

Annual Meeting

20 November 2009



Advancing the science and practice of pharmaceutical medicine for the benefit of the public

The Faculty of Pharmaceutical Medicine



President's Address

Introduction

For the last three years, it has been with very great pleasure that I have given the President's Annual Report; however, this year, I am very conscious that this is my last Report. It has been a wonderful experience, to be able to work to further the aims of the branch of medicine I chose many years ago, and to have had the opportunity to shape the future for our speciality. The greatest privilege has been working with so many dedicated colleagues, and realising just how much time, energy, and resource our membership give so freely to the Faculty. Without so much voluntary commitment from our members, the Faculty would not function.

We are a small Faculty compared with the other royal medical colleges, yet we carry out many similar functions. The breadth of our responsibilities as pharmaceutical physicians is as diverse as work within general practice or other specialties. First-in-man studies, clinical research, regulation, health economics, promotional material approval to name just a few notable subspecialties of pharmaceutical medicine. As President, I have been able to see and experience the input in every one of our activities, and I am so proud of all that our members contribute. To be able to stand alongside the other colleges and faculties at the Academy of Medical Royal Colleges and say yes, we do that too, and to the same high standard; and, yes, we have a membership who will want and will support similar activities. We may be small in terms of comparative numbers, only 5% of some colleges, nevertheless, we are prepared and able to find resources to mirror much of the work of the other colleges. What is not so easy is for anyone to realise, except perhaps the President and staff, is just how much is given and just how many members are involved across a wide range of activities. I want to record my very sincere thanks to all who give their time to the work of the Faculty. I also want to take this opportunity to thank all of you who have given me personally so much support and encouragement in my role. I have had enormous support from the Board, the committees and working groups as well as through emails from members.

The purpose of this AGM Presidential address is to review the past year, and to take a brief look at activities going forward.

Revalidation

Revalidation has been our most taxing and contentious activity this year and the one of concern to the largest number of our UK membership. The goal posts have a habit of changing, albeit subtly sometimes, and the timelines do get pushed further out. Whilst you might think that is a good thing, it has the danger of creating lethargy and a loss of momentum. Revalidation will be here as a reality for all of

us, probably from 2012 onwards, but with some physicians being revalidated, perhaps through pilots, in 2011. Revalidation is, in some ways, very simple, but in others very complex. It is all about demonstrating your competence to do the job you are employed to do, so that patients and the public can have confidence in you as a doctor and are protected.

Competence encompasses knowledge, skills and ethics, and their appropriate application in practice. We are an evidence-based profession and so naturally you will have to accumulate the evidence to demonstrate your competencies. It is no different from anything else we do – there will need to be sound evidence to support your competency, whether that is competency at reviewing preclinical studies to take the decisions on protocol design or safety data to formulate the wording for a SPC or to allow a particular marketing campaign. Whatever you practise unsupervised you must be competent to do and be able to demonstrate it. Physicians too tied up with their own concerns do not always take sufficient cognisance of the fact that all this relates only to your area of practice, it is not broader. You have to be competent at what you do not necessarily at anything else. Remembering that helps put revalidation in perspective. My message to all General Medical Council (GMC) registered pharmaceutical physicians who want to retain a licence to practise is twofold: keep up to date with developments through the Faculty website and other correspondence; start collecting your competency evidence including Continuing Professional Development (CPD) so that you get into the habit of doing so.

There will need to be processes that stand up to GMC scrutiny, just like those set for pharmaceutical medicine specialty training. It has been the knowledge that the Faculty has been able to set up rigorous processes as a virtual deanery for trainees that has given us the confidence to know that the Faculty can do it for revalidation too. One of these processes is the requirement for all doctors to have a Responsible Officer. In the NHS this will be the Medical Director of the doctor's trust. In the draft legislation, the Faculty, alongside the Medicines and Healthcare products Regulatory Authority (MHRA) as a government

organisation, has been designated as a body that will have a Responsible Officer. This Responsible Officer function will be available for those who do not work in organisations that will have their own Responsible Officer, but it is likely that some of the larger companies may be enabled to have their own Responsible Officer. The Faculty appreciated this very high profile recognition of our specialty. You may remember that, only a year ago there was concern that there did not appear to be recognition of our specialty in the revalidation proposals from either the GMC or Department of Health or of our unique requirements being a specialty outside the NHS. Recognition has now come about in statute. This recognition brings with it huge responsibilities for the Faculty. It is a major achievement for the Faculty, and we have been grateful to receive considerable financial support from the Department of Health, through the Academy of Medical Royal Colleges, for much of our set up work and for some of our proposed revalidation projects. On 5 November 2009, the Faculty organised a web conference to update pharmaceutical physicians on revalidation. We had around three hundred participants, and in a number of companies, colleagues grouped together to access the conference. The feedback has been very positive, and it was valued as an efficient method of communication, and the content was considered reassuring.

Innovating for Health

The Faculty has had to work hard to earn the respect it has gained from both pharmaceutical physicians and clinicians, and it must continue to earn that respect. The gauntlet was thrown in February 2009 by the Royal College of Physicians London in its report, *Innovating for Health: patients, physicians, the pharmaceutical industry and the NHS*. I was a member of the working party, on behalf of the Faculty, that produced this report. The Faculty has picked up the gauntlet and is working on the recommendations from this report that have been assigned to the Faculty alone or to the Faculty in conjunction with other bodies. For example, our Ethical Issues Subcommittee are reviewing the Faculty's Guiding Principles to incorporate the Nolan Principles of public service more overtly (transparency, probity,

honesty, etc.), and then to look, as recommended by the report, to how these can be advocated to the profession as a whole. We are contributing to the group actioned to take forward the need for a renaissance in clinical pharmacology, a subject that should be at the bedrock of any prescribing doctor's knowledge, but which is often sadly missing. The Faculty has started a dialogue with the Royal Pharmaceutical Society of Great Britain and Ireland to work on some aspects of the report jointly with them. It is satisfying to realise that the Faculty is becoming more widely known as an appropriate body to provide responses to consultation documents, and from which to seek membership of external bodies. For example, we were recently asked to provide a member for the newly formed independent Medicines Information Project Board.

Pharmaceutical Medicine Specialty Training

One area in the Faculty that is being held up as a model is its pharmaceutical medicine specialty training programme. Currently 220 trainees in 73 organisations are enrolled on the programme. This is a large number for a small specialty and it has created welcome logistical difficulties particularly in organising the annual Record of In Training Assessments (RITA). Thank you to all concerned, both the large number involved in running the programme, and also the trainees for their achievements and high standards.

Faculty Membership

An exciting initiative this year has been the convening of a working party, chaired by Dr Richard Tiner, to review Faculty membership criteria, with particular reference to the possibility of extending membership to pharmaceutical scientists as well as physicians. The practice of medicine is changing, whether that is clinical medicine or any other branch, including pharmaceutical medicine. Work as a pharmaceutical physician is very different from twenty years ago when the Faculty was first formed. Pharmaceutical physicians now work almost entirely in teams where there will be a leader who may or may not be a physician, but all the team members contribute on equal footings. Many of the roles that were at one time

the unique provenance of the physician are now shared with other colleagues, even the signing of promotional material. Pharmacovigilance is now often managed by scientists, with some Pharmacovigilance Qualified Persons also being non-physicians, although those persons must have access to a physician. Protocols can be written by a variety of members of a team, and in fact are usually a shared responsibility, as is the conduct of clinical studies. None of this teamwork or sharing of responsibilities denigrates the unique contribution that physicians make to drug development and to the safe and effective use of medicines. But, as with the practice of clinical medicine, whether in primary or secondary care, the physician now does not work in isolation. The physician may not even have the ultimate responsibility in many situations. If we are to work effectively, as a team, with our scientist colleagues for the benefit of patients, then we should want to work with them to set, maintain and also raise standards for the whole team. A professional body of physicians functioning in isolation from non-physician colleagues may no longer be appropriate nor serve our patients best. Many of these colleagues do not currently have a professional body to set their standards, and they may already look to the Faculty for those standards. Would it not be more appropriate to welcome them into our membership so that they can be active contributors to setting the standards that apply to us all?

A number of other royal medical colleges already have membership categories for non-physicians, including two of our parent colleges, as well as the Royal College of Pathologists and the Faculty of Public Health. In discussions with the latter two, they are both quite clear that this wider membership has brought major benefits to their specialty and contributed to patient safety. The working group has considered all these and many other aspects, and concluded that the Faculty should explore how this widening of membership could be best achieved. The Board was fully supportive of the concept and so later this year a detailed proposal will be circulated to the membership, and, subsequently, a formal proposal will be put to the membership at the Annual General Meeting on 19 November 2010.

The membership's input will be valuable in ensuring that, whilst widening the membership criteria, we do not alter the high standards the Faculty has striven so hard to achieve.

It is likely that one consequence would be that the Diploma of Pharmaceutical Medicine exam will be opened up to non-physicians, as is the case with Diploma examinations at the Free University in Brussels and Swiss Medical Association. Both these exams are recognised as equivalent to the Faculty's Diploma examination for physician membership of this Faculty. Currently, the Faculty's Good Clinical Practice examination and the Certificate in Human Pharmacology can be taken by physicians and non-physicians.

Diploma in Pharmaceutical Medicine

An initiative that involves both the Faculty's International Committee and Education Committee is the proposal to hold sittings of the Faculty's Diploma examination outside the UK. A number of countries are keen to have the exam run in their country, and the Faculty proposes to start with South Africa and India, possibly this year. The pool of candidates, and as a consequence the potential for setting and raising standards is huge. For example, in India there are well over two thousand pharmaceutical physicians, and increasingly many pharmaceutical companies are now undertaking their clinical studies there.

Diploma / Certificate in Human Pharmacology

One initiative currently underway is the Diploma and Certificate of Human Pharmacology. The Faculty received considerable funding from the Department of Health for the set up phase of the programmes. The enrolment numbers for the certificate are reasonably satisfactory, but enrolment on the diploma programme is less than expected. The current economic climate is not conducive to encouraging expenditure on training. It is still relatively

early days for the programmes, and the Faculty must find ways of promoting the programmes to companies and organisations in the UK and continental Europe to ensure that the standards set by the programmes should be those expected for physicians undertaking phase 1 studies.

Conclusion

Inevitably, this has been only a snapshot of the work that the Faculty undertakes and only a sample of its achievements in 2009. For example, I could have spoken about the Faculty's success in being awarded the work of one of the Innovative Medicines Initiative (IMI) work streams or of the Faculty's smooth transition from an unincorporated body to an incorporated one operating under a new constitution

Finally, through officers, staff, committee members and colleagues, I have been encouraged by the knowledge that we all share the same objectives and ambitions. These objectives and ambitions have resulted in many Faculty achievements, achievements which have contributed and will continue to contribute to patient and public benefit.

Dr Susan Bews, November 2009

*Dr Susan Bews welcomes the new President of the Faculty,
Dr Richard Tiner*



Annual Meeting 20 November 2009

Elections and Awards

The Faculty Board

Dr Susan Bews completed her second two-year term as President on 20 November 2009, and Dr Richard Tiner was elected as President for a three-year term on 21 November 2009. Dr Jane Zuckerman was elected Vice-President of the Faculty. Dr Neil Hounslow agreed to continue to act as Treasurer for one further year. Following the incorporation of the Faculty at the beginning of November and the implementation of the new governance structure, Dr Roger Bickerstaffe, Dr Peter Bowen-Davies, Dr Keith Bragman, Dr Kirsteen Donaldson, Dr Dominique Dubois, Dr Ibrahim Farr, Dr Chris Worth and Dr John Young left the Board. Dr Dipti Amin, Dr David Blowers and Dr Anthony Whitehead had been appointed as trustees under the new governance rules.

Annual Dinner

Dr Susan Bews took the Chair at the Annual Dinner at which the Guest of Honour was Professor Dame Carol Black, former Chair of the Academy of Medical Royal Colleges and currently National Director for Health and Work and Chair of the Nuffield Trust.

Faculty Awards Ceremony

The President welcomed all the new Fellows and Members and congratulated those members who had been placed on the GMC Specialist Register in Pharmaceutical Medicine and those individuals who had been successful in the Good Clinical Practice examination in 2009.

Faculty Medal

The Faculty Medal was awarded to Professor Nigel Baber for his services to the Faculty, particularly his contributions to the Board, the Board of Examiners and the Diploma/Certificate in Human Pharmacology programme.

The Faculty Medal was awarded to Professor Ken Paterson for his services to the Faculty, particularly his contributions to the Board as the Royal College of Physicians and Surgeons Glasgow representative and his contributions to the Ethical Issues Committee.



Professor Nigel Baber

Professor Ken Paterson



Honorary Fellowship

Honorary Fellowship was presented to Professor Sir Gordon Duff

Professor Sir Gordon Duff was a Scholar in Medicine at St Peter's College, Oxford in the late 1960s, followed by clinical training at St Thomas' Hospital in London, where he also gained a PhD in the neuropharmacology of fever. Following postgraduate medical training in the UK and post-doctoral work at Yale in the Infectious Diseases Section and also in the Howard Hughes Immunology Institute, he worked in the Medical Faculty of Edinburgh University before taking up his present post, Florey Professor of Molecular Medicine, at Sheffield in 1990.

Sir Gordon's research interests are in inflammation and genetics as evidenced by numerous research publications - and also by 30 patents. He is founding editor of the international research journal 'CYTOKINE', Past-President of the International Cytokine Society and past-Chairman of the UK's Committee on Safety of Medicines (CSM) and its Subcommittee on Biological Medicines and Vaccines.

In Sheffield he has held the posts of Research Dean of the School of Medicine and the Director of the Division of Genomic Medicine.

Sir Gordon advises on genetics research and biological medicines to the UK government and the European Union. He is currently Chairman of the UK's National Biological Standards Board, and since

2005 has been the inaugural chairman of the UK's Commission on Human Medicines. He was Chairman of the UK Secretary of State's Expert Scientific Group on Phase One Clinical Trials which reported in December 2006 – a remarkably speedy gestation, less than 9 months after the Northwick Park incident. He was also appointed inaugural chairman of the UK's Scientific Pandemic Influenza Advisory Group in 2008.

He received a Knighthood in the 2007 New Year Honours.

Sir Gordon has supported our Faculty and its activities over many years, including the recent implementation of the Diploma and Certificate in Human Pharmacology.

For his many significant contributions to medical science, patient safety and pharmaceutical medicine Sir Gordon was awarded Honorary Fellowship of the Faculty of Pharmaceutical Medicine.



Professor Sir Gordon Duff receiving Honorary Fellowship of the Faculty

Annual Meeting 20 November 2009

Elections and Awards

Honorary Fellowship was presented to Professor David Neal

Professor David Neal undertook his initial medical training at University College, University College Hospital Medical School, London. He qualified with a first class BSc in Anatomy in May 1972, proceeded to MB, BS (London) in 1975, FRCS, MS (London) and FRCS Edinburgh, culminating in an FMed Sci in March 1998.

He was been awarded the Hunterian Professorship at the College of Surgeons in England, the Shackman Fellowship in 1986, the Ethicon Travelling Fellowship, the Norwich-Eaton Fellowship and numerous visiting lectureships, surgical research society prizes and representative appointments to a variety of scientific committees relating particularly to urological cancer.

He has had a key role in NHS R&D policy groups, scientific grants committees, CRC clinical trials committees as well as NICE and indeed has been

involved with the GMC in developing a method for the testing of communication skills for Urologists and Surgeons, from 1999-2000.

His publishing record is impressive, as he has over 275 peer reviewed publications in journals of international distinction. Such activities of course are matched with peer reviewed case reports, book reviews, books, chapters, reviews and editorials and these amount to a further 72 publications. These represent the technical achievements of a committed, dedicated and focused expert Surgeon but such skills would be numerate only if they were not accompanied by his clear commitment to clinical and translational research, to patient safety and governances, to clinical innovation, management experience and of course, medical education and training for both undergraduate and postgraduate colleagues.

Professor Neal's research background has continued apace and his current area of research focuses on the possibility of using combinations of genomics and proteomics in the diagnosis, management and prognosis of patients afflicted with urological disease and in particular with prostate cancer.

For his many significant contributions to medical science and patient safety Professor Neal was awarded Honorary Fellowship of the Faculty of Pharmaceutical Medicine.



Professor David Neal receiving his Honorary Fellowship of the Faculty from the President, Dr Susan Bews

Annual Meeting 20 November 2009

Elections and Awards continued

Ordinary Fellowship

The following Members of the Faculty were awarded Ordinary Fellowship (FFPM) in 2009:

Dr Latif Akintade

Dr Maurice Bagot d'Arc

Dr Svyatoslav Balyakin

Dr Catherine Baxter

Dr Alice Butler

Dr Mireille Cantarini

Dr Ian Carbarns

Dr Joanne Collier

Dr Tristan Cooper

Dr Emma Dellow

Dr David Haynes

Dr Andrew Hockey

Dr Steven Hughes

Dr Robert Lai

Dr Mark Layton

Dr Ulrike Lorch

Dr Stephen McDonough

Dr Edwin David George
McIntosh

Dr Elinor Miller

Dr F John Mills

Dr Christopher Millwater

Dr Clive Morris

Dr Brian Muller

Dr Virginia Norris

Dr Rory O'Connor

Dr Andreas Orfanos

Dr Richard Philipson

Dr Stephen Phua

Dr Lindsey Rolfe

Dr Jonathan Ryland

Dr Paul Slade

Dr Howard Snow

Dr Eric Teo

Dr Martin Toal

Dr Marianne van Es-Gulinck

Dr Mikael von Euler-Chelpin

Dr Chris Worth



New Fellows, from the left: Dr Steven Hughes, Dr Richard Philipson, Dr Mikael von Euler, Dr Ulrike Lorch, Dr Andrew Hockey, Dr Tristan Cooper, Dr Ian Carbarns, Dr Stephen McDonough, Dr F John Mills, Dr Marianne van Es-Gulinck, Dr Andreas Orfanos, Dr Eric Teo and Dr Jonathan Ryland.

Membership

The following were granted Ordinary Membership (MFPM) in 2009:

Dr Anjan Banerjee
Dr Julie Beynon
Dr Neil Brickel
Dr David Chonzi
Dr Elizabeth Clark
Dr Renee De Waal
Dr Suzanne Green
Dr Meena Jain
Dr Pui Man Leung
Dr Stephen Lombardelli
Dr Nadine Martin

Dr Karla Martins
Dr Robert McLeod
Dr Michael Metcalfe
Dr Zoya Panahloo
Dr Vinay Patroe
Dr Mehdi Shahidi
Dr David Thomson
Dr Toby Shephard
Dr Andrew Webb
Dr Jens Wurthner



New Members (MFPM), from the left: Dr Vinay Patroe, Dr Meena Jain, Dr Pui Man Leung, Dr Suzanne Green, Dr Anjan Banerjee, Dr Karla Martins, Dr Jens Wurthner, Dr Andrew Webb, Dr Mehdi Shahidi and Dr Toby Shephard.

Annual Meeting 20 November 2009

Elections and Awards continued

Membership (by Distinction)

The following were awarded Membership by Distinction (MFPM) in 2009:

Dr Dipti Amin

Dr Jonathan Janes

Dr Stuart Mair

Specialist Registration in Pharmaceutical Medicine

The following doctors had been placed on the GMC Specialist Register for Pharmaceutical Medicine since the last AGM:

Dr Karen Atkin

Dr Mathew Goodman

Dr Sangeeta Jethwa

Dr Jonathan Jones

Dr Simon Dando

Dr Teng Jin Ong

Dr Alison O'Toole

Dr Vinay Patroe

Dr Dele Wallace

Dr Andrew Zambanini

Good Clinical Practice

The following successful candidates in the 2009 sitting of the examination were present at the Ceremony:

Mrs Yvonne Enever (recipient of the ABPI Prize for highest score in examination)

Dr Tun Tun Lin

Mrs Suzanne Sumara

Dr Kingsley Urakpo

Mrs Christiane Volkmann

Dr Jean Vonsey



New Members by Distinction (MFPM), from the left: Dr Stuart Mair, Dr Dipti Amin and Dr Jonathan Janes.



Specialist Registration in Pharmaceutical Medicine from the left: Dr Teng Jin Ong, Dr Vinay Patroe, President, Dr Dele Wallace and Dr Simon Dando

Successful Good Clinical Practice examination candidates from the left: Dr Tun Tun Lin, Mrs Yvanne Enever (recipient of the ABPI Prize for highest score in examination), Dr Kingsley Urakpo, President, Mrs Suzanne Sumara, Dr Jean Vonsey and Mrs Christiane Volkmann



The Faculty Board in 2010

Dr Richard Tiner President
Dr Jane Zuckerman Vice President
Dr N Hounslow Treasurer

Dr Dipti Amin

Professor Geoffrey Barker

Dr David Blowers

Dr Mike Cheshire
RCP London Representative

Dr Stephen Freestone
RCP Edinburgh representative

Dr David Gillen

Professor Ken Paterson
RCP&S Glasgow Representative

Dr Tony Whitehead

The confirmed minutes of the Faculty Board are available to members of the Faculty in the Members' section of the website.

Good Clinical Practice Examination

8 June 2010

In 2005, the Faculty introduced the Certificate in Good Clinical Practice, which is open to all personnel involved in the conduct of clinical trials to help promote the highest standards in clinical research. The examination comprises one written paper in multiple choice format lasting 1 hour and 30 minutes. Successful candidates will be awarded the Certificate of Good Clinical Practice. Further information about the examination and the syllabus can be obtained from the Faculty Office or website.

The 2010 Annual Meeting will take place on Friday, 19 November, at the Royal College of Physicians London.

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