Written evidence from the British Pharmacological Society to the CQC consultation on its strategy for 2021 and beyond

About us

The British Pharmacological Society (BPS) is the primary UK learned society concerned with supporting safe and effective use of medicines through research into drugs and the way they work. The Society has around 4,000 members working in academia, industry, regulatory agencies and the health services, and many are medically qualified. The Society covers the whole spectrum of pharmacology, including clinical, laboratory and toxicological aspects. The science of pharmacology is essential for the development and testing of medicines, and for their adoption in clinical practice. Teaching and research in pharmacology and clinical pharmacology are crucial to a thriving healthcare workforce, and to the pharmaceutical and biotechnology industry in the UK. Members of the Society identify therapeutic areas of clinical need, develop novel treatments that target these areas and ensure these new treatments are incorporated into healthcare practice bringing benefit to patients and saving the NHS money. The Society publishes three scientific journals: the British Journal of Pharmacology, the British Journal of Clinical Pharmacology, and, in collaboration with the American Society for Pharmacology and Experimental Therapeutics, Pharmacology Research and Perspectives.

Executive summary

We support the Care Quality Commission's (CQC) ambition to adjust the way they work to improve care for everyone and welcome the opportunity to submit evidence to this inquiry. The health and care of a population is an area which must have robust regulation. The CQC is responsible for making sure health and social care services provide people with safe, effective, compassionate, high-quality care and it encourages care services to improve. Our response focuses on how CQC can help drive access to research and improvements in safe and effective prescribing, for the benefit of patient health. In both cases, we suggest that CQC assessment can help drive the training and learning culture that would help realise these ambitions.

Driving improved patient outcomes through improving access to clinical research

The COVID-19 pandemic has brought into stark reality the importance of clinical research in hospital-settings, as is exemplified by the success of the RECOVERY trial[1]. The development of new medicines and treatments is essential to address unmet clinical need, bringing benefit for both society and the UK economy[2]. A recent 'Creating Time for Research' report[3] from Cancer Research UK, sets out how healthcare staff can be supported to conduct research. Supporting innovation that delivers to public needs, such as drugs and therapies for elderly patients and healthier ageing, is part of NHS England's Research Plan[4] and an NIHR Research Priority[5]. A system-wide Recovery, Resilience and Growth (RRG) programme[6] has been established to ensure the UK is able to take a

[1] https://www.recoverytrial.net/

[2] Keogh, B 'The NHS rose to the challenge of Covid, but its next test may be even harder' Guardian February 2021

[3] https://www.cancerresearchuk.org/sites/default/files/creating_time_for_research_february_2021_-_full_report-v2.pdf

[4] NHS England. (2017) NHS England Research Plan. Available at: https://www.england.nhs.uk/wp-content/uploads/2017/04/nhse-research-plan.pdf

[5] National Institute for Health Research. (2015) Statement on Areas of Research Interests. Available at: https://www.nihr.ac.uk/research-and-impact/research-priorities/areas-of-research-interests.htm

[6] https://www.ukrdleaders.org/2021/01/14/dhsc-guidance-on-prioritisation/

coordinated national approach to guarantee the recovery of the UK's clinical research delivery and restore a diverse and able research arm as soon as is sensible.

For the health and care system to truly support the patients it serves, embedding research into care must be a priority. Research is an integral part of clinical practice, polypharmacy, multimorbidity and medicines management. The importance of research can be inferred from sections of the current strategy, but we would strongly advocate for this to be brought to the forefront as a headline message. Research drives better patient outcomes[7,8,9,10], and this should be emphasised and incentivised.

Clearly aligning with national priorities on embedding research into care is an opportunity for CQC to make an impact, supporting implementation for the benefit of patients. We feel it would be a missed opportunity if the message on research is not made explicit: we have significant concerns about organisations being able to engage with this as a priority if it remains hidden.

To support research in the NHS, we recommend that the new CQC strategy should:

1. Clearly recognise that clinical research drives better outcomes for patients, and that lack of patient access to the benefits of research contributes to health inequalities.
2. Emphasise the importance of building research culture, capacity and capability through the use of appropriate metrics. For example, healthcare professionals must be familiar with, and have some exposure to, the disciplines and ethics of clinical research and structured data gathering. Assessment of research training provision would likely help drive improvements in training.
3. Commit to defining good practice in partnership with other organisations, investigating how systems and organisations are considering and embedding research and its translation in to practice in their culture. This will be a key part of accelerating improvement. Clinical pharmacologists are well-placed to provide advice on how to do this effectively.

Supporting patient safety through the safe and effective use of medicines

As the population ages, people increasingly have multiple co-existing chronic diseases (i.e., multimorbidity)[11], 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.

The safe and appropriate use of medicines is central to the work of the NHS in benefitting patients. However, the current workforce does not have the full skills base it needs to respond to the increasing challenges in the use of medicines. Over 1.1 billion prescription items are dispensed in the UK community setting every year[12]. Although medicines have many proven benefits, 6.5% of all hospital admissions are caused by adverse drug

[7] Jonker L, Fisher SJ (2018) The correlation between National Health Service trusts' clinical trial activity and both mortality rates and care quality commission ratings: a retrospective cross-sectional study. Public health, 157, pp.1-6.
[8] Jonker L, Fisher S J, Dagnan, D (2020) Patients admitted to more research-active hospitals have more confidence in staff and are better informed about their condition and medication: Results from a retrospective cross-sectional study. J Eval Clin Pract, 26 (1) 203-208
[9] Boaz A, et al. (2015). Does the engagement of clinicians and organisations in research improve healthcare performance: a three-stage review. BMJ Open 5, e009415.
[10] McManus RJ, et al. (2008). How representative of primary care are research active practices? Cross-sectional survey. Family Practice 25, 56–62.
[11] https://www.nature.com/articles/d41586-020-00837-4?utm_source=fbk_nnc&utm_medium=social&utm_campaign=naturenews&sf232045230=1
[12] NHS Digital. (2017) Prescriptions Dispensed in the Community, Statistics for England – 2006-2016 [PAS]. Available at: https://digital.nhs.uk/catalogue/PUB30014

reactions, and 237 million medication errors are made in the NHS every year[13,14]. The costs relating to these adverse reactions and medication errors is a significant burden on the healthcare budget.

To support the safe and effective use of medicines, we recommend that the CQC should:

1. Commit to monitoring and assessing communication about patient safety metrics:
    - Between senior management and frontline staff, to drive feedback and learning: many junior doctors are not aware when there are prescribing errors, and this can be detrimental.
    - Through incentivisation of data system connectivity between healthcare services, so that information can be better shared between institutions to improve patient safety.
    - Through monitoring and assessing the error reporting loop to encourage incident reporting and drive a learning culture.
2. The CQC should specifically look at medicine safety in organisations, this could be part of their intelligent monitoring service[15], but also culture around how prescription errors are handled and how learning is shared. Healthcare staff should be allocated sufficient time for their staff to develop professional skills e.g., for prescribing safety.
3. We recommend that the CQC strategy should include assessment of Trusts services pertaining to whether they are implementing and developing services to meet the government grand challenge of ageing society[16] e.g., evidence of specialist medicines specialist centres.

Clinical Pharmacology and Therapeutics is one of the few specialties where both research and safe and effective use of medicines is embedded as part of the curriculum. Therefore, the Society is well-placed to help support progress in both these areas and we would be keen to discuss this further.

Main response

We have categorised our evidence by the four themes, as laid out in the draft strategy:

1. People and communities

Inequalities in health and research

1.1 The strategy recognises that local health and care services and commissioners need to understand the diverse needs of their populations. To meet these needs, both primary and secondary care are striving to implement facilities that allow all members of the population to benefit from health and care services. We support calls for research communities to address these inequalities through an explicit focus on gathering data from underrepresented groups[17]. There must be measures that encourage more diverse participation in clinical research to reduce the existing inequalities e.g., research leaflets in multiple languages, advertising in areas that

[13] British Pharmacological Society. (2016) Clinical Pharmacology and Therapeutics: The case for savings in the NHS. Available at: https://www.bps.ac.uk/BPSMemberPortal/media/BPSWebsite/Assets/CPT-case-for-savings-in-the-NHS.pdf

[14] Policy Research Unit in Economic Evaluation of Health & Care Interventions. (2018) Prevalence and Economic Burden of Medication Errors in the NHS in England. Available at: www.eepru.org.uk/wp-content/uploads/2018/02/medication-error-report-revised-final.2-22022018.pdf

[15] https://www.cqc.org.uk/what-we-do/how-we-use-information/using-data-monitor-services

[16] https://www.gov.uk/government/publications/industrial-strategy-the-grand-challenges/industrial-strategy-the-grand-challenges

[17] Nature Genetics (2019). Editorial. Genetics for all. *Nature Genetics* 51, 579.

can reach out to different communities. The need to improve access to research is further emphasised in the Royal College of Physician's 'Research for All'[18] report.

1.2 The Society is a founding member of the Inequalities in Health Alliance[19], which is calling for the development of a cross-government strategy with the aim of reducing health inequalities. The influential Marmot report 'Health Equity in England: The Marmot Review 20 years on'[20] inspired the formation of the Alliance. It notes that life expectancy in England has stalled since 2010, and it worsens with socioeconomic deprivation. This is further illustrated by a University College London study which mapped the London Underground[21]. Among other stark statistics, one example was that between Lancaster Gate and Mile End (20 minutes on the Central line) life expectancy decreased by 12 years. If trusts are assessed and have to meet a certain uniform health equality standard, these inequities issues could start to be combatted.

1.3 Through our 'Vision for Equality, Diversity and Inclusion (EDI) in pharmacology'22 we highlight further inequalities in research, including the bias towards the male sex; that genetic data is predominately from people with European ancestry; the demographics of patients involved in clinical trials does not represent the real-world burden of disease and clinical trials generally exclude people with multiple long-term conditions[23].

1.4 This is a system-wide issue, but **we recommend including strong messages on research and reducing health inequalities at a headline level in the CQC strategy, and the development of appropriate metrics on research intensity, capability and impact to help drive this priority forwards.**

Multimorbidity and problematic polypharmacy

1.5 As the population ages, people increasingly have multiple co-existing chronic diseases (i.e., multimorbidity)[24], 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[25,26.]

1.6 The Polypharmacy Service Consortium is 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". The consortium includes a polypharmacy service scheme in Southwest London that will serve multimorbid patients, particularly those who are old and frail, and it also wants to encourage use of the service for those from demographics that are traditionally excluded from health care interventions, amongst others. Their focus is to help the patients with complex polypharmacy, but also to support education and training of healthcare professionals. This support for education and training is especially important, clinical members have informed us that they are seeing patients that GPs and clinical pharmacists would like help managing due to

[18] https://www.rcplondon.ac.uk/projects/outputs/research-all-analysis-clinical-participation-research
[19] https://www.rcplondon.ac.uk/projects/inequalities-health-alliance
[20] https://www.health.org.uk/publications/reports/the-marmot-review-10-years-on
[21] https://jcheshire.com/featured-maps/lives-on-the-line/
[22] https://www.bps.ac.uk/about/our-campaigns/equality,-diversity-inclusion-in-pharmacology/our-vision
[23] https://www.bps.ac.uk/about/our-campaigns/equality,-diversity-inclusion-in-pharmacology/equality,-diversity-inclusion-in-pharmacology/opportunities-for-members-(1)
[24] https://www.nature.com/articles/d41586-020-00837-4?utm_source=fbk_nnc&utm_medium=social&utm_campaign=naturenews&sf232045230=1
[25] Payne R (2014). Is polypharmacy always hazardous? A retrospective cohort analysis using linked electronic health records from primary and secondary care. *Br J Clin Pharmacol* 77 (6): 1073-1082.
[26] Rawle MJ, Cooper R, Kuh D, Richards M (2018). Associations Between Polypharmacy and Cognitive and Physical Capability: A British Birth Cohort Study. *J Am Geriatr Soc* 66(5): 916–923.

complexity, difficult medication issues or dependency on medications. The way clinical pharmacology can do this will be explored further below.

1.7 The Society is advocating for investment in such regional medicines' specialist services across the NHS, integrated care pathways to support patients with multiple long-term conditions, and removal of barriers to including such patients in clinical trials. Given the significant healthcare challenges of multimorbidity and polypharmacy and the government grand challenge on ageing society - , a recent report from the House of Lords highlights that the government is missing its key healthy ageing targets and must act now[27], **we recommend that the CQC strategy should include assessment of Trusts services pertaining to whether they are implementing and developing services to meet these challenges e.g., evidence of specialist medicines specialist centres**.

2. Smarter regulation

2.1 **Transition from primary care to secondary care and back to primary care.** Evidence from our members notes inconsistency in effective data-sharing during the cycle of primary care to secondary care and back into primary care. The medication history is a particularly challenging aspect during transitions of care as patients cannot be relied upon to accurately remember all of their medications and dosages. This can lead to harm during acute admissions if medicines are prescribed incorrectly or omitted. Medication changes as a result of the hospital admission also need to be communicated back to primary care on discharge and if done incorrectly or not in a timely manner also have the potential to cause harm. In an ideal world, pharmacists and other healthcare professionals can ring local pharmacies or GP practices but this practice is time-consuming especially during busy times when hospitals have a rapid turnover of patients. To mitigate this, some hospitals are able to have access to GP records to verify the relevant information. Other interventions such as post-discharge medication review clinics and telephone reconciliation have shown potential to improve medication continuity during transitions of care[28] . Getting this right would have many benefits, including supporting management of complex polypharmacy as discussed in sections 1.5-1.7. **The CQC should incentivise healthcare services to connect up data systems so that information can be better shared between institutions to improve patient safety.**

2.2 Related to this is the increased reliance on digital technology such as, patients ordering their repeat medications on the NHS app[29]. This has been mitigated somewhat by the ability to order on the NHS website. However, some elderly patients are not familiar or comfortable with any digital technology so this does not help them. However, improving patient confidence about how their data is used will also remove barriers to uptake. In a world where there is an ever-growing burden of polypharmacy, for regulation to be stringent, the appropriate digital infrastructure and interoperability must be put in place. It is also extremely important that digital innovations are tested and demonstrated to show clinical utility – the CQC could recommend health care services use appropriate devices. Otherwise, the health and care system could end up spending billions of pounds on digital innovations, which are later found to be useless[30].

2.3 There are considerable advantages to a systems approach, it will support medicines optimisations/polypharmacy management across the whole workforce through specialist advice and education. However, there are barriers to a systems approach,

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[27] https://publications.parliament.uk/pa/ld5801/ldselect/ldsctech/183/183.pdf
[28] https://academic.oup.com/ageing/article/49/4/558/5733075
[29] https://www.nhs.uk/nhs-services/online-services/nhs-app/nhs-app-help-and-support/repeat-prescriptions/
[30] The Lancet (2018). Is digital medicine different? https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)31562-9/fulltext

including people working in silos, professional barriers, governance issues. **We would welcome spotlight of the CQC as a driver to improve and promote systems and a learning culture.**

3. Safety through learning

3.1 The safe and appropriate use of medicines is central to the work of the NHS in benefitting patients. However, the current workforce does not have the full skills base it needs to respond to the increasing challenges in the use of medicines. Over 1.1 billion prescription items are dispensed in the UK community setting every year[31]. 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[32,33]. The costs relating to these adverse reactions and medication errors is a significant burden on the healthcare budget. Clinical pharmacologists are experts in the safe, effective, and cost-effective use of medicines. The King's Fund has already recognised the extent of polypharmacy across the NHS and the importance of clinical pharmacologists in meeting this challenge[34]. However, postgraduate prescribing training could be better and (as reported by some of our members) some healthcare professionals report their jobs are too focused on service delivery rather than professional development. As such, **the CQC should incentivise learning networks, those which allow for people of different backgrounds, professions, and specialties to teach each other. Alongside this, the CQC should encourage healthcare services to allocate sufficient time for their staff to develop professional skills, which may include prescribing.**

3.2 To have the greatest impact across the NHS, the whole workforce must be skilled in the use of medicines. We envisage a workforce across which clinical pharmacology skills are embedded[35]. To achieve this, we must address the current shortage of clinical pharmacologists in the NHS, who can lead upskilling of all healthcare professionals in the system in partnership with pharmacy. This also ties in with Health Education England's 'Future Doctor Programme' report[36], which talks of the emerging generalist who has a wide variety of competences. Not at the expense of specialist skills, but to help patients get the best treatment. These calls add further weight to the argument that the health and social care system needs to move away from being siloed, clinical pharmacology can play a key role in helping this happen. This need is in line with the strategy where it highlights "the approach of delivering care as a 'system' is very different to the 'single provider service model' that CQC was set up to oversee in 2009". Further, **we urge the CQC to demand better communication between senior management and those prescribing on the ground, many junior doctors are not aware when there are prescribing errors, and this can be detrimental**.

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[31] NHS Digital. (2017) Prescriptions Dispensed in the Community, Statistics for England – 2006-2016 [PAS]. Available at: https://digital.nhs.uk/catalogue/PUB30014

[32] British Pharmacological Society. (2016) Clinical Pharmacology and Therapeutics: The case for savings in the NHS. Available at: https://www.bps.ac.uk/BPSMemberPortal/media/BPSWebsite/Assets/CPT-case-for-savings-in-the-NHS.pdf

[33] Policy Research Unit in Economic Evaluation of Health & Care Interventions. (2018) Prevalence and Economic Burden of Medication Errors in the NHS in England. Available at: www.eepru.org.uk/wp-content/uploads/2018/02/medication-error-report-revised-final.2-22022018.pdf

[34] Duerden M, Avery T, Payne R. (2013) Polypharmacy and medicines optimisation. Available from: https://www.kingsfund.org.uk/publications/polypharmacy-and-medicines-optimisation

[35] https://wchh.onlinelibrary.wiley.com/doi/10.1002/psb.1893

[36] https://www.hee.nhs.uk/sites/default/files/documents/Future%20Doctor%20Co-Created%20Vision%20-%20FINAL%20%28typo%20corrected%29.pdf

3.3 There is limited feedback when reporting errors – of which a significant proportion are medication errors. Healthcare professionals report errors by completing a 'Datix' or 'IRL' form, this goes to senior leaders, but you rarely hear outcome of any investigation. Some argue it can feel like reporting does not go very far and thus, there is little incentive to report. Furthermore, collection of types and numbers of medication errors are needed to understand the scale of the problem and lack of incident reporting should not be seen as a good outcome[37]. **The CQC should incentivise completion of the error reporting loop – important lessons should be disseminated to staff to improve postgraduate prescribing and encourage incident reporting.**

3.4 We support a focus on investments and public health initiatives that aim to protect people from harm and reduce demand on the NHS. Clinical pharmacologists have expertise in prescribing and in drug–drug interactions, both of which are key to understanding patients taking multiple medicines and the problems that can occur. Further, current estimates suggest that approximately 65% of individuals aged 65 or older will have two or more chronic long-term conditions (LTC) and this figure rises sharply with age[38]. The skills of clinical pharmacologists can support a holistic overview of a patient's drug list and can provide advice to all prescribers when it comes to interpreting multiple guidelines. In addition, clinical pharmacologists are cost saving, with nearly £6 saved for every £1 invested[39]—e.g., through decreasing adverse drug reactions, prescribing errors and improved management of poisoning.

3.5 **The CQC should specifically look at medicine safety in organisations, this could be part of their intelligent monitoring service[40], but also culture around how prescription errors are handled and how learning is shared.** The Prescribing Safety Assessment (PSA), developed and delivered by the BPS and the Medical Schools Council, allows all medical students to demonstrate their competencies in relation to the safe and effective prescribing of medicines[41], and is an example of ensuring medicines safety and learning is embedded. It may be a helpful model to work from to set standards in prescribing post qualification and for the wider workforce.

4. Accelerating improvement

4.1 Outcomes for patients who participate in research are significantly better than for those who do not[42]. In a systematic review from the National Institute for Health Research, twenty-eight studies found that research engagement improved healthcare performance (six of these studies were positive/mixed). Seven of these studies reported improved healthcare outcomes for patients, the rest of the studies reported on improved processes of care[43]. The Royal Liverpool and Broadgreen University Hospitals NHS Trust was one the first unit in the UK to receive MHRA Phase

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[37] https://www.cqc.org.uk/guidance-providers/adult-social-care/reporting-medicine-related-incidents

[38] Barnett K et al. (2012). Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross sectional study. Lancet 380(9836):37-43.

[39] British Pharmacological Society. (2016) Clinical Pharmacology and Therapeutics: the case for savings in the NHS. Available from: https://www.bps.ac.uk/BPSMemberPortal/media/BPSWebsite/Assets/CPT-case-for-savings-in-the-NHS.pdf

[40] https://www.cqc.org.uk/what-we-do/how-we-use-information/using-data-monitor-services

[41] https://prescribingsafetyassessment.ac.uk/

[42] Jonker L, Fisher SJ (2018) The correlation between National Health Service trusts' clinical trial activity and both mortality rates and care quality commission ratings: a retrospective cross-sectional study. Public health, 157, pp.1-6

[43] https://evidence.nihr.ac.uk/alert/participation-in-health-research-may-be-linked-to-better-care-and-performance/

1 Accreditation[44] and continues to grow capacity. At any one time, the Trust has up to 400 research studies/clinical trials running across a number of various clinical settings in a wide variety of disease areas. Since 2012, over 26,000 people have been involved in clinical trials or other research projects with the Trust[45]. Alongside this, University Hospital Southampton NHS Trust, who also have MHRA phase I accreditation[46], have published a research and development strategy[47].

4.2 The field of drug development and clinical trials is an important part of the UK's success in health-related innovations, both in industry and in the NHS. The RECOVERY trial is a national UK clinical trial that aims to identify treatments that may be beneficial for people hospitalised with suspected or confirmed COVID-19[48]. It is not an exaggeration to say that this has been one of the fastest and most successful clinical trials developed during a global pandemic[49]. It was only possible because the NHS was directed to prioritise this research. Whilst this directive approach will not always be appropriate, the pandemic has shown how impactful NHS research has been on an international scale. It is not the job of the CQC to inspect and regulate clinical trials but promoting a learning environment and open and transparent culture is an imperative they must uphold. **The CQC should investigate how systems and organisations are considering and embedding research and its translation in to practice in their culture, as part of accelerating improvement. Clinical pharmacologists are well-placed to provide advice on how to do this effectively.**

4.3 Smaller initiatives around audits and quality improvement processes (QIPs) leading to service changes are also important and the CQC should examine the mechanisms, systems, and barriers in place that allow this type of innovation to happen.

4.4 The CQC strategy states it wants to 'encourage continuous improvement in quality', this could be done if those in the health and social care system are expected to embed research into care. To do this, the workforce must be 'research ready', meaning healthcare professionals must be familiar with, and have some exposure to, the disciplines and ethics of clinical research and structured data gathering. In section 1, we recommended appropriate metrics regarding research capability – we suggest that assessing the provision of research training and opportunity may be one way of doing this.

[44] https://www.rlbuht.nhs.uk/staff-blogs/research-development-blog/introducing-the-trust-s-clinical-research-unit-cru/
[45] https://www.rlbuht.nhs.uk/staff-blogs/research-development-blog/introduction-to-the-clinical-research-unit-blog/
[46] https://www.uhs.nhs.uk/Media/Southampton-Clinical-Research/Commercialandindustrymaterials/Southamptontranslationalofferinge-copyv1.pdf
[47] https://www.uhs.nhs.uk/Media/Southampton-Clinical-Research/RD-strategy-2017-2022.pdf
[48] https://www.recoverytrial.net/
[49] https://www.sciencemag.org/news/2020/07/one-uk-trial-transforming-covid-19-treatment-why-haven-t-others-delivered-more-results