What knowledge and skills are essential for specialists in Clinical Pharmacology and Therapeutics? Results of a Delphi study

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Aims To identify the knowledge and skills that should be considered essential for specialists in Clinical Pharmacology and Therapeutics (CPT) with a commitment to the National Health Service (NHS).

Methods A Delphi study using a sample of current specialists.

Results Members of the expert panel (20 in all, representative of the Clinical Section membership) identified 78 statements for consideration, in four domains (core of knowledge, therapeutic skills, educative skills, and investigative skills), of which 58 (74.4%) were accepted by more than two-thirds of respondents. Of these, 35 were knowledge items, whereas 23 were skills (11 therapeutic, 4 educative and 8 investigative). The large majority (79.3%) of these statements were endorsed by at least four out of five panel members.

Conclusions Despite the varied work patterns and responsibilities of specialists in CPT, it is possible to identify a core of knowledge and skill that most consider essential for the delivery of their commitment to the NHS. The findings will provide NHS Trusts with a clear idea of what they can expect from these specialists, and will act as a checklist for specialists themselves to direct their Continuing Professional Development within the consultant appraisal process. The results also describe a curriculum for continuing education in CPT, which the BPS Clinical Section can use to develop information resources and training opportunities.

Keywords: clinical pharmacology, continuing medical education, continuing professional development, Delphi process, revalidation, therapeutics

Introduction

In the consultative document 'Revalidating Doctors—ensuring standards, securing the future' [1], the General Medical Council (GMC) set out the general headings under which the information for revalidation will need to be collected and assessed as part of its fitness to practise procedures. The second of these headings—maintaining good medical practice (keeping up to date)—relates to paragraph 5 in the GMC's earlier publication 'Good Medical Practice' [2], which states 'You must keep your knowledge and skills up to date throughout your working life. In particular, you should take part regularly in educational activities which develop your competence and performance'.

A questionnaire survey among members of the British Pharmacological Society (BPS) Clinical Section in 1999 [3] revealed a desire for the Society to provide information resources and training opportunities for its members. Before responding to this request, the Clinical Section Committee needed guidance on the scope of the resources required.

In theory, the discipline of Clinical Pharmacology & Therapeutics (CPT) encompasses all the skills of an investigative clinical pharmacologist as well as a comprehensive knowledge of Therapeutics. However, few specialists in CPT would claim to possess such a broad range of competence, nor would most consider this necessary for them to discharge their National Health Service (NHS) responsibilities to a satisfactory standard. Individual specialists in CPT vary widely in the knowledge and skills portfolio they require in their everyday clinical practice, so identifying a core is not easy. Yet similarities exist, and it is reasonable to propose that assessment of this core could form part of revalidation, and could provide a useful

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reference point during consultant appraisal. So, in what elements of knowledge and skill should a specialist in CPT be expected to demonstrate that he/she is, respectively, up to date and competent? The answer to this question is not immediately apparent—it has never been asked before. The Committee of the Clinical Section decided to address the issue by deriving a consensus among a sample of specialists in CPT, representative of the variety of specialists at large, by means of a Delphi study. A small steering group was charged with organizing the study.

The objectives of the study were to identify:

- the knowledge base that should be considered essential for specialists in CPT;
- the skills that should be considered essential for specialists in CPT.

Methods

The Delphi process is an adaptation of a technique developed in the 1950s by the Rand Corporation as a forecasting tool to predict the effects of atomic warfare in the USA [4]. It provides a survey technique for decision-making among isolated anonymous respondents, and has been used to determine both the content of curricula [5, 6] and professional competencies [7] in a medical context. Its applications in health services research have been well reviewed by Cantrill *et al.* [8]. In relation to education and training in pharmacology and therapeutics, it has been used to determine the content of an undergraduate core curriculum [9], a postgraduate course in therapeutics for general practitioners [10], and a curriculum for specialist training in pharmaceutical medicine [11].

The process uses an iterative approach to guide group opinion towards a consensus, by seeking responses to statements about a reference topic and feeding back the results in a series of stages (rounds). Appropriate end-points include the completion of a fixed number of rounds, a predetermined level of agreement (consensus), or lack of change in the level of agreement between two successive rounds (stability). Whichever endpoint is chosen, it should be decided in advance. The higher the required level of agreement, the larger will be the number of rounds necessary to achieve consensus, raising the likelihood that participants will drop out through fatigue.

Although panel sizes have varied widely in different studies, it is customary for a Delphi exercise to seek the views of at least 20 independent experts, whose anonymity is preserved in order that they do not confer with each other. At the time this study was planned there were 79 specialists in Clinical Pharmacology and Therapeutics in the United Kingdom, contributing 55 whole time equivalents to the NHS. An attempt was made to ensure that those chosen as panel members not only had a

commitment to the NHS but were representative of the Clinical Section membership, in respect of age, gender and geographical location.

The preliminary list of questions for the panel was based on the curriculum for specialist trainees in CPT proposed by the Specialist Advisory Committee (SAC) in CPT for the Joint Committee on Higher Medical Training (JCHMT). The specialist training curriculum in 2000 included items in two categories: obligatory experience and recommended experience (Table 1). When considering the knowledge and skills required of a competent specialist this categorization seemed rather artificial. Nevertheless, the subheadings in Table 1 were used as a basis for identifying 67 statements relating to elements of knowledge and skill, which were eventually aggregated into four domains:

- 1 core of knowledge (34 statements);
- 2 therapeutic skills (10 statements);
- 3 educative skills (5 statements); and
- 4 investigative skills (18 statements).!

This draft list of statements was sent to the panel during the first round of the process. Respondents were asked to indicate whether they agreed or disagreed that each statement should be included. They were also invited to suggest additional statements if they felt the draft list was incomplete. Their responses were entered on to a database and statements were carried forward to the second round. The expanded list of statements was sent out again to the panel with an indication of the level of agreement achieved for each during the initial round.

During the second round of the process, respondents were asked to indicate the extent to which they agreed with each statement on the definitive list. It was emphasized that they should consider their responses in their role

Table 1 Content of CPT training curriculum in 2000.

<i>Obligatory experience</i>	<i>Recommended experience</i>
Drug action in man	Management, detection and reporting of adverse drug reactions
Clinical pharmacokinetics	The treatment of drug overdose
Theory and practice of statistics and experimental design	The epidemiological approach to drug usage, efficacy and toxicity
New drug development	Therapeutic drug monitoring
Rational and cost-effective use of medicines	The role and function of a local Research Ethics Committee
Evaluation of scientific literature	
Communication and educational skills	
Management in the NHS	
Medical audit	

as specialists providing a service to the NHS. Possible responses comprised strongly agree, agree, neutral, disagree, or strongly disagree. The responses were entered onto the database and statements were accepted unconditionally if the proportion of respondents expressing either agreement or strong agreement reached the pre-determined level (two-thirds). Responses were accepted conditionally if more than two-thirds of respondents expressed agreement, strong agreement, or were uncertain. Statements that failed to meet either of these criteria were rejected.

During the final round, respondents were presented with a selected list comprising those statements that had been accepted conditionally in the second round. They were again asked to indicate the extent to which they agreed with each statement, but this time no uncertain responses were permitted. Once again, their responses were entered on to the database, statements being accepted unconditionally if more than two-thirds of respondents expressed either agreement or strong agreement. Thus, a final list of statements was produced.

Results

The steering group identified 22 suitable specialists in CPT, of whom 20 accepted the invitation to take part. The final panel comprised 18 men and two women, employed by 15 separate universities/NHS Trusts in 13 different cities in the United Kingdom. All members of the panel replied to the initial request for their opinions, and 19 to the second and third requests. During the first round, no statements were rejected, but 11 further statements were added to the initial 67, giving 78 in all, within the four domains. During the second round, 45 of these 78 (58%) were accepted unconditionally and 18 (23%) conditionally; 15 (19%) were rejected. Within the core of knowledge domain, 26 (62%) of statements were accepted unconditionally and 12 (29%) conditionally. All statements within the therapeutic skills domain, and all but one within the educative skills domain, were accepted unconditionally. Disagreement was greatest with statements within the investigative skills domain; only half were accepted, 4 (20%) unconditionally and 6 (30%) conditionally.

Those statements accepted conditionally (18 in all) were returned to the expert panel for reconsideration. During this final round, in which no neutral responses were entertained, three further statements in the core of knowledge domain and two in the investigative skills domain were rejected. The final list of 58 accepted statements is shown in Table 2 together with the extent to which the members of the expert panel agreed with them, and whether consensus was achieved in the second or final round. Table 3 shows the remaining 20 statements

with which fewer than two-thirds of respondents agreed, and in which round the lack of agreement was finally confirmed.

Discussion

In selecting the members of the expert panel, aside from the criteria mentioned earlier, the steering group took into account how diligent individual members were likely to be in responding to the questions posed during several rounds of the enquiry. Limited data on the panel members have been presented in order to preserve their anonymity. However, they included consultants recently appointed and those well advanced in their careers, and an estimate of their ages suggested they were evenly distributed between those aged 35–45 and those aged 46–55 years. Specialists in CPT approaching the end of their careers were avoided partly because it was thought they might be too busy, but mainly because they would be least likely to face the consequences of their recommendations.

It could be argued that using the training curriculum as a starting point for identifying elements of knowledge and skill limited the scope of the study. It might have been interesting to solicit the views of the panel members on their current job descriptions and seek their unprompted opinions on the core knowledge and skills essential to a specialist in CPT. However, this would have extended the time taken to complete the study and, given the acknowledged variety of job descriptions among specialists in CPT, might have limited the extent to which its findings could reasonably be extended to others practising in the discipline. Using the approach chosen, the findings will be relevant to trainees acquiring specialist certification and being appointed to consultant posts during the next few years, who will have perhaps the greatest stake in the study's outcome.

What can we learn from the final consensus? Although two-thirds of the panel had to agree with a statement before it could be accepted, most statements attracted the support of a large majority of the panel. It is clear from Table 2 that only 12 statements (21%) were endorsed by fewer than four out of five panel members. This outcome is reassuring and affords a considerable measure of confidence in the overall result. It demonstrates that, despite the varied work patterns and responsibilities of specialists in CPT, it is possible to identify a core of knowledge and skill that most consider essential for the delivery of their commitment to the NHS.

Of the 20 statements rejected (Table 3), almost all were items of greater relevance to industrial clinical pharmacologists rather than to specialists in CPT, but would be within the purview of academic clinical pharmacologists involved in research in the area of drug development.

Table 2 Statements with which at least two-thirds of panel members agreed (showing level of agreement). A competent specialist in CPT should be able to:

Statement	%
<i>1. Core of knowledge</i>	
Explain receptor agonism and antagonism, enzyme inhibition and activation	100
Distinguish between competitive and noncompetitive effects	100
Explain the implications of competitive and noncompetitive effects for drug action	89.5
Explain the meaning of common terms used to describe dose–response relationships, such as efficacy and potency	94.7
Explain the concept of a minimum effective and a maximum tolerated dose	100
Explain the meaning of common pharmacokinetic terms	100
Explain the role of plasma drug concentration measurements as a guide to dose adjustment and the diagnosis of toxicity	100
Explain the optimal use of plasma drug concentration measurements as a guide to dose adjustment and the diagnosis of toxicity (e.g. sample timing, interpretation of result)	100
Explain the principles involved in the ethical review of clinical research	100
Explain the role and responsibilities of Research Ethics Committees	94.7
Explain the selection and use of appropriate statistical analyses	100
Explain the principles of clinical trial design and analysis	94.7
Explain the principles of Good Clinical Practice	68.4*
Explain the strengths and weaknesses of observational data	84.2
Explain the principles of pharmacovigilance	100
Define pharmaco-epidemiological concepts	73.7*
Define pharmaco-economic concepts	73.7*
Explain the basis for rational drug selection and use	100
List the most reliable sources of information available to guide rational drug use	100
Explain the principles of ‘evidence-based medicine’	100
Explain the application of ‘evidence-based medicine’	89.5
Explain the appropriate constitution, role and context of Drug and Therapeutics Committees	94.7
Explain the role of Area Prescribing Committees	73.7*
Explain the role of the National Institute for Clinical Excellence	84.2*
Explain the criteria used in establishing the diagnosis of an adverse drug reaction	94.7
Explain the mechanism of action of common and important poisons	89.5
Explain how to investigate suspected cases of poisoning	94.7
Explain how to manage common forms of drug poisoning	94.7
Explain the factors that cause medication errors	89.5*
Explain the mechanisms underlying drug interactions	73.7
Explain the place of placebos in clinical research	100*
Explain the factors underlying concordance with drug therapy	89.5*
Explain the principles embodied by the Declaration of Helsinki	84.2*
Explain the importance of pharmacogenetics in determining drug response	68.4
Display specialist knowledge of (at least) one area of Therapeutics	84.2
<i>2. Therapeutic skills</i>	
Use pharmacokinetic principles to optimize drug administration in man	84.2
Use pharmacokinetic principles to optimize the effectiveness and safety of drug treatment	84.2
Assess the therapeutic effects of drugs	100
Assess the adverse effects of drugs	100
Select drugs rationally when planning medical treatment	100
Take cost-effectiveness into account when selecting drugs for use in medical treatment	100
Adjust therapeutic regimens appropriately to maximize benefit and minimize risk	100
Investigate and manage suspected adverse drug reactions	94.7
Report suspected adverse drug reactions appropriately to the CSM using a Yellow Card	100
Advise on the management of poisoned patients	78.9
Write a prescription competently	89.5
<i>3. Educative skills</i>	
Evaluate scientific papers	100
Devise prescribing policies to govern the choice of medicines by those engaged in patient care	84.2
Develop formularies to guide drug selection	100
Develop guidelines to facilitate the optimal use of medicines	94.7

Table 2 (Cont.)

Statement	%
<i>4. Investigative skills</i>	
Interpret dose–response curves from <i>in vitro</i> and <i>in vivo</i> studies	84.2*
Interpret early phase studies of drug action in humans	68.4
Write a subject information sheet and a consent form in appropriate lay language	89.5
Choose the most appropriate statistical tests in the analysis of experimental data	78.9
Perform simple statistical analyses	89.5
Design a case-control study	73.7*
Investigate a suspected medication error	84.2*
Write a medico-legal report on a medication error	68.4*

* These items achieved only conditional agreement in the second round; they achieved two-thirds agreement only during the final round, when no neutral verdict was allowed.

Table 3 Statements rejected by the expert panel (showing extent of support among members for acceptance).

Statement	%
<i>Core of knowledge</i>	
Explain the principles of structure–activity relationships	21.1
Explain the implications of structure–activity relationships for the design of novel drugs	5.3
Describe the data required before administering a new chemical entity to humans for the first time	57.9*
Explain the clinical pharmacology component of a regulatory submission	5.3
Explain the nature and role of outcomes research	57.9*
Explain the mechanisms and legislation for drug licensing, control and pricing	57.9*
Explain the legislation affecting the experimental use of unlicensed drugs	21.1
<i>Educative skills</i>	
Produce comprehensive systematic reviews (meta-analyses) of specific topics	0
<i>Investigative skills</i>	
Interpret preclinical pharmacological and toxicological studies	26.3
Describe an approach to testing a drug effect in a major organ system in an early phase study	26.3
Undertake early phase studies of drug action in humans	31.6
Design phase 1 and phase 2 studies of new drugs	57.9*
Conduct phase 1 and phase 2 studies of new drugs	26.3
Design a drug utilization study	10.5
Conduct a drug utilization study	10.5
Generate and test pharmaco–epidemiological hypotheses	10.5
Conduct a case-control study	21.1
Design a cohort study	63.2*
Conduct a cohort study	21.1
Advise on the appropriate use of alternative pharmaco–economic analyses	0

* These items achieved conditional agreement in the second round, but failed to achieve two-thirds agreement in the final round when no neutral verdict was allowed.

How should the results be used? First, they will provide those NHS Trusts who currently enjoy the services of specialists in CPT with a clear idea of what they can expect from these specialists, and inform those who have yet to benefit from such diversity about what they have been missing.

Second, they will provide a checklist for specialists in CPT themselves, who now have clear guidance on what knowledge and competencies a representative

body of their peers consider they should possess. Newly registered specialists will have acquired these as part of their specialist training and will acknowledge the obligation to keep their knowledge up-to-date and their skills honed. Those less recently trained will be confident about certain items, but not so confident about others. The list will allow them to identify their need for Continuing Professional Development (CPD), which can be fed into the consultant appraisal process, to ensure that the

necessary time and funding are made available to allow this CPD to occur. The resulting portfolio of agreed and refreshed competencies should contain the necessary evidence to secure revalidation in CPT when this falls due.

Finally, the results describe a curriculum for Continuing Education in CPT, which the BPS Clinical Section can use to develop information resources and training opportunities. Options arising out of the questionnaire survey of the Clinical Section published in 2001 [3] included:

- setting up an electronic library of published material that members could access;
- commissioning review articles on recent developments;
- developing self-assessment material; and
- organizing symposia and workshops at BPS meetings.

Clearly, the results of this study will serve to focus these activities upon essential areas of knowledge and competence, so that they can be given appropriate priority.

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