Commentary

An agenda for UK clinical pharmacology

How should training of graduates in clinical pharmacology and therapeutics be delivered and assessed?

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The UK postgraduate curriculum in clinical pharmacology and therapeutics (CPT) incorporates the common competencies required of all physicians and shows how trainees from other specialties, including primary care, can train in CPT. Various models of training and assessment are possible. Evolution of the current system to meet new challenges would maintain an established tradition, with a ready source of training funds. However, this would require greater input from all consultants in CPT, including the training and assessment of trainees. A joint venture with the Faculty of Pharmaceutical Medicine would have the advantage, if the Faculty agreed, of introducing ready-made curriculum modules and assessment tools that have been accepted by the General Medical Council. However, extra modules relevant to CPT would have to be constructed to complement the common areas already in the pharmaceutical medicine curriculum, and there would be a perceived loss of the independence that clinical pharmacologists currently enjoy when making decisions about manufacturers' products. Abandoning externally approved training in CPT would allow the specialty to devise its own training and assessment in the necessary skills. Critically, however, this would impair the status of the specialty and would incur loss of financial support from postgraduate Deaneries. To attract high-calibre trainees, we must completely define CPT training and assessment structures. Most clinical pharmacologists seem to prefer to allow the current structures to evolve under external guidance. However, this will not succeed unless all trained clinical pharmacologists contribute to development of both the curriculum and specific assessment tools, and open their teaching and assessment skills to scrutiny.

Introduction

Here I shall deal with the UK graduate curriculum in clinical pharmacology and therapeutics (CPT), its history, its contents and the structure of training, as well as the methods of assessment. I shall not deal with nonmedical training or training outside the UK.

Background

The first structure for postgraduate training in CPT in the UK was suggested by the Royal College of Physicians in 1969 [1]. Since then, the curriculum has been frequently revised, most recently in 2010 under the auspices of the Joint Royal Colleges of Physicians Training Board (JRCPTB) [2]. Critical in informing the content of the current curriculum was John Mucklow's Delphi exercise published in 2002 [3]. This iteratively challenged a representative panel of UK

clinical pharmacologists to accept or reject a number of statements about the knowledge and skills expected of someone reasonably up to date and competent. The process was repeated, with feedback from previous responses, until two-thirds of the group reached full or conditional agreement. Surprisingly, given the diversity of roles played by clinical pharmacologists in the UK, there was remarkable agreement in the areas of core knowledge, therapeutic skills and educative skills. There was less agreement about the investigative skills that a clinical pharmacologist should have. Reassuringly, the overwhelming majority thought that a consultant in CPT should be able to prescribe competently.

The structure of the current curricula in medicine are dictated by the Postgraduate Medical Education and Training Board, now incorporated into the General Medical Council (GMC), although negotiations about the content and structure of the curricula are not direct but take place via the intermediary of the JRCPTB. Despite efforts to build

Figure 1

Structure of the basic training programme in CPT. Abbreviations: CCT, certificate of completion of training; FY2, second foundation year; GIM, general (internal) medicine; and MRCP, Membership of the Royal College of Physicians

Figure 2

Structure of the academic training programme in CPT. Abbreviations: ACF, Academic Clinical Fellowship; CCT, certificate of completion of training; FY2, second foundation year; GIM, general (internal) medicine; and MRCP, Membership of the Royal College of Physicians

flexibility into the CPT curriculum, its structure is currently entwined with that of general (internal) medicine, and it therefore incorporates the common competencies that are required of all physicianly disciplines, including medical leadership and management. However, the curriculum contains flow charts (Figures 1–3) that demonstrate an intention to allow trainees from other medical disciplines (in the broadest sense), from primary care to other hospital disciplines, and among those embarking on an academic path, to train in CPT. In addition, included in the curriculum is the pathway by which trainees might undertake a special module in research methods. Modules in hypertension and toxicology have recently been added and approved.

For those unfamiliar with the current regime of training oversight, it must be emphasized that double counting, that is allowing for some time to count towards completion in each of two or more specialties as long as trainees are registered for programmes for each, is no longer allowed. If a trainee embarks on training in two disciplines, the full time in training for each must be undertaken and, although there is some room for manoeuvre, it is minimal and requires dispensation from the local postgraduate Dean. This makes dual and triple certificate of completion of training (CCT) programmes, although theoretically feasible, unpopular both with trainees and with postgraduate Deans, who have to justify the funding of such lengthy schemes.

Figure 3

Structure of the training programme for CPT and general practice (GP). Abbreviations: CCT, certificate of completion of training; FY2, second foundation year; and ST1 & ST2, specialist training years

In the core CPT module, the domains are as follows: assessing the clinical pharmacology literature; use of statistical techniques pertinent to clinical pharmacology; mechanisms of drug action; dosing regimens; rational prescribing for individuals; rational prescribing for populations; drug regulation; pharmacoepidemiology; adverse drug reactions; and drug errors and drug overdose. Under each of these domains are described the knowledge, skills and behaviour expected of trainees and the methods by which these must be assessed. The general (internal) medicine curriculum also highlights some elements, particularly practical prescribing skills, that are related to clinical pharmacology, emphasizing the need to make the 'added value' of training in CPT more explicit in future versions of the CPT curriculum.

The curriculum says relatively little about how training should be delivered, but it does stress the importance of experiential (service-based) training, learning with peers, and formal postgraduate teaching. For CPT, in which many centres have only small numbers of trainees, learning with peers is difficult, and there can be problems of providing comprehensive training in knowledge and specific skills. It is proposed, in order to overcome these difficulties, that in collaboration with the British Pharmacological Society structured didactic training for Specialist Registrars should be provided at least once each year, in a cycle that will ensure coverage of the full knowledge component of the curriculum within the 5 years each trainee might be expected to spend in training. Other areas that individual centres have difficulty in covering are investigative skills, pharmacokinetics, pharmacovigilance and toxicology, although this can be overcome by careful secondments to willing units in pharmaceutical companies or National Health Service (NHS) units with specific interests in toxicology.

Much of the planned assessment, like those in most other areas of medicine, is based on a number of assess-

ments in the workplace, including directly observed procedures (DOPs), which are self-explanatory, mini-clinical evaluation exercises (mini-CEX), in which a trainee is observed and put through a structured assessment when undertaking a routine clinical encounter, and a case-based discussion (CBD), in which a structured discussion with a senior colleague forms the basis for assessment (Figure 4). These tools have been tested and nominally validated by the Royal College of Physicians in an exercise that, although showing some sensitivity of the mean outcomes to the trainee's stage of training, identified that many encounters were required to ensure that the overwhelming proportion of the variance in mean outcome for a trainee was due to the performance of the trainee rather than any confounding factor. Several unwelcome biases were confirmed, including the difficulty of the case, the context and the sex of the rater.

Unfortunately, the tools tested by the College are not appropriate to be used to test nonclinical skills and reasoning, such as those necessary in CPT. Other specialties, such as radiology, public health and pharmaceutical medicine, have grappled with similar problems, but have the luxury of larger numbers of trainees on whom to pilot and tentatively validate any new or adapted tools. On the back of this, we attempted to introduce the problem-based discussion without any specific piloting and, unfortunately, the current wording of the assessment tool still suggests a clinical encounter. So far, the Postgraduate Medical Education and Training Board and GMC have been very sympathetic to the difficulties that small specialties encounter when they are faced with the need to ensure reliability in assessments. However, they give the strong impression that they will require face validity of the tool, which we do not currently have, and some evidence that the supervisors who use the tool have received training, in order to impose an element of consistency and reproducibility. The rigidity of the current system required by the GMC, or at least

Curriculum area/competence		Knowledge based exam	Mini-CEX	DOPS	MSF	CBD	Patient survey
Objective 1. The trainee will be able to undertake and interpret early phase studies of drug action in humans.		√					
K	Describe theories of drug-receptor interactions and the related concepts of agonists, antagonists, structure action relations, dose response relations, pharmacodynamics (PD), pharmacokinetics (PK), PK/PD interrelations, efficacy and potency.	√					
	Understand the meanings of surrogate endpoints, tolerability and adverse effects.	√					
	Demonstrate knowledge of the principles of 'first into man' studies.	√					
	Demonstrate knowledge, and understand the limitations, of pre-clinical studies in the early phase human testing of biological products.	√					
S	Write trial protocols.		√				
	Write and submit REC submissions		√				
	Able to recruit subjects for studies and obtain valid informed consent.		√		√		
	Perform PD and PK studies in human volunteers (including nulation and other skills relevant to their clinical area of expertise).		√				
	Measure end points reliably.			√			
	Record data accurately.			√			
	Analyse data including risk-benefit analysis and dose determination for definitive phase-3 studies.		√				
	Identify, review and analyse relevant literature.		√				
	Draft papers for publication.		√				
	Communicate with co-workers and agree a final manuscript for submission.		√				

Figure 4

Part of an assessment blueprint for CPT. REC, Research Ethics Committee; CEX, clinical examination exercise; DOPS, directly observed procedural skill; MSF, multi-source feedback; CBD, case based discussion

implied by the JRCPTB, cannot be overstated. Each element of knowledge, skill and behaviour in the curriculum has to be covered by mapping from the completion of individual tools that test these areas, and when electronic completion with e-portfolio is fully introduced this mapping will have to be signed off by educational supervisors.

Future options for graduate training and assessment

How should specialists in CPT be trained and assessed in the future? Here I suggest some proposals and outline their advantages and disadvantages, without wanting to suggest that I am specifically advocating any of them.

We could soldier on under the present system, slowly refining our methods of assessment and clubbing together to provide training that covers the curriculum. The advantages of this are that we would maintain an established tradition and have a ready source of funding to employ our trainees. However, this would require a greater input from all consultants in CPT, in order to provide questions for the proposed annual short answer questions to test CPT knowledge. Furthermore, they would have to

undergo training themselves in assessing trainees and to participate in the provision of structured knowledge training for trainees.

An alternative would be to enter into discussion with the Faculty of Pharmaceutical Medicine, in order to explore the possibility of joining with them and using the areas of overlap between the two curricula to allow trainees to build their knowledge and skills using a base set of common modules, incorporating different additional modules for the two disciplines. This would have the advantage that the Faculty of Pharmaceutical Medicine has constructed curriculum modules and piloted assessment tools that have already been accepted by the GMC. There is, of course, no certainty that the Faculty would welcome such an approach, and training modules relevant only to CPT would have to be constructed to complement the common areas already within the pharmaceutical medicine curriculum. There would also be a perceived loss of independence that is currently enjoyed by doctors in CPT when involved in decision making about products from industry.

Finally, we could look at the unwelcome prospect of abandoning the CCT in CPT. This would free up the speciality from the constraints imposed by the GMC, focused as

it is on training in clinical areas, and allow it to devise its own independent training and assessment in the skills required to practise CPT. Importantly, it would allow us to focus on those academic elements of the discipline that have been its backbone for many years but are being squeezed out in the need to adhere to the NHS clinical training model. This would involve no loss to trainees, who all undergo dual training already, and would therefore achieve a CCT with which to gain employment in the NHS at consultant level. Critically, however, it would risk a loss of status for the speciality, which already suffers from a declining image, especially among medical students and doctors in training. In addition, there would be loss of financial support from postgraduate Deaneries that currently support training in CPT.

Clinical pharmacology and therapeutics faces a difficult time, but it is key to attracting high-calibre entrants to the speciality that we have the structure of training and assessment completely sorted out.

Competing Interests

There are no competing interests to declare.

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