

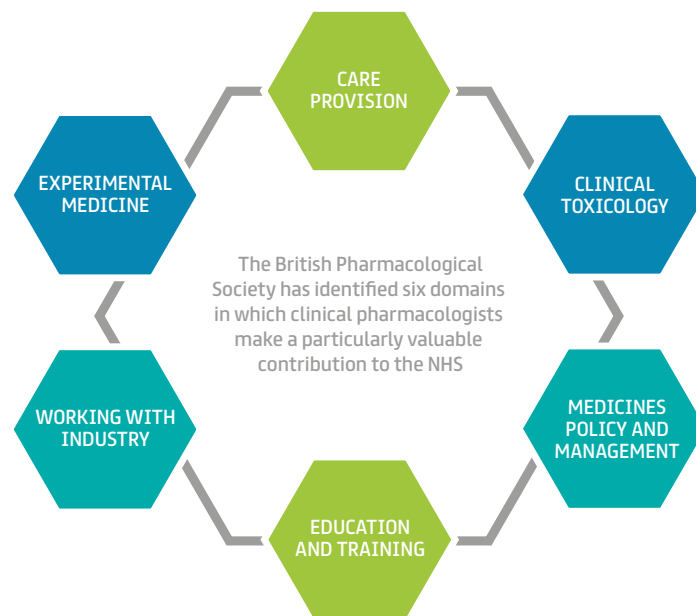


CLINICAL PHARMACOLOGY: A DYNAMIC MEDICAL SPECIALITY ESSENTIAL FOR UK HEALTHCARE

TODAY'S
SCIENCE
TOMORROW'S
MEDICINES

WHAT IS CLINICAL PHARMACOLOGY?

Clinical pharmacology is the only medical speciality focusing on the safe, effective and economic use of medicines. It is a diverse and wide-ranging discipline that plays an essential role across healthcare systems, contributing to their organisational objectives and, most importantly, improving patient outcomes and experiences:



EXPERIMENTAL MEDICINE

Clinical pharmacologists play an important role in bringing innovation to the NHS through experimental medicine by designing and running early phase clinical trials, establishing NHS clinical research facilities and providing overarching clinical support.

MEDICINES POLICY AND MANAGEMENT

Clinical pharmacologists make an essential contribution to medicines policy and management, providing synergy in partnership with clinical pharmacists and other specialties, to advance improvements. Clinical pharmacologists are also heavily involved in drug regulation, conducting health economic assessments, producing prescribing guidance and, ultimately, ensuring the best use of medicines.

CARE PROVISION

Clinical pharmacologists are among the doctors providing general medical and specialist care in NHS hospitals and very much fit with the vision of the *Future Hospital Commission*. Their pharmacological knowledge and clinical capabilities provide the specialist skills needed to care for the increasing numbers of people with multiple illnesses who are on polypharmacy; for example, determining the medicines of greatest benefit and those that can be stopped without any real loss to the patient.

CLINICAL TOXICOLOGY

Clinical pharmacologists with expertise in toxicology are uniquely qualified to lead specialist poison centres, which provide 24 hours a day, 7 days a week advice to clinicians from all disciplines all over the UK and especially to emergency medicine and intensive care clinicians. In hospitals where they work, clinical pharmacologists care directly for patients with poisoning.

EDUCATION AND TRAINING

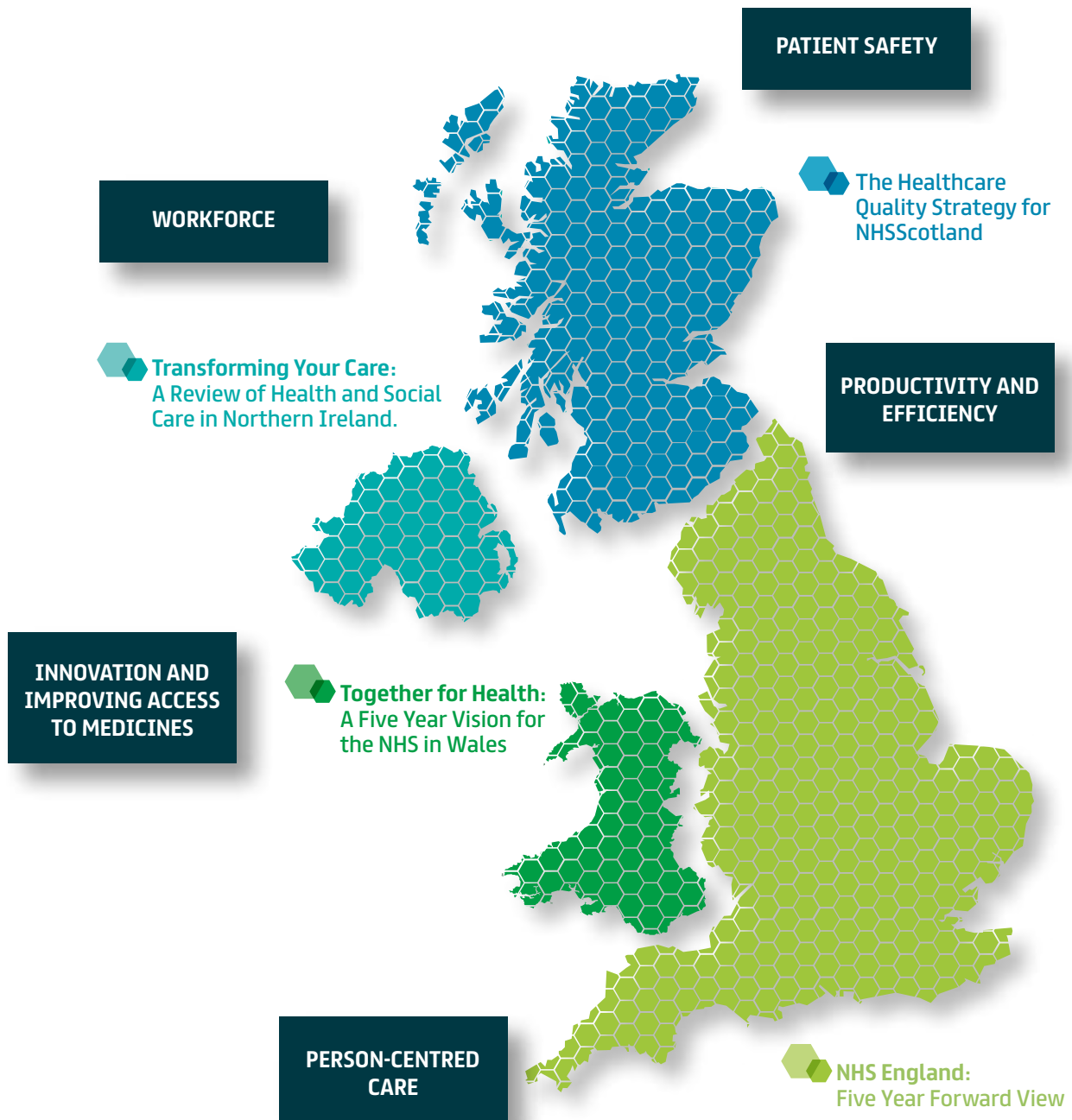
Clinical pharmacologists provide education and training for undergraduate and postgraduate medical trainees to ensure doctors have the appropriate skills to prescribe safely and effectively, taking into account the complexity of multiple medical conditions that co-exist in many patients.

WORKING WITH INDUSTRY

Clinical pharmacologists are involved in all phases of drug development, and their particular expertise in diagnostics means they are essential contributors to the continued success of the UK's life sciences industry. Cultivating this specialist knowledge in the life sciences industry is vital in the development of new medicines and new approaches to treat patients.

HELPING TO DELIVER FUTURE AMBITIONS

The diversity of the speciality makes it uniquely placed to deliver some of the key strategic priorities within health systems across the UK nations. This includes five main priorities:



This resource sets out how clinical pharmacology can help meet these core ambitions across the UK in order to help improve the quality of services, create the best possible outcomes for patients, and ensure health services are sustainable for the future.

PRODUCTIVITY AND EFFICIENCY

Health services across the UK are facing the most significant financial challenge in their history, with increasing demands for services and limited resources to meet them.

Productivity and efficiency are therefore strategic priorities in ensuring the sustainability of health services in England, Wales, Scotland and Northern Ireland. In England for example, within the *Five Year Forward View*, improving efficiency and productivity is identified as a key lever to transform the NHS. NHS England has called for a 1.5 per cent net efficiency increase each year from 2014, when the figure stood at 0.8 per cent¹.

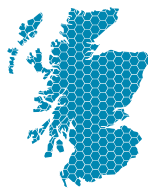
If the ambition of a 1.5 per cent efficiency increase in England is to be achieved, it is essential that wastage is minimised. For example, medicines form a significant part of NHS expenditure, and medicines optimisation is increasingly seen as a key opportunity to help meet this ambition². Clinical pharmacologists, working in partnership with other medical specialties and with pharmacists, can provide leadership and ensure efficiency measures are beneficial and not simply indiscriminate cuts in care.

A large proportion of NHS expenditure goes towards medicines...



England:

Expenditure on medicines was **£14.4 billion** in 2013-14³, **15 per cent** of NHS England's total spend that year (95.6 billion)⁴



Scotland:

Expenditure on medicines was **£1.4 billion** in 2013, **12 per cent** of NHS Scotland's total spend that year (11.9 billion)⁵



Wales:

Expenditure of prescriptions dispensed within the community was **£564 million** in 2013⁶, **10 per cent** of NHS Wales, total spend that year (£5.60 billion)⁷



Northern Ireland:

Community pharmaceutical services cost **£460 million** in 2013⁸, **11 per cent** of DHSSPS's total spend that year (£4.2 billion)⁹

...however a significant proportion is lost through wastage



£1 in every £25 spent on medicines in primary care is lost on wastage¹⁰



50 per cent of patients are believed not to take their medicines as recommended, suggesting that over **£7 billions-worth** of medicines are not being used correctly¹¹

How clinical pharmacology can support productivity and efficiency

Clinical pharmacology is the only medical speciality which focuses on the safe, effective and economic use of medicines. Clinical pharmacologists have the knowledge and expertise to advise on medicines policy and management including regulation, prescribing guidance, and formulary management, in order to optimise the clinical and cost-effective use of medicines. For example it has been demonstrated that for **every £1 of investment, clinical pharmacology can yield £10 of savings**¹². Synergistic partnerships with other healthcare professionals including pharmacists and other medical specialists, such as microbiologists, are essential in producing time- and cost-efficient improvements in our NHS.

PERSON-CENTRED CARE

Commitment towards delivering person-centred care across the UK is clear. All four main national strategies for each devolved nation set out the need for the implementation of a more personalised approach to care. For example in Northern Ireland, *Transforming your care*¹³, sets “promoting independence and personalisation of care” as a key future priority.

The need for this becomes increasingly pertinent in light of the UK's aging population, with 51 per cent more people due to be aged 65 and over in England in 2020 compared to 2010 – individuals who are more likely to live longer, and have multiple long term conditions¹⁴. With this in mind, key elements in helping to achieve person-centred care will increasingly be dependent on:

- **Generalist care:** as identified by the *Future Hospital Commission*¹⁵, through taking an overarching view over a person's health and care as opposed to simply focusing on one facet
- **Medicine optimisation:** as our population gets older and patients survive with multiple conditions, polypharmacy will become the norm rather than the exception

Person-centred care will become increasingly important amidst an ageing population



51 per cent more people due to be aged 65 and over in England in 2020 compared to 2010¹⁴

58 per cent of people over 60, compared to 14 per cent under 40, have a long-term condition¹⁹

How clinical pharmacology can support person-centred care

Clinical pharmacologists are well placed to deliver this ambition due to their expertise in the best use of medicines. The King's Fund has already highlighted the extent of polypharmacy in primary care, secondary care, and care homes, and called for the responsibilities of clinical pharmacologists supervising complicated drug treatments to be enhanced¹⁶. In the 2015 guidelines set by the National Institute for Health and Care Excellence (NICE) on medicine optimisation¹⁷, clinical pharmacologists can play a key role in assuring medicines are optimised according to best practice guidance. For example, clinical reviews include a critical evaluation of medications to ensure each patient is on the right dose of the right drugs (and combinations), minimising potential interactions and adverse drug reactions, and stopping superfluous medicines. With the increasing drive towards personalised or precision medicine, as highlighted in the development of a *Personalised Medicine Strategy* by NHS England¹⁸, clinical pharmacology skills will assist in providing patient-centred care using precious NHS resources to best effect.

Clinical pharmacologists are generally dual accredited professionally, being trained in a second speciality, often general internal medicine (GIM), in addition to clinical pharmacology and therapeutics (CPT). These comprehensive medical skills mean that they are well placed to provide leadership in the health service to ensure safe and effective use of medicines.



Long term health conditions account for **70 per cent of the budget** for NHS England¹



The proportion of serious **drug-drug interactions has more than doubled** between 1995 and 2010 to 13 per cent of adults, a significant proportion of whom are older and on polypharmacy²⁰

PATIENT SAFETY

Patient safety is central to the vision of care delivery in the future, in order to improve patient outcomes and reduce unnecessary costs in healthcare settings. For instance, a report commissioned by the Department of Health in England found that five to eight per cent of unplanned hospital admissions are due to medication issues²¹. In Scotland for example, the Scottish Patient Safety Programme is an ambitious effort to make substantial safety improvements for patients²².

Prevalence of poisoning

Poisoning is one of the most common causes of hospital admission.



There were over **153,500** admissions to Accident and Emergency departments with suspected poisoning in 2013/14 in England (including legal and illegal)²³

In England and Wales in 2013, there were **almost 3,000 deaths** caused by poisoning (including drug misuse)²⁴

Clinical pharmacologists have expertise in the detection and management of poisoning. They lead specialist poison centres, which provide advice to clinicians caring for poisoned patients, especially in emergency medicine and intensive care. In acute hospitals without clinical toxicology units, clinical pharmacologists apply their expertise to care directly for poisoned patients.



576,000 TOXBASE user sessions, which is the online database for the National Poisons Information Service²⁵



56,000 telephone calls recorded to clinical pharmacologists and call centres²⁵



1,527,000 separate product assessments made within poison centres²⁵

Cost of ADRs and medication errors

Adverse drug reactions (ADRs) and medication errors are prevalent and cause a significant financial burden to the NHS as well as harm to patients.



Prescribing errors in hospital inpatients affect seven per cent of medication orders and **50 per cent** of hospital admissions²⁶



ADRs during hospitalisation in England lead to bed days equivalent to the occupancy of **ten 800-bed hospitals** at any one time²⁷



33 per cent of patients post discharge had medication related problems in Northern Ireland²⁸



ADRs account for **6.5 per cent** of hospital admissions and **14.7 per cent** of adult hospital in-patients experience an ADR^{27, 29}



Prescribing or monitoring errors were detected in the care of **one in eight patients, involving one in 20** of all prescription items³⁰



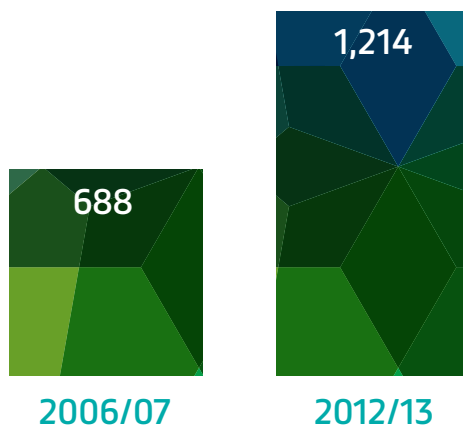
Various studies have estimated that ADRs cost between **£637 million – £770 million** annually in England^{21, 27}

How clinical pharmacology can support patient safety

Clinical pharmacologists help to support patient care and contribute to the cost-effective use of NHS resources by: preventing avoidable hospital admissions, reducing the number of unnecessary investigations and treatments, and facilitating shorter hospital stays for those admitted. Their expertise in care provision also means that the speciality plays a key role in treating cases of poisoning and the detection and reporting of ADRs, 70 per cent of which are avoidable – this helps in improving the benefit-risk ratio of current and new medicines³¹.

Clinical pharmacologists act as Directors of the five MHRA regional yellow card centres (Scotland, Wales, North West England, West Midlands and Northern and Yorkshire), and through these Centres have been able to implement important new initiatives that have led to improvements in yellow card reporting, a spontaneous UK ADR reporting scheme which celebrated its 50th anniversary in 2015. Clinical pharmacologists (working in the NHS, MHRA and academia) have played leadership roles in the development and refinement of this scheme over the past five decades.

Clinical pharmacologists have a significant role to play in improving safety, and demand for the speciality is increasing:



The number of outpatient CPT appointments have increased by **almost 90 per cent** between 2003/04 and 2013/14 in England³²

The number of finished CPT consultant episodes in Wales increased from **688 to 1,214** between 2006/07 and 2012/13³³

WORKFORCE

Key to meeting future ambitions is having the appropriate workforce to deliver it. In Scotland for example, *The Healthcare Quality Strategy for NHS Scotland*²² sets out that a workforce needs to be “supported, developed and equipped to respond to the challenges of the future”. Also in Wales, “creating a sustainable workforce” was highlighted as one of the key challenges to address within *Together for Health*³⁴.

As set out within this resource, medicines and their effective use can play a crucial role in improving services and reducing unnecessary cost and wastage. However, a report by the General Medical Council published in 2008 found that medical graduates demonstrated “under-preparedness for prescribing” and identified weaknesses “both in terms of their pharmacological knowledge and their understanding of the practical elements of prescribing”³⁵.

Are graduate doctors fully prepared to prescribe medicines?



Nine out of ten graduate doctors are prepared for the challenges of medical careers but lack an understanding of basic pharmacology and prescribing economically³⁶



24 studies suggested that medical graduates are unprepared in terms of providing safe and legal prescriptions³⁷

How clinical pharmacology can support the future workforce

Clinical pharmacology as a speciality is well placed to help deliver the training and education to undergraduate and postgraduate doctors to ensure they have the appropriate skills to prescribe safely and effectively. However, the scarcity of clinical pharmacologists in the NHS affects the quality of training provided.



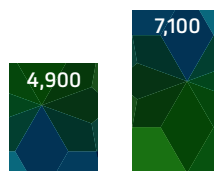
Some **94 per cent** of clinical pharmacologists contribute to prescribing and therapeutics education and training in universities and hospitals across the UK³⁸



Clinical pharmacologists report spending **10 per cent** of their time (about 5 hours per week) teaching medical students³⁹



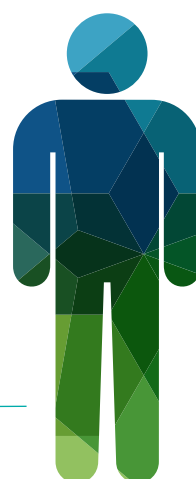
In 2015, **nine** medical schools required their students to pass the Prescribing Safety Assessment in order to graduate⁴¹ while Deaneries responsible for employing newly graduated doctors in Foundation medical training posts are increasingly seeking confirmation from applicants that they have passed the Assessment.



Following the 2008 report³⁵, clinical pharmacologists created the Prescribing Safety Assessment, a national examination to assess the prescribing knowledge and skills of graduating doctors that is fast establishing itself as a valued component of medical curricula in the UK. In 2014, **7,100** final year medical students from 31 of the UK's 33 medical schools sat the national Prescribing Safety Assessment, compared with just over 4,900 in 2013⁴⁰

In 2012, the teacher to student ratio in the UK was 1 CPT consultant to over **500** undergraduate medical students; in contrast, the teacher to student ratio for cardiologists was 1 consultant to approximately **40** undergraduate medical students^{42,43,44}

40 students for
each UK cardiology
consultant



500 students
for each UK CPT
consultant

Survey of clinical pharmacologists' contributions to patient care, medical education and prescribing training in the NHS in 2015³⁸

An examination in 2015 of clinical pharmacologists' work in the NHS and their contributions to medical education and training revealed a busy and dynamic group of consultants and trainees. Despite their small numbers and complete absence in many hospitals, almost all clinical pharmacologists, whether academic or NHS-employed, provided direct care for in-patients in the hospitals with which they were affiliated. Most provided direct in-patient care for 4 months or more per year in addition to providing out-of-hours on-call services. Out-patient care included specialist hypertension, cardiovascular, metabolic, toxicology and paediatric clinics, all conducted at least twice every month.

Clinical pharmacologists participated directly in prescribing and therapeutics training at both hospitals and universities, predominantly for medical students and junior doctors but also for nurses, pharmacists and allied health professionals including dentists, para-medics, physician assistants, and scientific support staff. All were strongly involved with local NHS activities promoting safe and effective use of medicines, including for example, drugs and therapeutics committees, formulary management, medicines safety committees, clinical guideline development, risk management planning, Trust drug expenditure committees, and non-medical prescribing committees.

Outside of their own Trusts and universities, clinical pharmacologists contributed to regional and national training for junior doctors and specialist trainees, adverse drug reaction monitoring, poisons and toxicology services, ethics committees, medicines regulation, national drug safety initiatives, and clinical guideline development. All described active links with learned societies including the British Pharmacological Society, national research institutes, professional representative groups, or national bodies associated with clinical governance. Many contributed to or led clinical research on new treatments or on evaluation of outcomes from existing treatments and were recognised experts in their fields nationally and internationally.

INNOVATION AND IMPROVING ACCESS TO MEDICINES

Speeding up the development of and access to new and innovative medicines is an increasingly important ambition across the UK. Key to achieving this is investment in the UK life sciences sector, growth in experimental medicine, and investment within medicine development.

Whilst the UK has clear strengths in this area, with strong academic and industrial sectors, challenges remain which prevent the UK from competing internationally in this regard⁴⁵, particularly due to skills gaps and the need for greater connections between academia and industry^{45,46}.

Efforts to meet this ambition are continual, with investment towards experimental medicine, the biotech industry and the evolution of precision or personalised medicine. Such efforts have also been evident within the *Accelerated Access Review*⁴⁷ being conducted by the UK Department of Health, which focuses on establishing needs, priorities and principles for innovation, new development pathways, and affordable national funding models to drive innovation and local adoption and diffusion.

The UK continues to lag behind internationally in access to new and innovative medicines



In a comparative international study, medicines in their 3rd year of launch in the UK have a usage level which is on average **50.7 per cent** less than other countries analysed⁴⁵




The UK can be slow in quickly adopting new and innovative medicines and then diffusing such treatments⁴⁸

How clinical pharmacology can support innovation and improve access to medicines

Clinical pharmacologists are at the centre of the drug development process and are essential for the continued success of the life sciences industry and in ensuring the availability of new medicines to treat patients. They also play a crucial role in supporting innovation, in particular because of their valuable contribution towards experimental medicine by designing early phase clinical trials, establishing NHS clinical research facilities and providing overarching clinical support. As set out in the *Ensuring UK leadership in experimental medicine* report, experimental medicines is heavily dependent on skills in clinical pharmacology and as such there is an urgent need for more of these specialists⁴⁶.

"The provision of high quality-care requires clinicians to be familiar with the relevant practices in clinical pharmacology and pathology. This is important to enable them to evaluate and prescribe innovative medicines"

HM Government, Life Sciences Blueprint: A statement from the Office for Life Sciences, July 2009⁴⁹



"Clinical pharmacologists are major players in translating advances in basic research and developing them into interventions that can be tested in the NHS, funded by NIHR or industry. This offers the potential of better health for patients and the UK public, and wealth creation by reducing healthcare costs and generating new products for a global market"

**Professor Tom Walley
CBE MD, Director,
NIHR Evaluations,
Trials and Studies
(NETS)⁵⁰**

"The earlier clinical pharmacologists become involved in clinical trials the better. We want to understand the desirable and undesirable effects of a drug before Phase II and III trials begin so we can advise on dosing and the design of the trial. This might include understanding how the drug might work in patients that have another condition or take other medicines. While there are pockets of excellence in clinical pharmacology in the UK, we need more specialists to help drive investment in our life sciences industry"

**Dr Richard Peck,
Global Head of Clinical
Pharmacology,
F Hoffman La Roche⁵⁰**

WHAT NEEDS TO HAPPEN NEXT?

Clinical pharmacologists have a key role to play in delivering these five key strategic priorities for health systems across the UK, due to their valuable generalist and specialist medical expertise, as well as the support they provide to broader clinical care within each hospital Trust and more widely, to the NHS at a national level. The preceding sections demonstrate both the needs for clinical pharmacology expertise across the NHS and the vast array of positive contributions made by clinical pharmacologists in those areas where they are active.

Yet, as identified in the British Pharmacological Society's report, *A Prescription for the NHS*, there were only 77 Clinical Pharmacology & Therapeutics (CPT) consultants in the UK (which has since decreased to just 72 consultants), significantly fewer than the 440 recommended by the Royal College of Physicians^{50,51,52}. Most of the NHS is therefore operating without the skills and expertise that clinical pharmacologists can bring to healthcare.

To address this and permit the NHS as a whole to benefit from clinical pharmacology skills, there must be a substantial increase in both the number of registrar training posts and the number of consultant posts.

The British Pharmacological Society believes that enhancing the value of the speciality is a long-term process that will require co-ordination across the entire health system. It therefore calls on the organisations responsible for workforce management in the four UK nations to:

1

Ensure that within the next decade NHS organisations across the UK have equitable access to clinical pharmacology expertise

2

Commit to increase the CPT consultant workforce to 150 whole-time equivalents by 2025, accompanied by an increase in the number of specialist registrar training posts

3

Develop a joint strategy to achieve this increase, including the provision of enhanced undergraduate and postgraduate education and training

4

Provide a clear career route for clinical pharmacologists, with associated career support and development

CLINICAL PHARMACOLOGY IN CONTEXT



A week in the life of a clinical pharmacologist

Professor Emma Baker

St George's University Hospitals NHS Foundation Trust

Monday starts with a *research clinic*, screening and recruiting asthma patients into clinical trials. I work with my research coordinator to set up and deliver clinical trials in our trust and across the region. This ensures that our patients get early access to new medicines and new inhaled therapies. It also helps to develop a culture of research and innovation to improve patient care. In this role I work with industry, providing early reviews of protocols and feasibility assessments, as well as working more specifically on individual studies.

Tuesday is focused on *experimental medicine* – independent research to develop new treatments for patients. Our group is interested in chronic obstructive pulmonary disease (COPD), particularly exacerbations and associated diseases. We design and deliver clinical studies and trials to find out more about these conditions and test new treatments. We collaborate closely with basic scientists, as laboratory work informs and is informed by our clinical findings. This has led to strong collaborations with industry.

Wednesday is *medicines management* day where clinical pharmacologists make important contributions. We review new medicines for prescription, ensuring that they are effective, safe and acceptable to patients and that they have advantages over existing therapies.

Thursdays are for *clinical care provision*. Although I see patients in my second specialty (respiratory medicine), much of my focus is on multimorbidity, polypharmacy and deprescribing. In an NHS siloed into specialties and single conditions, I see an increasing role for generalists who can look at the whole patient. Clinical pharmacologists are particularly suited to this type of work through their training in diagnosis, as well as an in depth knowledge of medicines. A man once brought me a sports bag full of drugs that he was supposed to be taking. I was able to pull together his primary and secondary care records, review all his past investigations and stop 4 of his 10 medicines, which were unnecessary, as well as optimising his necessary treatment.

Fridays are for *teaching and training*. I have helped design, and now deliver, a prescribing course which runs over the last three years of the undergraduate medical programme. All teaching is scenario-based

with simulated prescribing, and includes the principles of clinical pharmacology alongside their application through prescribing. Our students feel well prepared for prescribing as an F1 doctor and do well in our institution's prescribing exam.



Productivity & efficiency

1. Clinical pharmacologists ensure decision-making is cost-effective and rationalised

Dr Alyn Morice


Hull and East Yorkshire Hospitals NHS Trust

Clinical pharmacologists make a vital contribution to the governance of the drug policy within the NHS trust. As chair of Drugs & Therapeutics Committee, I have been a key coordinator with the primary care drug policy through the Area Prescribing Committee. This ensures that drug policy is aligned to the best interests of the whole healthcare community. I have worked with colleagues to ensure rational prescribing across the whole patch, saving money and providing an optimal service.

As Chair of the Drugs & Therapeutics Committee in my hospital trust, I draw upon my comprehensive knowledge of clinical pharmacology of a diverse background, from cancer chemotherapy to skin ointments. Through this role I have also contributed to:

- The preparation of the committee business to ensure the orderly consideration particularly of new applications, and in turn ensure consultation with all of the stakeholders; and
- The inevitable emergency approval of the drugs that are not listed on the formulary, by being on call to colleagues in other teams. Not infrequently this can be a potentially life-saving emergency and requires the successful coordination of a number of different parties.





2. Clinical pharmacologists help deliver more efficient formulary management

Raymond MacAllister

UCLH NHS Foundation Trust

Clinical pharmacologists appreciate that robust medicines management processes and implementation of formularies have been shown to reduce overall medicines expenditure and improve governance. However, until 2012, formulary management was independently managed by each local service provider. In response, clinical pharmacologists helped to successfully establish the North Central London Joint Formulary Committee (JFC) in September 2012 to oversee medicines management across Trusts and Clinical Commissioning Groups in the area. We also helped review its progress as it has continued to run to date, and I am its current chair.

The aims of the JFC were to facilitate collaborative working (between Trusts and across Clinical Commissioning Groups and between primary, secondary and tertiary care), increase procurement economies of scale and reduce duplication of effort and heterogeneity in outcomes. Although only scientific and advisory, Trusts agreed to abide by the decisions of the JFC (pending funding confirmations) and it was envisioned that this new model of working would deliver both qualitative (such as hospital to GP transitions) and quantitative (such as direct and indirect cost savings and cost avoidance) benefits.

During 2012–2015, the JFC oversaw approximately 233 recommendations. Approximately 60 per cent of formulary business was assessed at the new Committee with the remaining 40 per cent first assessed locally with a hub-and-spoke model, and 70 per cent of Committee business was Clinical Commissioning Group-relevant. The JFC running cost was approximately £350K in this time, and a conservative estimate of cost avoidance resultant from JFC activity is in the region of £1.1M; generating a potential three-fold return on overall investment. The majority of JFC recommendations have been implemented by the acute Trusts. JFC approvals are lower than a neighbouring formulary committee with a similar remit for North West London. Where a decision was taken not to approve a drug, its uptake in primary care was noted to be less than neighbouring areas of London where it had been approved.

3. Clinical pharmacologists help the NHS bridge the gap between drug efficacy/ effectiveness and value for money

Professor David Barnett

Emeritus Professor of Clinical Pharmacology, University of Leicester & Past Chair, Appraisals Committee, NICE

As the first Chair of the Appraisals Committee at NICE I was involved in setting up the appraisals process at NICE, the production of over 180 technology appraisal determinations as well as the development of the NICE Appraisals methodology guidance documents and subsequent revisions over a period of ten years (1999–2009).

My background in both clinical medicine (general and cardiovascular disease) as well as training as an academic research clinical pharmacologist was invaluable in this role. It enabled me to have insight and understanding of both the issues of the disease processes and their management, in addition to the problems associated with modern drug development and assessment of clinical/ cost effectiveness.

The appraisals committees draw their membership from across a wide spectrum of individuals including healthcare professionals, health economists, statisticians and lay members. However, a crucial decision in my view was to include at least one or two senior clinical pharmacologists on the first and subsequent committees.

The ability of these members with a clinical pharmacology background to bridge the gap between the various aspects of drug efficacy/effectiveness and value for money in healthcare was very important in aiding the understanding of the main issues being considered by the other committee members. A prime example was when trying to work through the minefield of health economic modelling and relevance to the 'real world'.

As a model for assessment of new interventions in healthcare and value for money, NICE now has a well-deserved worldwide reputation for excellence. The input of CPT specialists with clinical and research experience is essential in my view for this function at all levels, both in the UK and elsewhere.



Person-centred care

1. Clinical pharmacologists contribute to improved, person-centred care for clinical gerontology in-patients

Professor Stephen Jackson

King's College Hospital NHS Foundation Trust

All patients who take multiple medications, and are admitted on a medical take, should have their medications reviewed to identify medications that need to be stopped, medications that need a change in regimen and medications that should be offered that they are currently not taking. This is particularly relevant to older patients, because of their statistically higher medication count, multiple pathologies and higher prevalence of frailty.

In early 2014, I proposed to a consortium of local Clinical Commissioning Groups (CCGs) that medication review should be commissioned as part of the Commissioning for Quality and Innovation (CQUINs) framework for 2014/15. The CCGs ranked this proposal top of their list, with it subsequently being commissioned.

I was aware of poor evidence that medication reviews were taking place, so the objective set was that all clinical gerontology in-patients would undergo a medication review, and the outcomes were to list medications remaining unchanged, medication undergoing a change in regimen and new medication started. The rationale for each change would be recorded and the report would be sent at the time of discharge.

The project served to provide hard evidence, delivered in a way that GPs wanted, to show that the process was happening. The target for the first operational quarter was 70 per cent completion rate and 83.2 per cent was achieved.

This has improved clinical services, and is helping GPs to meet medication review targets. It is also helping patients by ensuring their medication regimens are appropriate. I have been able to share my experience of clinical pharmacology and medication review to benefit a wider group of patients by training other teams to implement this strategy on other geriatric medicine wards.

2. Clinical pharmacologists contribute to improved, person-centred care for hypertensive patients

Dr Una Martin

Queen Elizabeth Hospital, University Hospitals Birmingham NHS Foundation Trust

I was Programme Director of The National Institute of As a clinical pharmacologist, I set up and run the Hypertension Service at the Queen Elizabeth Hospital in Birmingham.

Patients are often referred because their blood pressure remains poorly-controlled, despite them being on antihypertensive medication. The reasons are varied, but

include difficulties in accepting the need to take tablets for an asymptomatic disease, poor adherence to medication because of adverse effects, drug interactions and intolerances, and the presence of co-morbidities which can lead to polypharmacy and complex medication regimens that are challenging for both patient and doctor.

My clinical pharmacology skills are useful as I work through these issues with my patients, identifying the reasons why they may find it difficult to take the tablets that have been prescribed, and establishing whether adherence is actually a factor in their blood pressure control.

In addition, an in-depth knowledge of the adverse effects associated with cardiovascular drugs often enables me to make a simple alteration to improve both adherence and blood pressure control. If urinalysis, for example, confirms that a patient is not taking their tablets as prescribed, I can explore the reasons why and come up with a mutually acceptable drug regimen to which the patient is happy to adhere.

Ultimately, the service reduces medication wastage, streamlines care and reduces cardiovascular risk through better blood pressure management. It also provides a platform for training of SpRs in clinical pharmacology and enables nurse specialists to learn how to prescribe.





Patient safety

1. Clinical pharmacologists develop guidance on safe and robust prescribing practices

Dr Patricia McGettigan

The Royal London Hospital, Barts Health NHS Trust

I was approached for advice about whether a colleague should have concerns about writing a private prescription for a drug not reimbursed by the NHS but requested by a patient attending an NHS out-patient clinic. I discovered that there was little clear knowledge among our hospital doctors of the circumstances in which they may issue private prescriptions or of the responsibilities assumed in doing so – and no single, clear or easily-accessible guidance.

I was involved in developing a group with clinical pharmacology, medical, public health and legal skills that investigated the clinical and legal responsibilities associated with private prescribing in the NHS. Our group exposed a real knowledge gap – and indeed area of vulnerability – among doctors who need to understand the considerable responsibilities assumed in writing private prescriptions for patients.

As a result, the group produced an article to raise awareness about the facts and risks of private prescribing and minimise potential adverse consequences for prescribers, patients and the Trust by:

- Outlining key aspects of the legal framework governing private prescribing in the NHS using helpful, illustrative clinical cases;
- Identifying the dispersed information existing on the topic; and
- Recommending that the General Medical Council should issue comprehensive guidance and education on the responsibilities, risks and liabilities associated with private prescribing.

The article was published in 'Prescriber' and has been shared with our Trust's Medicines Safety Committee for posting on the Trust intranet. It is also a good example of collaboration and skills sharing among multiple disciplines including clinical pharmacologists.

2. Clinical pharmacologists develop safer (and more cost-effective) protocols using existing medicines

Dr James Dear

Royal Infirmary of Edinburgh, NHS Lothian

Toxicology is often neglected in terms of clinical research, yet poisoning is a very common reason for hospital admission. Paracetamol overdose is a very common example of poisoning. It directly results in around 100,000 patients attending NHS hospitals every year with around half requiring admission for prolonged treatment with the antidote, acetylcysteine.

Clinical pharmacologists in Edinburgh and Newcastle performed a randomised clinical trial of a new shorter treatment regimen. During the study, patients from hospitals in Edinburgh, Newcastle and Aberdeen were randomly allocated to a new shorter treatment regimen (the antidote acetylcysteine administered over 12 hours) or the current regimen (acetylcysteine over 21 hours). The primary objective was to reduce drug side-effects and the new shorter regimen resulted in substantially fewer side-effects without being less effective.

The resulting treatment protocol has significant benefits: it is safer for patients and, because it is shorter, the new regimen will allow rapid discharge of treated patients, which is projected to free up 25,000 NHS hospital bed days per year. This protocol is now being introduced into clinical practice in order to improve patient safety, save the NHS money and clear space for acute hospital admissions.

By implementing this protocol, clinical pharmacologists, together with their emergency care colleagues, have demonstrated the benefits of research both for patient safety and NHS efficiency.

3. Clinical pharmacologists develop interventions to improve the health and wellbeing of local populations

Dr David Wood

Guy's and St Thomas' NHS Foundation Trust

Clinical pharmacologists make a vital contribution to the governance of the drug policy within the NHS trust. As chair of Drugs & Therapeutics Committee, I have been a key coordinator with the primary care drug policy through the Area Prescribing Committee. This ensures that drug policy is aligned to the best interests of the whole healthcare community. I have worked with colleagues to ensure rational prescribing across the whole patch, saving money and providing an optimal service.

As Chair of the Drugs & Therapeutics Committee in my hospital trust, I draw upon my comprehensive knowledge of clinical pharmacology of a diverse background, from cancer chemotherapy to skin ointments. Through this role I have also contributed to:

The preparation of the committee business to ensure the orderly consideration particularly of new applications, and in turn ensure consultation with all of the stakeholders; and

The inevitable emergency approval of the drugs that are not listed on the formulary, by being on call to colleagues in other teams. Not infrequently this can be a potentially life-saving emergency and requires the successful coordination of a number of different parties.

I also act as Director of the MHRA Yellow Card Centre in the North West, one of five such Centres in the UK. Spontaneous ADR reporting systems such as the Yellow Card system are beset by the problem of under-reporting; however, our work led to the introduction of yellow card reporting by nurses, and through the use of Yellow card champions, we have been successful in increasing yellow card reporting from our hospitals. This is an important indicator of patient safety.

The expertise of clinical pharmacologists can also help in advising regulatory authorities such as the MHRA and EMA. I am Chair of the Pharmacovigilance Expert Advisory Group for the MHRA and a Commissioner on Human Medicines – these committees play a vital role in protecting public health in the UK by ensuring that the drugs licensed and used in this country, and globally, are safe and efficacious. Indeed, clinical pharmacology has shown significant leadership in the activities of the MHRA and its advisory committees over the last 50 years.

My background in both clinical pharmacology and clinical medicine has been invaluable in trying to pursue the agenda for improving drug safety for NHS patients. The research I undertake in drug safety is having a direct impact on both patients and industry, while my training has allowed me to have a direct input into policy issues of relevance for the whole NHS.

4. Clinical pharmacologists make an important contribution to drug safety, and public health, in the NHS

Professor Sir Munir Pirmohamed

Royal Liverpool & Broadgreen University Hospitals NHS Trust

Clinical pharmacologists make a vital contribution to drug safety in the NHS. My work in drug safety has led to an evaluation of the overall burden posed by adverse drug reactions (ADRs) in causing hospital admissions and after admission to hospital in both adults and children (see earlier section of this document on Patient Safety for these data). This has led to the development of novel interventions that are being implemented in the NHS (for example, the use of genotype-guided dosing for warfarin), working in partnership with other NHS staff, the Academic Health Science Network (AHSN) and industry partners. The ultimate goal of these interventions will be to improve the benefit-risk ratio of existing and new medicines for patient benefit.





Workforce

Clinical pharmacologists improve the training of the wider NHS workforce

Professor Simon Maxwell

University of Edinburgh and NHS Lothian

Prescribing medicines is central to the work of trainee doctors in the NHS. Recent medical graduates write a large proportion of the prescriptions in most hospitals. This activity has major implications for both the patients and doctors involved: for the patients, medicines are a major influence on present and future health outcomes; for the doctors and hospitals, prescribing represents an important source of clinical risk and cost. Prescribing is also arguably one of the most complex intellectual challenges new graduates face.

As a clinical pharmacologist with a special interest in medical education, I was aware that students and new graduates often feel underprepared for and anxious about prescribing – a concern echoed by their supervisors.

Working with other clinical pharmacologists, I have been heavily involved in responses that are helping to deliver a safer future. This included work for the Safe Prescribing Working Group convened in 2007 that brought together key stakeholders. The group identified the tools needed part of a plan for better undergraduate training:

- a clear definition of the outcomes in relation to the use of medicines expected of students at the point of graduation, which was subsequently embedded in the regulatory guidance provided to medical schools;
- a national e-Learning strategy to support students in achieving these outcomes; and
- a reliable and valid assessment to enable final year medical students and medical schools to demonstrate that the required learning outcomes have been met and that new doctors have the necessary competencies to begin their training as junior prescribers in health service hospitals.

The last recommendation resulted in collaboration between the Medical Schools Council and the British Pharmacological Society, leading to the development of the UK Prescribing Safety Assessment (PSA). The expertise of clinical pharmacologists has been vital throughout the delivery of the assessment: I have been involved in every stage of this exciting collaboration and around half of the writers who have contributed – and continue to contribute – questions to the PSA are clinical pharmacologists.

By 2014, a total of 25,000 candidates had taken the PSA both in the UK and overseas. All candidates provided feedback on their experience, with the majority agreeing that the PSA is a relevant and appropriate test of prescribing skills at graduation level and that the assessment interface was easy to use. Many commented that the experience of preparing with online practice papers and subsequently taking the PSA had engendered a greater sense of confidence about prescribing.

The PSA has undoubtedly already prompted better training experiences in the UK with additional prescribing practice, development of new educational materials, new teaching appointments and a generally increased visibility of prescribing for students in undergraduate training. The future implementation of the PSA may include other prescriber groups such as more senior doctors, undergraduate and postgraduate pharmacists.



Innovation

1. Clinical pharmacologists show leadership in developing experimental medicine facilities in the NHS

Dr Richard FitzGerald

Royal Liverpool University Hospital, Royal Liverpool & Broadgreen University Hospitals NHS Trust

Clinical pharmacology has been instrumental in the development of the Clinical Research Unit (CRU) at the Royal Liverpool & Broadgreen University Hospitals NHS Trust (RLBUHT).

In May 2013, the RLBUHT CRU was the first NHS unit in England and Wales to gain MHRA Phase I accreditation, and was successfully reaccredited in June 2015. The CRU is dedicated to conducting first-in-human (FIH) and Phase I studies, particularly in patient groups: an important capability in order to demonstrate safety, tolerability and proof of concept in patients at the earliest stages of drug development. Over the last 18 months the CRU has conducted over 15 Phase I studies and recruited over 100 patients into Phase I clinical trials – thereby bringing novel therapies closer to patients and ensuring that Liverpool is involved at the cutting edge of research and development.

Key to this success has been Liverpool's strengths in clinical pharmacology. As clinical pharmacologists, with our broad general medical training, we are able to act as chief or principal investigator of FIH or Phase I studies across multiple disease groups or therapeutic areas. In addition, our knowledge of pharmacology and drug development enables us to design better and more adaptive clinical trials, as well as providing advice to industry or our academic and NHS colleagues – helping to bridge the gap between basic science and translation to clinical trials. This has allowed the CRU to develop bespoke capabilities in collaboration with our academic and industry partners, such as lung penetration work, renal impairment studies, radiolabelled microdose studies and novel models for testing the efficacy of new drugs.

The CRU has three clinical pharmacologists in the senior management team, two of whom are able to act as FIH and expert advisory group study principal investigators (PIs). As the director of the CRU, I am additionally responsible for leading the multidisciplinary team within the CRU as well as being the responsible person for our Phase I accreditation. Training the next generation of early phase researchers is a key component of our work: we provide early phase trial training for all of our specialist registrars and clinical lecturers in CPT, with each trainee rotating to the CRU for a period of four months each year. This ensures that on completion of training all of our trainees are capable of undertaking PI roles for FIH and early phase studies – a unique capability and vital to both academia and the UK life sciences industry.

Furthermore, we have developed bespoke clinical pharmacology training for other organ based specialities; this includes a dedicated consultant nephrologist with clinical pharmacology training to develop and deliver early phase trials in renally-impaired patients.

2. Clinical pharmacologists champion innovation and experimental medicine in the NHS

Dr Una Martin

Queen Elizabeth Hospital, University Hospitals
Birmingham NHS Foundation Trust

I was Programme Director of The National Institute of Health Research (NIHR)/Wellcome Trust Clinical Research Facility (CRF), a partnership between the University of Birmingham and University Hospital Birmingham Foundation Trust. The CRFs is an ideal place to put my expertise in CPT to good use. Its remit is to deliver clinical studies safely and effectively. In order to achieve this I lead a team of 30 people which include nursing, laboratory and administration staff who provide guidance and help on all aspects of research delivery.

The Birmingham CRF has excellent facilities and is responsible for a high volume of experimental medicine, incorporating the Advanced Therapeutics Facility, the Inflammation Research Facility, the Health Research Bus and the Institute of Translational Medicine. I co-chair the Scientific Advisory Committee (SAC) which reviews all applications to carry out research in the facility.

The major challenge as Programme Director is to ensure the studies coming through the SAC are of appropriate academic standard, and that we can deliver them safely and efficiently. My CPT training is particularly useful given the range and complexity of the research we take on, including a high volume of Early Phase and “first in man” studies using novel pharmaceutical agents.

The facility also provides a training platform for undergraduate and postgraduate medical, nursing and PhD students. It is an ideal place to train Specialist Registrars (SpRs) in CPT so that they become future leaders in experimental medicine.

Clinical pharmacology has the potential to significantly enhance design and delivery of experimental medicine within CRFs and other research facilities. It is particularly relevant to leadership of the CRF network nationally, including applications for Medicines and Healthcare Regulatory Agency (MHRA) Phase 1 accreditation. To reflect this, our SpR is based in the CRF where they sit on the Scientific Advisory Committee and have the opportunity to review studies with guidance from senior academics and receives training in all stages of research delivery (both commercial and academic) including site initiation visits, research governance procedures, data management and reporting of adverse drug reactions.



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ABOUT CLINICAL PHARMACOLOGY: A DYNAMIC SPECIALITY ESSENTIAL FOR UK HEALTHCARE

This is a follow-on resource from the British Pharmacological Society's 2014 report *A prescription for the NHS: Recognising the value of clinical pharmacology and therapeutics*. It again underlines the important role of clinical pharmacology in the NHS. In response to declining numbers of clinical pharmacologists in the UK, the Society is calling for co-ordinated action across the whole of the UK in order to increase the numbers of NHS consultants in clinical pharmacology (from the current level of 72 to 150 over a period of 10 years) and the numbers of trainees in this dynamic and essential speciality.



ABOUT THE BRITISH PHARMACOLOGICAL SOCIETY

Formed in 1931 the British Pharmacological Society is a charity with a mission to promote and advance the whole spectrum of pharmacology, including laboratory, clinical, and toxicological aspects. The Society now leads the way in the research and application of pharmacology around the world.

With over 3,500 members from more than 60 countries worldwide, the Society represents a diverse community working across academia, government agencies, industry and the health service.

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