

Quality Management in Medical Foundation Training: Lessons for Pharmacy

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Abstract

Background: This work forms part of a review of pharmacy education and training being undertaken by the pharmacy regulator in the U.K.

Aim: To gather and review information and experiences from medical Foundation training and to consider relevance and applicability to quality management in the Pharmacy Pre-registration Scheme.

Methods: Document analysis and semi-structured interviews with key stakeholders at regional and national levels.

Results: Nine interviews were conducted. The medical model is based upon three levels: quality assurance undertaken by the regulators, quality management undertaken at a regional level by Deaneries, and quality control undertaken by the local education provider. The medical regulators define the standards that foundation training programmes are expected to meet and have developed a process based on inspection visits to the deaneries to verify that standards are being met. Deaneries have some flexibility in designing their quality management systems.

Conclusion: The review of medical Foundation training identified some tools of quality management. Triangulation of data from several methods in the medical Foundation programme includes site visits, self-assessment and trainee and trainer feedback. These principles are worthy of debate and consideration for future quality management of the Pharmacy Pre-registration Scheme.

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

Introduction

The arrangements for professional regulation of pharmacists, including pre-registration training, in Great Britain were laid out in the Pharmacist and Pharmacy Technicians Order 2007 (Section 60 Order) (Statutory Instruments, 2007). This statutory instrument gives the pharmacy regulator (at the time, the Royal Pharmaceutical Society of Great Britain [RPSGB]), more powers to establish a programme of quality assurance for those involved in training, training establishments and training programmes for the Pharmacy Pre-registration Scheme.

As a result of the Section 60 Order, and the changing landscape of pharmacy practice (Department of Health 2000, 2003 & 2008) the RPSGB undertook a review of pharmacy education, from the undergraduate MPharm degree through to postgraduate specialist training. The research described in this paper was commissioned in 2008 as part of this review. Pharmacy regulation is now undertaken by the General Pharmaceutical Council (GPhC) who are using the findings of this study to inform their approach to the quality assurance of pharmacy pre-registration training.

Recent reports and policy strengthen the focus on the need for quality in education. The White Paper 'Liberating the NHS: developing the workforce', published in 2010 describes the need for 'high quality education and training, responsive to the changing needs of patients and local communities' (Department of Health, 2010). As a result of this White Paper, Health Education England (HEE) was established in June 2012. One of its key functions is to promote high quality education and training and it encompasses all of the healthcare professions. More recently, 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.

Pre-registration systems in the health professions have developed in isolation from each other. Medicine underwent a fundamental review of its arrangements for pre and post-registration training in the NHS and as a result introduced the Foundation Programme in 2005. This is a U.K. wide, two year run through programme for new medical graduates with a competency based curriculum (The Foundation Committee, 2007) which lays out the educational framework for the

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programme, and an operational framework (The UK Foundation Programme Office, 2007) defining a set of principles for the deaneries. Postgraduate deaneries are responsible for the management and delivery of postgraduate medical education, including quality management. Within each deanery, Foundation Schools were created to administer the Foundation Programme. Foundation Schools bring together medical schools, the deaneries, NHS Trusts and other organisations involved in Foundation training. Each Foundation School offers a certain number of training posts with the Trusts administered by the School.

The Foundation Programme, at the time of this research in 2008, was jointly regulated by the Postgraduate Medical Education and Training Board (PMETB) and the General Medical Council (GMC). Upon graduation from medical school junior doctors are granted provisional registration with the GMC (the independent regulator for medical practitioners in the U.K.). The GMC had responsibility for the Foundation Year One (F1) to ensure that provisionally registered doctors have acquired and demonstrated the required competencies to be granted full registration upon completion of the Foundation Year One training. The PMETB had responsibility for the Foundation Year Two (F2), *i.e.* post-registration training. The GMC and the PMETB worked together to create Foundation Programme specific standards and a joint Quality Assurance of the Foundation Programme (QAFP) process which satisfied the legal frameworks of both the GMC and the PMETB. On 1st April 2010, the PMETB merged with the GMC and the GMC is now responsible for regulating all stages of medical education in the U.K. The jointly developed quality assurance processes are now being implemented and further developed by the GMC.

The aim of this research, was to gather information about, and experiences from, medical Foundation training that might be used by pharmacy regulators and by education and training providers to improve the quality management strategies in the Pharmacy Pre-registration Scheme. The intention was that this information, together with a review of current practice in existing pharmacy pre-registration programmes would be synthesised to produce recommendations to inform the GPhC's review of pharmacy pre-registration training. This paper describes the findings from the review of quality management within the Foundation Programme for junior doctors. The findings on current practice in existing pharmacy pre-registration programmes will be presented in a second paper. A third paper synthesises the findings of both studies and describes the stakeholder consultation that contributed to the recommendations from the research.

Objectives

The objectives relating to the review of the Foundation Programme were to:

1. Understand and describe the component parts of quality management of pre-registration training for F1 doctors (including tutors and placements, monitoring and assessments, taught components, documentation).
2. Obtain views from key stakeholders on which components of this quality management system work relatively better and less well, and the reasons why.

Methods

Keele University has close links with the West Midlands Workforce Deanery (WM Deanery) which agreed to act as a case study and work collaboratively with the research team to enable in depth learning about how pre-registration training is quality managed in the Foundation Programme and the practical aspects of running such quality management systems.

A mixed methods approach was used in which data were collected from documentary analysis and interviews with key stakeholders. A document analysis relating to the quality management of the Foundation Programme in medical training was conducted, using sources from publicly available national and local policy and operational papers. The interview schedule was derived and developed from this analysis, and covered the quality management of the training environment, the taught components of the programme, tutors and supervisors, and the assessment of trainees as well as gathering views on the elements perceived to work relatively well and less well.

Staff within the Deanery were interviewed initially and then a snowballing approach was used for sampling through their recommendations for other participants. Interviews continued until saturation was reached and no new information was forthcoming. In addition a member of staff from the Postgraduate Medical Education and Training Board (PMETB) was interviewed to provide the national and regulatory context.

With participants' agreement the interviews were recorded and transcribed verbatim. Handwritten notes were made during the interviews to supplement the transcription. The interviews were analysed using a framework approach (Ritchie *et al.*, 2003).

The project was considered to be a service evaluation and therefore ethical approval was not required.

Results

The results present the findings of the quality management processes at the time the research took place in 2007-8.

Nine interviews were conducted. Table I shows the roles of the interviewees.

Table I: Details of the Interviewees

Interviewee Role	Number of Interviewees
Representative from the PMETB	1
Senior medical staff at the deanery	4
Quality manager at the deanery	2
Foundation school dean	1
Clinical tutor in an NHS trust	1

The National Picture

The system developed by PMETB comprised three levels. Table II provides a definition of these levels and their units of accountability.

Table II: Definitions of Quality Assurance, Quality Management and Quality Control

Level	Definition*	Description (Interview 1, PMETB)	Accountability
Quality Assurance	The policies, standards, systems and processes directed to ensuring maintenance and enhancement of the quality of postgraduate medical education in the UK.	'...we quality assure, in order to, having set the standards, established them, then we test that they are there.'	The Regulators (i.e. PMETB and GMC)
Quality Management	The arrangements by which the deanery discharges its responsibility of the standards and quality of postgraduate medical education.	<i>So the dean, not deanery, is accountable to PMETB for the training that is within their scope. ... if they (the trainee) are training with a trainee number that associates them with that deanery, that deanery is accountable to us, that our standards are being met.</i>	The Postgraduate Dean
Quality Control	The arrangements within local education providers that ensure postgraduate medical trainees receive education and training that meets local, national and professional standards.	'.....the fact is you have a trainer trainee interaction that is about learning, skills, knowledge and therefore patient care. So that is quality control, in our language. Foundation schools are that link, if you like, between the deanery and that interaction.'	The Local Education Provider i.e. the Foundation School

*Definitions taken from PMETB. The PMETB Quality Framework for postgraduate medical education and training in the U.K. Autumn 2007. Postgraduate Medical Education and Training Board: London; 2007

The regulators defined the standards that foundation training programmes are expected to meet (PMETB, 2007) and developed a process of visits to the deaneries to monitor whether and how these standards are being met, the Quality Assurance of the Foundation Programme (QAFP) process. The QAFP was a four stage process consisting of information gathering through self assessment in advance of a visit; a visit to the deanery once very five years; reporting of the visit findings to the deanery; and follow up of the recommendations from the visit. A national survey of trainers and trainees was also undertaken on an annual basis.

Other documentation developed to support the delivery of the Foundation Programme included a curriculum (The Foundation Committee, 2007) laying out the educational framework for the Foundation Programme, and an operational framework (The UK Foundation Programme Office, 2007) defining a set of principles for each deanery to follow in developing their programmes. The 'Standards for Training for the Foundation Programme (PMETB, 2007) specified that trainers involved in foundation training must be appropriately appointed, trained and appraised against their educational activities.

Foundation trainees were assessed through a series of workplace assessments against a defined set of competencies and using a standardised approach. Table III describes the different types of assessments used. Trainees provided evidence of their achievement of the competencies within a portfolio using the assessments, completed audits and

examples of reflective practice. At the end of the first year of Foundation training deaneries are required to recommend the trainees for full registration with the GMC, based on the evidence in the trainee's portfolio which is the collated views of all those who have been involved in the trainee's training.

Table III: Work Based Assessments

Type of Assessment	Examples	Description (from The Foundation Programme Curriculum ⁵)	Description (from Interview 2)
Multi Source Feedback (MSF)	360 degree assessment	The collated views of a range of co-workers which are anonymised and then discussed with the trainee. Usually carried out once a year.	'...their three sixty degree assessment of behaviours is being assessed, which is doctor patient communication, team working, communication and accessibility..... And if you are getting ten or more forms back on an individual, then we know that that is when you often spot problems of the more sort of attitudinal type of things that people have.'
	Team Assessment of Behaviour (TAB)		
	Mini-Peer Assessment Tool (mini-PAT)		
Direct Observation of Doctor/Patient Encounter	Mini-Clinical Evaluation Exercise (min-CEX)	Assessment of an observed clinical encounter with immediate developmental feedback. Usually carried out six times a year, each assessment representing a different clinical problem.	'Mini CEX assesses history taking, examination, clinical decision making and professionalism. This is assessed one to one by observation, while a doctor does the history taking examination somebody watches them and scores them.'
	Direct Observation of Procedural Skills (DOPS)	A structured checklist for assessing practical procedures. Two should be carried out for each placement (i.e. six a year). Each DOPS should represent a different clinical procedure.	'The DOPS, which is direct observation of procedural skills..... Again, it just goes through a procedure and it breaks it down into different things.....'
Case Based Discussion	Case Based Discussion (CBD)	A structured discussion of real clinical cases in which the trainee has been involved. Explores decision making and reasoning in detail. Six to eight a year.	'Case based discussion, that is when you sit down face to face, with the patient's records, not with the patient, but the records, and you are assessing record keeping, clinical assessment, investigations and treatment'

Case study: The Foundation Programme in the West Midlands Workforce Deanery

The WM Deanery developed a set of standards which were used in conjunction with the regulator's standards to form the basis of their quality management processes. These fifteen standards were known as the Job Evaluation Survey Tool (JEST). Trainees were required to complete the JEST survey at the end of each training post (every four months in Foundation Year 1). The Deanery, in common with other Deaneries, had a two year cycle of visits to individual trusts. The Foundation School Dean conducted an internal visit in the first year and a full peer review visit from the Deanery, including lay representation, in the second year. Trainees and supervisors were interviewed during the visit using questions

based on the JEST standards. This allowed for triangulation of the responses from the trainees and the supervisors with the survey responses and the identification of individual trainees who might be struggling in a post as well as a post that is struggling to meet the requirements. Any concerns raised in the survey responses triggered a visit outside of the scheduled two year visit programme. Most NHS Trusts in the region also had formal mechanisms in place to allow trainees to report concerns.

Although the regulators stipulated that trainers involved in foundation training must be appropriately appointed, trained and appraised, the extent to which these requirements are implemented appeared to be variable and in the case study Deanery seemed to depend at least in part on the amount of money allocated for training in a given year. Stakeholders attributed a shortage of educational supervisors to a lack of recognition for the role, with no extra pay rewards and little time to complete the role. This was implied to be a national issue, and not something the Deanery could easily address.

'There is no question that if there was remuneration for doing the job then we would then have a lever. And we could say – right, you will be employed as an educational supervisor, provided you meet every component of this job description, and we would then appraise you every year, and we would make sure, on the basis of the JEST surveys and on the appraisal that they had, that they really were doing the job properly.' (Interview 5, WM Deanery)

In order to ensure enough supervisors for the number of trainees, stakeholders reported that this role was not strictly regulated. The case study Deanery took a pragmatic approach, using the JEST survey, and the other mechanisms for trainee feedback, to quality manage the educational supervisors. Any issues with individual supervisors would be identified and the Trust expected to follow up on them.

Overall the interviewees suggested that the quality management system was working well, primarily because the system included a triangulation of data *i.e.* questionnaires from the trainees and the Deanery's site visits to individual Trusts using the same criteria and encompassing the supervisors views. A second reason given was because the WM Deanery were able to put in place a dedicated team to support quality assurance and therefore separate it from actual delivery of the programme.

'We had someone who was responsible for quality assurance and that was the first thing we did, was to professionalise quality assurance....but also being able to put dedicated staff in to support and separate quality assurance from delivering' (Interview 3, WM Deanery)

On the whole, the assessment system, where multiple assessors are involved in undertaking the work-based assessments of trainees was deemed by the interviewees to work well because the final decision is no longer based on one person's say so. However, two issues associated with the assessments were raised. The first relates to the validity and reliability of the assessment tools; one interviewee raised concerns that there was little evidence around the application of some of the assessment tools and also that they perhaps were not being used appropriately in that the evidence base for required numbers was not always applied. The second issue raised was around the time it takes to ensure that the

assessors are fully trained in using the tools, and then to actually conduct the assessments in addition to supervising the trainees properly.

Summary of Learning from the Foundation Programme

Table IV highlights eight key recommendations, learning points and advice from the interviewees that could be applied to the pharmacy profession.

Table IV: Recommendations for the Pharmacy Profession

Recommendation	Description
Site visits/External peer review are essential	<i>'I think you have got to visit the hospitals. I think you can't do it all on paper, I think you had got to go and speak to people face to face as well. I don't think it is an either or.'</i> (Interview 2, WM Deanery) <i>'And finally you would have an overseeing external process for checking up on those internal systems.....So as long, then, there is an opportunity for that overseeing body to go through a programme delivery group and say – show me your evidence, we will come along and check you every so often, and we might do it unexpectedly, and I think that is the right way to do it.'</i> (Interview 5, WM Deanery)
There should be a system of continuous quality improvement	<i>'And the point is, about this external system, that it is not just keeping information for the external body to check up on, but it is a continuous process of quality improvement, because as soon as you find a problem you are in the right place to deal with it. You don't wait for five years for someone to come and tell you you've got a problem. It creates the right atmosphere of continuous quality improvement.'</i> (Interview 5, WM Deanery)
Explicit standards are required	<i>'If you were going to take on in pharmacy I would get yourselves a set of explicit set of standards first. Because without the standards you are flailing about...'</i> (Interview 2, WM Deanery) <i>'Clear documentation which has to be national and agreed.....because you have to have clarity across all of your placements...'</i> (Interview 4, WM Deanery) <i>'I think the crucial thing with quality assurance..... is an essential standard, and uses a tool which fairly evaluates the standard.'</i> (Interview 5, WM Deanery)
Ensure assessment of trainees is appropriate	<i>'You need a curriculum for the junior pharmacists and you need a set of assessment tools based on your curriculum. You need a variety of assessment tools to assessand I think you need assessment tools to assess at the right level. If you are doing workplace based assessments you need to be assessing what people do in the workplace. You don't need to be doing a multiple choice test.'</i> (Interview 2, WM Deanery)
Involve trainees in quality management	<i>'And you also need the trainee pharmacists to assess their training as well, which is like our post evaluations.....'</i> (Interview 2, WM Deanery)
Keep the system simple and make it routine	<i>'.. set up a system which isn't remotely complex, and then have an internal structure, that each programme is expected to deliver. In other words it is auditing it's own education and is doing that routinely'</i> (Interview 5, WM Deanery)
Any new system should be piloted	<i>'If you are setting it up in pharmacy I think you need to pilot it first in one area. Don't, whatever you do, go for a big bang.'</i> (Interview 2, WM Deanery)
Need appropriate organisational structure and strong leadership	<i>'You need appropriate organisational structure. Don't rely on just goodwill.....It can get quite bloody. So strong leadership...Clear principles, steering committees, dedicated administration support...'</i> (Interview 3, WM Deanery)

Discussion

The research generated a rich description of both the national system for Foundation training and in depth information on its application in practice in one deanery. In 2010, the results of this work were presented to and informed the discussions of The Modernising Pharmacy Careers Programme Board in relation to their review of undergraduate education and pre-registration training.

The medical system has a number of fundamental differences from the current pharmacy pre-registration system, and these will be discussed below.

Infrastructure

The medical regulator has clarified the lines of accountability in postgraduate medical training through defining the three levels of quality assurance, quality management and quality control and assigning national, regional and local responsibility to the levels. This has been relatively easy to do in medicine since the deaneries already existed as a structure for the management of regional postgraduate medical education. Within the Deaneries, Foundation Schools were created to deliver the Foundation Programme. This educational infrastructure has been highlighted as a design strength in a review of the Foundation Programme (Collins, 2010). In pharmacy, a cross sector regional model is not so easily identifiable. Even within secondary care the structure of the regional pharmacy education and training units, and the involvement of the deaneries in pharmacy training varies considerably and traditionally, community pharmacy has not been included in the remit of the regional pharmacy education and training units. In 2011 The Modernising Pharmacy Careers Programme published a proposal for the reform of pharmacist undergraduate education and pre-registration training (Smith & Darracott, 2011). They proposed that pharmacy be integrated into existing infrastructure such as Deaneries to manage quality in major practice placements. These proposals, amongst others, are currently being considered by the Department of Health.

Standards for the Training Programme

The research into the Foundation Programme demonstrates the value of having defined standards for the training programme. The Deanery interviewees advised that this should be the first thing that is developed for pharmacy (Table IV) and that the quality management strategies should then be built around these standards. The GPhC published 'Future Pharmacists. Standards for the Initial Education and Training of Pharmacists' in May 2011 (GPhC, 2011). These ten standards provide a framework for education providers to review the provision of their training. The second standard states that the 'quality of pharmacy education and training must be monitored, reviewed and evaluated in a systematic and developmental way.'

Programme Curriculum

Those running Foundation Programmes are provided with guidance on the structure and content of Foundation training

and on the quality management systems that need to be in place (via the curriculum and operational framework). The curriculum is clear and well defined and has provided a structure for the content of early postgraduate medical education that did not previously exist. This has helped to establish the Foundation Programme as a credible U.K.-wide generic training programme (Collins, 2010). The operational framework (The UK Foundation Programme Office, 2007) sets out principles for foundation training including organisational arrangements, but allows the deaneries flexibility to accommodate local differences. These elements make the Foundation programme more robust and are needed to strengthen the pharmacy pre-registration programme.

Quality Management

The efforts made to manage the quality of the programme and ensure robust educational outcomes were highlighted as a strength of the Foundation Programme in the review of the programme (Collins, 2010). These efforts have resulted in greater scrutiny and transparency and provide an inbuilt improvement mechanism. However, an issue that was repeatedly highlighted in the work presented in this paper is that to be effective a quality management system must encompass more than one method. Each method (site visits, surveys, self-assessment) has its limitations. The WM Deanery perceived the strength of their local systems to be the collection of data using a variety of methods but against the same set of standards. This allowed those involved in quality management to distinguish between a problem that is universal across the Foundation Programme or an issue experienced by a single trainee. A study comparing a Royal College visit with a deanery visit and a web based survey and found that each method had advantages and disadvantages and that no single method alone would have picked up all the information (Turbull, 2007). The quality management system that is adopted in the Pharmacy Pre-registration Scheme should therefore encompass a mixture of methods.

Feedback from the trainees undergoing the training programme is deemed essential in quality management of medical Foundation training. The PMETB view a national trainee and trainer survey as the only way to gain direct feedback from those actually 'living' the training experience. However this is completed in relation to the whole year's experience and thus cannot provide detailed feedback on the different individual job placements that Foundation trainees undertake. Thus the WM Deanery developed its own survey tool for completion at the end of each training post. The administration of a feedback questionnaire by the regional organisation may encourage trainees to disclose problems and areas for improvement since they are not reporting directly to those they see as responsible for delivering their training. A mechanism for trainee feedback could be built into the quality management systems for the pharmacy pre-registration year, either a national survey, or locally implemented, or both. However, the introduction of a trainee survey needs careful consideration since there is currently no mechanism for 'external' or Head Office data collection in independent community pharmacies.

Site visits, both by the regulator to the Deaneries and the Deaneries to the individual Trusts, are deemed an essential

element of quality management in the Foundation Programme. An external site visit by the GMC to the deaneries forms the basis of the Quality Assurance of the Foundation Programme. Interviewees from the WM Deanery stated that this external site visit was vital as it ensures that the systems are transparent.

Trainers and Assessors

The selection and performance management of clinical and educational supervisors remained an area that was problematic. The one to one interaction between the trainer and the trainee is perhaps the most fundamental aspect of the training programme, however operationally quality management of the educational supervisors appears to be a weakness that is challenging to address. Respondents identified several barriers to implementing a more rigorous system for the quality management of supervisors. The review into the Foundation Programme acknowledged that those who teach and assess learners must be formally recognized and allocated the necessary time to undertake this work (Collins, 2010). This formal recognition of supervisors might begin to address some of the issues with the quality of clinical supervision highlighted in the review. For the pharmacy profession, any quality management measures introduced around supervision must not disengage tutors as this would risk leaving trainees without tutors or supervisors.

Assessments

In the review of the Foundation Programme, the workplace – based assessments used in the Foundation Programme are seen as a strength of the programme in that regular assessment ensures progression, provides documentary evidence of achievements and can be used to identify trainees with problems (Collins, 2010). Yet at the same time, the review acknowledges difficulties with the assessment tools in terms of their validity, the number of assessments required and the time involved in undertaking the assessments. These were the same issues raised by the interviewees.

Strengths and Limitations of the Study

A strength of our current study is the in depth information provided by the WM Deanery which not only provided an example of how medical pre-registration training is quality managed at regional level, but also insights into strengths and limitations of the components of the system. It is recognised that, whilst the WM Deanery has well developed quality management systems, theirs is not the only approach that could be taken. The Operational Framework for the Foundation Programme is flexible to allow for local delivery to be organised around local needs. As a result, different deaneries will have developed different infrastructures and systems and a national review of all Deaneries was beyond the scope of this project. None the less the review of the WM Deanery has provided a valuable general overview of the areas of a programme that should be quality managed and some general options for how this could be done. Once the priorities for developing the quality management of the pharmacy pre-registration year have been agreed, communication with other Deaneries could identify further options for how these could be implemented.

Conclusions

This review has identified the tools of quality management that can be included in 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. A second paper on this research will describe the findings of a review of existing quality management in the Pharmacy Pre-registration Scheme.

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