

SPECIALTY TRAINING CURRICULUM

FOR

CLINICAL PHARMACOLOGY
AND THERAPEUTICS

MAY 2007

Joint Royal Colleges of Physicians Training Board

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1. RATIONALE

1.1 Background and Introduction

The primary purpose of this curriculum is to provide detailed guidance for trainees in obtaining the appropriate level of knowledge, clinical skills, and competence to be awarded a certificate of completion of training (CCT) which is a prerequisite to a career as a consultant in Clinical Pharmacology and Therapeutics (CPT) working in hospital, community or research settings. This document will also enable postgraduate deans, regional specialty training committees, and educational supervisors to ensure that the required standards of clinical care are being met by having structured training programmes and objective assessment procedures within each region. The curriculum has been produced using the standards specified by the Postgraduate Medical Education and Training Board (PMETB).

Clinical pharmacologists usually combine their speciality with work as general physicians. About half of their time will involve the supervision of acute medical admissions, responsibility for medical inpatients and running outpatient clinics. These individuals will normally have another clinical speciality interest (eg cardiovascular risk management, toxicology) and will take a particular interest in prescribing issues on behalf of their employing NHS body. The work programme of a consultant in clinical pharmacology and therapeutics varies greatly, depending on the job setting. Approximately two-thirds of consultants in clinical pharmacology and therapeutics have academic appointments within universities. While having a service commitment, many of these individuals will have a strong research emphasis in their work that will contribute to knowledge about drug actions and their clinical usage. They will also play an important role in the planning and delivery of undergraduate teaching in therapeutics. Other clinical pharmacologists at consultant level are employed by the pharmaceutical industry and are involved in the development of new drugs and early clinical trials in patients. Some also hold joint appointments with academic units or trusts, a trend that may grow in the future.

The content of the curriculum and the teaching/learning methods described were agreed by the specialist advisory committee (SAC) in Clinical Pharmacology and Therapeutics (CPT). Regular meetings were held by the SAC involving all relevant stakeholders (guidance was given by the Joint Committee on Higher Medical Training (JCHMT) and officials from PMETB) with much work being done by a curriculum sub-committee. A curriculum subcommittee (Prof JM Ritter, Prof GT McInnes and Dr PR Jackson) drafted a document, which was circulated to other stakeholders, with amendments made in response to their inputs. The final version of the curriculum was approved by the SAC and submitted for approval by the JCHMT. It was then submitted for approval by PMETB. The majority of the members of the SAC are practitioners, teachers, trainers and trainees in the speciality.

The competencies to be achieved as described within the curriculum build on core training including acute medicine level 1, achieved in specialty training years 1 and 2. Core training and acute medicine competencies build on foundation training. The curriculum describes the level of achievement expected from each of the years of training and how competency is attained and assessed. The specialty curricula identify

competencies which are expressed as the knowledge, skills, attitudes and behaviours that trainees must achieve.

All trainees in CPT will undertake a programme of combined training using this curriculum, with the General Internal Medicine (Acute Medicine) curriculum for level 2. These curricula are to be used in conjunction with the Generic Curriculum for the Medical Specialties which includes the general professional competencies as specified in the domains of “Good Medical Practice” which are to be acquired by all specialist physicians and runs from the Core Medical Training to CCT.

The curriculum will be achieved by completing the necessary specialty posts within training programmes. Until 2007 these posts will be at Senior House Officer (SHO) and Specialist Registrar (SpR) level. From August 2007 these will be described as Specialty Training (ST) year 1 through to Specialty Training year 6.

Generic Curriculum

This specialty curriculum is complementary to the generic curriculum which applies to all 28 physicianly specialities. The generic curriculum follows the headings of good medical practice and runs through from core training to CCT (see fig 1). Trainees should read and understand both their specialty curriculum and the generic curriculum. Both curricula should be seen as integrated so that generic competencies are acquired at all stages of specialty training. Some generic components are also further expanded and deepened for some specialties (eg palliative medicine). When planning specialty programmes, deaneries and trainers should ensure that both specialty and generic competencies can be acquired and assessed.

General Internal Medicine (Acute) curriculum

The new curriculum for General Internal Medicine (Acute) is split into 3 parts.

Level one competencies will be achieved by all physicianly trainees during core training (core medical training – CMT or acute care common stem – ACCS) and must be achieved before progression to specialty training.

Level 2 competencies will be achieved by those trainees in acute specialties who plan to take part in the acute medical take in their consultant working lives (fig 1).

Level 3 competencies will usually only be achieved by those wishing to CCT in GIM (acute) medicine and practice as an acute physician

Dual Accreditation

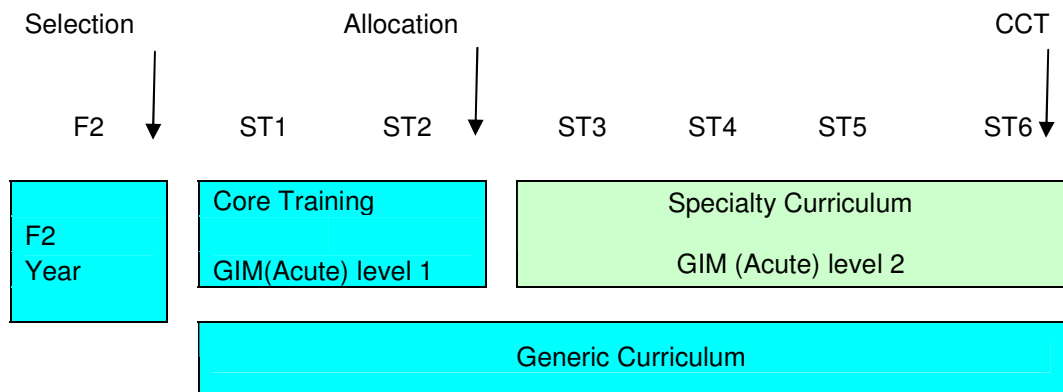
Trainees who wish to achieve a CCT in GIM (Acute) must have applied for and successfully entered a training programme which was advertised openly as a dual training programme. This programme will need to achieve the competencies as described in both the CPT and GIM (Acute) curricula and there must be agreed assessments (proposed by both SACs and approved by PMETB). These assessments

will be those blueprinted to both curricula. It is expected that a number of assessments will be shared without a need for the trainee to repeat them separately for both curricula. Postgraduate deans wishing to advertise such programmes should ensure that they meet the requirements of both SACs.

In addition to accrediting in clinical pharmacology and therapeutics and GIM (Acute) some trainees may wish to train and accredit in Intensive Care Medicine, achieving CCTs in three specialties. As above, they must have applied for and successfully entered a training programme advertised openly as training in all three specialties, with jointly agreed assessments and approval from PMETB.

Fig 1

Diagrammatic representation of specialty, generic and GIM (Acute) curricula for acute specialty training



1.2 Responsibility for the Curriculum

The medical director of the Joint Royal Colleges of Physicians Training Board – JRCPTB (formerly JCHMT) is responsible for the curriculum.

It was produced by the members of the SAC in clinical pharmacology and therapeutics by consensus following work by a curriculum subcommittee. This includes trainers and trainees as well as professional advisers and lay members. Teaching and learning methods were chosen based on the teaching experience of the trainers and the suggestions of the JRCPTB.

1.3 Entry Requirements

Applicants for medical specialist training will have satisfactorily completed and obtained the competencies of the Foundation training programme, the evidence being full registration with the General Medical Council and a certificate of completion of Foundation training or equivalent.

Before entering specialty training in CPT the trainee will have satisfactorily attained the competencies (or equivalent) of general internal medicine (GIM) (Acute) to level one, achieved during core medical, basic neuroscience or acute care common stem training in approved posts. The trainee will have experience of the unselected acute medical take of at least 12 months during core training or other post foundation training by the time of entering Specialty training in CPT. 'Unselected take' is defined as acute medical intake encompassing the broad generality of medicine, i.e. not restricted to any single or small group of specialities. If any major component of acute medicine (e.g. patients with stroke or myocardial infarction) is excluded from the take, this experience must be obtained in other posts. In order to ensure an adequate breadth of experience to supervise more junior trainees, on average at least 40 acutely ill patients should have been seen during each month of involvement in the acute take. These competencies will be demonstrated by satisfactory completion including assessments of the Acute Medicine level 1 curriculum.

1.4 Aims of Training

The primary purpose of training in CPT is the development of a physician who has the appropriate level of knowledge, skills, attitudes and competence to work independently and effectively as a consultant in CPT. Patient-centred approaches and team working are of vital importance. Training should be enjoyable in order to facilitate the learning of the trainee.

1.5 Duration and Organisation of Training

Although this curriculum is competency based, the duration of training must meet the European minimum of 4 (four) years for post registration in full time training adjusted accordingly for flexible training (EU directive 93/16/EEC requires that flexible training can be no less than 50% whole time equivalent). The SAC has advised that training from ST1 will usually be completed in 6 (six) years in full time training.

Trainees will pursue the learning outcomes described in the curriculum through a variety of learning methods. There must be robust arrangements for quality assurance in place to ensure consistent local implementation of the curriculum. Most competencies are acquired over a sustained period of experience. The curriculum will be delivered in a University and/or teaching hospital NHS-based department of clinical pharmacology, supervised by one or more trainers who are at least consultants or senior lecturers in seniority, and supported by an independent educational supervisor trained in CPT and of similar seniority. There will be annual appraisals and a record of in-training assessment.

The programme to which the trainee is appointed will have named consultant educational supervisor(s) for each slot in the programme. In addition, one consultant within the same region will act as programme director to the trainee. The programme director is responsible for ensuring the rotation of posts to which each trainee is attached will deliver the totality of the curriculum prior to acquisition of the CCT. If necessary,

attachments can be arranged outside the posts formally included in the programme to which the trainee has been attached in order that the curriculum is delivered. Alterations to the programme can be agreed with trainees usually after the annual record or review of in-training assessment (RITA) in order to meet the educational needs of the individual trainee. An academic mentor acceptable to the trainee will be appointed for the duration of the training programme.

There will be a record of training either written or electronic which will identify the components of training set out in the curriculum and will facilitate the recording of their completion, evidence of reflective learning and of the achievement of the prescribed competencies. Trainers will countersign the record and it will play an important part in the process of annual assessment.

Flexible Training

Trainees who are unable to work full-time are entitled to opt for flexible training programmes. EC Directive 93/16/EEC requires that:

- Part-time training shall meet the same requirements as full-time training, from which it will differ only in the possibility of limiting participation in medical activities to a period of at least half of that provided for full-time trainees.
- The competent authorities shall ensure that the total duration and quality of part-time training of specialist are not less than those of full-time trainees.

The above provisions must be adhered to. Flexible trainees should undertake a pro rata share of the out of hours duties (including on-call and other out of hours commitments) required of their full-time colleagues in the same programme and at the equivalent stage.

Funding for flexible trainees is now from deaneries and these posts are no longer supernumerary. Ideally therefore 2 flexible trainees should share one post to provide appropriate service cover.

To date flexible training has inevitably been prolonged (for instance a trainee working 50% will take 10 years to train). With competency based training although the indicative training time is 5 years equivalent, proof of completion to competencies may enable these trainees to finish their training in a shorter time. This will be the decision of the trainers in discussion with the SAC.

Research

Trainees who wish to acquire extensive research competencies, in addition to those specified in the generic element of the curriculum, may undertake a research project as an ideal way of obtaining those competencies, all options can be considered including taking time out of programme to complete a specified project or research degree. Time out of programme needs prospective approval from the SAC and the support of the Postgraduate Dean. Funding will need to be identified for the duration of the research period. A maximum period of 3 years out of programme is allowed.

1.6 Transitional Arrangements for trainees after implementation of this curriculum

There are no fundamental changes between this version of the curriculum and its predecessor other than an increased flexibility for additional training. In case of any programme director, trainer or trainee having uncertainty about the implications of the new curriculum this should be brought to the attention of the SAC who will adjudicate on the arrangements for the training programme of the individual trainee. All trainees will be encouraged to undertake the new assessment methods. For existing trainees this will not be insisted on except where the new methods are needed to verify the competence of the trainee. All trainees appointed from August 2007 will be expected to follow this version of the curriculum and its assessment methods.

2. CONTENT OF LEARNING

This section lists the specific learning objectives, core knowledge areas, skills, attitudes and behaviours to be attained throughout training in CPT.

At the completion of training, by a process of consolidation through the years of the training programme acquiring a variety of experience, the trainee should have acquired the following knowledge, skills and attitudes to function as a specialist in CPT:

- Undertake and interpret early phase studies of drug action in humans.
- Use pharmacokinetic principles to optimise drug administration and drug effect.
- Use drugs rationally and cost-effectively.
- Evaluate critically literature relevant to CPT including basic pharmacology, toxicology and phase I, II, III and IV clinical trials and meta-analysis.
- Design clinical trials, including phase 3 studies, and contribute to their execution and dissemination. Select prospectively appropriate statistical methods for planned experiments (including clinical trials), perform such analyses, and interpret the resulting statistical output.
- Describe and influence what determines the pattern of use of medicines in populations.
- Anticipate (and hence minimise), detect, manage, report and analyse adverse drug reactions (ADR).
- Advise on cases of overdose or poisoning, and to manage such cases as are relevant to their clinical speciality (e.g. children for paediatricians).

Learning Objectives

Objective 1. The trainee will be able to undertake and interpret early phase studies of drug action in humans.

Knowledge	Skills	Attitudes/Behaviours
<ul style="list-style-type: none"> - 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 preclinical studies in the early phase human testing of biological products. 	<ul style="list-style-type: none"> - 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. - Demonstrate communication skills in effective presentation of a paper at scientific meetings. 	<ul style="list-style-type: none"> - Consult appropriately. - Recognise the primacy of subject safety. - Appreciate the need for meticulous record keeping and research governance. - Appreciate the importance of communicating research data orally and in written form and is diligent in writing and rehearsal.

Objective 2. The trainee will be able to use pharmacokinetic principles to optimise drug administration and drug effect.

Knowledge	Skills	Attitudes/Behaviours
<ul style="list-style-type: none"> - Describe the principles of: correct choice of route of administration, absorption of drugs, metabolism and excretion of drugs, interpretation of drug concentration in body fluids, pharmacokinetics, drug assay, PK-modelling, pharmacogenetics, PK-based drug interaction, personalised medicine. - Demonstrate knowledge of common analytical methods and their limitations. - Demonstrate knowledge of good laboratory practice (GLP). 	<ul style="list-style-type: none"> - Construct and adjust dose regimens correctly. - Negotiate an acceptable regimen with the patient where appropriate 	<p>Recognise the need for individualisation of therapy where necessary.</p> <p>Recognise the importance of taking responsibility for repeated observation and ongoing patient follow-up on the wards, and for volunteer follow-up during clinical investigation.</p> <p>Respect patient/ subject autonomy.</p> <p>Recognise the importance of concordance.</p>

Objective 3. The trainee will be able to use drugs rationally and cost-effectively.

Knowledge	Skills	Attitudes/Behaviours
<ul style="list-style-type: none"> - Demonstrate knowledge of the mechanisms of action and modes of use of common therapeutic drugs. - Demonstrate knowledge of sources of individual variation including genetic, age- and gender- related (including pregnancy and lactation), and other sources of individual variation especially co-existing renal hepatic and other disease and drug interaction both beneficial and adverse. - Explain the roles of National and European bodies including the medicines and medical devices health regulatory agency (MHRA), European medicines evaluation agency (EMA), national institute for clinical excellence (NICE) in ensuring rational and cost effective use of medicines. - Demonstrate knowledge of non-physician prescribing, including patient group directives (PGD) and dependent and independent prescribing. 	<ul style="list-style-type: none"> - Communicate effectively with individual patients, clinical colleagues and in committee. - Select drugs and dose regimens rationally based on individual factors. - Develop prescribing policies, formularies and guidelines. - Evaluate guidelines on medicines utilisation in the context of D&T committees. - Write guidelines on medicines management for evaluation by D&T committees. - Make effective submissions to formulary committees for new drugs. - Audit drug utilisation. 	<ul style="list-style-type: none"> - Prescribe with due regard to general knowledge, as specified combined with specific patient related information relating to demographic characteristics, drug history and individual preference. - Respect the varied expertise of drug and therapeutics committee members with diverse skills and backgrounds. - Participate in decision making/consensus building in the context of D&T committee.

Objective 4. The trainee will be able to critically evaluate literature relevant to CPT including basic pharmacology, toxicology and phase I, II, III and IV clinical trials and meta-analysis.

Knowledge	Skills	Attitudes/Behaviour
<ul style="list-style-type: none"> - Demonstrate knowledge of basic pharmacology and clinical medicine at levels of competency defined in the CPT application to PMETB. - Know how to report misleading advertising claims to MHRA and ABPI. 	<ul style="list-style-type: none"> - Critically analyse papers regarding rationale, cogency, experimental design, analytical methodology, method of analysis, potential sources of bias, confounding, conflict of interest, appropriateness of discussion, validity of conclusions. - Critically analyse advertising claims made for medicinal products. - Uses electronic databases (eg Medline, Embase, Toxbase, Cochrane). 	<ul style="list-style-type: none"> - Respect ethical principles underlying peer review. - Participate in peer review. - Evaluate expert reviews (eg NICE). - Communicate effectively in journal clubs, drug and therapeutics and audit committee meetings.

Objective 5. The trainee will be able to select prospectively appropriate statistical methods for planned experiments (including clinical trials), perform such analyses, and interpret the resulting statistical output.

Knowledge	Skills	Attitudes/Behaviour
<ul style="list-style-type: none"> - Describe the sources of biological variation and explain the principles involved in quantifying this. - Describe common parametric and non-parametric tests including chi-squared, t-tests, ANOVA, Bonferoni correction and least squares and Spearman rank regression. - Analyse critically the pros and cons of sequential analysis. 	<ul style="list-style-type: none"> - Consult effectively with statisticians during the planning stage of complex experimental studies. - Interpret P values and confidence intervals (CI) including CI of differences in the case of negative trials. - Explain the biological meaning of non-inferiority trials. - Explain absolute versus relative risk reduction. - Use a modern statistics package. 	<ul style="list-style-type: none"> - Possesses a self-critical attitude that only accepts an outcome that is understood. - Demonstrate a willingness to consult appropriately. - Undertake work in a patient and meticulous manner.

Objective 6. The trainee will be able to design clinical trials, including phase 3 studies, and contribute to their execution and dissemination.

Knowledge	Skills	Attitudes/Behaviour
<ul style="list-style-type: none"> - Describe different trial designs. - Demonstrate knowledge of the principles of controlled experiments, randomization, use of placebo and blinding. - Describe principles underpinning ethics of research on human subjects including duties, rights and utilitarianism. - Demonstrate knowledge of good clinical practice (GCP). 	<ul style="list-style-type: none"> - Select a trial design appropriate to the research question. - Write an REC application. - Justify a research proposal in terms that are understood by the lay members of an REC. - Able to recruit research subjects. - Screen potential subjects for inclusion/exclusion criteria. - Obtain valid informed consent. - Arrange visits of research subject to clinical laboratory or research clinic - Perform and/ or supervise clinical measurements. - Keep records to the standard required by GCP. - Contribute to writing papers and reporting findings by oral and poster presentations at meetings. 	<ul style="list-style-type: none"> - Maintain absolute honesty. - Does not embark on a human investigation where an external sponsor has ultimate control over the right to publish or otherwise disseminate resulting information. - Maintain meticulous attention to detail. - Recognise the primacy of safety of the subject. - Maintain a professional relationship with study sponsors and their employees (CROs etc).

Objective 7. The trainee will be able to anticipate (and hence minimise), detect, manage, report and analyse adverse drug reactions (ADR).

Knowledge	Skills	Attitudes/Behaviour
<ul style="list-style-type: none"> - Demonstrate knowledge of: <ul style="list-style-type: none"> - Important (common and/or severe) adverse effects of drugs used in their area of clinical practice. - The mechanisms whereby drugs cause ADR. - Common clinical presentations of ADR. - Appropriate management of suspected ADR. - Explain how ADR are identified and reported. - Explain the classification of ADR. 	<ul style="list-style-type: none"> - Manage common and serious ADR, including anaphylaxis, appropriately. - Use printed and electronic resources to identify unusual or uncertain ADR. - Analyse post marketing surveillance studies critically. - Report suspected ADR appropriately. 	<ul style="list-style-type: none"> - Alert to the possibility that clinical events are drug-related. - Prepared to share information and suspicions and eschews secretiveness for perceived future aggrandisement or gain. - Consult with colleagues over judgements such as risk/benefit of rechallenge. - Maintain a healthy scepticism of marketing devices dressed up as post marketing surveillance.

Objective 8. The trainee will be able to describe and influence what determines the pattern of use of medicines in populations.

Knowledge	Skills	Attitudes/Behaviour
<ul style="list-style-type: none"> - Identify factors that affect drug utilisation including effects of: social class, ethnicity, nationality (especially within Europe), economic status, co-morbidity, age and gender (including pregnancy and lactation). - Demonstrate knowledge of factors affecting public perception of drugs and their use in treating and preventing disease, including effects of media on medicines utilisation. - Describe the role of the pharmaceutical industry in the public perception of drug use. - Explain the role of government in licensing, pricing and cost-benefit analysis underpinning drug availability in the NHS, and the legislation that underpins these. - Explain the role of local groups (D&T committees and formulary committees) in defining the availability of medicines in a local health context. 	<ul style="list-style-type: none"> - Apply this knowledge in individual patient practice and in drafting management guidelines. - Interact effectively with the media as well as in committees. - Handle potential conflicts of interest appropriately. 	<ul style="list-style-type: none"> - Respect ethnic diversity. - Respect individual autonomy. - Contribute to public education about drugs and their utilisation. - Respect the law relating to medicines in the UK and understands its main exclusions (eg the Medicines Act 1968). - Engage in the reform of current practice in the UK and Europe (e.g. via participation in public consultations on medicines utilisation initiated by MHRA or by NICE).

Objective 9. The trainee will understand the principles of research ethics and contribute to the process by which ethical research in human subjects is ensured.

Knowledge	Skills	Attitudes/Behaviour
<ul style="list-style-type: none"> - Identify ethical principles on which human research rests. - Explain how decisions are made when ethical principles conflict with one another. - Justify the constitution/ membership of research ethics committees (REC). - Demonstrate knowledge in the following areas: Appropriate terms of reference of REC. f International guidance on ethical research in humans (eg the Declaration of Helsinki and ICH guidelines). The legal framework in which REC operate in Europe and the UK. 	<ul style="list-style-type: none"> - Analyse REC applications and information documents. - Ask pertinent questions of applicants and fellow committee members including specialists such as lawyers and statisticians. - Communicate effectively in an REC. 	<ul style="list-style-type: none"> - Respect confidentiality of information. - Conscientiously read submissions to REC of which the trainee should be a member. - Contribute to discussion in committee. - Be open minded and prepared to change a view in light of discussion.

Objective 10. The trainee will be able to advise on cases of overdose or poisoning, and to manage such cases as are relevant to their clinical speciality (e.g. children for paediatricians).

Knowledge	Skills	Attitudes/Behaviour
<p>Demonstrate knowledge of mechanisms of action of important poisons, including therapeutic drugs commonly taken accidentally or deliberately in overdose.</p> <p>Demonstrate knowledge of strategies for management of poisoned patients including: protection of staff and other patients, decontamination, resuscitation, monitoring, antidotes including for digoxin, iron, cyanide and cholinesterase inhibitors.</p>	<p>Access information effectively, including via the National Poisons Units.</p> <p>Access and keep up to date with National Guidance on chemical attack.</p> <p>Develop diagnostic skills relevant to the epidemiological context of chemical attack.</p> <p>Maintain up to date qualifications in resuscitation skills.</p> <p>Possess skills in managing overdose with paracetamol, aspirin, opioids, benzodiazepines and tricyclics.</p>	<ul style="list-style-type: none"> - Prepares prudently in the face of possible chemical incident, protecting self and other staff and avoiding self contamination. - Once prepared, accept necessary residual risk in order to care for poisoned patients. - Respect patients with behavioural and psychiatric problems, and consult appropriately with colleagues in provision of psychiatric support.

3. The Learning Process

3.1 Model of Learning appropriate to CPT.

Trainees will pursue the learning outcomes described in the curriculum through a variety of learning methods. There must be robust arrangements for quality assurance in place to ensure consistent local implementation of the curriculum. Most competencies are acquired over a sustained period of experience.

The curriculum will be delivered in a University and/or teaching hospital NHS-based department of clinical pharmacology, supervised by one or more trainers who are at least consultants or senior lecturers in seniority, and supported by an independent educational supervisor trained in CPT and of similar seniority. There will be annual appraisals and a record of in-training assessment.

The majority of learning will comprise of a balance of **work based experiential learning**. Trainees will learn from practice (work-based training) on ward rounds and in outpatients. They will undertake activities both independently and directly supervised and observed by senior staff; trainees will have opportunities for concentrated practice in skills and practical procedures during their hospital placements; they will learn from peers and be supervised when not yet fully competent in skills by senior staff. This will be regularly backed up by feedback from senior staff including consultants and

monitored by clinical, educational and research supervisors. Experience will be graded to the level of training and proportionate to the level of expertise. Supervision will always be given where the trainee has not yet acquired a sufficient level of competence.

Trainees will learn about drug action in humans in the setting of a clinical laboratory; about pharmacokinetic principles in seminar rooms and from reading; about cost-effective use of drugs in committee and classroom; to evaluate literature in library and seminar room; about statistical analysis, clinical trial design and population drug epidemiology in lecture room, tutorial, reading and practical experience; about adverse drug reactions at the bedside and in one or more of poisons centre, library, office, drug information pharmacy and classroom; about rational and cost effective therapeutics in drug and therapeutics committees, formulary committees and about the process whereby ethical research in humans is ensured in research ethics committees. In each of these settings the trainee will be in contact with the trainer and their staff who will provide direct feedback and contribute to multi-source feedback.

Independent learning in clinical laboratory and laboratory settings, and off the job education in the form of reading relevant professional journals and textbooks and use of CDs, DVDs, searching the worldwide web and use of other library resources, attending courses, study days and meetings.

Peer learning is also important with discussion amongst colleagues at all levels in the clinical placements and at regional meetings.

Rotations to various work places will be arranged to enable delivery of the totality of the curriculum. Trainees will rotate to different work places often on an annual basis.

There will be regular work-based assessment by educational supervisors who will be able to assess, with the trainee, their on-going progress and whether parts of the curriculum are not being delivered within their present work place. The practice of educational supervisors is described below under supervision and feedback.

The curriculum will be blueprinted so that key competencies will be delivered, and the various assessments of knowledge, skills, behaviours and attitudes will be fit for purpose and give coverage across the domains of the curriculum by a process of sampling. All assessments will be appropriate to the training level of the trainee and will be valid, reliable, systematically collected, judged against pre-determined criteria and appropriately weighted. Feedback will be given confidentially to each trainee with suggestions for improvements where appropriate.

Trainees will however be expected to complete the MRCP prior to attaining a CCT. In addition there will be a formal knowledge based examination (KBA) to be completed satisfactorily by the time of CCT as well as day to day assessment of knowledge by clinical supervisors and reported to programme directors through annual reports.

Each year there will be an assessment of progress (RITA) led by the deanery utilising reports from educational and research supervisors and academic mentors with the results of formal assessments. There will be an interview with experienced teachers and assessors covering the various clinical areas in which trainees work. If trainees fail to meet the expected standards they may be asked to have targeted training or even repeat part of or a whole year of training if needed. Repeated failure to make satisfactory

progress may mean that trainees will be asked to leave the training programme. This decision will always involve the postgraduate dean.

3.2 Learning Experiences

The curriculum will be delivered through a variety of learning experiences.

Learning from practice

Much of the curriculum is suited to delivery by work-based experiential learning and on-the-job supervision in the clinical and clinical laboratory settings. Opportunities are created by trainees, programme directors and the specialty training committees for training in the main places of work but also practice outside the principal place of work. Where parts of the curriculum are not delivered in the work place, appropriate off-the-job education or rotations to other work places (eg centres with expertise in human toxicology, phase I drug research units, clinical trials centres) will be arranged. The key will be regular work-based assessment by educational supervisors who will be able to assess, with the trainee, their on-going progress and whether parts of the curriculum are not being delivered within their present work place. Appraisal will be by multi-source feedback, mini-CEX and knowledge-based methods as appropriate.

Distributed and concentrated practice

Trainees will have opportunities for concentrated practice in skills and procedures especially when learning new techniques in the clinical laboratory. Specialist training should include concentrated practice in CPT. As the trainee acquires competence in this area of training the emphasis of training should change such that more senior trainees take a supervisory and educational role for junior medical colleagues as well as continuing to hone their own clinical skills. Training programme directors within local faculties of education will decide upon the details of clinical attachments.

Learning with peers

There will be learning from peers and from clinical (eg research nurse) and non-clinical (eg basic scientist) members of the department both in everyday practice and as part of formal teaching. Teaching will be from clinical supervisors during clinical attachments, from peers in the same specialty and other specialties and as formal teaching in lectures and small groups. In each setting trainees will undertake activities both independently and directly supervised and observed by senior staff; trainees will have opportunities for concentrated practice in skills and practical procedures during their hospital placements; they will learn from peers and be supervised when not yet fully competent in skills by senior staff.

They will take part and lead in bedside teaching and will teach undergraduates, postgraduates and non-medical staff in small groups and formal lectures making personal presentations using a variety of audiovisual methods. They will be expected to present at journal clubs, and make case presentations at Grand Rounds or similar settings. They will be expected to undertake personal audit and research and make presentations of their findings at clinical meetings.

Learning in formal situations

There will be formal learning both within placements and by attendance at regional, national and international meetings and conferences as specified above under Model of Learning. The time allowed for the external activities is within the study leave allowance allocated by each deanery.

Personal study

Self motivation, supported by input from an experienced mentor, is crucial since much of the necessary knowledge must come from focused private study. They will learn about data interpretation and data presentation in one to one conference with their trainer in the setting of drafting presentations and manuscripts. Presentation at formal departmental meetings (held regularly) and rehearsal for presentations at national (British Pharmacological Society - BPS) and international (eg IUPHAR) meetings provides key opportunities to learn from peers as well as from more experienced members of the department. Learning (both active and passive) in the formal setting of the BPS national meetings is required.

Time will be provided during training for personal study. Such study may include; reading, use of CDs and DVDs and web-based resources, guidelines plus preparation for teaching, presentations, and writing up audit, guidelines, research and other publications. It may be possible for longer periods of private study to be offered as part of study leave.

Specific teacher inputs

Individual units within a teaching programme will identify, in the prospectus, where specific teacher inputs will be provided. These will vary from programme to programme.

Recommendations for good practice are;

Each trainee having a clinical supervisor for each attachment for work-based experiential teaching

- Specialty teaching in a clinical environment from a recognised specialist
- Advanced Life support teaching from a recognised training provider
- Procedural skills teaching delivered by a skilled specialist in both work-based and on formal course setting

4. ASSESSMENT STRATEGY

The domains of Good Medical Practice will be assessed using both workplace-based assessments and examination of knowledge and clinical skills, which will sample across the domains of the curriculum i.e. knowledge, skills and attitudes. The assessments will be supported by structured feedback for trainees within the training programme of CPT. Assessment tools will be both formative and summative and will be selected on the basis of their fitness for purpose.

It is likely that the workplace-based assessment tools will include miniCEX (clinical examination exercise), DOPS (direct observation of procedural skills) and MSF (multi-source feedback). The Federation of the Royal Colleges of Physicians has piloted these methods and has demonstrated their validity and reliability. It is proposed that the examination and assessment of knowledge will utilise elements of the MRCP (UK) examination relevant to training.

An assessment blueprint will be developed which will map the assessment methods on to the curriculum in a systematic way. The blueprint will ensure that there is appropriate sampling across the curriculum. It is expected the blueprinting exercise will have been completed by the end of 2006.

The SAC will be responsible for the blueprinting exercise.

5. TRAINEE SUPERVISION AND FEEDBACK

Mechanisms for ensuring feedback

Frequent and timely feedback on performance is essential for effective work-based experiential learning. To train as a physician, a doctor must develop the ability to seek and respond to feedback on clinical practice from a range of individuals to meet the requirements of Good Medical Practice and revalidation.

The local education faculty will establish clear processes for feedback, with close liaison with designated Educational Supervisors. The educational supervisor will be responsible (directly or through explicitly defined delegation) for ensuring the delivery of day-to-day training. The mentor will be responsible for longer term strategic career planning, motivation and encouraging philosophical reflection.

Constructive feedback should be provided throughout training in both formal and informal settings. Opportunities for feedback will arise during appraisal meetings, when trainees are undergoing workplace-based assessments, in the workplace setting, and through discussions with supervisors, trainers, assessors and those within the team.

Best practice guidance for the appraisal process is provided by the Royal Colleges of Physicians in the training portfolio (in the Appraisal Section).

This guidance emphasises the need for:

- An initial appraisal meeting shortly after the start of a training placement to establish learning objectives and construct a personal development plan
- An interim appraisal meeting to discuss progress against the learning objectives
- An appraisal meeting towards the end of the training placement to reflect on the learning achievements during the attachment with reference to the initial learning objectives within the personal development plan
- Structured written feedback from clinical supervisors
- Appropriately structured written feedback from medical colleagues and departmental staff (multi-source feedback, MSF) to include nursing staff, managerial, clerical and secretarial staff and medical staff in relevant directorates e.g. radiology, anaesthesia. This is collated by the Educational Supervisor to form the basis of a discussion with the trainee
- Feedback on performance in recent workplace-based assessments to inform future development

It is recommended the above guidance apply irrespective of the duration of that particular attachment. Evidence that feedback has been received and subject to

reflection by the trainee will be recorded in the portfolio, and discussed at the regular appraisals with the trainee's supervisor.

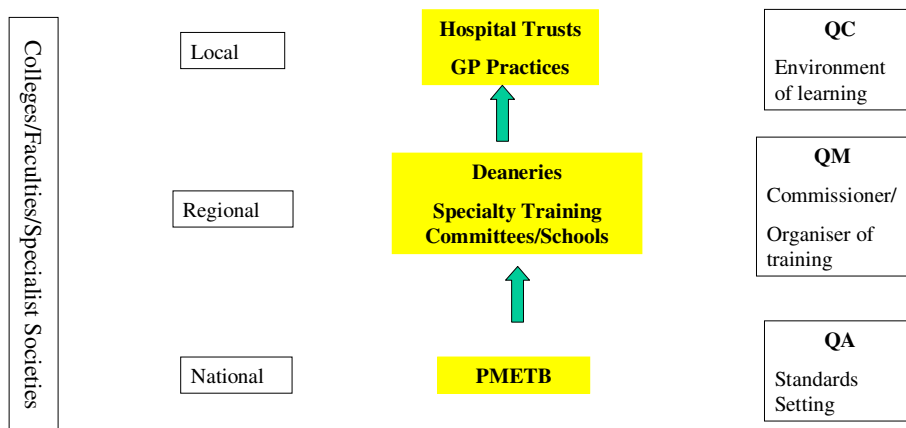
In addition there will be formal knowledge based assessment the format of which is yet to be determined.

A yearly Record of In-training Assessment (RITA) will take place with each trainee where the regional specialty adviser, representative of the postgraduate dean and other consultants will receive reports from educational and research supervisors and others on the trainee's progress combined with feedback on the formal work based assessments. (At this meeting plans for the next year for training, revision of practice and knowledge combined with plans to further develop knowledge, skills and attitudes will be made and agreed with the trainee. This information will be reported to the educational and other supervisors for the next year.

6. CURRICULUM IMPLEMENTATION

6.1 Deaneries are responsible for quality management, PMETB will quality assure the deaneries and educational providers are responsible for local quality control, to be managed by the deaneries. The role of the Colleges in quality management remains important and will be delivered in partnership with the deaneries. The College role is one of quality review of deanery processes and this will take place within the SACs on a regular basis.

The Organisation and Quality Assurance of PG Training



6.2 Intended use of Curriculum by trainers and Trainees

This curriculum, the General Internal Medicine (Acute Medicine) curriculum and the Generic Curriculum for the Medical Specialties are web-based documents which are available from the JRCPTB website.

Each trainee will be given copies of the curricula and portfolio upon enrolling as a specialist trainee with the JRCPTB.

Each trainee will engage with the curriculum by maintaining a portfolio. The trainee will use the curriculum to develop learning objectives, self-assess accomplishment in disparate areas of the curriculum, and reflect on learning experiences.

6.3 - Ensuring Curriculum Coverage

The details of how the curriculum is covered in any individual training programme and training unit is the responsibility of the local faculty of education in consultation with the Federation of Royal Colleges of Physicians. The need to show how trainees are progressing in their attainment of competencies will be a strong driver in ensuring that all the curriculum objectives are met.

6.4 – Responsibilities of Trainees

This curriculum puts the emphasis on learning rather than teaching. Trainees are responsible for their own learning and the utilisation of opportunities for learning throughout their training. The work-based assessment process is also trainee led.

6.5 - Curriculum management

Local management of the curriculum is the responsibility of the local faculty of education.

Coordination of the Curriculum at national and regional level is the joint responsibility of the Deaneries and the Federation of Royal Colleges of Physicians, with robust arrangements for quality assurance of training.

7. CURRICULUM REVIEW, UPDATE AND QUALITY ASSURANCE

Curriculum review will be informed by a number of different processes. For instance the SAC will be able to use information gathered from specialty heads, specialty deans and the National Health Service. It will have available to it results of the trainee survey, which will include questions pertaining to their specialty. Interaction with the NHS will be particularly important to understand the performance of specialists within the NHS and feedback will be required as to the continuing need for that specialty as defined by the curriculum. It is likely that the NHS will have a view as to the balance between generalist and specialist skills, the development of generic competencies and, looking to the future, the need for additional specialist competencies and curricula.

8. EQUALITY AND DIVERSITY

In the exercise of these powers and responsibilities, the Royal Colleges of Physicians will comply, and ensure compliance, with the requirements of relevant legislation, such as the:

- Race Relations (Amendment) Act 2000;
- Disability Discrimination Act 1995 and Special Educational Needs and Disabilities Act 2001;
- The Disability Discrimination Act 1995 (amendment) (further and higher education) regulations 2006
- Age Discrimination Act in October 2006

The Federation of the Royal Colleges of Physicians believes that equality of opportunity is fundamental to the many and varied ways in which individuals become involved with the Colleges, either as members of staff and Officers, as advisers from the medical profession, as members of the Colleges' professional bodies or as doctors in training and examination candidates. Accordingly, it warmly welcomes contributors and applicants from as diverse a population as possible, and actively seeks to recruit people to all its activities regardless of race, religion, ethnic origin, disability, age, gender or sexual orientation.

Deanery quality assurance will ensure that each training programme complies with the equality and diversity standards in postgraduate medical training as set by PMETB.

Compliance with anti-discriminatory practice will be assured through:

- Monitoring of recruitment processes
- Ensuring all College representatives and Programme Directors have attended appropriate training sessions prior to appointment or within 12 months of taking up post
- Ensuring trainees have an appropriate, confidential and supportive route to report examples of inappropriate behaviour of a discriminatory nature
- Monitoring of College examinations
- Ensuring all assessments discriminate on objective and appropriate criteria and do not unfairly disadvantage trainees because of gender, ethnicity, sexual orientation or disability (other than that which would make it impossible to practise safely as a physician). All efforts shall be made to ensure the participation of people with a disability in training

Statutory responsibilities:

The Royal Colleges of Physicians will comply, and ensure compliance, with the requirements of legislation, such as the:

- Human Rights Act 1998
- Freedom of Information Act 2001
- Data Protection Acts 1984 and 1998