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PHARMACOLOGY MATTERS

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Volume 2 Issue 2, June 2009

Clinical Special Issue

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Congress of the European Association for Clinical Pharmacology and Therapeutics Edinburgh, Scotland 12-15th July 2009

NHS National Institute for Health and Clinical Excellence

Prescribe
e-Learning for Clinical Pharmacology & Prescribing

PHARMACOLOGY MATTERS

Editorial

We welcome contributions from our readers, all suggestions should be e-mailed to the Managing Editor: hom@bps.ac.uk

Front cover Image:
Edinburgh
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Welcome to the first clinically themed issue of Pharmacology Matters. Timed initially to coincide with the EACPT 2009 meeting in Edinburgh (see page 5, Message from the EACPT President David Webb) this issue also nicely (pun intended) coincides with NICE's 10 year anniversary. The Chairman Professor Sir Michael Rawlins invites us to take a retrospective look at NICE's 10 years, his article 'Nice at Ten' can be found on page 6.

Some changes to the PM editorial board have taken place over the last few months, and I would like to take this opportunity to introduce and welcome to the Pharmacology Matters editorial board, Fraz Mir and Sara Barnes.

Fraz is a consultant physician at Addenbrooke's Hospital, Cambridge, and will join the board as Clinical Editor. Simon Constable stepped down from this post at the end of 2008. I would like to offer Simon our thanks, and appreciation for his invaluable work over the last few years, particularly during the transitional period from pA_2 to Pharmacology Matters, thank you Simon.

Sara will be our Younger Members Editor, taking up the mantle from Stephanie Francis, a big thank you to Stephanie for her contributions over the last few years!

Sara is a first year PhD student at the Department of Pharmacology, University of Cambridge. She is also the 2008 recipient of the AJ Clark Studentship. An interview with Sara can be found in Pharmacology Matters, Volume 1, Issue 2; pg 12-13. Sara has also reviewed Ben Goldacre's book, Bad Science for this issue of PM see page 18.

Finally, the last issue of 2009 will be a Darwin 200th birthday issue. If you would like to contribute to this issue, I would be very pleased to receive suggestions, and offers to author articles!

Enjoy!

Hazel O'Mullan
Managing Editor

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BPS BRITISH PHARMACOLOGICAL SOCIETY
Today's science, tomorrow's medicines

The Physiological Society

7th James Black Conference

Joint Meeting of the British Pharmacological Society & The Physiological Society 1 - 3 September 2009, King's College London
'Integrative Pharmacology and Physiology: Translating "omics" into Functional and Clinical Applications'

Topics:

Pain, inflammation and injury
Models of cardiovascular and respiratory disease-from bench to bedside
In vivo approaches to studying metabolism
Models of immuno-inflammation and infection: clinical predictive validity

Poster Prize:

A £250 prize for the best poster presentation by a young researcher (graduate students or newly qualified postdoctoral workers within 5 years of PhD) will be awarded.

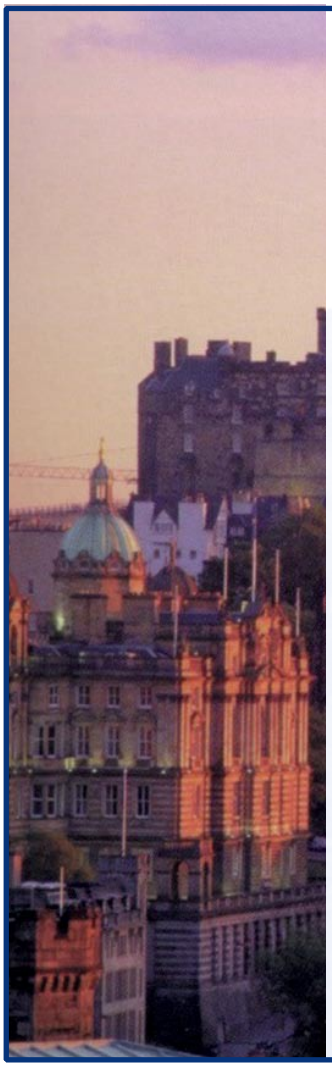
Travel Grants:

(£100.00 maximum) are available to student members of both the BPS and The Physiological Society to attend this conference.

For further information:

email: meetings@bps.ac.uk • web:www.bps.ac.uk • tel: 020 7239 0183

This meeting is supported by a grant from the Integrative Mammalian Biology initiative, funded by the BBSRC, BPS Integrative Pharmacology Fund (donors AstraZeneca, GSK and Pfizer), MRC, HEFCE, SFC and DIUS.



BPS 2009 Summer Meeting
University of Edinburgh, 8 - 10 July

BPS BRITISH PHARMACOLOGICAL SOCIETY
Today's science, tomorrow's medicines

WEDNESDAY 8 JULY

Challenges in respiratory disease drug development
GPCR signalling: new connections and ligand selectivity
Metabotropic Glutamate receptors: advancing novel drugs for treating CNS disorders

THURSDAY 9 JULY

Circadian rhythms - pharmacology and therapeutic potential
Developments in receptor imaging
Peripheral actions of MDMA and other amphetamine derivative drugs of abuse

FRIDAY 10 JULY

Alzheimer's Disease – Mechanistic insights and novel therapeutics
Imaging and targeting inflammation in stroke and atherosclerosis
Topical questions in cell death signalling - followed by a Satellite Meeting on 11 July

Socials

The Welcome Reception will be held at the Surgeons' Hall Complex on Wednesday 8th July in the Playfair Main Hall
The Official Dinner will be held at Playfair Library Hall, Old College, The University of Edinburgh on Thursday 9th July

For further information visit www.bps.ac.uk or Email: meetings@bps.ac.uk

View From Angel Gate

Kate Baillie
Chief Executive, BPS

Welcome to the first clinically themed issue of Pharmacology Matters, which will be distributed to all delegates at the EACPT Congress in Edinburgh. This is an event in which the BPS has been closely involved, particularly in the sponsorship of two major sessions on Working with Patients (capitalizing on the success of the joint RCP/ BPS Rational Prescribing meeting in May 2008) and Hypertension, and also with the provision of bursaries.

As members will be aware, from recent electronic issues of Pharmacology Matters, there have been several changes at the Society's offices in Angel Gate. The transition of the BJP Editorial Office to Wiley Blackwell was completed at the end of April 2009, and at the time of writing a good field of candidates for the posts of Editorial Assistant and Managing Editor for both journals had been received.

In conjunction with this development, the Society also took the opportunity to undertake a wholesale restructuring of the BPS office, in order to focus staff roles around the four key areas for the Society: Education, Meetings, Publications, and Communications.

As a result of this process, three members of staff elected to take voluntary redundancy – Anna Muir, Luisa Hambley, and Sarah Mackay – we should like to thank all three for their sterling contributions to the work of the BPS over many years and to wish them every success in their future careers. Further information about their work over the past eight years is featured on page 22 and 23.

Two new senior posts have been created, as a result of the restructuring: a Head of Education and Meetings and a Head of Communications and Development. Recruitment for these two new senior posts began in April, and it is envisaged that by the time this issue of Pharmacology Matters is published, candidates for these roles will have been identified and that it may be possible for them to meet members of the BPS in person during the Summer meeting in Edinburgh.

In the next issue we shall provide an introduction to the new staff and the roles that existing staff will be assuming in the new structure.

It is anticipated that these changes will enable us to offer improved and extended services, and to raise the profile of pharmacology and clinical pharmacology in a more integrated and systematic fashion.

In March, Council members received formal training in their role and responsibilities as charity Trustees. Arising from this training, the composition of Council was discussed and questions such as how to encourage greater diversity in membership, taking into account gender and race, and ways to introduce a public or non-pharmacological perspective, via the appointment of a patient representative, science teacher, journalist, or pharmacist were considered. It was also agreed that in future, all vacancies for Trustee and Officer vacancies would be advertised on the BPS website. To ensure greater transparency, all committee minutes are now available on the BPS website in the members' section.

A meeting with representatives of the British Toxicology Society took place in March, and it is hoped that this will lead to future collaboration in education and meetings, as well as possible reciprocal membership benefits. We have also agreed to provide a "What is Pharmacology" article for their Summer newsletter, and it is hoped that a "What is Toxicology" article will appear in the Winter edition of Pharmacology Matters, with more details of future collaboration.

A successful Hot Topics in Pharmacology and Physiology meeting was held in March, the highlights of which appear in an article on page 20. The Women in Pharmacology group have also planned a Leadership for Women workshop in June, in collaboration with the UKRC, and this year sees the launch of the Astra Zeneca Prize for Women in Pharmacology, which will be presented at the Winter meeting.

In addition to the existing press release service provided by Wizard Communications of research from BJP and BJCP and the news coverage of the BPS Winter Meeting outlined in the April issue of Pharmacology Matters, this has been a busy period for Pharmacology in the News.

Clinical pharmacology and BPS members were in the media spotlight on two occasions recently. In January, David Webb addressed the Commons Select Health Committee on Prescribing and both David and Jeff Aronson fielded questions at a press briefing organized by the Science Media Centre attended by journalists from all the major broadsheets. In April, Jeff Aronson was interviewed extensively on the story concerning the link between the sedation of girls in UK care homes during the 1970s and 1980s who have since had children with birth defects, postulated to be related to transgenerational (epigenetic) effects.

We have recently developed a section of the website where stories of interest related to pharmacology are posted. In due course we envisage providing a newsfeed service via the BPS website, but in the meantime please let me know if you would like the BPS to highlight any media coverage received for your research which may be of interest to the wider membership and public at large.

I look forward to seeing you in Edinburgh at the Summer meeting.

Kate Baillie, Chief Executive, BPS

Message from the Meeting President of EACPT 2009

David Webb holds the Christison Chair of Therapeutics and Clinical Pharmacology at the University of Edinburgh, named after Sir Robert Christison, a renowned toxicologist of the 19th century. He has led national Wellcome Trust initiatives in Cardiovascular Science and Translational Medicine, and is known for his work on vascular structure and function in cardiovascular disease. He is a practising physician, in clinical toxicology and cardiovascular risk management, based at the Royal Infirmary and Queen's Medical Research Institute, and Fellow of the Royal College of Physicians, Academy of Medical Sciences, British Pharmacological Society and Royal Society of Edinburgh.

EACPT, or to give it its full name the European Association for Clinical Pharmacology and Therapeutics, had its origins in a WHO working group in the early 1980s chaired by Professor Folke Sjöqvist. The association was established in 1993 and its first congress was held in Paris in 1995. EACPT now represents 32 European countries under its current President, Professor Ingolf Cascorbi, based in Kiel.

The objectives of EACPT can be broadly described as to support the discipline of clinical pharmacology in Europe, including promotion of: teaching in the rational use of drugs at both undergraduate and postgraduate levels; ethical and high quality clinical pharmacology research; sound clinical policy decisions regarding drug regulation in Europe; scientific meetings, workshops and courses in clinical pharmacology and therapeutics across Europe.

Education is, therefore, a major remit of EACPT. Its international Congresses are held biennially in different European cities, and chosen through a bidding system voted on by delegates from EACPT member countries. We were delighted when Edinburgh was chosen for its 9th meeting, the first to be held in the UK.

We now invite you to join us for the Congress, at the Edinburgh International Conference Centre in the heart of the city, for the 2009 meeting of EACPT, which will run from Sunday, 12th to Wednesday, 15th July 2009.

The Congress will have a major focus on translational medicine, with themes related to drug discovery, drug development and drug safety, and the therapeutics of organ-based diseases. As some of the highlights, we are delighted that Sir Alasdair Breckenridge will speak on MHRA, Hans-Georg Eichler on EMEA, Garret Fitzgerald on translational medicine, Sir Michael Rawlins on NICE, Patrick Vallance on the interface between industry and academia, and Alastair Wood on drug approvals.

Another highlight of the meeting will be the BPS-supported symposia: a whole day meeting on Working with Patients and a late afternoon meeting on Hypertension. We anticipate a busy, lively and informative meeting comprising strong science and educational programmes, highlighting major new developments in the field. The 600 plus abstracts submitted are very encouraging.

We look forward to you joining us in July this year, in the heart of a small and friendly city, where you can enjoy an outstanding scientific programme together with a social programme that includes evenings at Edinburgh Castle and Our Dynamic Earth.

For further information, go to www.eacpt2009.org.

David Webb, President, EACPT 2009

NICE at Ten

Professor Sir Michael Rawlins FMedSci, has been NICE Chairman since its formation in 1999. Professor David Barnett MD FRCP is Professor of Clinical Pharmacology at the University of Leicester and Chair of the NICE Technology Appraisal Committee since 1999.

This year NICE is celebrating its 10th anniversary. Of the institutions established between 1998 and 2000, such as the Commission for Health Improvement, the Modernisation Agency and the NHS University, it is the only survivor. What has NICE done? And why?

The what?

NICE exists to provide NHS healthcare professionals with advice on how to offer their patients the highest attainable standard of care. It does so by publishing what is generically known as "NICE guidance". Four forms of NICE guidance are published by the Institute covering technology appraisals, clinical guidelines, interventional procedures and public health. This article is confined to a review of NICE's technology appraisals and clinical guidelines programmes.

Technology Appraisals

This form of NICE guidance is concerned with providing advice on the use of new and existing health technologies (pharmaceuticals, medical devices, procedures and diagnostic methods). The Institute's advice is based on evidence of both clinical and cost effectiveness. NICE has, to date, published the results of 167 appraisals involving 343 indications (some appraisals involve more than one drug for the same indication – others are concerned with the same drug for multiple indications). The majority of appraisals involve pharmaceuticals.

The decisions about which technologies to commend to the NHS are made by members of the independent appraisal committees, drawn from the NHS and British universities, and not the staff of the Institute. In addition contrary to media mythology—especially in the Daily Mail—NICE only rarely (10/343) declines to recommend the use of a technology in the NHS. More commonly it recommends full (98/343) or restricted (188/343) use. Occasionally it advises on use of a technology only as part of a formal research study (31/343).

Clinical guidelines

NICE's clinical guidelines are defined as: "systematically developed statements intended to provide patient and practitioner decisions about appropriate healthcare for specific clinical circumstances". They therefore provide advice about the totality of care for a patient rather than one element (as is the case with the technology appraisals guidance).

The Institute has published 91 clinical guidelines and has a further 44 under development. NICE has also prepared 10 "clinical service guidelines" which advise commissioners, such as Primary Care Trusts, about the infrastructural requirements that providers require to deliver high quality services. These have all been in the area of oncology.

Clinical guidelines are major undertakings. They take up to 2 years to complete and may need to be supported by 20 to 30 full systematic reviews of the relevant literature if they are to provide the best advice. As with the technology appraisals programme (and in distinction to most other clinical guidelines) they take both clinical and cost effectiveness into account during their construction. NICE's published guidelines cover a wide range of common conditions ranging from schizophrenia to head injuries.

NICE's guidelines are developed by one of 4 National Collaborating Centres of which 3 are based on consortia of Royal Medical Colleges. The fourth – on cancer – is sited at Velindre Hospital near Cardiff. In constructing each guideline the National Collaborating Centre appoints a topic specific guideline development group to scrutinise the literature and decide on the recommendations that will be made.

The why

From the outset, we believed that NICE should be concerned, primarily, with improving the quality care that patients receive from the NHS health professionals. Inappropriate variation in the quality of care and inequitable access to new health technologies (often abbreviated to "postcode prescribing") bedevil healthcare systems in all developed countries and the UK was (and, in some respects, still is) no exception. But it was recognised, in 1999, that improving the quality of care, in the NHS, had to be accommodated within the fixed budget that parliament votes for the service. Hence, the Institute's statutory instruments specifically charged NICE with taking both clinical effectiveness, as well as cost effectiveness, into account when deciding which treatments and pathways of care it should commend to the NHS.

In 1999 many people were uncomfortable with the notion that the NHS – and explicitly NICE – should take cost effectiveness into account when deciding on the allocation of resources. Arguments ranged from "I've paid taxes all my life so the NHS owes me whatever treatments I now need" to Article 2 of the European Convention on Human Rights stating "Everyone's right to life shall be protected by law.

At the outset we were very aware that considering, explicitly, cost effectiveness as well as clinical effectiveness as a component of the NICE's decision-making paradigm, would be controversial. We expected that patients themselves,

patient organizations, professional colleagues and the pharmaceutical industry would object. And we have not been disappointed. But we both accepted, from the outset, that while sympathising with the plight of individuals we could not deny the necessity for basing the Institute's conclusions – at least in part – on considerations of cost and the need to ensure 'value for money'.

Ten years later the argument has moved on. There is now broad, though not universal, acceptance that the NHS has finite resources; and that providing one group of patients with cost ineffective treatments will inevitably deny others cost effective ones. The discussion is not whether, but how, the NHS's resources might be distributed most fairly.

Concluding thoughts

For two clinical pharmacologists to have had the opportunity to contribute to the development of NICE, has been the most rewarding, but challenging, parts of our professional careers. Our roles at the Institute have, we believe, been immeasurably enhanced by our knowledge and experience of clinical pharmacology. The evaluation of medical devices and surgical procedures is, in reality, little different from the evaluation of a pharmaceutical product. And although neither of us was versed in the black arts of health economics we have acquired sufficient knowledge to both understand the discipline's inherent strengths and weaknesses as well as be wary of the potential biases and prejudices of the health economists themselves.

We hope we've made a difference.

Professor Sir Michael Rawlins FMedSci, NICE Chairman

Professor David Barnett MD FRCP, Professor of Clinical Pharmacology, University of Leicester and Chair of the NICE Technology Appraisal Committee.

Prescribe

e-Learning for Clinical Pharmacology & Prescribing

Simon Maxwell Prescribing Sub-Committee Chair

The Clinical Section of the BPS has been concerned for some time that education in clinical pharmacology, which underpins safe and effective prescribing, has been losing visibility in the medical school curriculum. Although the BPS has developed statements about ideal curricular content, most recently in 2003 (*Br J Clin Pharmacol* 2003;**55**:496-503), these have not been implemented as widely as we might have hoped and, indeed, clinical pharmacology is no longer a guaranteed component within undergraduate curricula. These concerns have been expressed by other professionals and, more recently, by medical students themselves (*Br J Clin Pharmacol* 2008;**66**:128-34). Following widespread publicity on this issue, the General Medical Council and Medical Schools Council convened a *Safe Prescribing Working Group* in 2007, which included representation from the BPS as well as most of the key stakeholders in early postgraduate prescribing (Postgraduate Deans, the BMA, NHS managers, NPSA, NPC). That group developed, for the first time, wide agreement about the competencies that might be expected of all new doctors when they graduate from medical school (document available at www.chms.ac.uk/documents/finalreport.doc) which include the ability to:

- establish an accurate drug history
- plan appropriate therapy for common indications
- write a safe and legal prescription
- appraise critically the prescribing of others
- calculate appropriate doses
- provide patients with appropriate information
- access reliable information about medicines
- detect and report adverse drug reactions

The document was very influential in shaping the revised thinking on prescribing education identified in *Tomorrow's Doctors* 2009. It was also published just as a new GMC commissioned study of Foundation doctor preparation at three UK medical schools served to reinforce all of the points being made by the BPS about prescribing education in recent years (see Illing *et al* available at www.gmc-uk.org/about/research/research_commissioned.asp).

The second important outcome from the *Safe Prescribing Working Group* was support for a successful bid to the Department of Health to secure funding to develop a national e-Learning initiative to help UK medical students to achieve the identified competencies. That initiative is now well underway and is known as the *Prescribe* project, which is being developed as a partnership between the BPS and the Department of Health (e-Learning for Healthcare), with the collaboration of the Medical Schools Council.

Prescribe will provide high quality e-learning materials to support students in developing a firm grounding in the principles of basic and clinical pharmacology. There will be around 200 interactive learning sessions and further information covering the pharmacology, clinical pharmacology and therapeutics that students might expect to encounter within a standard medical curriculum. Also planned is an interactive student formulary, the opportunity to practice skills relevant to prescribing, self-assessment exercises, an e-library, a glossary and links to other resources. *Prescribe* is intended to complement existing teaching initiatives rather than replace them and will be made available free of charge to medical students (as well as students of allied professions) registered with UK universities and NHS-affiliated organizations.

Prescribe will be led by a team of 6-8 module editors who will then commission the writing of learning sessions from a large number of authors. Every author is assigned an expert instructional designer from e-Learning for Healthcare who will help deliver the material in a form that allows it to be built into an online learning session. The whole project is expected to take around 2 years to deliver but it is anticipated that students will be able to register for *Prescribe* at some point during the academic year 2009-2010. I hope that many colleagues in the BPS will see this as an excellent opportunity to enhance the visibility and prominence of clinical pharmacology in medical education and ultimately improve prescribing in the NHS.

The *Prescribe* team would be delighted to hear from any members of the BPS who would like to make a major contribution to the project (e.g. as a module editor, or session author) or have other suggestions. You can find out more and register your interest by visiting www.cpt-prescribe.org.uk or contacting me directly.

Simon Maxwell, Clinical Lead for the Prescribe Project
s.maxwell@ed.ac.uk

Non-Medical Prescribing— Where are we now?

AJ Basey
Consultant
Pharmacist

The BPS Prescribing Group has now been active for three years and has a remit to consider all issues relevant to the BPS that relate to prescribing. One of its missions has been to try and foster dialogue and relationships with representatives of new prescribing groups and we are delighted to include members from several other professions. They have helped us to explore considerable areas of common interest including education, assessment and continuous professional development. Independent prescribers from non-medical backgrounds clearly have an important contribution to make to the NHS and this interesting article describes one prescribers journey towards working in perhaps the highest pressure prescribing environment of all - the acute medical admissions unit.

Jan Basey is a Consultant Pharmacist - Acute Admissions at the Royal Liverpool and Broadgreen University Hospitals NHS Trust

Background
Non-medical prescribing is a relatively recent innovation in healthcare in the UK. Traditionally prescribing was the preserve of doctors and dentists and it is only in the last 15 years or so that prescribing by other healthcare professionals, enabled by legislative changes, has become more widespread.

There have been several drivers for change: the pressure to reduce junior doctors hours, the development of specialist roles by healthcare professionals and the publication of two Crown Reports in 1989 and 1999 which advocated an extension of prescribing to a wider range of healthcare professionals

Nurses were the first profession to gain limited prescribing rights with a small number of pilots being established in 1994. These allowed District Nurses and Health Visitors to prescribe from a very restricted formulary. The success of the initial pilots together with the recommendations from the second Crown report in 1999 led to approval in 2002 for a wider range of nurses to be able to prescribe from an extended (although still very restricted) formulary. In 2003 supplementary prescribing was approved for both pharmacists and nurses and 2005 legislation enabled supplementary prescribing by physiotherapists, podiatrists, radiographers and optometrists. Approval for the first non medical independent prescribers was given in 2006.

A more detailed time line is shown in box 1

Definitions
There are currently two classes of non-medical prescriber: supplementary and independent prescribers. Independent prescribers are responsible for the initial assessment of the patient, drawing up a treatment plan and prescribing as appropriate, in the same way as doctors have prescribed traditionally. Supplementary prescribers are authorised to prescribe for patients whose condition has been diagnosed or assessed by an independent prescriber, within the parameters of an agreed clinical management plan (CMP). The clinical management plan has to be agreed by the independent prescriber, the supplementary prescriber, and the patient so this type of prescribing is best suited to the management of long term conditions.

Training
Training to become a non-medical prescriber involves gaining a post-graduate practice certificate in supplementary and or independent prescribing. Courses are now available from a variety of Higher Education Institutes nationally; they were initially offered for a single professional group e.g. nurses or pharmacists but many are now multidisciplinary. This presents its own challenges as students join the course from different baselines and have different competencies with learning needs dependent on their professional group and personal experience. Applicants must have either

Box 1 The History

1986	Cumberledge report first proposes nurse prescribing
1989	First Crown report advocates nurse prescribing for district nurses / health visitors from a formulary
1992	Legislation to enable nurse prescribing from a formulary (V100 district nurse / health visitor)
1994	Pilot sites for district nurse / health visitor prescribing
1999	Second Crown report - supply and administration of medicines - recommended prescribing rights be extended to other nurses and other groups of healthcare professionals
2000	Pharmacy in the future - patient's needs will be better met by some pharmacists being able to prescribe medicines for them directly
2001	Legislation to enable extended formulary nurse prescribing including GSL and P* medicines (V200)
2003	Legislation to enable supplementary prescribing for nurses (V300) and pharmacists
2005	Legislation to enable supplementary prescribing for physiotherapists, radiographers, podiatrists and optometrists
2006	Legislation to enable independent prescribing by pharmacists
2006	Nurse prescribers extended formulary discontinued - extended formulary nurse prescribers can now prescribe any licensed medicine including some controlled drugs *General Sales List (GSL) and Pharmacy only (P)

2 or 3 years post registration experience, (dependent on the requirements of their professional body) before applying to train to become a registered non-medical prescriber.

Courses involve 26 learning days usually spread over 3 to 6 months with a maximum of 12 months.

Different methods of learning are used including face to face teaching, self directed study and practical classes. All require the development of a portfolio of evidence - a concept, which is often new, and challenging to professionals who have been in practice for some time.

The courses are based on the competency framework for non-medical prescribers that has been developed by the National Prescribing Centre in conjunction with the relevant professional bodies. There are 3 areas of competency in the framework:

- The consultation
- Prescribing effectively
- Prescribing in context

Each of these 3 areas contains 3 more specific competencies making 9 in total; for example The Consultation consists of:

- Clinical and pharmaceutical knowledge
- Establishing options
- Communicating with patients

Students must provide evidence for all 9 competencies within their portfolio.

All students must have a Designated Medical Practitioner (DMP) who must be an experienced doctor who normally has at least 3 years recent clinical experience in the field in which the student intends to prescribe. In addition to the taught aspects of the course students are required to undertake 12 days of supervised practice with their DMP who should facilitate discussion of interesting cases and help the student develop their skills. The DMP has the responsibility at the end of the training of verifying that the student is competent to prescribe. Often this proves extremely challenging as both student and DMP have to meet the requirements of their usual job and additional time is often required on a regular basis for case discussion.

The courses are examined in variety of ways and usually involve at least two methods of assessment, which may include OSCEs (Objective Structured Clinical Examinations), written examination, viva, and essays in addition to the development of a satisfactory portfolio.

Upon satisfactory completion of the course the student is awarded a Practice Certificate in Prescribing, which must then be forwarded to the relevant professional body (together with a fee) for registration. Successful candidates may not prescribe until the appropriate professional register has been annotated to indicate that they are a registered prescriber.

Limitations
Registration as a supplementary prescriber enables prescribing of all medicines, including unlicensed medicines and controlled drugs, in accordance with a CMP, which is agreed by both the independent prescriber and the patient. This process tends to be more suitable for the management of long term conditions and is less suitable for healthcare professionals working in Walk in Centres and Emergency Departments where care is unplanned.

Independent prescribers are not restricted by a CMP but are unable to prescribe unlicensed medicines and there are specific restrictions for controlled drugs. Pharmacist independent prescribers cannot prescribe controlled drugs; nurse independent prescribers may prescribe a limited number of controlled drugs in clearly defined circumstances.

Implementation / Benefits
Non-medical prescribing has enabled easier access to medicines by patients both in hospital and in the community. Nurse and pharmacist led clinics are now well established for conditions such as asthma and diabetes; in teaching hospitals non-medical prescribers may lead clinics in more specialist areas such as HIV. The healthcare professionals involved are able to complete the consultation without the need to refer to a doctor for a prescription reducing inefficiencies in the system and enhancing job satisfaction.

As a hospital pharmacist working in acute medicine, I realised the potential of non-medical prescribing to improve patient care on admission to hospital at an early stage. The process of taking an accurate medication history is complex, and pharmacists frequently identify prescribing errors as was demonstrated in a study by Collins et al in 2004. A pharmacist working in an admissions unit is ideally placed to correct many of these inaccuracies, avoiding both the delay in the patient receiving the correct medication and the need to interrupt medical staff. With the support of my Trust and one of the consultant medical staff who agreed to be my DMP I registered as a supplementary prescriber in 2004. However, as above, the supplementary prescribing model does not 'fit' Acute Medicine due to the requirement for an individual CMP, which requires patient agreement. With the support of my DMP I drew up a policy for my prescribing practice, which was approved by the Trust Drug and Therapeutics Committee and I commenced prescribing on the Acute Medical Unit (AMU) in January 2005. I registered as an Independent Prescriber as soon as the required training course became available in 2008.

Prescribing is now a routine part of my role on the AMU. An accurate medication history is obtained either by a member of the team of pharmacists or myself, and discrepancies (usually omissions or variations in dosage) between this and the current inpatient prescription are identified. I review the case notes taking particular note of the reason for admission, any abnormal test results and the provisional diagnoses; if possible I confirm with the patient which medicines they have been taking the regularly prior to admission. I then make a decision to prescribe the medicine, withhold it, or ask the medical staff to review it; I document the rationale for my decisions in the case notes. Situations are often clinically complex and have to be appropriately prioritised; urgent problems which require a medical review I discuss immediately with one of the consultant medical staff on AMU and agree an action plan, for less urgent problems clear documentation of the problem in the case notes may be sufficient. Patients and nursing staff appreciate the availability of a pharmacist non-medical prescriber as many medication problems can be resolved rapidly resulting in improved patient safety and experience.

In summary non-medical prescribing has developed steadily over the past 15 years enabling patients to realise the benefits and healthcare professionals to maximise their potential.

A J Basey, Consultant Pharmacist, Acute Admissions at the Royal Liverpool and Broadgreen University Hospitals NHS Trust

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BJCP Young Investigator Prize Award Winner

Celestino Obua
Makerere University

The BJCP Young Investigator Prize is now entering its third year. The British Pharmacological Society (BPS) awards a prize of £1000, a certificate and 1 year honorary BPS membership for the best paper by a trainee published in the print version of BJCP during the calendar year (currently 2009). Those eligible will be clinical trainees (of whatever specialty), or basic scientists in training registered for a PhD (or equivalent).

Once an article has been accepted for publication in BJCP, the authors will be invited to apply for the BJCP prize and to provide information about the provenance of the work and the precise role played by the potential award-winner. The award is judged by the editors of the Journal, but they may call for expert assistance in making their decision.

Celestino Obua has been a student of the Karolinska Institutet - Makerere University joint PhD degree program, under the supervision of Assoc. Prof. Urban Hellgren, Prof. Lars L Gustafsson and Prof. Jasper W Ogwal-Okeng. His research project focuses on the outcome and pharmacokinetic aspects of fixed-dose chloroquine (CQ) and sulfadoxine/ pyrimethamine (SP)treatment of malaria in Ugandan children with uncomplicated malaria.

I am very grateful to the BPS for having selected my article for the BJCP prize award as the best paper in 2008 by an author in training. This prize has inspired me to continue pursuing research in the area of pharmacokinetics in children.

CQ+SP dosages in children

With resistance to chloroquine (CQ), the drug that has been the main stay in the treatment of malaria for decades, reaching unacceptable levels, changes in malaria treatment policy became inevitable. Thus, Uganda in 2002 changed the malaria treatment policy to CQ+SP combination (a local formulation that was called "Homapak"). In children, this formulation was recommended as age-based fixed-dose combination. At the same time efficacy studies with these drugs reported high treatment failures. While resistance genes could have explained most of the treatment failures, issues related to the drugs needed to be explored. Malaria mortality is highest in the under five children, and yet drug dosage designs in children have for long been extrapolations of pharmacokinetic data from adult population studies. There have also been no pharmacokinetic data used to back the age-based fixed-dose policy. To explore dose design and pharmacokinetic aspects of CQ+SP combination, population approach was applied to their pharmacokinetics in children with uncomplicated falciparum malaria.

Eighty six children aged between 6 months to 5 years with uncomplicated malaria were treated as per the Ministry of Health policy recommendations for the age groups. The younger children (6 - 24 months) were given fixed-doses of CQ+SP (75 mg base + 250/12.5mg) which was half of what the older children (> 24 -60 months) got (150mg base + 500/25mg). The assumption in this age-based dose design was that all children would be treated with similar dose for body weight (mg/kg body weight). However the reported treatment failure rates were 48% and 18% in the younger and older age groups respectively. To minimise repeated blood sampling from the children, the study was designed such that field adapted finger prick sparse blood sampling was possible using precision capillary tubes. At each sampling, 100µl of blood was applied and dried on filter paper and later analysed for concentrations of CQ and sulfadoxine (SDx).

Pharmacokinetic data and outcome

The CQ and SDx data were best described by a two-compartmental model. For CQ, the typical apparent clearance (CL/F) and volume of distribution (V_c/F) values were estimated to be 2.84 L/h and 230 L. The typical CL/F for SDx was 0.023 L/h, while the factor relating its V_c/F to normalized body weight was 1.6 L/kg. *Post hoc* parameter estimates for both drugs showed lower maximum concentrations (C_{max}) and concentration-time curve areas (AUC_{0-336h}) in younger children. The AUC_{0-336h} for SDx and CQ were independently significant factors for

prediction of cure. Thus, using the data generated, it was possible to demonstrate that drug exposure and treatment outcome could be correctly predicted. In this regard, it was found that children who got the higher doses attained higher exposure (AUC) and consequently achieved better treatment outcome. For the younger children who had been treated with lower dose regimen because of their age, the lower exposure observed in their group lead to poorer outcomes bringing to question the dose recommendation for this age group.

Proposal for dose modification

In determining the predictive exposure levels for cure using logistic regression, the AUC_{0-336} cut-off value for SDx and CQ that best discriminated between responders and non-responders were determined to be 12,000 µg*h/mL and 76 µg*h/mL respectively. These cut-off values correctly predict 90% and 88% treatment responders for SDx and CQ respectively. By plotting (AUC0-336) against age with the cut-off values inserted, it could be seen that children who got the lower dose regimen had lower exposure and more treatment failure. This prompted the simulations for dose modification which demonstrated that giving the same higher dose to all children under five years would lead to higher exposures (AUC) for all children above the desired cut-off values that would improved cure rates. Simulation for safety considerations showed that the attained maximum concentrations would be nearly uniform across the age range, hence suggesting that the children would not be unduly exposed to toxic levels of the drugs.

This work is one of few population pharmacokinetic studies in children with uncomplicated malaria. The study opens possibilities for further pharmacokinetic studies that could improve treatment outcomes for children in areas where these drugs are still useful. I will use population pharmacokinetic skills I have gained from this work to study newer artemisinin containing treatment combinations to improve dose design and outcomes in children.

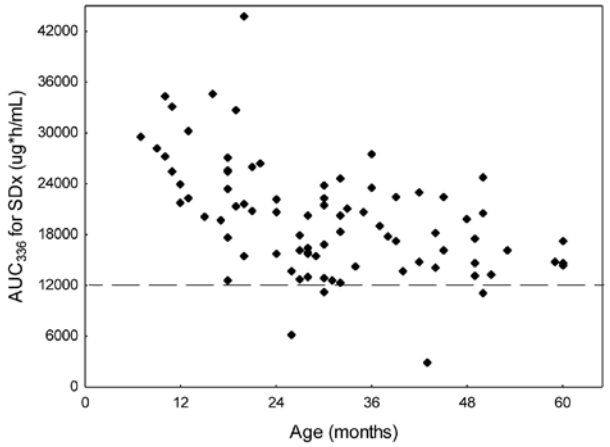
Joint PhD experience

Makerere University and Karolinska Institutet offer a joint PhD program. This program provided me with the unique opportunity to work with researchers, not only from Makerere University and Karolinska Institutet, but also from other Swedish institutions. I particularly enjoyed working alongside Associate Professor Urban Hellgren and Professor Lars L Gustafsson who both supervised my project and from whom I learnt a lot about patience. I also acknowledge Dr. Markus Jerling and Dr. Toufigh Gordi from whom I learnt a lot about population pharmacokinetics. While back at Makerere University I worked alongside Professor Jasper W Ogwal-Okeng to whom I am very grateful. During my study period I attended 4th MIM Pan African Malaria Conference Yaounde, Cameroon, 13th – 18th Nov 2005 where I made a poster presentation. I have also attended several courses on pharmacokinetics, pharmacogenetics, ethics in health research and clinical trials, greatly broadening my knowledge in these areas.

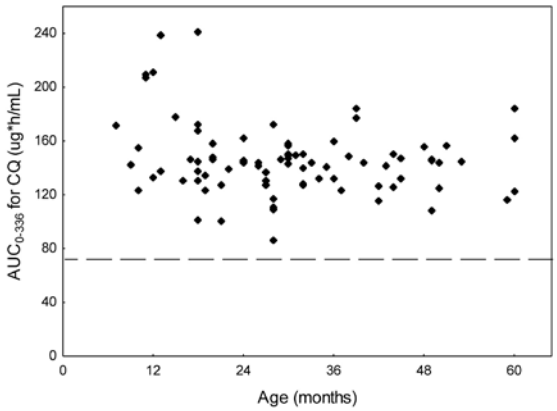
A joint program of this nature may have its low and high moments, but it may also be exciting for the student. Without referring to specific instances, I was more often than not required to perform delicate balancing manoeuvres between my senior researchers who by virtue of their different experiences occasionally had divergent opinions on some issues. Working with fellow PhD students on common aspects of the projects, also required compromises, for which I commend especially Mr. Muhammed Ntale a fellow PhD student who contributed greatly to the methods used for HPLC analysis of drug levels. I am proud to say that this experience has actually served to strengthen my capacity for collaborative research which I hope to exploit in my Post Doctoral and other future projects.

I am grateful to SIDA/SAREC for funding my PhD projects including establishing a pharmacokinetic laboratory which made it possible for me to complete my work.

a)



(b)



Figures: Predicted AUC_{0-336} vs. age (a) for SDx and (b) for CQ if the higher Homapak dose had been administered to all children 6 months to 5 years. Broken line depicts optimal cut-off value for AUC_{0-336h} to predict treatment response.

Celestino Obua, Makerere University.

The BPS Advanced Pharmacology Diploma and the Clinician: A Training Opportunity

It would be a pity, though it is certainly a possibility, if some trainees in clinical pharmacology were unaware of the Diploma in Advanced Pharmacology that the BPS organizes. But from the outset it was the intention to involve clinicians as well as basic scientists, while appreciating that in some respects the needs of the two groups were rather different. For both groups the overriding intention is to provide an up to date picture of major areas of the pharmacological spectrum, ranging from detailed analysis of receptor-effector systems at a cellular and molecular level to pharmacokinetics. Whatever the specialist area might be the organizers and presenters are nationally and internationally recognized experts. One really important point to emphasise is the flexibility of the diploma programme and this is of particular significance to clinical trainees. Their time is literally not their own, as they have always to adapt their educational needs to clinical responsibilities, and this has to be negotiated with colleagues on an event by event basis.

The Diploma does not require participants to attend for every workshop and in fact it is recognized that not everyone will even want to formally complete the Diploma, and some trainees do indeed choose to attend the workshops (which are open to all) as and when their other commitments allow. Although of course it would be preferable if they did attend all workshops, it is still a very valuable programme if they do not. Firstly it provides credits towards their external Continuing Professional Development Programme (Royal College accreditation 6 points for each workshop). But perhaps more importantly it provides a far greater range of training and learning opportunities for the trainee clinical pharmacologist than any individual department or institution could undertake. This has to be a very major consideration as otherwise fulfilling the requirements of the national training syllabus can be very difficult, even in major academic centres. And last but certainly not least, doctors in particular are working in an assessment-oriented, some might say obsessed, environment. From my own experiences as a teacher of undergraduates this is something that originates in secondary school. But sometimes one wants to learn about something not because it will be examined or appraised or assessed but because it I interesting. This is what education should be about, at least to a large extent. The Diploma not only provides opportunities for professional development but also for expanding knowledge and understanding of the vast field of pharmacology. There is nothing wrong with enthusiastic amateurism-some of the time at least!

Workshops of particular interest to trainees include:

- Pharmacokinetics (July 7th 2009; Edinburgh)
- Early Phase Trials of New Drugs (September 1st 2009; London)
- Drug Discovery (December 14-15th; London)
- Hypertension (Summer 2010; Edinburgh)

For further details of how to apply for the Diploma or register for workshops please go the webiste www.bps.ac.uk or contact jmh@bps.ac.uk

Dr Mike Schachter, Department of Clinical Pharmacology, National Heart and Lung Institute, Imperial College London and BPS Diploma Committee member

Update on the Faculty of Pharmaceutical Medicine (FPM) Diploma and Certificate in Human Pharmacology

John Posner

You may remember reading an article in pA_2 a little over a year ago about the new Diploma and Certificate in Human Pharmacology being established by the Faculty of Pharmaceutical Medicine of the Royal College of Physicians. The objectives of these programmes is to provide physicians and scientists with the skills needed to design, conduct and interpret exploratory studies of potential new medicines in humans. The emphasis is on providing a comprehensive understanding of both the scientific principles which underlie human pharmacology and the practical aspects of conducting safe and informative studies.

To summarise the curricula, the Diploma in Human Pharmacology is a two-year training programme for physicians intending to serve as clinical investigators for Phase I/II studies. It involves attendance at courses with post-course assignments, written examinations and on-the-job supervised training in the workplace with production of a portfolio to provide evidence of achieving specified learning objectives and competencies. The examinations test knowledge of pharmacological principles, practical aspects of designing and running studies, ability to interpret pre-clinical and clinical data and clinical skills focussing on management of adverse events that may occur during Phase I studies. The Certificate in Human Pharmacology is a part time programme for

scientists and physicians, who want to gain a comprehensive knowledge of early clinical drug development based on sound pharmacological principles. It involves attendance at two courses with completion of assignments and one day of examinations.

Two courses have been run so far with twenty delegates registering for each. Approximately a half were medically qualified and the remainder were scientists, many with PhDs. Almost all had experience of Phase I studies and the teaching was, as intended, at an advanced level.

The first course entitled 'Exploratory Development and Phase I studies', ran in December 2008 at King's College London with Professor Tim Mant as Course Director. There were five intensive days of lectures, workshops, problem-solving exercises and discussion. The feedback was consistently positive with high ratings by the delegates for almost all the sessions. Delegates felt they had learned much that was directly applicable to their daily work and gave them a broad knowledge of early drug development.

The second course entitled 'Principles of Pharmacology' ran in April 2009, also at King's with Professor Clive Page as Course Director. Again the feed-back was overwhelmingly positive. Delegates are now completing their course assignments and will then start preparing for the examination which will be held in January next year.

While it takes time for any new training programmes to become fully established, we in the FPM consider that these Diploma and Certificate programmes have got off to a very positive start. There is a great deal of interest from people with a variety of backgrounds, who are not necessarily committed to becoming life-time clinical pharmacologists but who have clearly identified that they need this training. Judging from their feedback, there is no doubt that all feel they have benefited greatly.
The current delegates come from mainland Europe and Canada, as well as the UK, and we have had expressions of interest from India and South Africa. Most are from Industry but we hope the Certificate programme will also appeal to those in academia, who would like to learn more about early drug evaluation. Registration for the Diploma and Certificate is on-going. The next course on Exploratory Development and Phase I will be running in the week beginning 14th December 2009. Early registration is recommended as places are limited to a maximum of 25 delegates on each course. It may be possible to register simply to attend a course rather than the whole Certificate or Diploma programme but priority will go to those intending to complete the full programmes.

Enquiries and applicants for the Diploma and Certificate in Human Pharmacology should contact the Faculty of Pharmaceutical Medicine at 1 St Andrew's Place, Regents Park, London NW1 4LB, Tel: +44 (0)20 7224 0343, email: l.cooper@fpm.org.uk

John Posner, Director of FPM Diploma and Certificate in Human Pharmacology

BPS Prescribing Initiative

The BPS Prescribing Initiative was established in 2008 to address concerns about undergraduate medical education in prescribing skills. One of the first tasks has been to undertake a systematic review of educational interventions that have been used to improve prescribing by medical students and junior doctors. The results of this review will be published in the British Journal of Clinical Pharmacology.. available now on Early View:

Do Educational Interventions Improve Prescribing By Medical Students and Junior Doctors? A systematic review. Sarah Ross, Yoon K Loke.
DOI: 10.1111/j.1365-2125.2009.03395.x

Eleven controlled and four 'before and after' trials of educational interventions were identified. Ten controlled trials showed improvements in the scores of the intervention group on written scenarios or clinical examination stations, but one study in junior doctors showed no effect on real-life prescription errors. The WHO Good Prescribing Guide was the most frequently tested intervention in the controlled trials. This training scheme requires the students to develop a 'rational prescribing' process to systematically consider the efficacy, safety, suitability and cost of available drugs for a particular condition. The theoretical aspects are then followed by case scenarios where the students work through selecting a drug and prescribing it with appropriate follow-up and monitoring. Compared to controls, the WHO Guide yielded some demonstrable beneficial effect when the students were tested on therapeutic problem solving scenarios, across a wide range of medical schools internationally, as well as students of different seniorities. All four 'before and after' trials reported significant improvements in written tests or clinical stations However, most studies tested only small numbers of participants and were affected by a range of methodological flaws.

There is only moderate evidence in the literature to inform medical schools about how to prepare medical students for the challenges of prescribing. There is a need for further development of educational interventions. Robust methods of assessment are required to show clearly whether particular interventions are successful. The BPS prescribing initiative is now focused towards development of teaching materials and methods for assessing prescribing.

Sarah Ross, Clinical Lecturer and Phase III Deputy Coordinator Division of Medical and Dental Education University of Aberdeen Polwarth Building Foresterhill Aberdeen

Writing Pharmacological History

Dick Barlow

COLLECTING pA_2 VALUES (continued from Pharmacology Matters, Volume 1, Issue 2):
Results for antihistamines compared with those for muscarinic antagonists in guinea-pig ileum.

In a recent note ('Collecting pA_2s ...', Pharmacology Mattters 1, issue 2, 8-9, 2008) I suggested that it would be useful to set up libraries of values of pA2/logK which could be used (among other things) for comparing differences between receptors. I was particularly interested in comparing results for antagonists acting at histamine receptors in guinea-pig ileum with values I had collected for antagonists at muscarinic receptors in this tissue. Such a collection was made by Marshall (1955) and this note reports the results of re-examining his data using cumulative frequency curves and compares the results with those for muscarinic receptors in the same muscle.

Marshall measured values of pA_2 and pA10 and used the difference between them to see whether the compounds acted competitively: pA_2 – pA10 should be log 9 (i.e. 0.95). He concluded that 53 of the compounds were probably competitive and 36 were noncompetitive. This division is confirmed by the cumulatively frequency curve for the same data (Fig.1), which has two components with means of 0.54 (34) and 0.99 (55). The separate curves for the values of pA_2 and pA10, however, also have two components (Fig. 2). With those in the lower group there is less separation between pA_2 and pA10. When values of pA2-pA10 are plotted against pA2 (Fig.3) the scatter of the data can be appreciated but the correlation is statistically significant ($p<0.05$) in parametric and nonparametric tests.

Figure 4 shows cumulative frequency curves for these antihistamines alongside those for antagonists acting at muscarinic receptors in guinea-pig ileum and at nicotinic receptors in the frog rectus abdominis muscle. Results on the frog rectus appear to belong to a single population but binding at muscarinic receptors, like that at histamine receptors, has at least two components. With some of the compounds experiments were made in the presence of atropine to test the nature of the antagonism. The combined dose-ratios were all close to the value for competition (<1.5 compared with 3.8 for papaverine which is noncompetitive). If, as it appears, there are different binding areas within the receptor it may not be possible for antagonists and agonists to bind to exactly the same arrangement of hydrated protein so there may not be a sharp division between competitive and noncompetitive antagonism. Nevertheless in actual experiments the estimates of logK for many antagonists are independent of concentration over a wide range.

Almost all the compounds examined by Marshall were bases and their ionisation constants (pKa) were measured. When this is less than 7.6 the compound will be less than 50% ionised at physiological pH and their low activity indicates that it is the ionised form which is involved. For compounds with pKa >8.0 Marshall claimed that pA_2 decreased from the highest value, 9.64, for bromothen (pKa 8.63) and that the relation between pA_2 and pKa was bell-shaped and similar to that for the antibacterial activity of sulphonamides (Bell and Roblin, 1942). This is not obvious (Fig.5) and involves selecting suitable data. Maximum activity in sulphonamides is thought to depend upon ability to cross the bacterial cell wall) as well as on binding to its receptor (enzyme). There should be no such barrier with *in vitro* measurements of pA_2. The preparation is frequently washed with fresh antagonist and time is allowed for the antagonist to reach equilibrium. Values of pA_2/logK are measurements exclusively of fit and depend on size. This can be seen from the result with the only quaternary ammonium salt tested, 3554 RP, (pA_2 8.18) obtained by methylating promethazine (pA_2 8.93). Quaternization reduces affinity (6-fold) but does not abolish it. Results obtained with muscarinic antagonists suggests that the methyl group simply gets in the way.

In the antihistamines the charged amino group is usually attached to a large aromatic or heteroaromatic group by a chain of 3 carbon atoms or a heterocyclic ring: in the muscarinic antagonists this 'backbone' is usually longer. The effects of quaternization were observed for many pairs. They are variable and can be related to size (Fig.6: estimates of length from crystallographic data). Methylation usually increases affinity but decreases it in the longer compounds and with esters of 3-hydroxyquinuclidine, where the backbone contains a rigid bulky ring.

The importance of 'fit' has been recognized ever since it was found that optical isomers can differ greatly in biological activity. From values of pA2 of enantiomers it is possible to compare the chirality of muscarinic and histamine receptors. Chlorpheniramine has pA_2 8.82 for histamine receptors: benzhexol has pA_2 8.75 for muscarinic receptors. Both are highly stereospecific: (+)Chlorpheniramine is about 500 times as potent as (-): (-)benzhexol is 1000 times as potent as (+).

Understanding the binding of drugs to receptors and the differences between receptors needs collaboration between people measuring binding, people working on drug structure and people

working on receptor structure. It is important that all this information is readily available and not overlooked.

The values of pA_2/logK for histamine receptors have been added to the collection of values for muscarinic receptors and will be sent to anyone interested.

Dick Barlow, Honorary Fellow BPS

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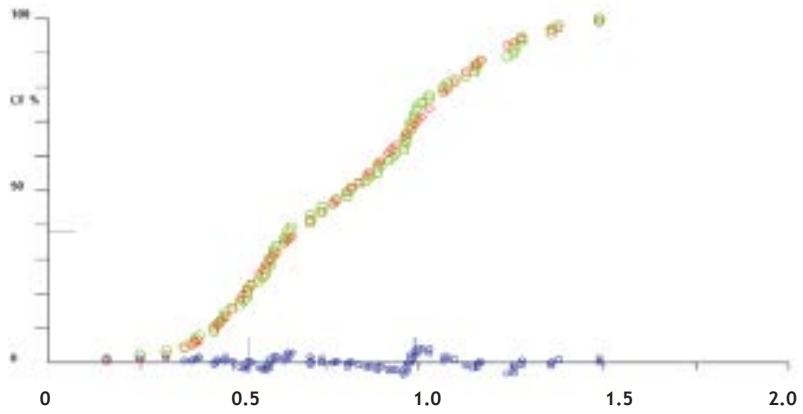


Figure 1 Cumulative frequency for values of pA_2 - pA10
Experimental points (green) have been fitted by least-squares to two components with their ratio shown on the Y-axis and the two means marked on the X-axis. The blue points show the difference between experimental and fitted values.

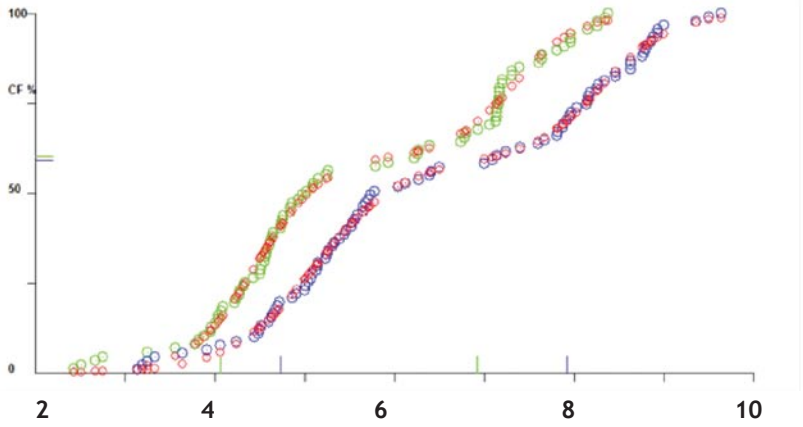
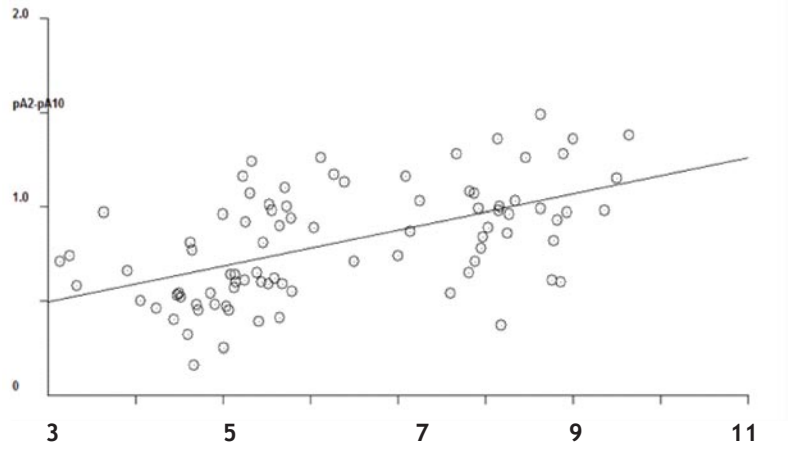


Figure 2. Cumulative frequency curves for pA_2 (blue) and pA10 (green) with fitted points shown in red.
The separation is greater at the top than at the bottom as can be seen by comparing the mean values of the components marked on the X-axis.



pA_2
Figure 3 Values of pA_2 - pA10 plotted against pA_2: for competition the value should be 0.95 but it is less than this for many weaker compounds.

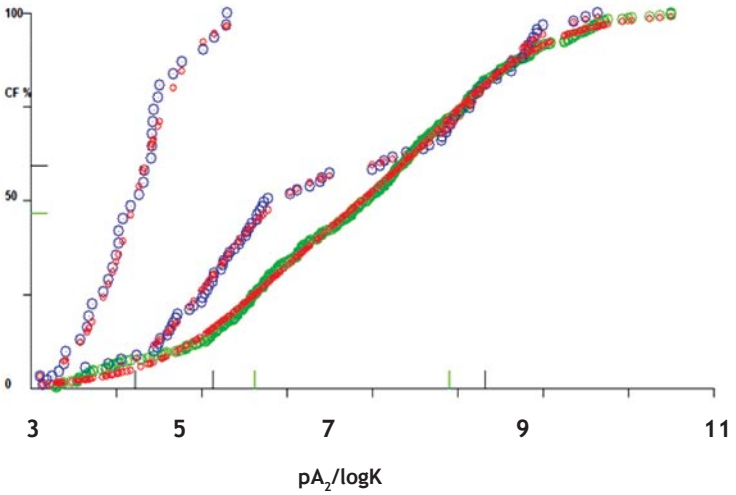


Figure 4 Cumulative frequency curves for antagonists at
(i) nicotinic receptors in the frog rectus abdominis (blue).
(ii) histamine receptors in guinea-pig ileum (blue).
(iii) muscarinic receptors in guinea-pig ileum (green):
red points are calculated values for a single population (i) and for two populations in (ii) and (iii)

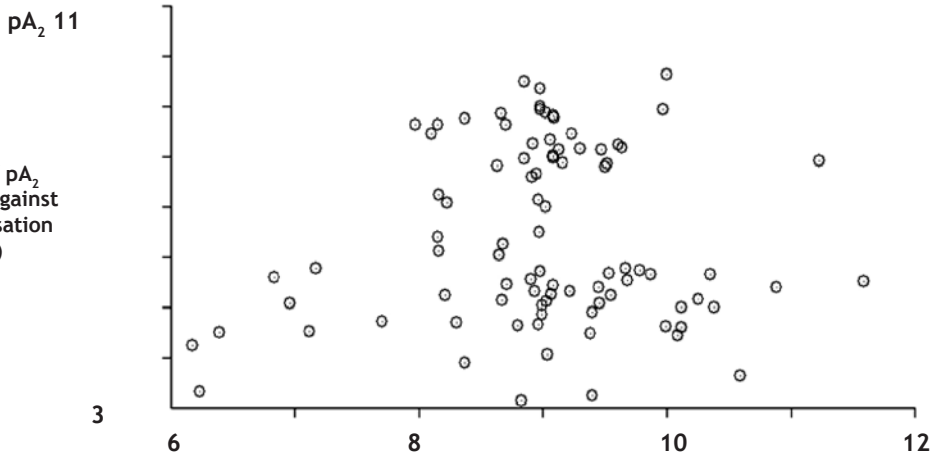


Figure 5
Values of pA_2 plotted against pK_a (ionisation constant)

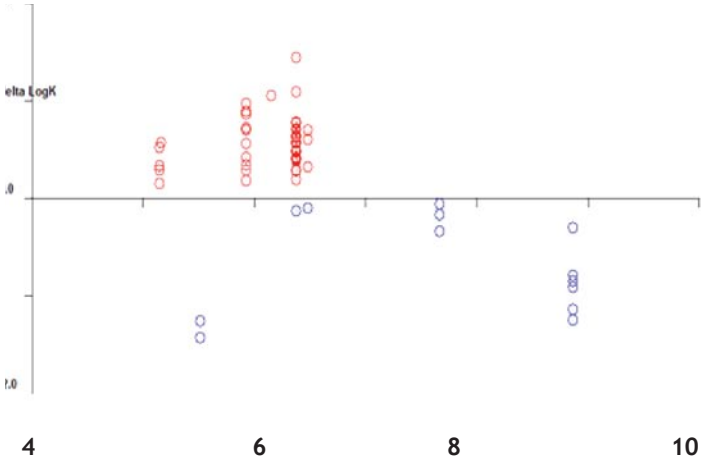


Figure 6 Effect of methylation: Δ pA_2 plotted against 'backbone' length (picometres)
Methylation reduces binding (blue) if the backbone is long and with esters of 3-hydroxyquinuclidine (on the left)

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Book Review: Bad Science

Sara Barnes
Younger Members Editor

Sara Barnes is a first year PhD student at the Department of Pharmacology, University of Cambridge. Sara is supported by the BPS AJ Clark Studentship award and will be the Younger Members Editor for Pharmacology Matters from June 2009.

Bad Science—
Ben Goldacre
Fourth Estate Ltd
(1 Sep 2008)
ISBN-13: 978-0007240197

Ben Goldacre's book *Bad Science*, based upon his Guardian newspaper column of the same name, deals with the abuse and distortion of medical science by businesses and the media. Sensation sells, and as Western societies increasingly turn to science for explanations of how the body works, pseudo-science is the perfect peddler for marketers. Goldacre convincingly illustrates how belief in such nonsense can result in serious harm to society, as well as unburden us of a lot of cash.

After discussing a few of the ridiculous 'healthcare' products widely available in high-street chemists (such as the detox foot-bath that claims to drain away 'toxins' from the body through special 'pores' in the feet) he ups his game to dismantling the bogus claims of the multi-million-pound alternative medicine industry. Pharmacologists will be pleased to hear that homeopathy comes in for particularly heavy criticism. By taking the reader through an interesting overview of the history and methods of this therapy Goldacre reveals homeopathy for what it really is—a placebo effect and nothing more.

Nutritionism and its infamous advocates Gillian McKeith (who misled the public on her TV shows into believing she had a doctorate) and Patrick Holford (who wrote 'AZT, the first prescribable anti-HIV drug, is potentially harmful and proving less effective than vitamin C') also come under the knife. It is no surprise to find their confident assertions to be (at the very best) spurious conclusions based on over-analysed data from poor studies in obscure journals.

The culmination of the book is the story of the MMR debacle orchestrated by the media. Goldacre lays into the 'humanities graduates with little understanding of science' who run the media, 'who wear their ignorance as a badge of honour.' He lays the blame for the deleterious drop in MMR vaccination rates primarily down to their scare story, wilfully created in order to sell more newspapers. Goldacre urges scientists to become more vocal in such topical debates to ensure that the voice of scientific scepticism and rationality is heard above the din of newspaper scare-mongering.

The message throughout the book is the importance of evidence-based medicine, and Goldacre successfully introduces the layperson to the fundamentals, such as double-blind randomised control trials and meta-analyses. His acerbic and sarcastic tone can become a little grating in places but this doesn't detract significantly from what is an instructive and lively read for both scientists and laypeople alike.

Sara Barnes, Younger Members Editor, University of Cambridge

Young Persons News

Robin Plevin
Chair of Younger Members Sub-Committee

Spring is here again and it's time to tell you all about the future activities of the YPs. Just to remind you, The Young Persons section of the society is not just for students, but for any BPS member with up to five year postdoctoral experience so please come along, we'd love to see you. You don't want to get boring too quickly! Also don't forget our social events are also open to full members- we just charge you a little extra!

Our committee welcomes two new members. Liz Rosethorne, who comes from our industrial wing and secondly James Dear who bolsters our clinical section. We're also looking for a young female member to join the Women in Pharmacology committee of the society and to feedback to YP committee on this issue. If you are interested in this role we'd be delighted. Please email Karen Schlaegel, at ks@bps.ac.uk. Also keep an eye out for YPs activities; reports, book reviews, interviews and other stuff in future editions of Pharmacology Matters.

Activities Planned for the coming year
We have a host of activities going on for the coming year but if you have any ideas for events please let us know!

Social Event at the Summer Edinburgh Meeting.
A number of Edinburgh Pharmacologists have volunteered to organize a social/networking event on Wednesday 8th July (put it in your diary now!). The organizers, "the four musketeers", have

decided on a Tartan Quiz and games evening at the Pleasance Cabaret Bar in Edinburgh. Rumours have it there will be an "all the haggis you can eat in a minute" competition, "how many pints of Irn Bru does it take to make your hair turn ginger" test and a blindfold "pin the sporran on the Scotsman's kilt" challenge. We can't wait. All welcome and just £5 for YPs, which includes a buffet and refreshments. See you all there in Edinburgh and bring your tartan bunnets.

Young Pharmacologists Sponsored Research talks.
Pharmacology associated student societies are invited to apply for up to £200 to bring an external speaker to their department for a research talk. The money can also subsidise a networking event afterwards and a chance to chat to the speaker face to face. It's available all year round and six student societies came forward last year. We hope to sponsor many more over the coming twelve months. So drop us an email.

Winter Meeting 2009 –Young Person's day
We have a host of YPs events coming up at the 2009 winter meeting as part of the Young Person's Day. First and foremost is the first YPs organised symposium titled "Translational Pharmacology- Optimizing Academic / Industry Partnerships". This is a very exciting topic for young pharmacologists who as PhDs and postdocs are often involved in this type of project. Also due to the success of last years undergraduate sponsored poster session last year, we are repeating this initiative and have increased the bursaries to 30 students. We will also be nominating a speaker for The Tocris Lecture on a pharmacological topic of wide interest to YPs and older members (ideas welcome). And of course we will be having a networking/social event somewhere near the venue. So come along it's a meeting and a day not to be missed by Young Pharmacologists.

On behalf of the Young Persons Committee. Contact Karen Schlaegel, at ks@BPS.ac.uk for any further information.

Integrative Pharmacology Workshop Report

The first Integrative Pharmacology BPS workshop was held at the University of Bristol on March 31st 2009. The workshop was organized by Emma Robinson (Bristol), Mike Trevethick (Pfizer) and Mark Christie (Akranim) and in attendance were 13 diploma students and 6 non-diploma delegates of whom 7 were from academia and 12 from industry. Nikole Wadell, a newly-registered Diploma candidate from Pfizer describes below her first experience of a Diploma workshop.

The workshop was preceded the evening before by a dinner, attended by around 20 delegates and the organizers at Pizza Express. The workshop itself kicked off with registration at 8.30am the next morning. Thankfully the workshop organizers had the foresight to give explicit directions with a map and a big red arrow to lead us to the university's well hidden School of Medical Sciences building. A group of us staying in a nearby hotel still managed to get lost.

However once we'd managed to find our way into the building, which I thought was really very impressive, we were quickly organized into a seminar room and diligently warned that the tables we were sat at had a tendency to chuck unwary cups of coffee across the floor. I think we managed the whole day without any accidents, but there were a few near misses!

Emma Robinson started us off with an apology for the lack of caffeine on arrival (she was very quickly forgiven) and a very warm welcome. The morning session was filled by four different topics from a perfect mix of academic and industry speakers. Malcolm Watson from the University of Bath started us off by very effectively defining 'integrative pharmacology' emphasized nicely by what it isn't. This was followed by a very enthusiastic overview of the ethics, laws and regulations for *in vivo* models that was in no way hindered by Bristol's own Paul Watkins suffering from a seasonal cold. Other delegates I spoke to were as impressed as I was by how unbiased and even-handedly the subject was discussed.

After a break and a chit-chat among the delegates we moved swiftly onto the heart-warming tale of his work at Merck on an NK1 antagonist by BPS's president elect Ray Hill. The use of *in vivo* models and the incredible perseverance behind the efforts for the many indications described made for a great success story. This presentation was contrasted nicely with a very technical look into inflammation models and asthma research by Julie Escott from Astra Zeneca. She gave the group a broader understanding of the applications of *in vivo* models in research and their possible limitations.

Lunch (wonderful breaded mushrooms and strawberries with chocolate sauce being the highlights for me) provided the opportunity for mingling and discussion with the wide variety of delegates and presenters. The mix of professors, PhD and post doctorate students and industry colleagues from all walks of science and life meant that the conversations were enthusiastic and the hour went before we knew it.

The afternoon presentations were kicked off by Pfizer's Mike Trevethick, who emphasised to the room the role that scientists play in the use of animal models in drug discovery, highlighting the ways that we as scientists can help reduce attrition and improve the success of our research. Emma Robinson from the University of Bristol then took the floor to discuss her research into animal models for psychiatric disorders and their translation into humans, and the importance of thinking outside the box was a message that strongly shone through.

The afternoons presentations were then nicely punctuated by Pfizer's Pat Dorr, who told the group about the discovery process for a high impact HIV treatment he'd worked on. His story was not only poignant and thought provoking but also unique for the day as the intrinsic lack of animal models possible for the project highlighted what can be done without and instead of using *in vivo* models.

The morning and afternoon discussion sessions were both filled with debate and provocative theories. Jane Escott and Paul Watkins provided the discussion material for the morning session, and all three of the afternoons presenter's topics were possible discussion points at the end of the day. While the choices were difficult we all opted for groups for the discussion in both session and during them the room was full of voices and ideas. The presenters and organisers spent their time wandering between the groups where possible providing insight and really making delegates examine the topics they were discussing. I joined Jane's discussion in the morning session where she, with a little help from Mike Trevethick, spurred a discussion around the limitations and possibilities that are inherent in *in vivo* science, giving us several things to ponder. I also had the privilege of discussing behavioural models for psychiatric disorders with Emma Robinson, which was along a very different vein to

the other discussions and may have (through the groups genuine and enthusiastic interest) turned into a continuation of the presentation through our questions about Emma's research.

Overall delegates that I spoke with agreed that the day was a great success. The variety of discussion topics along with the variety of speakers and delegates made for a very interesting and informative day on many levels. As a delegate I can only hope that the organizers and presenters thought that the day was as much of a success as we did. For those of us that were finishing our diploma I hope this workshop was a nice addition, and as someone just starting I'm hoping it's a sign of great things ahead. The workshop has given me a great many things to think about and a greater insight into the industry I work in. It has also provided new insight to think differently and challenge the things I do and how.

With thanks to the organizers and speakers.

Nikole Waddell, Senior Associate Scientist, Pfizer

The next Workshop, Applying Receptor Theory to Drug Discovery, takes place at the BPS Summer Meeting on the 6 July 2009. If you would like to reserve a place contact meetings@bps.ac.uk, or register online at www.bps.ac.uk/site/cms/contentCategoryView.asp?category=396

Hot Topics in Pharmacology and Physiology: RAE 2008 and REF 2013

Anthony Davenport, VP External Affairs

A joint Meeting of the British Pharmacological Society and Physiological Society was held between 26-27 March 2009, at the University of Warwick with a major focus on feedback from the 2008 Research Assessment Exercise (RAE), www.rae.ac.uk/ and its replacement in 2013. The objective of the 2008 RAE was to produce quality profiles for each submission of research activity made by institutions. This was used by the four higher education funding bodies (Higher Education Funding Council for England, Scottish Funding Council, Higher Education Funding Council for Wales and the Department for Employment and Learning, Northern Ireland) to assist with the efficient allocation of resources to support research. The undeclared purpose of the RAE was to devolve the responsibility of distributing research funds from central government to institutions.

Data submitted included information on research active staff, with research output measured by four papers or other items published during the period 1 January 2001 to 31 December 2007; numbers of full and part-time postgraduate research students and degrees awarded; numbers of postgraduate research studentships and source of funding; external research income, description of the research environment and indicators of esteem. In the 2008 RAE, there were 15 main panels that had an overview role but did not assess. About 60 sub-panels assessed outputs, environment and esteem the results were expressed as a percentage of research activity in the submission judged to meet the standard for:

4* world-leading
3* internationally excellent
2* recognised internationally
1* recognised nationally
Unclassified: below the standard of nationally recognised work

The meeting was chaired by Professor Peter Roberts for the Committee of Heads of Pharmacology. Talks were given by sub-panel members on each of the three units of assessment that mainly considered pharmacology and physiology:

- **UoA 1 Cardiovascular Medicine,** Professor Jeremy Pearson (King's College London, UK).
- **UoA 12 Allied Health Professions and Studies** (biomedical sciences; as well as an eclectic mix of other diciplines ranging from nutrition to radiography and physiotherapy), Professor Ian Kitchen (University of Surrey, UK)
- **UoA 15 Pre-clinical and Human Biological Sciences,** Professor Graeme Henderson, (University of Bristol, UK).

It was very clear that panel members were meticulous and thorough in the assessment of each submission according to published methods and criteria. Society members should be grateful that they were prepared to commit substantial amounts of time to reviewing our discipline. The Society had the opportunity to suggest names for membership to the panels. It will be important to continue this in the future for the replacement of the RAE. Given the importance of accurate returns it was surprising that panel

members reported a significant number of errors in the returns such as failing to explain in the 50 words the contributions of an author to a particular paper. Ian Kitchen noted some particularly poor submissions to sub-panel 12, with outputs that did not fit the descriptor of research for this UoA and often there was little evidence of institutional review prior to submission. Concern was expressed after the 2001 RAE about the esteem in which applied research had been held by assessors. Surprisingly the speakers reported that few submissions contained evidence of patents granted to institutions and they did not have much impact on the results, but this may change in the future. The complexity of *in vivo* animal studies was noted in UoA1 with few sites deemed internationally competitive, this is an area the Society, with partners from the pharmaceutical industry, has sought to improve.

What features led to the panels classifying research into the two highest categories of world leading and internationally excellent? Most are perhaps self-evident:

- High success rate in obtaining peer-reviewed, competitive funding with a particular high correlation to long term major programme grants that tend to be reviewed internationally.

- Strong research leadership and long term goals with evidence of investment from the submitting institution in research groups, and importantly in infrastructure.

- Large groups undertaking multidisciplinary research, particularly to address complex research questions. This was achieved by bringing together a range of disciplines from within the same institutions and/or through national and international collaborations. So big is beautiful and in marked contrast to the arts, lone researchers are bad for RAE submissions.

- Sustaining the next generation of research. This was achieved through evidence of supporting scientists at early stages of their careers and for PhD training. There were good PhD training schemes particularly UoA1 with some of the best in 4-year programmes where there is the opportunity to rotate through a number of different labs during the first year.

- A clear and strong interface with the NHS particularly dedicated clinical research facilities fostering translational research and the development of specialist NHS-funded research hubs leading to research having a clear impact on human health and wellbeing, policy and practice.

The RAE is dead

The RAE is to be replaced by the research excellence framework (REF). Graeme Henderson explained that the precise form it will take is not yet known but Expert Advisory Groups, drawn from Chairs and representatives of RAE sub-panels are currently providing advice on how the next REF is to be run. It is agreed that the same assessment system will be used for all disciplines but it is still being discussed if all staff will be included or if institutions will still be allowed to choose who they put in.

Components of assessment in the 1013 REF

Outputs are likely to remain the dominant component of assessment but will not be confined to bibliometric analysis of citations alone (as originally proposed by Gordon Brown, the then Chancellor of the Exchequer, in the 2006 Pre-Budget Report) and will involve some peer review. It is unclear whether this will be outputs from certain individuals or a sample of papers from an institution. **Environment** will remain but might be divided into headed sections. Ian Kitchen reported that although difficult to write the description of the research environment across a number of diverse departments and disciplines in UoA12, this was an important component of assessment. **Impact** replaces **Esteem**, with new indicators of economic and social benefit of research, dissemination of the results of research and public good. It is hoped that any changes will reduce the costs in time and money of the 2013 REF but it is unlikely to dramatically change the way funding is divided between institutions.

In the US, $10 billion is being injected into research through the national economic recovery bill where the importance of biomedical research in universities, biotechnology and the pharmaceutical industry is recognized for the health and wealth of a nation. HEFCE has allocated £1,572 million for recurrent research in 2009-10. The 2008 RAE demonstrates a significant proportion of UK research is world leading or internationally excellent. This provides a compelling argument for the UK to follow the lead of the US and substantially increase government support particularly in maintaining strategically important but vulnerable subjects such as pharmacology.

Anthony Davenport, Vice-President External Affairs

Medicines Forum established at the Royal College of Physicians - Clinical Pharmacology a priority

In its recent report, 'Innovating for health. Patients, physicians, the pharmaceutical industry and the NHS', a Working Party of the Royal College of Physicians, under the chairmanship of the Editor of the Lancet, Dr Richard Horton, made the following recommendation:

The RCP should create a Pharmaceutical Forum – to include physicians, scientists, research funders, industry representatives, editors and patient groups – to deliver and build on these recommendations and to create an appropriately collaborative culture between physicians and the pharmaceutical industry, with quality of patient care as the single most important outcome of their work. Ways to trigger a renaissance of clinical pharmacology should be a priority issue for this Forum.

The Forum has now met and has agreed to call itself the 'Medicines Forum Implementation Group'. It was agreed that of all the 42 recommendations that the report contains, the renaissance of clinical pharmacology was the first of four important priorities, the others being a joint effort between industry and the medical profession to improve research quality and unbiased reporting, tackling the tension between regulation and translational research in the NHS, and enhancing patients' engagement in clinical trials.

Dr Jeff Aronson, President of the BPS, has been asked to chair a subgroup of the Forum to take the first of these initiatives forward.

BPS Office Staff Changes
Anna Muir

Anna Muir

Anna Muir joined the BPS office at Angel Gate in July 2000, taking over from Theresa Potter as Journal Manager for BJP during the period when David Brown was the journal's editor. She quickly transformed the journal office from an entirely paper-based operation to an electronic one, with the help of two able assistants, Hazel O'Mullan and Paul Tizard, whom she recruited the following year.

Alan North became editor-in-chief in 2001, and undertook to overhaul completely the journal's editorial structure and operations, a substantial task that was managed, with their customary competence and good humour, by Anna and her staff. When I took over as editor-in-chief in 2005, the system was, to my huge relief, running smoothly and efficiently under Anna's guidance, and continued to do so throughout my tenure. Like all good operations, it was made to seem effortless, but actually Anna's careful management was crucial. The office handled more than 1200 incoming manuscripts each year, assigning them to editors and referees, and dealing with queries from wayward and sometimes touchy authors, occasionally enlivened by cases of plagiarism, breach of copyright and alleged falsification of data.

Though Anna lacked a science background, her cheerful and outgoing personality, and impressive organisational skills, quickly endeared her to the group of 100 or more editors and senior editors, many of whom became her personal friends. She worked closely with the frequently-changing management team at Nature Publishing Group who were responsible for publishing BJP, maintaining amicable relationships while pushing them hard.

Running the BJP office was only part of Anna's work. She enjoyed the challenge of arranging meetings- finding venues, bargaining on prices, cajoling venue managers, herding editors and other participants, and on occasion raising money.

Whenever the BPS and BJP were represented at scientific meetings, Anna could be found organising the publicity and the handouts, and making everyone welcome. She had a particular fondness for Asia, and played a large part at the Beijing IUPHAR meeting in 2006, where the BPS was celebrating its 75th anniversary, and in the China tour the following year to promote the society and its journals at the major research centres. This very successful trip by Jeff Aronson, Graeme Henderson and myself, so ably organized by Anna, was certainly one of the highlights of my period of office. 'Miss Anna' left our Chinese hosts deeply impressed.

Anna was also a key member, representing the BPS, on the Biosciences Federation Journal Committee, a forum for discussion of the implications for societies of Open Access publishing.

The decision to switch from Nature Publishing Group to Wiley-Blackwell necessitated major changes, requiring careful management and attention to detail in order that the transition ran smoothly. Even though the change has meant discontinuing the BJP office at Angel Gate, which Anna had built up so effectively, she and her team participated fully in this operation. Having done so, Anna understandably felt that it was time to move on. I know that the staff and members of the BPS, especially those actively involved in the journal, will want to join me in expressing our deep thanks to Anna for all that she has contributed, and in wishing her well in her future career.

Humphrey Rang, Former Editor-in-Chief BJP

Graeme Henderson, Anna Muir, Humphrey Rang

Paul Tizard, Anna Muir, Hazel O'Mullan

BPS Office Staff Changes
Luisa Hambley and Sarah Mackay

Members of the Society will be sad to learn that Luisa Hambley left our Meetings Office on 30 April after 7 years' outstanding service.

Luisa's welcoming smile will be missing from the reception desk for the Edinburgh meeting and I am sure that I will not be the only one to miss her warmth and helpfulness.

Luisa started conference work at the Biochemical Society, where she worked between 1994 and 1997, before taking a chance to see the wider world by a working break in Australia. A stint in a toy company was also fitted in before she joined us at the Hatfield meeting for a change-over period with Pam Dale, with whom she is still in touch.

They meet regularly despite Pam now living and working in Wales. The first meeting in which Luisa was in charge was the inaugural James Black meeting held in Churchill College, Cambridge. The high standard to which she works was evident there, and has continued through until her last meeting, the Focused Meeting on Cell Signalling in Leicester. She has seen the types of meeting develop into the complex pattern that they now have, and has dealt with the changes in our procedures effectively and with good humour.

Luisa tells me that she is grateful to the Society for supporting her through an HNC in Business and Conference Event Management at the University of Westminster, though I think it should be the members who are grateful that she wished to carry this load along with that of keeping the meetings office going.

On the whole, it seems that the members of the Society have behaved well, or that Luisa is exceptionally discreet, since she remembers only one academic dispute at a meeting that would have interested the tabloids. There have certainly been some difficult meetings, and I remember particularly the July Meeting in Cambridge when the suicide attacks on the London Underground, and the bus in Tavistock Square, both disrupted travel for our speakers and caused concern for those attending. Several of those at the meeting had family and friends in London on the day and could not get in touch because of the close-down of the mobile phone system. Throughout the day, Luisa kept members and the chairs of symposia informed as well as she could and the meeting did not have to come to a premature end.

The Brighton Meeting in 2003 particularly sticks in her mind as it was subject to increased security following problems at a 3Rs symposium which led to the Security Service being in the lobby. She remembers also that some delegates were escorted back to their rooms by people with large bulges in strange places in their clothes! But, on the subject of Winter Meetings, she assures me that she will not miss constantly being away from home and working long hours in the week before Christmas, nor will she miss the struggle to find members willing to referee posters and judge contributions for the prizes that the Society offers at meetings.

Sadly, Luisa is leaving us before achieving one of her aims for the improvement of the Society's meetings. This winter, we will be meeting at the Queen Elizabeth II Conference Centre in Westminster, and Luisa has wished for some time to revitalise this meeting and make it more accessible by bringing it back to London - perhaps we should drink a toast to her at the Official Dinner in London and celebrate the achievement of her goal by having a first-rate meeting.

Luisa has been such a long-standing member of staff that she has seen four Meetings Vice Presidents come and go - Graeme Henderson, Steve Hill, Mandy MacLean and, for the last 4 months, me. I am sure that they will join with me, and you, in wishing her every success and happiness for the future.

Sarah Mackay also left the Meetings Office on 1st May having joined the BPS in July 2007 as Meetings Administrator. Sarah quickly picked up the numerous and sometimes complex administrative processes involved and soon became the primary contact for enquiries. Despite receiving requests, often at the last minute, for information which she had already sent to exhibitors, panic stricken requests for deadline extensions from members and speakers, and tracking down inserts for delegate bags, Sarah demonstrated exceptional patience and her helpful nature and welcoming smile will I am sure be missed by all the members who crossed her path at BPS Meetings. Sarah looks set to progress her career in events after stepping in and managing the Lysophospholipid Focused Meeting in October last year when Luisa was unable to attend at the last minute.

Following this success Sarah was given responsibility for organizing the recent Cell Signalling Focused Meeting in Leicester, which, judging from the feedback from those who attended was considered an excellent meeting. We thank her for the exceptional contribution she made and wish her every success in the future.

Robin Hiley, Vice-president Meetings

Future BPS Meetings

2009

6 July—Applying Receptor Theory to Drug Discovery Workshop. Open to all (including non-diploma attendees). Edinburgh, UK. E-mail: meetings@bps.ac.uk

7 July—Pharmacokinetics Workshop. Open to all (including non-diploma attendees). Edinburgh, UK. E-mail: meetings@bps.ac.uk

8-10 July—BPS Summer Meeting. University of Edinburgh, UK. E-mail: meetings@bps.ac.uk

12-15 July—EACPT Congress of the European Association for Clinical Pharmacology and Therapeutics. Edinburgh, UK. E-mail: eacpt2009@ed.ac.uk

12 July— A symposium hosted by the British Pharmacological Society, in association with the 9th Congress of the European Association of Clinical Pharmacology and Therapeutics (EACPT). 'Clinical Pharmacology: Working with Patients'. Edinburgh, UK. www.eacpt2009.org/

13 July—A symposium hosted by the British Pharmacological Society, in association with the 9th Congress of the European Association of Clinical Pharmacology and Therapeutics (EACPT). 'Hypertension'. Edinburgh, UK. www.eacpt2009.org/

1 September— Early Phase Trials of New Drugs Workshop. Open to all (including non-diploma attendees. King's College, London, UK. E-mail: meetings@bps.ac.uk

1-3 September—7th James Black Conference 'Integrative Pharmacology and Physiology'. King's College, London, UK. E-mail: meetings@bps.ac.uk

7-8 September—Drug Discovery 2009: Joint Meeting with ELRIG (European Laboratory and Robotics Interest Group) & SBS (Society for Biomolecular Sciences), Liverpool, UK.
E-mail: jackie.howard@lab- robotics.org

14-15 December—Drug Discovery Workshop. Open to all (including non-diploma attendees) London, UK. E-mail: meetings@bps.ac.uk

15-17 December—BPS Winter Meeting. The Queen Elizabeth II Conference Centre, London, UK.
E-mail:meetings@bps.ac.uk

2010

17-23 July- WorldPharma 2010 (IUPHAR Congress). Copenhagen, Denmark. www.worldpharma2010.org/

For further information about any of these meetings please email meetings@bps.ac.uk

or visit www.bps.ac.uk