BRITISH PHARMACOLOGICAL SOCIETY

Investing in UK clinical pharmacology will save and improve lives

The Society, as part of the Clinical Pharmacology Skills Alliance (CPSA), welcomes the UK-wide government vision - "**Saving and improving lives: the future of UK clinical research delivery**" - that aims to "to create a patient-centred, pro-innovation and digitally enabled clinical research environment, which empowers everyone across the NHS to participate in delivering research and ensures that patients from across the UK are supported to take part in research that is of relevance to them".

The vision recognises the extraordinary challenges posed by the COVID-19 pandemic – particularly pertinent as it was published a year after the first lockdown. Despite these challenges, it was a year in which UK clinical research rose to the occasion. Researchers, healthcare professionals, industry, regulators, and participants have collaborated on world-leading trials, supporting global recovery from the pandemic by delivering proven treatments and vaccines.

Clinical pharmacology, a medical specialty and scientific discipline focusing on the safe, effective and cost-effective use of medicines, has been a golden thread running through the COVID-19 response, helping patients access evidence-based treatments and care. UK clinical pharmacologists have played a central role, with contributions that span **research design, discovery, development and delivery** (e.g., through running national platform trials like RECOVERY and developing potential interventions including monoclonal antibodies and vaccines), **regulatory decision-making** (e.g., through rapid approval of COVID-19 vaccines) and **patient care** (e.g., clinical leadership for surge hospitals in Cardiff and Birmingham, and advice on therapeutics in a time of uncertainty).

In this article we set out how clinical pharmacology can be a fundamental part of delivering the government's vision – and we are asking government to partner with us on a workforce strategy that will enable it to do so.

For all its impact and potential, UK clinical pharmacology is at risk. Over the past few years, the CPSA has worked at a ground level to raise the visibility of, and recruitment to, clinical pharmacology. We have made great strides: filling all training posts in the most recent round and taking the number of UK clinical pharmacology consultants from 72 to 100. We have an ambition to reach 150 clinical pharmacologists by 2025. Based on calculations by PwC[1], we estimate this would cost an additional £6.9m per year - but the same report showed that for every £1 invested, this would save nearly £6. Moreover, decision making about the medical workforce is split across the NHS, Health Education England, industry and local trusts, making it hard to be strategic about planning. Through investment and government support for a strategic coalition to drive growth of clinical pharmacology across the NHS academia and industry will build on the work that has underpinned research success in COVID-19 and realise the full potential of UK clinical pharmacology. Working together, we can grow a clinical pharmacology workforce that saves and improves lives on a national scale. If we do nothing, we risk losing a critical area of strength. The time to act is now.

Clinical pharmacologists are experts in the development and use of medicines. They investigate the mechanism of action of potential therapeutics, working to translate these into clinical use through the design and delivery of innovative trials, and ensuring safety and effectiveness through regulatory evaluation and pharmacovigilance. They support the uptake and implementation of therapeutics through health technology assessment, advise local formularies, drive prescribing education[2] and work on the frontline as general physicians who take an integrated approach to patient care. Their roles are critical across life sciences and healthcare.

The current Government Chief Scientific Adviser, Sir Patrick Vallance, is a clinical pharmacologist whose experience in R&D enabled him to drive the UK's vaccine strategy and advise government on pandemic decision making at the highest level. Sir Patrick has reflected that principles of clinical pharmacology including dose, randomisation, evidence-based medicine and risk-benefit have been the "bread and butter" of discussions with government during the pandemic and should be at the heart of future UK clinical research strategy. Sir Patrick advocates for a leadership role for clinical pharmacologists as part of creating a vibrant and innovative clinical research and life sciences ecosystem for the future.

Clinical pharmacologists can help the government achieve its ambitions by supporting each of the five key themes in the new vision:

1. **Clinical research embedded in the NHS**
   NHS staff and patients engaged with research at an unprecedented scale over the pandemic. Clinical pharmacologists led national platform trials including RECOVERY and AGILE, ensuring that partnership with NHS staff was embedded in trial design and delivery.

2. **Patient-centred research**
   Clinical pharmacologists can help reach more patients with research through de-risking early phase studies in primary care and the community. Safety is paramount in first in human studies and clinical pharmacologists are qualified to be principal investigators on such trials. Investment in clinical pharmacology can also support a patient-centred, evidence-based approach to care - for example through managing multimorbidity, problematic polypharmacy and a personalised approach to the use of medicines.

3. **Streamlined, efficient and innovative research**
   Investment in clinical pharmacology can support the UK to deliver trials across all phases of research. Clinical pharmacologists evaluate risk-benefit, through a structured approach to levels of evidence, mechanism, dose and safety. They advise on proportionate regulatory decisions, supporting trial set up and approval, whilst ensuring safety, effectiveness, and quality standards.

4. **Research enabled by data and digital tools**
   Clinical pharmacologists can support the recovery of, and advance, non-COVID-19 research through innovative digital trials. This will help to not only widen participation in trials, but also enable quicker and more cost-effective recruitment, leveraging the huge benefits of the NHS at both primary and secondary care levels.

5. **A sustainable and supported research workforce**
   Clinical pharmacology is one of the few medical specialties with research in its curriculum. Clinical pharmacologists are well-placed to support education and training of healthcare professionals. Clinical pharmacologists are currently developing introductory training for healthcare professionals to support research capability in the NHS.

The vision sets ambitious goals to support the research capacity and capability of the NHS, as part of a patient-centred and integrated approach to care. Research drives better patient outcomes[3,4,5,6] but it still will not be easy to achieve the systems and cultural change that will be needed to realise the potential of this strategy. The vision rightly takes a step-wise approach, cognisant of the pressures on frontline service and NHS people at

a still challenging time. It recognises the need to balance long-term goals with the short-term imperative to ensure recovery - of people and of research. Ultimately, it recognises the need to invest in, and support the workforce – so that recovery means recovering back better, so no one is left behind.

We fully support the ambition to develop a culture of research and evidence-based care. Clinical pharmacology can help, but it needs help. Implementation of the vision is the time to think carefully about the investment, stewardship, and creative training solutions[7] that can make this a reality. We are keen to work with the government and contribute to the Recovery, Resilience and Growth programme to help deliver the ambitions of this vision, which we share.

Long read – how clinical pharmacology can save and improve lives through helping to deliver the government's new vision.

1. Clinical research embedded in the NHS

NHS staff and patients engaged with research at an unprecedented scale over the pandemic. Clinical pharmacologists led national platform trials including RECOVERY and AGILE, ensuring that partnership with NHS staff was embedded in trial design and delivery.

Clinical pharmacology made contributions across all stages of the research and regulatory pathway. From the simple, large scale, phase III RECOVERY trial that was rolled out across the NHS, to the early phase AGILE trial (Professor Saye Khoo, Dr Richard Fitzgerald and Dr Lauren Walker in Liverpool) that worked through primary care and the community to run phase I and IIa trials with candidate therapeutics targeted at the early stages of the disease, aiming to address the therapeutic gap in enhancing viral clearance.

Clinical pharmacologists also advised on which candidate drugs should be prioritised for all the national COVID trial platforms (Professor Sir Munir Pirmohamed, Professor Duncan Richards, Professor Ian Hall), supporting a rational and coordinated approach to the therapeutic pipeline. Further, Chief Scientist of Genomics England, Professor Mark Caulfield, has worked with a UK wide genomic consortium (GENOMICC) to run whole genome sequencing in patients with COVID-19 to identify new therapeutic opportunities[8]. Clinical pharmacologists within industry gave advice and support to help identify medicines that could be considered as potential treatments for COVID-19 and supported vaccine development. This covered medicines that had already been approved for other indications - some of which ended up in the RECOVERY trial - and early-stage products that had a suggested mechanism of action or results that supported a possible use in COVID-19.

The RECOVERY trial, led by Professor Peter Horby and clinical pharmacologist *Professor Martin Landray*, demonstrated the benefits of dexamethasone and tocilizumab and definitively established that hydroxychloroquine, ritonavir, convalescent plasma and colchicine were not beneficial in hospitalised patients with severe COVID-19 disease. It was an excellent example[9] of a simple yet adaptive, trial, delivered rapidly and at scale. The platform design[10], was just as important in terms of stopping therapies which do not work. It has had a global impact on treatment guidelines, shows the value of simplified platform trials beyond COVID-19. Dexamethasone by itself has been estimated to have saved around one million lives worldwide and around 22,000 lives in the UK[11].

Observational studies embedded into routine clinical care are another opportunity to create a platform-based approach for discovery and delivery. Working with the NIHR's Clinical Research Network (CRN), Professor Reecha Sofat used adoption onto the NIHR CRN to leverage collection of 10000 participants presenting to stroke services in two years. Data collected through the study is now being linked to electronic health care data, genomic

and other blood-based data. This provides a platform for discovery for drugs that can be used to target subtypes of stroke, and when such discovery's mature also provides a platform which can be used for trial participation including digitally enabled trials. Frontline clinical and research staff facilitated recruitment to the study, supporting its success.

On the RECOVERY trial, Professor Landray recognised the importance of making research accessible to healthcare professionals and being realistic about capacity and capability. Speaking to the BMJ, he said:

> *"It had to be easy for the clinician on the ground, in PPE and in a pressurised situation, and a minimal burden for the patient. Many academic and commercial trials have accumulated so much extra baggage over the years, such as long case report forms and 10-page patient consent forms."*

Professor Duncan Richards is also co-investigator on the HEAL study (which will address the excess mortality observed in people recently discharged from hospital having had COVID-19) where he is responsible for developing study design and coordinating the selection of therapies for inclusion in the study. He has also led clinical planning at Oxford University, and has reflected on the importance of partnership with frontline NHS staff and the opportunity that clinical pharmacologists have to deliver patient-centred trials that are cognisant of the reality and needs on the ground.

At the beginning of the pandemic and amid great uncertainty, Professor Reecha Sofat and colleagues established the COVID-19 Therapeutics Advice & Support Group. This is a group of experts in multiple specialties that collaborate on the appraisal, formulary work and implementation of access to medicines for COVID-19. This information has been made available to frontline clinicians across more than 20 Trusts with the aim of supporting evidence-based care and to support recruitment to trials. The group provides updates to guide use at a local level, bridging the gap to formal guidance while evidence is emerging. Clinical pharmacologists in Wales also developed a COVID Therapeutics information website for healthcare professionals. There is potential to build on this framework in partnership with NICE to improve connectivity of the therapeutic evidence base with decision-making on the ground.

2. Patient-centred research

Clinical pharmacologists can help reach more patients with research through de-risking early phase studies in primary care and the community. Safety is paramount in first in human studies and clinical pharmacologists are qualified to be principal investigators on such trials. Investment in clinical pharmacology can also support a patient-centred, evidence-based approach to care - for example through managing multimorbidity, problematic polypharmacy and a personalised approach to the use of medicines.

The AGILE trial team pioneered expanding early phase research into primary care and the community. Beyond COVID-19, primary care is where the majority of disease burden lies and so creating platforms that are not reliant on recruitment through secondary care removes barriers to patient engagement with research. Moreover, widening participation in this way may address unacceptable health inequalities, ensuring recruitment is representative of the population for which the medicines are being developed. Investing in clinical pharmacology supports such research to go ahead because clinical pharmacologists are qualified to be principal investigators on first in human trials, mitigating against the higher risk associated with early phase research.

> *"Through AGILE, we are filling a gap in potential treatments for COVID-19 by looking earlier in the disease – trying to stop people from getting sick to begin with. The*

pandemic has challenged us to think creatively about how we do research. We have been actively recruiting patients by embedding our work into primary care and the community - chasing up on positive test results and recruiting people with early symptoms.

We've seen lots of benefits for the patients and have been able to refer those who need further care onto services through the trial rather than putting additional burden on A&E departments. We've seen tremendous buy in from patients and primary care – even to the extent that we set up a portacabin in a GP car park! Our experience is that patients are much more aware of the benefits of research now and want to get involved. We have noticed that the healthy volunteer recruitment is much higher than usual, and we are starting to see this transferring over to other disease areas too.

There's a real opportunity to build on this, and with more clinical pharmacologists the UK could do even more of this work."

Dr Richard Fitzgerald, Director of the NIHR Royal Liverpool and Broadgreen Clinical Research Facility, consultant clinical pharmacologist, and one of the leads on the AGILE trial.

Investment in clinical pharmacology can also improve patient outcomes by addressing health challenges such as the growing burden of multimorbidity and problematic polypharmacy, and by realising the potential of personalised prescribing. Clinical pharmacologists are working across the health service to support an evidence-based approach to the safe and effective use of medicines.

As the population ages, people increasingly have multiple co-existing chronic diseases (i.e., multimorbidity)[12], necessitating the use of multiple medicines - over 1 million people take 8 or more medicines per day, this is referred to as polypharmacy. As the number of medications increases, so does the possibility of drug interactions and adverse drug reactions resulting in hospital admission and further morbidity[13,14.] Over 1.1 billion prescription items are dispensed in the UK community setting every year[15]. Although medicines have many proven benefits, 6.5% of all hospital admissions are caused by adverse drug reactions, and 237 million medication errors are made in the NHS every year[16,17]. The costs relating to these adverse reactions and medication errors is a significant burden on the healthcare budget (over £1.6 billion/year).

Clinical pharmacologists including Dr Lauren Walker, Dr Fran Bennett, Dr Andrew Scourfield, Professor Reecha Sofat and Professor Emma Baker are also working across the UK as the Polypharmacy Service Consortium, a collaborative venture between Clinical Pharmacologists, Clinical Pharmacists, Geriatricians and General Practitioners with a vision that "every medicine brings worthwhile benefit to the person for whom it is prescribed". Their focus is to help the patients with complex polypharmacy, but also to support education and training of healthcare professionals. The coming challenge will be to address multimorbidity, to which polypharmacy is both a contributor and consequence. Moreover, as the natural history of COVID-19 is more precisely understood its contribution to multimorbidity will be too.

Professor Emma Baker and Dr Rupert Payne contributed to the National Overprescribing Review. Professor Baker is co-chair of the Polypharmacy subgroup of the Regional Medicines Optimisation Committee of NHS England, promoting best practice in polypharmacy. Emma Baker and Chris Threapleton contributed to NHS England policy on the structured medication review and GP contractual framework.

The genomic revolution is also likely to have a profound effect on the practice of medicine. The 100,000 genomes project has already highlighted the utility of using genomic data for diagnosis in rare diseases, and in identifying novel drug targets for targeted anti-cancer therapy. The 100,000 genomes project, which was developed as a transformational NHS-facing initiative, has led to re-structuring of genomics laboratory services, and the development of the NHS England Personalised Medicine Strategy. Pharmacogenomics is the study of how genetic variation affects drug response, both efficacy and safety. However, knowledge of pharmacogenomics is poor in the clinical community, and ability to engage with and implement the outcomes of this research may ultimately negatively impact patient outcomes.

Clinical pharmacologists, led by Munir Pirmohamed, working in collaboration with NHS England and Genomics England, are already playing a leading role in developing the plans for implementation of pharmacogenomics in the NHS, and are well-placed to support education and training of the wider NHS workforce. Pharmacogenomics is a tangible example of how genomics can be relevant to every individual as in our lifetime we will all require medicines in some form. As such, upskilling of the NHS workforce is important, and clinical pharmacologists are leading a working party with the Royal College of Physicians to define training needs for the use of pharmacogenomics in the NHS.

3. Streamlined, efficient and innovative research

Investment in clinical pharmacology can support the UK to deliver trials across all phases of research. Clinical pharmacologists evaluate risk-benefit, through a structured approach to levels of evidence, mechanism, dose and safety. They advise on proportionate regulatory decisions, supporting trial set up and approval, whilst ensuring safety, effectiveness, and quality standards.

The RECOVERY trial did not require Principal Investigators to provide GCP certificates to take part. This was one of several examples, including the use of remote monitoring and site visits, that demonstrated how proportionate regulation could help the UK realise ambitions of setting up trials more quickly.

UK's long-standing leadership in medicines regulation and safety also meant that the UK was able to prioritise assessment, and progress decisions quickly. The MHRA has played a vital regulatory role in supporting vaccine manufacture, licensing and global standards for COVID-19 vaccines. Professor David Webb, a clinical pharmacologist, is deputy Chair of the MHRA Board. Not only did MHRA support the rapid approval of a range of platform trials, including RECOVERY, the UK was the first country globally to licence the Oxford-AstraZeneca and Pfizer-BioNtech vaccines. Professor Sir Munir Pirmohamed (Chair of the Vaccine Benefit-Risk Expert Working Group) and other clinical pharmacologists including Professor Jamie Coleman were responsible for advising the MHRA through their role on the Commission for Human Medicines (CHM), ensuring COVID-19 vaccines meet the highest standards of quality, safety and effectiveness. Sir Munir was recently appointed Chair of the CHM, recognising his expertise and long-standing contributions to medicines regulation.

UK clinical pharmacologists also provided advice on the appropriate pathways to use for COVID-19 study approval via the MHRA, EU National Medicine Regulatory Agencies and the US FDA, and subsequently the possible regulatory emergency approval pathways. For UK based projects, advice and support was given in relation to applying for the NIHR Urgent Public Health Priority designation for medicines.

Further, MHRA post-Brexit innovative Licensing pathway[18] will require dialogue between industry and various groups that will involve clinical pharmacologists to bring innovative

medicines to patients efficiently. University departments of clinical pharmacology might be nodal points that can provide regulatory science links to support the work of MHRA. For example, Professor Isla Mackenzie, Professor Tom MacDonald and colleagues have set up a UK-wide online study[19] to track COVID-19 vaccines and provide data to support vaccine monitoring that will report to the MHRA.

As therapeutic interventions become more complex, so do regulatory decisions. Clinical pharmacologists in the NHS, academia and industry have the expertise to consider risk-benefit decision making in innovative ways. For example, rethinking the boundary point at pre and post marketing assessment could help the UK to be a world-leader on real world evidence collection – more robust evidence of high generalisability in the clinical context would mean less need to collect data in large expensive trials. Interrogating risk-benefit across a product life cycle in this way could support therapeutics reach patients at an earlier stage. This is the area of regulatory science, and clinical pharmacologist will be able to work with the MHRA to maintain and strengthen the UK as a leading global regulator.

In addition to medical skills, enhancing the UK's capability to deliver clinical trials will depend on investment in clinical pharmacology scientists. Following cross-sector consultation about the challenges in addressing scientific skills gaps, the CPSA worked with a Trailblazer Group to develop a Clinical Pharmacology Scientist (level 7) apprenticeship in response to industry concerns that there was not a clear training pathway for these important roles. The Clinical Pharmacology Scientist will design, analyse, interpret and report clinical research and clinical trials aimed at understanding what a drug is doing to the body (pharmacodynamics), what happens to a drug in the body (pharmacokinetics), and how it works in terms of treating a particular disease. They will also offer clinical pharmacology expertise to resolve issues that arise during conduct of studies. It is a varied role, supporting the discovery and development of new medicines, and improving understanding of existing ones. The apprenticeship was formally approved by the Department for Education in October 2020, and we are now working with partners to enrol the first intake of apprentices. An integrated approach to workforce planning should include investment in scientific and medical clinical pharmacology skills.

4. Research enabled by data and digital tools

Clinical pharmacologists can support the recovery of, and advance, non-COVID-19 research through innovative digital trials. This will help to not only widen participation in trials, but also enable quicker and more cost-effective recruitment, leveraging the huge benefits of the NHS at both primary and secondary care levels.

Clinical pharmacologist, Professor Tom MacDonald, has supported the recovery of non-COVID-19 research through innovative digital trials - for example on Pragmatic Randomised Open Blinded Endpoint (PROBE) trials[20], including some, like the Treatment in Morning versus Evening (TIME) study[21], that have involved patient recruitment and data collection entirely online. Clinical Pharmacologists can advise on appropriateness and likely validity of trials conducted outside clinical settings, such as at home or via roving clinics. Innovations like this have huge potential to decentralise trials and engage patients with research that is relevant to them[22].

Investment in data, and data interoperability is needed to realise the potential of patient data across the NHS and research pathway. Clinical pharmacologists can advise on data priorities and strategy. Working with Health Data Research-UK (HDR-UK) and Office for National Statistics (ONS), and with approval of the Government Office of Science, Professor Sir Munir Pirmohamed has also been leading the development of the data infrastructure require to undertake research following the roll-out of vaccines. This has included developing data linkages needed to ensure vaccines data at the point of

vaccination, as well as data from hospitals are available for research purposes in a timely manner. Investment in clinical pharmacology and a broader data skills base will support this work and broader applications of it in the future. A data strategy for medicines more broadly will enable support for all aspects of drug discovery, cost-effective delivery as well as supporting regulation and linked pharmacovigilance to create an agile mechanism for the safe use of medicines in society.

5. A sustainable and supported research workforce

Clinical pharmacology is one of the few medical specialties with research in its curriculum. Clinical pharmacologists are well-placed to support education and training of healthcare professionals. Clinical pharmacologists are currently developing introductory training for healthcare professionals to support research capability in the NHS.

Formalising research as part of the NHS system will require alignment across NHS strategy and workforce planning – and investment in education and training. As one of the few specialties with research in its curriculum, clinical pharmacology is well-placed to help build research capacity and capability in the NHS. One way of doing this is through support for education and training for all healthcare professionals. The Society and the Royal College of Physicians are partnering on developing research training with the aim of building confidence and competence in research across the NHS workforce.

Next steps

We hope this article demonstrates the breadth of contribution that UK clinical pharmacology has made over the course of the pandemic – and could continue to make with appropriate and coordinated investment.

We congratulate government on its far-reaching and ambitious vision, recognising the challenges that still lie ahead and extending our support for the next phase of this work. In turn, with the right support from government, we can act as stewards of UK clinical pharmacology workforce to help save and improve lives across the UK whilst also being a part of bringing forward the medicines that will see the UK recognised as a world-leader in the development of evidence-based therapies of the future. We look forward to working with government and the sector to develop the implementation plan that will deliver this vision, for the benefit of patients and the UK as a 'science superpower'.

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