Revalidation in Pharmacy: Evaluation of appraisal and alternative sources of evidence

Volume 1: Main report

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Abstract

Following a number of high profile cases highlighting failures in doctors’ competence and performance, and the subsequent publication of ‘Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century,’ systems of revalidation are to be implemented for all healthcare professionals. Revalidation has been described as a mechanism that allows health professionals to demonstrate that they remain up-to-date and fit to practise, thus ensuring public trust and safety. Different approaches to revalidation are possible and, whilst Continuing Professional Development (CPD) is likely to form a key element, other sources of evidence are possible. The use of appraisals, for example, is being implemented for doctors, and there are other more pharmacy specific structures which may also play a role.

Project aims

The aim of this project was to evaluate the use of appraisals and alternative sources of evidence for the purpose of revalidation in pharmacy in Great Britain. The objectives were to:

- Gather information on existing structures, processes, and items covered in appraisals implemented in the main sectors in pharmacy, and explore the views of pharmacy employers on if, and how, appraisals could feed into revalidation in future;
- Explore other possible sources and structures for evidence gathering for the purpose of revalidation, which already exist in pharmacy
- Examine the views of practising pharmacists and registered pharmacy technicians working in all sectors on assessment methods and processes for the purpose of revalidation – in England, Scotland and Wales;

Methods

A mixed-method design, combining qualitative and quantitative methods, was used. Semi-structured interviews and/or questionnaire surveys were conducted with pharmacy employees and employers in different sectors providing NHS services (i.e. community pharmacies, hospital trusts, primary care organisations), in the sector of academic pharmacy teaching (i.e. schools of pharmacy), and in the pharmaceutical
industry. Those involved in other processes of relevant evidence gathering (i.e. the RPSGB Inspectorate and PCT contract monitoring) were also interviewed.

**Key findings**

**Revalidation standards:** A clear understanding of what revalidation is and involves will require clear standards against which any assessment would have to be made. The current lack of these had implications for respondents’ ability to comment on revalidation and the potential usefulness or adaptability of existing systems, such as appraisals or inspection and contract monitoring processes.

**Employer appraisals:** Despite employer appraisals being widespread in all sectors involved in this study, those who were not employed, such as locums or independent pharmacy owners, did not fall under these management and appraisal structures. Appraisals commonly focused on performance specific to the sector or organisation in question. In community pharmacy and the pharmaceutical industry, there was a clear focus on business targets; in academia, the focus was on academic performance. Issues of clinical or professional performance did not commonly feature, other than in primary and secondary NHS organisations involved. Appraisals as well as inspection and monitoring visits were seen as supportive and formative, which created a potential conflict with a more summative assessment approach.

**The appraiser/assessor:** There were some differences of opinion as to who should be responsible for an individual’s fitness to practise, with many stressing the individual’s own responsibility. Respondents also raised concerns about their own ability to assess another individual’s fitness to practise, and acknowledged requirements for appropriate training and consistent, objective and fair approaches. The importance of role understanding was raised, so was whether an appraiser or assessor would need to be a pharmacy professional. Overall, the varied nature of pharmacy and its different sectors was acknowledged, as well as the difficulties this potentially poses for revalidation.

**Premises versus individuals:** The main issue with inspection and monitoring processes was that they are geared towards pharmacy premises rather than individual pharmacy professionals. Apart from some exceptions where individuals and premises may be relatively closely linked, such as owners, these systems did not appear to be easily adaptable to revalidation, other than to support employers and governance.
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Finally, we would like to thank the individuals in all the different stakeholder organisations who agree to be interviewed or took the time to complete a survey. Without their help and willingness to share their experiences and views, this study would not have been possible.
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Chapter 1 – Introduction

1.1 Background and study context

Over the last decade, high profile medical cases such as the Bristol\(^1\) and Shipman\(^2\) Inquiries have highlighted failures in doctors’ competence and performance and called for the introduction of a system of regulation for all healthcare professionals. This recommendation was recently reiterated in the reviews by Donaldson\(^3\) and Foster,\(^4\) who independently reviewed the future regulation of doctors\(^3\) and other non-medical healthcare professions.\(^4\) These recommendations resulted in the White Paper ‘Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century.’\(^5\) This – with the aim of ensuring health professionals, including pharmacy professionals, do not pose a risk to patients, and to maintain public confidence and trust – set out a programme of reform for the future regulation of all healthcare professionals within the United Kingdom (UK). The White Paper outlines the need for professional regulators to be independent and impartial in their actions, and they are charged with:

- Setting standards for admission to, and remaining on, the professional register
- Maintaining a record of registrants who meet, and continue to meet the standards
- Dealing with allegations of impaired fitness to practise
- Ensuring high standards of education for the health professionals that they regulate

To address the first of the above points, the White Paper\(^5\) tasks all UK health professional regulatory bodies with putting arrangements for revalidation in place. Through this, all registrants would be required to periodically demonstrate their continued fitness to practise. Whilst being quite specific with regards to the revalidation of doctors, the White Paper is less so on revalidation arrangements or systems for other healthcare professions, including pharmacy. It does, however, stipulate that such arrangements are likely to involve evidence provided as part of the
normal staff management and clinical governance systems, i.e. appraisals. This would particularly apply to those working in an NHS organisation, with employers providing recommendations to the professional regulator. The White Paper continues that “for those, including self-employed contractors, performing services commissioned by NHS primary care organisations” (such as community pharmacists), “the revalidation processes will be carried out under the supervision of either the NHS commissioning organisation […] or the regulatory body.” In either case, revalidation should be carried out in collaboration between the two bodies.

According to the White Paper, the appraisal process will be a central component of revalidation and should be both formative and summative. It can thus be ensured objectively that required standards are met. The White Paper also endorsed a recommendation in the Foster review (reviewing the regulation of non-medical healthcare professionals, including pharmacists and pharmacy technicians), that information gathered under the Knowledge and Skills Framework (KSF) be used where possible as the basis of revalidation.

The Royal Pharmaceutical Society of Great Britain (RPSGB), as the current regulatory body for pharmacy professionals, has thus been charged with implementing a system of revalidation, which has not previously existed. The time scales for implementing revalidation vary from each profession with medics aiming to be one of the first to introduce it from 2011. Besides no specified timescales in pharmacy, there are also currently no specific standards against which pharmacists and pharmacy technicians could be assessed. Furthermore, no specific recommendations on how revalidation should be conducted were made. However, the RPSGB have proposed a number of options available for revalidation of pharmacists and pharmacy professionals. Proposed models include the use of continuing professional development (CPD) portfolios and their monitoring and assessment, the use of appraisals, or indeed other sources of evidence, for the purpose of revalidation. As the RPSGB have commissioned a research study to inform the potential use of CPD for revalidation, we will not delve into this element further at this point, but focus on those sources of evidence which are the focus of this report.
1.1.1 Appraisals

The use of appraisals forms an important strand in the portfolio of evidence likely to be used by UK doctors for revalidation.\textsuperscript{8,9} Appraisals have also been suggested by the RPSGB Revalidation Advisory Group’s report to the Department of Health ‘a draft model for revalidation in pharmacy’\textsuperscript{7} as one possible model for revalidation in pharmacy. However, little is known about the use of appraisals for pharmacy professionals in all sectors, their content, structure and the extent to which they might lend themselves to a system of revalidation. Furthermore, there is likely to be considerable variation in the use and focus of appraisals in the different sectors. This is likely to be the case particularly in the private sector of community pharmacy, but also the pharmaceutical industry, where a focus on performance targets may be predominant. Furthermore, there may not be common or regular approaches to appraisals across the different sectors, in particular in community (the biggest sector in pharmacy). Willingness for commercial organisations to incorporate issues of revalidation into their own procedures may be limited. It is therefore important to also consider alternative existing structures, which may have the potential to be adapted for the purpose of revalidation.

Pharmacy professionals employed within NHS organisations, i.e. hospital trusts and primary care organisations, are likely to undergo appraisals based on the Knowledge and Skills Framework (KSF).\textsuperscript{6} Again, little is known about its use for pharmacy professionals, and its potential adaptability for revalidation. Nevertheless, Foster,\textsuperscript{4} when reviewing the regulation of non-medical healthcare professionals, including pharmacists and pharmacy technicians, recommended for NHS staff and self-employed staff providing NHS services a system of revalidation based on the NHS KSF. Indeed, general information on the use of appraisals and the KSF for different healthcare professions suggests that, despite varying implementation across NHS organisations, the KSF may offer benefits for the development process of revalidation.\textsuperscript{10}

Appraisals are commonly the responsibility of the employer. However, not all pharmacy professionals, pharmacists in particular, are employees, so may not fall under any appraisal system. Even though corporate ownership has increased over
recent years, a significant number of community pharmacies remain in independent ownership, where pharmacist owners may be less likely to undergo appraisals. Furthermore, a large proportion of pharmacists are self-employed and many work as locums.\textsuperscript{11} Many may therefore not undergo formal appraisals within the organisations where they work or through the agencies which may be involved in their recruitment. Additionally, it is not uncommon for pharmacists to work in more than one sector, often referred to as portfolio or multi-sector working,\textsuperscript{11} and they may not undergo an appraisal either within each one, or covering all sectors.

\subsection*{1.1.2 Other sources of evidence}

Besides CPD and appraisal systems, there are a number of other sources of information that could be used as evidence for fitness to practise and revalidation in pharmacy. In the community sector, the largest within pharmacy, there are two existing systems and structures through which information is currently being collected on pharmacy premises and/or delivery of services. They are the RPSGB inspectorate\textsuperscript{12} and, in England and Wales, contract monitoring of community pharmacies through primary care trusts (PCTs)\textsuperscript{13} and Local Health Boards (LHBs).\textsuperscript{14} These organisations do not undertake appraisals as such, but routinely produce other inspection or monitoring reports, which could be adapted for use as other sources of potential revalidation evidence. Inspectors currently inspect registered pharmacy premises (mainly community pharmacies), and PCT staff in England monitor service delivery under the community pharmacy contract. Both involve site visits, and there may be scope for extending the remit to also undertake some revalidation assessment of registered pharmacy staff.

With any of these sources of evidence, it will be important to explore what information is currently collected and how, and whether any of it lends itself to revalidation. It is also important to explore this from the perspectives of the different organisations involved in collecting the respective pieces of information, as well as from those who will be undergoing revalidation, i.e. pharmacists and pharmacy technicians.
1.2 Aim and Objectives

The aim of this project was to evaluate the use of appraisals and alternative sources of evidence for the purpose of revalidation in pharmacy.

The objectives were to:

- Gather information on existing structures, processes, and items covered in appraisals implemented in areas of pharmacy providing NHS services (i.e. hospital trusts, primary care organisations and private sector community pharmacies), in the sector of academic pharmacy teaching (i.e. schools of pharmacy), and in the pharmaceutical industry – in England, Scotland and Wales;
- Explore the views of pharmacy employers on whether issues of revalidation form part of current appraisal systems (if in place) and their views on incorporating such issues in future;
- Explore other possible sources and structures for evidence gathering for the purpose of revalidation, i.e. the Royal Pharmaceutical Society of Great Britain (RPSGB) inspectorate in Great Britain, and community pharmacy contract monitoring through primary care trusts (PCTs) in England;
- Examine the views of practising pharmacists and registered pharmacy technicians working in all sectors on assessment methods and processes for the purpose of revalidation – in England, Scotland and Wales.

1.3 Contextual constraints

Relatively little is known about the use of appraisals as sources of evidence for revalidation in the health care professions, and this is particularly the case in pharmacy. It was therefore important not to impose our own pre-conceived ideas or assumptions on the structure within which appraisals are conducted (or not), the process and content of appraisals, or the views of those who would potentially be involved in either implementing them, actually conducting them, or those who will be subject to revalidation and related appraisals. We therefore opted for a multi-method
approach, which involved in-depth qualitative work as well as some survey work which aimed to quantify findings. Drawing on different data sources from different stakeholder groups has allowed us to triangulate and compare findings, thus lending particular strength to our analysis and subsequent recommendations. Documentary evidence of existing appraisal forms, as well as procedural guidance covering appraiser training, appraisal process, performance indicators etc., was also gathered from employers where possible, to underpin the related interview and survey data.

In the qualitative parts, we conducted semi-structured interviews with a selection of those stakeholders who are likely to have a role in appraisal processes, particularly those potentially relevant or useful to revalidation in pharmacy. There are two main groups: i) those who will be the subjects of revalidation, i.e. practising pharmacists and registered pharmacy technicians, and ii) those who are (or may be in future) involved in managing the implementation or collection of information to inform revalidation. Where this information relates to that collected during appraisals, we identified relevant stakeholders as employers of practising pharmacists and registered PTs in different sectors. Where information potentially relevant to revalidation may come from other sources, we specifically identified those undertaking monitoring or inspection of service delivery or premises.

Employers of pharmacists and PTs delivering patient services are either NHS trusts, who are likely to undertake appraisals within NHS relevant frameworks (i.e. knowledge and skills framework (KSF) in NHS trusts, i.e. PCOs and hospital trusts) or private sector employers (i.e. community pharmacies – independent contractors, small to medium size chains, national multiples and supermarket pharmacies). Self-employed pharmacists, such as locums, were also included (themselves and through their agencies). Furthermore, practising pharmacists and pharmacy technicians are also employed in other sectors (generally without direct patient contact), and two main sectors here are the pharmaceutical industry and academia, particularly schools of pharmacy.

Some other groups of pharmacy employers may not have been captured, such as, for example professional and/or regulatory organisations, such as the Medicines Control Agency, or the RPSGB, or other non-pharmaceutical industries. Academic
institutions or further education colleges who were not schools of pharmacy, yet employ pharmacy professionals, were also not specifically included. Even though the majority of pharmacists and pharmacy professionals work in sectors providing NHS services, i.e. community, hospitals and PCOs, a notable proportion do not. Even though the majority of them work as employees, self-employment (locums and independent ownership) is not uncommon. They also work in many different roles, sometimes in the form of portfolio working.

We are, however, confident that we have included key pharmacy employers and would suggest that some of the features encountered in these organisations may be present in those not captured here. Furthermore, we conducted a large, representative survey of pharmacy professionals in all sectors, thus getting a representative view from all who would be undergoing revalidation. The benefit of the other, mostly qualitative, parts, has been to gain an in-depth insight and understanding about the use of appraisals and other existing sources of evidence from employers, contracting organisations, and other agencies.

1.4 Report overview

This report is organised in two volumes: Volume 1 contains the main report; Volume 2 contains all supporting evidence, or in other words, presents the detailed analyses of the individual study parts.

Volume 1 of this report has the following structure: Following a general introduction in this chapter 1, chapter 2 reviews the existing literature and some relevant policy documents to describe a framework for revalidation, with particular emphasis on potential sources of revalidation evidence (the focus of this study) rather than possible systems and structures of delivery (addressed in another work stream). Chapter 3 provides detail on the design and methodology employed in this project. Chapter 4 contains a summary of key findings based on the individual study parts. Chapter 5 discusses the findings and compares them across the different study parts. This interpretation will help set the backdrop for our main conclusions and recommendations, which can be found in chapter 6.
As mentioned previously, a more detailed presentation of the findings from the individual study parts can be found in Volume 2, which contains the following individual sections:

1. Secondary analysis of a survey of a random sample of registered pharmacists and pharmacy technicians in England, Scotland and Wales, exploring their views on revalidation criteria and assessment;

2. Semi-structured telephone interviews with community pharmacy stakeholder representatives (employers, owners, locum agencies and pharmacy technician (PT) stakeholders) in England, Scotland and Wales;

3. Semi-structured telephone interviews with stakeholder representatives from the pharmaceutical industry;

4. Semi-structured telephone interviews with stakeholder representatives from schools of pharmacy;

5. Surveys of NHS pharmacy employers in England (Scotland and Wales): acute hospital trusts and PCTs; and

6. Semi-structured telephone interviews with the chief inspector, regional lead inspectors and a sample of RPSGB inspectors from each region; and with PCT staff involved in contract monitoring.
Chapter 2 – Literature Review: Revalidation in pharmacy

Before embarking on a review of the literature relating to revalidation in pharmacy, and particularly the use of appraisals and other sources of evidence, we define what revalidation actually means. Furthermore, we emphasise the importance of clearly defined and transparent standards, as any assessment needs to be made against these. One important aspect is that standards remain current and that registrants demonstrate that they meet this contemporary standard. They will further inform what constitutes evidence for revalidation in pharmacy. We will provide some information on professions where such standards may either already exist, or at least where there is a clear basis for their development.

In the UK, there are two main proposed models for revalidation using other sources of evidence: an appraisal based (devolved) model, which is that proposed by the General Medical Council (GMC), or a portfolio and assessment based (centralised) proposal, as put forward by the General Dental Council (GDC). CPD is central to the GDC model, whereas the integration of appraisals into revalidation is the model adopted by the GMC in the form of ‘(re)licensing’ for doctors. As medicine is at the forefront of developing a process for revalidation, and one where appraisals play a significant role, we will present this medical model in this chapter. We will use this example and structure, to refer to current developments in other healthcare professions in the UK, but also further afield, particularly if specifically relating to the pharmacy profession.

The remainder of this chapter will discuss different sources of evidence which either are, or could be, used to inform revalidation of healthcare professionals in general, and pharmacy professionals in particular. By discussing the above elements of revalidation, and relating them to pharmacy in Great Britain, this chapter will finish by pulling all of this together to help describe a framework for revalidation in pharmacy. To do so it draws on the existing published, peer reviewed literature on the use of appraisals and other possible sources of evidence to inform the assessment or revalidation of healthcare professionals. It further draws on relevant insights and experiences from pharmacy in other countries and also current developments in
other healthcare professions, particularly in the UK, which all follow the overall moves towards systems of revalidation.

2.1 Revalidation of doctors

Before discussing revalidation in pharmacy, and any evidence that exists in relation to different possible sources of evidence for revalidation, including appraisals, this section will provide a summary of current developments with regards to revalidation of the medical profession. This is done for two reasons: firstly, the medical profession are the most advanced in working towards, and implementing, a system of revalidation; and secondly, appraisals are a key element of medical revalidation, with other sources of evidence feeding into appraisals conducted for revalidation.

The model for revalidation adopted by the General Medical Council (GMC) takes the form of a ‘licence to practise’ for doctors, which was introduced in November 2009. All doctors wanting to practise in the UK have to hold such a licence (as well as professional registration), and this will need to be renewed periodically (‘relicensing’). This renewal will be underpinned by a devolved system of revalidation, which will have three main elements: participation in annual appraisal within the workplace, participation in an independent process for obtaining feedback from patients (where applicable) and colleagues, and confirmation from the ‘responsible officer’ (RO) in their local healthcare organisation. Obtaining feedback from colleagues and patients is also commonly referred to as 360-degree or multi-source feedback (MSF).

In order to retain their licence to practise, or in other words so that they can be revalidated, doctors will need to demonstrate to the GMC that they are up to date and fit to practise. Any supporting information (evidence) will have to show that they are practising in accordance with the generic standards set by the GMC, against which doctors' practice can be appraised and objectively assessed. The GMC are currently in the process of developing a framework for agreed generic standards of practice, which is based on ‘Good Medical Practice’ (GMP). For General Practitioners (GPs) and doctors on the Specialist Register, a second element of revalidation will also be required – ‘recertification’ – for which these doctors would be required to demonstrate
that they meet an additional set of specialist standards relevant to their speciality or
general practice. These sets of specialist standards are being developed by the
medical Royal Colleges and Faculties, specialist associations and others.\textsuperscript{19,20}
Despite therefore potentially involving two sets of standards, it is proposed that
revalidation for all doctors will follow a single set of processes.

As mentioned earlier, appraisals form a cornerstone of revalidation for doctors, and
these will build on existing appraisal systems, particularly those existing in the NHS.
In fact, annual appraisals for all doctors working within the NHS were first introduced
by the Department of Health in 2001.\textsuperscript{21} These appraisals were a formative process,
which aimed to identify development needs in addition to providing doctors with
regular feedback on past performance.\textsuperscript{21} They were normally conducted by a trained
appraiser familiar with the work of the doctor and included such aspects as past
clinical and non clinical achievements, audit, training and education, and complaints.

More recently, an NHS Revalidation Support team has been established, which is
working towards “strengthening NHS medical appraisal to support revalidation in
England.”\textsuperscript{9} This approach to appraisals is central to revalidation and aims to ensure
a consistent approach to revalidation for all doctors, regardless of where they work.
For revalidation, an appraiser will review various sources of evidence together with
the doctor, thus aiming to gain a rounded impression of that doctor’s practice. It will
inform a mutually agreed development plan, but will also have to demonstrate
achievement of generic and specialist standards. Pre- and post-appraisal
assessment forms exist and are being consulted on and piloted as part of current
developments.\textsuperscript{9} Despite serving the purpose of revalidation, these appraisals still
aim to be formative, i.e. supportive for doctors and encouraging and directing their
professional development.\textsuperscript{9}

To support their revalidation, besides feeding information into appraisals, doctors
must also collect information about their practice to demonstrate that they are up to
date and fit to practise. One source of such information which doctors will be
required to collect is feedback from colleagues and patients (where appropriate, i.e.
for those doctors who have direct patient contact).\textsuperscript{22} To this end, the GMC has
developed ‘GMC Principles, Criteria and Key Indicators for Colleague and Patient
Questionnaires in Revalidation. The GMC has also commissioned research to test existing colleague and patient questionnaires, with results anticipated in 2011.

According to these proposals, this process will be overseen by a Responsible Officer (RO). This will be a senior licensed doctor, who will be nominated or appointed by an appropriate healthcare organisation, typically an NHS organisation. The post of Responsible Officer is a new statutory role with responsibility for evaluating the fitness to practise of doctors associated with the appointing organisation. In this local structure, the RO will make a recommendation to the GMC on a doctor's revalidation, based on clear and unambiguous statements from appraisers, and also reliable information from clinical governance systems.

2.2 Definitions and terminology

2.2.1 Revalidation

There is little discussion in the literature, whether through industry, academic or healthcare professional publications, as to how to define revalidation, or an explicit attempt to develop a working definition. However, without a definition of what constitutes revalidation there are implications and potential problems in addressing how to evidence revalidation, what system or process to use, how often this should occur, and where the responsibility for collection and assessment should lie.

According to the Longman dictionary, to revalidate means “to make valid again,” and in this case valid could mean “able to be used lawfully for a stated period or under certain conditions, legally acceptable.” Revalidation is generally described as the process that allows healthcare professionals to demonstrate to their regulator that they remain up to date and fit to practise. The overarching purpose of revalidation is to ensure the public can be confident that all healthcare professionals are indeed up to date and fit to practise. Revalidation is expected to involve periodic assessment, a period which has been set as a five-yearly cycle of revalidation and relicensing for members of the medical profession, whilst a timeframe has not been decided for pharmacy. In endorsing a system of revalidation, the White Paper highlights a commitment to ensuring that all healthcare professionals will “continue to...
apply, through their practice, the values that they committed themselves to when their names were first placed on their professional register” (1997:31). Revalidation thus updates what being registered and qualified has meant until now, shifting the emphasis away from qualifications alone to being up to date and fit to practise. It also emphasises that such assessment will be against contemporary standards, rather than standards which may have been in place when the individuals first registered.

Recognising that healthcare professionals develop their practice (which may include specialisation) and also work in different areas and sectors, the different healthcare regulators further emphasise the importance of practitioners demonstrating that they are competent and fit to practise in their particular area of work.

Besides defining revalidation as a formal system for ensuring that healthcare professionals remain fit to practise, several sources also note that it is a positive affirmation that health professionals are safe and keeping up to date, rather than just an absence of concerns. Particularly if a formative element of learning is meant to be retained for healthcare professionals undergoing revalidation, it will be important that the process should be a positive one affirming an individual’s ability to conduct their job, rather than an assessment (or enforcement) process which suggests looking for shortcomings.

Common to all definitions found for revalidation were the following themes or concepts: assessment of fitness to practise, and a mechanism or process by which it could be ensured that individuals are up to date. To retain the positive and formative emphasis in revalidation, the research team decided to use the succinct working definition: “positive affirmation of one’s fitness to practise,” as communicated by one of the original members of the research steering committee.

### 2.2.2 Other terminology related to revalidation

There are a number of other terms which are relevant to revalidation, and which we therefore define here to ensure clarity and avoid later misunderstandings.
Two such terms are ‘competence’ and ‘performance.’ Competence is defined as “what health professionals are able to do in artificial, testing situations,” whereas performance is “what health professionals do during daily practice.” In the context of revalidation and assessment, it is important that such assessment relates to performance rather than competence alone.

For the revalidation process to be meaningful, some form(s) of ‘evidence’ needs to be collected, and it is therefore useful to define this. Evidence is defined by the Longman dictionary as “something, especially a fact, that gives proof or reason for believing or agreeing with something.” Evidence for revalidation purposes requires ‘something’ which can be agreed with and proven as being true, and that ‘something’ could be a standard (see below). Evidence that is gathered must be timely, accurate and free from bias as much as is feasibly possible with subjective data collection. Furthermore, evidence does not necessarily have to be gathered from the same source.

2.3 Standards for revalidation

As discussed and defined above, revalidation generally involves some form of assessment. Any such assessment will have to be made against clearly defined standards, which will need to be generic enough to apply to pharmacy professionals working in a variety of sectors.

Amongst the healthcare professions in the UK, the GMC and doctors are the most advanced in their move towards revalidation and also in terms of setting standards against which to evaluate. These standards will be based on Good Medical Practice (GMP), and the GMC are in the process of developing a framework for agreed generic standards of practice. This framework covers the domains ‘knowledge, skills and performance,’ ‘safety and quality,’ ‘communication, partnership and teamwork,’ and ‘maintaining trust.’ It lists attributes which cover the core requirements of good practice and shows suggested generic standards as well as possible sources of evidence. GMP probably provides the clearest differentiation between descriptions of ideal, minimum practice and standards of practice. The related standards...
framework is being tested in a number of projects and pilots across the UK.\textsuperscript{34} Specialty-specific frameworks for revalidation have also been developed by each medical Royal College and Faculty, again based on the four domains and 12 attributes defined in the GMP Framework.

The General Dental Council (GDC) also has a set of Standards for Dental Professionals,\textsuperscript{35} which dental professional have to meet to stay on the register. This guidance document is built around six principles: 1) put patients’ interests first and act to protect them; 2) respect patients’ dignity and choices; 3) protect the confidentiality of patients’ information; 4) co-operate with other members of the dental team and other healthcare colleagues in the interests of patients; 5) maintain your professional knowledge and competence (through CPD); and 6) be trustworthy.

In pharmacy, the Ontario College of Pharmacy (OCP) in Canada has a number of Standards, Policies and Guidelines,\textsuperscript{36} and specifically has had Standards of Practice in place since January 2003.\textsuperscript{37} These have been used to assess the competencies of patient-facing pharmacists (Part A of the OCP register). From January 2010, the OCP Standards of Practice\textsuperscript{37} have been replaced by new Model Standards of Practice (MSoP) for Canadian Pharmacists.\textsuperscript{38} They now apply to all Canadian pharmacists and cover the following four domains: expertise in medications and medication use; collaboration; safety and quality; and professionalism and ethics. They have built on the practice standards of other healthcare professions, in particular Good Medical Practice,\textsuperscript{18} and pharmacy. Here, they refer to Good Pharmacy Practice from the International Pharmaceutical Federation (FIP)\textsuperscript{39} and the UK Pharmacy Practice Framework,\textsuperscript{40} the latter explicitly intended to be used as a basis for developing standards of practice.

The RPSGB has prepared Performance Standards separate from their Pharmacy Practice Framework. These can be found in the Preregistration Trainee Workbook and can be found on pages 45 to 58 in the most recent edition for 2010/11.\textsuperscript{41} These Performance Standards cover three domains: personal effectiveness; interpersonal skills; and medicines and health.
The Pharmacy Order 2010\textsuperscript{42} contains provisions for the newly established General Pharmaceutical Council (GPhC) to establish a number of different sets of standards. These include standards of proficiency for safe and effective practice at the point of registration as well as standards of conduct, ethics and performance. The latter set of standards have been largely based on the existing Code of Ethics for Pharmacists and Pharmacy Technicians\textsuperscript{43} and have undergone a first round of consultation.\textsuperscript{44} These standards set out the behaviours, attitudes and values expected of pharmacy professionals and will apply to all registrants.

Explicit standards of proficiency, on the other hand, do not exist under the current regulator, the RPSGB, so it is anticipated that further consultation will take place once the GPhC is fully functional.\textsuperscript{45} Following this, proficiency standards for pharmacists and pharmacy technicians are likely to be implemented, and these will be new standards. They may also include standards (and annotations) for advanced or specialist practice, which currently only exist for prescribing.

As the proficiency standards relate to the time of first registration, it is recognised that a registrant's scope of practice will change over time. It is further recognised that, with time and experience, a registrant's practice is likely to become more focused and specialised. It is therefore possible that not all proficiency standards will apply to all practitioners at all points throughout their careers.

Both sets of standards, i.e. those relating to proficiency as well as conduct, ethics and performance, are likely to underpin the requirement for pharmacy professionals to demonstrate how they meet these standards in their field of practice. In the first instance, meeting standards of proficiency and safe practice will be demonstrated through meeting the continuing professional development standards. These are currently interim standards which are based on the RPSGB’s current professional standards, until revised CPD standards have been developed for future consultation.\textsuperscript{44} Whether additional standards for renewal of registration (‘revalidation standard’) will be available remains to be seen. How any of these standards, once developed and completed, will feed into revalidation is currently not clear and will require further work.
2.4 Evidence for revalidation

What evidence should be collected for revalidation will depend largely on the final standards developed by the GPhC, but any evidence collected will have to ensure that an individual is up to date and fit to practise. In other words, this evidence would need to support that the individual is able to do their job to a satisfactory level, which does not endanger patient safety. The medical profession intends to collect a wide variety of evidence, both written (in the form of documenting skills, qualifications, any research, examples of patient records, and CPD), and observational (through peer review and patient satisfaction surveys). A review of at least some (if not all) of this evidence will have to take place during an appraisal. However, the NHS revalidation support team currently hold the view that a number of sources of evidence, including multi-source feedback (MSF) and whether doctors meet their CPD requirements, should be reviewed and assessed outside of the appraisal. The information from these processes should then merely feed into the appraisal for confirmation that they have indeed occurred, and to inform the discussion during the appraisal.

For this reason, and for the purpose of explaining the different sources of evidence that are being used in other healthcare professions (particularly medicine) and how these may be relevant and applicable in pharmacy, individual components are discussed separately below. We start with appraisals, as they may be one of the key elements of revalidation in pharmacy, as they are in medicine, and they are a key focus of the revalidation project reported here.

2.5 Using appraisals for revalidation

Performance appraisals are often associated with a basic process involving a line manager completing an annual report on a subordinate’s performance and (usually, but not always) discussing it with him or her in an appraisal interview. They have become a general heading for a variety of activities through which organisations seek to assess employees and develop their competencies, enhance performance and distribute rewards. Any assessment of competencies and achievements must be
based against set goals or objectives. There are two main aspects of the appraisal: content (what is appraised) and process (how it is appraised).

As noted previously, the GMC are following a model for revalidation, which has appraisal as a cornerstone and builds on existing structures. For doctors, appraisals have been defined as:

“…a professional process of constructive dialogue in which the doctor being appraised has a formal structured opportunity to reflect on their work and to consider how their effectiveness might be improved.”

Even though evidence from other sources, such as feedback questionnaires, (may) feed into doctors’ appraisals for revalidation, we will consider these other sources of evidence or information under a separate heading. Here, we will review published literature which exists specifically looking at appraisals. The main interest here is obviously anything that may be known about the use of appraisal in pharmacy, either in the UK or other countries, but very little has been published about the use of appraisals in pharmacy. We therefore draw mostly on the literature around appraisals for doctors.

2.5.1 Appraisals in pharmacy

The literature that does exist about the use of appraisals for pharmacy professionals, mostly relates to clinical pharmacists in hospital pharmacy in the US and is somewhat dated, i.e. pre-2000. One of these studies explored hospital staff pharmacists’ knowledge of the existing performance assessment process and their satisfaction with this. It found that pharmacists were more satisfied with this process when a written performance plan was used and when they received feedback. A further US study published in 1996 explored the creation of a performance appraisal template for pharmacy technicians working in community pharmacy. They came up with a technician’s job responsibilities and practice functions, which may serve as a performance evaluation template. Pharmacists and pharmacy technicians alike judged customer service related activities as the most important technician function.
This study further noted that many community pharmacies either lack formal appraisal systems or fail to implement them properly.

One recent study explored performance appraisal systems in US based corporations, including the pharmaceutical industry. They found that all respondents performed appraisals annually and also commonly provided feedback to their employees about six months before. The majority (85.2%) of these appraisals helped employees set their objectives, and as many as 79.6% solicited feedback about employees’ performance from their peers. Somewhat less (68.5%) worked on career development plans for their employees. What was measured as performance was not explicitly stated, but it seemed that this would usually concern organisational performance targets.

No studies were found which reported on the use of appraisals used for pharmacy professionals in any sector in the UK. Nevertheless, pharmacists employed in NHS organisations may already participate in appraisals under the Knowledge and Skills Framework (KSF). Indeed, in reviewing the regulation of non-medical healthcare professionals, including pharmacists and pharmacy technicians, Foster proposed a system of revalidation based on the NHS Knowledge and Skills Framework (KSF). The KSF has seven key dimensions: communication; people and personal development; people safety and personal development; health and safety; service improvement; quality and equality, diversity and rights. The dimensions identify broad functions that are required by the NHS to enable it to provide a good quality service to the public. There are also further specific dimensions which relate to more explicit descriptions of competences and role. This framework defines the knowledge and skills that all NHS staff must have in order to provide quality services within the NHS, and includes a development review to ensure staff are given the opportunity to learn and develop. The KSF is essentially a competency framework based around an ongoing cycle of review, planning, development and evaluation.

2.5.2 Appraisals for other healthcare professionals, esp. doctors

As outlined above, very little is known about the use of appraisals in different pharmacy sectors. However, there is some evidence about the use of appraisals
from other healthcare professions, particularly doctors. Annual appraisals for all doctors working within the NHS were introduced by the Department of Health in 2001. Their introduction followed the publication of the consultation document ‘Supporting Doctors, Protecting Patients’ in 1999, which aimed to protect patients by the early detection of doctors who were poorly performing.

These appraisals are normally conducted by a trained appraiser who was familiar with the work of the doctor and included such aspects as past clinical and non clinical achievements, audit, training and education, and complaints. In its current form, an adequate medical appraisal takes about three hours. This makes about 90 minutes available for discussion of the doctor’s evidence and behaviours under the domains of Good Medical Practice (GMP), and 45 minutes for feedback and planning their personal development plan (PDP). The remaining 45 minutes are used to complete the paperwork. This does, of course, not include the appraisee’s time preparing the necessary paperwork or that of the appraiser reading the material and planning the discussion.

Up until now, appraisals within the NHS have been a formative process, the aim being to identify development needs in addition to providing doctors with regular feedback on past performance. Appraisals should therefore be a structured developmental and formative process which encourages and facilitates self-reflection. It should aim to establish a link between experience and reflection, thus encouraging learning, with the ultimate aim of changing behaviour to improve practice. With this purpose, they provide an opportunity to discuss progress, problems and potential solutions in a supportive and confidential environment. They also serve to identify learning needs which (ideally) can be translated into practice. A number of studies have identified clear benefits of such a purely formative approach, including enhanced learning and improved practice. The support, encouragement and opportunity to reflect one’s practice is also commonly appreciated.

A study in Scotland mapped the Scottish appraisal system for doctors, which is already designed to be consistent with Good Medical Practice, and asked GPs what impact appraisal had had on a number of items grouped under the seven sections of
GMP.\textsuperscript{67} They found that appraisals appeared to have the most impact in the areas of ‘maintaining medical practice’ and ‘probity’ (the latter referring to whether appraisal had led the GP to consider how they accounted for their professional conduct).\textsuperscript{67}

For revalidation purposes, an appraisal would become summative rather than formative. However, to date, “the lack of objectivity and the absence of explicit outcomes and judgements on performance have been criticised.”\textsuperscript{58} This is something that would need to be addressed for revalidation, which would add an element of assessment and judgement on an individual’s fitness to practise against clearly defined standards.

This purpose of appraisals for revalidation is therefore rather different from that of a formative appraisal, and the feasibility and acceptability of the use of appraisals for revalidation would need to be explored. Respondents in some studies with doctors have expressed concerns about links between appraisals and revalidation.\textsuperscript{66,76} They question whether it is appropriate to change or link the formative, supportive nature of appraisals to a more summative approach under revalidation. Their purposes were potentially conflicting, and making appraisals about assessment may make them more threatening for doctors, who may become more defensive as a result.\textsuperscript{72,74} Concerns have also been raised that the current appraisal process was not robust enough for revalidation,\textsuperscript{72} but this is likely to be addressed under current developments.

### 2.5.3 Who conducts appraisals and who oversees the process

It has been recognised that one important part to support a more structured, objective and evidence-based approach to appraisal is that appraisers are appropriately trained to a high standard.\textsuperscript{62,83} A number of publications are available which discuss and/or evaluate initial and continuing appraiser training and development.\textsuperscript{58,64,65,84} Here, the importance of learning by doing is emphasised, thus ensuring the appraiser’s ability to deliver a challenging and worthwhile appraisal.\textsuperscript{58} This training would require further development to allow the use of appraisals for revalidation.
Other authors, exploring effective appraisals with GPs in Wales, have developed an appraisals skills model under six broad headings: initiating the discussion; reviewing progress; PDP construction; closing the discussion; advanced skills (managing difficult appraisals); and generic skills. This has been built on further to develop a behavioural competency model describing behaviours necessary to be an effective medical appraiser. This identified six behavioural competency domains: professional responsibilities; appraisal management; self-awareness (personal emotional intelligence); empathy (social emotional intelligence); developing others; and communication.

Following on from the above detail specifically relating to appraiser training, the wider concept of appropriate quality assurance has also been raised as important. Whilst appraisal systems in Scotland and Wales are centrally controlled and already highly standardised, this has not been the case in England. The National Clinical Governance Support Team (NCGST) was therefore tasked with designing and agreeing criteria by which appraisal systems throughout the UK could be quality assured. These criteria cover organisational ethos and commitment to appraisal, appraiser skills and training, the actual appraisal interview, and systems and infrastructure supporting appraisal. This approach has been shown to be a useful instrument to assess the quality of GP appraisal, thus identifying areas of good practice, but also areas where quality criteria were not fully met.

### 2.6 Other possible sources of evidence

As alluded to earlier, other sources of evidence are used in medical revalidation, such as CPD and multi-source feedback (MSF). CPD is also likely to play a role on revalidation in pharmacy, but there are further potential sources of evidence which may be specific to pharmacy. These will be discussed in this last section.

#### 2.6.1 CPD

CPD involves a cyclical, self-directed process of reflection, planning, action and evaluation. It was first introduced into pharmacy in the UK in 1996, and the use of an
approved recording format followed in 2002. The undertaking and recoding of it are now embedded in the ‘Code of Ethics’ and are a requirement for practising pharmacists and pharmacy technicians registered with the RPSGB. When renewing their annual registration, all practising pharmacists and PTs have to declare that they will undertake and record CPD. Currently, a minimum of nine CPD records are required per year, and these can be called for inspection by the RPSGB and soon the GPhC. Starting in 2009, the RPSGB began to review CPD records.

There is thus some support that this form of evidence for revalidation may be acceptable and workable for the pharmacy profession, but further research will be required to establish the possibility of effectively linking CPD records for revalidation purposes, and that CPD can indeed assure professional competence, which has not yet been demonstrated. The use and/or adaptability of current CPD records to a process of pharmacy professionals’ revalidation is the focus of another work stream commissioned by the RPSGB.

CPD is a requirement for the revalidation of dentists and doctors, and outcomes of CPD may be reviewed during revalidation appraisals for doctors. It is possible that this would be the case in the revalidation of pharmacy professionals as well, yet the extent to which CPD or wider issues of clinical and professional competence and performance are reviewed during appraisals in not known. Furthermore, there is some overlap between the purpose and role of appraisals, even currently, as both generally aim to reflect on an individual’s practice, identify learning needs and come up with a personal development plan. The main difference is that CPD is a self-directed process undertaken by the individual alone, whereas appraisals are a process of facilitated reflection. Indeed, one study with Scottish appraisers and CPD explored links between appraisal and CPD.

2.6.2 Exam / assessment (observation)

At present, only pharmacists in Canada and New Zealand are required to participate in periodic revalidation as set by their professional regulator. There, revalidation is based on a combination of peer review and CPD. The Ontario College of Pharmacy (OCP) has had Standards of Practice in place since January 2003, and
these have been used to assess the competencies of patient-facing pharmacists (Part A of the OCP register). This involves a learning portfolio to demonstrate lifelong learning commensurate with the individual’s practice and a practice review process, where selected competencies, particularly those relating to patient care, are assessed. The latter review involves direct assessment of a randomly selected subset of patient-facing pharmacists and covers the domains of clinical knowledge, the ability to gather information from patients, patient management and education, and communication skills. Assessment involves a written test of clinical knowledge and a standardised patient interview scenario (OSCE) with a focus on communication skills. However, the cost of developing and running such assessment methods is relatively labour intensive and costly, and the RPSGB has deemed these not to be economically viable for routine use in pharmacy in the UK. These sources of evidence, which are also not a focus in this study, are therefore not discussed further.

2.6.3 Multi-source feedback (MSF)

Multi-source feedback (MSF), also called 360-degree assessment, is an established approach to assessing professional attitudes and behaviours in the workplace. It requires a number of colleagues to act as assessors of an individual, record their assessment on a pro-forma, and this is fed back to the individual. Such an assessment, it seems from the existing literature, can be practical, valid and reliable. Feedback from both peers and patients will feed into the process of medical revalidation. Colleague and patient questionnaires have been developed and are being evaluated with encouraging findings. However, some concerns have also been raised, such as confidentiality, sampling issues and feedback, and also whether MSF could effectively identify doctors in difficulty.

In community pharmacy in England, it is a contractual requirement for all providers to ensure clinical governance requirements are met. Community pharmacies must have an identifiable clinical governance lead and apply the principles of clinical governance to the delivery of their services. Key components of clinical governance
include: using standard operating procedures; reporting and learning from adverse incidents; participation in CPD and clinical audit; and assessing patient satisfaction.\textsuperscript{104}

Community pharmacies must now undertake an annual patient satisfaction survey (the Community Pharmacy Patient Questionnaire = CPPQ) as part of their contractual arrangements. The pharmacy (premises) is required to share the results of the survey with the PCT, who monitor all aspects of clinical governance for compliance.\textsuperscript{105} This is an element that could form part of revalidation and make efficient use of resources through using existing evidence.

Patient feedback questionnaires do not exist in other sectors of pharmacy, including hospital, and peer assessment questionnaires or tools do not exist in any pharmacy sector. Particularly in community pharmacy, the largest sector of the profession,\textsuperscript{15} peer assessment may be difficult to operationalise, as community pharmacists commonly work as the only pharmacist and therefore not as part of a multi-disciplinary healthcare team.

\subsection*{2.6.4 Inspectorate monitoring visits}
RPSGB Inspectors currently inspect registered pharmacy premises (mainly community pharmacies).\textsuperscript{12} They are responsible for monitoring and inspection visits to pharmacy premises examining how the pharmacy operates, ensuring that the supply and provision of pharmacy services do not possess a risk to patient safety. The inspection covers pharmacy procedures, pharmacy records, staff training, service provisions, medicine stock, containers and storage, record keeping, waste disposal, chemicals, information sources, computer and a general check of the premises.\textsuperscript{12} The RPSGB inspectorate do not undertake appraisals as such, but routinely produce other inspection or monitoring reports, which may be adaptable for use as other sources of potential revalidation evidence. They could also provide evidence on pharmacies that are underperforming or have breached rules and regulations. However, the feasibility and acceptability of such an approach needs to be explored.
2.6.5 PCT contract monitoring visits, England

Clinical governance is undertaken by patient-facing pharmacists. The overarching stipulations of clinical governance make participation in clinical audit and reflective learning mandatory for all healthcare professionals.\textsuperscript{5,106} As one of the essential services, clinical governance forms a major part of the Community Pharmacy Assurance Framework (CPAF).\textsuperscript{105} Pharmacy organisations and pharmacists who operate under PCT pharmacy contracts also have to undergo contract monitoring assessment, which can include a pharmacy visit and/or the completion of a self-assessment questionnaire. PCTs have responsibility for contract monitoring and the successful implementation of essential and advanced services.\textsuperscript{13,104}

In the first two years of the new pharmacy contract, experience showed that the use of a pre-visit questionnaire enabled visiting teams to concentrate on priority areas, and could also reduce the time spent in the pharmacy.\textsuperscript{107} Aligning the pre-visit questionnaire, the monitoring visit and the Contract Workbook produced for pharmacy contractors by the Pharmaceutical Services Negotiating Committee (PSNC) minimised duplication, whilst ensuring the components of the pharmacy contract are fully met.\textsuperscript{107} Again, little is known about what contract monitoring involves, and whether any aspects or processes would lend themselves to feed into, or be adapted for the purpose of, revalidation.

2.7 Conclusion

In this chapter we have defined revalidation and a number of other important related terms. We have explained the importance of explicit standards against which any revalidation assessment would need to be made. We have also discussed current developments in revalidation, in medicine in particular, and also referred to existing standards in pharmacy, or others which are likely to be developed in the future.

This chapter then served to identify possible sources of evidence which could feed into a system of revalidation in pharmacy. It has predominantly concentrated on appraisals, as they are the primary focus of the study reported here. The reviewed policy and research literature relating to appraisals has particularly drawn on
developments in the medical profession. This was for two main reasons: firstly, doctors have appraisals at the core of revalidation and are most advanced in moving towards implementing a system of revalidation; secondly, the existing research evidence around appraisals mainly concerns doctors.

This chapter also presented a number of other possible sources of evidence with potential relevance for revalidation. This either covered sources which are being developed, or are already in use, in other healthcare professions, particularly medicine, such as patient and peer feedback. Sources already in use in pharmacy, such as CPD and written knowledge tests or practice assessments (including OSCEs) were also mentioned but not discussed in detail, as they are either subject of another revalidation study (CPD) or unlikely to feature in UK pharmacy revalidation. Finally, other possible sources were presented, such as RPSGB inspection and PCT contract monitoring visits, as they are existing sources specific to pharmacy and, as such, also part of the project reported here.

Based on the presented policy and research literature, we have developed a schematic framework of what constitutes revalidation evidence in pharmacy, which is represented below in Figure 1. This summarises the different aspects which have been discussed in this chapter.

In the following chapter we summarise the methods we employed to conduct the various study parts, thus addressing the aims and objectives outlined in section 1.2. This is then followed by a main results chapter 4, a subsequent discussion (chapter 5) and recommendations (chapter 6). Detailed summaries of findings from the individual study parts can be found in a separate volume 2.
Figure 1. Framework for revalidation evidence in pharmacy

- Why evidence?
- What is evidence measured against?
- Who collects, assesses, judges?
- Process for collecting evidence

**Type of evidence:**
- CPD
- Appraisal
- MSF, 360
- Self-declaration
- Tests: Written, oral, observed

**Requirements**
- SMART:
  - Specific
  - Measurable
  - Agreed upon
  - Realistic & relevant
  - Timely

**Meeting legal requirements**

**Measured against clearly defined, agreed & contemporary standards**

**Who collects?**
- Self
- Employer
- Local / National?
- Regulator

**Who assesses**
- Self
- Employer (e.g. NHS, CP, industry, etc)
- External
  - (regulator etc?)

**Cyclical Timeframe**

Data collected – how is it processed / stored?
Chapter 3 – Design and methodology

To determine (and compare across pharmacy sectors and/or types of employing organisation) existing appraisal systems, content, relevance to revalidation, and feasibility and willingness to incorporate items for the purpose of revalidation, the research team undertook a number of separate but linked studies. We used a combination of qualitative and quantitative approaches to collect new empirical data, and we also gathered relevant documentary material on the different appraisal processes. Some parts of the study involved data collection in parallel with two other projects currently undertaken in the Centre for Pharmacy Workforce Studies (CPWS) at the Workforce Academy (WA) at The University of Manchester. One was an 8-month scoping study funded by the National Clinical Assessment Service (NCAS), to inform the extension of their remit to pharmacists. The other was a final year PhD project entitled ‘Identifying Performance Criteria for Pharmacists and Pharmacy Technicians.’

Qualitative interviews were conducted to gain in-depth insights, and we involved both pharmacists and pharmacy technicians as pharmacy professionals who would be undergoing revalidation procedures in different sectors, to gather their views. We further involved organisations who would, or might in future, be involved in revalidation processes, such as appraisals, to gain their perspective. The latter are organisations that employed practising pharmacists and registered technicians (in the main sectors, i.e. community, hospital and primary care pharmacy, schools of pharmacy, and the pharmaceutical industry. Those managing self-employed pharmacists, e.g. locum agencies, were also included. Furthermore, RPSGB inspectors and PCT staff involved in contract monitoring were also included to explore possible alternative sources of evidence (in addition to appraisals and already existing in pharmacy) to be used for revalidation.

The following sections outline the methodology used for each individual part of the study. They are presented in the same sequence as in Volume 2 (see also section 1.4), where a more detailed description of the methods employed for each study part, incl. interview topic guides and survey questionnaires, can be found.
3.1 Registered pharmacists and pharmacy technicians

This part of the study used secondary analysis of survey data collected by Helen Potter, a final year PhD student supervised by Professors Hassell and Noyce, at The University of Manchester. Its aim was to collect the views of pharmacy professionals, as those who would undergo revalidation, on issues related to revalidation. Two very similar questionnaires (one for pharmacists and one for pharmacy technicians) were constructed. These were based on the results of qualitative focus groups and semi-structured interviews conducted by Helen Potter in the early stages of the PhD, and from relevant research literature about revalidation in other health professions. The majority of questions used closed scaled responses. Both questionnaires were piloted, both for substantive content validity and ease of completion. Probability sampling was used as the sampling strategy to recruit participants so that the cohort included people from all sectors, thus covering community pharmacy, hospitals, primary care organisations, academia, and industry. Only pharmacists and pharmacy technicians registered with the RPSGB, who were currently on the practising register and were residing in England, Scotland or Wales were selected. The study received ethics committee approval from Tameside and Glossop local research ethics committee on February 25th, 2009.

The questionnaires were sent by post between April and July 2009 to 3,902 pharmacists and 738 pharmacy technicians, representing 10% of the practising register from each part of the profession. Return rates without a reminder totalled 816, and after a reminder was sent to remaining candidates, a further 390 questionnaires were returned, giving a total of 1,206 received overall. Nine-hundred-and-sixty-six pharmacists and 240 pharmacy technicians completed the questionnaire (a response rate of 26.4 %). The relatively poor response rate was likely due to the length of time required to fill in the questionnaire (~30 minutes) as well as practitioners’ limited knowledge about revalidation and thus perceived lack of saliency and contribution for pharmacists and technicians invited to respond. Despite the low response rate, respondents were representative of pharmacy practitioners registered with the RPSGB and the sample size allowed statistical comparisons to be drawn between groups of respondents.
3.2 Key stakeholder representatives in community pharmacy

A total of 43 semi-structured telephone interviews were carried out, with consent being given prior to the interview. Originally, 30 interviews were carried out between May and September 2009 as part of a project commissioned by NCAS, which investigated issues surrounding poor performance of pharmacists and also incorporated some questions relating to appraisals and revalidation. Ten interviews were carried out with senior members of regulatory and professional organisations, ten interviews were conducted with senior staff (e.g. superintendents; professional development managers) within eight chain pharmacies and a further seven interviews were completed with managers / owners from independent community pharmacies. Finally, three interviews with senior management from three locum agencies were also conducted.

Due to insufficient depth and detail concerning appraisals and their usefulness and potential adaptability for revalidation available from these interviews, it was suggested by the research team and agreed by the RPSGB Research Steering Committee (RSC) that further interviews be conducted. Thirteen additional telephone interviews were thus undertaken to gain more insight into appraisal systems within community pharmacy. These interviews were conducted with seven chain pharmacies (six being revisited; one, first time); four pharmacy technician stakeholders, including members of the Association of Pharmacy Technicians UK (APTUK), and two with pharmacy owners from two independent pharmacies (both interviewed for the first time). This second round of interviewing was completed between February and April 2010. All interviews were tape recorded and subsequently transcribed verbatim. The transcripts were analysed using the ‘Framework’ technique, and sought to unravel key themes emerging from the data. This – and the remaining parts of this study were considered service evaluation by the National Research Ethics Service (NRES), and this was subsequently endorsed by the University of Manchester’s research ethics committee.
3.3 Pharmaceutical industry

Nine semi-structured interviews were conducted with seven pharmacists and two pharmacy technicians employed in seven different pharmaceutical companies in England and Scotland. All participating pharmacists were on the practising pharmacists’ register. A purposive sampling strategy was used which sought to include pharmacists and pharmacy technicians employed in a range of organisations based in different areas of England and Scotland (there is no pharmaceutical industry in Wales) and undertaking different roles. The interviews were conducted by telephone between January and June 2010, audio recorded and transcribed verbatim. The transcripts were analysed using a thematic approach. Analysis was guided by the interview schedules (see Volume 2 for details) and by the data themselves.

3.4 Schools of pharmacy

Five interviewees were selected from a mix of Russell Group, ex-polytechnic, and new schools of pharmacy from a range of geographical areas of Great Britain. These individuals were pharmacists and were either heads of school or heads of pharmacy practice. They were involved in conducting and managing appraisals, so were capable of responding to questions relating to appraisals within their workplace, as well as their potential relevance to revalidation. The five interviews followed a semi-structured format and were conducted by telephone between November 2009 and May 2010. With consent, they were digitally recorded and transcribed verbatim. Qualitative analysis of the interview transcripts was carried out using the ‘Framework’ technique to identify and collate emerging themes.

3.5 Survey of NHS pharmacy employers

A questionnaire survey was sent to individuals with clinical governance responsibilities within NHS organisations (primary care and hospitals). The questionnaires were designed based on the findings from qualitative interviews with
some of the key stakeholder representatives in community pharmacy (see section 3.2). This survey was funded by NCAS, and the questionnaire consisted of two parts, part two being the one relevant to revalidation, whilst part one contained questions about poor performance as commissioned by NCAS. Part two of the questionnaire asked respondents about the appraisal systems in place within their organisation and their potential adaptability for revalidation. Questions included who (pharmacists/pharmacy technicians) were covered by the appraisal system, how often appraisals were conducted, and how the current appraisal system could be adapted for the purpose of revalidation.

Questionnaires were initially sent by post in late 2009 to clinical governance leads in all 178 PCOs: 152 in England, seven in Wales, and 15 in Scotland (n=15). Two postal and e-mail reminders were sent to boost response rates. The PCO survey was completed by 69 clinical governance leads; 67 respondents were from English PCTs and two from Scottish PCOs; none responded from Wales. The response rates were thus 44% for England, and 13% for Scotland, which lead to the decision to only present the analysis of responses from England.

The postal questionnaires for NHS acute hospitals/hospital trusts were initially sent in late 2009 to clinical governance leads in 50% of acute hospitals, excluding community and mental health trusts, in England (n=85), Wales (n=10), and Scotland (n=23). Two postal reminder surveys were sent to all non responding clinical governance leads and/or chief pharmacists to boost response rates. In total, 32 hospital trust questionnaires were returned: 28 from England and three from Scotland; none were received from Wales. The resulting response rates were 33% for England and 13% for Scotland, which again lead to the decision to focus the presentation of responses on those received from England.

3.6 RPSGB Inspectorate and PCT contracts monitoring staff

Semi-structured qualitative interviews were conducted with a selection of personnel from the RPSGB Inspectorate and English PCTs. Seven interviews were conducted with RPSGB inspectors from each of the three regions, the chief inspector and the
three regional leads. Six interviews were carried out with PCT personnel all directly involved in community pharmacy contract monitoring processes in England. PCTs were purposively selected to cover a range of localities (urban, semi-urban and rural) and, in each, a representative was identified with experience of conducting contract monitoring visits.

All interviews were conducted by telephone, were audio recorded with permission and transcribed verbatim. The qualitative data analysis software package NVIVO 8 was used to store and manage the data and assist with the data analysis process. The data were analysed thematically with themes initially being derived from the semi-structured interview schedules (see volume 2) and latterly from the data themselves.  

### 3.7 Divergence from original proposal

As the project progressed, it emerged that a number of changes were necessary from the study approach originally planned. These have been detailed and explained in the preceding sections, as well as in volume 2, but – at the request of the research steering committee (RSC) – will be summarised again here.

Originally, 30 interviews were carried out with stakeholders in community pharmacy between May and September 2009 as part of a project commissioned and funded by the National Clinical Assessment Service (NCAS) to investigate issues surrounding poor performance of pharmacy staff. To allow further exploration and verification of some of the findings and observations obtained during these interviews, as well as ensure data saturation, it was discussed and agreed with the RSC to conduct further interviews. Therefore, nine additional semi-structured telephone interviews were conducted with superintendents of seven multiples and two independent owners. Further detail can be found in section 2 of volume 2.

Between six and ten interviews with pharmacist and pharmacy technician representatives in the pharmaceutical industry had been anticipated to be adequate in the original project proposal, and nine were conducted. Further detail can be found in section 3 of volume 2.
Initially, three senior pharmacy practice academics in schools of pharmacy were interviewed in January 2010. However, preliminary analysis suggested that data saturation had not been reached, and a proposal for further interviews was therefore made to the RSC and subsequently accepted in March 2010. This meant that rather than conducting a maximum of four interviews, as originally planned and funded, a total of five interviews were conducted with representatives in schools of pharmacy. Further detail can be found in section 4 of volume 2.

Despite a plan to only interview the RPSGB chief inspector and the three regional leads, and then survey the remaining 22 inspectors, it again emerged that this number was not sufficient to reach data saturation. The possibility of undertaking focus groups with inspectors was explored, to capture responses from a larger number of them, whilst retaining the flexibility and depth of exploration offered through the use of qualitative methods. However, the timing of the inspectorate’s regional and national meetings did not match the project timetable or already had a fully allocated agenda. The research team therefore proposed to undertake further telephone interviews with inspectors, using a revised topic guide, a proposal again discussed with, and subsequently agreed to by, the RSC in March 2010. Three additional telephone interviews were thus conducted, and further detail can be found in section 6 of volume 2.

Following conduct of the ‘contracted’ number of interviews with RPSGB inspectors and senior pharmacy academics, a survey of the whole population of inspectors and schools of pharmacy (in both cases n=26) had been planned in the project proposal. However, as early data analysis suggested that, in order to reach data saturation, additional interviews in both project parts would be beneficial, this was agreed with the RSC (see above). Following the conduct of the originally planned and additional interviews, it emerged that the range of available experiences and views explored during these interviews provided detailed and varied insight into interviewees’ views. Extending this to the rest of the relatively small overall populations by means of a small scale survey with limited possibilities for any statistical analysis was unlikely to add benefit.
To explore view regarding contract monitoring and its potential relevance or usefulness for revalidation, a minimum of five interviews had been contracted, and six semi-structured telephone interviews were conducted; further detail can be found in section 6 of volume 2.

To summarise, there were some changes from the original commissioned project proposal, and all were discussed and agreed with the RSC. Two small scale surveys of 26 RPSGB inspectors and 26 schools of pharmacy were dropped; and an additional 13 semi-structured interviews were conducted, transcribed and analysed.
Chapter 4 – Results: Summary and analysis

As has been reported, this study involved a number of different strands of data collection, covering a range of different stakeholders in a number of different pharmacy-related contexts. Detailed presentations and analyses of the data from each of these different strands can be found sequentially in Volume 2 of this report. This allows the reader access to the detailed evidence from which the results presented in this chapter are derived.

In this chapter we summarise the key findings from each strand of the study. Firstly, we present a summary of practitioners’ opinions about revalidation. We then consider each of the potential sources of evidence for revalidation we studied in turn (appraisals in each of the main sectors of pharmacy; RPSGB inspections and investigations; and PCT contract monitoring processes) in terms of its current fitness for purpose and prospects for future development. We will go on to discuss the crosscutting themes arising out of each strand of the study in chapter 5 (the portfolio of evidence; who should conduct revalidation assessments; and sector specific issues).

4.1 Practitioners’ opinions about revalidation

This section draws on the postal survey of 966 practising pharmacists and 240 pharmacy technicians working across all sectors (n=1206 out of 4565 surveyed).

4.1.1 How competencies for revalidation could be assessed

The majority of pharmacy professionals surveyed in all sectors agreed that revalidation should be an ongoing, continuous process rather than a periodic comprehensive assessment. Three quarters believed it should include evidence from a fitness to practise appraisal and even more (86%) that it should include evidence of CPD. A smaller majority (60%) thought that revalidation should include feedback from work colleagues and peers with fewer still agreeing that observations
or information from ‘mystery shoppers’ should contribute to the revalidation process. There was general agreement between pharmacists’ and pharmacy technicians’ responses as to how competencies for revalidation should be assessed. However, more technicians than pharmacists supported the proposal for a component of observation. Across pharmacy sectors, pharmacy professionals from the hospital sector were more likely than their community counterparts to support a portfolio of written evidence and observation as methods of assessment for revalidation. Community pharmacy practitioners were, conversely, more supportive of self-certification of fitness to practise.

4.1.2 Who should conduct the revalidation assessment

The largest proportion of respondents (although not a majority) stated a preference for revalidation assessments to be carried out by someone within their employing organisation. This proportion was greater for hospital pharmacists and pharmacy technicians (44%) than for those working in the community sector (33%). Around one-fifth expressed no preference at all, suggesting either that the topic had received little consideration or that many were not concerned. However, a large majority of all respondents believed that this person should be a pharmacy professional with an understanding of their role who is trained and accredited by the regulator.

4.1.3 The revalidation of locums and pharmacy owners

The largest proportion (nearly half) of both locums and pharmacy owners favoured an independent pharmacist based within the geographical area where they most practised or else the pharmacy regulator as the assessor of choice. The majority of self-employed pharmacists disagreed that locums should have their revalidation assessment conducted by an assessor from a locum agency.
4.2 Appraisals – community pharmacy sector

These findings were drawn from a series of semi-structured telephone interviews with community pharmacy employers (from most of the leading multiples and a sample of independent pharmacies and locum agencies).

4.2.1 Structure and process

Eight out of the nine multiples participating in this study had appraisal systems in place for both pharmacy technicians and pharmacists. The ninth was developing a system of appraisals but for pharmacy managers only. None of the nine independent pharmacies had any formal appraisal system for pharmacists although four had one in place for pharmacy technicians. Appraisals in community pharmacies were generally conducted by an individual’s line manager who may or may not be a pharmacist. Appraisals by non-pharmacy professionals appeared more common for those with increasing management responsibilities (and less direct patient contact). Locums were generally not covered by any system of appraisal in these organisations or by locum agencies. Appraisals, where they existed, generally took place annually, sometimes with quarterly or six-monthly reviews.

4.2.2 Content

Appraisals for both pharmacists and pharmacy technicians had a strong focus on business-related performance; with a few notable exceptions they were not generally used to assess clinical skills or professional performance. This was even more pronounced for more senior pharmacists in the larger organisations; these were generally appraised by non-pharmacists against business targets and managerial competencies. When more clinical or professional competencies were mentioned as part of the appraisal process, communication skills were the focus. Instances of clinical and/or professional underperformance were more commonly picked up through customer complaints or peer reporting, and occasionally through routine monitoring processes. Furthermore, appraisals were not perceived as an appropriate
context within which to identify performance concerns, as they should be picked up as they occurred.

4.2.3 Opportunities for revalidation

Some respondents agreed that appraisals had the potential to feed into revalidation, but this should be as part of a portfolio of evidence rather than the only form of assessment. Most pharmacy multiples already have the infrastructure in place for conducting annual staff appraisals. A small number of superintendents felt that the employing organisation was responsible, at least in part, for the fitness to practise of their pharmacists. This was by no means universal though.

4.2.4 Barriers to revalidation

Current appraisal systems do not adequately cover clinical and/or professional performance to be able to contribute to an assessment of fitness to practise. There was strong resistance from many employers to appraisals being adapted to cover these aspects of a pharmacist’s or pharmacy technician’s competencies which were often seen to be an individual’s own responsibility to maintain. Pharmacists owning or working for independent pharmacies are unlikely to be covered by existing systems of appraisal. Pharmacists in managerial or superintendent positions are commonly appraised by non-pharmacists. Locums are not currently covered by any employers’ systems of appraisal and locum agencies did not consider themselves well placed to conduct appraisals. To ensure objectivity, independence and fairness, clearly defined assessment standards would be required, and appraisals would need to be structured and consistent. Training would be required for an appraiser to be able to assess professional and clinical competence against specified standards. Many, however, did not feel comfortable passing judgements on another’s professional or clinical performance.

4.2.5 Verdict

Not currently fit for purpose. Systems of appraisals where they exist do not generally cover aspects of fitness to practise. Furthermore, there is significant resistance
amongst the major community pharmacy employers to incorporating the assessment of professional and/or clinical competencies into appraisal processes.

4.3 Appraisals – NHS (English primary care and hospital trusts)

These findings were drawn from two postal surveys of clinical governance leads from English NHS primary care trusts (n= 67 out of 152 surveyed) and hospital trusts (n=28 out of 85 surveyed).

4.3.1 Structure and process

All NHS hospital trusts responding to the survey had appraisal systems in place for both pharmacists and pharmacy technicians. However, only eighty percent of the PCTs responding to the survey had appraisal systems in place for pharmacists and/or pharmacy technicians. In all cases it was the line manager’s responsibility to conduct appraisals although it is not clear how commonly this was another pharmacy professional. Appraisals were usually conducted annually, but in some organisations, more commonly hospitals, every six months.

4.3.2 Content

Appraisals in these NHS organisations almost always contained a review of progress on the personal development plan (PDP) of pharmacy professionals, together with identification of learning and development needs, an agreement on a new personal development plan, and a review of performance. In most hospital trusts, a review of the appraisee’s CPD record was also included. However, this was the case in less than half of the responding PCTs. Within NHS hospital trusts, the KSF was usually incorporated within an appraisal (this option had not been included in the PCT survey).
4.3.3 Opportunities for revalidation

Systems of appraisal for pharmacy professionals are widespread in NHS organisations. Most hospital trust respondents indicated that their appraisal system might be adaptable for revalidation purposes as did almost one half of PCT respondents. However, 28 per cent of PCT respondents (and a small percentage of hospital trust respondents) did not see their current appraisal system as being adaptable. Almost 70% of hospital trust, and 60% of PCT, respondents had no or only minor concerns with incorporating additional questions into appraisals for the purpose of revalidation.

4.3.4 Barriers to revalidation

A number of open text comments were provided by survey respondents highlighting some of the potential barriers to using NHS appraisal systems for revalidation: Training may be required for an appraiser to be able to assess professional and clinical competence for revalidation purposes. Appraisals conducted by non pharmacy professionals may not be appropriate for revalidation purposes. Extra time would be needed to conduct appraisals for revalidation purposes. Appraisals and revalidation have a different focus and should be kept separate. Revalidation based on the assessment of a single line manager introduces the potential for bias.

4.3.5 Verdict

May be the most easily adaptable systems of appraisal for revalidation purposes in any sector of pharmacy investigated. Professional and clinical competencies are already covered by systems incorporating, or based on, the KSF. There appears to be less resistance to using or adapting existing appraisal systems for revalidation purposes, particularly in the hospital sector.

4.4 Appraisals – Pharmaceutical industry

These findings were drawn from a series of nine semi-structured telephone interviews with pharmacists and pharmacy technicians with management
responsibilities in a range of roles from seven pharmaceutical companies of differing sizes across Scotland and England.

4.4.1 Structure and process

All pharmacy professionals in all organisations participating in this study were subject to appraisals. Appraisals were generally conducted by an individual’s line manager who was often a non-pharmacy professional. All participating organisations had an annual cycle for appraisals, some with interim reviews which could be monthly, six-monthly or quarterly. The use of standard operating procedures and audit was widespread.

4.4.2 Content

Appraisals were based around reviewing targets and objectives set at a previous appraisal. Organisational objectives were cascaded down to individual objectives and performance against those objectives may be linked to bonus payments. Standards were often based on the Medicines and Healthcare Products Regulatory Agency’s ‘Good manufacturing practice’ – the “orange guide.” Targets relating to the clinical or professional competencies of being a pharmacy professional were rarely included. Associated training and development needs were generally covered.

4.4.3 Opportunities for revalidation

Systems of performance management and appraisal are well developed in the pharmaceutical industry. Some respondents thought it vital that the revalidation process included input from a workplace assessor. Others felt that this would only be achievable if that person was a pharmacist, or otherwise suitably qualified. Some believed, conversely, that this should be a role for the professional body and not the employer.
4.4.4 Barriers to revalidation

Pharmacy professionals were not generally appraised as pharmacists but in relation to their industry role. Industrial roles and competencies differ markedly from those in patient-facing roles, and there was a significant lack of clarity over what constitutes fitness to practise for industrial pharmacy professionals in different roles, including specialist roles such as ‘nominated signatories’ and the ‘qualified person’. Moreover, concerns were expressed that the diversity of pharmacists’ roles in this sector were not fully understood by the professional body. Training would be required for an appraiser to be able to assess professional and clinical competence against specified standards for revalidation purposes. Locums/ temporary staff were not currently covered by any system of appraisal, but organisations only had very low numbers of these.

4.4.5 Verdict

Even though the pharmaceutical industry is a highly regulated sector, and although systems of performance management are well developed in industry, these may be the furthest removed from capturing a pharmacy professional’s fitness to practise (depending upon how that is ultimately defined for those working in this sector).

4.5 Appraisals – Academia (schools of pharmacy)

These findings were drawn from a series of semi-structured telephone interviews with senior academics from five schools of pharmacy in Great Britain.

4.5.1 Structure and process

Every school of pharmacy we spoke to had an appraisal system in place although some did not cover part-time staff (e.g. teacher practitioners also employed in a patient-facing role elsewhere). Pharmacists’ appraisals were generally conducted by their line manager who was not necessarily a pharmacist; in some schools pharmacists could choose their appraiser. This was not always perceived to be an issue for respondents who were being appraised on their academic and/or research
roles as opposed to being a pharmacist per se. Appraisals were usually conducted annually although occasionally more frequently, particularly for newer members of staff.

4.5.2 Content

Appraisals generally had a developmental focus rather than performance focus with the objective of developing an individual within their role and academic career, providing feedback and support, setting targets and identifying training needs. Appraisals generally covered: a review of the previous year’s objectives, setting the following year’s objectives, identifying training needs, and comments on personal/career issues. Objectives generally had a research and teaching focus and included curriculum design, increasing student participation in large classes, preparing research proposals and writing up research publications. The content was not specific to pharmacy professionals and their fitness to practise.

4.5.3 Opportunities for revalidation

Systems of appraisals exist in most schools of pharmacy. Some respondents recognised a role for appraisals in a system of revalidation for academic pharmacists but only as part of a portfolio of evidence.

4.5.4 Barriers to revalidation

Appraisals did not generally measure clinical or professional performance. They were not specific to pharmacists and therefore did not cover aspects of a pharmacists’ fitness to practise. They were also not necessarily conducted by someone who would have an understanding of the requirements of revalidation. There was a significant lack of clarity over what constitutes fitness to practise for an academic pharmacist compared to a patient-facing pharmacist and therefore little understanding of how appraisals might assess that. Using appraisals for revalidation might jeopardise their developmental function. Moreover, the veracity of individuals’ self reports of their performance during appraisals was highlighted as a potential problem should they be used for revalidation purposes.
4.5.5 Verdict

Not currently fit for purpose. There is widespread lack of clarity over what constitutes fitness to practice for an academic pharmacist and therefore how that should be assessed. There are particular issues for those with dual roles, in academia and in patient-facing practice.

4.6 RPSGB inspections and investigations

These findings were drawn from a series of semi-structured telephone interviews with the chief inspector, regional lead inspectors and a sample of inspectors from each of the three regions of the RPSGB Inspectorate.

4.6.1 Structure and process

The role of RPSGB inspectors is twofold: firstly to conduct routine inspections of pharmacy premises (between 500 and 600 each) and secondly to conduct investigations into complaints about pharmacy professionals. Pharmacy premises are inspected at least once every three years and are asked to complete an initial self assessment, which is followed by a visit, the findings of which are recorded in a report. For any pharmacy premises not meeting the standards at an inspection visit, this report may be followed up by a second visit to ensure subsequent compliance and only in very serious cases will an investigation be opened. The majority of complaints are made by members of the public but a number are also received from PCOs, GPs or other pharmacists. Complaints undergo a form of triage and are either dealt with locally, referred to the RPSGB investigating committee or referred, ultimately, to the RPSGB disciplinary committee.

4.6.2 Content

The areas covered by an inspection include controlled drugs monitoring, storage of medicines, dispensing facilities, standard operating procedures (SOPs), training and
continuing professional development (CPD), housekeeping, error reporting systems and the responsible pharmacist requirements. Inspectors stressed the supportive nature of their work with non-compliant pharmacies. Most complaints were as a result of dispensing errors made by the pharmacist but the inspectors we spoke to had experience of dealing with complaints about advice-giving, pharmacists’ attitudes and behaviour, health issues, or more serious cases such as fraud.

4.6.3 Opportunities for revalidation

Inspectors were generally better informed about revalidation than other interviewees in this study. Some inspectors interviewed believed that some of the information collected during inspection visits (e.g. the pharmacist’s knowledge of current legislation; the level of training offered to, and achieved by; staff and the quality of SOPs; record-keeping; and the premises itself) might be indicative of a pharmacist’s performance, in particular independent pharmacy owners. A small number of interviewees could envisage that inspections could be developed to contribute to a wider revalidation processes. Records of complaints and investigations link directly to individual pharmacists’ performance. Many interviewees proposed that a portfolio of evidence would be required for revalidation including employers’ appraisals and CPD records and possibly also observations, peer review, PCT contract monitoring data, patient surveys and exams. Many were in favour of a targeted system of revalidation based on risk (e.g. age, patient-facing or not, employment status).

4.6.4 Barriers to revalidation

Inspections relate to premises and not individual pharmacy professionals. Inspectors are not trained to assess clinical competence. Complaints and investigations do not provide a measure of performance for the majority of pharmacy professionals. Concerns were raised about the resource implications of inspectors assessing pharmacists on top of an already large caseload of pharmacy inspections. Information systems are currently inadequate to bring together the different strands of evidence from different sources. Many inspectors were concerned about the consistency and objectivity of information gathered from a range of sources. Locums are not easily captured by any system. Independent pharmacists, who were
recognised as not falling under employer appraisal systems, would require external support with revalidation, with a possible role for the inspectorate.

4.6.5 Verdict

Inspection data have little or no utility in the revalidation of individual pharmacy professionals. Data from complaints and investigations may be indicative of underperformance in some cases. The inspectorate might usefully have a role in the revalidation of locum pharmacists and/or independent pharmacy owners; or in providing infrastructure or governance support.

4.7 PCT contract monitoring processes

These findings were drawn from a series of six semi-structured telephone interviews with community pharmacy contract monitoring personnel from a representative sample of English PCTs.

4.7.1 Structure and process

Wide variability exists in the structures and processes developed by PCTs to monitor community pharmacy contracts. PCT contract monitoring personnel are generally located either within commissioning or medicines management teams; usually have a dual role in monitoring community pharmacy contracts and developing community pharmacy services; and are often not pharmacists themselves. Whilst guidance is available, no standard format has been imposed and a range of documentation and processes have developed across England. In most cases, monitoring involved an element of self assessment but the degree to which this formed the basis for contract monitoring varied. Monitoring visits had been conducted in most but not all areas, usually on a two- or three- yearly basis, but sometimes annually, and involved all or only a sample of contracted pharmacies, the number of which ranged from 30 to 120 in the PCTs we sampled. Following a monitoring visit, PCTs generally produced a report highlighting any areas of non compliance or where improvements were
needed. This may be followed either by further communication with the pharmacy contractor or subsequent visits.

4.7.2 Content
The areas covered by contracts monitoring processes included monitoring essential and advanced service provision and any enhanced services where these were commissioned. PCTs also received patchy evidence of pharmacies’ annual patient surveys and customer complaints through contract monitoring processes. As with the Inspectorate, PCT interviewees were keen to stress the supportive nature of their work with pharmacies in maintaining the standards of the services they delivered.

4.7.3 Opportunities for revalidation
Some PCT respondents thought that contract monitoring processes could inform revalidation processes at the organisational level, e.g. whether or not pharmacies had systems in place for ensuring the CPD and training of their staff and ensuring the quality and consistency of the systems employers might put in place for revalidating their staff. A small minority suggested that PCTs may have an additional role in appraising pharmacists in a similar manner to that proposed for the revalidation of GPs. Some believed that PCTs were well placed to take responsibility for the revalidation of independent pharmacy owners. PCT respondents were less likely than RPSGB inspectors to support the idea of a targeted system of revalidation.

4.7.4 Barriers to revalidation
Contract monitoring processes assess aspects of community pharmacy organisations and services and not individual pharmacy professionals. Contract monitoring personnel are often non pharmacists and may not have the skills to assess the competence of pharmacy professionals. Additional resources would be needed for PCTs to undertake revalidation assessments. If PCTs were responsible for revalidation this may be in conflict with the otherwise supportive nature of their role. Concerns were raised as to the quality of revalidation assessments conducted
by pharmacy employers. Locums are not easily captured by any system. Independent pharmacists would require external support with revalidation.

4.7.5 Verdict

Contract monitoring data have little or no utility in the revalidation of individual pharmacy professionals. PCTs might usefully have a role in the revalidation of locum pharmacists and/or independent pharmacy owners. They may also have a role in providing some of the infrastructure required to support the collection, storage and accessibility of different sources of evidence collected for revalidation purposes.
Chapter 5 – Discussion

In Chapter 4, we summarised the evidence garnered through each of the different strands of this study (whilst full details can be found in Volume 2 of this report). In this chapter, we aim to discuss the similarities and differences between the different appraisal systems examined (and other sources of evidence), their suitability and/or adaptability for revalidation processes, and a number of cross-cutting themes arising from the study. However, before doing this, it is worthwhile reiterating and summarising the main strengths and weaknesses of this study.

With revalidation due to be introduced for different healthcare professions, with doctors leading relevant research, development and implementation, pharmacy is due to follow suit. Some research and pilot studies are available in medicine, and some insights relevant to pharmacy are available, in some cases from outside of the UK, and these have been reviewed in chapter 2. This study aimed to specifically evaluate the use of appraisals and alternative sources of evidence for the purpose of revalidation in pharmacy. As CPD, which is likely to form part of revalidation in pharmacy, was the focus of another project commissioned by the RPSGB, this project focussed on two potential alternative sources of evidence which are very specific to pharmacy, namely the RPSGB inspectorate and community pharmacy contract monitoring through English PCTs.

One of the study’s strengths was that stakeholder representatives in all of the main pharmacy sectors were involved, namely community, hospital, primary care, academia and the pharmaceutical industry. Qualitative semi-structured interviews provided varied and detailed insights into the use of appraisals from an employer perspective in these different sectors, and these were followed up by surveys of NHS employers. The timely availability of a large scale survey conducted by Helen Potter for her PhD studies allowed secondary analysis of views regarding revalidation from a representative sample of practising pharmacists and pharmacy technicians.

One potential limitation might be seen as the relatively low response rate (26.4 %) to the above mentioned survey. This was likely due to the length of time required to fill
in the questionnaire (~30 minutes). Practitioners’ limited knowledge about revalidation at the time of the survey (2008/09) and thus perceived lack of saliency limited the response from pharmacists and technicians. Nevertheless, the 966 pharmacists and 240 pharmacy technicians who completed the questionnaire were representative of pharmacy professionals registered with the RPSGB. Furthermore, the sample size was sufficient to allow insightful statistical comparisons to be drawn between groups of respondents, for example by main sector of practice. Helen Potter has since been awarded her PhD.111

Despite a questionnaire being distributed to clinical governance leads (and subsequently medicines management and chief pharmacists) in primary care organisations (PCOs) and acute hospital trusts across all three countries of GB, response rates from Scotland and Wales were very low, despite two reminders. A decision was therefore made, in agreement with the RSC, to only present analysis of responses from England in the main reports. Even though the response rate of 44% from English PCTs was acceptable, the 33% response from hospital trusts was somewhat disappointing. This restricted the ability of making statistical comparisons between these two types of NHS organisations, and views from Scotland and Wales would be important to feed into any further developments regarding revalidation in pharmacy. Nevertheless, the findings still provide useful insights into the current use of appraisals and their potential adaptability to revalidation, and a paper reporting these findings has been accepted for publication in the Pharmaceutical Journal.112

5.1 A note on terminology

There was a lack of awareness amongst many study respondents over what revalidation is and what it might involve. Following recommendations in the White Paper ‘Trust, assurance and safety,’5 the overarching purpose of revalidation is to ensure the public can be confident that all healthcare professionals are up to date and fit to practise. In Chapter 2, we defined revalidation as the “positive affirmation of one’s fitness to practise,”30 thus placing the emphasis on positive affirmation rather than just an absence of concerns.28,29 However, others may place more emphasis on its purpose of the detection of poor practice.113
Furthermore, from analysing different systems of appraisal, the concept of pharmacists'/ pharmacy technicians’ performance was applied and interpreted differently in different sectors of pharmacy employment: in community pharmacy, for example, it tends to have a business or target-driven focus; whereas the NHS Knowledge and Skills Framework (KSF)\(^6\) used in appraisals of hospital pharmacists and pharmacy technicians incorporates aspects of clinical and professional performance. In this report we aim to differentiate clinical and professional performance from business and organisational performance to be clear about the competencies being assessed. We see clinical and professional performance as what would be assessed for revalidation.

### 5.2 What is being assessed?

Revalidation will involve an assessment of whether an individual is up to date and fit to practise. For such an assessment to be possible, it is crucial that clear and explicit standards exist, against which an assessment can be made – regardless of what source(s) of evidence may be used. These standards do not currently exist in pharmacy and will need to be developed by the GPhC (see section 2.3 standards in Chapter 2). However, it is worth looking to how the medical profession approach the development of their framework for appraisal and assessment,\(^{34}\) which is based on Good Medical Practice (GMP).\(^{18}\) GMP is organised under the headings good clinical care; maintaining good medical practice; teaching and training, appraising and assessing; relationships with patients; working with colleagues; probity; and health. Their current working framework for appraisal and assessment\(^{114}\) is organised under the domains knowledge, skills and performance; safety and quality; communication, partnership and teamwork; and maintaining trust. Under each domain, the framework lists a number of attributes, generic standards (with an explicit link to individual items in GMP) and possible sources of evidence. The generic standards are further divided into subsections which apply to all doctors, doctors with management, teaching or research roles, and doctors with clinical roles.
In order to comment fully on the relative merit of existing systems in terms of their suitability, adaptability, availability, consistency and reliability it would be necessary to have clarity over the standards of revalidation that pharmacy professionals will be assessed against. The absence of such clarity at this early stage also had important implications for respondents in this study who were asked to discuss their views on their own appraisal systems and their utility for revalidation purposes. Particular difficulties existed in defining, and therefore identifying suitable ways of assessing, revalidation standards for pharmacy professionals in non patient-facing roles. Many respondents to this study who worked in academia and in the pharmaceutical industry were employed in positions which could equally be filled by non pharmacists, or where only part of their role required a pharmacy background. For those pharmacists in more senior managerial roles within the larger community pharmacy organisations (e.g. superintendents), the issues are similar to pharmacists in other sectors with non patient-facing roles. These pharmacists are also generally appraised by non-pharmacists and against management competencies as opposed to professional or clinical competencies or performance standards. Therefore the competencies required to fulfil large parts of these roles were not pharmacy specific. In order to adapt appraisal systems in these sectors for revalidation purposes it first would be necessary to identify a set of competencies required for a pharmacist working in these roles to remain on the practising register. Is there a core set of general competencies which would be required to be maintained by all pharmacists irrespective of role or sector? If so, what would be the additional specialist competencies required which were role- or sector- specific? There might therefore be a case for introducing a two-element system, with relicensing for all pharmacy professionals on a core set of standards (which might include subsets specifically for pharmacy professionals in patient-facing roles, or those with management or other responsibilities) and recertification for those pharmacy professionals in certain specialist positions. This would be similar to the type of framework being proposed by the GMC for doctors (described earlier in section 2.1).  

5.3 The portfolio of evidence
A large majority of respondents to the different strands of this study indicated that appraisals (and other sources of evidence) should contribute to a portfolio of evidence which could be used for revalidation purposes. This might include appraisals and CPD but could also incorporate evidence from other sources, including the Inspectorate, PCTs, patient surveys, peer/360° feedback, observations and exams/tests. The focus of the current study, however, was on existing appraisal frameworks and other routinely collected pharmacy data (Inspectorate/PCT) as suitable and/or adaptable sources of evidence for the purposes of revalidation.

5.3.1 Appraisals

Existing systems of appraisal are widespread in community pharmacy multiples, NHS primary care and hospital trusts, the pharmaceutical industry and schools of pharmacy. They are far less common, however, in independently owned and small chain pharmacies, as supported by some of the few US studies exploring appraisal in pharmacy.\(^{54}\) Appraisals are generally conducted annually, with or without six-monthly reviews, and are based around reviewing performance over the previous period. Appraisals further served to identify learning and development needs and setting objectives for the following period. Thus, at first sight, existing appraisal systems might appear to form a useful basis on which to develop a system of revalidation for pharmacy professionals. However, there are a number of important ways in which many existing systems of appraisal are not currently fit for purpose in terms of revalidation.

Firstly, there is wide variability in existing systems of appraisal in terms of who gets appraised, who conducts the appraisals and the content of appraisals. Whilst this reflects the wide variation in employing organisations, employment status, and subsequent roles of pharmacists and pharmacy technicians across the different sectors, it has implications for the ease with which existing systems can be used as the basis for revalidation across the pharmacy profession. For example, pharmacy owners and self-employed locums are not currently subject to appraisals, raising questions of how such a system could be developed and who should be responsible for conducting those appraisals. The roles and, therefore, the necessary competencies of pharmacists in patient-facing positions (in community and hospital
pharmacy) differ markedly from those in non patient-facing roles (in industry and academia, but also in more senior management positions in community pharmacy, for example) which is borne out, to some extent, by the differences in the content of their appraisals. This raises further questions as to what a revalidation appraisal should cover and the appropriate balance between core and specialist competencies. Moreover, appraisers are currently either pharmacy professionals or non-pharmacy professionals. This raises the issue of the relative importance of having a pharmacy professional conducting a revalidation appraisal compared to having someone close enough to the appraisee’s day-to-day performance to be able to provide an adequate assessment. These questions will be addressed in more detail later in this discussion. However, this variation is of itself an important issue when considering how appraisals could be used as the basis for a system of revalidation that is both equitable and yet sector- and role- specific.

Secondly, the focus of many systems of appraisal for pharmacists and pharmacy technicians is on organisational and/or business performance, and not on clinical and/or professional performance. Therefore, there are serious doubts as to whether these appraisal systems are currently suitable as a source of evidence for revalidating pharmacy professionals’ fitness to practise. This is particularly the case in the largest sector of pharmacy practice, community pharmacy, where pharmacists are often appraised against business targets, and also in the pharmaceutical industry and academia, where pharmacists are appraised according to their role and irrespective of their professional background. It may be less of an issue for pharmacy professionals employed by those NHS organisations where appraisals currently incorporate KSF standards. Nonetheless, in the absence of any existing standards of pharmacy practice, it is difficult to assess the extent to which even these appraisals might already assess fitness to practise. It also made it very difficult for respondents across all sectors to comment on the potential utility of developing existing appraisal systems for that purpose. That said, there was strong resistance from many, most notably in the community pharmacy sector, towards incorporating elements of clinical and/or professional competence into existing appraisals.

Thirdly, respondents in many strands of this investigation were keen to stress the formative nature of their appraisal systems i.e. appraisals were focussed on
supporting the development of the individual as opposed to measuring levels of performance per se. For revalidation, pharmacy professionals will need to be able to demonstrate that they are maintaining a certain standard across a number of different competencies, however those will be defined. Thus, to be able to contribute to a system of revalidation, appraisals would need to be adapted to include a more **summative** focus. This, however, has the potential to lead to a conflict of interest with some respondents suggesting that such a shift would make appraisees more wary of the appraisal process and less likely to be honest and open. This may jeopardise the supportive nature of appraisals which many currently viewed as a strength of their system. These issues are very similar to those voiced by doctors, who also expressed concerns about any linkage between appraisals and revalidation. Doctors are also worried that making appraisals a more summative assessment may make them more threatening and may make doctors become more defensive as a result.

Lastly, there remains the question of the mechanism by which information from an employer’s appraisal might feed into a process of revalidation. Most existing appraisals are annual events (with or without ongoing monitoring or interim reviews), and where performance is assessed this provides a ‘snapshot’ of evidence. Revalidation for pharmacy professionals, however, is likely to follow a longer cyclical process, for example a five year cycle as in medical revalidation. Potentially, therefore, information from each annual appraisal could be collated over the relevant time period (e.g. five years) and then submitted as a source of evidence which could be assessed centrally or locally. The latter decentralised approach may require an infrastructure similar to that being established in medicine, where the responsible officer (RO) makes a recommendation to the GMC regarding an individual’s fitness to practise. This is where the PCO (or similar organisations fulfilling the current roles of PCOs) or, potentially, the pharmacy employer, may have a role. A central approach may require an infrastructure located and/or coordinated through the General Pharmaceutical Council. This is where the RPSGB Inspectorate may have a role.

However, from our surveys of NHS employers it would appear that existing appraisal systems for hospital and primary care pharmacists may be more suitable for
adaptation for revalidation purposes than those in the community pharmacy or other sectors. In particular, appraisals which are based on, or incorporate, the NHS Knowledge and Skills Framework (KSF) cover many aspects of clinical and professional performance which may be suitable for assessing the fitness to practise of pharmacy professionals. Indeed, the majority of respondents in NHS hospital trusts (fewer in PCOs) agreed that their current appraisal system was adaptable or very adaptable for revalidation purposes. Moreover, there appeared to be fewer objections in these sectors to adapting appraisal systems to include further questions specific to revalidation. Where concerns were raised, however, many of these mirrored similar issues raised by respondents in other sectors. These included the appraisal of some pharmacists by non-pharmacists, and the possible conflict of interest arising out of combining appraisal (as a mainly formative process) and revalidation (which would focus on assessment). This also mirrors concerns expressed by doctors commenting about potential conflicts between appraisal and revalidation.\(^{66,72,74,76}\)

5.3.2 Inspectorate and PCT contract monitoring processes

Both the RPSGB Inspectorate and, in England, PCT commissioners of pharmacy services currently collect detailed information about the quality and standards of pharmacies and the services they offer through regular inspections and contract monitoring processes. In addition, information relating to concerns with individual pharmacists’ performance is collected through complaints and investigative procedures. However, even more so perhaps than with appraisal systems, difficulties exist with using these processes as sources of evidence for revalidation purposes.

One key difficulty with using information routinely collected through inspection and contract monitoring visits is that this information relates to either the pharmacy premises or service provision and not to individual pharmacy professionals. Moreover, there is no control over which pharmacist is present at the time of a visit – it could be the owner, a second or relief pharmacist or a locum. Therefore, individuals cannot currently be targeted. Where compliance with inspection standards or the terms of the community pharmacy contract falls short, this does not
therefore necessarily relate directly to the fitness to practise of one individual. Indeed, the performance of the individual pharmacists and pharmacy technicians employed by that pharmacy may well be at an acceptable level. The only instance where there may be a more direct link with levels of compliance to inspection standards or contractual obligations is within independently owned community pharmacies and only in relation to the owner managers themselves.

As was the case with appraisals, in the absence of specified standards for revalidation, it was difficult for respondents to comment upon whether or not any of the information routinely collected during these visits would be appropriate for revalidation purposes. However, the general perception that came across during interviews was that, unless the performance of an individual pharmacy professional had reached a particularly low level, it would not be picked up during inspection/contract monitoring visits. Moreover, in the case of PCT contract monitoring processes, the fact that visits were often conducted by non-pharmacists was a further potential barrier to them being used to assess a practitioner’s fitness to practise.

Also mirroring respondents’ concerns with adapting appraisals to use for revalidation purposes, inspection and contract monitoring visits were seen as being constructive, with the aim of supporting the development of pharmacies and pharmacy services, rather than punitive. This focus was viewed as essential to ensuring the cooperation of those participating and securing better outcomes for pharmacies. Should these visits be adapted to assess the performance of individual pharmacists and pharmacy technicians in order that they might stay on the register, the risk may be that pharmacists would be less willing to be open and honest and the good working relationships that had been built over time would be threatened. These concerns are similar to those expressed in this study, and in other studies conducted with doctors, regarding the potential conflict between the more traditionally formative approach to appraisals and a summative one for revalidation.

Respondents suggested that the underperformance of pharmacists and pharmacy technicians was far more likely to be picked up through complaints and investigations rather than through routine visits. If and how such information should be used for revalidation purposes would depend upon how the system is designed and who
should have access to this information. If a decentralised system of revalidation was implemented, for example, with employers responsible for undertaking revalidation assessments, should they have access to information currently held by the Inspectorate or PCTs? What information systems would be needed for a centralised system of revalidation to access a range of information from a variety of sources and what data protection issues will need to be addressed?

The final source of information collected by PCTs which has the potential to be used for revalidation purposes is the annual patient survey which community pharmacies are now contractually obliged to conduct.\textsuperscript{115} The system of revalidation currently being developed by the GMC plans to incorporate evidence from patient surveys into revalidation appraisals for those doctors who have direct patient contact.\textsuperscript{22} The GMC has developed guiding principles and criteria for such feedback questionnaires,\textsuperscript{23} and research is currently underway to test existing questionnaires.\textsuperscript{25} However, it was clear from respondents that the compliance of pharmacies to this part of their contract was highly variable, as was the detail and quality of the survey data received by PCTs. As with inspections and contract monitoring visits, information from patient surveys would also be difficult to link to individual pharmacists or pharmacy technicians, more so than would be the case for GPs who have a less mobile workforce,\textsuperscript{116} thus limiting its utility for the revalidation of pharmacy professionals.

5.4 **Who should conduct revalidation assessments?**

In the vast majority of cases, pharmacists and pharmacy technicians, where appraised, are done so by their line manager. There is no guarantee, however, that the appraiser will be another pharmacy professional. Indeed, it is common for non-pharmacists to appraise pharmacy professionals in schools of pharmacy, the pharmaceutical industry and in community pharmacies, particularly those working in supermarkets and those in managerial positions. The question therefore arises as to how important it is that pharmacists and pharmacy technicians are assessed for revalidation purposes by another in the pharmacy profession and the relative importance of this in different sectors of pharmacy and for pharmacists with differing roles and responsibilities.
Many pharmacists in non patient-facing positions (e.g. in academia, industry) have roles identical to other non-pharmacists in similar jobs. Yet most who we spoke to in this study still considered themselves pharmacy professionals, bringing their professional knowledge and skills to their jobs, and they were keen to remain on the practising register. To address the problem of whether or not it would be necessary for another pharmacy professional to conduct their revalidation appraisal, it will first be important to address what, if anything, makes a pharmacy professional different to others in similar roles and what specialist competencies they would be required to maintain as a pharmacy professional in these roles (see section 5.2 above).

If it is then deemed necessary for another pharmacy professional to be conducting revalidation assessments, there may be difficulties in some employing organisations identifying who that person might be. If, however, it is not important for the appraiser to be a pharmacy professional, these individuals will nevertheless need to have an adequate understanding of pharmacy professionals’ revalidation which has training implications. This is also an issue for pharmacists in senior management positions in the hospital and community sectors. There may be a further risk in that it might become too onerous for some organisations to continue to employ pharmacists in some roles if they are required to be assessed in this way.

Even in situations where an appraiser is more likely to be another pharmacy professional, e.g. in hospitals or some community pharmacy organisations, many study informants who expressed an opinion suggested that they felt uncomfortable passing judgement on another pharmacist’s ability. Others maintained that this should not be their responsibility and that demonstrating fitness to practise for revalidation purposes should remain the responsibility of an individual pharmacist. This is clearly indicative not only of a need for training of assessors to feel confident in taking on this role but also a reluctance of existing appraisers to take on this role. Furthermore, this highlights again the importance of appropriate training of the appraiser / assessor, which had already been emphasised in the literature review chapter in section 2.5.3. It also underlines the importance of general quality assurance, where consistent structures ensure a common, fair and objective approach to appraisals.
For the other potential sources of evidence for revalidation considered by this study, RPSGB inspections and PCT contract monitoring visits, the assessors were sometimes, but not always, pharmacists. Whilst inspectors are most commonly pharmacists, even here there were concerns that they were not suitably qualified or experienced to assess clinical and professional competencies. In PCTs, those conducting contract monitoring visits were less likely to be pharmacists but even those who were expressed concerns that they would be unable to make any judgement on the performance of pharmacists or pharmacy technicians during visits other than in extreme cases of underperformance. This adds strength to the argument that adequate training for the assessor to be confident in assessing clinical and professional competence is as important as whether or not they are a pharmacist themselves. Moreover the skills and knowledge required are likely to differ between sectors and may need to be role specific.

One further issue raised in this study around who should conduct revalidation assessments was the potential problem of having just one person (the appraiser or line manager) assessing clinical and professional ability, raising concerns about confidentiality, objectivity and consistency. This risks the potential for personality clashes or other subjective opinions to cloud an assessor’s judgement of an individual’s competence. The suggestion was made during this study that an independent assessor or panel should judge the evidence submitted for revalidation purposes and this may overcome this problem to a certain extent. The submission of a portfolio of evidence from a variety of sources including peer or 360° review may also counteract any one assessor’s bias. Indeed, there are parallels here with current arrangements of the training and assessment of foundation doctors, who have both education and clinical supervisors and undergo regular assessments involving by many observers from multidisciplinary backgrounds. They acknowledge the importance of multiple assessors, which will allow the building up of a coherent picture of competences and performance, which will help form a balanced judgement of a doctor’s performance supported by the assessment results. They further note that “such an approach will prevent any individual having undue influence over a doctor’s progression.”
5.5 Sector- and role-specific issues

5.5.1 Community pharmacy multiples

There was widespread agreement amongst Inspectorate and PCT respondents that the systems and infrastructure was already there to support community pharmacy multiples developing revalidation assessments/appraisals for their employees. Indeed, these organisations already have in place systems for assessing and assuring the fitness to practise of pre-registration trainees for their inclusion on the pharmacy register. However, the comment regarding the potential problem of having just one assessor, as acknowledged in the preceding paragraph, would need to be considered here too. It would then fall to either the Inspectorate or PCTs to ensure the quality and consistency of the systems in place to support revalidation. However, as we have already seen, there was also widespread resistance amongst these employers to incorporating revalidation standards into existing appraisal systems or to taking responsibility for the revalidation of their pharmacy staff. If the system of revalidation for pharmacy professionals should choose to support this option, substantial groundwork will therefore be involved in changing the mindset of community pharmacy employers to secure its implementation.

As suggested above, it is unlikely that inspection reports or contract monitoring processes would be appropriate sources of evidence for the revalidation of pharmacists working for these larger community pharmacy organisations as they would be difficult to link to any individual pharmacy professional. If they were then used as part of a portfolio of evidence for independent contractors, for whom links to performance could more easily be made, what would this entail for the consistency and equity of a system of revalidation for community pharmacists as a whole? Alternatively, it may be that the infrastructure of the inspectorate or PCT contract monitoring could be used or rather built on. The evidence to be collected, however, would need to be amended to ensure suitability for individual practitioners’ revalidation.
5.5.2 Locums and independent contractors

Two groups of pharmacists posing particular problems for designing a system of revalidation that is both consistent and equitable appear to be locums and independent community pharmacy owners.

It was clear from this study that locum pharmacists, who make up 26% of the overall pharmacy workforce and 40% of those working in the community pharmacy sector,\(^{15}\) are not covered by any employers’ system of appraisal. Moreover, few respondents in any of the study’s constituencies (employers, locum agencies, Inspectorate, PCTs) appeared willing to take on the responsibility for assessing locums for revalidation purposes. This is due to a combination of factors, in particular their employment status and patterns of work. For locums with a regular place of work, employers were more willing to support them in a similar way to employees. However, there was a widely held belief that Her Majesty’s Revenue and Customs would construe offering appraisals to locum staff as evidence of a contract of employment with implications for tax, national insurance and redundancy.

For those who are mobile, working for different employers and sometimes across different PCT localities, it would be difficult to identify an appropriate person in any one organisation who should be responsible for their revalidation assessment. Moreover, it is currently difficult for either PCTs or the Inspectorate to keep track of locum pharmacists with whom they have no ongoing relationship. Many locums are not registered with agencies but for those who are, it is unlikely that locum agency staff have the necessary knowledge and skills to appraise the pharmacy professionals who are on their books. Moreover, most self-employed locums objected to the proposal in our survey that locum agencies should conduct revalidation appraisals. Yet there was some suggestion from interviewees that there might be a greater risk of fitness to practise issues arising in relation to some locums. This therefore poses a serious conundrum for the regulator designing a system of revalidation which will capture all pharmacists irrespective of employment status.

Independent community pharmacy owners are similarly self-employed and therefore not covered by any existing appraisal systems. Moreover, in the absence of any
management structure above or around them, and no support or resources to implement one, it is difficult to see how a system of appraisal could be developed to inform the revalidation of this group of pharmacy professionals. Moreover, without the resources and training provided by the larger companies to support their pharmacists in keeping up to date and addressing performance or learning needs, pharmacy owners may face greater obstacles in maintaining contemporary standards. However, there was far greater enthusiasm amongst the inspectors and PCT personnel we spoke to for taking on the responsibility for supporting and/or revalidating pharmacy owners. In particular, PCTs described the good working relationships they had built up with the pharmacy owners in their localities putting them in a strong position to undertake this role.

5.5.3 Portfolio workers

According to the 2008 pharmacy workforce census, more than one in ten (11.4 %) of all pharmacists work in more than one sector of employment.\textsuperscript{15} The findings from the current study demonstrate the difficulties in capturing this important group of portfolio workers through systems of appraisal. For example, the teacher practitioners (TPs) who are employed part time by schools of pharmacy may work as locums for the rest of the week or may have part time employment in a hospital or community pharmacy organisation. Their part-time academic role can also be funded through their main community pharmacy or hospital pharmacy employer, which means that they are not employed by the academic institution but merely hold honorary contracts. Particularly in these situations, TPs may not be subject to appraisal by their academic institution. Therefore, their fitness to practise as an academic practitioner may not easily be captured by an appraisal based system of revalidation even if they were appraised in their patient-facing role. Thus it will be important to consider whether portfolio workers should undergo revalidation appraisals in every sector of pharmacy they work in and/or in every job or whether one revalidation appraisal would be sufficient but adapted to capture every pharmacy role they performed.
Chapter 6 – Summary and recommendations

The aim of this project was to evaluate the use of appraisals and alternative sources of evidence (other than CPD) for the purpose of revalidation in pharmacy. In this report we have presented the evidence collected from multiple key stakeholder sources using a variety of data collection techniques in the context of the existing literature. We have then discussed in depth the opportunities and barriers to using appraisals and other sources of evidence for the revalidation of pharmacy professionals in the main sectors of pharmacy employment and for those in different roles.

In this final chapter, we will pull together and summarise all of the key issues that have arisen from this study and provide a set of recommendations for the regulator. These recommendations are grouped under three headings: standards for revalidation; evidence for revalidation; and processes for revalidation. These recommendations do not necessarily constitute a set of clear answers as to if and how appraisals and other sources of evidence should be used for revalidation purposes. Rather, they highlight the areas which will need to be addressed before any final decisions are made.

6.1 Standards for revalidation

The standards against which pharmacy professionals will be required to be assessed for revalidation purposes are yet to be developed. This had implications for respondents in this study who were asked to provide their views on the suitability for revalidation of existing sources of evidence and the potential for their adaptation. A lack of clarity over what these standards will be rendered many of the views expressed hypothetical at best. Moreover, it becomes difficult to provide any definitive answers to questions of the suitability, adaptability and acceptability of appraisals and other sources of evidence. Therefore, it is recommended that, before being able to design a system of revalidation for pharmacy professionals and the set of processes that will be involved, development work
is undertaken on defining and elucidating a set (or sets) of contemporary standards against which individuals will be assessed.

The diversity of roles and responsibilities of pharmacy professionals across the different sectors of employment covered by this study was clear. Not only were there marked differences between those in patient facing and non-patient facing roles but there were also a number of different specialist roles undertaken by pharmacy professionals. Thus, the set of competencies required to be maintained by those across the range of positions held by pharmacy professionals will be equally diverse. Therefore, it is recommended that a single set of generic standards, to be met and demonstrated (by whatever means) by all pharmacy professionals for revalidation purposes, may not be sufficient. One approach may be to develop a framework similar to the framework for appraisal and assessment being developed by the GMC for medical professionals. Not only have the GMC proposed a set of generic standards for all medical doctors, these generic standards are further broken down into those applying to all doctors, those in management positions, those in teaching or research roles and those with clinical responsibilities. Furthermore, a number of additional sets of specialist standards for GPs and doctors on the specialist register are being developed by the medical Royal Colleges and Faculties, specialist associations and others.

6.2 Sources of evidence for revalidation – a portfolio

Where respondents to our study agreed that appraisals should be used as evidence for revalidation purposes, it was generally only as part of a portfolio of evidence. Other sources of evidence which were also variously suggested by some as necessary for revalidation included CPD, patient surveys, complaints and investigations, 360° peer appraisal, observations and exams/tests. It is currently difficult to identify which sources of evidence would be suitable for demonstrating which standards for the reasons mentioned above, and this study specifically focussed on appraisals and monitoring visits. However, it is recommended that, if any kind of appraisal system is used to feed into the process of revalidation, it is only one element of a range of evidence to be presented.
Existing systems of appraisal differ widely in terms of content and process, both between and within different sectors of pharmacy employment in relation to the roles of the individual pharmacy professionals being appraised. Moreover, the other potential sources of evidence for revalidation under study – RPSGB inspections, complaints and investigations, PCT contract monitoring processes and related patient surveys – have more or less utility for assessing fitness to practise in different pharmacy sectors (e.g. community pharmacy or not) and for different individuals (e.g. independent pharmacy owners or not). Therefore, it is recommended that the regulator considers whether the same sources of evidence should be used for every pharmacy professional or whether different sources are more appropriate for some professionals in different roles and different sectors of employment.

6.2.1 Appraisals

Existing systems of appraisal are widespread in community pharmacy multiples, NHS primary care and hospital trusts, the pharmaceutical industry and schools of pharmacy. They are far less prevalent in independently owned and small chain pharmacies. Pharmacy owners and self-employed locums are not currently subject to appraisals. Thus, if appraisals are to form the basis of a revalidation process for pharmacy professionals, it is recommended that development work is undertaken in those sectors of employment and self-employment, where appraisals do not currently take place to identify who would be suitable to conduct such appraisals and to develop an appraisal system for this purpose.

The focus of many existing systems of appraisal for pharmacists and pharmacy technicians (in particular in community pharmacies and the pharmaceutical industry) is on organisational and/or business targets and not on clinical and/or professional performance. Thus, appraisals within these organisations would not be suitable for use in their present form to assess fitness to practise and therefore are unlikely to be suitable to be used as evidence for the revalidation of pharmacy professionals working in these sectors. Therefore, it is recommended that the regulator looks to secure engagement of employers of pharmacy professionals in ensuring
their fitness to practise, and that development work is undertaken in partnership with the employers of pharmacy professionals to adapt appraisal systems to be able to assess clinical and professional competencies, should the regulator choose to adopt appraisals as a core element of revalidation. Clearly, this will only be possible after a draft framework with clear and explicit contemporary standards for revalidation has been developed.

However, there is clear resistance in many sectors of employment to using or adapting existing appraisal systems for this purpose. This resistance was surprisingly strong in the community pharmacy multiples who considered that pharmacy professionals should themselves be responsible for maintaining and demonstrating their own clinical and professional standards. However, there also was resistance in other sectors to adapting what they perceived as successful formative appraisal processes to ones incorporating a more summative focus for revalidation purposes. Therefore, it is recommended that resources are dedicated to undertaking the important groundwork required in the different sectors of pharmacy employment to begin to engage employers in this endeavour. With little existing leverage available to the regulator, the absence of sufficient employer buy-in will hinder the success of developing existing appraisal systems for revalidation purposes.

It would appear that many NHS hospital trusts use or incorporate the NHS Knowledge and Skills Framework (KSF) into their systems of appraisal for pharmacy professionals. The KSF covers many aspects of clinical and professional performance which may be suitable for assessing fitness to practice. Moreover, there appeared to be less resistance amongst NHS employers of pharmacy professionals, particularly hospital trusts, to adapting existing appraisal systems for revalidation purposes. Therefore, it is recommended that the regulator looks to NHS employers, in particular the hospital sector, as a potentially conducive setting in which to conduct further in depth explorations and initial piloting of any appraisal-based system of revalidation it might choose to develop.
6.2.2 Other sources of evidence – RPSGB Inspections and PCT contract monitoring processes

The majority of information collected during pharmacy inspection and contract monitoring processes (England only) related to either pharmacy premises or service provision and not to individual pharmacy professionals. Moreover, there are inherent difficulties in using current visiting procedures to make assessments of individuals in that, unless the performance of an individual pharmacist or pharmacy technician was of a particularly low calibre, it is not easily detectable during visits. The targeting of individual practitioners during visits is also not currently the intention of inspectors or contract monitors and would be hard to achieve. Other than in the case of independent pharmacy owners where there is a more explicit link between the pharmacy and an individual practitioner, therefore, it is recommended that these processes in their existing form have little utility in contributing towards a system of revalidation for pharmacists and pharmacy technicians. [At the time of writing, the abolition of PCTs in England had only just been announced. It is not clear at this stage, who will be responsible for monitoring the community pharmacy contract, which is to be held by the new NHS Commissioning Board, nor what processes for this are to be used.]

The adaptability of these systems was also called into question by Inspectorate and PCT respondents. Pharmacies were said to value the supportive nature of current relationships which might be jeopardised if visits by either the Inspectorate or for contract monitoring purposes were to be adapted to contribute to a system of revalidation for pharmacy professionals. Moreover, respondents suggested that to adapt current processes in that way would have significant resource implications. Therefore, it is recommended that, unless properly resourced, routine inspections and contract monitoring processes cannot be easily adapted for revalidation purposes.

Respondents suggested that the under-performance of pharmacy professionals was far more likely to be identified though complaints and investigative procedures than routine visits. If information from these sources is used for revalidation purposes, it is recommended that consideration is first given to issues of confidentiality.
and data protection and to the information systems which would be required to link these data to other sources of evidence for revalidation purposes.

The system for revalidation currently being developed by the GMC for doctors with direct patient contact plans to incorporate evidence from patient surveys.\textsuperscript{16,22} Whilst community pharmacies are contractually obliged to conduct annual patient surveys, it was clear from respondents that the compliance of pharmacies was highly variable, as was the detail and quality of the survey data received by PCTs. Moreover, this source of evidence may again be difficult to link to an individual pharmacy professional. Thus, \textit{it is recommended that processes used currently for conducting and reporting patient surveys in community pharmacy may be unreliable sources of evidence for revalidation of individual community pharmacists.}

\textbf{6.3 Processes for revalidation}

Together with providing evidence as to the suitability and adaptability of current systems of appraisal and other existing sources of evidence for the revalidation of pharmacy professionals, the findings from this study can also help to inform who should conduct revalidation assessments and the components of and responsibilities for the overarching processes.

\textbf{6.3.1 Who should conduct revalidation assessments}

Where pharmacy professionals are regularly appraised, it is generally by their line manager. However, that manager may not be a pharmacy professional themselves. In schools of pharmacy, the pharmaceutical industry and community pharmacies (particularly – although not exclusively – those working in supermarkets and/or in managerial positions) it is common for pharmacists and pharmacy professionals to be appraised by non-pharmacy professionals. Therefore, if employers’ appraisals are to be used as a source of evidence for a system of revalidation for pharmacy professionals, \textit{it is recommended that the regulator gives consideration to the importance of having a pharmacy professional conduct those appraisals. This}
may be dependent upon the sector and/or role in which an individual pharmacist or pharmacy technician works.

Respondents from employing organisations, the Inspectorate and PCTs suggested that even some pharmacy professionals felt uncomfortable assessing another pharmacist’s professional and clinical ability. It is therefore recommended that appraisers/assessors have adequate training in conducting appraisals or other assessments for revalidation purposes, whether or not they are pharmacists themselves. This training is likely to be sector and/or role specific. Moreover, as this may have significant resource implications for employers, it is again recommended that steps are taken to engage employers in such developments.

The issue was raised of the potential problem of having just one person assessing clinical and professional ability, raising concerns about confidentiality, objectivity and consistency. This also risked the potential for personality clashes or other subjective opinions clouding an assessor’s judgement of an individual’s competence. Thus, it is recommended that the options are explored of having a number of different appraisers and/or an independent assessor from outside the employing organisation and/or a panel to judge the evidence submitted for revalidation purposes (see below).

Locum pharmacists are not covered by any employers’ systems of appraisal and may not be able to be in light of their self-employed status. Moreover, few respondents in this study (employers, locum agencies, Inspectors, PCTs) appeared willing to take on the responsibility for assessing locums for revalidation purposes. Particularly for those who are mobile, it is difficult to identify an appropriate person in any one organisation who should be responsible for conducting locums’ appraisals for revalidation purposes. Therefore, to prevent risking concerns with fitness to practise in this large proportion of the pharmacy workforce going unchecked, it is recommended that particular consideration is given to who might undertake the appraisals (or other forms of assessment) of locum pharmacists for revalidation purposes and the necessary support processes and infrastructure. This role may ultimately fall to the regulator or Inspectorate.
Independent community pharmacy owners are similarly self-employed and therefore not covered by existing appraisal systems. Moreover, the absence of existing support structures for this group of pharmacy professionals hinders the development of a system of revalidation based on appraisals. However, there was greater enthusiasm amongst Inspectors and PCT respondents for taking on the responsibility for supporting and/or revalidating independent pharmacy owners. Therefore, it is also recommended that particular consideration is given to who might undertake the appraisals (or other forms of assessment) of independent pharmacy owners for revalidation purposes and the necessary support processes and infrastructure. This may be a suitable role for PCTs or whichever body/ies supersedes them.

There are difficulties in capturing the fitness to practise of pharmacy professionals working in more than one sector of employment (‘portfolio workers’) using existing systems of appraisal. For example, teacher practitioners may be appraised in their patient facing role but not in their academic role; or they may be appraised by their academic employer but not in part-time locum positions. Therefore, to use appraisals as a source of evidence for the revalidation of this group of pharmacy professionals, it is recommended that the regulator explores whether portfolio workers should undergo appraisals in each sector of pharmacy they work in, or whether appraisal by one assessor would be sufficient to capture every pharmacy role they perform.

6.3.2 Who should oversee and/or coordinate the revalidation process

Whilst employers/ line-managers may be best placed to conduct appraisals which the regulator may choose to be a source of evidence for a process of revalidation for pharmacy professionals, they are unlikely to support overseeing and/or coordinating that process for individuals. There was, however, some support for individual pharmacists and pharmacy technicians being responsible for submitting and therefore coordinating the various sources of evidence for their own revalidation. Given the recommendation that a portfolio of evidence should be submitted for the revalidation of pharmacy professionals, it is recommended that the information systems required for an individual pharmacist/ pharmacy technician (or their
employer or other informant) to submit evidence from a variety of sources are investigated.

Some concern was expressed over the potential variability in standards of existing systems of appraisal for pharmacists and pharmacy technicians. However, there was some evidence that PCTs’ current contract monitoring processes (or processes used by organisations which supersede PCTs) might lend themselves to be adapted to include the quality assurance of employers’ appraisal structures and processes. This might ensure consistency in the standards of employers’ appraisals to provide evidence of fitness to practise. Alternatively, the RPSGB Inspectorate’s programme of routine inspections might provide a similar route for the accreditation of systems of appraisal for revalidation. Thus, should employers’ appraisal systems be used as a source of evidence for the revalidation of pharmacy professionals, it is recommended that options are considered for ensuring their quality and consistency.

However, the question remains over who then assesses the portfolio of evidence for revalidation purposes. In the system being proposed by the GMC for doctors, annual appraisals provide a source of evidence for revalidation but there is also a five-yearly revalidation assessment. This is to be conducted by the Responsible Officer, a senior doctor based in the appropriate NHS organisation, who will make a recommendation to the GMC based on clear and unambiguous statements from appraisers and other reliable information from clinical governance systems. It is therefore recommended that the regulator considers who might be suitably placed to make an assessment of a pharmacy professional’s fitness to practise and subsequent recommendation to the regulator regarding the individual’s revalidation, and where they might be based.
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