Clinical pharmacology and therapeutics in a changing world

REPORT OF A WORKING PARTY

1999

ROYAL COLLEGE OF PHYSICIANS
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MAY 1999

ROYAL COLLEGE OF PHYSICIANS
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Foreword

The art of therapeutics is as old as medicine, but the specialty of Clinical Pharmacology and Therapeutics has its gestation in the 1960s when a fast developing pharmaceutical industry produced new drugs that needed to be scientifically and clinically evaluated in man.

The specialty developed quickly in the 1970s, and the research emphasis of the training attracted many trainees who went on to develop their careers in a wide range of other areas. New therapeutic developments by the UK pharmaceutical industry have led to an increasing demand for industry-based clinical pharmacologists. In addition, the need for government to more carefully examine the economic implications of new therapies has led to the development of new academic areas, in particular pharmacoepidemiology and pharmacoeconomics.

Over the past decade universities have restructured their academic configurations, the medical school curriculum has changed, and a new system of training junior doctors has been introduced. These changes have had more impact on small specialties, particularly on a non-organ based discipline such as clinical pharmacology and therapeutics. It was therefore timely for the College to set up this working party.

The conclusions and recommendations in this report have important implications for all those interested in the development and use of drugs. The working party’s carefully reasoned action points, particularly those relating to flexibility, training and planned career progression are important for both the NHS and universities. If the next generations of doctors are to be educated about how to use the important therapeutic weapons that are delivered by an ever-increasingly versatile and innovative pharmaceutical industry, the working party proposals should be acted on. Those practising in this area should be proud of their achievements. This report should ensure that the specialty has a dynamic future.

May 1999

KGMM ALBERTI

President, Royal College of Physicians
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>ABPI</td>
<td>Association of the British Pharmaceutical Industry</td>
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<tr>
<td>AFPhM</td>
<td>Associate of the Faculty of Pharmaceutical Medicine</td>
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<tr>
<td>AHPPI</td>
<td>Association of Human Pharmacology in the Pharmaceutical Industry</td>
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<tr>
<td>BNF</td>
<td>British National Formulary</td>
</tr>
<tr>
<td>BPS CPS</td>
<td>British Pharmacological Society, Clinical Pharmacology Section</td>
</tr>
<tr>
<td>BPS</td>
<td>British Pharmacological Society</td>
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<tr>
<td>CCST</td>
<td>Certificate of Completion of Specialist Training</td>
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<tr>
<td>CME</td>
<td>Continuing Medical Education</td>
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<tr>
<td>CSM</td>
<td>Committee on Safety of Medicines</td>
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<tr>
<td>DGH</td>
<td>district general hospital</td>
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<tr>
<td>DipPhM</td>
<td>Diploma of Pharmaceutical Medicine</td>
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<td>DoH</td>
<td>Department of Health</td>
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<tr>
<td>DTI</td>
<td>Department of Trade and Industry</td>
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<td>EC</td>
<td>European Community</td>
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<td>EL</td>
<td>Executive Letter</td>
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<td>FPhM</td>
<td>Faculty of Pharmaceutical Medicine</td>
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<td>G(i)M</td>
<td>General (Internal) Medicine</td>
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<td>GCP</td>
<td>good clinical practice</td>
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<td>GMC</td>
<td>General Medical Council</td>
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<td>GP</td>
<td>general practitioner</td>
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<td>GPT</td>
<td>General Professional Training</td>
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<tr>
<td>HMSO</td>
<td>Her Majesty’s Stationery Office</td>
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<td>HMT</td>
<td>higher medical training</td>
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<td>HSE</td>
<td>Health and Safety Executive</td>
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<td>JCHMT</td>
<td>Joint Committee on Higher Medical Training</td>
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<td>MCA</td>
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<td>Medical Research Council</td>
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<td>NHS</td>
<td>National Health Service</td>
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<td>NHSE</td>
<td>NHS Management Executive</td>
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<td>NICE</td>
<td>National Institute for Clinical Excellence</td>
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<td>NPIS</td>
<td>National Poisons Information Service</td>
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<td>National Prescribing Unit</td>
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<td>NTN</td>
<td>National Training Number</td>
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<tr>
<td>OTC</td>
<td>over-the-counter</td>
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<tr>
<td>PGEA</td>
<td>Postgraduate Educational Assessment</td>
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<tr>
<td>PYA</td>
<td>Penultimate Year Assessment</td>
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<tr>
<td>RCP</td>
<td>Royal College of Physicians of London</td>
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<tr>
<td>SAC</td>
<td>Specialist Advisory Committee</td>
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<tr>
<td>SHO</td>
<td>senior house officer</td>
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<tr>
<td>VMD</td>
<td>Veterinary Medicines Directorate</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Executive summary

The Royal College of Physicians set up a working party on clinical pharmacology and therapeutics with the following terms of reference:

1. To advise on the development of clinical pharmacology and therapeutics so as to enhance the health of the population and meet the needs of government and industry.

2. To review education and training requirements and the provision of expertise for universities, the NHS, pharmaceutical and other industries with particular regard to future manpower requirements and career structures.

Background

Clinical pharmacology and therapeutics is a relatively new discipline in medicine concerned particularly with improving the care of patients by promotion of safe and more effective use of drugs and developing and evaluating drug therapy. Following its development over 30 years ago, the specialty flourished in the UK, but more recently this expansion has stopped. The specialty’s scope includes clinical involvement in the NHS, teaching, research and development of new therapeutic approaches using the latest biotechnology techniques.

Clinical pharmacology has also developed as a major discipline in the pharmaceutical industry, with specific responsibilities for early evaluation of potential new medicines.

Changes within the NHS have led to a more service- and organ-based medical practice. In a sense the breadth of the specialty of clinical pharmacology and therapeutics has been a weakness, in that its role within both the health service and academia has been obscured. In addition, the new structured training programmes for junior doctors impact particularly on specialties such as clinical pharmacology and therapeutics where in the past their flexibility has been a strength. There has been a resultant loss of definition of career progression for those in the specialty within both the NHS and universities.

Issues considered in the report

The working party considered the roles of the specialty and the challenges facing it in five areas. These are within the NHS (Chapter 2), within universities (Chapter 3), and within the pharmaceutical industry (Chapter 4), the advisory role to government and its agencies (Chapter 6), and the relationships of the specialty to other specialties in medicine and other health care professionals (Chapter 7). The working party considered training in the specialty with particular emphasis on what it saw as the future needs for the NHS, academia, and industry (Chapter 5).
The working party considered a number of documents which are included as Appendices to this report. These are:

A1 Information on doctors working within the pharmaceutical industry
A2 A core curriculum for undergraduate education in clinical pharmacology which the working party considered should be adopted by medical schools
A3 A paper on pharmacoeconomics prepared for the working party
A4 The curriculum for Higher Specialist Medical Training in clinical pharmacology and therapeutics
A5 A job plan for a consultant in clinical pharmacology and therapeutics
A6 Examples of job plans for clinical pharmacologists working in the NHS, academia and industry

SUMMARY OF RECOMMENDATIONS

1 There is a need for a coordinated approach to the recruitment, training and retention of clinical pharmacologists in the NHS and universities in order to build upon the specialty’s acknowledged successes.

2 To facilitate training, links with other medical specialties should be encouraged. The working party is pleased to note formal endorsement by the specialist training authority of ‘triple certification’: that is, certification in clinical pharmacology and therapeutics, general (internal) medicine and another medical specialty. The working party wishes to see links developed formally with a range of other specialties, and endorsed by postgraduate deans.

3 Cost-effective prescribing is of major importance to the NHS. Clinical pharmacologists can have significant impact at all levels of the service. Joint appointments between health authorities and trusts would benefit both organisations and are endorsed by the working party.

4 The working party also recommends the continued expansion of other flexible training approaches, in particular the initiative of the Association of the British Pharmaceutical Industry (ABPI) and NHS Executive for joint training posts. The importance of clinical pharmacology units in industry for the development of new therapies, including biotechnology, is acknowledged.

5 The working party recommends that a core curriculum for undergraduate clinical pharmacology and therapeutics should be adopted in the UK, and has endorsed a model curriculum (Appendix 2). Delivering this core curriculum may have manpower implications for universities that will need to be addressed.

6 Postgraduate education, particularly in therapeutics, is currently heavily dependent upon support from the pharmaceutical industry. There is a danger that this will produce an agenda set by industry rather than address the needs of the NHS. The working
party considers that educational programmes should be tailored to the needs of health professionals. Clinical pharmacologists are well placed to advise and assist in the development of these programmes and the working party recommends more formal links to regional specialist advisers and postgraduate deans to facilitate this.
Historical background

Therapeutics, the use of drugs for treatment of disease, is as old as medicine itself. In contrast, the scientific basis of therapeutics – clinical pharmacology – is a relatively young specialty, and almost all the techniques it utilises have been developed during the past 50 years. Physicians who practise clinical pharmacology and therapeutics aim ‘to improve the care of patients by promotion of safer and more effective use of drugs’ (WHO, 1970).

Clinical pharmacology and therapeutics was established as a separate specialty in the late 1960s. Universities recognised that specific expertise in the teaching of drug use was a topic not adequately covered at that time by non-clinical pharmacologists or organ-based specialists. Within a very short time almost all medical schools had representation in clinical pharmacology and therapeutics, often in the form of an autonomous university department headed by a Professor in Clinical Pharmacology and Therapeutics. This rapid expansion of academic clinical pharmacology was reflected in the emergence of a very strong Clinical Section of the British Pharmacological Society, and the launch of the highly successful British Journal of Clinical Pharmacology.

The specialty flourished in universities and teaching hospitals and many young physicians with a training in the specialty moved to other disciplines within the NHS. In addition, they contributed significantly to the development of the successful UK pharmaceutical industry.

In the 1970s development of the specialty in the UK was the envy of most other countries. This period of success and rapid growth was then followed by a period of change for the universities and the NHS. The first generation of leaders in the discipline were remarkably gifted and on the whole retained a broad, generalist outlook. They inevitably moved onwards and upwards to head departments of medicine and several became deans of medical schools. It will be important for the specialty to sustain the high expectations raised by such promising beginnings.

Although the main base of the specialty was in academic departments, clinical pharmacologists are to be found in consultant posts in general internal medicine, clinical pharmacology and therapeutics, clinical toxicology, and in other NHS specialties; within the pharmaceutical industry; and in regulatory bodies, in particular the Medicines Control Agency. In addition, many UK clinical pharmacologists have moved to other countries to lead departments of clinical pharmacology and therapeutics and develop the specialty.

In practice, very few NHS posts in general medicine and clinical pharmacology have been created, but many young doctors who have completed a period of research in departments of clinical pharmacology and therapeutics and gained postgraduate qualifications have obtained consultant posts in other medical specialties, in particular, cardiology, respiratory medicine and geriatric medicine.
INTRODUCTION

1.1 Drug therapy is fundamental to the practice of medicine. It is crucial that new medicines continue to be developed in the UK, and that the NHS uses these medicines appropriately in order to improve the health of the population. In the UK the pharmaceutical industry has been outstandingly successful as an innovator, and in 1997 there was a net trade surplus of more than £2.5 bn for pharmaceutical products. Approximately 30 new active substances are released as drugs each year into the UK market. In 1997 the British pharmaceutical industry spent approximately £2.2 bn on research (ABPI, 1998). The cost of developing new drugs is high, and this is reflected in the price of newly introduced products. The NHS spends over £5 bn per year on prescription medicines; in addition, over £1 bn is spent by members of the general public on over-the-counter (OTC) medicines.

1.2 As a result of the success in new drug development there has been an increase in demand for clinical pharmacology and pharmaceutical expertise in all sectors:

- The pharmaceutical industry requires clinical pharmacologists and pharmaceutical physicians to develop new drugs, conduct clinical trials on the efficacy and safety of the new products, and to monitor their safety after marketing.

- Nationally there is a demand for clinical pharmacologists within those central government agencies responsible for licensing new products and assessing their efficacy and safety.

- At regional and district levels, there is a similar need to monitor safety and efficacy, and an additional requirement to monitor drug prescribing to ensure that prescribing is appropriate and effective and represents the best use of available resources.

- At hospital and community levels there is a requirement to monitor overall and individual levels of prescribing and to provide expert advice to clinicians on problems in clinical therapeutics such as appropriate drug choice, adverse drug reactions, drug interactions, therapeutic drug monitoring, and the treatment of patients in special categories, eg during pregnancy, children, elderly people and those with renal or hepatic disease.

- Within universities there is a continuing need to teach clinical pharmacology and therapeutics to both undergraduates and postgraduates and to provide continuing education for doctors and allied professionals working in primary care, hospital specialties and the pharmaceutical industry.
SCOPE

1.3 Paradoxically, the evolution of clinical pharmacology and therapeutics to encompass a range of diverse interests which impact on many areas of the NHS and the pharmaceutical industry has made it difficult for those outside the specialty to grasp its scope. The range of contributions to the health service spans the clinical care of patients, both acute and outpatient referrals; clinical toxicology; public health issues, such as the use of medicine in the community (pharmacoepidemiology), drug safety (pharmacovigilance) and the cost-effective use of medicines (pharmacoeconomics); teaching of undergraduates and postgraduates; basic research in molecular medicine, cellular pharmacology and drug metabolism; and the highly specialised area of evaluation of new drugs, performed largely within the pharmaceutical industry. These areas may appear to have little in common, but as a whole are essential to support the needs of the NHS and the pharmaceutical industry.

1.4 Thus the scope of clinical pharmacology and therapeutics is broad, and covers:

- the initial investigation of new drugs and new therapeutic approaches such as gene transfer in man
- the evaluation of new drugs in clinical trials in patients, including assessments of safety, tolerability and efficacy
- advice on the appropriate place of drugs in therapy, including economic assessments (pharmacoeconomics)
- studies of drug use in the community (pharmacoepidemiology)
- the adverse drug reaction profiles of marketed products (pharmacovigilance)
- advice on the management and treatment of patients suffering from poisoning with drugs and chemicals (clinical toxicology)

1.5 The safe and effective use of drugs has been promoted by involvement in basic and applied research; through teaching both undergraduates and postgraduates in medicine, pharmacy and nursing; and by contributions to the NHS, through clinical practice and via local, regional and national bodies concerned with the use of medicines.

1.6 The specialty of clinical pharmacology and therapeutics therefore has three main responsibilities:

1 Involvement in improving the health of the community, principally through activities in the NHS.

2 Teaching in universities and in NHS postgraduate programmes for practitioners in both primary and secondary care.

3 Research in the universities and pharmaceutical industry.
KEY ISSUES

1.7 There are several key issues for clinical pharmacology and therapeutics which need to be addressed:

- the provision of training programmes in the NHS that will enable physicians with an interest in the specialty to work within the service, advise on new therapeutic developments, and work as clinical toxicologists
- in academia, the new curriculum has increased the workload of academic clinical pharmacologists, and departmental mergers have blurred the definition of the specialty and reduced its profile
- in industry, the career structure for clinical pharmacologists is poorly defined, with no clear career development programme or final qualification

1.8 Development of new drugs in industry continues to grow and presents new challenges as biotechnology products are developed. To sustain this growth and meet existing requirements, the UK pharmaceutical industry has estimated the immediate need for an additional 50 trained clinical pharmacologists.

1.9 Changes in the NHS have focused on a purchaser/provider separation in which the purchaser of particular procedures and types of patient care dominates the service. The economic benefits of appropriate drug use in primary and secondary care are clear, but the present NHS structure does not facilitate the appointment of specialists in clinical pharmacology and therapeutics. The new postgraduate training programme for clinical pharmacology and therapeutics under the Calman proposals will produce its first certificated trainees within five years. A clear career structure needs to be put in place in order that these individuals are not lost to the UK.

1.10 The challenge for the working party was to devise strategies that would support the continued growth of the specialty in a changing world.

1.11 In the past five years there have been important developments which led to the establishment of the RCP Working Party on Clinical Pharmacology:

- The pharmaceutical industry recognised that its need for clinical pharmacologists had not been met.
- Increasing pressure on drug budgets brought the need for appropriate advice on the therapeutic use of drugs, in both primary and secondary care, to the front of the political agenda.
- Changes in the education of medical students, as a consequence of recommendations from the GMC (1993), fundamentally changed the teaching of therapeutics in medical schools.
- The introduction of the Calman proposals for postgraduate medical education initiated the need for training programmes to be more flexible in order to meet the requirements of both industry and the NHS.
The career structure for consultants in clinical pharmacology and therapeutics in both the NHS and universities required clarification, and the benefits that these specialists bring to the health care system require formal recognition in order that training and career posts continue to be funded.

1.12 It is ironic that, as the demand for clinical pharmacology expertise increases in both the NHS and the pharmaceutical industry, the number of specialists in clinical pharmacology and therapeutics in the NHS has been falling, and that the pharmaceutical industry has had to initiate a programme with the NHSE to increase the number of clinical pharmacologists in training to supply its needs. In addition, recent changes in both undergraduate and postgraduate medical education present particular challenges to a small Specialty with many competing demands on its time.

**TERMS OF REFERENCE**

1.13 As a result of the above concerns, the RCP established a working party to examine the national position within the following terms of reference:

1. To advise on the development of clinical pharmacology and therapeutics to enhance the health of the population and to meet the needs of government and industry.

2. To review education and training requirements and the provision of expertise for universities, the NHS, the pharmaceutical and other industries, with particular regard to future manpower requirements and career structures.

1.14 Strengths and weaknesses of clinical pharmacology and therapeutics in the UK over the past 30 years are summarised in Table 1.
Table 1. Strengths and weaknesses of clinical pharmacology and therapeutics

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
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<tr>
<td><strong>The NHS</strong></td>
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<tr>
<td>Contributions to clinical care, particularly in the field of clinical toxicology</td>
<td>Deficiencies in the present career structure within the NHS for clinical pharmacologists, with resultant lack of job opportunities at consultant level.</td>
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<tr>
<td>Expert knowledge about medicines use</td>
<td></td>
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<tr>
<td>Prescribing practice, and drug safety</td>
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<tr>
<td>Development of new therapies</td>
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<td>Specific knowledge on cost-effective use of medicines</td>
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<td>Involvement in drug and therapeutic committees</td>
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<td>Therapeutic audit</td>
<td></td>
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<tr>
<td><strong>Universities</strong></td>
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<tr>
<td>Strengths in academic research on modes of drug action and the application through clinical research of this knowledge to disease management</td>
<td>A reduction in the specialty’s profile as a result of the amalgamation of departments</td>
</tr>
<tr>
<td>Important educational contribution to undergraduate and postgraduate training.</td>
<td>Increasing demands on time because of teaching commitments</td>
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<tr>
<td><strong>Industry</strong></td>
<td></td>
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<tr>
<td>Involvement in the production of new medicines</td>
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<tr>
<td>The development of novel therapeutic approaches</td>
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<tr>
<td><strong>Medicines regulation</strong></td>
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<tr>
<td>Contribution to the regulation of medicines via membership of licensing bodies</td>
<td>Insufficient numbers of appropriately trained clinical pharmacologists</td>
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<td>The development of adverse drug reaction monitoring schemes.</td>
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</table>
2 The NHS

SCOPE

2.1 Clinical pharmacology and therapeutics has traditionally been a predominantly academic and research-based discipline. Although each NHS region can identify individual specialists in clinical pharmacology and therapeutics, most of whom work within academic units, clinical pharmacology and therapeutics, unlike the larger specialties, does not have an established group of NHS specialists in every region.

2.2 Most academic clinical pharmacologists hold honorary appointments in NHS trusts, and in some instances with health authorities. A handful of clinical pharmacologists previously employed by health authorities also have contracts held by individual NHS trusts. However, the majority of trusts have no direct access to a specialist in clinical pharmacology and therapeutics, and therefore have little experience of what the discipline has to offer in an NHS setting.

2.3 The scope of activities that a consultant in clinical pharmacology and therapeutics can offer was originally set out in a report by the RCP Clinical Pharmacology Committee in 1974 (RCP, 1974), and further expanded by recommendations from the Clinical Section of British Pharmacological Society (1978).

KEY ACTIVITIES

- giving guidance on the effective and economic use of new and powerful remedies
- involvement in postgraduate education for hospital staff and general practitioners
- specialist consultations on therapeutic problems
- care of patients with drug overdosage and drug toxicity
- reporting of adverse reactions
- provision of drug information services in cooperation with the pharmaceutical service
- clinical work in internal medicine with a special emphasis on drug therapy
- clinical trials of both new and old therapeutic agents
- developing and monitoring safe and efficient prescribing systems
- encouraging sound prescribing policies
advising local management on drugs and drug therapy

monitoring drug costs in collaboration with local pharmacists

2.4 The way in which individual specialists in clinical pharmacology and therapeutics have delivered these services has varied with location and personal interests (Davies, 1976; Wood et al, 1980; Mucklow & Bennett, 1982; Pearson & Mucklow, 1984).

2.5 A key feature of the success of specialists in clinical pharmacology and therapeutics in the NHS is their close collaboration with other disciplines, both medical and non-medical, and in particular pharmacy and nursing (see Chapter 7).

2.6 All physicians, whatever their discipline, have had to rise to the challenges presented by recent changes in the organisation of the NHS. Although the concepts underpinning the key activities set out in para 2.3 are recognisable 20 years later, both the emphasis and – in some cases – the nomenclature have changed. The activities of the NHS specialist in clinical pharmacology and therapeutics in the 1990s can be grouped under four principal headings:

1. Patient care.
3. Influencing drug use.
4. Research and development.

Patient care

2.7 The specialist in clinical pharmacology and therapeutics is, first and foremost, a clinician. Individual clinical pharmacologists will tend to give drug therapy a special emphasis within the delivery of clinical care. Some have special expertise in the management of chronic conditions, for example hypertension and epilepsy, in which drug therapy predominates. They will also be able to investigate and treat patients with drug-associated problems, in particular unexplained treatment failure, adverse drug reactions and polypharmacy. In addition, collaboration between specialists in clinical pharmacology and other disciplines within medicine is important: the working party received evidence to this effect.

2.8 Some specialists in clinical pharmacology and therapeutics have focused their clinical expertise on the management of drug overdose and in the field of clinical toxicology. Clinical pharmacologists are actively involved in six of the present seven UK centres of the UK National Poisons Information Service (NPIS). With effect from April 1999, all of the services at six designated centres will have Directors trained in the specialty.

2.9 The management of acute poisoning is often complex and requires understanding of organ systems, including drug and chemical effects on the heart, the nervous system, the liver and kidneys. Appropriate management also involves the knowledge
of pharmacokinetics and dose–response relationships outside normal therapeutic ranges. The working party was concerned that expertise in poisons management should also be provided in the NHS, outside the specialist NPIS centres.

2.10 Clinical pharmacologists are heavily involved in the activities of the NHS National Prescribing Centres and in the production of national publications such as the Drug and Therapeutics Bulletin, the British National Formulary and Prescribers Journal, as well as local treatment policies. This illustrates the key role clinical pharmacologists have in influencing patient care in the NHS.

**Monitoring drug safety**

2.11 The use of medicines always entails some risk, and this must be weighed against the expected benefit. However cautious prescribers may be, adverse reactions will occur and may be serious. A specialist in clinical pharmacology and therapeutics is well qualified to monitor the occurrence of these events, and to encourage the completion of reports for the Committee on Safety of Medicines (CSM). The study of the pattern of adverse drug effects among the population – pharmacovigilance – is an important and growing area of interest. Spontaneous reports are a key element of pharmacovigilance and a vital signal in the monitoring of drug safety. Clinical pharmacologists currently run the four regional monitoring centres of the CSM, set up to improve adverse drug reaction reporting in the UK (CSM, 1992). These centres work closely with the Medicines Control Agency (MCA), and interact with doctors and pharmacists in their localities, providing clinical feedback and educational input. In this way they have contributed to the increase in adverse reaction reports received by the CSM over the past decade.

2.12 In recent years, clinical pharmacologists have extended their role to cover other aspects of toxicology including environmental and occupational toxicology, chemical incidents, and the effects of veterinary medicines and pesticides. All these activities are important public health roles.

**Influencing drug use**

2.13 Education in therapeutics is important in CME programmes in hospitals and for GPs in courses delivered under PGEA regulations. Some of these postgraduate programmes lack structure, and the input from the pharmaceutical industry, often being product-based, may be inappropriate in content and quantity, particularly in general practice.

2.14 The NHS must ensure that its training structures are effective, and that clear educational goals are established for meeting the needs of patients, commissioners and providers. There may be incompatibilities between some existing educational programmes and this more critical approach. Clinical pharmacologists have an important role in the development of suitable educational programmes.
2.15 Since the late 1950s an increasing stream of new therapeutic products has been introduced into the UK. Current legislation, now including European law, requires that new pharmaceutical products are effective and safe. However, there is no requirement for comparative studies prior to licensing, and the place of new products in therapy is often uncertain. In this situation, the most successful product is often the one that is first on the market, rather than the one that is safest and most cost-effective. Continuing education on this aspect of therapeutics therefore is most important.

2.16 The large sums of money committed to new drug development, and the introduction of new genetically engineered products and treatments for unusual conditions, have once again placed drug purchasing policies at the forefront of the health policy agenda, and stimulated the demand for pharmacoeconomic studies (Appendix 3).

2.17 There are wide variations between clinicians in prescribing patterns, indicating that some are practising more cost-effective prescribing than others (Audit Commission, 1994). Skilled evaluation of such differences offers the possibility of significant savings for the NHS, as well as improved care for patients.

2.18 Although most prescriptions are written by GPs, a significant proportion of long-term prescribing costs results from prescribing by hospital doctors (Eccles et al, 1996). This pattern of prescribing has been affected by the different pricing structures that may apply between hospitals and primary care. It has led to the development of area prescribing committees — which would seem a natural place for clinical pharmacologists to apply their expertise and influence through the development of local formularies and prescribing protocols. These committees have often arisen from the drug and therapeutics committees which have existed in many hospitals since the 1970s. In some districts, the policy of developing local formularies has led to an integration of hospital and primary care prescribing strategy, with a consequent reduction in the rate of increase of drug costs and improvement in the quality of prescribing.

2.19 At a national level, assessment of the relative efficacy of new and existing products and more detailed analysis of cost-effectiveness is an approach adopted in a number of countries (Ferner, 1996). In the UK there is a tension between the desire for a profitable and successful pharmaceutical industry and the concern that a cost-driven approach by the NHS could adversely affect the profitability and success of the pharmaceutical industry. The National Institute of Clinical Excellence (NICE), first proposed in the White Paper *The new NHS — modern, dependable* (DoH, 1997), will include clinical pharmacology expertise, and its first Head is a clinical pharmacologist. There also will continue to be a central role in supporting national policy for organisations such as the National Prescribing Unit (NPU), and the production of articles for publication in periodicals such as the *Drug and Therapeutics Bulletin* and *Prescribers Journal*.

2.20 Coordination of policies on new drug introduction has in the past been more successfully delivered when carried out at a regional, rather than local, level (NHS Executive, 1994). The role here is to summarise available evidence and provide a
neutral expert interpretation for the target population, including assessment of health benefits and cost. These activities are likely to continue to be required when the NICE is fully operational, since its brief is directed particularly at medicines about to be marketed. There are already successful models of regions in England acting as potential bridges between purchasers, providers and primary care (eg Northern & Yorkshire, West Midlands).

2.21 There is also scope for a more direct influence on local issues. The development and implementation of appropriate interface prescribing policies with local clinicians, pharmacists and public health physicians is a particularly important function. An active interaction between provider units and purchasers, with a clinical pharmacologist bridging the gap between the two, is a model which merits consideration, and one which the working party endorses.

2.22 The optimal placement of the clinical pharmacologist in the interaction between primary care, secondary care and purchasing is critical in promoting the cost-effective use of medicines. The aims should be to facilitate the appropriate introduction of new drugs and the modification of old prescribing policies, in order that monies can be appropriately apportioned within the health budget to drug expenditure. In this role the clinical pharmacologist will interact with pharmacists and other specialist physicians but will be ideally placed to advise and influence local policies. The foci for the official forms of interaction are the hospital Drug and Therapeutics Committee and the Area Prescribing Committee (NHS Executive, 1994).

2.23 Clinical pharmacologists may have more overall influence on local prescribing if they function as clinicians immersed in the practical issues of delivering patient care. As active members of hospital clinical staff they can influence practice by personal example and by contributing to the formal and informal exchanges of information that are an integral activity of the hospital clinical community. The failure of the specialty to make a larger contribution to this aspect of the NHS is due partly to its emphasis on research rather than clinical practice, and on pharmacology rather than therapeutics. One consequence of this has been the failure of NHS purchasers and trusts to appreciate the potential importance of clinical pharmacology in patient care, and therefore to fund posts.

2.24 Clinical pharmacologists in the NHS can also contribute to the education of pharmacists and nurses, who have an increasing influence in prescribing, particularly with their growing role in primary care. Therapeutics and clinical audit of prescribing are topics of particular relevance. Clinical pharmacologists may also contribute to the development of pharmacy drug information units.

Research and development

2.25 The NHS research and development initiative has highlighted many therapeutic issues as targets for research. Clinical pharmacologists have contributed to identifying the targets and to the research initiated. These developments are to be welcomed, but if the research and development programme is to meet its objectives, appropriately
skilled NHS consultants in clinical pharmacology and therapeutics need to be in post to carry out the work programme.

2.26 All specialists in clinical pharmacology and therapeutics require experience in the investigation of drug effects in man, including the design and conduct of clinical trials. They are therefore a particular asset for national, multicentre or local ethics and research committees. Their contribution to the deliberations of such committees is important in ensuring that research performed within the NHS is ethically sound.

2.27 NHS hospitals are the site of many clinical trials. Some have established specific clinical trial units for clinical research of the type to be performed. Such units benefit from the supervision of their activities by clinical pharmacologists, and advice on research as it is planned.

2.28 The volume of prescribing in NHS hospitals and in primary care affords a ready source of data for audit and research. Where available, the NHS clinical pharmacologist is the local expert who can facilitate these activities and devise strategies to improve the quality of therapeutics.

**CHALLENGES TO THE NHS**

2.29 The elements of a strategy for incorporating the specialty of clinical pharmacology and therapeutics into the NHS are to:

- facilitate access to, and uptake of, expertise in clinical pharmacology and therapeutics by NHS trusts and health authorities
- consolidate the varied clinical roles of clinical pharmacology and therapeutics
- define the roles of clinical toxicology within the NHS, and provide a supportive infrastructure
- incorporate clinical pharmacology and therapeutics into postgraduate education programmes in both primary and secondary care in a more structured manner
- make optimal use of clinical pharmacology and therapeutics skills in guiding and monitoring drug utilisation at national, regional and health authority levels
- continue the involvement of clinical pharmacology and therapeutics in monitoring drug safety
In the university setting

3.1 Within universities the specialty of clinical pharmacology and therapeutics has three principal responsibilities. These are:

1. Undergraduate education, mainly of medical students.
2. Postgraduate education for trainees and as part of continuing medical education in primary and secondary care.
3. Research encompassing a range of activities from the primary actions of drugs in man, through the effects of drugs in disease, to research into drug policy and the epidemiology of drug use.

Undergraduate education

3.2 ‘Education of future clinicians in clinical pharmacology and therapeutics needs intensive reconsideration for two main reasons which are perhaps interlinked. The first is evidence that medical students are not always trained adequately in pharmaco therapy, and the second is that less than optimal prescribing of drugs still occurs, and is difficult to correct.’

De Vries, 1993a

3.3 There have been major changes in medical education over the past decade. The GMC’s concerns about undergraduate medical education and its subsequent recommendations in the report Tomorrow’s doctors (GMC, 1993) have led to revision of the medical curriculum, which in turn has resulted in medical students being exposed to more areas of education and more information than at any previous time. These changes have had an impact on the time available for teaching individual subjects and the methods by which those subjects are taught.

3.4 The GMC has promoted a reduction in formal lecturing, with the development of self-directed learning, increased clinical contact, and training in scientific methods. Nevertheless, there is recognition that a core curriculum for clinical pharmacology and therapeutics is necessary. Although some outline goals and objectives have been set out by the GMC (1993) (see Table 2), a core curriculum in clinical pharmacology and therapeutics had not been defined at the commencement of the working party’s deliberations.

<table>
<thead>
<tr>
<th>Table 2. Knowledge objectives: principles of therapy</th>
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<tr>
<td>1. Management of acute illness</td>
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<td>2. Action of drugs, their prescription and administration</td>
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<tr>
<td>3. Care of the chronically ill and the disabled</td>
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<td>4. Rehabilitation, institutional and community care</td>
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<td>5. Amelioration of suffering and the relief of pain</td>
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<td>6. Care of the dying</td>
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Reproduced by kind permission from the GMC. Tomorrow’s doctors: recommendations on undergraduate medical education (GMC, 1993).
3.5 Without clearly stated aims that can be measured objectively, the success of the delivery of any teaching curriculum is difficult to assess. Furthermore, the development of more broadly based examinations covering several subjects may mean that lack of knowledge of individual subject areas can pass undetected (Turner, 1993).

3.6 Students traditionally have been taught about drugs in both their pre-clinical and clinical years. For convenience, such teaching was often divided into: basic pharmacology, addressing principally the mechanisms of drug action; clinical pharmacology; and therapeutics, which was usually linked to clinical teaching.

3.7 In a survey of university departments in the UK in 1993, clinical pharmacologists rated undergraduate education as their second priority, after research (Walley et al, 1994a). They agreed on rankings for teaching priorities (Walley et al, 1994b), with prescribing for elderly people and the management of poisoning ranked first and second in a suggested list of topics.

3.8 Other therapeutic skills that might be regarded as core, such as intravenous drug administration, have often been taught in the past in an unstructured manner in medical schools (Teahon & Bateman, 1993). Errors in intravenous drug administration have been responsible for misadventure in a number of highly publicised medico-legal cases. This has led many medical schools to reconsider their approach, and for postgraduate deans to include formal instruction in intravenous drug administration as part of the induction programme for junior doctors. Other specific areas of concern include coping with new drugs, the pressures of commercial promotion, and the cost implications of prescribing (Collier & Herxheimer, 1991).

3.9 The reduction in formal teaching suggested by the GMC (1993) might be assumed to reduce pressures on teachers. In practice, this has not been the case for clinical pharmacologists since more group teaching, interactive sessions, and problem-solving exercises require higher teaching input than lectures (BPS, 1996, unpublished confidential survey of BPS members). Furthermore, there is a need for a contribution from clinical pharmacology and therapeutics to most medical course modules, and this tends to fragment teaching of the discipline.

3.10 Pressures on universities have led to the amalgamation of university departments, and a significant number of departments of clinical pharmacology and therapeutics have been assimilated into departments of medicine. There has also been a reduction in the number of full-time academic appointments, particularly at clinical lecturer level. This poses a threat to the academic base of the specialty.

3.11 A proposed core content of teaching in clinical pharmacology and therapeutics has been developed by a Delphi process (Walley & Webb, 1997a,b). This is included as Appendix 2 of this report. The working party wholeheartedly endorse this approach.
CHALLENGES FOR UNDERGRADUATE EDUCATION

3.12 Key elements in a strategy to improve undergraduate education are:

- implement an agreed core curriculum in pharmacology, clinical pharmacology and therapeutics
- develop appropriate teaching and assessment methods for the integrated teaching of pharmacology, clinical pharmacology and therapeutics, whilst retaining identity of the specialty
- address the changes of the university infrastructure which affect university departments of clinical pharmacology and therapeutics. We are particularly aware these departments are merged into larger academic blocks. This also impacts on the clear career progression of staff within departments of clinical pharmacology and therapeutics, particularly at clinical lecturer level
- recognise that teaching of clinical pharmacology and therapeutics does not end with the final MB exam, but should continue into the pre-registration year and beyond, to address the practical issues of prescribing in the NHS

Postgraduate education

3.13 Although UK prescribers are relatively conservative in comparison with doctors in most other countries in Europe (Audit Commission, 1994; House of Commons Health Committee, 1995), and the prescribing behaviour of UK doctors compares well with that of other European countries (Garattini & Garattini, 1993), there is considerable variation in drug usage both between health authorities and between general practices within the same area (Roberts & Bateman 1995; Healey et al, 1994; Morton-Jones & Pringle, 1993). A reduction in variation in prescribing practice might be attained by more rational and cost-effective choice of drugs (Audit Commission, 1994).

3.14 Postgraduate education in therapeutics is presently provided largely in an ad hoc manner, principally through postgraduate educational meetings for hospital doctors and GPs. Many of these activities are sponsored by the pharmaceutical industry. Other postgraduate education programmes, offered by a few universities, include specific courses in therapeutics, some leading to a diploma. Informal education is promoted nationally by independent publications such as the Drug and Therapeutics Bulletin, Prescribers Journal, the British National Formulary and the bulletins of the National Prescribing Resource Centres in England, Scotland and Wales.

3.15 Though at present, few specialties have a CME curriculum, the working party considered that therapeutics should be a part of such programmes. This will be particularly appropriate in primary care. In addition, the wider availability of computers in general practice could facilitate distance learning programmes and a continuing review of prescribing behaviour.

3.16 One challenge for CME is to update hospital doctors in new therapeutic areas. It is important that such information is objective, and that commercial and financial pressures are removed from the message delivered. Systematic reviews and meta-
analyses can provide estimates of average drug effects under specified conditions. Doctors need to understand both the value and the limitations of these approaches if prescribing is to be appropriate for individual patients, as well as cost-effective overall. Clinical pharmacologists are specifically qualified to do this.

3.17 Information support systems are currently being evaluated in primary care (Anon, 1996). While these are still in their infancy, information technology has considerable potential for education in both primary and secondary care. Education in research methods and in the critical evaluation of research techniques is underdeveloped in the UK; the expertise of clinical pharmacologists is particularly relevant to this important area of continuing professional development.

3.18 The development of evidence-based practice increasingly will involve clinical pharmacologists in the production and evaluation of evidence, and the construction, implementation and monitoring of guidelines and protocols to support rational prescribing. The development of postgraduate programmes which educate GPs and others in therapeutics leads to the possibility of clinical pharmacology educationalists based in primary care. The working party heard evidence from Dr De Vries that this approach had been successful in the Netherlands (De Vries, 1993a,b,c,d).

3.19 The postgraduate training requirements of pharmaceutical industry physicians also need recognition. The activity of professional organisations representing physicians in industry is welcomed, and the development of postgraduate qualifications deriving from a syllabus of core skills is one method by which industry can ensure the quality of its employees.

3.20 Clinical pharmacologists have much to offer in the postgraduate training and CME of GPs and hospital doctors. A close liaison between regional advisers in general practice and local clinical pharmacologists is therefore desirable. Initiatives that the working party endorse are those of the Clinical Pharmacology Section of the British Pharmaceutical Society (BPS CPS) in offering postgraduate lectures, and of universities in promoting diploma courses in therapeutics targeted at primary care.

**CHALLENGES FOR POSTGRADUATE EDUCATION**

3.21 Key points for the improvement of postgraduate education:

| ▪ provide appropriate, targeted postgraduate education in clinical pharmacology and therapeutics |
| ▪ monitor the effects of education |
| ▪ respond to the opportunities of new methods of education |
| ▪ deliver integrated postgraduate educational programmes in clinical pharmacology and therapeutics in primary and secondary care |
| ▪ serve the postgraduate needs of physicians working in the pharmaceutical industry |
Research

3.22 Clinical pharmacology is a research-based specialty, focused on the scientific understanding of drug action. It is concerned with what the human body does to drugs (pharmacokinetics) and with what drugs do to the body (pharmacodynamics), and identifies sources of variation in the responses of healthy subjects and patients to drugs (Turner, 1993). The complementary practice of therapeutics harnesses this research to improve health and reduce the burden of illness.

3.23 Research in the specialty can be broadly defined under three main themes:

1. Fundamental research on the pharmacological factors involved in the pathogenesis of disease.
2. Research on the scientific basis for safe and effective drug therapy, often involving clinical trials.
3. Research on the epidemiology of the use of drugs, their toxicity and their cost-utility, pharmacoepidemiology, pharmacovigilance and pharmacoeconomics.

Pharmacological factors in pathogenesis of disease

3.24 The first theme, fundamental research on the pharmacological factors involved in the pathogenesis of disease, involves the study of endogenous mediators and drugs as ‘probes’ to explore physiological systems and their alteration by disease or in surrogate models of disease (Grahame-Smith, 1991). This involves close links with the basic biomedical sciences. Even though this work has relevance to drug development, funding generally has to be obtained from the grant-giving bodies. This type of research needs particularly close liaison with colleagues in pharmacology and the cellular and molecular sciences. Many issues arise in human studies that can be resolved only by studies in animals or in vitro, whereas the clinical importance of findings in the laboratory can be resolved only by studies in patients (Laurence, 1964).

Safe and effective drug therapy

3.25 The second theme, research on the scientific basis for safe and effective drug therapy, often involving clinical trials, involves pharmaceutical, pharmacokinetic, pharmacodynamic and therapeutic studies encompassing in particular randomised controlled clinical trials. This research generally involves close liaison with the pharmaceutical industry, which funds much of the work.

Epidemiology of the use of drugs

3.26 The third theme, pharmacoepidemiology, involves studies on the use of drugs in primary and secondary care. It encompasses pharmacovigilance, ie the study of the safety profile of marketed pharmaceuticals, and pharmacoeconomics.
3.27 Pharmacoeconomics is an emerging discipline within the specialty of clinical pharmacology and therapeutics. It is concerned with the analysis of the economic costs and utility of therapy, of growing importance with increasing financial pressures on health care delivery. Further details of the scope of pharmacoeconomics are provided as Appendix 3 of this report.

Links with other disciplines

3.28 Clinical pharmacologists differ from many other clinical scientists in that their focus on the study of drugs is not limited to particular organ systems, thus allowing a broad approach to disease. Their work applies specific skills in experimental pharmacology, clinical medicine and statistics, and brings particular attitudes and expertise to bear on clinical questions. In this regard, clinical pharmacology serves as a ‘bridging specialty’ linking the basic biomedical sciences with clinical medicine and the public (Abernethy, 1992).

3.29 Clinical pharmacology in the UK has a particularly strong base in cardiovascular medicine, and the application of the principles of clinical pharmacology has made important contributions in this field. There are particular strengths in research on the vascular endothelium, atherosclerosis, physiology, integrated biology and the molecular genetics of cardiovascular disease risks. These four areas are given high priority for strengthening cardiovascular research in the recent report Foresight in science, funded jointly by the British Heart Foundation, MRC and the Wellcome Trust (Anderson & Williams, 1995). Indeed, the high level of research activity among clinical pharmacologists in cardiovascular medicine and the general focus of the specialty on academic training have led to the proposal that clinical pharmacology might be the natural home for academic cardiovascular medicine (Baber et al., 1997).

3.30 Clinical pharmacologists have also made important contributions in many other areas, for example in asthma, epilepsy and the use of drugs for elderly people. However, there remains a need to expand their research role in other areas – for instance in intensive care, psychiatry, infectious diseases and paediatrics – and to increase this contribution to areas where drug research is already prominent, such as oncology, rheumatology, geriatric medicine and anaesthetics.

3.31 Clinical pharmacology is well placed to meet a number of government initiatives. These include the technology foresight exercise (DTI, 1996a) and the initiative relating to New drug creation and delivery from the MRC. In the future it is also likely that clinical pharmacology will make important contributions to the goals outlined in the Crusade for biotechnology (DTI, 1996b) as successful drugs arising from this programme reach the clinical arena.

3.32 There have been more research fellows training in clinical pharmacology departments than could eventually become clinical pharmacologists and the resultant seeding of clinical pharmacology skills into other specialties has been of considerable importance. A number of senior clinical scientists in cardiology, geriatrics and respiratory medicine, for example, view their specialty from a distinctively pharmaco-
logical perspective. However, the recent changes in training programmes for junior doctors (Calman, 1993, 1994) have resulted in this process being increasingly difficult, and present a major problem in the future of training in the specialty.

3.33 The future holds many challenges, but perhaps the most important is maintaining the stream of young researchers entering the specialty. This will require the development of more flexible training programmes to enable experience in clinical pharmacology and therapeutics and other specialties to continue side by side. The possibility of accreditation in more than two areas is a crucial first requirement. Clinical pharmacology and therapeutics is currently the only specialty that provides a whole year’s training in investigational skills as part of its programme, in addition to allowing a year of research to count towards specialist certification – recognition that it is a research-based specialty. This may prove attractive to junior doctors intent on a career in research.

3.34 The recent initiative between the NHS Executive and the ABPI (Baber & Brown, 1996) should be valuable in the healthy development of the specialty. By providing support for young clinicians to begin a career in clinical pharmacology with exposure to the pharmaceutical industry environment, this initiative should ensure the continued availability of enthusiastic young researchers, and help to break down any existing barriers between departments of clinical pharmacology in academia and industry.

3.35 Funding is a central issue. Following the Culyer recommendations, it is envisaged that financial support for clinically-related research on safe, effective and affordable drug therapy, with direct impact on patient care, should come from health service research initiatives (Culyer, 1994). It is also to be hoped that the grant funding bodies increasingly will recognise the importance of fundamental research on the pharmacological factors involved in the causation of disease, particularly as progress in molecular biology leads to the development of new drugs that need to be investigated in man. Suggestions that genotype may dictate the response to specific drug classes in conditions such as hypertension, and the resultant combination of molecular genetics and exploratory clinical pharmacology, seem likely to provide a powerful approach to the understanding of disease and the development of more rational drug treatment (Dollery, 1997).

3.36 Precisely targeted new drugs emerging from molecular and cellular biology and developed through biotechnology, including gene therapy, will require ingenuity in the development and testing of new surrogate models for disease in humans, and will provide major challenges for the clinical pharmacologist.

3.37 The new research areas of pharmacoepidemiology, pharmacovigilance, and pharmacoconomics are needed to inform government policy, the pharmaceutical industry, and clinical practice.
3.38 Strategy for the maintenance of high quality research programmes:

- maintain a stream of young researchers into the specialty
- identify, make secure and support the university research base
- respond to the change in research methodology arising from the new technologies
- integrate the new epidemiological aspects of research in clinical pharmacology and therapeutics, which will inform health policy in the future
4 The pharmaceutical industry

4.1 The pharmaceutical industry employs medically qualified staff in a variety of roles. One key activity is the development of potential new drugs for use in man. Other medical activities are concerned with monitoring the safety of marketed products, pharmacoeconomics, product development, and marketing.

4.2 Clinical pharmacology within the pharmaceutical industry is concerned predominantly with the administration of new drug substances to man to determine their safety and tolerability, their metabolism and kinetics, and the pharmacodynamic responses they induce, with the overall objective of determining the dose–plasma concentration–effect relationship (Phase I clinical studies).

4.3 Studies to effect these objectives are frequently conducted in healthy volunteers, and also in small numbers of the target patient population. The clinical pharmacologist responsible needs a firm grounding in general medicine and therapeutics (most appointees have the MRCP or equivalent), and will have knowledge of:

- pharmacological principles,
- toxicological testing in animals,
- drug metabolism,
- pharmacokinetics,
- study design and statistics, and
- regulatory requirements for the administration of drugs to man.

4.4 Academic and health service training and experience may provide some aspects of the above, especially if the entrant has an intercalated BSc, MD or PhD in a research topic, but most of the necessary skills have to be learnt within the pharmaceutical industry.

Responsibilities of clinical pharmacologists

4.5 Clinical pharmacologists in departments of clinical pharmacology have two major responsibilities:

1. To organise and execute the Phase I clinical trial.
2. To plan the early development of a potential new medicine.

Some departments, especially the smaller ones, are organised so that one person is responsible for both aspects. Larger departments usually specialise, so that the administration of Phase I trials is separate from project design and execution.
4.6 Together with the responsibilities outlined above, clinical pharmacologists in industry undertake two other main duties:

1. To respond to queries from the regulatory authorities that arise from a drug submission.
2. To assist in the promotion of drugs that are registered for sale.

The latter function requires a thorough knowledge of the strengths and weaknesses both of the product and of alternative drugs, and a knowledge of the safety and efficacy databases of the company’s products.

4.7 The development of established products into new therapeutic areas and, where appropriate, of combinations with other drugs also forms part of the clinical pharmacologist’s remit.

**Future needs of industry**

4.8 Three major changes that are occurring in the pharmaceutical industry will affect the responsibilities of the industrial clinical pharmacologist.

4.9 First, the requirements for safety testing of new drug substances in pre-clinical studies are being revised by the major regulatory authorities, partly to reflect the introduction of biologically produced materials and partly to reduce the time spent in early drug development. Clinical pharmacologists will need to keep abreast of the regulatory requirements as well as understanding the ethical issues and practicalities that these new guidelines will impose on Phase I studies.

4.10 Second, the increasing use of genetic and molecular techniques will, potentially, increase the number of new agents to be tested in man. Clinical pharmacologists in industry will need to have an appreciation, if not a thorough understanding, of molecular techniques and their implications for toxicity and safety in man. Furthermore, animal ‘models of disease’ may become less relevant and perhaps less frequently used, placing a greater onus on early efficacy evaluation in man (so-called ‘proof of concept’). This will place more emphasis on the early evaluation of new drug substances in patients, using markers (or ‘surrogates’) of potential therapeutic activity.

4.11 Third, increasing economic and competitive pressures on the pharmaceutical industry have meant that new drugs must be assessed not only for their effectiveness and safety, but also for their economic value to future customers. This assessment of value embraces a knowledge of the principles of pharmacoeconomics, systematic reviews and evidence-based medicine.

4.12 These changes in drug development will be in addition to the core responsibilities of clinical pharmacologists to which reference has already been made (see 4.5). Not all these new activities will be centred in departments of clinical pharmacology, and the clinical pharmacologist of the future in industry will find himself increasingly acting in an advisory or consultative capacity, working on a project-team basis, as...
Training for industrial clinical pharmacologists

4.13 In the past, most physicians who entered industry following completion of two years in medical practice, post-registration, and in possession of a higher qualification (usually MRCP or equivalent) did not have the necessary skills to fulfil the duties and responsibilities of a clinical pharmacologist in a major pharmaceutical company. The attainment of skills has been largely through four mechanisms:

1. Apprenticeship to a senior clinical pharmacologist in the company.
2. Attendance at specific external courses.
3. Tutorials and project-based work within the company.
4. Clinical or research attachments to an academic department.

4.14 By far the most common of these approaches is apprenticeship – learning ‘on the job’ – with increasing responsibility and freedom of action as experience builds up. The overall objective of training in this respect is for the individual to become a competent and independent investigator for clinical pharmacology studies on experimental drugs (known as the ‘medically qualified person responsible’). Physicians require detailed clinical knowledge for the conduct of these investigations and the ability to make clinical decisions allowing safe participation by the subjects involved. They need a detailed understanding of the animal investigations (biology, pharmacology and toxicology) performed prior to these human studies, and their interpretation and application in the design of clinical studies.

4.15 Clinical pharmacologists in industry have strong links with their academic colleagues and with the organ-based specialties. This is essential for the development of an early clinical plan and to build up an understanding of the efficacy, safety and dose–response relations in small-scale non-patient and patient trials. Physicians learn the skills of scientific and financial negotiation through working with academic departments and with contract research organisations, where much of the work of industrial clinical pharmacology is also conducted. An area underdeveloped in the UK is the interchange of academic and industrial clinical pharmacologists; such interchange should be encouraged.

Higher medical training

4.16 There are certain features of the clinical pharmacologist’s responsibilities that distinguish him/her from medical advisers working in other parts of the pharmaceutical industry. Predominant among these is the direct medical responsibility for the early human experiments, the detailed knowledge of study design to maximise the
4.17 The current provisions for higher medical training in pharmaceutical medicine do not take into account these specialist requirements and the depth to which they are required, nor does the examination for the Diploma of the Faculty of Pharmaceutical Medicine (DipPhM) provide a sufficiently rigorous probing of the knowledge and experience required to be a clinical pharmacologist responsible for a Phase I unit, or to design and execute early clinical trials in man.

Regulatory authorities

4.18 The requirements for Phase I studies are set by regulatory authorities (in the UK this is the MCA) as guidelines, and are interpreted by individual departments of clinical pharmacology. Regulatory control of Phase I studies may be expanded under proposals for an EC Directive on clinical trials (III/5778/96). The record for the safe evaluation of novel drug substances in the British pharmaceutical industry is extremely good. The opportunity to share best practices, and to raise standards and issues of mutual concern (as far as is possible between organisations that are commercially competitive) comes through four other bodies:

- The British Pharmacological Society, Clinical Pharmacology Section.
- The Association of Human Pharmacology in the Pharmaceutical Industry.
- The Clinical Pharmacology Subcommittee of the ABPI Medical Committee.
- The Clinical Pharmacology Specialist Committee of the RCP.

4.19 A recent development in the training and examining of clinical pharmacologists in industry and in contract research organisations is the establishment of a Diploma in Clinical Pharmacology, under the auspices of the Society of Apothecaries. To an extent, this diploma is planned to make up the shortfall in the current system, but it is unclear how it will operate in practice and what status it will achieve (Jackson & Tasker, 1996).

4.20 None of these bodies has the authority or remit to introduce and monitor clinical pharmacology standards or training within the pharmaceutical industry. The DipPhM, contains aspects of clinical pharmacology within its course modules and examination but, as mentioned previously (para 4.17), does not take specific account of the requirements of clinical pharmacology or set appropriate questions to probe practical knowledge associated with clinical pharmacology.

Faculty of Pharmaceutical Medicine (FPhM)

4.21 The FPhM is currently revising its higher medical training programme for pharmaceutical physicians. One option under consideration is to introduce a series of specialist modules after the DipPhM has been obtained to lead to specialist certification. One of these modules would be in clinical pharmacology and therapeutics, where
competency would be tested using performance-based assessments. In addition, it might well be argued that there should be a practical examination before a physician can become a study investigator and take sole responsibility for a Phase I trial.

Certification in industry

4.22 The Joint Committee for Higher Medical Training (JCHMT) requires that each specialty defines a training syllabus as part of the awarding of specialist certification. The working party believes that clinical pharmacologists in the NHS and academia should generally have certification in clinical pharmacology and general (internal) medicine (G(I)M), with the possibility of adding a therapeutic specialty (triple certification).

4.23 Procedures for specialist certification of pharmaceutical physicians are not yet determined. It is anticipated that in industry, members of the FPhM will be awarded certification. An application is also being prepared by the FPhM to request the addition of pharmaceutical medicine to the European Specialist Order (a precondition for establishing training programmes leading to specialist certification).

4.24 However, as previously noted, the FPhM’s current modular training curricula and diploma examination for pharmaceutical medicine are not suited to the physician who is in training in clinical pharmacology and/or wishes to continue a career in clinical pharmacology (see para 4.17). A suitable model would be for membership of the FPhM to be awarded to candidates who had completed the new joint NHS-industry training programme in clinical pharmacology and therapeutics (see para 5.15). In this model clinical pharmacology would be one of several specialist areas leading to the award of membership of the FPhM.

4.25 Many physicians of course will not have undergone this joint academic/industrial training programme, but could still be subject to training approval under the auspices of the FPhM.

Staffing levels

4.26 The working party has been told by representatives of the pharmaceutical industry that there will in future be a need to increase the number of physicians in clinical pharmacology, and to ensure they are adequately trained and given the right experience. It is essential that the right balance is struck between ensuring adequate standards and avoiding unnecessary bureaucracy. Thus, while common standards of expertise for conduct of Phase I/IIa studies could be set and agreed by the pharmaceutical industry in partnership with the RCP and the FPhM, their regulation and monitoring should ideally be by these same bodies, not imposed by the regulatory authorities.

4.27 In order to increase the potential number of physicians who can be trained in industry, and who may wish to take up a full time industrial career, a working party of
industrial and academic clinical pharmacologists, under the auspices of the ABPI, has established a joint training programme whereby physicians can experience both academic and industrial clinical pharmacology before finally selecting a career in one or the other (Baber & Brown, 1996). This will benefit industry and academia by bringing them closer together.

4.28 CHALLENGES IN INDUSTRY

- to address the manpower needs of the pharmaceutical industry by a reorganisation of training within the NHS and industry (see also Chapter 5)

- to increase interchange of specialists in clinical pharmacology and therapeutics between the NHS, academia and industry, and consider means for achieving this, such as joint appointments

- whilst recognising the different training needs of physicians in different branches of the pharmaceutical industry, to develop appropriate training programmes that will unify postgraduate qualification requirements for industry and the NHS, and avoid duplication and potential confusion for trainees
5 Training

Career scope

5.1 Specialists in clinical pharmacology and therapeutics have a wide range of job opportunities in the NHS, universities and the pharmaceutical industry. This range presents a challenge for any training programme, which needs to be flexible enough to cater for the possible goals of the individuals undergoing training.

5.2 Training programmes must therefore offer experience of all aspects of clinical pharmacology and therapeutics necessary to the future requirement of individuals and to the health service in general. Programmes will comprise core and optional components.

5.3 Careers that require previous training in clinical pharmacology and therapeutics include NHS consultants in G(I)M and clinical pharmacology; NHS consultants in another discipline with an interest in clinical pharmacology; university academics with clinical responsibility (senior lecturer, reader and professor in clinical pharmacology and therapeutics); senior positions in the pharmaceutical industry within departments of clinical pharmacology and in management posts; clinical research organisations; and specialist advisers to drug regulatory authorities.

Training programmes: the need for flexibility

5.4 It is important to recognise the potential contribution of clinical pharmacology and therapeutics to other clinical specialties. Closer integration of training in clinical pharmacology and therapeutics with that of other specialties is felt by the working party to be an important future development.

5.5 There is no category of patients for whom the clinical pharmacologist has exclusive responsibility. Poisoning, whether accidental, iatrogenic or self-inflicted, is a potential exception, but it is impractical to suggest that all poisoned patients should be directly cared for by clinical pharmacologists, although advice will often be sought from the National Poisons Information Service (NPIS). A trainee in clinical pharmacology and therapeutics can gain the necessary clinical experience caring for patients in, for example, G(I)M.

5.6 Until recently, the formal training required for specialist certification in clinical pharmacology and therapeutics had been coupled with that of G(I)M. However, the research interests of many trainees have led them to acquire expertise in aspects of work in other areas such as hypertension, asthma, epilepsy and stroke. The Calman training programmes (Calman, 1993, 1994) call for a more formal approach, acknowledging that the principles of clinical pharmacology and therapeutics may be learned either through G(I)M or another specialty. In the latter case, it is necessary to design
local programmes in which the training requirements of the SAC in clinical pharmacology and therapeutics can be combined with those of another specialty SAC. The current curriculum for higher medical training is included as Appendix 4 of this report.

5.7 In addition, it is desirable that training in the Calman structure in clinical pharmacology and therapeutics, G(I)M and a third specialty should be possible. Here again, training programmes may need to be slightly longer: six or perhaps seven years. However, the advantage of this triple training is that physicians will have more diverse career opportunities open to them, and the NHS will gain substantially from the broader experience and expertise they have to offer.

5.8 At present, the bureaucratic nature of specialist certification makes this flexible approach difficult to achieve in practice. The working party considered this was a significant and undesirable impediment, and felt all SACs should be asked to consider ways in which flexible training could be facilitated.

5.9 The diversity in career opportunities implies that a trainee wishing to maintain a full range of career options should spend some time in an academic NHS setting and also in industry. Trainees considering a career in clinical pharmacology in the pharmaceutical industry at present follow one of three main pathways:

1 A clinical specialty.

2 A period of practical and research experience in a post jointly agreed between the industry and a university but outside a formal training programme.

3 Tenure of a training post supported in the new academic/industrial initiative by the ABPI.

Research during training

5.10 An important component of clinical pharmacology and therapeutics training is the acquisition of clinical research skills. The specialty has a large academic component. A significant proportion of its practice involves research, including both fundamental research, in particular in relation to drug actions in man, and applied research in the study of drug usage in the population (see paras 2.25–2.28, 3.21–3.26).

5.11 Clinical pharmacology and therapeutics should, however, also be in the vanguard of research made possible by the rapid expansion of knowledge of the human genome, other advances in genetics and other new research areas, particularly the use of gene therapy. The following areas need to be considered:

- detection and evaluation of new therapeutic mechanisms drawn from novel receptors or enzymes, and from better understanding of disease pathogenesis, including critical assessment of surrogate models
- use of drug response to detect differing genetic groups within a common disease phenotype
gene therapy for the treatment of cancer and for genetic modification of monogenic and polygenic disorders
optimal analysis of clinical trials, including meta-analysis
pharmacoeconomic evaluations

5.12 In contrast with clinical pharmacology and therapeutics, some specialties are struggling, at least initially, to provide the opportunities for research previously available in their training programmes. It is likely that clinical pharmacology and therapeutics will maintain, and perhaps increase, its reputation and appeal as a natural home for trainees wishing to concentrate on a training geared to an academic research career, while at the same time maintaining flexibility of outcome for those who do not wish to commit themselves to the academic ladder at the early stage that Calman specialisation starts. In particular, the dual and triple certification programmes should be attractive to trainee clinical pharmacologists wishing to have another string to their bow, and to trainee specialists in a large number of areas who wish to broaden their training or to give it a more academic foundation than some specialty training programmes currently permit.

Cardiovascular medicine

5.13 One specific challenge is how to maintain the strong link, traditional in the UK, between cardiovascular medicine and clinical pharmacology. The working party received evidence that, in contrast with other European countries, the specialty of cardiovascular medicine has given way in the UK to cardiology, which has adopted one of the more demanding training programmes. Cardiovascular medicine has a broad span, with clinical pharmacology at one extreme and cardiology at the other. The latter requires a specific amount of ‘hands on’ experience in intervention techniques, and differs from the experience of many existing clinical pharmacologists in cardiovascular medicine and also from the requirements of the cardiovascular medicine programmes elsewhere in Europe. It is therefore important for training in clinical pharmacology to provide for trainees wishing to pursue a career in academic cardiovascular medicine. It is notable that many academics currently practising non-interventional cardiovascular medicine are certificated clinical pharmacologists. In the future, the formal certification of such individuals could be in clinical pharmacology and therapeutics as their primary specialty, with recognition of cardiovascular and G(I)M as subspecialties.

5.14 In order to be attractive to the high calibre of trainees that currently seek entry to cardiology programmes, it may still be desirable at a local level to offer a limited degree of interventional cardiological training during the early years, so that trainees can postpone the choice between the paths leading to academic or intervention careers. Parallel cases can also be drawn in other specialties, including respiratory medicine, endocrinology and diabetes, geriatric medicine, anaesthetics, oncology, psychiatry, and palliative care. The working party received evidence to this effect.
Joint training programmes between industry and academia

5.15 The prospects for clinical pharmacology have received a substantial boost from the injection of new training programmes funded jointly by the NHS (through the postgraduate deans’ budgets) and members of the ABPI. This initiative, established in recognition of the need in the pharmaceutical industry for more clinical pharmacologists than are currently completing training programmes, aims to double the current number of clinical pharmacologists in training as a minimum measure. Except for some local examples, the scheme is the first to provide and formalise arrangements for trainees to receive some of their training with a pharmaceutical partner, and thereby fulfil training needs. Early signs are that high calibre trainees can be recruited into this scheme, especially where dual certification is available. The working party consider it sound practice to expose such individuals to clinical pharmacology in an industrial as well as in a university or NHS setting. It is anticipated that some such individuals will also wish to seek additional three-year research fellowships leading to higher academic degrees. The specialty already has a reputation as a successful avenue to MRC and research charity fellowships. A research period within the pharmaceutical industry, making use of its excellent facilities, should strengthen this.

Industrial clinical pharmacologists

5.16 Clinical pharmacologists working in Phase I units in industry have some training requirements in common with academics, but some quite different skills are also needed. Common features comprise a sound clinical knowledge of clinical trial design and statistics. Additional skills include an understanding of toxicology and pharmaceutical requirements for early drug evaluation in man, and regulatory requirements and procedures.

5.17 Training of clinical pharmacologists in industry has been largely by apprenticeship ‘on the job’. However, formal programmes now being developed offer training of various types. Examples include a programme established by the Faculty of Pharmaceutical Medicine and, more recently, another leading to a qualification offered by the Society of Apothecaries (see para 4.19–4.27).

CHALLENGES IN TRAINING

5.18 The key points to be considered when training programmes in clinical pharmacology are being developed are:

- maintaining the flexibility of training programmes in clinical pharmacology and therapeutics
- ensuring that there are opportunities to develop a special interest in an area of clinical practice other than, or in addition to, G(I)M. Potential examples for such specialisation include specialties such as cardiology, or more widely based specialties such as geriatrics, paediatrics and psychiatry. Training programmes leading to triple specialist certification will be essential to this objective
the importance of the pharmaceutical industry to the UK economy places particular importance on the training of clinical pharmacologists for industry, and the development of joint programmes between the NHS, academia and industry to facilitate such training. This might result in specialist certification in clinical pharmacology and therapeutics alone for physicians working entirely in the pharmaceutical industry.
6 The advisory role to government and its agencies

SCOPE

6.1 In the UK, government agencies provide advice on health policy and health care strategy. Within this responsibility is the obligation to fund new therapeutic strategies, particularly for high cost medicines, such as genetically engineered material and preventive therapies likely to be widely applied in the community, such as treatment for hypertension and hyperlipidaemia.

6.2 Advice on human health issues is also required by government departments other than the DoH, including the Ministry of Agriculture, Fisheries and Food, the Department of Environment, and the Ministry of Defence, and also by agencies, in particular the Medicines Control Agency (MCA), the Veterinary Medicines Directorate (VMD) and the Health and Safety Executive (HSE).

6.3 In order to determine policy, the responsible ministers must be fully briefed. Advice on the clinical toxicology of drugs and chemicals is also often required by government departments and agencies, particularly in the context of risk assessment and management.

6.4 Clinical pharmacologists have contributed extensively to advisory processes, as illustrated by the range of advisory committees on which they currently serve and in several cases chair (Table 3). The maintenance of this pool of expertise in the future will require a continuing supply of experienced clinical pharmacologists.

6.5 One particularly important area of involvement of clinical pharmacologists is that of medicines control. The control of human medicines in the UK is the responsibility

<table>
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<tr>
<th>Table 3. Advisory committees to government and its agencies with clinical pharmacology and therapeutic input</th>
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<tr>
<td>• Advisory Board on Homeopathy Products</td>
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<td>• Advisory Committee on Pesticides</td>
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<td>• British Pharmacopoeia Commission</td>
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<td>• Pesticide Incident Appraisal Panel</td>
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<td>• Standing Group on Health Technology Assessment</td>
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<td>• Veterinary Products Committee</td>
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Examples of European committees

• Committee for Proprietary Medicinal Products
• Committee for Proprietary Veterinary Products
• Medicines Control Agency
of the Licensing Authority (Ministers) with the day-to-day executive responsibility delegated to the MCA which protects and promotes public health by ensuring that marketed medicines are safe and effective and of required quality. The VMD carries out a similar function for medicines used in animals. An outline of the structure of the UK human medicines regulatory system is shown in Figure 1. This system is now part of the wider system of medicines control in the EC.

6.6 The MCA has several divisions, two of which – licensing and post-licensing – employ medical, scientific and pharmaceutical professionals.

6.7 The MCA licensing division must evaluate data presented by applicants in order to decide whether clinical trials should be permitted, and subsequently whether a medicine should be marketed and under which constraints.

6.8 The MCA post-licensing division has as its main task the evaluation of data from licence holders and other sources, in order to respond to changes in the risks and benefits of medicines, and their further development.

6.9 The MCA currently holds 43 posts for physicians, several of whom have experience and training in clinical pharmacology derived from industry and/or academia.

6.10 In addition to its in-house professional expertise, the MCA obtains expert independent advice through a system of statutory advisory committees, notably the Committee on Safety of Medicines (CSM) and other independent expert advisers. The MCA has close links with senior academics in many specialties, but in particular clinical pharmacology. The current chairman of the Medicines Commission, and the chairman of the CSM are professors of clinical pharmacology.

6.11 Clinical pharmacologists employed by the MCA are involved in a number of key activities. During the assessment of an application for a new active substance a detailed review is undertaken of human pharmacology studies, including pharmacokinetics, pharmacodynamics and drug interactions, together with clinical trials relevant to efficacy and safety.

6.12 When a medicine is licensed for sale, it is usual that only a small number of patients will have been exposed to its effects (Rawlins, 1996). Continued monitoring for adverse reactions is therefore important. This will identify unexpected hazards and promote safe use of medicines under normal conditions of use. Clinical pharmacologists have an important role in this process in two ways: first, they are involved as employees of the MCA and as specialist advisers; second, as practising clinicians they can maintain local awareness of the importance of adverse drug reactions or contribute to the work of the MCA’s regional monitoring centres (CSM, 1992).

6.13 The skills of clinical pharmacologists are therefore required within the MCA as basic tools for the assessment process of both the licensing process and post-licensing safety monitoring. A broad view of therapeutics is also essential for making judgements across the diverse range of issues which arise in medicines control.

32 The advisory role to government and its agencies
6.14 The MCA seeks to recruit medical staff who are trained to the equivalent level of a consultant in the NHS, although in a few cases more junior appointments have been made – equivalent to the former senior registrar grade. Most medical staff recruited to the agency are therefore fully trained to a specialist grade. The MCA provides training for its recruits in specific skills, for example in the principles and practice of the legal regulation of medicines.

6.15 There is an interchange between staff of the MCA and industry. The MCA is keen to strengthen its links with academic departments, particularly clinical pharmacology, through joint or rotating posts, although none yet exists.

6.16 The DoH has a ministerial responsibility to support the UK pharmaceutical industry. The support will include the provision of an infrastructure to train clinical pharmacologists for industry (Chapters 4 & 5).

6.17 There is a continuing and potentially increasing need for physicians trained in clinical pharmacology and therapeutics both to staff government agencies and to advise arms of governments. Appropriate training structures need to be developed to enable a smoother transition of staff from the NHS to the MCA, and for an interchange of staff at junior and senior level between the MCA and academic departments of clinical pharmacology.
CHALLENGES IN THE ADVISORY SECTOR

- securing a base from which the skills and expertise of physicians trained in clinical pharmacology and therapeutics can continue to be available to departments of government, government agencies and advisory bodies

- maintaining expertise in clinical pharmacology and therapeutics that will itself develop as new technologies and developments place increasing demands on health care delivery systems, and to continue to provide timely, relevant and appropriate advice

- exploration and encouragement of more formal links between academic departments, NHS physicians and agencies such as the Medicines Control Agency
7 Relationship to other specialties in medicine and the health care professions

7.1 Prescription and administration of drugs may involve staff other than medical doctors, in particular nurses and pharmacists. Key tasks to which they may contribute include the selection of appropriate medicine and its effective administration. Collaboration between professionals can be enhanced by skill sharing; this is a growing area in the NHS and one that has been highlighted by the RCP and the Royal College of Nursing (Royal Colleges of Physicians and Nursing, 1996).

Medical specialties

7.2 Physicians in all areas of practice are aware of the need to base the care of patients on appropriate evidence. The design, conduct and appraisal of clinical trials are therefore of crucial importance; clinical pharmacologists have particular expertise in these areas.

7.3 The working party received evidence of specific collaborations between clinical pharmacologists and other hospital based specialties contributing to the benefit of clinical research. These specialties include paediatrics, gastroenterology, cardiology, geriatric medicine, anaesthetics and psychiatry.

7.4 The nature of useful collaborations between clinical pharmacology and another specialty varies, but examples include joint training and joint certification with eventual appointment of consultants experienced in both specialties. The working party also considered that the inclusion of clinical pharmacology and therapeutics in the CME programmes for all specialties would greatly enhance the development of a critical approach to medical treatments.

Pharmacy

7.5 The disciplines of clinical pharmacy and clinical pharmacology and therapeutics are closely related, with individuals in each specialty recognising the contribution the other has to make in academic, clinical, industrial and government environments.

7.6 The practice of clinical pharmacy developed during the late 1970s and early 1980s and was endorsed by an independent inquiry which concluded that ‘pharmacists have a distinctive and valuable role to play in the treatment of individual patients in hospitals...’ and that ‘clinical pharmacy should be practised in all hospitals’ (Nuffield Foundation, 1986). In 1988, the UK Departments of Health called for action by all health authorities and health boards to review their pharmaceutical services and plan for the implementation of clinical pharmacy and formulary management systems.
7.7 The development of clinical pharmacy services may have been in part a response to a scarcity of clinical pharmacologists. Hospital clinical pharmacy services are widely welcomed by medical, nursing and other ward staff as a source of complementary information and advice. This view has been endorsed by the Scottish Office Clinical Resource and Audit Group (1996) who define clinical pharmacy as ‘a discipline concerned with the application of pharmaceutical expertise to help maximise drug efficacy and minimise drug toxicity in individual patients’.

7.8 In universities, clinical pharmacologists contribute to the training of pharmacists at undergraduate level in some schools, but more particularly at the postgraduate level. Examples include contributions to teaching on postgraduate diploma or masters’ programmes in clinical pharmacy. The new four-year training programme to a master’s honours degree in pharmacy, with effect from the 1997 intake, may alter this relationship to some extent. This programme will provide the NHS with pharmacists who have a greater expertise in the skills of clinical pharmacy.

7.9 In NHS clinical practice pharmacists and clinical pharmacologists work closely together, for example on drug and therapeutics committees. They are involved together, especially in the introduction of new drugs, the development of formularies, therapeutic guidelines and the production of ‘group protocols’. Pharmacists and clinical pharmacologists may also sit together on local research ethics committees.

7.10 Clinical pharmacists have demonstrated the benefits of integration into the primary health care team (Hamley et al, 1997; Macgregor et al, 1966). Joint working between clinical pharmacists and clinical pharmacologists may be particularly appropriate in the development of strategies to deal with the interface between primary and secondary care. Precedent for this has already been established through joint formulary initiatives, such as the Grampian Joint Formulary in Scotland (Grampian Medicines Committee, 1995). In addition, a DoH Directive (EL (94)72) stimulated the development of a number of prescribing committees in England in which purchasers, GPs and prescribing advisers, including clinical pharmacologists and pharmacists, have become involved. Medical and pharmaceutical prescribing advisers in particular have played a key role in this initiative.

7.11 The research interests of pharmacists and clinical pharmacologists are also often complementary. Areas of mutual interest include pharmacoeconomics, adverse drug reactions and health technology assessments.

7.12 An additional impact of pharmacy activity on therapeutics could stem from the second report of the Crown inquiry (DoH, 1999) into the prescribing, supply and administration of medicines. The report recommends that certain health professionals other than doctors, dentists and certain nurses may become legally authorised ‘independent prescribers’. It also suggests that some health professionals, including pharmacists, could become ‘dependent prescribers’ with a responsibility for continuing care which may include prescribing or continuing established treatments by issuing repeat prescriptions, with the authority to adjust the dose or dosage form according to the patient’s needs.
Nursing

7.13 The training of registered nurses changed fundamentally in 1986 with the replacement of the basic qualification by a diploma in nursing. This has a core curriculum which includes biological, social and behavioural sciences, together with nursing studies and research. Following on from this change there developed bachelors’ and masters’ degree courses in nursing and nursing related subjects. From 1996 the English National Board for Nursing, Midwifery and Health Visiting has recommended that nurses working in specialist capacities should possess a degree in that discipline, in addition to evidence of study in advanced pharmacology and therapeutics.

7.14 The Crown Report (DoH, 1989) recommended that nurses possessing either a health visitor or district nursing qualification and working in primary care should be able to prescribe medicines from a set formulary. With the implementation in 1997 of pilots, this proposal has been adopted for fuller implementation in 1998 of nurse prescribing in primary care. This recent development calls for additional skills and knowledge on the part of community nurses, particularly because in primary care settings the community-based nurse and the GP work together in a partnership based on complementary skills and roles.

7.15 Recent evidence from pilot studies of nurse prescribing found that nurses possess insufficient knowledge in pharmacology to ensure safety. Recommendations suggest that such nurses require additional training and support (DoH, 1997; Luca, 1997). Clinical pharmacologists and pharmacists have a role to play both in the education of nurses who prescribe medicines within primary health care settings, and in assisting lecturers in therapeutics within schools of nursing. They can also provide a resource for nurses and GPs in devising specific treatment protocols for disorders such as asthma, diabetes and hypertension, and for more general advice on rational prescribing in the community.

7.16 The development of a more academically based nursing profession, with skills in prescribing, is likely to alter the practice of medicine in primary care, and in due course may also affect hospital nursing. Pilot schemes for nurse prescribing in community and primary care are already operating in all eight English health regions (NHS Executive Press Release, 1997). Items included in the Nurse Prescribers’ Formulary account for approximately 10% of prescribing expenditure in primary care although, to date, most prescribing of these items is still undertaken by GPs (DoH, 1997).

7.17 In hospitals, it is hoped that better training of nurses in pharmacology will enhance their understanding of drug action, and improve collaboration with medical and pharmaceutical staff in the delivery of therapy, for example under ‘group protocols’. Nurses may also become involved with medical and pharmaceutical staff in the management of hospital drug budgets, particularly in specialist nursing areas such as intensive care and renal dialysis.

7.18 It is therefore important that close links between clinical pharmacology, pharmacy and nursing are maintained and developed in order for the potential advantages of an increasingly skilled nursing profession to be utilised by the NHS.
7.19 An additional impact of nursing activity on therapeutics may result from the second report of the Crown inquiry, DoH, 1999, referred to in paragraph 7.12 above. Appropriately trained practice nurses could also have an effect on public awareness of medicines in specific therapeutic areas.

CHALLENGES IN RELATIONSHIPS WITH SPECIALTIES

- to facilitate continuing collaboration between other medical specialties and clinical pharmacology and therapeutics, particularly in joint training programmes
- to maintain existing links between clinical pharmacology and pharmacy, and to develop these in the areas of service and training of pharmacists to benefit patients and health care providers
- to develop professional relationships between nursing and clinical pharmacology and therapeutics, particularly with regard to education and training and areas of specialist practice
8 **Recommendations**

8.1 The UK has been at the forefront of the specialty of clinical pharmacology and therapeutics since its development as a separate discipline in the late 1960s. However, at present there is no systematic provision of clinical pharmacology expertise throughout the NHS. In order that such expertise be made available, a coordinated approach to the recruitment, training and retention of clinical pharmacologists in both the NHS and universities is required.

8.2 The specialty has major existing strengths in research, and its programme for specialist certification offers training in investigational skills as well as supervised research (one year for each). It should therefore be particularly attractive to junior doctors considering a career in academic medicine. For these strengths to be maintained the working party considered that links with other specialties should be developed. The Standing Advisory Committees (SACs) should therefore be encouraged to examine ways in which certification in their specialties could be facilitated, either in addition to clinical pharmacology and therapeutics (dual certification) or together with general internal medicine and clinical pharmacology and therapeutics (triple certification).

8.3 Cost pressures on drug budgets mean that cost-effectiveness of drug therapy is of major importance in the NHS. Clinical pharmacologists can have a significant impact on this process by contributing to pharmacoconomic evaluations, by membership of area prescribing committees, by involvement in local decision making at health authority and hospital level, and by education of both hospital doctors and GPs. A model put to the working party was that of a combined appointment of clinical pharmacologists between health authorities and hospitals. The working party supports such developments.

8.4 The pharmaceutical industry contributes significantly to the UK economy and to pure and applied research in the UK. There is a shortage of trained clinical pharmacologists in industry at a time when both traditional and new specialist skills (such as molecular biology and genetics) are crucial to the development of new drugs. Clinical pharmacology units within industry play a pivotal role in the process of drug discovery, and it is important that this role is recognised.

8.5 The development of the joint training programme between industry and academia was welcomed. The working party wishes to see this supported, as well as other steps being taken to encourage young physicians into the pharmaceutical industry, for example joint appointments between academia and industry at consultant level. At present, the standards for the acquisition and exercise of the skills necessary for clinical pharmacology in industry are being determined by the Faculty of Pharmaceutical Medicine in conjunction with the AHPPI, and the Clinical Pharmacology Subcommittee of the ABPI.
8.6 Changes in the undergraduate curriculum for medical students have placed increasing pressures on academic departments of clinical pharmacology and therapeutics. The Faculty of Pharmaceutical Medicine working party considers that the principles for an undergraduate core curriculum in clinical pharmacology and therapeutics for medical students should be agreed, and endorses the core curriculum developed by the BPS. In addition, universities should address the manpower pressures on departments of clinical pharmacology and therapeutics, recognising the importance of this specialty in the teaching of medicine.

8.7 Postgraduate education programmes in therapeutics are underprovided both through CME and under PGEA schemes for GPs. The NHS has much to gain from such programmes, which would support rational prescribing. The working party particularly welcomed recent new postgraduate qualifications in therapeutics, and felt that an expansion of such programmes, both for doctors in the NHS and industry, should be encouraged. New techniques for delivering such educational programmes to prescribing doctors, particularly in primary care, should be developed and promoted.

Addressing the recommendations

In order to address the working party recommendations, a series of steps must be taken, in the short and medium term. These are detailed below.

1 TRAINING

In the short term, training in clinical pharmacology and therapeutics in combination with training in other specialties needs to be facilitated. The JCHMT has approved a seven-year training programme for trainees in clinical pharmacology and therapeutics, respiratory medicine, and G(1)M. SACs should be encouraged to develop similar training programmes of appropriate length, and postgraduate deans should encourage these programmes and facilitate them in their deaneries. A target of one or two such posts in each postgraduate deanery would seem an appropriate target in the next five years.

2 UNIVERSITIES

Within universities there is a need to address the delivery of the core curriculum in clinical pharmacology and therapeutics. The view of the working party is that this should be in place within three years. Appropriate infrastructure support to deliver this curriculum will need to be identified.

3 CONTINUING EDUCATION PROGRAMME

There should be a move away from the significant pharmaceutical industry component of CME programme provision in primary and secondary care. Programmes focused more on the needs of the NHS and its staff, particularly with respect to education in therapeutics, need to be developed.
4 INDUSTRY

Industry needs to continue to recruit appropriately trained clinical pharmacologists to run its research programmes. Present arrangements for postgraduate deans to part fund training posts with industry should continue to be encouraged. Expansion of such a programme is endorsed. Retention of qualified staff within industry is an issue that needs consideration, and universities, the NHS and the pharmaceutical industry should examine the possibility of joint appointments at consultant level.

5 CAREER STRUCTURE

Consideration should be given to the planning of consultant level appointments in both the NHS and universities. A clear link should be established between NHS priorities, particularly with regard to drug utilisation and expenditure, and appointments of consultants in clinical pharmacology and therapeutics. The model of joint appointments between health authorities and trusts (see para 2.21) is endorsed by the working party. To be successful, such appointments would obviously require the availability of suitably trained individuals, but planning for them should be implemented at this stage with a view to their creation over the next 5–10 years.
References


References


Appendices

1 Useful information on doctors working in the pharmaceutical industry

2 Core content of an undergraduate course in clinical pharmacology

3 Clinical pharmacology and pharmacoeconomics

4 Curriculum for higher specialist training in clinical pharmacology and therapeutics

5 Job plans for a consultant physician in clinical pharmacology and therapeutics

6 Job descriptions
   6a Job description for a Whole-time/maximum Part-time Consultant in General Internal Medicine and Clinical Pharmacology
   6b Appointment of a whole-time or maximum part-time consultant physician in general medicine with a special interest in clinical pharmacology and therapeutics
   6c Job description for a clinical pharmacologists, unit physician
   6d Job description for a clinical pharmacologists, project physician
Appendix 1

Useful information on doctors working in the pharmaceutical industry

The pharmaceutical physician
A generic title describing a physician employed in the pharmaceutical industry, where he or she could hold any position.

The medical adviser
An older term but sometimes used to describe industry physicians working in Phase III and after registration of drugs, advising on marketing strategies.

British Association of Pharmaceutical Physicians (BrAPP)
This association was set up 40 years ago at a time when there were fewer doctors in industry. It has evolved into a large membership and is particularly concerned with teaching the skills, in the broadest sense, of pharmaceutical medicine. It has had a training programme in pharmaceutical medicine since 1975, which from 1976 has been ran on its behalf as the Postgraduate Course on Pharmaceutical Medicine by the University of Wales, Cardiff.

The Faculty of Pharmaceutical Medicine
This was founded eight years ago as a joint venture between the three UK Royal Colleges of Physicians and physicians working within the pharmaceutical industry and clinical research organisations in order to gain a more formal recognition for the specialty of Pharmaceutical Medicine, and to establish and monitor standards for its members. It has a properly constituted board, standing committees, and various sub-committees, including a board of examiners responsible for setting, marking and reporting on the Diploma in Pharmaceutical Medicine. Its first president was Professor Sir Abraham Goldberg and its current president is Professor Peter Stonier. The organisation is currently seeking certification in the specialty of pharmaceutical medicine by application, via the JCHMT, to the Specialist Training Authority.

The proposed career path is that a new physician to industry would register with the Faculty as an affiliate. After two years he or she would sit the exam for the Diploma in Pharmaceutical Medicine. If successful he or she would then become an Associate of the Faculty of Pharmaceutical Medicine (AFPM). A further period of Higher Medical Training, still under discussion, would lead to Membership of the Faculty (MFPM) and Specialist Certification. A second route to MFPM, as at present, is for an Associate to prepare a dissertation on a subject in pharmaceutical medicine. A Continuing Medical Education (CME) programme for Members and Fellows was inaugurated in January 1998.
The Faculty also has Fellows who are distinguished physicians. The parallel would be similar to the Fellowship of the Royal College of Physicians.

**Diploma in Clinical Pharmacology of the Society of Apothecaries**

This Diploma has arisen because of concern among some senior clinical pharmacologists presently working in industry and others who have left the industry, that medical practitioners who conduct Phase I studies in human volunteers should have appropriate training and testing of their skills and competence. The first exam was held in 1997. A training programme is being run as a course organised by non-profit making organisations.

**Association of Human Pharmacology in the Pharmaceutical Industry (AHPPI)**

This Association when founded comprised a group of physicians, scientists and nurses doing practical clinical pharmacology studies in industry. More recently, clinical pharmacologists from Contract Research Organisations have joined the Association. The AHPPI holds meetings to which academics are invited as guest speakers. The Association has more than 150 members and has as its theme an interest in clinical pharmacology techniques, and generic topics including volunteer recruitment, payment, constitution, ethics and training of Phase I staff.
Appendix 2

Core content of an undergraduate course in clinical pharmacology*

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Keywords: core curriculum, clinical pharmacology and therapeutics, medical undergraduate education

Introduction

The GMC has repeatedly called for changes to traditional medical school curricula which were considered to be overburdened with factual material and which too often emphasise teaching rather than learning. The GMC published recommendations (1993) for the development of new medical curricula, which should take the form of a core curriculum, mandatory for all students and occupying about two-thirds of the course, and special study modules, occupying about one-third of the course, for which the student should be offered a range of options for study in depth. The new curricula should emphasise learning by the student, partly self directed and partly faculty directed.

The core curriculum itself was only broadly defined by the GMC, which argued that curricula should not be specialty or department based but should be integrated both horizontally and vertically, ie with true interdisciplinary synthesis rather than just coordination. The GMC did not have the resources to define the core content of all subjects even if this were desirable, but indicated that it would promote the definition of core content for specific subjects by other organisations who might be concerned to improve undergraduate education in that area. Such course definitions could then be made widely available so that they could be adopted by any medical school, with appropriate local modifications.

In this spirit, the committee of the Clinical Section of the BPS proposed to develop a core content for courses in clinical pharmacology and therapeutics. This core content was developed from an American model (Nierenberg et al, 1990) by academic clinical pharmacologists with experience in undergraduate learning, using a Delphi technique (Walley & Webb, 1997a). The following is the result of this work.

* Reprinted from Walley and Webb 1997b. Published with permission from the British Journal of Clinical Pharmacology.
Aim

The purpose of the work was to identify what should constitute the core content of courses in clinical pharmacology and therapeutics, ie the knowledge, skills and attitudes that medical students should learn in order to become competent to prescribe drugs safely and effectively, and to maintain this competence throughout their professional lives. The approach and understanding of optimal drug use fostered by clinical pharmacology and therapeutics should be applicable to drugs used in any specialty, and to drugs currently available as well as to those yet to be developed.

Implementation of the core content

The pattern of courses will differ in different medical schools, and this work does not attempt to define how any individual school should ensure that these issues are learned. In general, the curriculum is confined to those areas in which the learning is best directed by clinical pharmacologists and unlikely to be adequately directed by other specialists.

This work does not address either the learning of the clinical pharmacology of commonly used drugs or the therapeutics of major clinical problems or medical emergencies. This learning is of major importance and should ideally be directed by clinical pharmacologists. Recognising the shortage of clinical pharmacologists to take on this workload, many medical schools will opt to use specialists in individual medical specialties for the task but, at the very least, clinical pharmacologists should be involved in defining the content of this element of the course and in its coordination.

The curriculum in clinical pharmacology should be learned as a continuum throughout the medical school course. It should start with more basic pharmacology, with some content of clinical pharmacology and therapeutics, gradually moving to a more clinically based course, with greater emphasis on clinical pharmacology and therapeutics whilst retaining links to basic pharmacology. Finally, the skills and attitudes introduced to undergraduates should be refined during the pre-registration house officer year (which is also the responsibility of the university).

This course should be closely integrated with the other subjects under study by the students or, in more problem-based courses, incorporated as a vital part of each problem area. The curriculum should ideally be learnt in small amounts over the full medical course, building on what was previously learnt and with key points frequently recurring. Some schools may in addition want to have a discrete section or sections devoted predominantly to clinical pharmacology and therapeutics at one specific time.

Assessment – Any core curriculum must be tested rigorously. Assessment of the course content here should be progressive, and test factual knowledge, as well as skills; attitudes are more difficult to assess. Its ultimate test will be the testing of competency to prescribe effectively and safely, which is the measure of a cluster of skills, knowledge and attitudes. The assessment of the general approach to learning as opposed to teaching is also important but difficult; this assessment would depend on measuring the motivation of students and their ability to learn in the future rather than their factual knowledge at a given point.
Core content

In keeping with the format described by the GMC, the core content is divided into three areas that students should acquire or develop: a) core knowledge and understanding, b) skills, and c) attitudes.

**CORE KNOWLEDGE AND UNDERSTANDING**

1 **Basics of pharmacology** – Students should understand the mechanisms by which drugs produce their pharmacological effects. They should appreciate the links between pharmacological effects at the molecular, cellular, and tissue/organ levels, and how these effects can be disrupted by disease processes and other drugs. Hence, they should understand the principles through which therapeutic and adverse effects occur.

2 **Clinical pharmacokinetics** – Students should understand how drugs are absorbed, distributed, and cleared by biotransformation and/or excretion. They should understand the concepts of drug half-life and clearance. (Application to clinical situations should be emphasised and detailed calculations avoided.)

3 **Monitoring drug therapy** – Students should understand how to monitor drug therapy by observing and recording therapeutic responses directly, or indirectly by measuring pharmacodynamic responses or plasma drug concentrations. They should understand that interindividual variations in response to drugs limit the value of a therapeutic range for drug concentrations. The basic principles should be emphasised and their relevance to clinical practice illustrated by concentrating on clinically important examples.

4 **Adverse drug reactions** – Students should understand the epidemiology of adverse drug reactions and how to recognise and avoid them. They should understand the importance of reporting adverse drug reactions and the yellow card scheme.

5 **Drug interactions** – Students should understand the epidemiology of adverse drug interactions. They should understand the mechanisms by which interactions may occur so that they may predict them and understand how to avoid them.

6 **Pharmacogenetics** – Students should understand the principles of pharmacogenetics and its importance in determining variation in response to drugs in terms of efficacy and toxicity; this should be illustrated using common clinical examples.

7 **Prescribing for paediatric patients** – Students should understand the principles of prescribing for paediatric patients, including differences in pharmacokinetics and pharmacodynamics compared with adults.

8 **Prescribing for elderly people** – Students should understand the special problems of prescribing for older patients, including, altered physiology, pharmacokinetics and pharmacodynamics, and in particular, the special problems caused for older people by polypharmacy.
9 **Principles of prescribing for pregnant and breast-feeding women** – Students should understand the special concerns for drug toxicity to mother, fetus, and nursing infant. Students should also know the drugs of choice in disease states common in pregnant and breast-feeding women.

10 **Prescribing for patients with renal disease** – Students should understand the problems associated with prescribing for patients with renal disease, including altered pharmacokinetics, especially renal excretion; altered pharmacodynamics; the drugs to be avoided in patients with renal disease; and drug-induced nephrotoxicity.

11 **Prescribing for patients with hepatic disease** – Students should understand the problems associated with prescribing for patients with hepatic disease, including altered pharmacokinetics, especially biotransformation; altered pharmacodynamics; the drugs to be avoided in patients with hepatic disease; and drug-induced hepatotoxicity.

12 **General approach to the treatment of the poisoned patient** – Students should understand the principles of managing patients who have been poisoned by drugs or other toxic substances, including how to assess such patients and how to recognise common presenting syndromes; how to remove the toxic substances, including decontamination and procedures to increase drug clearance; the use of antidotes where appropriate; and the specific management of common poisonings (eg aspirin, paracetamol and tricyclic antidepressants).

13 **Regulations affecting prescribing** – Students should know the national regulations concerning the availability and use of drugs, in particular those affecting controlled drugs (eg opiates etc); BNF guidelines on prescription writing; and regulations concerning the use of experimental therapies or established therapies for experimental purposes. Students should understand the role of local formularies and drug and therapeutics committees.

14 **The process of new drug development, testing and approval** – Students should understand pre-clinical development and testing; testing in Phase I (human pharmacology), II (therapeutic exploratory) and III (therapeutic confirmatory); the essential elements of a good clinical trial; the need for informed consent and ethical approval in clinical research; the role of the CSM and European agencies; the importance of Phase IV (therapeutic use) studies for drug safety and for the development of new indications.

15 **Practical criteria for selecting among drugs in a therapeutic class** – Students should understand the practical criteria for selecting among drugs in a therapeutic class, including differences in pharmacokinetics or pharmacodynamics; approved indications; possible adverse effects or drug interactions; and cost-effectiveness.

16 **Routes of administration and drug formulations** – Students should be aware of the various formulations of medicines available, of the routes by which medicines may be administered, and of their advantages and disadvantages. Students should be able to select the most appropriate formulation and route for drug administration in common clinical situations.
CORE SKILLS

1 **Clinical pharmacokinetics** – Students should be able to indicate how knowledge of a particular pharmacokinetic profile of a drug would alter the way in which it should be prescribed in common clinical problems, and in addition indicate how alterations of renal and hepatic function might alter the pharmacokinetics of a drug.

2 **Adverse drug reactions** – Students should learn to consider adverse drug reactions as possible causes of symptoms and clinical signs, especially in complicated cases in which patients have several diseases and complaints, and are taking several drugs.

3 **Drug allergy** – Students should become skilled at recognising and treating the most common presentations of allergic responses to drugs; know the correct approach to managing a patient with an acute anaphylactic reaction; and be able to take a history of drug use, including history of medication allergy or intolerance.

4 **Drug interactions** – Students should become skilled in recognising common drug interactions. It is equally important that they should be skilled in using common reference materials to ascertain potential drug interactions with the drugs they will be prescribing in order to avoid unintended and unexpected drug interactions; when interacting drugs must be prescribed, students should be familiar with approaches to optimal prescribing in order to minimise toxic interactions.

5 **Seeking information** – Students should develop the ability to use reference sources, including the BNF, other reference texts, original research literature and drug information services, to find information on aspects of drug therapy with which they are unfamiliar for specific patients or indications. Students should be able to use common reference sources and poisons centres for rapidly obtaining accurate information about the diagnosis and treatment of acute poisoning.

6 **Therapeutic drug monitoring** – Students should understand what therapeutic effect to observe in order to monitor the effects of a given drug. Students should know for which drugs to request measurement of drug concentrations and when it is appropriate; they should be aware of the principles of how to adjust therapeutic regimens in the light of results.

7 **Prescribing for elderly people** – Students should be able to recognise and avoid drugs that pose special problems and risks for elderly patients and understand the characteristics of drugs which require dosage modification in elderly patients.

8 **Prescribing for pregnant and breast-feeding women** – Students should be able to use current reference sources to ascertain drug risks in pregnant women; and be able to prescribe drugs of proven safety and efficacy for commonly encountered illnesses such as urinary tract infections and hypertension.

9 **Routes of administration and drug formulations** – Students should be able to select the most appropriate formulation and route for drug administration in common clinical situations, and be able to administer drugs safely by parenteral routes.
10 **Writing prescriptions and keeping records** – Students should be able to write complete, accurate, and unambiguous prescriptions for use in both inpatients and outpatients, including drugs with special restrictions such as controlled drugs. Students should understand why all prescriptions (and ideally the response to them) should be recorded.

11 **Use of evidence** – Students should learn how to assess evidence concerning drug therapy, presented either as clinical trials or reviews or as promotional material. This includes understanding the need to consider real clinical end-points as opposed to surrogate end-points wherever possible, the basics of clinical trial design and conduct, and the basics of medical statistics. Students should begin to develop skill in reading and assessing scientific papers describing clinical trials, and in distinguishing valid studies from those with serious methodological flaws or bias. They should learn to use properly evaluated evidence as the scientific basis of their clinical practice whenever possible.

12 **Learning about new drugs** – Students should be familiar with sources of accurate information concerning new drugs and their appropriate use. All students should know how to use sources of objective information about current and new drugs. Students should learn how to use available reference texts, library resources, computer databases (e.g., Medline) and objective newsletters (e.g., Drug and Therapeutics Bulletin) to carry out their own programmes of continuing education concerning developments in drug use.

13 **Communication skills** – Students should become able to talk with patients to elicit a complete drug history, including prescription and non-prescription drugs, and to ascertain previous adverse drug reactions and drug allergies. Students should know how to use the various written materials that are available as patient inserts. They should have an understanding of the nature of informed consent and how it applies to drug use.

14 **Patient adherence to therapy** – Students should understand that patients may not adhere to prescribed drugs and why this may occur. They should learn to assess the degree of non-adherence, and consider non-adherence as a possible cause of therapeutic failure. They should learn to encourage adherence by the use of simple drug regimens and by ensuring that the patient understands and agrees the aims of the treatment, as well as the proper manner in which to use the prescribed drugs.

**CORE ATTITUDES**

1 **The process of optimal therapeutics** – Students should be accustomed to proceeding through a logical sequence of deliberate steps before prescribing. They should attempt to make a firm diagnosis; understand the pathophysiology of the disease they have identified; list possible treatments and select the most appropriate, given the features of the particular patient; establish what end-points to follow; and communicate adequately with the patient concerning goals, risks, and appropriate follow-up. Developing such an optimal therapeutic plan depends on the ability of the student to assess and estimate the potential risks and benefits of using a drug in a specific patient.

2 **Balanced approach to drug prescribing** – Students should understand the balance that must be struck between benefit and risk in deciding to use drug therapy, and that this
balance may vary between patients and indications. Students should therefore learn to avoid either an excessive readiness or an inappropriate reluctance to prescribe. Students should also accept the duty of making best use of limited resources in their prescribing, realising that resources spent in one area are not available for use in others: they should therefore learn to avoid wasteful and unnecessary prescribing.

3 The prescription as an experiment – Students should develop the attitude that every prescription is really a carefully designed experiment that can produce a useful clinical effect, toxicity, or both. They should learn how to choose appropriate drugs for appropriate indications and appropriate patients, and how to individualise therapy in specific cases. They should be aware of the implications of individual variation in responses to drugs and understand the benefits and limitations of applying data from clinical trials to the individual. They should learn to observe the results of their prescribing systematically and review their prescribing in the light of these outcomes.

4 Learning for the future – Students should understand that therapeutics as currently practised will be modified by future medical advances, and that it is their professional duty to adapt to changes and to keep up to date with such advances so that their patients may benefit accordingly. They must understand that new therapies often bring new risks as well as benefits, and learn to weigh the potential benefits of new therapies against their possible hazards, even where these hazards are as yet unrecognised. Students should also learn the limitations of their own knowledge and be ready to use reference sources or seek advice when necessary.

References


Appendix 3

Clinical pharmacology and pharmacoconomics

Prepared by J Griffin, Chairman, Board of Examiners, Faculty of Pharmaceutical Medicine and formerly Professional Head of Medicines Division (DoH), and Director of ABPI

Health care costs continue to rise in all developed countries. In the UK the cost of pharmaceuticals has risen from 10% of the total NHS annual cost in 1948, to 14% in 1996. Health care spending is made up of 70% fixed costs and 30% variable costs. Pharmaceuticals therefore account for almost half of the variable element, which has made it a specific target for savings.

To date, government initiatives have, to some extent, been directed towards price control rather than necessarily addressing the issue of cost-effective prescribing. Such initiatives have tended to lead to a slower uptake of new therapies in the UK than in other European countries (Griffin, 1996; Griffin & Griffin, 1993).

McGavock (1993) made the point that most of our effective drugs for the management of serious illnesses have been discovered in the last three decades: unfortunately practising doctors’ understanding of pharmacology has not kept pace with these advances so therapeutics is often left to the idiosyncratic choices of individual clinical teachers in later years.

To establish whether a new product is cost-effective will inevitably require pharmaco-economic analyses of new drugs to be conducted by the manufacturer, probably at the later stages of clinical development (Phase III) (Griffin, 1995).

Pharmaco-economic analyses of new drugs are therefore of considerable importance to government departments, purchasers of health care, and practising physicians. Clinical pharmacologists have a particular role in the economic evaluation of new drugs, and it is somewhat controversial whether economic evaluation should be conducted alongside traditional randomised controlled clinical trials, as proposed by Drummond (1994). Clinical trials to define efficacy and safety of a new treatment are conducted for licensing and registration purposes, and involve patients being seen more frequently, and investigated more extensively, than would happen in post-marketing use. An economic assessment at this stage may therefore produce inappropriate estimates of cost of care, although it is possible that allowances could be made in an analysis to discount these elements. Such reservations are not universally applicable to Phase III development of new products where evaluation of use begins to approximate future clinical practice. However, at this stage the full health benefits of a product may not be available, and valid evaluation of economic benefit of new drugs may only be made with confidence some years after marketing. For decision-making policies by the pharmaceutical industry, government and the NHS this may be seen as too late. Pre-marketing economic evaluation should therefore be regarded as an interim economic assessment.

All economic evaluations of new medicines involve the use of a comparator. Therefore, the choice of an appropriate comparator is fundamental in all pharmaco-economic studies irrespective of whether the economic evaluation is a:

- cost-benefit analysis: measuring the benefit in pecuniary units or computing a net financial gain/loss,
cost-effectiveness analysis: comparing programmes of treatment with benefits measured in physical units,

- cost-minimalisation analysis: seeking the least costly programme of treatment among those shown to be of equal benefit, or

- cost-utility analysis: facilitating comparisons of interventions across different therapies in terms of their impact on survival and quality of life.

This last type of analysis is the most complicated and controversial. Whilst other techniques calculate value in terms of money, cost-utility evaluates outcomes in terms of quality and duration of life.

Many pharmacoeconomic analyses have been fundamentally flawed by an inappropriate choice of comparator treatment, or selection of the wrong pharmacoeconomic methodology (Griffith, 1998). In the same way that statisticians had to be integrated into the team designing controlled clinical trials, it is to be expected that a multidisciplinary approach involving clinical pharmacologists, health economists and statisticians will have to develop, since well designed and credible studies need all these skills. Clinical pharmacology developed as the scientific interface between basic pharmacology and medical practice and, in the UK at least, has tended to be an academic or research-based discipline rather than a service specialty. This may account in part for the failure of clinical pharmacologists to influence prescribing to a greater extent (Walley & Davey, 1995).

It is incumbent upon all doctors to be good stewards of the resources at their disposal to ensure that they are used to maximum benefit. Clinical pharmacologists should therefore be able to assist in the evaluation of therapy, not necessarily with the aim of reducing the overall medicines expenditure but to establish the most effective and efficient use of drugs. Walley and Davey (1995) stated that clinical pharmacologists have been successful in delivering the needs of society in relation to efficacy and safety of drugs. We must now play our part in delivering what will be increasingly demanded in the future: evidence of the value of therapy.

Clinical pharmacologists who have recognised the complexity of decision making in therapeutics, and appreciate that making a choice in selecting treatment involves economic factors as well as factors related to quality, safety and efficacy, will have a more significant role in the future as their influence spreads into the pharmacoeconomic area of evaluation. How the NHS will choose new drug evaluation in the future is as much a political as a clinical decision. In some countries, for example Australia, pharmacoeconomic analysis is required before a drug is allowed to be prescribed within the federal health system. Because of the importance of the UK pharmaceutical industry, it has always been assumed that such a fourth hurdle would not be adopted in the UK. The recent introduction of very high cost medicine, for example interferon-β-1b, has led to some clinical pharmacologists suggesting that expensive new drugs should be put into some type of probation system until their full value can be demonstrated (Ferner, 1996).

In conclusion, pharmacoeconomics is a new discipline which has the potential to significantly alter the pattern of health care delivery. The appropriate involvement of clinical pharmacologists and economists in this process is essential in order that the discipline of pharmacoeconomics be appropriately applied for maximum health care in the community.
References


Appendix 4

Curriculum for higher medical specialist training in clinical pharmacology and therapeutics

Prepared by the Joint Committee on Higher Medical Education

Entry requirements

Applicants for higher specialist training must have completed a minimum of two years GPT in approved posts and obtained the MRCP (UK) or (I). A period of experience in clinical pharmacology and therapeutics at SHO grade is considered desirable before entry to HMT, although not essential.

GPT is defined as follows:

- a minimum of two years in approved posts with direct involvement in patient care and offering a wide range of experience in a variety of specialties
- 18 months of the two years must be spent in posts providing experience in the admission and early follow-up of acute emergencies
- at least six of these 18 months must be spent on a service or services on which the emergency take is unselected
- unselected take is defined as acute medical intake encompassing the broad generality of medicine (ie not restricted to any single or small group of specialties). If any major component of acute medicine (eg cerebrovascular accidents, myocardial infarctions) is excluded from the take, this experience must be obtained in other posts. During the period on unselected take trainees should have an on-call commitment which averages no less than four takes per month

Non-UK graduates without the MRCP who compete for HMT posts must provide evidence of appropriate knowledge, training and experience, particularly in the care of acute medical conditions.

Duration and organisation of training

The programme will occupy four years. For trainees intending to practise in G(I)M as well as clinical pharmacology and therapeutics an additional year will be required. The first year of the joint programme will comprise experience in G(I)M, but should include early experience in clinical pharmacology and therapeutics. Two of the remaining four years will provide methodological experience of clinical and laboratory research, fundamental to the specialist in clinical pharmacology and therapeutics. During this period, one year will be spent in supervised research, and the other year will involve comprehensive training in investigational skills relevant to clinical pharmacology and therapeutics. The remaining two years must be spent in a DGH or a teaching hospital with DGH facilities undergoing training for equal periods in G(I)M and clinical
pharmacology and therapeutics. Trainees intending to practise in clinical pharmacology and therapeutics and another specialty in addition to, or instead of, G(I)M should seek guidance from JCHMT on the duration and organisation of their training. It is possible also for a trainee to undertake a programme leading to certification in three specialties. A model programme combining clinical pharmacology and therapeutics, G(I)M and respiratory medicine lasting seven years is described on page 63.

HMT will provide experience both in teaching hospital(s) or other major centres with academic activity and in hospitals with DGH facilities. The programme to which the trainee is appointed will have named consultant trainers (educational supervisors). In addition, one consultant within the same region, but not necessarily involved in the particular training scheme, will act as programme director to the trainee.

Research

One year of supervised research will count towards the overall programme. Some trainees may wish to spend two or three years in research, either before entering HMT or by stepping aside from clinical training after entering a programme. This is perfectly acceptable, but only one full year will count towards the programme. For those undertaking an extended period of research after entering a programme and obtaining their NTN, a limited amount of additional educational credit may be granted at the discretion of the SAC for clinical work relevant to the programme undertaken in the course of research beyond the initial year. This concession does not apply to those undertaking research prior to entry to a higher training programme.

Investigational skills

The year that comprises training in investigational skills is necessary because the specialist in clinical pharmacology and therapeutics is expected to guide and direct the clinical assessment of drugs, and requires a broad experience of the investigational methods used in pharmacological research. Necessary skills for the design and ethical conduct of drug investigation in accordance with GCP* are best acquired through practical experience of pharmacokinetic, interaction and dose ranging studies, studies of efficacy and safety, clinical trials, and pharmacovigilance studies. These skills are frequently sought by local research ethics committees for the effective execution of their function.

Training record

A training record will be maintained by the trainee. It will be countersigned as appropriate by the educational supervisors to confirm the satisfactory fulfilment of the required training experience and the acquisition of the competences enumerated in the specialty curriculum. It will remain the property of the trainee, and must be produced at the annual assessments.

* Good Clinical Practice (GCP)– a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and recorded results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.
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 specialists 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.

For details of appointment and funding arrangements for flexible trainees, please see the revised Guide to Specialist Registrar Training (February 1998).

Assessment

Assessment of trainees will be based upon the standard format of annual review, including the PYA to which particular importance attaches. Full details may be found in the introduction to the JCHMT handbook. The award of the CCST will be based on satisfactory completion of the entire series of annual assessments.

Clinical experience

See curriculum for HMT in G(I)M. The trainee should take an active part in the local inpatient and outpatient consultation service in clinical pharmacology and therapeutics, and in local approaches to rational and cost-effective prescribing.

Management training

This should include awareness of the organisation and function of the NHS, and of the relation between purchasers and providers; an understanding of clinical budgeting, personnel management, medical staff employment and complaints procedures; and acquisition of skills in interviewing, written communication, and committee participation.

Medical audit

The trainee should attend and contribute to regular peer-group audit meetings at which clinical practice and drug therapy are exposed to critical scrutiny.
Industrial experience

Some trainees seeking certification in clinical pharmacology and therapeutics may undertake part of their training in the pharmaceutical industry. The entry criteria and duration of HMT will be the same for these trainees, although approved experience in the pharmaceutical industry can be counted towards the overall requirement, giving up to a total of one year’s credit towards investigational skills training and/or supervised research.

CURRICULUM

OBLIGATORY EXPERIENCE

The trainee should acquire a sound knowledge of:

- **Drug action in man**
  A clinical pharmacologist should have a broad knowledge and understanding of the consequences of administering drugs to humans. This should include experience of the administration of drugs in one or more disease states in an investigational setting; knowledge and experience of the consequences of giving drugs to normal volunteers; and knowledge of the action of drugs at a cellular and molecular level. The extent to which training in each of these areas is provided during specialist training will depend on the previous experience of the trainee. For example, a trainee who already has an undergraduate degree in pharmacology or a closely related area would have different requirements from one who does not.

- **Clinical pharmacokinetics**
  During the period of training, a clinical pharmacologist should acquire knowledge of the different routes of drug administration together with methods of measuring the time course of drugs and their metabolites in blood and other body fluids. At least a basic understanding of different analytical techniques for measuring drug concentration should be acquired, and all clinical pharmacologists should understand the methods of pharmacokinetic analysis and the interpretation of the results.

- **Theory and practice of statistics and experimental design**
  During the period of training, a clinical pharmacologist should demonstrate an understanding of the principles underlying the design of clinical trials and of the appropriate use of statistics in analysing data. In addition, trainees should be personally involved, under supervision, in the design of at least one clinical trial or normal volunteer study.

- **New drug development**
  The trainee should become familiar with the regulatory requirements covering the development and licensing of new medicines by acquiring knowledge of:
  - how to interpret pre-clinical pharmacological and toxicological studies
  - the design and conduct of phase I and phase II clinical studies of new drugs
The trainee should acquire practical experience of:

**Rational and cost-effective use of medicines**

The trainee should acquire competence in the application of clinical pharmacological principles to drug therapy and develop a critical approach to the choice and use of drugs, with a view to setting standards for others to follow. The trainee should acquire experience of the development and management of prescribing policies, guidelines and formularies, and of the role and function of drug and therapeutics committees by full membership of the local committee.

**Clinical assessment of medicines**

This will be to a large extent dealt with in clinical training

**Evaluation of scientific literature**

The trainee should be familiar with all methods of literature searching and should have supervised experience of the evaluation of scientific papers (eg through a journal club).

**Communication and educational skills**

Teaching is an important part of the professional service offered by clinical pharmacologists. Trainees should therefore obtain supervised experience in undergraduate and postgraduate teaching and, if appropriate, attend courses designed to improve teaching skills.

**Management in the National Health Service**

**Medical audit**

**RECOMMENDED EXPERIENCE**

The trainee should become familiar with:

- the management, detection and reporting of adverse drug reactions
- the treatment of drug overdose
- the epidemiological approach to drug usage, efficacy and toxicity
- therapeutic drug monitoring
- the role and function of a local research ethics committee (by attendance as an observer)
JOINT PROGRAMMES IN CLINICAL PHARMACOLOGY AND THERAPEUTICS, GENERAL (INTERNAL) MEDICINE AND A THIRD SPECIALTY

It has been customary in the past for those undergoing higher specialist training in clinical pharmacology and therapeutics to combine this with specialist training in G(I)M alone. However, most of those trainees will eventually work in academic departments, and it is some time since any NHS consultant posts were created for those who had undergone such combined training. Furthermore, several organ-based specialties are now appreciating the value of recruiting specialists who have experience in clinical pharmacology and therapeutics. Such a breadth of training leads to a better qualified specialist with a deeper understanding of drug therapy, but also a specialist who has a firmer grounding in the principles of clinical investigation. Academic departments of clinical pharmacology and therapeutics are also tending to specialise in an organ-based way in respect of their research activities. Potential specialist trainees in clinical pharmacology and therapeutics are looking for opportunities of this type, and the specialty greatly needs their interest and support. The following programme sets out a way in which triple certification could be secured within seven years, using respiratory medicine as an example of an organ-based specialty. The programme could equally well apply to, for example, gastroenterology, renal medicine or endocrinology and diabetes mellitus.

Programme including respiratory medicine with clinical pharmacology and therapeutics and general (internal) medicine

Year 1. G(I)M in a DGH with limited exposure to clinical pharmacology and therapeutics or respiratory medicine. This year would count as one full year towards certification in G(I)M.

Year 2. Clinical skills training in clinical pharmacology and therapeutics and respiratory medicine. This year would count as one full year towards certification in each of these two specialties.

Year 3. Clinical skills training in respiratory medicine.

Year 4. Investigational skills training in clinical pharmacology and therapeutics.

Year 5. Supervised research in respiratory medicine with a bias towards drug action and/or drug treatment. It should be noted that the research year must be relevant to training in respiratory medicine. Otherwise, the training programme in respiratory medicine will be one year short.

Year 6. Clinical skills training in respiratory medicine and G(I)M. At this stage, experience in G(I)M would involve a lower commitment to on-take (at least two days per month averaged over the year, with at least 10 patients admitted on each take day), the trainee to have ongoing care for approximately one-third) and a minimum of one G(I)M outpatient clinic each week. This year would count as a full year towards certification in each of the two disciplines.
Year 7. Clinical skills training in clinical pharmacology and therapeutics and G(I)M (at the lower level of commitment defined above). This year to count as a full year towards certification in each of the two disciplines.

In reckoning the contribution of elements in the training programme towards the requirements of each specialty for awarding a CCST, years 2, 4, 5 and 7 would fulfil a four-year requirement for a CCST in clinical pharmacology and therapeutics. Years 2, 3, 5 and 6 would fulfil a four-year requirement for a CCST in respiratory medicine. Years 1, 6 and 7, when added to two years GPT, would fulfil the five-year requirement for certification in G(I)M.

The order of training in years 2–5 and years 6 and 7 could be varied according to local requirements.

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Job plan for a consultant in clinical pharmacology and therapeutics

The work programmes of consultants who have specialist expertise and certification in clinical pharmacology and therapeutics vary depending upon the setting in which they are based. Consultants within the NHS will normally be based within a general medical setting, but individuals may have specific expertise in other specialities which may mean that their clinical base will be within that speciality rather than in general medicine. Examples include, for example, expertise in cardiovascular medicine or respiratory medicine. Academic clinical pharmacologists, who are the majority of consultants working within the UK, will be based in university departments and have significant research commitments. Some clinical pharmacologists working in the NHS have extensive involvement in prescribing issues and others are involved in the National Poisons Information Service in the clinical care of poisoned patients.

Within the pharmaceutical industry, clinical pharmacologists at consultant level are employed in all sectors, but in particular in the development of new drugs through their study in Phase 1 trials in man, and in their further development in Phase 2 and Phase 3 investigations in patients.

Clinical pharmacologists in the NHS are actively involved in drug & therapeutics committees and in ethics committees. A key role in the job description of many new appointments is the promotion of rational and cost-effective prescribing.

In view of the above comments it is clear that there is no standard working pattern for clinical pharmacologists within the health service or industry.

Clinical patient care

From the point of view of the NHS, most clinical pharmacologists function as general physicians, and approximately half of their working week will be devoted to active clinical work including general medical ward rounds, responsibility for acute medical receptions, and out-patient clinics, both general medical and specialised, reflecting their own expertise. Examples of the latter may include, for example, hypertension clinics, epilepsy clinics and Parkinson’s disease clinics.

New patients may also be referred with specific drug-related problems, both therapeutic and toxicological. Because of their academic base many clinical pharmacologists will be involved in student teaching, and in the education of junior medical staff and training during these activities. Junior staff will include both specialist trainees at SpR level, and more junior medical staff, who will often be involved in general medical rotations.

In-patient medical activities will include responsibility for post-reception ward rounds, and routine ward rounds. Working patterns in different hospitals vary, but clinical pharmacologists may work either with a team of physicians from other disciplines on the same general medical unit, or in a team together managing a general medical unit as a core activity.

Research activities are likely to be integrated in clinical activities, both in out-
patients and inpatients. In addition, clinical pharmacologists may be involved in basic research in the laboratory, in formal clinical trials and studies involving healthy volunteer subjects. Appropriate facilities are necessary for such studies, and will include the availability of appropriately trained nursing staff, and dedicated clinical research facilities. Not all clinical pharmacologists working in the NHS require the same research facilities, and this will depend on local arrangements and responsibilities. The facilities are, however, essential if such work is to be performed.

Management

Management activities will include, in particular, involvement in drug and therapeutics committees, in the establishment of drug policies both in the hospital and in primary care, and often in ethics committees.

Teaching and training

Clinical pharmacologists are generally actively involved in both undergraduate and postgraduate training and appropriate time needs to be set aside in their work programs for these activities. Training at postgraduate level will often include sessions at hospitals distant from the host Trust since the numbers of clinical pharmacologists are small, and there is a generally acknowledged need for training in appropriate drug therapy.

Clinical audit

Drug use is a very appropriate topic for clinical audit and clinical pharmacologists will often be involved in audit programs.

Research

Research activities are a fundamental part of the day-to-day activities, and training of clinical pharmacologists. There is therefore need to recognise this and set aside appropriate sessions in the job program for research activities. Generally a minimum of two NHDs are required for these purposes.

On call for emergencies

As most clinical pharmacologists working in the NHS will be responsible for acute receptions, this will normally be covered by on-call duty arrangements. There may, however, be a requirement for advice on the telephone in other situations. This particularly applies to those consultants involved in advice on poisons information and management of drug side effects and overdoses.

Continuing Medical Education (CME)

CME is an important part of continuing professional development and appropriate time will need to be spent on this.
Facilities

In view of the wide variability in job description, facilities that are required by clinical pharmacologists in the NHS will vary. In general, however, the following requirements apply.

- Appropriate numbers of inpatient medical beds to support acute medical services, with protected research beds for those involved in clinical research activities
- Out-patient facilities which permit teaching
- Access to laboratory facilities, either directly controlled by the consultant, or within areas in which laboratory investigations can be conducted in collaboration with other specialists (for example, clinical biochemists)
- Secretarial support for both inpatient and outpatient activities
- Appropriate support facilities in the form of office space, library facilities, and teaching areas
- Facilities to enable the training of specialist registrars in the speciality, which will include research facilities and computer and word-processing support.

Recommended work program

Patient care:

Out-patient work – 1-2 NHDs
Ward work – 2 NHDs (plus on-call)

Supporting activities:

Training and teaching – 1-2 NHDs
Research – 2 NHDs
CME – 0.5 NHDs
Clinical audit – 0.5 NHDs
Management – 0.5-1 NHDs

Note this is not an exhaustive list. Many clinical pharmacologists are involved in national committees, in particular, in respect of drug regulation and national advice on prescribing. Clinical governance will also become part of the work programme.
Appendix 6a

Example of a job plan for a whole-time/maximum part-time consultant in General Internal Medicine and Clinical Pharmacology

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<table>
<thead>
<tr>
<th>Grade</th>
<th>Consultant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accountable to</td>
<td>Trust, Director of Public Health and Health Policy, Health Authority</td>
</tr>
<tr>
<td>Department</td>
<td>Acute General Medicine</td>
</tr>
</tbody>
</table>

PRINCIPAL ACTIVITIES

Clinical

This post is a full-time appointment by the hospital for five years. Its subsequent continuation will be dependent on the availability of funding. There are two components to the post, with equal time being given to each. One half is a part replacement consultant general physician and the other, the clinical pharmacological component, is a new development made possible through monies made available by the health authority and fundholders.

MAIN PURPOSES OF THE POST

- The provision of detailed advice to purchasers and providers on the effective, safe and economical prescribing of drugs, and particularly on the introduction of new drugs and new uses for established drugs.
- The provision of acute general medical services at the hospital.

DESCRIPTION OF THE CLINICAL PHARMACOLOGY HALF OF THE POST

Responsible to: for this half of the post, the director of public health and health policy at the health authority.

Key areas of responsibility

- Providing strategic advice to the health authority and fundholding practices on matters relating to drugs and drug use both in hospital and in the community and also at the interface between the two. The purpose of this advice is to contribute to the fulfilment of the overall aim of the purchasers to make the best use of their resources in the provision of health care for their populations.
- Contributing to the awareness by purchasers of all aspects of new drugs, and of new uses for established drugs, at as early a stage as possible so that their introduction can be planned in a way consistent and compatible with the overall aim of the purchasers.
Providing detailed advice to trusts, as and when appropriate, on matters relating to the quality and cost-effectiveness of drugs and prescribing.

Providing detailed advice to general practitioners (GPs), as and when appropriate, and, in conjunction with the pharmaceutical and consultant primary care medical adviser of the health authority, on matters relating to the quality and cost-effectiveness of drugs and prescribing.

**Detailed description of the likely work:** examples of specific tasks likely to be undertaken in the fulfilment of the above areas of responsibility are given on page 71.

**Time commitment:** an average of 5.5 notional half days a week, or their equivalent, will be available for this work.

**Administrative support for the post:** an office base and secretarial support for this half of the post will be made available in association with the university department of clinical pharmacology.

**DESCRIPTION OF THE MEDICINE HALF OF THE POST**

**Background:** this is a replacement post for two retired consultants who had sessional commitments to general medicine. Specific details are given on page 72, which should be read in conjunction with this section.

**Responsible to:** for this aspect of the work, the post-holder is responsible to the hospital.

**Key areas of responsibility:** this is a replacement post and will provide acute medical services. The post-holder will undertake similar duties to the other half-time acute medicine consultants and, in general terms, undertake half the duties of a whole-time on-take physician or, as currently, provide one-twelfth of the acute medical service for the trust.

**Time commitment:** 5.5 notional half days a week are allocated to medicine.

**Teaching/Research**

The trust allows up to two sessions per week for teaching clinical students, training junior doctors and research.

Teaching and examination of clinical students and junior doctors in training is an important part of the normal commitments of this teaching hospital trust, and it is expected that time for these activities will be included in the post-holder’s timetable.

Time for research will be available, subject to the exigencies of the service. A successful candidate with a substantial record of research would be eligible for consideration for an A+B appointment, for one session per week. This is a joint contract with the university clinical school (further details are available from the clinical school offices).

The post-holder’s clinical activities, as well as input into teaching, training and research, will be subject to periodic review by the trust.
Clinical audit

The appointee will be expected to participate in clinical audit and quality improvement initiatives, as agreed with colleagues from within the specialty, other professions and the employing trust.

Personal and professional development

The post-holder will be expected to keep himself/herself fully up to date with their relevant area of practice. Professional or study leave will be granted at the discretion of the trust, in line with the prevailing terms and conditions of service, to support appropriate study, postgraduate training activities, relevant continuing medical education courses and other appropriate personal development needs. The trust currently makes a financial contribution in support of these activities up to an agreed limit.

Management

The post-holder will be expected to work within the trust’s management arrangements, accepting that the resources available to the trust are finite and that all clinical activity, especially changes in workload and developments requiring additional resources, must have prior agreement through these arrangements. He/she will undertake the administrative duties associated with the care of his/her patients, and the running of his/her clinical department under the direction of the clinical director.

General

The post-holder will assume a continuing responsibility for the care of patients in his/her charge and for the proper functioning of his/her department. Office accommodation and secretarial support are available for this post.

Weekly sessional commitment — for the clinical pharmacology half of the post

A total of 5.5 notional half days are available, worked flexibly in agreement with the director of public health and health policy. It is essential that the post-holder holds a valid driving licence; he/she can expect to attend meetings in various parts of the country.
EXAMPLES OF WORK LIKELY TO BE CARRIED OUT BY THE POST-HOLDER IN RESPECT OF CLINICAL PHARMACOLOGY

The following are examples of the sort of work anticipated to be necessary to fulfil the key areas of responsibility stated in the job description of the clinical pharmacology component of the post:

- Clinical pharmacological advice, as appropriate, to the hospital and other trusts in the area.
- Clinical pharmacological and therapeutic advice to GPs, both through the medical and pharmaceutical advisers of the health authority and directly.
- Providing a two-way link between hospital specialists and GPs, and between trusts and the health authority and fundholders.
- Advice and support to the health authority and GPs, both fundholding and non-fundholding, in prioritising drug therapies in the context of limited resources.
- Identifying new drugs in development with potentially significant therapeutic and/or resource implications, and helping manage their subsequent entry into local NHS use, both by trusts and in primary care.
- Advice on the introduction of new uses for established drugs with important therapeutic and/or resource implications in both secondary and primary care.
- Advice in the compilation of hospital and GP formularies and treatment guidelines, and ensuring their compatibility between secondary and primary care.
- The provision of drug information in conjunction with the drug information service provided by the hospital pharmacy, and of advice to doctors in the areas of adverse drug reactions, therapeutic drug monitoring and other therapeutic problems.
- Pharmacological advice on the design of clinical trials and of research and audit projects as they relate to drug therapies.
- Involvement in the teaching of pharmacology and therapeutics to clinical medical students, hospital doctors, GP registrars, established GPs, pharmacists, nurses and other health professionals, as appropriate.
- Help in training nurses in the development of their expanded role as nurse prescribers both in hospital (e.g., accident & emergency, intensive care) and in general practice.
- Advice on rational prescribing, drug cost-effectiveness and risk/benefit ratios, including the treatment of common conditions, to GPs, and on problem areas of over- and underprescribing both in hospital and in the community.
- Assistance and advice to the medical and pharmaceutical advisers of the health authority and to GPs in countering inappropriate pressures by the pharmaceutical industry, and in helping GPs evaluate the cost-effectiveness of their existing prescribing patterns and to change them where necessary.
- Advice on the appropriateness or otherwise of the transfer of prescribing responsibility for certain drugs from hospital to GP.
- Advice on the effects of therapeutic developments on GP drug budgets.
- A role in supporting GPs who may be in conflict with patients and/or colleagues as they attempt to implement evidence-based prescribing, and also in deciding on the appropriateness of applying sanctions where doctors appear to be prescribing in grossly inappropriate ways.
FURTHER PARTICULARS OF THE MEDICINE HALF OF THE POST

- The post-holder will have continuous responsibility for patients admitted under his/her care unless specific mutually agreeable arrangements are made with his/her colleagues. It is expected that at least two formal rounds of every patient will be conducted per week, with additional time allocated for dealing with matters arising, patients, relatives, discharge meetings, etc. An integral part of high quality medical management is a serious commitment to the expeditious and cost-effective use of resources and the early involvement of consultants in discharge planning. It is anticipated that arrangements will be made to provide continuous consultant advice to the junior medical staff, equitably shared with colleagues on a weekly basis. For this purpose, a long-range pager will be provided if required.

- The post-holder will be expected to make a significant personal contribution to the on-take service. This and all future appointees in acute medicine can expect to be required to be physically within the hospital when on-take during normal working hours and to be immediately and easily available for advice, and to be available to attend the hospital within 30 minutes when on-take at other times.

- It is an obligation within the acute medicine Directorate that all emergency admissions are reviewed by their consultant within 12 hours of admission, and that a physical post-take round of the recently admitted patients will take place immediately after each on-take session. Currently, this is at 4.30 pm or 8.30 am, but the precise timing of on-take sessions will be reviewed from time to time.

- There is an outpatient (OPD) slot allocated to this post. It is intended that the post-holder should do at least one OPD clinic per fortnight relating to follow up of inpatients, but that a weekly slot is available if required. There are no junior staff specifically allocated to OPD work.

- It is expected that the post-holder will contribute to the normal activities, which include a weekly X-ray review meeting, a student formal presentation session and the teaching of clinical medical students on the wards. The post-holder will be expected to shoulder a reasonable share of the firm’s commitment to junior staff training.

- It is anticipated that the post-holder will provide clinical pharmacology support to the junior staff, and take a lead role in advising on drug prescribing and the monitoring and audit of drug usage within the acute medicine SDU.

- Leave (subject to normal terms and conditions of the trust) must be arranged with colleagues. The post-holder can expect a reasonable share of any resources available to the other half-time consultants in support of annual and study leave.
Appendix 6b

Example of a job plan for a whole-time or maximum part-time consultant physician in general medicine with a special interest in clinical pharmacology and therapeutics

This new post will be expected to develop clinical pharmacology and therapeutic services for the trust, and to promote rational and cost-effective prescribing. An interest in hypertension and hyperlipidaemia would be welcomed, but other therapeutic interests would not be discouraged. The post has been created as part of a bid to the regional task force and is also expected to relieve some of the pressures on middle-grade junior staff within the trust.

If the person appointed elects to undertake a maximum part-time contract, he/she will be required to devote a substantial part of his/her professional time to the duties of the post.

Any candidate unable for personal reasons to work full-time will be eligible to be considered for the post. If such a person is appointed, modification of the job content will be discussed with senior managers of the trust in consultation with consultant colleagues.

GENERAL INFORMATION

Health services are managed by the health authority for a resident population of approximately 538,000. Main hospital services are provided in two district general hospitals, and paediatric services by the children’s hospital. All hospitals house university departments in various disciplines and have academic, laboratory and library facilities on their respective sites.

Clinical pharmacology and therapeutic services are currently provided from the university department of medicine and pharmacology at the hospital.

DUTIES OF THE POST

1 To develop services for hypertension and hyperlipidaemia within the medical department. This will include close liaison with:
   - all general physicians,
   - the department of cardiology,
   - the department of nephrology, and,
   - the department of chemical pathology.

   There is a well established weekly lipid clinic and a recently established community clinic for assessment of cardiac risk factors.

2 To promote rational and cost-effective prescribing policies across the trust. This will entail:
   - a major input into the hospital drugs and therapeutics committee;
liaison with the pharmacoeconomics pharmacist to promote cost-effective prescribing;

liaison with pharmacy to supply appropriate information on prescribing and use of medicines to all grades of medical staff and to general practitioners where appropriate; and

in collaboration with the drugs and therapeutics committee and the pharmacy department, to provide input into the risk management structures of the trust with regard to drug policies/control/monitoring.

3 The successful appointee will be expected to take a full part in general medical responsibilities of, and will share junior staff, clinic and secretarial facilities. There is a specific requirement to relieve pressures on the middle-grade junior staff in general medicine, which will extend to the junior staff of other medical groups. This will occur by:

- the provision of a formal consultant-led specialist referral service to surgical wards,
- a resulting reduction in outpatient load, and
- direct supervision of the emergency admission ward on a rotational basis.

4 The successful appointee will be encouraged to develop a particular research interest which may be combined with duties under (2) above.

5 The appointee will be expected to take part in the administrative work relevant to his clinical commitment, and to contribute as appropriate to the work of the clinical management team (CMT). The appointee will also be expected to take an active part in clinical audit meetings of the CMT.

PROPOSED TIMETABLE

The allocation of activities will be adjusted to suit the requirements of the successful appointee and to accommodate the requirements of teaching, education and clinical governance, after discussion with consultant colleagues. The person appointed will:

- take his/her equal share in providing emergency cover and be required to cover for colleagues during periods of absence;
- he/she will have a continuing responsibility for the patients in his/her care and for the proper functioning of the department; and
- be expected to take an active part in undergraduate and postgraduate training, and in this respect is likely to be granted an honorary clinical lectureship by the university.

The trust will require consultants to participate actively in continuing medical education, both within and outside the trust.
Appendix 6c

Job description for a clinical pharmacology unit physician or for a clinical pharmacologist working in a clinical pharmacology unit

Note that this job description applies to a clinical pharmacologist working in industry

Reports to: Director of Clinical Pharmacology Unit

Purpose of job:

- To conduct studies in healthy normal (HN) non-patient volunteers for the timely and safe evaluation of the company’s experimental or established entities.
- To establish and maintain a panel of HN non-patient volunteers.
- To manage a team of nurses and clinical scientists for the execution of Phase I studies.

Tasks to be undertaken:

- To review study protocols with study team leader and agree on practical aspects of their execution.
- To plan and execute Phase I studies according to Standard Operating Procedures
- To review safety and adverse event data during and after the study.
- To take medical responsibility for the welfare and safety of trial subjects before, during and after completion of each trial.
- To ensure each study is conducted to the optimal ethical standards.

Main interactions:

- Director of Unit and Head of Nursing.
- Responsible for nursing and scientific staff during conduct of the studies.
- Work with the study team leader in the project to finalise and agree the protocol and jointly design the case record forms.
- Clinical documentation and statistics.
- Drug metabolism.
Job description for a clinical pharmacologist, project physician

Note that this job description applies to a clinical pharmacologist working in industry

Reports to: Therapeutic Director

Purpose of job:
- To make the clinical pharmacology contribution to the exploratory development plan of new medicinal entities, and to the full development plan beyond Phase I.
- To become the recognised therapeutic expert in ‘X’ disease area.
- To give the authoritative CP view to the project team in ‘X’ disease area.

Tasks to be undertaken:
- Devise and write the exploratory development plan for novel medicinal entity.
- Write or supervise writing of individual protocols.
- Represent CP on the therapeutic project team
- Attend relevant research team meetings, and give the CP input.
- To present protocols to the internal scientific review committee and to the Ethics Committee.
- To review and interpret the safety and efficacy results of each study.

Main interactions:
- Therapeutic Director.
- Project team members (research, toxicology, drug metabolism, planning, pharmacy, commercial).
- Clinical pharmacology unit staff.
- Ethics Committee.