Core content of a course in Clinical Pharmacology

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Introduction

The General Medical Council (GMC) has repeatedly called for changes to traditional medical school curricula which were considered to be overburdened with factual material and to often emphasise teaching rather than learning. The GMC published recommendations [1] 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 departmentally based but should be integrated both horizontally and vertically, i.e. with true interdisciplinary synthesis rather than just co-ordination. 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 or medical schools, and this work does not attempt to define how 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.

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. Recognising that there is a shortage of clinical pharmacologists to take on this workload, many medical schools will opt to use specialists in individual medical specialties for this task, but at the very least clinical pharmacologists should be involved in defining the content of this element of the course and in its co-ordination.

The curriculum in clinical pharmacology should be learned as a continuum throughout the medical school course, starting with more basic pharmacology but with some content of clinical pharmacology and therapeutics, and gradually moving to a more clinically based course with greater emphasis on clinical pharmacology and therapeutics, while retaining links to basic pharmacology. Finally, the skills and attitudes introduced to undergraduates should be refined during the preregistration 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 learned 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 should test factual knowledge, as well as skills, attitudes...
are more difficult to assess. In 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 areas of a) core knowledge and understanding, b) skills, and c) attitudes, that students should acquire or develop.

a) 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 level, the cellular level, and the tissue/organ level, 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 the scientific basis for measuring 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 the elderly
   Students should understand the special problems in prescribing for the elderly, including altered physiology, pharmacokinetics and pharmacodynamics, and in particular the special problems caused in the elderly 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 (e.g. aspirin, paracetamol and tricyclic antidepressants).

13. Regulations affecting prescribing
    Students should know the national regulations concerning the availability and use of drugs and in particular those affecting controlled drugs (e.g. opiates etc.); British National Formulary 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 Committee on Safety of Medicines 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.

b) 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, have several 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 should 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 British National Formulary, 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 the elderly Students should be able to recognise and avoid drugs that pose special problems and risks for elderly patients and should understand the characteristics of drugs which require modification of dosage in elderly patients.

8 Prescribing for pregnant and breast-feeding women Students should be able to use current reference sources to ascertain drug risk in pregnant women; 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. Students should 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 the prescription) 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 data-bases (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 nonadherence, and consider nonadherence 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.

c) 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 also should 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 should 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 must learn to weigh the potential benefits of new therapies against their possible hazards, even where these hazards are as yet unrecongnised. Students should also learn the limitations of their own knowledge and be ready to use reference sources or seek advice when necessary.

References