



BRITISH
PHARMACOLOGICAL
SOCIETY

Today's science, tomorrow's medicines

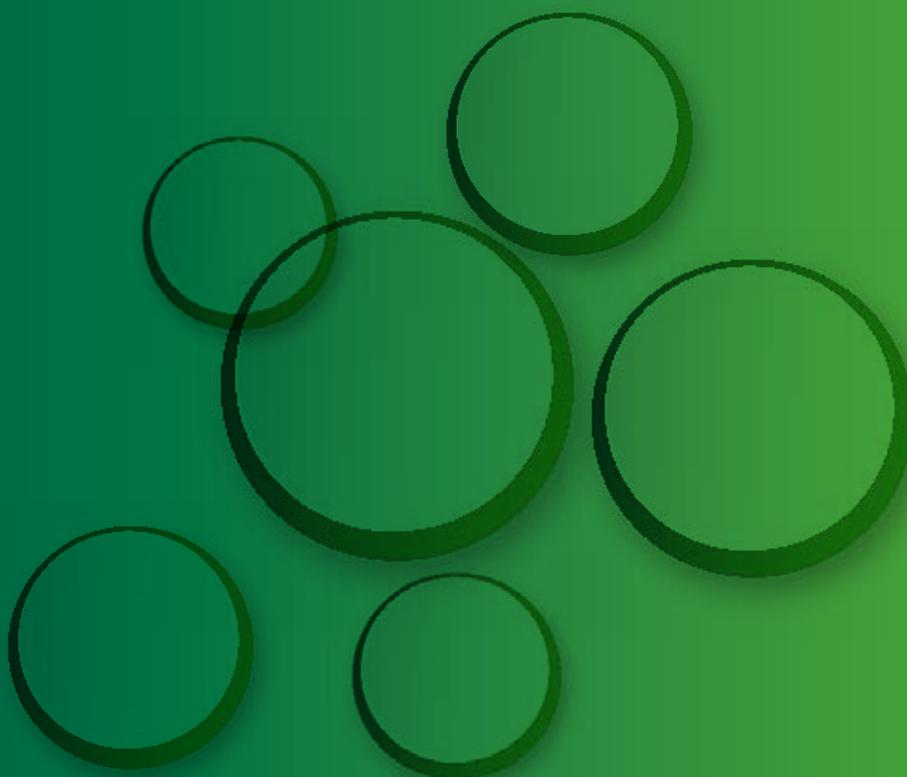


A PRESCRIPTION FOR THE NHS

Recognising the value
of clinical pharmacology
and therapeutics

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Foreword

The medical speciality of clinical pharmacology and therapeutics (CPT) makes a major contribution to the health and wealth of the nation. It improves patients' lives by developing new medicines, by ensuring they are used safely and effectively, and by providing general and specialist medical services, often as part of a multidisciplinary team of healthcare professionals, both in hospitals and the community. It also brings unique benefits to the UK's academic and life sciences sectors, attracting investment to our shores and bringing much-needed improvements to care in the NHS for the benefit of patients.

Although the value of CPT is well-documented, it remains a little-known specialty outside the medical establishment, and has perhaps been a little too shy in coming forward. This report aims to put the record straight.

The four health systems across the UK are changing rapidly, and are facing similar long-term challenges of providing safe, equitable, high-quality patient care within restricted budgets. As the population ages and medicines increase in cost and sophistication, the need for novel models of care in the NHS is becoming increasingly clear. Clinical pharmacology can play a vital role in this. The British Pharmacological Society intends that this report will highlight the vital impact clinical pharmacologists already make, and the high-level actions needed from governments and health services to support the speciality to achieve more.

In recent years clinical pharmacologists have proved themselves to be instrumental in increasing research capacity and improving prescribing skills among medical graduates. If clinical pharmacology is to rise to the strategic demands facing the NHS, as identified by the Future Hospital Commission, immediate action is needed to sustain and enhance the speciality's role and attract the brightest and the best trainees during the challenging years ahead.



A white cursive signature of Professor Munir Pirmohamed on a dark green background.

Professor Munir Pirmohamed
Chair of the Clinical Section



A white cursive signature of Professor David Webb on a dark green background.

Professor David Webb
President-Elect



A white cursive signature of Professor Humphrey Rang on a dark green background.

Professor Humphrey Rang
President

On behalf of the British Pharmacological Society

Executive summary

Clinical pharmacology is an exciting speciality and the only medical speciality focusing on the safe, effective, and economic use of medicines. It is a diverse and wide-ranging discipline that plays a key role across multiple aspects of the NHS, contributing to its organisational objectives and, most importantly, improving patient outcomes and experiences. It is therefore well positioned to support the NHS to respond to the changing nature of medicines and continue to meet the strategic challenges of the 21st century.

Clinical pharmacologists make a particularly valuable contribution to the NHS in areas including:

- **Providing specialist and generalist patient care** in hospitals (including paediatrics) and other settings, using their expertise in the use of medicines to improve outcomes and prevent avoidable harm
- Leading **clinical toxicology** services and the National Poisons Information Service
- Advising on all aspects of **medicines policy and management** including regulation, health economic assessments, prescribing guidance, and formulary management in order to optimise the clinical and cost-effective use of medicines – for every £1 of investment, clinical pharmacology has delivered savings of £10 to the NHS
- Providing **education and training** for undergraduates and postgraduates to ensure doctors have the appropriate skills to prescribe safely and effectively
- **Working with industry** and supporting the UK's life sciences sector to enhance the development of innovative new medicines and improve the use of current medicines
- Bringing innovation to the NHS through **experimental medicine** by designing early phase clinical trials, establishing NHS clinical research facilities, and providing overarching clinical support

However, the benefits that clinical pharmacology can provide to the NHS have not yet been fully realised. In 2012 there were 77 CPT consultants in the UK, significantly fewer than the cohort of 440 recommended by the Royal College of Physicians, and the current workforce is under significant pressure as a result. To address this, there is a need for both a substantial increase in the number of registrar training posts and the number of consultant posts to meet current and future demands.

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 is therefore calling on the organisations responsible for workforce management in the four UK nations to:

1

Ensure that NHS organisations across the UK have equitable access to CPT consultants' expertise

2

Commit to increase the size of 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

Introduction

The NHS is currently facing the biggest financial challenge since its creation, with limited resources available to meet ever-increasing demands driven by demographic change and technological advancement.

It is essential to ensure that the services and products the NHS provides are clinically- and cost-effective, and deliver the maximum benefit both for patients and taxpayers. As this report will demonstrate, clinical pharmacologists are critical in providing valuable generalist and specialist medical services, as well as supporting activities to enhance the provision of broader clinical care. They also contribute to the cost-effective use of medicines, both by developing local and national formularies and providing expert advice on prescribing to reduce the costs associated with adverse drug reactions (ADRs).

Clinical pharmacologists make a substantial contribution to the development of innovative new medicines and the success of the UK's life sciences sector, identified by the UK Government as a key contributor to sustained economic growth¹.

As the Future Hospital Commission and the Shape of Training Review of medical education have identified, there is a long-term need to expand the generalist medical workforce after a period of emphasis on increasing specialisation. Clinical pharmacologists, who tend to be dual accredited in clinical pharmacology and therapeutics (CPT) and general internal medicine (GIM), are well placed to take on an enhanced role across the health service in response to this need.

The demand for clinical pharmacologists is already extensive, and CPT consultants are known to provide more clinical work than they are contracted for and contribute more to supporting professional activity than any other specialty². There is, however, a significant shortfall in the number of CPT consultants, and an associated shortage of specialist registrars.

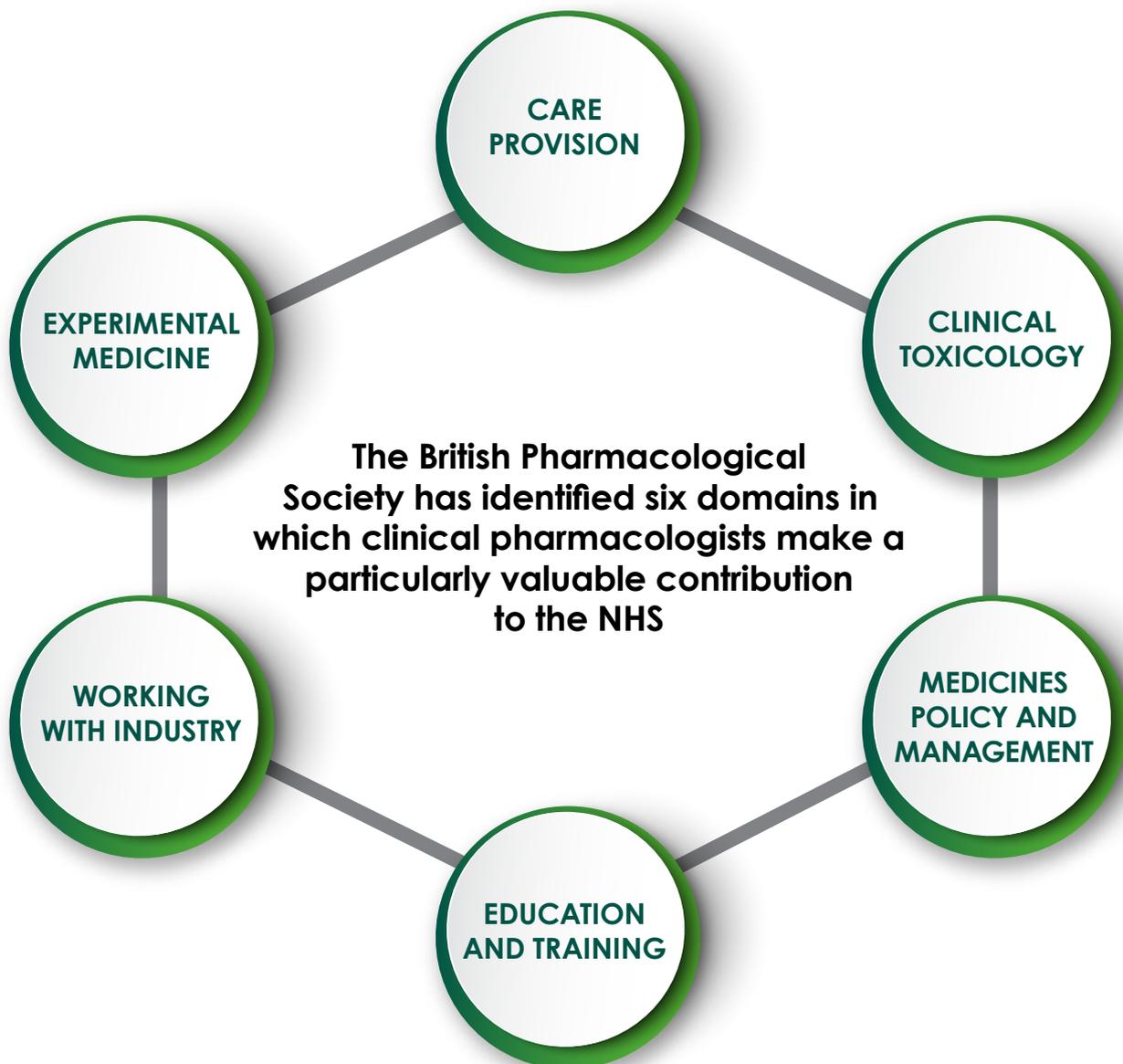
In order to optimise their value to the NHS, and help meet its strategic objectives, there must be a strong commitment from governmental and NHS organisations in England, Wales, Scotland, and Northern Ireland to encourage growth of the discipline through improved specialist training opportunities and a clearer career pathway.

This report outlines the value that clinical pharmacologists bring to the NHS and the UK, the current state of the CPT workforce, and a prescription for the priority actions that are needed to secure the brightest future for the NHS.

“ Clinical pharmacologists are critical in providing valuable generalist and specialist medical services, as well as supporting activities to enhance the provision of broader clinical care. ”

The value of CPT to the NHS

CPT is the only medical specialty focusing on the safe, effective, and economic use of medicines. It is a diverse and wide-ranging discipline that plays an essential role across multiple areas of the NHS, contributing to its organisational objectives and, most importantly, improving patient outcomes and experiences.



This report will demonstrate the value of CPT across these six domains, in the context of the strategic needs of the NHS. It will also provide evidence of the growing pressures facing the current CPT workforce and, in turn, the case for increasing the number of CPT consultants employed by the NHS.

Care provision

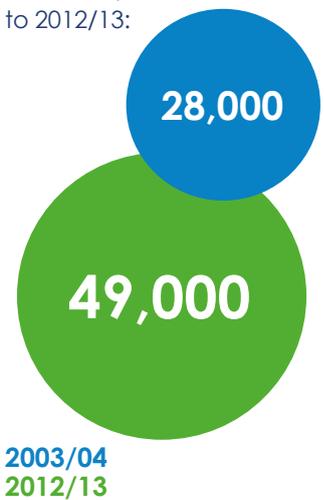
On average, CPT consultants work 50 hours per week³, and demand for their services has increased significantly in England and Wales over the last decade^{3,4}.

In England, the number of outpatient CPT appointments increased by 75% from almost 28,000 in 2003/04 to almost 49,000 in 2012/13⁵.

Figure 1: Outpatient CPT appointments in England

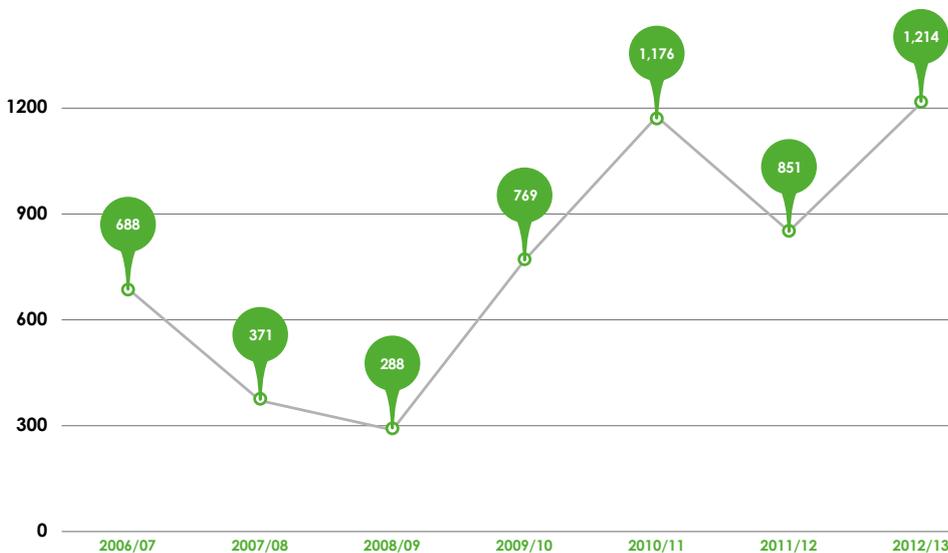


The number of outpatient CPT appointments in England increased by 75% from 2003/04 to 2012/13:

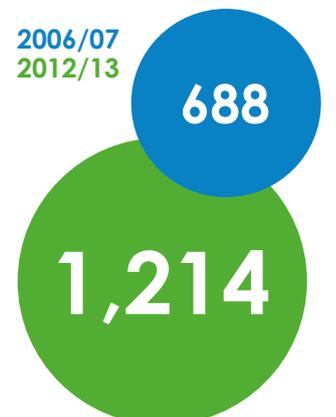


Furthermore, in Wales the number of finished CPT consultant episodes (i.e., the time a patient spends under the continuous care of one consultant) increased from 688 in 2006/07 to 1,214 in 2012/13⁶. In reality, these data are likely to underestimate the amount of clinical work conducted by CPT consultants, as activity is often attributed to GIM⁷.

Figure 2: Finished consultant episodes for CPT in Wales



The number of finished CPT consultant episodes in Wales increased from 688 to 1,214 between 2006/07 to 2012/13:



The Future Hospital Commission identified enhancing the role of the generalist physician as a strategic priority for the NHS, complementing consultants in other specialities and providing high-quality, coordinated hospital care⁸. Most CPT consultants are dual-accredited in CPT and GIM (although some also practice in other specialities including geriatric medicine, cardiology, oncology, respiratory medicine, and rheumatology⁹) and are therefore well-placed to take on this enhanced role.

Furthermore, the value of generalist physicians, and the need to enhance their role in the health service, was a central theme of the Shape of Training Review of the medical workforce¹⁰. As generalists, the “undervalued champions of the acute hospital service”⁸, clinical pharmacologists often act as the first point of medical contact for patients with both acute and chronic conditions.

“I had issues with my heart last year and I have always had high blood pressure. My GP and cardiac specialist were treating me and then referred me to a clinical pharmacologist, who then tailored my medication regimen to a combination which fitted me, and it's working. They simply know what they are talking about. My blood pressure is lowering, I'm not experiencing any more problems and I can finally see the light at the end of the tunnel.”

Samuel Kingsbury, Patient

“Hypertension can often be managed in primary care by GPs. However, some patients are referred to CPT consultants because they have adverse drug reactions or find that their tablets are ineffective. Clinical pharmacology expertise is essential in treating these patients, preventing avoidable harm, and reducing medicines wastage.”

Dr Una Martin, Reader in Clinical Pharmacology, University of Birmingham

“Clinical pharmacologists are well suited to provide the generalist role which is outlined as a key strategic NHS policy and the Royal College of Physicians' Future Hospital Commission, through their delivery of general internal medicine and their ability to look after patients with a wide range of conditions, including those with polypharmaceutical needs and complex diseases affecting multiple organ systems.”

Dr Simon Constable, Divisional Medical Director & Honorary Senior Lecturer in Clinical Pharmacology, Royal Liverpool and Broadgreen University Hospitals NHS Trust

In addition to this generalist service, CPT consultants can apply their specialist knowledge and skills to the benefit of the NHS. These specialist skills are in safe and effective medicines use and are particularly beneficial to help the NHS in reducing prescribing errors, reducing adverse drug reactions, and bridging the gap between primary and secondary care.

Reducing prescribing errors

A UK study found that prescribing or monitoring errors were detected in the care of one in eight patients, involving one in 20 of all prescription items¹¹. In England, reducing the incidence of medication errors has been incorporated as a key improvement area within Domain 5 of the NHS Outcomes Framework¹². Clinical pharmacologists can work to minimise errors by playing a key role advising specialists in other disciplines on the safe, effective, and evidence-based use of medicines. This specialist role is crucial in protecting patient safety and improving outcomes.

Reducing adverse drug reactions

As both generalists and specialists, clinical pharmacologists often work in multidisciplinary teams to provide continuing care for patients with long-term conditions, where polypharmacy predisposes them to drug-drug interactions and ADRs. ADRs in particular place a significant burden on the NHS. As shown in Table 1, it is estimated that ADR-related admissions and ADRs during hospitalisation in England lead to bed days equivalent to the occupancy of ten 800-bed hospitals at any one time, which is conservatively estimated to have an annual cost in excess of £637 million¹³.

It is likely that the need for this expertise will increase as the population ages and as the prevalence of complex long-term conditions and co-morbidities rises: the number of older people with a long-term limiting illness or disability will increase from 4 million to 6 million by 2030¹⁷. 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 enhanced¹⁸.

“Drug safety is a major clinical issue for the NHS and creates a huge cost – clinical pharmacologists provide the expertise to allow for rational prescribing by using their knowledge in drug efficacy and toxicity to reduce the risk of ADRs, achieving the optimum risk-benefit level in a patient’s drug therapy treatment.

Multi-disciplinary teams would greatly benefit from the skills of clinical pharmacologists who can assess whether the drug therapies a patient is on is optimal, an area often not discussed during medication reviews. This will become increasingly important given the burden of polypharmacy on the NHS.”

Professor Munir Pirmohamed, Chair of the Clinical Section, British Pharmacological Society and NHS Chair of Pharmacogenetics in the UK, University of Liverpool

Table 1: The burden caused by adverse drug reactions (ADRs) in UK hospitals

Study	Setting	Number of patients studied	Frequency of ADRs
Adults			
Pirmohamed <i>et al</i> ¹⁴	Hospital admission	18,820	6.5%
Davies <i>et al</i> ¹³	In-patients	3,695	14.7%
Children			
Gallagher <i>et al</i> ¹⁵	Hospital admission	8,345	2.9%
Thiesen <i>et al</i> ¹⁶	In-patients	16,601	17.7%

Bridging the gap between primary and secondary care

The reduction of hospital admissions, by moving the care of people with (and at risk of developing) long-term conditions into the community, is an increasing priority for both patients and the NHS. Clinical pharmacologists play a key role in bridging the gap between primary and secondary care, and are well positioned to oversee transitions and ensure that drug therapy, adverse reactions, drug interactions, and evidence of efficacy are monitored effectively¹⁹. In primary care, clinical pharmacologists may also be involved in community-based medicines use reviews and the provision of hypertension or vascular risk clinics⁹. This role will become increasingly important as the proportion of care provided in the community increases.

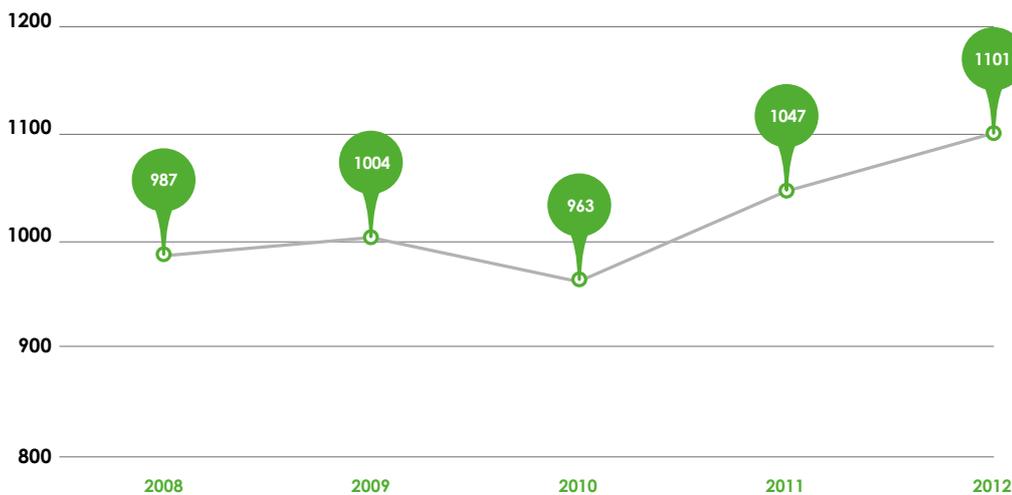
Clinical toxicology

Poisoning is one of the most common causes of hospital admission. For example, in England alone there were over 150,000 admissions to Accident and Emergency departments with suspected poisoning in 2012/13, and the number of admissions has been increasing in recent years²⁰. In England and Wales in 2012 there were 1,100 deaths caused by poisoning (excluding drug misuse)²¹.

Figure 3: Admissions to accident and emergency departments in England with suspected poisoning



Figure 4: Deaths caused by poisoning (excluding drug misuse) in England and Wales



As a substantial proportion of all poisoning cases relate to the use of prescribed medicines, clinical pharmacologists with expertise in toxicology are uniquely qualified to lead specialist poison centres, which provide advice to clinicians from a range of disciplines including emergency medicine and intensive care²².

These poison centres support patient care and contribute to the cost-effective use of NHS resources by, for example, preventing avoidable hospital admissions, reducing the number of unnecessary investigations and treatments, and facilitating shorter hospital stays for those who are admitted. The improvement to patient outcomes and the cost-savings to the NHS are estimated to be substantial²².

CPT consultants lead the National Poisons Information Service, which provides advice and on-call support to all healthcare professionals from its units in Birmingham, Cardiff, Edinburgh and Newcastle using its TOXBASE database and 24-hour telephone service. There has been a sustained growth in demand for support from the service, with over 550,000 TOXBASE user sessions and 53,000 telephone calls being recorded in 2012/13²³. It is likely that this growth in demand will continue.

**550,000
TOXBASE
user sessions**



**53,000
telephone
calls
recorded**



“More clinical pharmacologists with expertise in toxicology are needed in the NHS to improve the management of poisoning. Toxicology is such a complex area that it is impossible for doctors in other specialties to understand every aspect. Clinical pharmacologists, working alongside their colleagues at the National Poisons Information Service, are an essential part of every hospital.”

Dr James Dear, Consultant Clinical Pharmacologist and Toxicologist, Royal Infirmary of Edinburgh

Medicines policy and management

Clinical pharmacologists make an essential contribution to medicines policy and management, and are heavily involved in developing regulation, conducting health economic assessments, producing prescribing guidance and ensuring the best use of medicines.

Regulation

The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for ensuring that medicines licensed for sale in the UK are acceptably safe, and operates post-licensing surveillance for reporting, monitoring and investigating adverse events.

Clinical pharmacologists hold a number of posts within the MHRA, including on the British Pharmacopeia Commission, the Commission of Human Medicines, the Pharmacovigilance Expert Advisory Group and the Herbal Medicines Advisory Committee. A former Chair, Sir Alasdair Breckenridge, and the former Chief Executive, Sir Kent Woods, are also both clinical pharmacologists.

The MHRA's Yellow Card scheme, which collects information on side-effects and ADRs, has centres in Birmingham, Cardiff, Edinburgh, Liverpool and Newcastle that are led by clinical pharmacologists and are responsible for education and research into Yellow Card reporting.

Health economic assessments

The UK health system is under significant financial pressure. Medicines spending currently accounts for approximately 10% of the NHS budget, and is predicted to increase from £14.3 billion in 2013 to £16 billion by 2015^{24,25}.

The UK's health technology appraisal organisations, the National Institute for Health and Care Excellence (NICE), the Scottish Medicines Consortium (SMC) and the All-Wales Medicines Strategy Group (AWMSG), were established to ensure the best use of NHS resources by establishing the cost-effectiveness of new treatments and making recommendations on their use. These three organisations were established and led by clinical pharmacologists (Professor Sir Michael Rawlins, Professor David Lawson and Professor Philip Routledge respectively), who have expertise in assessing the safety, efficacy and cost-effectiveness of new medicines, as well as an overarching knowledge of general medicine within clinical practice and an ability to make complex clinical judgements.

“Clinical pharmacologists have unique skills and an abundance of background experience which they can bring to health technology assessments. Any health care system has a finite budget and you have to make priorities; and these assessments are essential in helping the Government decide where they spend their money.

The majority of acute admissions are elderly patients with multiple conditions, which is only likely to increase. We therefore need to have clinicians with both specialist and generalist skills in the NHS. Clinical pharmacologists are well suited to provide this service.”

Professor Sir Michael Rawlins, Chair of NICE from its formation in 1999 until 2012

Producing prescribing guidance

In addition to contributing to health economic assessments, clinical pharmacologists are key in supporting the efficacious and cost-effective use of medicines by developing national and local prescribing guidance.

At a national level, clinical pharmacologists play a key role in developing the British National Formulary, the most influential and authoritative collection of prescribing advice in the UK, and clinical guidelines on the management of a range of diseases and therapeutic areas for NICE and the Scottish Intercollegiate Guidelines Network (SIGN).

Similarly, at a local level clinical pharmacologists are involved in the development of drug formularies and providing a local medicines information service, as well as working with purchasers of NHS services to ensure national guidance is implemented appropriately in response to local conditions.

“It is vital that there is a robust evidence-based approach to developing local formularies. Many specialties contribute to this, but clinical pharmacologists have the broadest perspective across multiple areas of disease. Our role is often to ensure we achieve the maximum health gain from the medicines we use. With medicines becoming increasingly complex, it is vital to ensure that clinical pharmacology has critical mass as a specialty.”

Professor Simon Thomas, Professor of Clinical Pharmacology and Therapeutics, Newcastle University

“Clearly, there is a level of understanding that all clinicians have in relation to national formularies. However, evaluating drug combinations for patients who are on multiple medications is exceedingly complex. In the context of an ageing population, and patients with a range of comorbidities, I believe specialist clinical pharmacologist input is increasingly important.

At my hospital we spend £50 million every year on drugs, and we must ensure that we get the best possible value for patients from that expenditure. To do this, drug treatments need to be tailored to individual patient needs, and the interaction between drugs fully understood. I don't think clinicians in the traditional specialties can be expected to have expert knowledge of this complex area of clinical care. As such, I think the establishment of clinical pharmacologists in every Trust would undoubtedly improve patient safety, quality of care, and the cost effectiveness of drug treatments.”

Aidan Kehoe, Chief Executive, Royal Liverpool and Broadgreen University Hospitals NHS Trust

Ensuring the best use of medicines

The number of prescription items prescribed in the community each year has increased steadily in England, Wales and Northern Ireland, from 649.8 million in 2003 to over 1 billion in 2012^{26,27,28}.

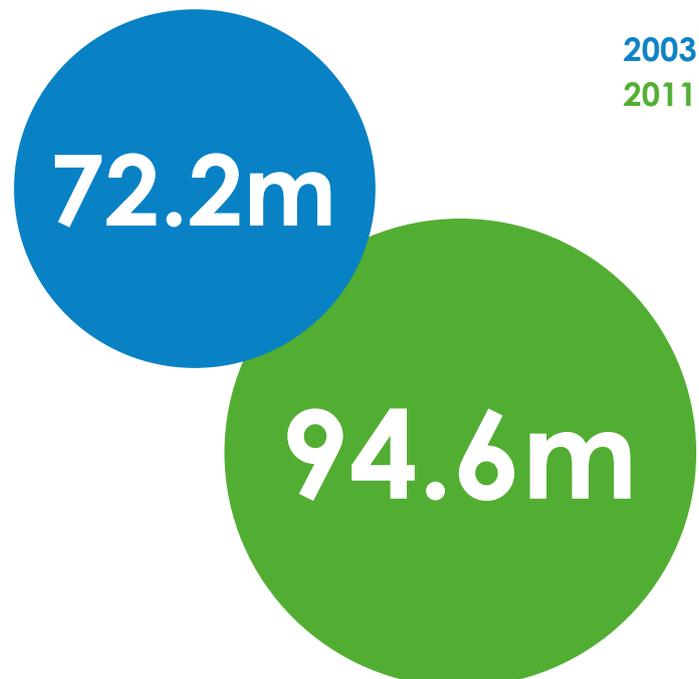
Figure 5: Total prescription items dispensed in the community in England, Wales and Northern Ireland by thousands by year



The number of prescriptions dispensed has increased at a similar rate in Scotland, rising from 72.2 million in 2003 to 94.6 million in 2011²⁹.

Ensuring that these medicines are used effectively is a significant challenge for the NHS. For example, NICE has noted that up to 50% of patients are believed not to take their medicines as recommended, suggesting that over £7 billion of medicines are not being used correctly, and an independent report commissioned by the Department of Health estimated that £1 in every £25 spent on medicines in primary care is lost on wastage^{30,31}.

The number of prescriptions dispensed in Scotland:



The All Wales Therapeutic and Toxicology Centre (AWTTC), a partnership led by clinical pharmacologists working together with pharmacists in Wales was able to provide resources and training to support prescribers in Wales in reducing primary care prescribing costs in three main areas. An investment of around £600,000 was associated with savings of £5.8 million (an approximate £10 saving per £1 of investment) in drug costs alone in proton pump inhibitor, benzodiazepine and NSAID prescribing over the study period³². This case study highlights that clinical pharmacology and clinical pharmacy are not competitive, but by working together, they can achieve significant synergies for the benefit of patients and the wider NHS.

Clinical pharmacologists also play a key role in ensuring that medicines use is in line with broader government priorities, such as combating antimicrobial resistance. The Chief Medical Officer has called for an organisational or healthcare system-wide approach to best practice in the use of antimicrobials, with the goal of optimising therapy for individual patients, preventing overuse, misuse, and abuse, and minimising the development of resistance at patient and community levels³³. As specialists in the best use of medicines, clinical pharmacologists working with microbiologists are well placed to drive this agenda forward.

“ My experience has been that clinical pharmacologists and pharmacists have worked closely together in pharmacovigilance, the promotion of safe, effective and prudent prescribing, health technology appraisal and the training of new and established prescribers. By bringing their unique yet complementary knowledge and skills to these collaborations, both professions have made a much greater contribution to patient care than either could have achieved by working alone. ”

**Professor Roger Walker, Chief
Pharmaceutical Officer, Welsh
Government**

“ CPT consultants, in collaboration with microbiologists, can help in antimicrobial stewardship by helping to develop antimicrobial policies and promoting rational antibiotic prescribing to providing antibiotic therapeutic drug monitoring advice. The clinical pharmacologist's knowledge and skills can complement that of their colleagues in delivering safe and effective care of patients suffering from infections. ”

**Dr Jamie Coleman, Senior Clinical Lecturer
in Clinical Pharmacology and
Medical Education, University
of Birmingham**

Education and training

As Professor Philip Routledge has noted, "prescribing a medicine is one of the most effective and yet potentially dangerous things any healthcare professional can do"³⁴. However, a report for the General Medical Council (GMC) 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. Addressing this weakness in prescribing was subsequently identified as a priority for the GMC.

Concerns about weakness in prescribing have been exacerbated by recent changes in junior doctor training, a reduction in working hours, and the increase in the number and complexity of pharmaceutical products available¹⁹. In response the British Pharmacological Society has collaborated with MSC Assessment to introduce the Prescribing Safety Assessment³⁶ which will allow medical students to demonstrate their competencies in relation to the safe and effective use of medicines.

“The most common form of treatment issued by a GP is through prescriptions. However most doctors practicing don't have any idea about how to rationally prescribe or to assess whether the treatment is compatible with that individual.

Some other European countries are doing far more to nurture and utilise clinical pharmacology in comparison to the UK. Russia has about 600 clinical pharmacologists, with every district general hospital required to have at least three. In Sweden and Norway, there is also a far stronger emphasis on clinical pharmacology within education and training.”

Professor Michael Orme, a former Dean of the Faculty of Medicine, University of Liverpool and a former Director of Education and Training, NHS in Northwest England

Clinical pharmacologists are well placed to provide education on practical prescribing, and report spending 10% of their time (about five hours a week) teaching medical students both the basic principles of clinical pharmacology and practical therapeutics. They also report teaching junior hospital doctors and pharmaceutical physicians, as well as other groups of healthcare professionals who might prescribe, including nurses, pharmacists, dentists, and general practitioners³. Clinical pharmacologists also serve as directors of postgraduate training programmes and supervise MD and PhD students³⁴, and are therefore training future prescribers and creating a better skilled workforce.

“The NHS influences the health outcomes of the majority of its patients through the use of drugs. The NHS drugs budget is very large, but a very small proportion of that money is spent on ensuring that drugs are used wisely. Clinical pharmacology is the science that underpins the rational use of medicines, and it is therefore essential that the NHS expands its expertise in this area.

A large proportion of medical schools do not have an assessment on clinical pharmacology and some medical students might not even know what the term means. The Government should ensure that every medical school has at least one clinical pharmacologist contributing to the teaching curriculum, and encourage medical schools to integrate the Prescribing Safety Assessment into their curricula.”

Professor Simon Maxwell, Medical Director, UK Prescribing Safety Assessment and Director of Clinical Pharmacology and Therapeutics Education at the University of Edinburgh

Working with industry

Clinical pharmacologists are at the centre of the drug development process and are essential for the continued success of the UK's life sciences industry. Cultivating this specialist knowledge in the life sciences industry will be vital in improving the success rate of early phase trials, contributing both to the economic success of the industry and, in the longer term, the availability of new medicines to treat patients.

In the early stages of drug development, clinical pharmacologists provide expertise on the potential desired and undesired effects of a molecule on the patient population that is likely to receive the drug. This specialist knowledge of the pharmacokinetic and pharmacodynamic characteristics of drugs, alongside knowledge of the pathophysiology and treatment of disease, is increasingly important as polypharmacy becomes more widespread and new approaches to laboratory and clinical trials are developed³⁷.

As medicines become increasingly stratified, clinical pharmacologists in industry are likely to have an increasing role at the forefront of the development of new technologies to realise the ambition of the Technology Strategy Board's stratified medicine innovation platform³⁸.

During the later stages of development, licensing and marketing, clinical pharmacologists have the expertise to support industry to ensure the safe use of new drugs in diverse patient populations, and can support the development of trials to capture data to demonstrate the benefits of new products over and above existing treatments and competitors.

“GSK concur with the views that clinical pharmacology is a key discipline for pharmaceutical R&D in industry and in clinical research organisations and warmly welcome proposals to strengthen training and capabilities in the United Kingdom.”

**Dr Patrick Vallance, President,
Pharmaceuticals R&D,
GlaxoSmithKline**

“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
Roche**

“Principles of clinical pharmacology are very important for all medical disciplines and are particularly important within the pharmaceutical industry and regulation. The way in which drugs are being developed and licensed is a long and expensive process. Often drugs fail to get through clinical trials as people guiding these processes don't always understand the principles of pharmacology.

It is widely recognised that there are not enough clinical pharmacologists within the pharmaceutical industry. Regulators also need clinical pharmacological advice to understand the benefits and risks when assessing new medicines. Clinical pharmacology can help play an important role in enabling quicker access to new innovative drugs through their involvement in programmes such as adaptive licensing, which involves intensive early research and study about drugs before they go to clinical trial.”

**Professor Sir Alasdair Muir Breckenridge CBE, Chairman of the Medicines and
Healthcare products Regulatory Agency from its founding in 2003 to 2012**

Experimental medicine

In 2010 the critical role of clinical pharmacologists in developing safe and effective innovative treatments was recognised by the Office of Life Sciences, which resulted in a £3.5 million flagship programme in clinical pharmacology and pathology being launched by the Medical Research Council to enhance the workforce and drive collaboration with industry. Alongside the Wellcome Trust's Translational and Therapeutics Scheme, this has strengthened CPT as an academic discipline and will undoubtedly contribute to a stronger and more productive UK life sciences sector. This also represents an excellent example of clinical pharmacology rising to a specific challenge in research.

The Strategy for UK Life Sciences also sets out a vision for the UK to become "the global hub for life sciences in the future, providing an unrivalled ecosystem that brings together business, researchers, clinicians, and patients to translate discovery into clinical use for medical innovation within the NHS".

As the Minister for Universities and Science identified in his speech one year on from the launch of the strategy, the UK has retained a robust infrastructure and breadth of expertise for conducting Phase I and II clinical trials, which are unparalleled in the developing countries that are now so popular for Phase III trials³⁹.

Clinical pharmacologists are essential to increasing the volume of early stage clinical trials in the UK, and can contribute significantly both to the income of NHS organisations and UK economic growth.

As specialists in pharmacokinetics and pharmacodynamics, clinical pharmacologists are well placed to design trials and provide ongoing pharmacovigilance. Their expertise also allows them to lead in establishing NHS clinical research facilities, develop their standard operating procedures, respond appropriately to regulation, engage with colleagues in the life sciences industry, and provide overarching clinical support. These clinical research facilities have the potential to be accredited by the MHRA and could, over time, gradually lead to an increase in UK-based late stage clinical trials.

An improved environment for experimental medicine in UK hospitals will in turn foster clinical pharmacology skills in the medical workforce, which it is hoped will result in a virtuous circle of further interaction with industry and further growth in early stage trials.

“ Research is a frontline activity for the NHS if it is to meet the challenges of new technologies, new demography, and new patterns of illness while remaining efficient and effective. 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. Britain's strength in this kind of work so far is in no small measure down to the success of clinical pharmacology as a discipline, but we need to do more still. ”

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

“ Clinical pharmacology brings a unique set of experience and expertise which are key in early phase accreditation drug trials, which allow patients' access to the most innovative treatments available through cutting edge drugs, technology and science. Clinical pharmacologists are not only ideally suited to design the clinical trials themselves, but are also well suited to take care of the volunteers within them as practicing general physicians. ”

Dr Richard Fitzgerald, Consultant, Clinical Pharmacology and Therapeutics and General Medicine, Royal Liverpool and Broadgreen University Hospitals NHS Trust

Spotlight on the clinical pharmacology and therapeutics consultant workforce

Data from the Federation of the Royal Colleges of Physicians' census of the consultant physician workforce show that the size of the CPT consultant workforce has fluctuated significantly over the last decade, ranging from a low of 52 consultants in 2006 to a high of 77 in 2012².

Table 2: Actual figures of consultants, 2002-2012

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Consultants in all medical specialities	7,582	7,854	8,279	8,541	8,716	9,135	9,545	10,522	11,225	11,810	12,221
CPT consultants	74	68	61	60	52	57	58	66	67	73	77

The CPT workforce remains significantly smaller than is required to cope with either existing need or rising demand. For comparison, from 2002 to 2012 the rest of the medical workforce has increased year-on-year with a total increase of 62% (4,636 consultants) in consultant physicians working in the UK, with only a 4% increase (3 consultants) in CPT consultants in the same time period.²

Figure 6: Percentage change in the number of CPT consultants and consultants in all other medical specialities in the UK, comparing 2003-2012 to 2002

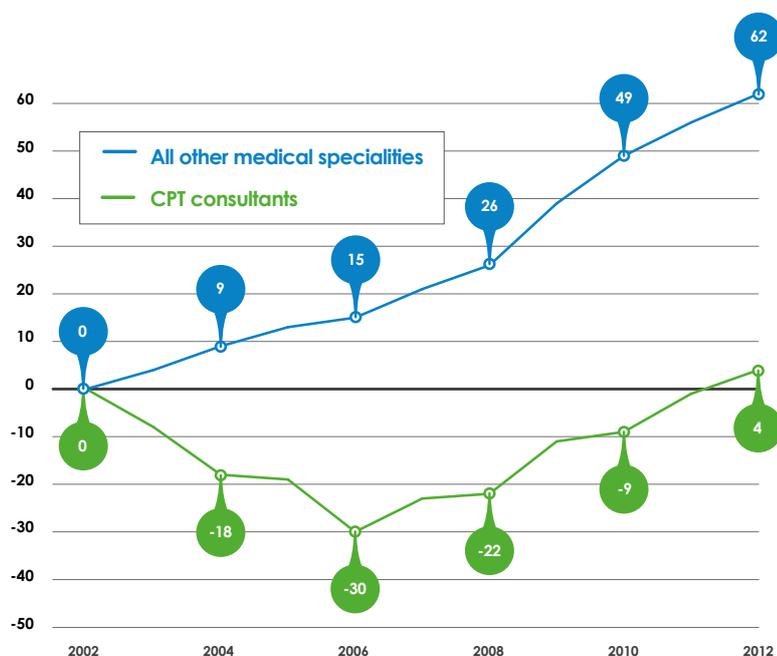


Figure 7: Number of CPT consultants



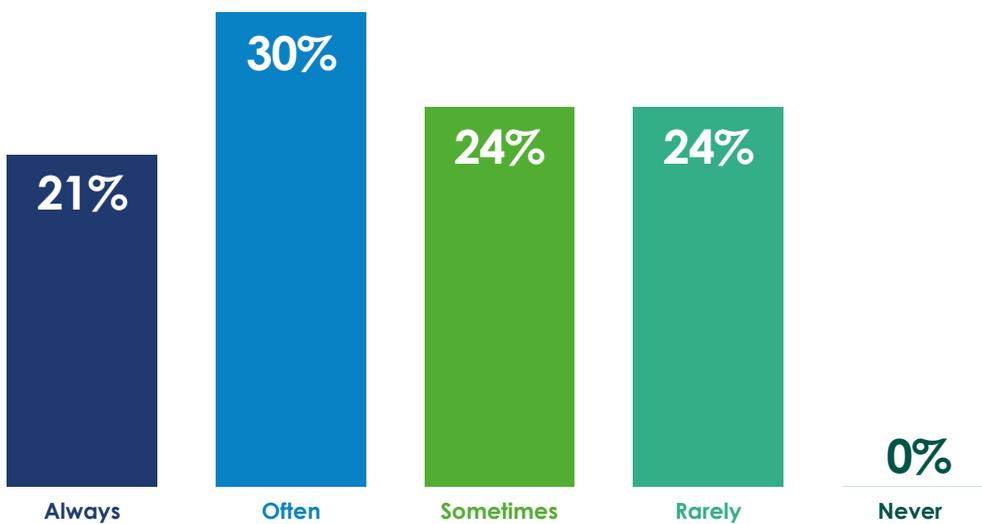
The Royal College of Physicians of London has recommended that there should be a whole-time equivalent workforce of 440 CPT consultants, one in each large district general hospital serving a population of 250,000 and one per 180 medical students in training⁹. While this figure is aspirational, increasing the number of consultants to 150 over the next decade is thought to be achievable⁹.

Pressure on clinical pharmacologists

The existing clinical pharmacology workforce is substantially overburdened. CPT consultants are known to contribute a higher proportion of supporting professional activity to the NHS than any other specialty, and conduct significantly more clinical work than they are contracted for².

One in five CPT consultants reported that they 'always' work under excessive pressure, a larger proportion than consultants in any other clinical specialty².

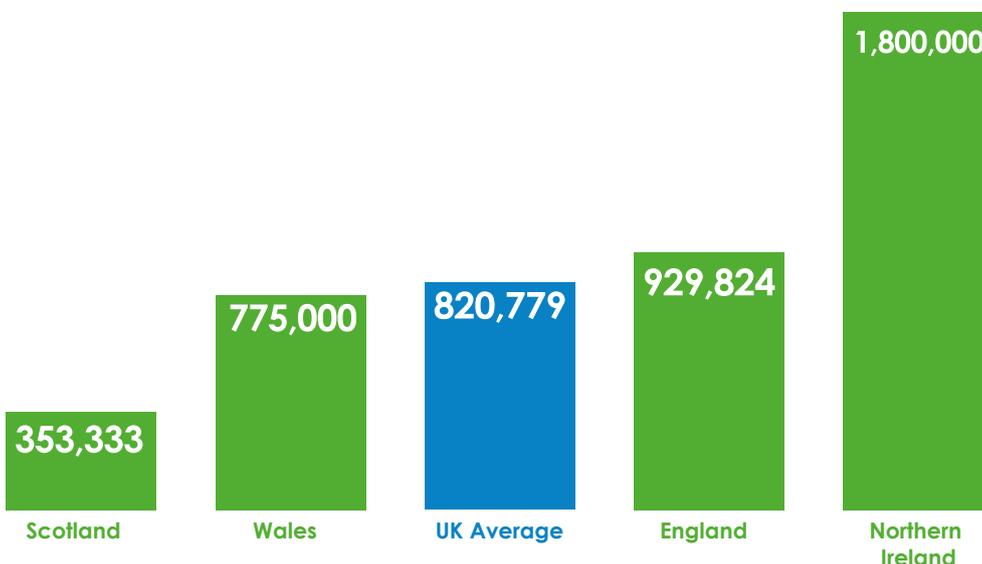
Figure 8: Proportion of CPT consultants who feel that they work under excessive pressure



The distribution of CPT consultants across the UK

The CPT consultant workforce is distributed unevenly across the UK nations, with 57 in England, 15 in Scotland, four in Wales, and one in Northern Ireland². As a result there is widespread variation in the size of the population served by each consultant.

Figure 9: Number of people per CPT consultant in each UK nation



Registrar training posts

27 CPT consultants (35% of the current workforce) are expected to retire over the next decade, and a substantial increase in the number of registrar training posts is therefore required to take on their responsibilities². However, over the last five years the number of clinical pharmacology and therapeutics registrars has decreased significantly from a high of 54 in 2010 to lows of 34 in 2011 and 2013⁴¹. The lack of consultant posts in CPT has had a detrimental impact on recruitment at registrar level, as junior doctors will naturally prefer specialties where they are more likely to progress into secure future employment.

Figure 10: Number of CPT registrars per year



This trend must be reversed to prevent a decline in the attractiveness of clinical pharmacology as a specialty and a future reduction in the number of CPT consultants. This can only be done through the development of clear career pathway accompanied by an increase in the number of specialist registrar and consultant posts.

Looking ahead

In terms of the current workforce, there is a need to increase the number of current consultants because the level of demand on the clinical pharmacology workforce is expected to increase significantly in the coming years. This increase is driven by a number of factors including:

- The increasing need to contain the medicines budget by assessing the clinical and cost-effectiveness of new and expensive drugs
- The rising number of acute general medical admissions
- The growing number of medical students and the associated increase in teaching and training responsibilities for consultants
- The reduction in junior doctors' working hours and associated increase in the consultant workload
- The limited availability of clinicians running specialty services to provide acute medical cover
- The ageing population and an increasing prevalence of complex long-term conditions and co-morbidities is also expected to increase the demand on services across the NHS as a whole.

Conclusion and recommendations

Clinical pharmacology is an exciting specialty that is perfectly positioned to support the NHS to respond to the changing nature of drug development and drug use, and support the NHS to meet the strategic challenges of the 21st century.

Clinical pharmacologists make a vital contribution to the health of patients and the wealth of the NHS, providing unparalleled generalist and specialist expertise across the breadth of its services.

Significant progress has been made in improving the UK's academic expertise in clinical pharmacology through the Medical Research Council's and the Wellcome Trust's initiatives, and in improving prescribing practice through the British Pharmacological Society's collaborative project with MSC Assessment: the Prescribing Safety Assessment.

However, the benefits that clinical pharmacology can provide to the NHS have not yet been fully realised. The British Pharmacological Society believes that enhancing the contribution of the speciality will require a co-ordinated approach across the entire health system over the medium- to long-term.

The British Pharmacological Society therefore calls on the organisations responsible for workforce management in the four UK nations to:

1

Ensure that NHS organisations across the UK have equitable access to CPT consultants' expertise

2

Commit to increase the size of 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

About the British Pharmacological Society

Formed in 1931, the British Pharmacological Society, including its Clinical Pharmacology Section, is the professional association for pharmacologists in the UK and is one of the leading pharmacological societies in the world.

The British Pharmacological Society has, at its heart, the development and promotion of pharmacology and of those who are training and working in the field. With over 3,000 members from 60 countries around the world, we are a truly international organisation.

We cover the whole spectrum of pharmacology, including laboratory, clinical, and toxicological aspects, and support our members at work in academia, industry and the health service.

The British Pharmacological Society promotes and advances pharmacology, including clinical pharmacology and therapeutics, in the following ways:

- **Assisting, promoting and encouraging research, and providing a forum for the presentation of pharmacology**
- **Publishing the results of research**
- **Promoting and encouraging the education and training of pharmacologists**
- **Publishing resources in various forms**
- **Promoting and arranging conferences and meetings**
- **Providing expert advice and opinion to policy-makers and media**

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