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RE: Our NHS care objectives: a draft mandate to the NHS Commissioning Board  

Research underpins our understanding of disease, enabling us to develop new methods of prevention and treatment and improve the standards of care that patients receive. We are a coalition of charities and organisations who fund and support health research in the UK. We are committed to ensuring that research and innovation sit at the heart of the NHS to improve all aspects of patient care, deliver cost-effective healthcare and facilitate the growth of a strong commercial life sciences sector. We welcome the opportunity to comment on the draft mandate for the NHS Commissioning Board. Many of us are also submitting individual responses.  

Key points  

- We strongly welcome the inclusion of Research, Innovation and Growth in the draft mandate for the NHS Commissioning Board. We are pleased to see how the Board will satisfy its duty to promote the use of research and research evidence and welcome the commitment to ensure the new commissioning system promotes and supports participation by NHS organisations and NHS patients in research.  
- The Board’s responsibility to make certain the commitment to ensure payment of treatment costs for NHS patients who are taking part in research funded by Government and Research Charity partner organisations is extremely welcome. It is crucial that mechanisms are put in place to overcome practical barriers and deliver this commitment which will make a significant impact on our ability to fund research in the NHS. We are pleased to see that the Board will play a valuable role in this.  
- We welcome the publication of a choice framework alongside the mandate and we are pleased to see Choosing to participate in research included. The NHS should take steps to ensure that patients from every part of England are made aware of research that is of particular relevance to them.  
- The Board’s relationship with other bodies engaged in supporting, coordinating, funding and regulating research within the NHS will be essential to foster a culture of research.  
- The Board could take further steps to embed research throughout the NHS in order to generate future improvements in healthcare and support growth:  
  - The Board should champion steps to embed and support research and innovation as part of the redesign of NHS services to ensure high quality care.  
  - The Board can play a valuable role in ensuring standardised data collection and sharing throughout all NHS bodies and private providers, improving the quality of information available safely and securely for research.  
  - The Board can play a valuable role in championing education and training which is crucial in embedding a culture of research. We are disappointed by the lack of attention to education and training within the current draft mandate and would urge the government to introduce more detail and work to develop recognised career paths for scientists and clinical staff wishing to engage with research within the NHS to ensure that the Commissioning Board can deliver on its duty within the Health and Social Care Act 2012.
Introduction
We are a coalition of charities and organisations who fund and support health research in the UK. We share an interest in the reforms to the NHS and public health system.

We strongly welcome the inclusion of Research, Innovation and Growth in the draft mandate for the NHS Commissioning Board reflecting the NHS’s strong commitment to research. In particular, the commitment to ensure the payment of excess treatment costs associated with public and charity funded research in the NHS will make a significant difference to our ability to fund research within the NHS. We are also very pleased to see the strong focus on evidence throughout the draft mandate and the value the Research, Innovation and Growth objective places on the role of research to improve quality and outcomes for patients. The legal duty to promote research must translate into new treatments reaching patients faster than ever before. David Cameron recently referred to the NHS as one of five strengths making the UK a great place to invest in life sciences. To deliver this and attract investment and economic growth, drive efficiency savings through innovation, and ultimately benefit patients, we must embed research throughout the NHS and foster a culture of research.

The NHS Commissioning Board has a valuable role to play in delivering this. And we therefore welcome the reflection of this core role in the draft mandate and the opportunity to comment on this and the vision for the NHS outlined within this.

Will the mandate drive a culture which puts patients at the heart of everything the NHS does?

Recognising the value of research
Research underpins our understanding of disease, enabling us to develop new methods of prevention and treatment and improve the standards of care patients receive. Patients and the public are overwhelmingly supportive of research in the NHS – a poll last year found that 97 per cent of the public believe that it is important the NHS should support research into new treatments. Developing an NHS which supports research and innovation and embeds it throughout it’s activities is therefore a key factor in delivering a culture which puts patients at the heart of everything the NHS does.

We welcome the recognition of the value of research in this draft mandate, reflected by the section Promoting growth, innovation and research and Objective 17. In particular we strongly welcome the role outlined for the Board in protecting and developing NHS involvement in research and innovation, including increasing patient participation in research and driving the uptake of research findings into practice, through its leadership of the NHS commissioning system. It is important that the mandate reflects the value of research to patients, generating improvements in healthcare, in addition to the economic benefits outlined in the current draft. The Department of Health’s stated agenda to spread innovation throughout the NHS can only be successful if the research needed to develop these innovations is supported.

Education and Training
The Health and Social Care Act 2012 states that the NHS Commissioning Board must have regard to the need to promote education and training so as to assist the Secretary of State in the discharge of his duty in this regard. We are therefore disappointed by the lack of attention to education and training within the current draft mandate. To truly establish research as a core role of the NHS, we must embed a culture of research throughout the workforce and this will be facilitated by providing all trainees with fundamental research skills and experience and developing recognised career paths for scientists and clinicians wishing to engage with research within the NHS. We would urge the government to reconsider this aspect of the draft and to introduce more detail, or even a specific

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Clarifying the Board’s relationship with other bodies

We are also interested to better understand the planned relationship between the NHS Commissioning Board and other bodies engaged in supporting, coordinating, funding and regulating health research within the NHS. All of these bodies will play a role in fostering a culture of research. We would be interested to understand how the NHS Commissioning Board will engage with the National Institute of Health Research (NIHR) and Public Health England as it leads the NHS commissioning system to ensure no perverse incentives develop and all bodies work in concert towards the same ends. In particular we are interested to know if there will be statutory procedures or measurements of performance to ensure this joint working.

The Health Research Authority (HRA)\(^3\) shares a similar purpose “to protect and promote the interests of patients and the public” in health research. It will be important for the NHS Commissioning Board and the HRA to work closely together to deliver their ambitions.

Are the objectives right? Could they be simplified and/or reduced in number; are there objectives missing? Do they reflect the over-arching goals of NHS commissioning?

We welcome Objective 17 focused on promoting growth, innovation and research. We are pleased to see how the Board plans to satisfy its duty to promote the use of research and research evidence and welcome the commitment to ensure the new commissioning system promotes and supports participation by NHS organisation and NHS patients in research.

We are also pleased to see the Board will have a responsibility to make certain the commitment to ensure payment of treatment costs for NHS patients who are taking part in research funded by Government and Research Charity partner organisations. Currently the treatment costs for patients taking part in research studies are covered by Primary Care Trust (PCT) commissioning budgets but negotiations over these payments can lead to significant delays in setting up research studies. The case studies below illustrate why it is very important that this hurdle is overcome to enable valuable research to go ahead within the NHS:

**Case study:** *Arthritis Research UK forced to redirect research funds due to lack of payment of excess treatment costs*

In July 2011, Arthritis Research UK agreed to fund the Arthritis Research UK Gout Trial Phase 2, a two year trial assessing the effectiveness and cost effectiveness of nurses treating patients with gout in primary care, rather than in secondary care under a consultant. The first patient was expected to be recruited in February 2012. Even though the research team had worked with the Nottingham City Primary Care Trust (PCT) to define the excess treatment costs (ETCs), when the ETCs required to fund the research nurse salaries were requested from other PCT’s in the East Midland area, the applications were refused, preventing the study from starting. In July 2012, Arthritis Research UK agreed to support these NHS costs, which increased the overall costs of the trial by 22%, so that work could get underway. The researchers have also modified their research plan to reduce costs, and are now in the process of recruiting research nurses to work on this project but to date no patients have been recruited. Negotiations also continue with the PCTs with respect to ETCs.

**Case study:** *Clinical trials of significant new treatments for MS delayed by lack of commitment to pay excess treatment costs*

The MS Society is currently negotiating two new research trials. One is focussing on translating basic laboratory discoveries funded by the Society over the last 6 years into a possible new type of therapy for people with MS, who number 100,000 in the UK. The combined ETCs for these trials would be approximately £1 million (equivalent to 25% of the

\(^3\) Health Research Authority - [http://www.hra.nhs.uk/hra/about-us/](http://www.hra.nhs.uk/hra/about-us/)
Society’s annual research budget). The Society is negotiating with the pharmaceutical companies involved to reduce the cost. However indications are that the respective PCTs will not pay for the ETCs. So far this issue has led to one of the trials being delayed for 9 months.

Case study: **Trial of insulin pumps for children and young adults delayed by lack of commitment to pay excess treatment costs**

In 2010, Diabetes UK were approached to cover the shortfall in a government-funded trial of insulin pumps for children and young adults. Although the project was fully funded, the insulin pumps were classified as ETCs, and so had to be funded through the Primary Care Trusts. Researchers spent many months negotiating with PCTs and subsequently looking to secure the funds from other sources, to allow the trial to commence.

**Difficulties arise because the current mechanisms in place for PCTs to claim for these costs are not clear or consistent.** Providing clarity and ensuring the payment of treatment costs in the new system will remove a significant practical barrier to research, so helping the Board deliver its duty to promote the use of research and research evidence. There are some existing examples of good practice which the Board may find valuable in developing this guidance, for example:

Case study: **Comprehensive Local Research Network ensures payment of excess treatment costs – meeting excess treatment costs at a regional level**

Under the previous structure of the NHS, all PCTs in the South Central region contributed part of their commissioning budget to a central pot. The South Central Comprehensive Local Research Network (CLRN) then allocated treatment costs from that pot based on activity. Coordination of this type is one example of the valuable role played by CLRNs in supporting research. More widely, the funding and practical support the networks provide (including covering some facilities costs, supporting research posts and facilitating patient recruitment) enable charitable research funders to concentrate their resources on the direct costs of research. This means that charity investment can be used to best effect.

**In delivering this objective, the Board should provide details and guidance to all those involved.**

We also welcome the commitment in the draft mandate to “promote access to clinically appropriate drugs and technologies recommended by NICE in line with the NHS Constitution.” However it is important that the Board also has a duty to promote technologies that do not have NICE guidance associated with them, but are agreed to constitute best clinical practice. This is particularly an issue for orphan medicines for rare diseases, and some advanced forms of radiotherapy used in the treatment of cancer.

As we better understand conditions and move to a more stratified approach, developing therapies targeted to sub-groups of a condition, one of the major issues in rolling out new therapies is the delay in developing diagnostic tests to identify those that can benefit from them. This is an issue particularly for genetic diseases and many targeted cancer therapies. We recommend that “and companion diagnostics” be added after “access to clinically appropriate drugs” in point two of objective 17.

**Reflecting the central role of research within the NHS to generate future improvements in healthcare, research must be embedded throughout the NHS structures.** There are important opportunities to achieve this by explicitly including steps to support research in further objectives.

**Objective 9: Putting mental health on a par with physical health.** This section references the Prime Minister’s *Challenge on Dementia* and the third aim of this strategy - to promote better research. This strategy includes increased investment in spend on dementia research. However the opportunity to reference support for research as one of the key goals for the NHS to deliver in responding to this

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4 See also response from Cancer Research UK
challenge is missed. Research is key to improving diagnosis rates, support and treatment for people with dementia and mental health issues; an increase in research and monitoring of spend on research in these areas would be welcome. We seek reassurance that support for research will not be overlooked in the indicator framework measuring delivery in this area and suggest that one of the key measures for delivery should be “Evidence that mental health research in the NHS has increased”.

Objective 14: Improving information. We welcome the Board’s role in collaboration with the Department of Health to set national information standards, to support integration and to implement electronic patient and user records. Improving the quality and integration of information across the NHS is valuable to support research.

To maximise the value of patient data for research, structured data recording in health records must be standardised throughout the NHS. For example, at present, a single disease can be recorded and coded in many different ways and free text added, and changes in an individual’s health status are difficult to monitor. This impairs the ability to collate and link data, and the validity of analysis for research. Work to support integration of patient records should consider these issues. The Royal College of Physicians Health Informatics Unit has published evidence and consensus based standards for clinical record keeping which have been widely endorsed, and are the first steps in a professionally led national programme of development and implementation throughout the NHS, which could offer significant benefits for research in the future. These should be considered as information standards are developed.

In some areas, a lack of systematic data collection is a limitation to research. For example, although there is good data collection in some areas of musculoskeletal services including joint replacement, in consultations for people with arthritis referred to specialists in hospital rheumatology departments, data is not recorded about the patient’s arthritic condition or treatment. Nationally-led expansion of NHS datasets in these ‘data poor’ areas would facilitate research, and in turn lead to improvements in care and outcomes.

Researchers often experience difficulties in accessing local datasets such as those held by individual GP surgeries which can prove a barrier to valuable research, or limit the reach of projects such as the one below:

Case study: Overcoming challenges when linking maternity data in England & Wales

When a baby is born in England, birth and maternity data are routinely recorded in three separate national data systems, each of which records different information. In Wales, four systems are involved. The aim of this project was to link these datasets together, increasing the scope of maternity data collected, for use in both statistical analysis and research.

The initial phase of the project linked data recorded at birth registration, which are mainly socio-economic, with data recorded when NHS numbers are allocated to newborns. The latter dataset contains information such as the baby’s ethnicity and the amount of time the mother had been pregnant, providing data on numbers of preterm babies.

Linking data on the birthweights of babies born in England and Wales and lengths of the associated pregnancies, with routinely collected data on parents’ countries of birth allowed the researchers to highlight variations in the extent of preterm births in babies of women from individual African countries, rather than just grouping these children into a single ‘black African’ category.

These linked datasets can be used to identify groups of women more likely to have interventions during birth, or to compare levels of infant mortality in different countries. However, problems with the processes required to access data and delays in releasing information have proved a major barrier to this research.

5 http://www.rcplondon.ac.uk/projects/generic-standards-clinical-records
6 Funded by the Medical Research Council as part of the Joint Wellcome Trust/Research Councils Electronic Patient Data Initiative
As a national body, the NHS Commissioning Board can play a valuable role in expanding the data collected and ensuring standardised data collection and principles for sharing data safely and securely throughout all NHS bodies and private providers. The value of facilitating the quality and flow of patient data for research should be considered as this system is developed. This will be a valuable step in delivering the goal of "comprehensive, transparent, and integrated information and IT, to drive improved care and better healthcare outcomes".

**Objective 20: Redesigning services to ensure high quality care**

This section outlines,

‘one of the aims of the Government's reforms is to create more flexibility for NHS services to adapt and evolve, to respond to the choices of patients, meet new health challenges, take advantage of new technologies and medicines, and improve the quality of care.’

Those delivering NHS services must be supported to recognise the value of research, enabling them to engage with research and utilise the results. This understanding, and the flexibility to adapt and evolve that it brings, will strengthen their ability to take advantage of new findings, technologies and medicines to improve the quality of care, pulling new innovations through the system.

We are pleased to see that the Secretary of State’s four tests outlined in objective 20 reflect the value of research, stating the importance of a clear clinical evidence base underpinning services. We welcome the proposal that the Board be assessed on its support of appropriate redesigns to enable NHS services to meet the four tests. The Board should champion steps to embed and support research as part of this redesign of services.

**Objective 21: The Board’s own commissioning**

As the Board is responsible for around £20 billion of direct commissioning, including specialised services for patients with rare conditions, we would be interested to understand how the Board will fulfil its duty to promote the use of research and research evidence in its own commissioning. For example, research conducted in primary care settings will be within the Board’s remit. We welcome the proposal for the Board to be assessed on its payment of excess treatment costs when funding this research. As outlined above, this commitment is important to ensure practical barriers to research are removed.

With a national commissioning role in rare diseases, the Board should play a role in ensuring the rapid implementation of the UK plan for rare diseases. We would be keen to have further clarification on the role the Board will play in implementation of other national strategies, for example *Improving outcomes: a strategy for cancer*.

**Annex D: Choice Framework**

We welcome the publication of a choice framework alongside the mandate and we are pleased to see *choosing to participate in research* included. As outlined in the NHS Constitution⁷, an individuals choices about their healthcare should include choices about whether and how they participate in research and it is good to see this reflected here. The consultation on changing the NHS Constitution expected later this year⁸ is a welcome step in clarifying the system to ensure the NHS does all it can to ensure that patients from every part of England, are made aware of research that is of particular relevance to them. Disappointingly, only 33% of patients taking part in the Cancer Patient Experience Survey 2011/12⁹ said that taking part in research had been discussed with them. We know that patient want to have this discussion as the same survey showed that 95% of patients who had discussed research were glad they had had the opportunity. Of the patients who were not asked about research, 53% said they would like to have been asked.

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However, patient participation in research is not just limited to the opportunity to choose whether to be involved in relevant research projects. It also includes involvement in developing the regulatory system and the research agenda. It is important that the NHS Commissioning Board recognises this aspect of patient participation in research when fulfilling its objective to promote and support participation of NHS patients in research.

What is the best way of assessing progress against the mandate, and how can other people or organisations best contribute to this?

Commenting on the key measures for assessing progress in objective 17:

- Evidence that the treatment costs for patients who are taking part in research in the NHS are paid by the Board when it commissions services.
- Evidence that the Board has used its systems and processes to ensure that treatment costs for patients who are taking part in research in the NHS are paid by CCGs when they commission services.

We are pleased to see the payment of treatment costs included as a measure of the NHS Commissioning Board’s delivery of objective 17. As stated above, ensuring the payment of these costs will remove a significant practical barrier to research. As a major issue to our members, AMRC monitors this area closely and will be seeking evidence to ensure this commitment is delivered in practice. We would be happy to share our findings with you and can offer to undertake a short periodic qualitative review to support this assessment.

- Evidence that patient recruitment to research in the NHS has increased.
- Evidence that performance of the NHS in initiating and delivering clinical research to time and target has increased.

This evidence is gathered by the NIHR Clinical Research Network Coordinating Centre (NIHR CRN CC) through their portfolio system. NIHR plays a key role in developing incentives and support to improve the performance of the NHS in this area, and will work alongside the NHS Commissioning Board to embed a culture of research. It is important to recognise the engagement of both bodies in delivery of this target and that this data is not sensitive to delays caused by factors beyond NHS control to ensure this is a fair measure. It would be helpful to provide further detail on how the two bodies are envisaged to work together to deliver these targets.

The Board may wish to consider the value of using a more comprehensive picture of clinical research activity across the NHS to further inform and assess progress in delivering objective 17. The Secretary of State could consider using data gathered by the NIHR CRN CC portfolio using the Health Research Classification System – and ensuring all research conducted in the NHS is classified in this way - to allow a more detailed ongoing analysis of clinical research underway within the NHS. If made public, this data would also prove valuable for commercial and non-commercial partners, at a national and international scale, to showcase opportunities to invest in and compliment research underway.

Do you have views now about how the mandate should develop in future years?

Research is a long-term process. Evidence suggests that it can take up to 17 years for a treatment to move from initial research to application\(^{10}\). We are pleased to see that this mandate is intended to be a multi-year document, revised each year, with objectives which will roll forward until they have been achieved. This continuity is important to provide a long-term framework for research. We hope the

Government will continue to consult widely with stakeholders as the mandate is revised and that research and innovation remain a key priority for the NHS Commissioning Board, and the entire NHS, to ensure the future excellence of UK healthcare and the UK life sciences industry.

Yours sincerely,

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On behalf of: