially have greater face validity as risk predictors. However, they have the disadvantage of being more subtle and possibly more difficult to measure directly. Therefore, if they were to be used then some effort would be required to find suitable “markers” of these characteristics that can be measured.

3.4.2 Task characteristics

Type of product. Some types of drug or medicinal product were considered by participants to engender a greater risk than others. Chemotherapy, aseptic products and controlled drugs were often described as high risk.

There are also some technical services that we provide such as aseptic services and again they are inherently very, very risky [...] even though they’re very highly controlled by the MHRA in quality control there’s still the opportunity because they’re largely intravenous products...well if something does go wrong with an intravenous product the effect on a patient can be far more catastrophic because its given intravenously than maybe something which is given orally in medicine, which is dispensed and given orally [Pharmacy manager, Teaching hospital 1]

I suppose the areas that we concern ourselves with more are where if something does go wrong it has a much more profound attack...and it tends to be like chemotherapy things...or potassium chloride where somebody has ended up with the wrong dose or its been given in the wrong way like with chemotherapy ...you know the outcome is that they’ve died because of it. So with things like that...we’ve got
lots and lots more legislation around those because the outcome would be so catastrophic. The outcome would be so catastrophic that we make sure that we’ve got lots and lots more checks in process as more people are involved so that we absolutely minimise it to the nth degree. [Technician, Teaching hospital 3]

If you work in an area where you do a lot more controlled drugs, for example, or you do a lot more supervised methadone or something like that then the potential for risk is not necessarily you’re more likely to make with those, but the result of making a mistake with those kinds of medicines is obviously…the outcome can be a lot worse. [Locum pharmacist]

[On dealing with hospital prescriptions in a community pharmacy]. Well, for a start they use a lot more unusual medicines. The GPs tend to use a very, very tight formulary where we get to know what they use, so we tend to keep the six that we dispense a lot of. But with hospitals, really it could be anything and sometimes they can go off license, which means that you’ve got to chase after and say “Do you know that it’s off license…and would you still want it?” and you’re trying to find a hospital doctor, it’s a nightmare. You ring round and they don’t know where they are half the time. [Pharmacy proprietor]

Specialty. As well as there being “high risk” products, certain specialties were described as having particular risks. These included oncology, critical care, and paediatrics.

We’ve got the added problems of chemotherapy and clinical trials, so you know, it’s making sure that you’ve got exactly the right product against the prescription, certainly with the clinical trials prescriptions, you’ve got bigger issues because you’ve got patent numbers to consider as well, so it’s not just the drug, but it’s actually patient-specific drugs as well. [Technician, Specialist hospital]

I think with regards to areas of pharmacy practice that are risky, I think the difficulty comes in the areas that are less evidence based […] so for example PICU or well, intensive care sort of situation where these patients are life or death anyway and you’re forced into a very quick situation. For example in paediatrics, although we are bringing out more and more evidence hopefully in paediatrics where the doctors are
so used to doing what they want to do, which isn’t appropriate, it needs to be
evidence based, those are areas of high risk. Other areas of high risk are things like
where drugs, they’re old drugs, they’ve always been used but there’s actually no
written evidence for it, it’s just word of mouth that, “Oh this person’s been using this
and they say it’s fine” and actually research into it shows that actually it can cause
problems later on. [Pharmacist, Teaching hospital 1]

To the extent that pharmacist risk is due to the type of product or speciality in
which he or she is engaged, risk is amenable to analysis using the task-
specific methods described in Section 2.2. For example, Bateman & Donyai
(in press) analysed patient safety incident reports involving aseptic product
preparation and found that the most frequently reported errors occurred
during the labelling of products. However, while such information is certainly
useful from a risk management perspective, it is of less use from a risk
regulation point of view, unless particular individuals are found to be more
likely to be involved in especially high-risk tasks.

What might be useful, then, is to compare the rate and severity of incidents
between discrete staff functions or specialties – for example, between aseptic
and non-aseptic services, or between chemotherapy and other specialties.
Interestingly, though, Bateman & Donyai found that paediatric incidents,
despite their relative infrequency, were more often perceived to have a high
potential of harm. This is consistent with the quote provided by one of the
pharmacists here, but it also illustrates a point made earlier, that there is more
to perceived risk than just probability (see Section 2.2).

Incidentally, a specific task characteristic is alluded to in some of these quotes
– using medication off-license or outside of the conditions of the established
knowledge base. Potentially this is an activity that in itself could increase risk
in adult and paediatric care (see also Phipps, Parker, Pals, Meakin, Nsoedo &
Beatty, 2008), but it may also interact with the pharmacist’s level of
knowledge or attitude to risk-taking, such that a pharmacist who has a high
level of specialist knowledge may be of less risk when working with off-licence
medication. For example, in the case of the community pharmacist who is
presented with an unusual hospital order, it could be assumed that one who dispenses the medication without checking with the prescriber, despite having little knowledge of the medication, has higher risk.

**Seniority or supervisory role.** The risks involved with level of seniority, or with holding a supervisory role, were not perceived to be particularly greater or less than in more junior roles. However, some interviewees felt that the risks were different – for example, they were associated more with policy-making about medicines than with medicine handling itself.

Junior staff do a lot of the day-to-day work which is the checking of prescriptions and stuff like that, but as you climb the ladder, [...] you do a lot less of that sort of work and you do a lot more towards the prevention side of things with SOPs, guidelines, working with the team, so it’s slightly different. [Pharmacist, Teaching hospital 1]

I think it’s going to be interesting how risk is measured for people who aren’t patient facing. I don’t know how that starts because we’re having, having this conversation on Tuesday with a group of my, my peers who have similar jobs to me, but we all have different responsibilities and each of us saying well you know somebody revalidating you [...] wouldn’t necessarily understand what I do over here in a different company, so I think it’s easy to say “Right we could do that for community,” “We could do that for hospital,” “We could do that for industry” but then it’s all the sort of weird back-office functions that we all have, that’s going to be an interesting part I think, and then trying to look at risk in that is a hugely difficult process. [Superintendent, Large chain 2]

In light of these quotes, it is apposite to draw out a point that has been alluded to previously in this report. The stereotype of pharmacist risk appears to be the “frontline” pharmacist giving out the incorrect medication in the dispensary. However, as shown in Section 2.5, harm can occur in a number of ways, some of which might be a direct consequence of “back-office” or supervisory activities. An example was provided in one of the focus groups:

Not necessarily relating to one individual but financial risk might be if you’re, you didn’t store a drug properly and a very expensive drug wasn’t refrigerated and had
been discarded…we very nearly threw away something like seven thousand pounds worth of drug. [Focus group 1]

Even if only dispensing errors are examined as a pharmacy risk, it is worth revisiting the Swiss Cheese model outlined in Section 3.1. In a similar vein to this model, Wagenaar (1992) suggests that while managers consider risk-taking by workers to be a safety issue, it may be the case that the risks are actually taken during the managerial and organisational design decisions that create the context for worker behaviour, rather than by the workers themselves. In other words, managerial and supervisory functions warrant attention in risk-based revalidation. However, as the second quote suggests, this is not a straightforward matter, as (similarly to advanced and specialist practice, discussed earlier) there can be considerable diversity of activity in such functions. Nevertheless, it is possible that common risk factors might be found between “back-office” and “shopfloor” pharmacists; for example, their attitude to risk-taking or commitment to professional development. As discussed in Section 4.2, one implication for the design of a revalidation scheme is to ensure that it is appropriate for all pharmacist roles and functions.

Advisory or consultation role. While the traditional role of pharmacy was viewed as dispensing, interviewees also recognised the advisory role often played by pharmacists. This can be either advising other healthcare professionals on medicines management or running clinics for service users. Again, such “extended” tasks were seen by some participants to bring with them particular risks, although they were also argued by some to be important for the development of the profession.

I suppose it also depends on what sort of additional services community pharmacists offer. I mean, if they’re offering solely a basic dispensing service, then I would have thought that risk is fairly well managed, but if they’re doing the additional services, if they’re providing further advice to the patients, then that must be at a higher risk. [Consultant pharmacist, Specialist hospital]
There’s also a risk associated with what might be described as medicines information so somebody might end up giving the wrong information, so a doctor might phone and say what can you tell me about the dose I need to give this particular patient and for some reason, I don’t know, lets say they’ve looked in the wrong place or they’ve given out of date information and then they’ve suggested giving this drug or this dose and then it turns out that actually they’ve given incorrect information. [Consultant pharmacist, Teaching hospital 2]

So I put myself at risk by taking on extra work, by working for the PCT, by doing travel health, by doing flu vaccines, by doing the Champix on support to stop but I get more out of my job by doing that whereas some pharmacists are perhaps happy to just take on a dispensing role in the same place, all the time, with the same staff but they keep up to date with their journals and things so I’d say they’re the lowest risk but they’re not really embracing the profession as a whole. So I’d rather be higher risk but put the necessary steps in place to protect myself and others. [Manager, Supermarket-based pharmacy]

Again, consultation roles could be regarded in a similar manner to advanced and specialist practice. They too are not as well defined as traditional roles and so might engender new sources of risk from a technical point of view. However, like advanced and specialist practice, there are also likely to be some risk factors that are common to other pharmacist roles. Incidentally, that consultation roles are a product of efforts to develop the pharmacy profession indicates a political context to risk; the third quote suggests that there is a balance to be struck between eliminating risk completely and allowing the profession to develop.

Staffing. An often-cited risk factor was the presence of other pharmacy staff. These served a number of functions: firstly, as a source of peer guidance to a pharmacist; secondly, as an additional resource to manage workload; thirdly, as a safeguard against risky practice on the part of any one member of staff. By the same token, solo working was considered to be a particular risk.
Within the community pharmacy there’s usually only one person who deals with that prescription and that’s the pharmacist, so obviously the pharmacist dispenses, labels, checks, whilst obviously in hospital settings what we do is we have someone who clinically checks it, someone who labels it, someone who dispenses it and someone who accuracy checks it, four different eyes on that one prescription, and the reason for the four different steps is to have four different people looking at it because hopefully by having different people looking at it and different people being involved in it, the error will be reduced and spotted. [Pharmacist, Teaching hospital 1]

[In a hospital] you’ve got more work colleagues around you who can potentially see that you know something maybe going wrong or perhaps you haven’t quite grasped something that you know you need to understand. And so there’s, there’s more sort of an awareness of an insight into that something could be going wrong for a certain individual. Whereas within the community sector there’s nobody really around that sole pharmacist to identify that. [Pharmacist, PCT 1]

[Pharmacist X]…because of family life a tragedy happened and he started consoling himself by taking certain drugs […] and he worked for independents and I think eventually he worked with a company and somehow he was found out and was struck off. […] He was the only pharmacist there…no-one could really see what he was doing […] in community pharmacy there’s a lot of trust. You just don’t think that the pharmacist is going to do anything, say if the staff are not like, looking, helped, whereas in a company you’ve got a lot of people, there’s more staff around […] and so somehow, someone had seen because it something that they’re doing wrong you know more than in the community, but like here there’s only three of us and we’re all out there everywhere doing different things. [Pharmacy proprietor]

Workload and work design. Many participants referred to workload as a risk factor in pharmacies. This appeared to be closely related to staffing, such that a greater number of staff allowed the pharmacy to better cope with the workload. Conversely, time and production pressure were felt to increase workload.

I think it’s probably the stress and the pressure in the department causes people to rush and make silly errors, and it’s trying to to educate people to self check before
they send the prescription over to the checking bench, and it’s something that we try and drill into everybody, you know, ‘you must self check before you release it.’ But unfortunately, because everyone’s rushing, it’s something that doesn’t get done and then, of course, it goes to the checking bench, it might have waited on the checking bench for half an hour before someone checks it, and then they see that there’s an error, so then it goes back to the dispenser, you know? So these are the problems that we’ve got, we’re trying to keep our performance figures, and making sure that we achieve that. [Technician, Specialist hospital]

You’re concentrating as a pharmacist, you know, its proper full on concentration pretty much all the hours that you’re there, there’s a lot of distractions going on, you’re never sort of allowed to get on with one task you’re always being pulled in sort of two or three different ways at once and that makes for risk, errors can occur that way. I think its that because at the moment, although I’ve just given you my apprehensions about the new roles like ACTs [accredited checking technicians], I think at the moment pharmacists are being asked to be in too many places at the same time and that is a huge risk, because then you’re not giving any one job your full attention and therefore things can slip through and that can be risky. [Locum pharmacist]

The pharmacist in the dispensary was checking a prescription for a patient who was on Prednisolone. […] When the person was discharged to their GP, [the order] didn’t say at all whether they were supposed to stay on their current dose or whether the dose was supposed to be reduced. Now, everybody knows including the pharmacist involved that you have to make it clear to the GP whether or not the dose is reducing by one tablet every 5 days or whether they are to stay on that dose until they’re seen in clinic in four weeks time. This pharmacist knew this and in fact had seen this patient on the ward during their stay and had written it all over the prescription cardex saying not normally on maintenance, however during the speed of the discharge, as I said before about the workload and time pressures in the dispensary, this person checked that prescription and signed it off with the Prednisolone dose remaining at this high dose without actually, well the doctor hadn’t said it, which they should have anyway, but the pharmacist would have normally intervened, checked with the doctor and made it clear to the GP and this is what we want to do, but he didn’t do that so the person that ended up on that high dose level of steroids and then six months later actually was admitted and was discovered to have long-term effects of too high a dose of steroids. [Consultant pharmacist, Teaching hospital 2]
The comments made here about staffing and workload issues highlight the importance of looking at the interaction between risky individuals and the work environment. It is apparent that risk is attributed interchangeably to individuals (for example, the technician who talks about the need to self-check), and to the circumstances of the situation (for example, the consultant pharmacist who refers to time pressure mitigating against the individual pharmacist following-through an intended check). Incidentally, one interviewee describes having reservations about accredited technicians as a solution to staffing problems. These reservations, which might be shared by other pharmacists, were due to a perceived lack of clarity as to whether it is the ACT or the pharmacist who is liable for any harm incurred as a result of the ACT.

**Summary.** In addition to the personal characteristics identified previously, there are also characteristics of the pharmacist’s task itself that are related to his or her risk. Some of these characteristics are intrinsic to the task, others to the circumstances under which it is carried out. Each may be amenable to work design or training interventions to reduce the risk.

### 3.4.3 Organisational characteristics

**Business demands.** A prominent feature of community pharmacy, and one that is becoming increasingly apparent in hospital pharmacy, is the need to maintain financial viability. This can place a limit on the resources that are available to a particular pharmacy.

I’ve got a manager who services with a budget and you know within hospitals those budgets are always under pressure because workload increases…and budgets tend not to increase to match that workload. In times of financial difficulties then budgets will be cut but workload tends not to be cut and so you’ve got exactly the same issues as you would have in the commercial sector in that it’s always a pressure to do more and provide more service for less. [Pharmacy manager, Teaching hospital 1]
There’s always that pressure to try and balance the services and prescription members against staffing levels […] Some organisations really put pharmacists under a lot of pressure to complete MURs etcetera without offering double cover but I have sort of a day and a half a week […] of double cover, which I […] use for admin and services and staff training. [Manager, Supermarket-based pharmacy]

These comments serve to reinforce the business context within which pharmacists work. While pharmacists might have some responsibility for their own risk, it is clear that there are factors outside of their control that also influence their ability to deal with risk. For example, they are subject to organisational agendas concerning the prioritisation and allocation of resources and work efforts, as well as external sources of workload such as organisational targets and customer demands. Again, this points to the need to consider sources of risk that are not specific to the pharmacist.

Risk management. Some pharmacies were perceived to have well-established structures in place for managing risk. These include both dedicated risk management systems (for example, patient safety incident reporting and audit) and general HR systems (for example, recruitment, appraisal and staff development). These systems were thought by participants to reduce the level of pharmacist risk.

So, for example professionally we would have people checking […] what we do at the moment in hospital pharmacy is we have a checking log, an accuracy log, a dispensing log and [the trainee would] have to do a certain number of items and then they get asked a few questions to make sure that they’re safe and what their thought processes are and it’s all appropriate before we will pass them to be able to work fully functionally as a pharmacist. [Pharmacist, Teaching hospital 1]

In the hospital […] we have an AIR [adverse incident reporting] system […] so when something happens …a report is done and that would be…whether that be a patient hitting somebody in the face or whether it’d be a dispensing error or it could be something quite catastrophic. Depending on the level of harm to the patient they would then be graded a colour and it would either be given red, amber or green. Red
[denotes] the [...] serious errors. [...] The reports would then go to whichever department the error has come from then the manager there would have the responsibility for doing the investigation, finding out what had happened and saying what would she do in the future. The people involved might not be aware until that point and then if it was say a dispensing error then we would speak to the pharmacist or the technician whoever had done it and talk about the error and make them aware of the error. But in our hospital we have what we call “just blame” and the fact is that you would only take blame if you had actually not been following the procedures and had been doing something that was just like...you had decided so if there was a procedure for doing something that way and you decided to do it totally differently then you would have to be accountable for that. If by following the systems you made a mistake then you know you still would be at fault but there would be no particular punishment [...]. But I think obviously if there was an individual who was making repeated errors and you had a worry about their competency then you might need to do sort of particular remedial action for that person. If it’s a one off mistake and they’ve made a genuine error and its not, it’s not due to their routine practice then [...] you would warn her about it. [...] You might change the actual system but if there was something then you might need to do something about that person to some extent you might have to withdraw them from doing clinical duties until we knew that they were competent again [Principal pharmacist, Teaching hospital 3]

In a company like ours, we do everything we can to minimise risk by having strict procedures and SOPs to follow so, although you’ll never eliminate risk, making errors will be minimised because of having strict procedures in our company and in any other big company I’m sure would be exactly the same. I guess an independent, or possibly in independent pharmacies they probably don’t, some won’t have such strict procedures, and therefore there would be a much bigger element of risk there...it’s certainly what I find when we buy independents, although they’re supposed to all have the same procedures and all be getting their contract monitoring visits from the PCT, who are supposed to monitor that they’ve got all their SOPs etcetera in place. We do buy independents still and it is quite frightening to see what happens. [Superintendent, Large chain 1]

As the quotes indicate, there is some variety between pharmacies with regard to the presence of risk management systems; some have quite well-established systems, while others do not. In addition, they echo the theme
alluded to previously, of interplay between organisational and individual sources of risk. Lucas (1992) identifies three alternative models of safety management that are implicit in risk management systems. One is a *person-specific model*, in which the focus of risk management is on the behaviour of individuals. The other two are an *engineering model* that focuses on design of the work system, and an *organisational model* that focuses on the way in which the organisation is managed. Reason (1997) observes that risk management needs to be informed by all three perspectives, but that there can be conflict between the person model and the other two. The principal pharmacist refers to one approach that organisations adopt in an attempt to reconcile the different perspectives: the “just blame” culture, in which individuals are held accountable only for incidents that can actually be attributed to their negligence. As the quote suggests, though, it can be difficult in practice to make a clear demarcation between such incidents and those that are more usefully explained in terms of work system or organisational factors. Reason (1997) suggests some principles for making a distinction between the two. To put Reason’s discussion into (perhaps overly) simple terms, behaviours that are intentional, unmitigated, knowingly violate safe operating procedures\(^3\) and specific to the person could be considered attributable to the person performing them as opposed to the system or organisation.\(^4\)

*Organisational culture.* A pervasive feature of many organisations is the presence of an organisational culture; in other words, a prevailing set of beliefs, attitudes and behavioural norms. A subset of this is “safety culture”, which influences the way that organisational members deal with safety issues and safety-critical tasks – for example, staffing and incident reporting

\(^3\) Procedural compliance, and the circumstances under which it might be judged an appropriate or inappropriate course of action, are discussed in more depth in Reason, Parker & Lawton (1998).

\(^4\) At this point, is worth mentioning the National Patient Safety Agency’s Incident Decision Tree (http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59900), which is based on Reason’s work. Incidents that are attributed to individuals by the decision tree may point to issues that need to be addressed in future revalidation processes.
(Ashcroft et al., 2005). Some interviewees referred to cultural matters within their pharmacies.

We have such a big clinical governance agenda, and also, we have SOPs. Every time something goes wrong we have a reporting system, and we look at why it’s gone wrong and what we can do to prevent it happening again. So we have a different mind set here, and we have a no-blame policy…which is important, or else people won’t report. [Technician, Teaching hospital 2]

There’s always that pressure to try and balance the services and prescription members against staffing levels, but [supermarket X] have said their policy is that you’d always have that qualified technician and they’d have a workforce planner which estimates […] proposed income and then they’ll balance that against staffing levels. [Manager, Supermarket pharmacy]

Again, it would appear that safety culture can vary between pharmacies. It can be surmised that safety culture has a reciprocal relationship – it is both an emergent property of staff attitudes and managerial activities within the organisation (for example, whether staff believe it is in their interest to report incidents) and an influence on these attitudes and activities (for example, the extent to which the organisation values safety in relation to profitability. Hence, it would appear to be an important characteristic to consider when assessing pharmacies.

Summary. While risk could be attributed to individual pharmacists, organisational characteristics also have an influence on the risk of the pharmacists who work within them. Hence, it is important to take them into account when assessing the relative risk of different pharmacists.

3.4.4 General observations from the interviews

Interactions between characteristics. While the characteristics have been presented here as if they had completely separate influences on risk, in practice some may well co-occur. Also, some characteristics may serve to either mitigate or amplify the effect of others. For example, as this participant
observes, individual differences between pharmacists may affect their responses to the same working environment.

It’s difficult to say whether working in a quieter pharmacy would make you less at risk because some, again that depends slightly on your personality, because some people if they’ve gone, if they’ve gone off the boil slightly because they’re not being asked to continually focus, some people will make more errors when they’re actually not, when they’re only checking one prescription every hour or something like that, so I think it’s difficult to say whether how busy you are directly affects the risk. [Locum pharmacist]

Familiarity with the work setting. A key interaction, which underpins many of the other risk factors, is how familiar the pharmacist is with the system in which he or she is working. For a number of the interviewees, it was this that determined the ultimate level of risk of an individual pharmacist.

I think the risk is around their awareness of the structures and processes that are in place. I think if they are from a clinical point of view and I always look at risk from a point of patient safety. And I think if you have, if you have the knowledge and you’re clinically aware and you know where to look for information and then, then that is, is the important thing. [Pharmacist, PCT 1]

When considering the pharmacist’s employment and/or training background (for example, being a locum, being overseas trained or changing sectors), many interviewees felt that it was ultimately a matter of how well prepared the pharmacist was for the work environment in which he or she was placed.

Usually I’ve got a few locums …they are usually trained to a very high standard, they’ve usually brought a lot of skills with them….they’ve got a depth of experience that you wouldn’t normally see with somebody just working in one place. But it’s more about having the confidence that they understand procedures and you know if we have had had problems we’ve dealt with them [Technician, Teaching hospital 3]

Obviously [the risk associated with overseas-trained pharmacists] would be dependent on the length of time they’ve practiced in the UK and also dependent on their adaptability and their ability to take on and understand and adapt to the UK
health system and customs...there’d be a time and experience component
[Pharmacy manager, Teaching hospital 1]

I stand by my point that if you’re a hospital pharmacist, of course there are
exceptions to this rule, but if you’re a hospital pharmacist your training is such that
you’re likely to be more clinically able [...]. The difference in community is that just
like if I went and worked in community pharmacy tomorrow, even though I’m very
confident of my own clinical abilities and speaking with patients and speaking with
doctors, I would be very unfamiliar with the system of dispensing because I don’t do
any dispensing, its done by the robot and I spend very little time in the dispensary at
the hospital, so I put myself in a high risk situation because I’m not used to
dispensing anymore and therefore there’s a risk, of course, that I will dispense the
wrong thing. So a community pharmacist coming into the hospital if they were mainly
based doing dispensing, they wouldn’t be doing any dispensing in the hospital, they
would be out on the wards talking to doctors with patients, making decisions clinically
about whether that person’s treatment was the safest and most effective, so their risk
would be completely different. So you can be very skilled in your own area and then
when you move to a different type of area, you know, you’ve got to put yourself at
risk because the system is different. [Consultant pharmacist, Teaching hospital 2]

Community pharmacists versus hospital pharmacists. As indicated in Section
3.3, the one statistically significant finding from the record review was an
elevated risk of disciplinary action for community pharmacists when compared
to pharmacists in non patient-facing roles. During the interviews, this issue
was explored with participants to determine whether in their view, community
pharmacy was intrinsically more risky or whether there was some other factor
that accounted for the greater presence of community pharmacists at
disciplinary committee hearings. Participants referred to three general
differences between the two sectors with regard to risk management:

- Hospital pharmacists are more likely to become involved in clinically
  complex cases, whereas community pharmacists generally deal with
  less complex cases (although they may find themselves the first port of
  call for a patient who presents with a serious illness);
- Hospital pharmacies typically have more staff than community pharmacies, and in the latter it can be common for pharmacists to work alone;
- Hospital pharmacies tend to have well-established risk management systems inherited from the hospital trust, which means that risks associated with pharmacy practice are likely to be anticipated and dealt with “in-house”.

Hence, the apparent difference in risk could be due to differences in the way that hospital and community pharmacies are organised and managed, rather than pharmacists working in the latter being intrinsically more risky. Interestingly, Austin, Marini, Croteau & Violato (2004) found that, on competency-based assessments in Ontario, Canada, community pharmacists performed less well than hospital pharmacists, despite the latter perceiving a bias in the assessments towards the work of the former. The authors speculate that this could be due, amongst other things, to community pharmacists developing a more abbreviated style of interaction with patients as a result of having a greater volume of patients. It should be noted however that, as with the record review reported earlier in this section, a greater number of community pharmacists than hospital pharmacists were present in Austin et al.’s sample.

Members of the public as stakeholders. An argument has been made previously in this report for members of the public to be included as stakeholders. However, while this argument still stands, it was apparent from the interviews that the public’s awareness of risks in pharmacy varied. The members of the public interviewed for this study felt unable to say much with regards to pharmacist risk factors; the general message, it seems, is that they “delegate” their decision-making about risk to the professional regulator, and indeed do not perceive pharmacy to be a particularly risky profession.

I assume if they’re pharmacist they are qualified to practice and therefore they will do it right and if they make a mistake then you know everyone makes a mistake, but […] I’ve never considered it being a high risk profession or myself being at risk from a pharmacist in anyway. I assume that there are people who regulate pharmacists so I
would be as confident in all of them because I assume that there are regulations, so if they’re confident to practice, they will be confident to practice. [Member of the public, SureStart group]

You know they are trained and they don’t [...] give general advice [...] they’ll only give advice that they are allowed to do [...] you know they don’t go that deeply into it they’ll just give you advice that’s on the particular medicines and what they do and things like that. [...]I wouldn’t go to a pharmacist and ask her you know anything other than a minor illness anyway so I don’t really think I can say anything about that. [Member of the public, SureStart group]

Incidentally, remarks made by community pharmacists during a previous study by the authors (Phipps et al., 2009) suggest that patients may place demands on pharmacists for a fast service without considering the risk inherent in sacrificing accuracy for speed. A similar observation was made by one of the pharmacists in the current study.

[Hospital pharmacists] don’t have the general public standing there chanting at them you know, ‘I’ve got my bus to catch,’ or ‘I’ve got to pick the children up from school,’ and sometimes you know, you can be forced into a situation where you rush something. [Manager, Supermarket pharmacy]

It should be added, by way of a caveat, that only two laypeople were recruited for the current study, both from the same source (a SureStart parents’ group). A third participant was also a layperson, but had some insights into pharmacist risk from her work as a hospital PALS representative. Hence, a very restricted range of laypeople’s views was obtained for this study.

3.4.5 Quantitative findings from the rank-ordering exercise

As described in Section 1, the interview included a card-sorting exercise in which participants rank-ordered 12 fictitious pharmacists in terms of their perceived level of risk. Twenty-eight of the participants carried out this exercise, and the median rank awarded to each pharmacist is shown in Table 3.4. The most consistent finding here is that overseas-trained pharmacists were perceived to have the greatest level of risk. Two points, though, need to
be made when interpreting this finding. Firstly, the ranks are relative; that is to say, the pharmacists were compared against each other rather than against any absolute measure of risk. Secondly, the participants qualified their rankings during the discussions that ensued from the card-sort. The participants’ views were incorporated into the qualitative data described previously. With regard to the specific issue of overseas-trained pharmacists being apparently higher risk, some general observations from the interviews are:

- The risk was believed to depend on two factors. One is the similarity between the training and pharmacy work systems in the country of origin and those in the UK. The other is the similarity between the countries in terms of language and culture. The latter was thought to lead to problems of communication rather than of technical competency;
- In this respect, pharmacists from particular countries were considered to be of less risk. For example, the US and Commonwealth countries were sometimes considered to have less risk because they are more similar to the UK on both dimensions;
- However, participants often noted, by way of qualifying their rankings, that “overseas- versus UK-trained pharmacists” is a broad distinction and that, in practice, standards vary between individual pharmacists, regardless of their country of origin.
- The risk attached to overseas-trained pharmacists from any country is reduced to the extent that they have had previous exposure to working practices in the UK. Hence, for example, pharmacists who received their initial training overseas but then undertook pre-registration training in the UK were, all other things being equal, perceived to be less risk than pharmacists who had received their entire training overseas.

Also attracting slightly higher rankings for perceived risk were locum pharmacists and pharmacists who had changed sector. The participants made similar qualifying statements about these pharmacists as they did for overseas-trained pharmacists. As described in Section 3.4.4, the main issue
appeared to be the level of familiarity the pharmacist had with the work setting in which he or she was now placed, and how well prepared he or she was for working in that setting.
Table 3.4 Median rank of pharmacists in the risk-rating exercise. A value of 1 indicates the highest level of risk, a value of 12 indicates the lowest level of risk

<table>
<thead>
<tr>
<th>Rank</th>
<th>Sector</th>
<th>Employment status</th>
<th>Training location</th>
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<tbody>
<tr>
<td>2</td>
<td>Hospital</td>
<td>Locum</td>
<td>Overseas</td>
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<td>2</td>
<td>Community</td>
<td>Locum</td>
<td>Overseas</td>
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<td>3.5</td>
<td>Community</td>
<td>Employed in new sector</td>
<td>Overseas</td>
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<tr>
<td>4</td>
<td>Hospital</td>
<td>Employed in new sector</td>
<td>Overseas</td>
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<tr>
<td>5.75</td>
<td>Community</td>
<td>Employed in same sector</td>
<td>Overseas</td>
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<tr>
<td>6</td>
<td>Hospital</td>
<td>Locum</td>
<td>UK</td>
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<tr>
<td>6.75</td>
<td>Hospital</td>
<td>Employed in same sector</td>
<td>Overseas</td>
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<tr>
<td>8</td>
<td>Hospital</td>
<td>Employed in new sector</td>
<td>UK</td>
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<tr>
<td>8</td>
<td>Community</td>
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<td>8</td>
<td>Community</td>
<td>Locum</td>
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<tr>
<td>11</td>
<td>Hospital</td>
<td>Employed in same sector</td>
<td>UK</td>
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<tr>
<td>11</td>
<td>Community</td>
<td>Employed in same sector</td>
<td>UK</td>
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3.5 What criteria should be used to identify high-risk pharmacists?

3.5.1 Criteria suggested for use

The literature review, record review and interviews have yielded a variety of factors that could be used to identify high-risk pharmacists. It was decided that for each factor to be used as a criterion for assessing risk, it needed to satisfy four conditions:

(i) Able to be expressed in terms of a measurable criterion;
(ii) Supported by evidence from the previous studies;
(iii) Able to be applied to the assessment of individual pharmacists;
(iv) Transparency.

Against these conditions, the following factors were selected for use as risk assessment criteria.

Length of practice. The literature review indicated that both age and length of practice are linked to the risk of disciplinary action in medicine and nursing –
generally, older practitioners and those with more years of experience are at greater risk. In Ontario, a decline in performance on competency-based assessments has been found amongst pharmacists with more than 25 years of experience (Austin, Croteau, Marini, & Violato, 2003). The review of RPSGB disciplinary cases found no relationship between age/length of practice and risk; however, this was possibly due to year of registration being used to match pharmacists in the disciplined and non-disciplined groups. In the interviews, participants generally attributed greater experience to lower risk; however, some also noted a risk of skill fade or lack of CPD engagement in long-serving pharmacists. Some difficulty was encountered in setting a criterion for minimum years served, as newcomers to the register will already have recently undergone a period of supervised practice; hence, it was felt that little more could be done for them in terms of risk-based regulation.

**Overseas training.** A consistent finding from previous research is that being trained outside of the country of practice increases a healthcare practitioner’s likelihood of being sanctioned. A study of Ontario-based pharmacists’ performance on competency-based assessments found that those trained outside Canada performed less well (Austin et al., 2004). The disciplinary case review found an elevated risk for those pharmacists trained outside the UK, although this finding was not statistically significant. The interview data, as did the findings of Austin et al. (2004) suggests that there are two separate issues that could affect overseas-trained practitioners: a lack of familiarity with pharmacy practice in the UK; and a lack of familiarity with language and culture in the UK. The extent of both issues clearly depends on where the practitioner was trained; also, it could be surmised that the risk will become less the longer the practitioner works in the UK.

**Change of sector.** A general index of risk identified from the interviews is the level of familiarity a pharmacist has with a particular pharmacy work system. Hence, there may be a risk associated with pharmacists moving from hospital to community practice, or vice-versa, due to their being in an unfamiliar environment. Again, this risk, if it does exist, is likely to become lower as the pharmacist becomes more accustomed to the new work environment.
Break in practice. Some interviewees suggested that a consequence of having a period of time away from practice is that, like those who change sector or country, the pharmacist may not have knowledge of current working practices.

Patient contact. The record review found that pharmacists in patient-facing roles (i.e. hospital and community pharmacy) were at greater risk of being disciplined, hence there appears to be a general risk factor of the pharmacist having patient contact. The Ontario programme has separate certification for pharmacists in patient-facing roles and those who are not; those pharmacists who wish to be certified for patient-facing practice are required to demonstrate having worked in this role for a minimum of 600 hours over the previous three years. However, while this criterion has also been adopted for the current risk assessment, it should be noted that it is arbitrary and ideally should be validated through empirical work.

Previous sanctions. Previous studies have found that healthcare practitioners who have previously been the subject of disciplinary action, either during training or while working, are at increased risk (Papadakis et al., 2005; 2008). While there was insufficient data in the record review for a direct comparison to be made between sanctioned and non-sanctioned pharmacists, approximately one-fifth of the sanctioned pharmacists had previously been the subject of disciplinary action.

Sole pharmacist on duty. A previous study found that, in the UK, GPs working single-handed were at increased risk of disciplinary action (Watts, 2009). The interview data suggested that solo working was also a risk factor in pharmacy practice.

3.5.2 Criteria not included in the study

A number of other risk factors were also identified in the previous studies, but did not meet the criteria described earlier for inclusion in the instrument.
Gender. Previous studies have indicated that male healthcare practitioners are at increased risk of disciplinary action (e.g. National Patient Safety Agency, 2009). However, gender was felt to lack transparency as an assessment criterion. Studies of healthcare professionals’ attitudes towards engaging in particular behaviours have found that, where gender predicts intention to behave in a particular way, the relationship between gender and behavioural intention is mediated by attitude.

Ethnicity. Like gender, this has been linked to the risk of disciplinary action, but also lacks transparency. A study by NCAS (National Patient Safety Agency, 2009) found that ethnicity interacted with overseas training in the prediction of practitioner risk, while data from the GMC suggests that overseas training accounts for the relationship between ethnicity and risk. In the pharmacy population, the effect of ethnicity on risk might be due to there being more Asian pharmacists in community pharmacy than in hospital pharmacy; pharmacists working in the former type of pharmacy are more likely to be sanctioned.

Socio-economic status. One study has found that doctors from a working-class background were at increased risk of disciplinary action (Yates & James, 2010). However, this also lacks transparency as an assessment criterion; furthermore, there is no evidence from pharmacy settings.

Employment record. Key risk factors with regard to employment record – changing sectors, taking a break from practice, being sanctioned for poor performance, and lack of patient contact – have been suggested in preference to this more generic factor.

Locum pharmacist. As with employment record, specific risk factors have been used in place of general status as a locum pharmacist.

Advanced / specialist practice. Again, specific indicators have been used, as the framework is intended for use in both general and specialist practice. As yet, there is little evidence that advanced or specialist practice is a particular
risk; indeed, unpublished data from the Ontario programme suggests that pharmacists in these roles perform better than non-specialists on competency-based assessments.

**Specialty.** The framework is intended to be used across all specialties; hence, more specific indicators of pharmacist risk have been used.

**Sector.** Specific indicators have been identified for use in place of this general factor.

**Workload and staffing.** These are considered to be characteristics of pharmacies rather than pharmacists. Nevertheless, they are considered to be important risk factors that could be incorporated into a pharmacy assessment.

**Risk management and HR systems.** Again, these are considered to be better assessed during pharmacy inspections rather than as a characteristic of individual pharmacists.

**Organisational culture.** This also is better suited to a pharmacy assessment. The authors have developed a measure of safety climate that is intended for use in primary and secondary care pharmacies (Ashcroft & Parker, 2009; Phipps, Malley & Ashcroft, 2010).

**3.5.3 Criteria that could potentially be used.**
The following are criteria that, while not currently meeting the conditions for inclusion in a risk assessment, could potentially do so in the future as methods of assessing them are developed.

**Knowledge and skills.** General competence may underlie the relationship identified earlier between poor work or training performance and subsequent disciplinary action. During the interviews, participants alluded to low risk pharmacists being those who were known to be competent. In the revalidation system adopted in Ontario, British Columbia and Alberta (described in more detail in the next section), pharmacists now undergo
competency-based skills tests, although the relationship between performance on these tests and the risk of disciplinary action has not been assessed.

**Attitude.** Reason, Parker & Free (1994) and the Federal Aviation Administration (1991) note that driver and aviator behaviour respectively can be influenced by so-called “hazardous attitudes”, which influence the way that the subject appraises a risky situation and responds to it (for example, an assumption that one is “invulnerable” or “superior”). It is possible that a corresponding set of attitudes can be identified in healthcare practice, which could form the basis of a self- or observer assessment (Gaba, Fish & Howard, 1994; Stripe, Best, Cole-Harding, Fifield & Talebdoost, 2006; Phipps, 2008). Appendix A describes some hazardous attitudes that might be present in pharmacy practice. Alternatively, a generic measure of risk-related attitude, such as a pharmacist’s attitude to dealing with errors in his or her work (Rybowiak, Garst, Frese & Batinic, 1999; Schell, Hernandez & Rosebeary, 2008) could be used. In any case, what is not clear is the nature and strength of the relationship between attitudinal factors and risk; this would need to be explored in further empirical work.

One concept that is closely related to knowledge, skill and attitude is “error wisdom” (Reason, 2004). The potential application of this to pharmacist revalidation is described in Section 4.3.

**Engagement with Continuing Professional Development.** As with competency-based assessments, the relationship between CPD engagement and disciplinary risk has not been established. However, it might serve as a behavioural marker of a pharmacist’s being up-to-date with current practice, which was identified in the interviews as being a risk factor.

**Health and stress.** At present, registrants are required to complete a health declaration and to report any health concerns to the regulator; hence there is already a basic mechanism for detecting health problems. There may be scope to make use of a more extensive “stress audit”, using a psychometric
instrument such as OSI or ASSET (e.g. Cooper et al., 1999). However, a potential limitation of any self-reporting scheme is registrants' perceptions of the support they would receive from the regulator and their employers should they disclose any health or stress concerns (see Sections 3.4.1 and 4.2 for further discussion).

3.6 Focus group study

Having identified the criteria for use in assessment of pharmacist risk, the researchers presented these to the focus groups. Participants were invited to comment on their face validity; that is, how plausible they appear to be as a measure of risk. The final set of risk criteria are shown in Table 3.5.

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5 At the time of writing this report, studies are in progress in the University of Manchester’s School of Pharmacy and Pharmaceutical Sciences that aim to examine the use of psychometric stress measures in pharmacist risk management.
Table 3.5 The assessment criteria selected

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<th>Low</th>
<th>High</th>
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<tbody>
<tr>
<td><strong>Length of practice</strong></td>
<td>&lt; 25 yrs</td>
<td>&gt; 25 yrs</td>
</tr>
<tr>
<td><strong>English proficiency</strong></td>
<td>IELTS =&gt; 7</td>
<td>IELTS &lt; 7</td>
</tr>
<tr>
<td><strong>Overseas training</strong></td>
<td>UK trained</td>
<td>Non-UK trained</td>
</tr>
<tr>
<td><strong>Change in sector</strong></td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td><strong>Had a career break</strong></td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td><strong>Patient facing role?</strong></td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>If in a patient-facing role:</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Patient contact in the last 3 yrs</strong></td>
<td>=&gt; 600 h</td>
<td>&lt; 600 h</td>
</tr>
<tr>
<td><strong>Sanctioned previously</strong></td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td><strong>Sole pharmacist on duty</strong></td>
<td>N</td>
<td>Y</td>
</tr>
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While the criteria themselves were generally accepted, some participants queried the specific parameters – for example, the cut-off values for length of service. Similarly, some participants suggested a need for greater specificity on some of the criteria.

Participant 1: [With regards to English proficiency] I know lots of people who can answer a comprehension exercise on the Australian dung beetle very well, and not hold a conversation with a patient about what it is the patient needs to know […] which is [more to do with] communication isn’t it?

Participant 2: Communication skills […] it’s quite hard to measure. [Focus group 1]
Sanctioned previously [...] by whom? Anecdotally [...] there was an awful lot of performance management issues that were referred to the regulator [by employers] which may or may not have been appropriate. [Focus group 1]

I wonder what the difference is between [the sole] ‘owner’ of a pharmacy [and] a sole practitioner [...] employed in a team. [Focus group 2]

Participant 1: Most community pharmacies would only have one pharmacist. So it’s really not just about sole practitioners, it’s about how much support they’ve got when they’re practicing.

Participant 2: Yes, I wrote on mine ‘Registered Technician’ because that’s...having a registered technician work...in a community pharmacy working with you is actually almost as good as potentially another pharmacist...[Focus group 2]

As discussed previously in this section, some of the parameters are arbitrary (for example, the 600-hour threshold for patient-facing roles) while others are based on the best available evidence (for example, the 25-year cut-off for years of service, which is based on data from the competency assessment of Canadian pharmacists). The general point to be made is the need to ensure that any criteria used have as strong as possible an evidence base and a clear conceptual link to risk.

Whatever factors you are using to define risk would have to be evidence based, because you are making frankly, a determination about someone’s livelihood...that’s about risk it [could] be challenged. [Focus group 1]

In addition, participants alluded to other criteria that they felt were important but, at present, difficult to measure. These echo factors described previously – for example, staffing, skills and attitudes, and CPD engagement. Again, the considerations of having a strong evidence base apply.

There’s something I was gonna bring up just about...an extra thing to add on this, about the responsible pharmacist and the hours, and that obviously is being recorded
now, so that’s something that’s measurable...and whether people are...again it’s subjective at the moment, there’s probably no evidence but whether that relates to the risk, the longer that you are responsible...it’s not so much in hospital. [Focus group 1]

You see some employers move their staff around when they know they can’t take the pressure, they put them somewhere with ‘less’ pressure. Now that’s not...they don’t change the pharmacy they’re in, they change the person around, so they’ve...they’re doing some assessment of it, I don’t know whether it’s in number of errors or some other assessment but they do some. [Focus group 2]

I think there are some things that a number of people have done which people who’ve brought in checking technicians have often done competency based assessments on accuracy checking and have...so we have a five hundred item log, you have to...you make any mistakes you’re back to the start and then they have revalidation on some of those type of things or...and we’ve all sat our tests, so within our organisation, that was a standard thing to say you are an accuracy checker, and there has been the big debate which is, “When I was signed off as a pharmacist, I’m a pharmacist because RPSGB have said I am so why do I have to prove I’m a pharmacist when I come and work in ‘your’ organisation?” [Focus group 2]

I could imagine thinking through some of the criteria raised with some standards around CPD, some of the risk factors and some personal reflection on that you know, “Do you, do you work in an organisation where you feel supported?” You know “Don’t you work in an organisation with people?” “Do you complete a range of tasks which may be seen as simple?” [...] “Have you had an appraisal in the past year?” [Focus group 2]

The foregoing comments from the focus groups are offered by way of evidence for the assessment criteria’s face and content validity, pending future work to establish their criterion-related validity. It is intended that the criteria will be used to distinguish between high-risk and low-risk pharmacists, who will subsequently be subjected to differing regimens for revalidation. The
application of the criteria to revalidation will be discussed in more detail in Section 4.5.

3.7 Section summary

By definition, risk-based revalidation should focus on the practitioner, and a number of factors are suggested here on the basis of the study findings. Some of these factors have been used to create a risk assessment framework. Ultimately, this framework will be used as the basis for an instrument whose reliability and validity can be examined through an empirical exercise.

In addition to practitioner characteristics that can be incorporated into a risk assessment, the researchers have also highlighted other risk factors that are characteristic of the work situation or of the organisation. That do not form part of the presented risk assessment but that might lend themselves to an assessment of pharmacies. Specifically, these are workload, staffing, and risk management and HR systems. The empirical evidence for the practitioner-specific and pharmacy-specific characteristics varies across them; however, bringing together the findings from the different component studies indicates broadly consistent support for the factors adopted here.
4. How can risk-based revalidation be conducted?

4.1 Introduction

According to Rasmussen (1997), risk management is an activity that involves not just the organisation itself, but also the social and governmental systems within which it operates. Regulation provides one mechanism by which these different “levels” of risk management are linked. There is a long tradition of using regulation as a means of quality assurance in healthcare, as it holds professionals to defined practice standards. However, accumulated evidence of patients being harmed by healthcare professionals whose malpractice was not stopped by established regulatory regimes, societal expectations of greater accountability to stakeholders and the general public, and an increasing recognition of the role played by work systems and organisational factors in influencing healthcare effectiveness, have all led to calls for regulatory processes to be reformed (Bevan, 2008; Smith, 2004; Walshe, 2009). A specific issue for consideration is the greater use of revalidation—that is, a periodic re-evaluation of fitness to practise against role-relevant competencies—rather than the traditional approach of initial registration with no further assessment of competence for the remainder of one’s career (Buckley, 1999; Walshe & Benson, 2005).

Across pharmacy regulators in Western Europe, North America and Australasia, there is at present some variety in the use of revalidation. For example, there is no formal revalidation system in Germany or Holland (Prof. Martin Schultz, Federal Union of German Associations of Pharmacists, Personal Communication, 17 Dec 2009; Dr Henk Buurma, Institute for Pharmacy Practice and Policy, Leiden, Personal Communication, 17 Dec 2009), although in Holland there is a revalidation system for medical specialists consisting of peer review, continuing medical education and workplace assessment (Swinkels, 1999). Pharmacists registered in New Zealand are subject to periodic practice audit as well as being required to carry out continuing professional development in order to maintain their
annual practicing certificates (Prof. Jane Sheridan, University of Auckland, Personal Communication, 17 Dec 2009; Dr Owain George, Pharmacy Council of New Zealand, Personal Communication, 22 Dec 2009). In Denmark, there is no formal system, but there is a responsibility on pharmacy owners to maintain the competence of their staff; hence there may be pharmacy-specific systems in place (Hanne Herborg, Danish College of Pharmacy Practice, Personal Communication, 17 Dec 2009). In the United States, the National Association of Boards of Pharmacy has proposed a “continuing competency assessment” scheme in which pharmacists maintain a portfolio of continuing professional development; however, this proposal has reportedly met with resistance from members of the profession (Name withheld, Personal Communication, 17 Dec 2009).

Allsop & Jones (2006) examined medical regulatory practice in a number of countries, and in doing so identified three models for detecting and dealing with poor performance:

i. Under the investigation and learning model, investigation of a doctor occurs in response to a patient complaint or a report by a manager or another professional;

ii. The performance assessment model attempts to identify doctors who are likely to perform below an acceptable standard and subject them to more intense scrutiny. The criteria for determining these “high risk” doctors include demographic variables (such as age) or deviations from practice norms (for example, dispensing an unusually high or low amount of a particular medication);

iii. The surveillance model makes use of a data bank, consisting of doctors who have been the subject of complaints or negligence claims or faced disciplinary action. Those who are in this data bank are subjected to more intense scrutiny.

It would appear that a combination of the second and third models best supports the use of risk assessment, as they involve the identification of risk factors either on an a priori (performance assessment) or a post hoc (surveillance model) basis. Allsop & Jones do, however, highlight limitations
to both models. The use of predictors in the performance assessment model, much like the risk rating approach outlined earlier, has the potential to generate “false positives” – that is, target practitioners who actually are not at elevated risk. For a regulation regime to be proportionate as the General Pharmaceutical Council intends, clearly such cases need to be kept to a minimum; hence, classification criteria need to be as well informed by empirical data as possible. The surveillance model, meanwhile, depends on cases being reported to the agencies that are responsible for maintaining data sets. It may be the case that, in practice, not all cases are reported to external bodies; for example, healthcare organisations in the United States (where the surveillance model is used) sometimes choose to rely entirely on their own internal disciplinary procedures.

At this point, it would useful to consider the well-developed use of continuing professional development schemes in Canada. One example is the programme used in Ontario for the quality assurance of pharmacists (Austin, et al., 2003). Here, registered pharmacists are required to maintain a learning portfolio containing reflection on learning needs and evidence of undertaking activities to address these needs. In addition, pharmacists are subject to a periodic practice review, in which a randomly selected sample is required to complete a self-assessment of their knowledge and skills, and is eligible to be assessed further by means of a written and practical examination. Drawing from local schemes such as Ontario's, the Canadian National Association of Pharmacy Regulatory Authorities (NAPRA) has developed a model for professional practice assessment (Winslade, Tamblyn, Taylor, Schuwirth, Van der Vleuten, 2007). Under this model, all pharmacists are subjected to a periodic initial screen using indicators of pharmacy performance. Those who are judged to have an adequate level of performance undergo “targeted” continuing professional development and their pharmacies undergo continuing quality improvement, while those who perform exceptionally well are requested to undertake a voluntary diagnostic assessment that aims to identify determinants of their better performance. Those who perform below standard are required to undertake a diagnostic evaluation, on the basis of which remedial measures are chosen. There are three aspects of the NAPRA
model that are worth highlighting. Firstly, the subject of the assessment is both the pharmacist and the pharmacy in which he or she works. Secondly, the diagnostic data from both good and poor performers are used to inform the future development of standards as well as the remediation of pharmacists and pharmacies. Thirdly, it is intended that assessment will take a number of methods, including questionnaires, written and practical examinations, on-site assessment, and practice management assessment. The reasoning behind this multi-method approach is that it captures the range of influences on pharmacy practice, including individual, work system and organisational factors.

As models already exist for the assessment of healthcare professionals’ performance, it would be useful to consider the extent to which these can contribute to a risk assessment. Rethans et al. (2002), similarly to NAPRA, propose an assessment system consisting of three components:

i. A periodic, general screening component for all practitioners. This is of moderate intensity and makes use of performance assessments and regular monitoring of parameters;

ii. For those who perform well on the screening component, a quality improvement component that is of minimal intensity and places more emphasis on self-directed learning and development;

iii. For those who perform poorly on the screening component, a more intensive assessment component consisting of diagnostic investigation and remediation, rehabilitation or removal of the practitioner.

The system proposed by Rethans et al. would appear to be consistent with the aspiration for a revalidation regime that is proportionate to risk; it is possible that risk assessment could inform its general screening component. In a similar vein to Rethans et al., Southgate & Pringle (1999) and Baker (2006) suggested behavioural criteria that could be used to assess GMC members for revalidation. These include indicators of good clinical care, record keeping, professional relationships, and dealing with complaints. As suggested by some of the previously cited studies (Papadakis et al., 2005;
Papadakis et al., 2008), unprofessional behaviour such as might be picked up by these proposed GMC assessments can be a precursor to future disciplinary offences, and hence could usefully be incorporated into a risk assessment. Bardsley et al. (2009), meanwhile, demonstrate the use of a normative quantitative risk profiling method to identify “high risk” healthcare providers requiring an inspection; the authors suggest that this approach will, with refinement, provide a more sensitive targeting of healthcare inspections than the current approach of visiting a random selection of providers. Incidentally, Rethans et al. also suggest that performance is a product of the practitioner’s competence combined with system influences (for example, practice facilities) and individual factors (for example, personal health); hence, all three should be taken into account during assessment.

It would seem that there are structures and processes, either proposed or currently in place, that could accommodate or facilitate the use of risk assessment. So far, the focus of this section has been on the technical aspects of risk assessment for regulation and revalidation. A final issue to consider is one that was introduced in Section 2; namely the social and political context of risk assessment.

“If the first hurdle [to the application of new technologies] is the established regulatory process based on sound science, the second and potentially more problematic hurdle is public opinion, informed by considerations and values beyond those of the probabilistic formulation of risk. Those who ignore the second hurdle invite the possibility of political conflicts and public resistance” (Gaskell & Allum, 2001, p.7)

This is an issue of particular relevance to the current subject matter, given that regulatory reform (which forms the background for revalidation) has been driven largely by social and political agendas (Shaw, Cassel, Black & Levinson, 2009). In particular, regulatory bodies aspire to change their focus from serving the economic and social interests of healthcare professionals towards maintaining standards of public protection and patient safety (Noyce, 2006; Walshe, 2009).
Walker and colleagues (Walker et al., 1998; Irwin, Simmons, & Walker, 1999) studied the public perception of the risks associated with seven chemical processing sites in the UK. They found that participants evaluated industry regulators according to the extent to which they were perceived to act in the public interest (rather than in the interests of industry or government) and their effectiveness in maintaining safety. Of particular interest though are the findings that:

- participants did not feel well informed about activities at these sites, nor did they feel empowered to exert any influence over risk management;
- participants’ risk perceptions were informed by their own experiences of risk and regulation, their knowledge of the risks encountered in other settings, and their recognition of the interplay between social, economic and moral considerations.

These findings point to the matter of stakeholder engagement in risk regulation (Poortinga & Pidgeon, 2003; Walker et al., 1998; Walker, Simmons, Irwin, & Wynne, 1999). It would appear pertinent to investigate the relationship between stakeholder engagement and risk assessment. As well as the public consumers of pharmacy services there is another set of stakeholders in risk management; namely, the pharmacists and pharmacy staff themselves. According to Irwin (1995), knowledge relevant to risk management does not reside solely with risk “experts” but also with those laypeople who actually work in the settings under consideration. Bennett & Shaw (2003) draw from Irwin’s “citizen science” model to examine the role of airport ramp workers’ experiential knowledge in their risk assessment and management. The emphasis of Bennett & Shaw’s study was on the workers’ use of rules and procedures, which the workers felt did not take sufficient account of the experience of carrying out ramp work. The authors suggested a need for managers to draw from workers’ experiential knowledge when formulating rules and procedures. Macrae (2008) proposes the use of participative networks in healthcare risk regulation; these are networks of local workers who have experience of the activity in question, and so are able to contribute to the understanding and management of risks associated with the
activity. Macrae claims that such an approach, already used in the aviation industry, leads to the creation of accountability and leadership as well as the production of knowledge. It appears to bear similarities to communities of practice (Goodwin, Pope, Mort, & Smith, 2005; Weinger, 1998) and participatory design (Misumi, 1989; Salminen, 2008), both of which have also been used in industry and healthcare settings to involve workers in the improvement of their practice. It is worth considering the role of worker participation in pharmacy risk management, for example in the identification and assessment of hazards.

4.2 Interview study

As discussed in the previous section, participants alluded to the presence of risk management systems; these, which have the advantage of already being established in some pharmacies, could be used as a basis for risk-based revalidation. However, it is apparent that, even with these in place, some further governance processes may be needed.

I really don't know why [other companies don't refer pharmacists to the Society], I think they go through their process and dismiss and then think “It's not my problem”. It’s like this drunk one, who's worked for me […] she's worked for many other companies but they've not reported her to the Society, I don't know, can't speak for them but I, I don't agree with that at all […] whether they don’t want the hassle of it, or, I, I don’t know, I really don’t know, but it, it’s not right. [Superintendent, Large chain 1]

We wouldn't necessarily know that there was a concern raised about a pharmacist or a pharmacy technician unless it had been reported to the PCT because obviously within large chain companies they have their own internal mechanisms in place to take individuals to disciplinary [or] to try and help them […] by shadowing or mentoring, which I have to say I think is more difficult in community pharmacy in terms of trying to find a mentor. So as a PCT we would find out if there were problems with any pharmacist or pharmacy technician only if they were actually reported to us and perhaps a complaint came in or there'd been a number of errors that had happened and which had been reported to us. […] And I think that's one
of...that in itself I think is a risk for pharmacy that the, the fact that we don't have a mechanism in or a process in place to, to track events on an individual...

[Pharmacist, PCT 1]

The only thing I have thought about is the fact that we have a lot of our junior pharmacists [...] who also do community locums to build up extra money on top of their salary and I must admit that [...] when we've had pharmacists who've we've been concerned about their competence we've never physically said to them, “They shouldn't be doing locums” cos while we've maybe taken them off wards we really should have said to them shouldn't we...or should we have told the Society we've got concerns about this pharmacist, we're dealing with it...it would be wrong if they were then just going into a community shop isn't it...but we've never thought, I've never really thought of that...that we should really be saying to them, “Should you be doing locums if we were worried about what you’re doing here” but we've never done that but probably should shouldn’t we? [Principal pharmacist, Teaching hospital 3]

There are two issues identified here, with respect to reporting pharmacists to a governance body. The first is that the employer may consider his or her responsibility to end once a risky pharmacist has been dismissed from the company. The second, related, issue is that, as suggested in the previous section, pharmacists might be retained within the organisation but disciplined using “in-house” processes. Perhaps, as the superintendent quoted here suggests, the employer has an implicit responsibility to pharmacy stakeholders outside of the organisation (for example, the profession and other employers) to ensure that performance issues are followed up either by the regulator or by another formal body such as the National Clinical Assessment Service.

Some participants suggested the adoption of specific methods for monitoring pharmacists. These included performers’ lists, which are already used for other healthcare professions, and CPD portfolios.

When a doctor or a dentist moves into [an] area then they have to register onto the performers list when they first come into the area. They can be on a performers list somewhere else, that’s okay, but they have to be on a performers list somewhere.
And certainly as a result of being on a performers list there is I think a better mechanism shall I say to track where you know concerns have been raised because they’re on a performers list. And obviously from a PCT’s point of view it is easier to manage those individuals who may be having problems. From pharmacists and pharmacy technicians point of view there’s […] no performers list […] people are just allowed to move from one sector of the profession to another and you know move from one job to another without any real track of, of where they’ve been or you know like what they’ve done in the past, where they’ve worked in the past or whatever. So I do think a performers list is something that perhaps for pharmacy needs to be considered. Having said that with revalidation on the cards one could also argue that if revalidation is coming in then [pharmacists who are] on the register […] will have to provide evidence that they’re fit to practice. So [it] just depends [on] what happens with that really. [Pharmacist, PCT 1]

I think [that CPD could be useful]. The problem with CPD is we do it because we've got to do it and I don’t think the CPD is always targeted at areas that would improve your practice. […] So for instance, my technicians will do CPD…they all do CPD and they keep up to date with it and they’ve all done loads of entries, and they’re of a high standard and a lot of it. […] I will ask them to do a particular CPD entry because I think it’s relevant to practice today whereas if I didn’t do that I don’t know how relevant all their CPD entries would be, it might just be personal interest, which is fine but I think it also needs to be a personal interest that’s related to practice. […] I think you just need to have that combination but just let them know why they’re doing CPD and the relevance of CPD to practice as opposed to “this is a tick box exercise that you have to do to satisfy the Society”. [Pharmacy manager, Supermarket chain]

There is a general theme underlying a consideration of performers lists and CPD portfolios for performance monitoring: how should effort be distributed in a revalidation process? In a model based on performers lists, the burden is placed on individual trusts, whereas in a model based on CPD, more of the burden falls onto individual registrants. The issue of who bears the responsibility for the assessment of pharmacists was echoed in one of the focus groups, when another option – peer rating – was suggested.

Participant 1: Would it have to fall on the employer to [assess pharmacists]? Because they are the ones that know if you’re making mistakes or that kind of thing.
Peers that you don't actually work with ever, how do they know how you're performing?

Participant 2: But it would allow you to build up a better picture of somebody. So if you worked in an area and you were friendly with the local four or five pharmacists around you, and you spoke to them regularly, then those people would actually form a better picture of you.

Participant 3: That's easy to do if they all work for the same company. [...] And a number of people need to undertake that assessment. So that would be staff, that would be employers, that would be pharmacists from the same company, it would be pharmacists from the other company. It would be local doctors, nurses, dentists as well, and it would be patients. And you'd build up a picture, you don't take the word of one person, you need to actually go out and ask a number of these people. How you do that practically, I don't know. And [...] I think that you do need some screening tool in some way, shape or form, you can't do this for every pharmacist every year or however often you need to do this.

Participant 4: Do you think some companies actually know how competent their pharmacists are? When the only time they ever come across a problem is when they make a mistake? You don't know if the pharmacist is struggling but coping, or quite competently doing it easily, as long as the figures are fine and there's no complaints coming in. [Focus group 3]

It is clear that the various options for revalidation would place differing demands on pharmacy stakeholders. At one extreme, the responsibility might fall primarily to one stakeholder (for example, the regulator carrying out competency-based assessments, or the registrants maintaining a CPD portfolio). At the other extreme, the responsibility is shared across all stakeholders (for example, in the case of a 360 degree assessment of competence). One issue for consideration, then, is how much should be expected and from whom.

However revalidation is implemented, it is important to consider the extent to which any scheme has “buy-in” from the pharmacists themselves. Three possible barriers to engagement in a proposed scheme were identified in the interview data. The first was a perception that it would place an additional burden on pharmacists without any obvious benefit. The second was a perceived lack of relevance to the pharmacist’s work; this was particularly
noted by those pharmacists working in management or “back-office” roles. The third was a perceived focus of the regulator on punishment rather than support of nominally “high-risk” pharmacists.

You [fill in the monitoring form] one year and you send it off to the PCT but we don’t know what happens to it after…but if there’s a department that looks at it and says “Look, there’s a problem with this pharmacy,” then perhaps they can go there and say “Look, we need ‘this’ doing,” to address the situation, and then do it next year to see any improvement. I think that would be a better way of doing it than everyone doing a hundred and sending them off to the PCT every year and nothing happens. I can’t see the point in it because there’s no feedback. […] So this is adding a lot of workload and stress, unnecessary to me. [Pharmacy proprietor]

If you take a superintendent of maybe a chain of two pharmacies, more than likely they’re going to be working in one of them. […] The superintendent of [my] company [though] […] never really sees a customer unless he’s doing a branch visit but even then he wouldn’t be involved in the accuracy checking process or giving advice. He spends eighty percent of his time either on a negotiating body in one of the three countries that we operate in or at board level of CCA or board level of other organisations or dealing with, dealing with politics. And so I don’t quite know how you would categorise the risk for him […] If you’re saying “superintendent you need to do this”, well his role of superintendent is vastly is vastly different to the role of the superintendent that does...that has two jobs because of the, the national scale of it. [Superintendent, Large chain 2]

I’ll give you another example of somebody we’ve got, and I think this is why people maybe don’t go to the Society. This is a young pharmacist we’ve got who was off sick with depression, now, rather than speak to us about it he made the decision whilst he was off sick with depression, to let the Society know. He thought “I’m doing the right thing, I’m off with depression, I’m not fit to work, I should let them know about it.” […] They’ve been very harsh the way they’ve treated him, he’s not found them supportive in any way…he wasn’t getting the letters […] and he feels that they’ve made his health issues worse, with this constant worry of what’s going to happen and are they going to refer him to the Investigatory Committee. [Superintendent, Large chain 1]
The interview data highlight issues to consider when designing and implementing a revalidation scheme. The general point, it would appear, is that there is a range of pharmacist roles and functions, and any scheme that is put in place would need to take into account this variety. Furthermore, it would greatly assist engagement on the part of pharmacists if they believed that the scheme was of benefit to the profession.

4.3 A candidate model for revalidation

Following the literature review and interviews, the researchers proposed a model for the implementation of risk-based revalidation, which is illustrated in Figure 4.1. It has been adapted from the assessment models proposed by NAPRA (Winslade et al., 2007) and Austin et al. (2003), which were described earlier. From these, the proposed model takes the concept of a periodic screening process for selected registrants. However, unlike these, it focuses on practitioner rather than pharmacy characteristics, and (as explained later) incorporates an appraisal of the risk factors identified in Section 3. It comprises an assessment cycle in which a proportion of all registered pharmacists are subjected to an initial screen (1). This screen may involve

Figure 4.1 A candidate model for risk-based revalidation
the use of CPD portfolios or competency-based assessments such as the General Level Framework. On the basis of the screen, one of two outcomes may occur. If the pharmacist meets the set standards from the initial screen, then he or she would be allowed to continue practice for the remainder of the cycle, with a requirement to maintain CPD (2). The pharmacist would also be invited to undertake an assessment of his or her practice, and that of the pharmacy in which he or she works, with the aim of improving the profession’s and the regulator’s understanding of how to manage risk in pharmacies (4). Alternatively, a pharmacist might be found at the initial screen to fall below the required standards (3). In this case, the pharmacist would undergo a compulsory assessment; while this also has an educational component, the main purpose is a diagnostic one, in order to inform remediation measures for that pharmacist (5). These measures may include retraining, limitations on practice, a requirement to work under supervision, or another undertaking. The emphasis is on bringing the pharmacist up to a sufficient standard that he or she can resume independent professional practice; if this cannot be achieved, then a last resort would be suspension or removal from the register.

In Section 3, it was noted that an influence on perceived risk is the pharmacist’s general attitude towards safe working, but that an attitudinal measure was not included amongst the risk factors carried forward into the revalidation model. However, Reason (2004) suggests the existence of a cognitive style that he refers to as “error wisdom”. This is the ability to recognise situations that are likely to give rise to errors, and to take action to prevent errors happening. He proposes that error wisdom, if it is not already present, can be developed in healthcare professionals. At present, “foresight training”, which aims to develop error wisdom, has been implemented in nursing and midwifery (NPSA, 2008). In the context of pharmacist risk, foresight training could be applied in one of two ways. Firstly, it could be incorporated into pharmacist pre- and post-registration training. Secondly, it could be incorporated into the revalidation model described here. In the latter application, pharmacists would be required to include in their CPD portfolios a review of patient safety incidents and evidence of their learning about how to anticipate and prevent such incidents in the future. It is possible that error
wisdom – or rather, a lack of it – could itself be a risk factor, although at present it is unclear exactly how to assess it for the purpose of distinguishing high- and low-risk pharmacists. As with the knowledge, skill and attitudinal factors considered in Section 3, the measurement and validation of error wisdom as a risk factor might usefully be the subject of future research.

4.4 Review of the revalidation model

During the focus groups, an early version of Figure 4.1 was presented to the participants, who were invited to comment on its applicability to risk-based revalidation of pharmacists. In order to stimulate discussion, the participants were also presented with three “use cases” – pharmacists who were nominally high-, medium- and low-risk according to the criteria in the previous section (see Table 4.1).
Table 4.1 Examples of pharmacists with different levels of risk

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>High risk</td>
<td>This pharmacist has been registered for less than one year. The pharmacist was trained outside the UK and obtained a score of less than 7 on the IELTS English proficiency test. The pharmacist has recently left a hospital pharmacy to run a community pharmacy single-handedly. Whilst in the hospital, the pharmacist was suspended from duty for a breach of departmental policy.</td>
</tr>
<tr>
<td>Medium risk</td>
<td>This pharmacist was trained outside the UK, but obtained a score of 8 on the IELTS English proficiency test. The pharmacist has been registered for ten years, and has accrued 600 hours of patient contact time over the past three years. The pharmacist has recently returned to practice following a period of suspension imposed by the RPSGB. The pharmacist will be resuming single-handed running of a community pharmacy.</td>
</tr>
<tr>
<td>Low risk</td>
<td>This pharmacist was trained in the UK, and is a native speaker of English. Having worked for the previous ten years in a community pharmacy, the pharmacist has recently taken up a role in the management team of the same organisation.</td>
</tr>
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While being broadly in agreement with the process illustrated in Figure 4.2, which has been modified in light of their comments, the focus group participants did identify a number of issues which would need to be considered when deciding how to implement it. These issues are as follows.

*How can pharmacists be supported through the process?* Some participants raised the question of the support given to pharmacists who have been identified for the screen. If the aspiration for revalidation is for it to have an educational and professional development function, rather than be seen purely as a way of “policing” pharmacists, then this is an important matter.
How do I identify whether I’m at risk of potentially failing that screen before I get to the pass or fail of the regulator of year five? […] If I get to […] day three hundred and sixty four in year four, I should have a fairly good idea of what that regulatory decision is going to be. [Focus group 1]

I think individuals who are willing to put themselves through some of those testing processes voluntarily, most likely paying for it could bypass the system as well as in you know I’d put myself up for this test every year or every two years cos I like to do that as part of my personal development could actually be…so instead of it being a punitive approach actually turn it round the other way round and say actually proactively people put themselves through it to raise standards… [Focus group 2]

Should revalidation be a replacement for employers’ risk management?
Some participants expressed a concern that revalidation might be used to deal with performance issues that are more appropriately dealt with by pharmacists’ employers. On the other hand, though, it is possible that revalidation could be used to supplement existing employers’ schemes, and indeed there are some pharmacists (notably, sole proprietors and locums) who may not have a manager to answer to.

Participant 1: Often [health cases] aren’t picked up until it’s too late, and something’s happened or somebody’s reported something whereas the aim of revalidation would be to prevent risk. […] Participant 2: I think if you’ve got somebody who is sort of prone to health issues or has sited health issues then there’s a risk to the individual and that almost needs managing outside of revalidation. [Focus group 1]

There are lots of people…everyone, its like when they go to the Coroner’s Court, “We always knew so and so was a problem” and actually everyone goes well, “So why didn’t you do anything about it?” and I think of all the people that I’ve taken through various disciplinaries and ended up re-training them and you’ve never had enough to get rid of them you just know at the back of your mind that they’re the ones who you think, “God I wish that they had some external person who will almost keep on their back as well to try and keep their practice up to a suitable level” and if you just randomly, suddenly got a call saying, “Well we’d just like to do a quick assessment
on you” and people are aware that there is this sort of thing it might be one of those things just to improve things. [Focus group 2]

Oh yes, I mean [Chain X] has a system of professional staff outside their line management structure which picks up all the errors and deals with them and transmits them to the Superintendent’s office […] …where all the records are kept, so they would have pretty good details on every pharmacist and their performance. I don’t know what they do with them because they don’t appear to do as much as they ought to do with some of them but they’ve got it there so a big organisation I think are capable of producing that, it’s the small ones that I think are the problem. [Focus group 2]

If you work in an organisation where you have to pass an assessment for dispensing or working clinically, as a yes or a no, if it’s a yes, and have you passed it, then actually you stay above the line and you don’t just sort of fall through just sort of almost to the next sort of level that sort of comes on I think. And it may be that you actually end up asking questions about an error log that people might have. Have you thought…have you actually…do you keep an error log, has it been reviewed? I’m thinking of ways that different places use to actually try and find poor performance and then trying to re-train people. […] If I’d been a hospital pharmacist and I’d been suspended from duty for a breach of department policy, that would probably never have came through to […] the Society, and I think that’s one of the things that are wrong with the current hospital set up is that we don’t…we’re meant to, but for whatever reason you don’t report the errors going through and some of the other sort of breaches. [Focus group 2]

Specialist roles. While the process was felt to be appropriate for many pharmacy roles, some participants pointed out that there are specialist roles that cut across different healthcare professions – notably, independent and supplementary prescribers. It is possible that regulation of these roles is carried out outwith the pharmacy regulator, or that the regulators of the different professions involved in prescribing adopt a common process.

Participant 1: Do you think you know people with, with specialist roles like prescribing status, ought to be regulated differently?
Participant 2: Well I think there needs to be some re-assessment. I think whether it’s an OSCE based sort of process that we did [...] but I think there should be some regular revalidation probably of those, probably even more than being a registered pharmacist.

Participant 1: But that should be common with other prescribers you know in terms of you know, everybody who’s got prescribing rights ought to have the same competency based, you know, revalidation regime in place to assess that. So for instance the medics, you know, the nurses, how…? [Focus group 2]

A non-practising register? One option, that is currently in use in Canada, is to maintain a two-part register. Those who are in patient-facing roles – “practising” pharmacists – would be on one part of the register, and subject to closer scrutiny (as reflected in the risk criteria adopted in this study). Meanwhile, those who are “non-practising” (for example, those in managerial or industrial roles) would be on the other part of the register and subject to less scrutiny. There were mixed views amongst the participants as to whether such an arrangement would be of use to them.

We’re looking at revalidation and what we ought to be looking at is the science behind that, what are the privileges I get for being a pharmacist, what would the public, the patient, the profession reasonably expect me to get up and do to exercise those privileges and if what I do doesn’t require me to exercise those privileges, should I be a pharmacist? [Focus group 1]

A pharmacist who’s dispensing all day is more of a patient risk but they’re still as much of a pharmacist as a pharmacist who’s not in a patient facing role. So they, they…I think it may be difficult to focus the regulatory process on dispensing pharmacists, patient facing pharmacist’s proportionately more than non patient facing ones. I think I might feel uncomfortable with…dispensary staff are constantly being caught. [Focus group 1]

Participant 1: I would always consider myself practicing pharmacy but would I still be, in ten years time now, or twenty years have to be on the register, still would I be able to do that because that doesn’t…I have no intention of walking into a pharmacy tomorrow. […] I like the GPhC’s ruling that a pharmacist is a pharmacist is a
pharmacist, and so, but I don’t know if a knowledge based test would be…I think I’d be alright because I passed the MUR assessment in one go without practicing community pharmacy, so I think I’d be alright, but I wonder if others would be.

Facilitator: So do we favour this model? But you’re still pharmacists and you’re on the register, it’s just that you’re not patient facing…and those that aren’t patient facing […] should they for instance [have to undertake] a knowledge based assessment?

Participant 3: But there are some people…I suppose if you look in the hospital sector and some of the others, there are those people and people who work in medicines information in industry or things like that, who ‘do’ make I have to mention a lot of clinical type of thought process and decision making, either be going through a drug and therapeutics committee and to actually talk through, looking at the evidence based pros and sort of cons, and it’s an indirect patient contact isn’t it, in sort of some ways? [Focus group 2]

The data from the focus group echo, in part, issues identified in the literature and the interviews; the overriding concern, it seems, is to have a revalidation scheme that is seen to deal with all parts of the profession in an equitable manner. Hence, where pharmacists are being treated differently on the basis of supposed risk, such decisions need to be transparent and robust. In addition, there should be an emphasis on professional development as well as on minimising the opportunities for “substandard” practitioners to inflict harm.

4.5 How frequently should revalidation be undertaken in order to manage risk?

A final research question, which has not yet been discussed in this report, is defining the frequency and intensity with which revalidation should be undertaken in order to manage risk. There is a paucity of published empirical evidence from which to answer this question, and study participants found it difficult to define what might be an appropriate frequency, given the novelty of revalidation to the British pharmacy profession. Instead, the authors have used existing healthcare revalidation schemes, both in the UK and overseas, to provide a yardstick. Across Western Europe, Australasia and North
America, the time gap between revalidation assessments of medical practitioners varies between one and 10 years, but the modal period appears to be five years (Dauphinee, 1999; Newble, Paget & McLaren, 1999; Norcini, 1999; Southgate & Pringle, 1999; Winkels, 1999). In New Zealand, pharmacists are currently required to undergo revalidation once every three years (Dr Owain George, Pharmacy Council of New Zealand, Personal Communication, 22 Dec 2009), while in Ontario, 20% of registrants are selected for revalidation each year, and so each registrant can be expected to be revalidated once every five years (Austin et al., 2003).

The authors, therefore, suggest that in the first instance, revalidating each pharmacist once every five years would be consistent with practice in other professions and countries. However, a major theme of the current study has been to explore how the intensity of revalidation might be informed by differences in the level of risk posed by individual pharmacists. Accordingly, in Section 3, a set of criteria was generated for distinguishing between high- and low-risk pharmacists. The authors suggest that, in order to adjust the intensity of revalidation to account for levels of risk, the period between assessments should be reduced for those participants who are designated “high” risk according to the criteria; a period of three years is consistent with the standard period used in New Zealand. In addition, it is suggested that pharmacists who either are actively engaged in managing their own risk (for example, by engagement in CPD or the foresight training described in Section 4.3), or whose pharmacies have comprehensive risk control measures, may not require as intense a revalidation regime from the regulator as others. They could, for example, receive some form of dispensation in terms of the timing or content of the revalidation assessment.6 In deciding whether three- and five-year intervals would be suitable in practice, the projected costs of running programmes with these intervals, in relation to the perceived benefits,

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6 The authors note that the use of CPD and employer resources, such as appraisal, in revalidation has been examined in more detail by other studies within the RPSGB’s Revalidation Research programme.
would need to be considered carefully by those who are responsible for implementing revalidation.

A further observation might be made at this point, with regard to intensity of revalidation. As shown in Section 2, “harm” in pharmacy practice can take a number of forms. It is likely that some of these are more amenable to practitioner revalidation as a risk control measure than others. Conversely, others are comparatively infrequent and difficult to detect. One such example is deliberate malpractice of the kind identified in the Shipman Inquiry; Dame Janet Smith (Secretary of State for Health, 2004) concluded that had clinical governance procedures such as the ones proposed in this report existed at the time, then they would have been unlikely to have detected Shipman’s behaviour, given the apparently high standards of his practice. The point is not that revalidation is without value, but that its implementation should be based on a realistic appraisal of what it can achieve (Bevan, 2008). For example, should the regulator wish to create a more intensive scheme, then additional indicators such as dispensing or incident rates, or even psychological screening, could be included (e.g. Allsop & Jones, 2006; see also Table 2.1 of this report). However, this comes at the cost of greater resources and effort, and potentially a high number of “false positives”, with possibly little extra benefit in terms of reducing harm. The authors of this report have focused on providing a scheme for the purposes that revalidation has been argued to be best suited:

“I do not think that clinical governance will ever be the method of choice for detecting deliberate malpractice. Those who deliberately do wrong usually take steps to cover their tracks. The usefulness of clinical governance is to be found, in my view, in what it discovers about doctors who are not performing badly on purpose and who may be quite unaware that their clinical performance is poor.” (Secretary of State for Health, 2004, paragraph 12.143).

4.6 Summary

This section has considered the purpose of risk-based revalidation and methods that could potentially be used to carry it out. There is variation
across Europe and North America in terms of healthcare revalidation; however, there are established assessment frameworks that could be adopted for use in revalidation. A particularly promising approach is that currently used in parts of Canada, which is based on periodic CPD reviews and competency assessments. In this section, a similar model has been proposed for risk-based revalidation, incorporating the risk assessments introduced in the previous section.

The interview and focus group data highlight issues that need to be considered when implementing risk-based revalidation of any kind. These appear to cluster around two main themes. Firstly, there is a need to ensure that the scheme can be applied to all pharmacist roles and functions. Secondly, there is a need to ensure that the scheme is seen to contribute to development of the profession, rather than a mere barrier to participation in it. Therefore, it is crucial to involve pharmacists and their employers in the design and implementation of a revalidation process.
5. Conclusions and recommendations

5.1 Conclusions

5.1.1 Defining risk in pharmacy practice

In many professions and industries, the notion of risk is one that, whilst intuitive at face value, is in practice difficult to define fully. Pharmacy is no exception: it has a variety of stakeholders, most obviously patients and the general public, but also the healthcare profession itself. Any or all of these could be harmed in some way by pharmacy practice, and so all need to be incorporated into a definition of pharmacist risk. This study has offered a definition based on a review of the literature and the authors’ own empirical data. The authors believe it to encompass the various forms of pharmacy practice, the stakeholders involved, and the different ways of conceptualising risk (for example, whether it is expressed in terms of risk probabilities or of beliefs about which risks “matter”). The ultimate value of the definition offered will be its conceptual and practical application to risk management.

5.1.2 Identifying areas of high risk and factors that distinguish high risk from low risk practice

Several potential risk indicators were identified using both previous studies of healthcare regulation and empirical data collected as part of the current study. With regard to areas of high risk, a review of the RPSGB’s disciplinary records suggested that, while both hospital and community pharmacists were more likely to face disciplinary action than were pharmacists working in other settings, a stronger effect was found for community pharmacists. At face value, it could be inferred from this finding that community pharmacy poses a greater risk, and indeed there are features of this setting which possibly predispose pharmacists to greater risk – notably, the greater likelihood of solo working. However, this finding needs to be viewed in the context of the pharmacy population: not only are there greater numbers of community pharmacists in the population, but hospital pharmacists are often more likely to be subject to comprehensive “in-house” performance management
processes, potentially reducing the need to involve the pharmacy regulator. Similarly, within the hospital sector, activities that are nominally “high risk”, such as chemotherapy and aseptic preparation, often have more strict controls, such as procedures and competency requirements. Advanced and specialist areas of practice are relatively uncommon and are not always defined in a consistent manner; hence they are also difficult to identify as being consistently higher or lower risk than standard pharmacy practice (cf. Royal Pharmaceutical Society of Great Britain, 2009c).7

A number of practitioner characteristics have been suggested as being potentially related to risk across different practice settings. However, some of these are quite broad, and as such do not have a clear conceptual link to risk (that is to say, they do not obviously distinguish between “high risk” and “low risk” pharmacists). Others do appear to have a direct connection to risk, but are difficult to assess. For example, a key factor identified by interview participants was the level of familiarity a pharmacist was perceived to have with his or her working environment; there is a clear conceptual link between this factor and risk, but it is difficult to determine how it would assessed in practice. Hence, only a few of the characteristics have been used to develop a framework for assessing pharmacist risk. This framework, shown in Table 3.5, is proposed as a basis for identifying high-risk pharmacists. However, as a caveat it should be noted that these indicators are based on the best available evidence, and it is highly desirable to validate them further through empirical work. In addition, some practitioner characteristics have been suggested for potential future use as risk indicators, subject to a workable assessment method being developed. These include knowledge and skills, attitude, and engagement with continuing professional development.

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7 A recent study by Hassell et al. (2010) found that the perception of what constituted “performance concerns” differed between hospital and community pharmacy; for example, behavioural, attitudinal and communication problems were more salient concerns for hospital trusts than for primary care trusts. They also found that within the community sector, the nature and extent of proactive performance management measures differed between organisations.
While the emphasis was on practitioner characteristics, this study highlighted the role of work system and organisational characteristics in shaping pharmacist risk. It is worth reflecting on the implications for a practitioner revalidation scheme of acknowledging such “contextual” factors. As outlined earlier in this report, the stated objective of regulatory reform is to improve quality and safety in healthcare. Insofar as meeting this objective requires improved quality assurance of practitioners, risk-based revalidation can, as has been demonstrated in this report, make an important contribution. However, there is a limitation to revalidation: having being revalidated and so declared fit to practice, the practitioner is then required to work in situations that are at times complex, uncertain and possibly inherently risky. To take just one example from the many that have been discussed in this report, one can verify that a paediatric specialist has up-to-date knowledge (according to what is understood at the time of revalidation to constitute “up-to-date”) and that the practitioner meets other risk criteria such as having a suitable level of English proficiency. However, the nature of paediatric medicine, for reasons that lie outside the scope of individual revalidation, is such that the pharmacist can find him- or herself working with off-licence medication (Shirkey, 1968; Neubert et al., 2004). Clearly, in such a situation, a pharmacist with sound knowledge of paediatrics is less risky than one without – but will not be completely without risk solely by virtue of having met revalidation standards.

Where does this argument leave a revalidation scheme such as that proposed in this report? It is, perhaps, a challenge to incorporate work system and organisational characteristics into an assessment of individuals, although as described in Section 4, some assessment schemes do attempt to incorporate pharmacy as well as pharmacist characteristics. In any case, though, it is essential to take the pharmacist’s work context into account. Not only will this minimise the number of “false positives” identified as being high-risk, but it will also avoid overreliance on person-specific versus organisation- or systems-
based approaches to risk management (Lucas, 1992; Reason, 1997). Hence, there is potential scope for combining the data from pharmacist assessments with that obtained from the regulator’s pharmacy visits. Methods for doing so might usefully become the focus of future work in the development of revalidation processes.

5.1.3 Developing a method for assessing risk

There are several approaches currently in use across Europe and North America for revalidation and performance assessment. From these, the authors have composed a candidate model of risk-based revalidation. This aims to bring together existing assessment approaches (specifically, CPD and competency-based assessment) with the risk criteria identified as part of the current study. An initial evaluation of this model by subject matter experts suggests that it could potentially be used as a basis for risk-based revalidation. It appears to be applicable to different areas of pharmacy practice, and to facilitate professional development as well as regulation.

However risk-based revalidation is implemented, there are a number of issues that have been raised by participants. Generally, these reflect a concern that any scheme that is used should deal with all members of the profession in a fair and supportive manner, and should provide a benefit to the members of the profession as well as to the regulator and society at large.

5.2 Recommendations

5.2.1 Recommendations for policy and practice

In conceptualising pharmacy risk, the authors suggest using the definition provided in Section 2.5: “the potential for harm to occur to the pharmacy workforce, their organisations or the recipients of their services, as a result of pharmacists’ activities”. In particular, the authors would encourage those who carry out risk management activities to consider whether the sources of harm depicted in Figure 2.3 and Table 2.2 are being addressed.
The criteria described in Section 3 (in particular, those summarised in Section 3.5 and Table 3.5) are recommended as a basic framework for identifying “high risk” pharmacists. Regardless of the criteria used, though, it is particularly important that risk assessors can make a clear and unambiguous link between each criterion and risk, at least in concept if not on the basis of evidence (ideally, however, the case should be made on both grounds). This report has provided initial evidence for the criteria presented in Table 3.5, which nevertheless merit further validation work. The authors recommend that, the pharmacist’s work context is also taken into account in any assessment, for example by combining the findings from pharmacy visits into the assessment of individual pharmacists who work within the pharmacy.

The model provided in Section 4.3 is recommended as a framework for risk-based revalidation. This process could be applied to a proportion of professional registrants during each assessment cycle. The risk criteria described earlier are recommended as a means of deciding on the interval between cycles for each registrant (that is, the frequency of revalidation). However the model is implemented in practice, attention should be given to the “buy-in” from pharmacy stakeholders, including pharmacists themselves. Hence, it is recommended that revalidation is designed on a participative basis, with input from the various pharmacist roles that will be subjected to the scheme.

5.2.2 Recommendations for research

This study has drawn from risk research literature across the healthcare professions, as well as generating insights from new empirical research. In doing so, it has provided a basis for understanding how to identify and manage risk in pharmacy practice. However, there remain knowledge gaps, and it is recommended that these be addressed through further research.

A general agenda for research is illustrated in Figure 5.1. Within this agenda, a number of specific items for research can be identified as follows.

Disciplinary record data. As described in Section 3.3, the review of disciplinary record data conducted for this study was limited by restrictions in
the dataset available for analysis. It is recommended that the analysis be repeated with a larger sampling frame (for example, all registrants referred to the Investigating Committee). In addition, it would be useful for more data to be routinely collected from registrants (for example, the pharmacist’s location of employment); in future, it may be possible to link such data with records from undergraduate study or initial training for research purposes (cf. Papdakis et al., 2005; 2008).

Risk assessment criteria. Future research should address two issues. The first is to provide further evidence of the relationship between the identified risk factors and a measure of risk (for example, a subjective risk rating, or referral to the regulator or to NCAS). The second is to investigate the use of the additional risk factors identified – these include health and stress, engagement with continuing professional development, and knowledge, skill and attitudes. With respect to the latter, evidence to suggest the presence of “hazardous attitudes” in pharmacy is presented in Appendix A.

Implementation of risk-based revalidation. Three key issues are identified here. The first is to investigate methods by which assessment of individual registrants can be integrated with assessment of the registrant’s work context for the purpose of revalidation. The second issue is the feasibility of using existing risk control measures, such as in-house risk management systems and resources such as the National Clinical Assessment Service, to contribute to revalidation processes. Finally, the potential for integrating revalidation with other methods of risk management, for example “foresight training”, should be examined.

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8 It is noted that the National Clinical Assessment Service (2010) has developed methods for assessing the performance of pharmacists, for example workplace based assessments. It is recommended that the potential use of NCAS resources to conduct the initial screen phase of the revalidation model is investigated.
Figure 5.1 An agenda for future research in risk-based revalidation

Social, economic and cultural context

Stakeholders
Governance

Practitioner → Task → Setting

Risk assessment
Nature and sources of risk
Risk indicators
Assessment methods (prospective analysis; retrospective analysis; risk rating)

Revalidation
Methods
Content
Implementation

Risk management
Identification
Prediction
Control
6. References


Appendix A. Supplementary data: hazardous attitudes and pharmacist risk

The interview data suggests the presence of attitudinal factors that might predispose certain individuals to riskier practice than others. These attitudes are presented and discussed here, and warrant further examination to determine their prevalence and relationship with risk amongst the pharmacy workforce (see for example Gaba et al., 1994; Strip e et al., 2006).

“Macho”. This is described in Federal Aviation Administration (1991) as a desire to create the impression of being capable (e.g. “I’ll show you I can do it”). In a pharmacy context, participants felt that some degree of confidence in one’s ability was necessary, but that there was a danger of being overly confident to the extent of taking unwarranted risks.

I think the most risky thing is over-confidence. People who think they know more than they do, definitely. Sometimes you, kind of, know junior people who are like that, who are a big worry, but also very senior people […] [They] need to make themselves look good and will say anything even when they’re not sure, they won’t kind of go and check and back up the facts. So they’re the most risky people. [Pharmacist, Teaching hospital 1]

When we have a new batch of juniors, the ones who worry me most are the ones that are very over confident because […] they kind of think that they know better and they […] might not have a lot of experience but they think they know what they’re doing. […] I think you need to have a degree of caution […] [and] think carefully about what [you’re] doing and what you want. […] You don’t want those ones who just go, “Yeah, yeah, yeah I know what I’m doing that’s fine” [Principal pharmacist, Teaching hospital 3]

“Invulnerable”. The FAA describes this as a perception that one’s activities will not have any adverse consequences. Again, when a pharmacist displays such a level of invulnerability as to lack cognisance of potential hazards, he or she is likely to be a more risky practitioner.
What makes a pharmacist high risk? One that thinks they don’t make mistakes. One that thinks they don’t need a second check, because they’ve always done that and they’re fine with it. That’s what makes someone high risk. [...] You get some pharmacists that are a bit blasé, and will just sign things off. [Technician, Teaching hospital 2]

Sometimes we have pharmacists who are not...cautious is not the right word...but you know what I mean, I think you should take into full account of the significance of what you might be doing. And somebody who doesn’t have experience in an area but thinks, “Oh yeah I can muddle through I roughly know what I’m doing” you don’t...that kind of person I think can be quite risky. [Principal pharmacist, teaching hospital 3].

“Anti-authority”. This was also identified in the FAA’s work as an aversion to following established policies: “don’t tell me what to do”. While there may be circumstances in which it is appropriate – or at least, adaptive – to deviate from established protocols (Reason et al., 1998; Phipps, Parker et al., 2008) this can, whether justified or not, engender increased risk in the pharmacist’s practice.

You have those people that you would class as innovators and they’re quite risky pharmacists I think in some ways, because they are trying to do new things, they’re trying to work in new ways and they’re trying to think of ways to cut corners and sometimes they can be quite a risky group of individuals because they may not follow the normal procedures and those procedures have been brought in to have safe ways of doing it. [...] They worry me as a manager because I worry about what systems have they set up themselves that maybe don’t follow the old safety things and they’re maybe cutting corners. [Technician, Teaching hospital 2]

Sometimes they can be quite mouthy, but not questioning, there’s a difference between asking the ‘why’ question, you know ‘why do you do that’ scenario to actually being forcibly not engaged with the process. [Pharmacy manager, Teaching hospital 3]

“Resignation”. Also from the FAA’s work, this refers to a view that a particular process is outside of one’s responsibility or control. As discussed in Section
3, in a complex system such as pharmacy it may well be the case that a given individual is not wholly culpable for any events that occur despite being at the “sharp end”. However, a resigned attitude may lead to the pharmacist failing to recognise when he or she could take responsibility for averting a problem.

Sometimes [...] they’ve not particularly focused on the process so we have an SOP that says “You must sign the signature box on the label to show that you’ve accuracy checked it.” Because sometimes it just sort of gets thrown into a bag. When an error comes back sometimes we get “Well it wasn’t me.” you know, or “If it was me, I’ve got insurance.” [Superintendent, Large chain 2]

[He] didn’t care about the job. [...] There were a couple of errors [which were detected and corrected]. The errors were simple ones, but he wasn’t very bothered about them. [Technician, Independent pharmacy]