

# Quality Management in Pharmacy Pre-registration Training: Recommendations for the Future

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## Abstract

**Background:** This work forms part of a review of pharmacy education and training undertaken by the pharmacy regulator in the U.K.. It is the last in a series of three papers describing a review of quality management systems for pharmacy pre-registration training in the U.K..

**Aims:** To synthesise the data collected in the first two stages of the study and with key pharmacy stakeholders identify specific quality management strategies for implementation in the pharmacy pre-registration year.

**Methods:** Interim analysis of data collected from questionnaires and interviews to produce a preliminary set of recommendations which were presented for discussion at a stakeholder meeting.

**Results:** The stakeholders agreed to the recommendations with a number of provisos. There was support amongst stakeholders for a national quality management system in pharmacy that applies to all sectors.

**Conclusion:** This paper makes some general recommendations for the Pharmacy Pre-registration Scheme. What is now needed is clarification of the infrastructure within which the quality management systems are to be implemented. This will then allow a quality management system to be built defining the roles and responsibilities of each level of organisation within the infrastructure.

**Keywords:** *Medical training, pharmacy pre-registration training, quality assurance, quality control, quality management*

## Introduction

The regulation of all healthcare professionals was highlighted as an area that needed improving in the report into the events at the Bristol Royal Infirmary (BRI) (The Bristol Royal Infirmary Inquiry, 2001). This has prompted many professions to review their systems for regulation, encompassing undergraduate education, registration, training, continuing professional development, revalidation and investigation and disciplinary machinery including the handling of complaints. More recently the White Paper 'Liberating the NHS: developing the workforce', described the need for 'high quality education and training, responsive to the changing needs of patients and local communities' (Department of Health, 2010), and the Francis Report (Francis, 2013) made a number of recommendations around the quality management of training programmes, including the need for routine visits to each local education provider.

The medical profession has already undergone a fundamental review of its arrangements for pre and post-registration training in the NHS. The Modernising Medical Careers (MMC) initiative was launched in 2003 in response to

concerns first raised in the NHS Plan (Department of Health, 2000) about problems with medical training at Senior House Officer (SHO) level. It was a widely held view that SHOs had had no clear educational or career pathways, no defined educational goals, no limit to time spent in the grade and a lack of distinction between service and training. The MMC programme aimed to improve patient care by improving medical education with a transparent and efficient career path for doctors. One of the changes introduced was the development of the Foundation Programme, a U.K. wide, two year programme with a competency based curriculum for new medical graduates. This was introduced in 2005, along with the requirements for the deaneries to quality manage the programme.

A review of the regulation of the non-medical professions (Department of Health, 2006) highlighted the importance of pre-registration education in developing the professional standards, attitudes and behaviours which normally protect patients effectively. The review stated that setting the necessary standards and verifying that education providers and students meet them should be at the heart of professional regulation.

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The Royal Pharmaceutical Society of Great Britain (RPSGB), who was the regulator for the pharmacy profession at the time of the research described in this paper, commissioned the research as part of its review of pharmacy education from undergraduate right through to specialist training. The overall aim of the research was to review existing quality management arrangements and produce a set of recommendations to inform the review of the Pharmacy Pre-registration Scheme. This paper is the third in a series of papers describing the research. The first paper (Mills, Blenkinsopp & Black, 2013a) presents our review of information and experiences from the Foundation Programme used by the medical profession that could be used by pharmacy education and training providers to improve the quality management strategies in the pharmacy pre-registration scheme. The second paper (Mills, Blenkinsopp & Black, 2013b) presents the findings of our review of good practice examples of quality management from existing pharmacy pre-registration programmes. This third paper describes a stakeholder event where the findings from the first two phases of the study were considered and a set of recommendations for national quality management strategies for implementation in the pharmacy pre-registration year were identified.

## Objective

The objective of this stage of the study was to:

- Synthesise the data collected and with key pharmacy stakeholders identify specific quality management strategies for implementation in the pharmacy pre-registration year.

## Methods

### *Interim analysis*

An interim analysis was conducted by the project team consisting of a review of the data collected from the document analyses, interviews and questionnaires used to investigate experiences of quality management in the medical Foundation Programme, and the review of good practice examples of quality management from existing pharmacy pre-registration programmes (Mills, Blenkinsopp & Black, 2013a; 2013b). The aim of the interim analysis was to identify the key quality management strategies arising from the data to take forward for discussion at a stakeholder meeting.

### *Stakeholder meeting*

The stakeholders identified for this project included all those involved in co-ordinating regional NHS pharmacy pre-registration training and those responsible for pre-registration training in the multiples and some independent community pharmacies. These stakeholders had participated in an earlier stage of the research through responding to the survey requesting details of existing quality management strategies. In addition representatives from academia, representatives from industry, the National Pharmacy Association (NPA) and the British Pharmaceutical Students' Association (BPSA), the

RPSGB and NHS Education for Scotland (NES) were included in this stage of the study.

Stakeholders were invited to attend a stakeholder event to consider the preliminary recommendations. Attendees were divided into groups of six to eight, ensuring a mix of pharmacy sectors and experiences in each group. The groups considered some key questions posed by the project team and relating to the preliminary recommendations. Each group recorded their discussions on a specially designed proforma which enabled the project team to gain a deeper understanding of the views of the stakeholders than by simply recording the final outcomes of the discussions. The proforma were analysed following the event to produce a summary of the key issues emerging from the groups' discussions. These key issues led to the production of a final set of recommendations for quality management in pharmacy pre-registration training.

## Results

### *Interim Analysis*

Table I shows the six preliminary recommendations for quality management that emerged from the interim analysis of the data collected up to this point in the research.

**Table I: Preliminary Recommendations Discussed at the Stakeholder Meeting**

Recommendation	
1	There is a need for a curriculum on which pharmacy pre-registration training schemes should be based. A curriculum should include all aspects of teaching, learning and assessment that support the pre-registration training scheme.
2	A system should be introduced for assessing the competence of tutors against defined standards.
3	There is a need for defined standards for training (the site and the programme).
4	Training providers should be required to provide evidence, through their quality management systems (for example, self-assessment and site visits) that their sites and programmes are meeting these standards.
5	A quality management system should include a mechanism for obtaining feedback from tutors and trainees on the training programme and the tutor, such as a questionnaire.
6	There is a need for a standard assessment system that uses work-based assessment tools to be applied across all sectors.

### *Stakeholder Event*

Forty-five stakeholders were invited to take part in the stakeholder meeting. In total 28 stakeholders attended the meeting. These included ten from secondary care, ten from community pharmacy including three from small independent companies, three from academia, one from industry, one from BPSA, one from the NPA, one from the RPSGB and one from NES.

In general the stakeholders agreed to the preliminary recommendations, with the following provisos:

- There must be flexibility within a curriculum (*i.e.* agreed outcomes or framework for training) for it to be implemented locally and in different sectors of pharmacy, and to be able to share good practice across the sectors.
- The curriculum and assessments should be linked to the undergraduate curriculum and to further postgraduate training so that a continuum of training is achieved, rather than distinct stages.
- There needs to be a common approach to pharmacy pre-registration training across all sectors.
- There needs to be a shared infrastructure across the sectors, for example IT systems for assessment of trainees, that is supported at a higher level (*e.g.* the deaneries).
- There must be clarity about accountability, whatever system is used.
- The systems must encourage and support tutors, not put them off.
- There are resource and political issues. A fully costed model is needed to ensure funding.

The majority of the stakeholder meeting focused on recommendations 2 and 6 (see Table I). These related to the competence of tutors and an assessment system for trainees. These were the two areas where the initial stakeholder survey showed least consistency (Mills, Blenkinsopp & Black, 2013b) and more data needed to be gathered to inform the final recommendations. Tables II and III provide a summary of the discussions around these two recommendations.

There was support among the stakeholders for a national quality management system in pharmacy that applies to all sectors. There was strong feeling that whatever national guidance is put in place for the pharmacy pre-registration

scheme, there should remain enough flexibility for it to be implemented locally and in different sectors, and that the sharing of good practice should be encouraged. Stakeholders felt that the approach could be based on the three levels of quality control, quality management and quality assurance defined by the Postgraduate Medical Education and Training Board (PMETB) (PMETB, 2007) that is employed in the Foundation Programme (Mills, Blenkinsopp & Black, 2013a). Within this approach, stakeholders advocated that individual training providers, whether single or larger organisations, should be required to provide evidence of the quality of the training programme to a regional quality manager (*e.g.* deanery or some other organization). They felt that the regional quality manager should manage the quality of the training programmes through collating and analysing this evidence to present it to the Regulator (the quality assurer). They expressed the view that it should be the responsibility of the Regulator to quality assure and accredit the quality managers. Figure 1 provides a model for the implementation of these recommendations, illustrating the responsibilities at regulator, regional and local (individual training provider) levels and how the activities at each level link with each other.

The final recommendations for the quality management of pharmacy pre-registration training are shown in table IV.

## Discussion

### Assessment of trainees

Some pharmacy stakeholders stated a need to review the assessment methods in pharmacy pre-registration training as the current requirements are perceived to allow too much subjectivity and there was too much focus on the examination at the end of the year rather than what was being learnt during the training. The need for a more standardised

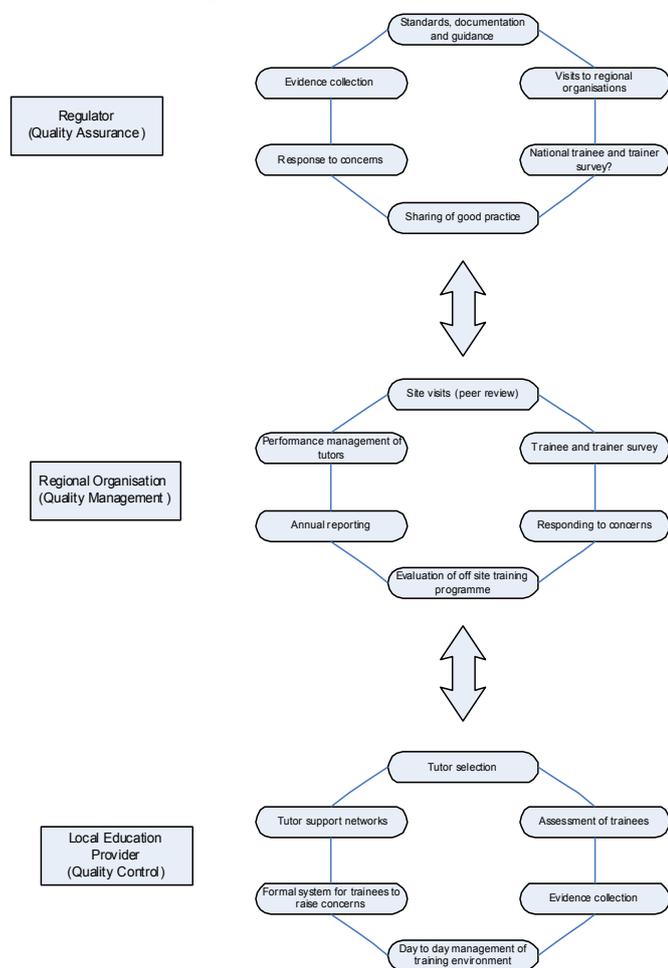
**Table II: Summary of Discussions on the Principles for an Assessment System**

Theme	Description
<b>Assessment tools</b>	<ul style="list-style-type: none"> <li>• Workplace assessment tools are appropriate for assessment in the pharmacy pre-registration year and are the preferred option for assessment. The tools should be linked to the performance standards and use rating scales.</li> <li>• The knowledge exam should not be the focus of the pharmacy pre-registration year and could take place during the undergraduate course or earlier in the pre-registration year. The pharmacy pre-registration year should test the application of knowledge and skills.</li> <li>• OSCEs were not considered suitable for implementation on a national basis.</li> </ul>
<b>Assessment system</b>	<ul style="list-style-type: none"> <li>• Assessment of the student should use a variety (a basket) of standardised tools to allow a triangulation of assessments.</li> <li>• Trainees should be assessed in different environments and by a variety of assessors from the wider healthcare professional group.</li> <li>• The system must be applicable across all sectors of pharmacy but should not be too prescriptive. There must be flexibility within the system to tailor the assessments to the training site and to the trainee.</li> <li>• Assessment should be part of the overall experience for the trainee. They need to be planned and structured, with protected time and resources.</li> </ul>
<b>Assessors</b>	<ul style="list-style-type: none"> <li>• The assessment system needs to be supported by a network of tutors, who have been provided with training and guidance on the assessment methods to ensure a consistent approach.</li> <li>• Tutors should be active in assessment rather than involved in a passive review of evidence only.</li> <li>• There needs to be support available to tutors and trainees to address trainees who are having difficulty meeting the required standards in their assessments.</li> </ul>
<b>Self-assessment</b>	<ul style="list-style-type: none"> <li>• Self-assessment is important in the pharmacy pre-registration year as it encourages trainees to take responsibility for their learning and development at an early stage and will promote life-long learning and CPD.</li> </ul>
<b>Performance standards</b>	<ul style="list-style-type: none"> <li>• The current performance standards are ambiguous and open to interpretation so need to be reviewed or an alternative set of competencies used, for example, the General Level Framework.</li> <li>• Some of the current performance standards are not best assessed using ‘evidence’ <i>e.g.</i> professionalism. These standards need to be identified and measured differently.</li> </ul>
<b>Clarity of standards</b>	<ul style="list-style-type: none"> <li>• There needs to be clarity around the expected standards, perhaps in the form of further guidance around acceptable assessment of standards/level etc.</li> </ul>
<b>Curriculum</b>	<ul style="list-style-type: none"> <li>• A clear curriculum is required (curriculum in a holistic sense, which includes elements and self-assessment and facilitated development).</li> </ul>
<b>Infrastructure</b>	<ul style="list-style-type: none"> <li>• There needs to be a clear deanery type infra-structure that is jointly owned across sectors.</li> </ul>

**Table III: Summary of Discussions on the Performance Management of Tutors**

Theme	Description
<b>Role of the tutor</b>	<ul style="list-style-type: none"> <li>The role of the tutors needs to be valued and recognised in its own right, not as just another part of the day job. It is advanced practice.</li> </ul>
<b>Standards</b>	<ul style="list-style-type: none"> <li>There is a need for specified tutor competencies to ensure the role is open, transparent and valued, but there is a big gap between the current criteria and ideally what should be expected. This needs careful management to avoid losing tutors.</li> <li>The regulator needs to set standards to be applied locally and needs to monitor evidence that standards have been met.</li> </ul>
<b>Tutor training</b>	<ul style="list-style-type: none"> <li>There is a need for consistency in the training and assessment of tutors against tutor competencies and standards, for example something like the NVQA1 award for assessors which requires demonstration of competence in assessment.</li> <li>Initial training and revalidation of tutors should be funded and should cover training in assessment tools.</li> <li>The regulator needs to specify what training is required i.e. define the 'syllabus' and also quality assure the training.</li> <li>Training should be standardised, face to face, covering assessing evidence and coaching skills (e.g. feedback, dealing with different trainees). It also needs to cover assessment methods. The training needs to be dovetailed to the pre-registration scheme itself and be practical and accessible.</li> <li>The tutor role and tutor training could be incorporated into existing professional development frameworks e.g. ACLF.</li> <li>Training could be provided by local network/regional groups and should be for both new and experienced tutors. There needs to be flexibility around who delivers the training e.g. multiples, Higher Education Institutes, NHS, independent providers, NPA, as long as the course and the provider are accredited according to regulator requirements and by (or on behalf of) the regulator.</li> </ul>
<b>Assessment of tutors</b>	<ul style="list-style-type: none"> <li>A variety of assessment methods should be used as appropriate including assessment of a portfolio of evidence.</li> <li>Peer review and feedback from the trainees are essential.</li> <li>Self-assessment should be part of assessment, to inform CPD.</li> <li>Whatever assessment system is used, it needs to be kept simple and should use IT wherever possible. It should be 'tiered' to provide support and guidance and facilitated to ensure problems solved on the ground.</li> <li>Those that could be involved in the assessment of tutors include: peer review via local tutor networks, RPSGB facilitator at a local level, Local Pharmaceutical Committee, superintendent and different companies for community tutors, Teacher- practitioner team, or regional NHS training/Deanery team, tertiary assessors/NPA/ other providers to assess the standards.</li> </ul>
<b>Tutor support</b>	<ul style="list-style-type: none"> <li>Tutor networks and peer review of trainers are important to provide support and share good practice.</li> <li>Tutors need ongoing support particularly in providing feedback to trainees.</li> <li>A cross sector meet up once a year and a sector specific meet up three times a year to share and support each other.</li> <li>Virtual networks on-line with face to face support a couple of times a year.</li> </ul>

**Figure 1: A Model for the Quality Management of Pharmacy Pre-registration Training**



**Table IV: Recommendations for quality management in pharmacy pre-registration training**

Recommendation
A shared infrastructure that is jointly owned across the sectors needs to be developed to undertake regional quality management.
There is a need for national guidance on the quality management of the pre-registration year, for example an 'Operational Framework', but there should remain enough flexibility for it to be implemented locally and in different sectors.
There is a need for defined standards for all aspects of the training programme.
There is a need for the performance standards to be written as a curriculum on which pre-registration training programmes should be based. A curriculum should include all aspects of teaching, learning and assessment that support the pre-registration training scheme. The curriculum for the medical Foundation Programme is a model that could be used.
A quality management system should incorporate different methods to allow for a triangulation of data.
A quality management system should include a mechanism for obtaining feedback from tutors and trainees on the training programme and the tutor, such as a survey.
Site visits conducted by a body external to the delivery of the programme (e.g. the quality manager or the regulator depending on structures) should be part of the quality management system.
Formal mechanisms should be put in place at a local level for trainees to voice concerns about their training programme.
There is a need for an assessment system that uses a variety of standardised workplace assessment tools to allow for triangulation of assessments.
A system should be introduced for assessing the competence of tutors against defined standards.
Tutor training and support networks need to be put in place.
The sharing of good practice should be encouraged and co-ordinated through a national body.

assessment system that draws on work based assessment tools was endorsed by the discussion at the stakeholder meeting where it was generally agreed that work based assessment tools were appropriate for the pharmacy pre-registration year and that assessment of the student should use a variety of tools to allow for triangulation of assessment.

Careful consideration, however, should be given to what is feasible and practical to implement in the pharmacy pre-registration year, given the variations in organisational structure between secondary care and community pharmacy. Any assessment system must be applicable across all sectors of pharmacy.

The workplace assessments tools were an area that was found to be problematic in medical training (Mills, Blenkinsopp & Black, 2013a). It was generally felt that the assessment system was robust as it relies on evidence, and incorporates the views of all those who have been involved in the trainee's training. However, there are concerns about the reliability of some of the tools and that some are not being used to the levels at which they have been shown to be reliable (*i.e.* on smaller numbers of occasions). There are also issues with the practicality of using the assessment tools in a busy work setting where time is limited.

In 2011 the GPhC commissioned a literature review of the assessment of observed practice to provide evidence on the strengths and weaknesses of practice-based assessments in the context of pharmacy pre-registration training for use in policy decision making. The GPhC are still considering the results of this review.

### ***Performance Management of Tutors***

The one to one interaction between the trainer and the trainee is perhaps the most fundamental aspect of the training programme and so the selection and performance management of tutors should be a priority. The GPhC introduced new standards for the initial education and training of pharmacists in 2011 (GPhC, 2011). Standard 7 relates to the support and development of academic staff and pre-registration tutors. Training providers, therefore, now need to demonstrate the mechanisms they have in place to support tutor development.

### ***Issues for Implementation of the Recommendations***

A barrier to implementing a national quality management system is the resources required for both the initial setting up and the ongoing running of the system. This was an issue consistently raised by the pharmacy stakeholders and they called for a fully costed model to be developed to aid negotiations. A regional infrastructure to support quality management will need to be developed, with a dedicated quality management team to develop and administer the quality management system. Funding would need to be ring fenced for tutor training, and also training for other assessors in the use of the work based assessment tools. Ideally the tutor role would attract additional remuneration, to ensure that it is encouraged and promoted as being aspirational and valued. NES have developed a regional infrastructure and have a dedicated quality management team. However, there is no additional funding for tutor remuneration.

A further potential barrier, but one that can be overcome with careful negotiations, is the private ownership of community pharmacies. Foundation Programme trainees are all NHS employees and thus only one employer needs to sign up to the requirement of the scheme. The experience in Scotland shows that the NHS and private sector can agree on standards; however NES found that community pharmacies wanted to retain control over certain elements of the scheme, such as recruitment. A process of careful negotiation was required to gain the full support of all the stakeholders. This included helping employers understand the benefits of the new scheme and the shortfalls of the previous scheme. The development of the new Scheme in Scotland was Government led, and so new funding arrangements were implemented; an employer had to sign up to the requirements of the PRPS in order to gain funding for training a pre-registration trainee.

This issue of control of the funding for the training posts was raised by both the West Midlands Deanery and NES. It was felt that without this control, no sanctions can be applied if a training programme consistently fails to meet the required standard. It was also felt that there is no incentive for the private sector to commit to the quality management process.

There was strong feeling that whatever national guidance is put in place for the pharmacy pre-registration scheme, there should remain enough flexibility for it to be implemented locally and in different sectors, and that the sharing of good practice should be encouraged. This is similar to the experiences of the medical profession when setting up the Foundation Programme. It was recognised that there was a great deal of variation in learning experiences between the four countries of the U.K., and within the countries, between rural and urban settings for example, but that trainees needed to be skilled to reach the same outcomes, irrespective of setting. The U.K. Foundation Programme Office was set up to co-ordinate practical delivery and the sharing of good practice. It has done this through the development of the Operational Framework for Foundation Training and through the co-ordination of national events to share good practice. The regulators are invited to the national events to enable them to understand the realities of implementing the Foundation Programme. There are some learning points for pharmacy, in terms of clearly delineating the roles and responsibilities of the various organisations involved in the co-ordination and delivery of the pre-registration training programme.

### ***The Future***

Since the research was undertaken the NHS organisation Modernising Medical Education, through the Modernising Pharmacy Careers Programme Board, has reviewed current pharmacist undergraduate education and pre-registration training to assess its content and continuing relevance and to identify options for change. The research described in this series of three papers contributed to the review. Proposals for change were submitted to the Secretary of State for Health in June 2011. One of the key recommendations is the integration of pharmacy into local infrastructure to manage quality in pre-registration training. The infrastructure would include employer representation from hospital and community pharmacy, and possibly industry, in partnership with schools of pharmacy and would build on existing infrastructures such as medical deaneries and foundation schools. This would

allow local systems of quality control to develop in order to ensure proportionate regulations of training placements (Smith and Darracott, 2011). The proposals are currently being considered by the Department of Health, Department of Business Innovation and Skills (BIS) and the Higher Education Funding Council for England (HEFCE). One of the key issues is how the reforms will be funded.

### Conclusions

There is a clear need for a national quality management system in pharmacy pre-registration training. This paper has made some general recommendations for the Pharmacy Pre-registration Scheme. No single quality management tool is adequate on its own and so a triangulation of methods should be employed including site visits, self-assessment and trainee and trainer feedback. What is now needed is clarification of the infrastructure within which the quality management systems are to be implemented. This will then allow a quality management system to be built defining the roles and responsibilities of each level of organisation within the infrastructure. The recommendations from this research have informed the national review of pharmacy education and training undertaken by the Modernising Pharmacy Careers Board and the proposals for change are currently being considered by the Government.

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### References

The Bristol Royal Infirmary Inquiry, (2001) The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol. The Stationery Office; Norwich.

Department of Health, (2000) The NHS Plan: A plan for investment. A plan for reform. Department of Health; London.

Department of Health, (2006) The regulation of the non-medical health care professions. Department of Health; Leeds.

Department of Health, (2010) Liberating the NHS: developing the healthcare workforce. From design to delivery. Department of Health; London.

Francis, R. (2013) Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry. London: The Stationary Office.

General Pharmaceutical Council, (2011) Future Pharmacists. Standards for the initial education and training of pharmacists. London, GPhC.

Mills, E., Blenkinsopp, A. & Black, P. (2013a) Quality management in medical foundation training: Lessons for Pharmacy. *Pharmacy Education*, **13**(1), 75-81.

Mills, E., Blenkinsopp, A. & Black, P. (2013b) Quality management in pharmacy pre-registration training: Current Practice. *Pharmacy Education*, **13**(1), 82-86.

PMETB, (2007) The PMETB Quality Framework for postgraduate medical education and training in the U.K.. Autumn 2007. Postgraduate Medical Education and Training Board: London

Smith, A. & Darracott, R. (2011) Review of pharmacist undergraduate education and pre-registration training and proposals for reform. Report to the Medical Education England Board.