Commentary

An agenda for UK clinical pharmacology The roles of clinical pharmacologists in UK universities

David John Webb

Queen's Medical Research Institute, The University of Edinburgh, Room E3.22, Edinburgh EH16 4TJ, UK

Clinical pharmacologists in universities play major roles in research and teaching and provide important contributions to National Health Service (NHS) activities, such as work for research ethics, drug and therapeutics, and clinical governance committees. Their research extends from preclinical studies using drugs to understand physiology and the mechanisms of disease to large-scale clinical trials and population studies. This work is truly translational, with a focus on drugs and medicines and an emphasis on efficacy and safety. The lack of an organ base has allowed clinical pharmacologists to follow their interests wherever they lead, but their visibility has been hampered by successive earlier versions of the General Medical Council's *Tomorrow's Doctors* document, which undermined some of the necessary scientific underpinning of medical practice and reduced the time clinical pharmacologists had to interact with medical students and recently qualified doctors at the point of choosing their careers. Additional problems have arisen from the stifling effect of the European Union Clinical Trials Directive, and its UK interpretation, on clinical research. For future success, clinical pharmacologists need to embrace translational research, use recent changes to *Tomorrow's Doctors*, linked to the creation of safe prescribing skills, to spend more face-to-face time with their students, fight for a simplification and proportionate regulation of research, and persuade doctors, health service planners and the government of the importance of clinical pharmacology for UK clinical research, the NHS, patient safety and creation of health and wealth.

Introduction

Since the creation of the first departments of clinical pharmacology in the UK in the 1950s, the discipline has played a substantial role in studies in translational pharmacology, experimental medicine, proof-of-concept and large-scale clinical trials. Clinical pharmacologists have also played a leading role in research in pharmacogenetics, pharmacovigilance and pharmacoepidemiology. Concerns have been expressed in recent years that the number of clinical pharmacologists in the UK is falling; many individuals are within 10 years of retirement, so that there may be a critical shortage of clinical pharmacologists in the near future [1, 2]. Here I review the roles that clinical pharmacologists play in universities and identify key developments for a successful future of the specialty.

Research

Universities, and their medical schools, are keen to attract bright young academic clinicians to join them, working in

fields in which they can make important contributions to the medical scientific literature and, ultimately, to patient care. Universities are judged externally on the quality of their research in a roughly 5-year cycle. These Research Assessment Exercises have focused appointments towards individuals who generate large grants and publish papers in high-impact journals. In general, UK clinical pharmacologists have been very successful in these reviews. The next round – the Research Excellence Framework [3] – will provide a new way of assessing higher education institutes and will be completed in 2014. Primarily, judgement is still made on the basis of grants awarded and papers published, but with the addition of a new measure of the 'impact' of the research. In the case of medical research, this includes clinical impact, which should favour the work of clinical pharmacologists, much of which has direct and broad-ranging effects on patient outcomes.

For many years, many clinical pharmacologists have worked in what has come to be known as translational medicine [4], long before this term was coined; some work primarily in the laboratory, others mainly in the clinic. However, as Fitzgerald has argued, much is changing in

drug discovery, and it is important to remain at the cutting edge of new technologies. Others have undertaken population studies and large clinical trials, and many individuals are leaders in their fields. An academic career has always carried a higher risk than a career in the National Health Service (NHS). In recent years, researchers have had to develop additional skills, focusing on a business model in which negotiation, communication and persuasion, as well as leadership skills, are very much to the fore. The current training programmes have generated serious concerns about how easy it will be to persuade young doctors to pursue their academic aspirations, even with the new opportunities for junior academic training programmes and the creation of Academic Clinical Fellowships.

Clinical pharmacologists have no defined organ base, and this gives them the flexibility to follow their scientific interests into whatever proves the most fertile clinical area in which to work. Their common involvement in general (internal) medicine provides an interface with most clinical specialists and sufficient knowledge to collaborate successfully in a broad range of areas in specialist medicine. Cardiovascular medicine, respiratory medicine and infectious diseases have been areas of particular strength, although there have also been substantial developments in, among other areas, medical oncology, epilepsy, paediatrics and general practice. The breadth of research available to clinical pharmacologists, in basic mechanisms of drug action and of disease, in translational medicine, clinical trials, pharmacogenomics, pharmacovigilance and pharmacoeconomics, has made this a vibrant specialty, with much to offer universities and health services. This emphasizes the concern that the number of individuals able to train clinical pharmacologists in universities is now at a very low level.

During the decline in the numbers of consultant clinical pharmacologists (most of whom are employed in the universities), it has proved difficult to persuade successive governments that there is value in increasing or even sustaining the current number of posts. Indeed, there is evidence that consultant numbers in clinical pharmacology are declining [2], whereas the number of consultants in the broader range of medical specialties has grown substantially in recent years. Most of the consultants in clinical pharmacology are currently over 50 years of age, and there is a serious concern that critical mass in expertise in the discipline could be lost within the next few years.

Furthermore, following the universities' responses to the first *Tomorrow's Doctors* document from the General Medical Council [5], pharmacology and therapeutics became far less visible in medical undergraduate programmes, restricting the opportunities for clinical pharmacologists to explain the importance of the specialty and thus to attract trainees. Assessment in final medical qualifying examinations previously involved a paper in clinical pharmacology and therapeutics in most medical schools, and its almost complete loss has diminished the impor-

tance placed on learning in this area among medical students. Many young doctors are not clear what a career in clinical pharmacology involves and have not had the opportunity to discuss this with a clinical pharmacologist to appreciate what a varied and interesting role one can play. Indeed, recent rounds of recruitment in clinical pharmacology have, in contrast to other specialties, left many posts unfilled. This is a new phenomenon, suggesting that there is a deepening crisis that needs to be addressed urgently.

Again related to *Tomorrow's Doctors* [5], there was a reorganization of many medical schools, with loss of the undergraduate scientific disciplines, including pharmacology. Although many universities still have pharmacologists on their staff, many do not have an overarching physical or virtual organization that encompasses pharmacology and therapeutics. For clinical pharmacology to thrive, strong links with pharmacologists are essential. Where possible, such virtual organizations should be formed to protect and develop the discipline.

A further problem for the UK is its very robust implementation of the European Union Clinical Trials Directive (EUCTD), which has led to very heavy regulation (or 'gold-plating') of clinical research in the UK and has made it much less attractive to generate clinical research projects with investigational medicinal products [6]. This has substantially hindered the development of clinical trials in the UK in recent years, and a recent report, led by Professor Sir Michael Rawlins, has provided recommendations for overcoming these problems [7]. The mechanistic and 'proof-of-principle' studies that comprise experimental medicine, a particular strength of UK clinical pharmacology, have been very much undermined by implementation of the EUCTD. No longer is it usually possible to build a focused PhD project around a piece of clinical research that is generated, funded and then undertaken by a single medical graduate. In addition, the UK has in the past had a thriving pharmaceutical industry, working alongside academia, and many UK clinical pharmacologists have made important contributions to the development of medicines that have substantial health benefits. However, it is a concern that UK pharmaceutical companies are currently contracting their activities; the recent closure of Pfizer's Sandwich site, with the loss of around 3000 jobs, gives just one indication of the potential size of this problem. In general, pharmaceutical companies seem to be moving much of their research to environments in which there is an abundance of patients and a willingness to undertake research at lower costs. In contrast, some of the added value brought by an intelligent and experienced approach to, for instance, proof-of-principle studies, is being neglected.

Clinical pharmacology was identified by the previous government as a critical skills gap for a successful UK economy, recognizing that drug discovery and drug development are essential to a thriving pharmaceutical industry and that clinical pharmacology is central to this process [8].

The Medical Research Council has recently created a Clinical Pharmacology and Pathology initiative, in order to tackle the skills shortages in these two fields in relation to pharmaceutical research, with the aim of training individuals, through clinical PhD fellowships, to develop the skills that are relevant to drug development. Two centres have been supported through this initiative, one in Liverpool/Manchester and the other in the Scottish Clinical Medical Schools (Aberdeen, Dundee, Edinburgh and Glasgow) in both of which the clinical pharmacology programme is run by a clinical pharmacologist. The Wellcome Trust had already supported an initiative in translational medicine and therapeutics, again recognizing the skills shortage in clinical pharmacology, but aiming to extend this to a broader range of modern techniques in drug discovery and drug development than was always the province of clinical pharmacologists in the past. Four centres have been created that will provide clinical PhD fellowships to train outstanding individuals in these new skills (in Cambridge, Imperial College, Newcastle and the Scottish Clinical Medical Schools); three are led by a clinical pharmacologist, and the other has strong clinical pharmacology input. While neither of these initiatives will add to the core pool of clinical pharmacologists in the UK, they will spread the relevant skills to a broader group of individuals and provide important recognition that such skills are critical to the future of UK medical science.

Teaching

Universities have neglected clinical pharmacology as a teaching discipline in the last 20 years. Since the publication of *Tomorrow's Doctors* by the General Medical Council in 1993 [5], and the subsequent reorganization of undergraduate teaching in many medical schools, eliminating the preclinical sciences, there has been a disconnection between pharmacology on the one hand and clinical pharmacology and therapeutics on the other; as a result, teaching of the basic principles that underlie rational prescribing has suffered. This development has also not been good for the specialty in terms of visibility, because undergraduates do not meet the doctors who focus on safe and effective prescribing during their undergraduate years. Indeed, a number of medical schools now no longer provide direct teaching in clinical pharmacology and therapeutics, wrapping this into specialty teaching, in which it is only a small part of the management of disease rather than a particular focus of attention.

Clearly, prescribing is one of the major roles and responsibilities of a doctor, and poor prescribing is one of the major ways in which patients can come to harm. Following concerns raised in 2006 [2], and a series of encouraging further developments [9], there has been a broader appreciation of the importance of good prescribing and the need for teaching to underpin this practical skill effec-

tively. The latest version of *Tomorrow's Doctors* [10] has a much clearer focus on the learning of skills necessary in this field. It must be hoped that medical schools will address this requirement through appropriate teaching and assessment. With initial support from the Department of Health, and subsequent support from the British Pharmacological Society, Simon Maxwell has led an initiative to provide online support for training in prescribing (Prescribe; <http://www.prescribe.ac.uk>), but this will be no substitute for face-to-face teaching of the principles of clinical pharmacology and therapeutics, and a discussion of their applications in clinical practice. It is to be hoped that the revision of *Tomorrow's Doctors*, together with assessment of prescribing skills, will provide a renaissance in this area of teaching, to the benefit of junior doctors, who have clearly had concerns about their own prescribing skills in recent years [11].

Other duties of the clinical pharmacologist

There is no doubt that the major roles of clinical pharmacologists in universities are to undertake research and contribute to teaching. However, in almost every case, these individuals also provide major support to the NHS in the broad area of patient safety. Such individuals tend to lead regional drug and therapeutics committees, contribute to research ethics committees, run or contribute to Yellow Card Centres, develop local and national formularies and be well represented at the Medicines and Healthcare products Regulatory Agency, the National Institute for Health and Clinical Excellence, the British National Formulary and other relevant organizations. Such activities are largely unsung, although they are all relevant to the key NHS priorities of clinical effectiveness, sound budgetary management, clinical risk management and clinical governance. Importantly, some of the strongest centres of excellence in UK clinical pharmacology combine academic and NHS clinical pharmacologists working together in a complementary fashion, the NHS physicians being largely focused on the management of adverse drug reactions, self-poisoning and pharmacovigilance work through Yellow Card Centres. I would argue that a combination of an academic and NHS faculty within a centre provides the critical mass to support teaching and research, to strengthen the clinical base and to ensure that individuals with an interest in clinical pharmacology are nurtured and encouraged to consider the specialty as a potential career.

The way forward

Critical to the future success of clinical pharmacology and therapeutics is the need to attract bright young doctors into the specialty. To achieve this, clinical pharmacologists

need to be at the cutting edge of research and provide relevant high-quality teaching. They need to be seen as role models in medicine, visible in clinics, active in teaching and participating at grand rounds. In addition, there need to be senior posts for these individuals to take up. In such a small specialty, it will be crucial to ensure that existing posts are not lost as some of the more experienced clinical pharmacologists reach retirement. The fact that there is a shortage of skilled academic clinical pharmacologists is underlined by the number still fulfilling key UK national NHS roles into their 70s.

Clinical pharmacologists need to persuade universities, the Department of Health and the NHS of the value they provide in clinical research, in teaching and in the safe, effective and cost-effective use of medicines. They also need to use every opportunity to encourage undergraduates into the specialty, through support for intercalated BSc programmes, special study modules and summer vacation projects. In addition, for those who have already chosen their specialty, we have the opportunity, through translational medicine and therapeutics clinical PhD programmes, to instil in these individuals core research principles, applicable not only to clinical pharmacology but to clinical research in general. In addition, we can provide clinicians in relevant specialties with key skills linked to clinical pharmacology, by providing advanced training modules in clinical toxicology and clinical trials, and in such areas as cardiovascular and respiratory medicine, among others. These are areas in which clinical pharmacology has excelled and, although currently these advanced training modules are restricted to the specialty, there is every reason to think that access should be broadened to others who want to develop a special interest in these areas.

Competing Interests

There are no competing interests to declare.

REFERENCES

- 1 Bateman DN, McInnes GT, Webb DJ. Clinical pharmacology and therapeutics in a changing world. *Br J Clin Pharmacol* 1999; 48: 1–3.
- 2 Maxwell SRM, Webb DJ. Clinical pharmacology – too young to die? *Lancet* 2006; 367: 799–800.
- 3 Higher Education Funding Council for England. Research Excellence Framework. Available at <http://www.hefce.ac.uk/research/ref> (last accessed 16 March 2012).

- 4 Fitzgerald GA. Anticipating change in drug development: the emerging era of translational medicine and therapeutics. *Nat Rev Drug Discov* 2005; 4: 815–8.
- 5 General Medical Council. Tomorrow's Doctors. 1993. Available at http://www.gmc-uk.org/Tomorrows_Doctors_1993.pdf_25397206.pdf (last accessed 16 March 2012).
- 6 Rawlins M. A new era for UK clinical research? *Lancet* 2011; 377: 190–2.
- 7 Rawlins M. A New Pathway for the Regulation and Governance of Health Research. A Report from the Academy of Medical Sciences. January 2011. Available at <http://www.acmedsci.ac.uk/p47prid88.html> (last accessed 16 March 2012).
- 8 Office for Life Sciences. Life Sciences Blueprint: Building Britain's Future. HM Government. July 2009. Available at <http://www.nisw.co.uk/getattachment/e7870cf5-5fd4-4c6d-aaff-3fffd15cebc1/Life-Sciences-Blueprint.aspx> (last accessed 16 March 2012).
- 9 Aronson JK. Clinical pharmacology and therapeutics in the UK: a great instauration. *Br J Clin Pharmacol* 2010; 69: 111–7.
- 10 General Medical Council. Tomorrow's Doctors. 2009. Available at http://www.gmc-uk.org/education/undergraduate/tomorrows_doctors_2009.asp (last accessed 16 March 2012).
- 11 Heaton A, Webb DJ, Maxwell SRJ. Undergraduate preparation for prescribing: the views of 2413 UK medical students and recent graduates. *Br J Clin Pharmacol* 2008; 66: 128–34.

RECEIVED

13 January 2012

ACCEPTED

30 January 2012

ACCEPTED ARTICLE PUBLISHED ONLINE

22 February 2012

CORRESPONDENCE

Professor David John Webb, Queen's Medical Research Institute, The University of Edinburgh, Room E3.22, Edinburgh EH16 4TJ, UK.

Tel.: +44 131 242 9215

Fax: +44 131 242 9215

E-mail: d.j.webb@ed.ac.uk