Background

The Royal Pharmaceutical Society is the body that represents all sectors of pharmacy, including community, hospital, industrial and academic practice in Great Britain.

We lead and support our members in the development of the pharmacy profession within the context of public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, we promote the profession’s policies and views to a wide range of external stakeholders in a number of different forums. Our vision is that pharmacists should be the universally accessible frontline clinical provider of all aspects of pharmaceutical care and medicine use. Pharmacists aim to be the healthcare professional entrusted by patients and public to take care of their every pharmaceutical need. We are the experts in medicines – their management, use and information about them.

Pharmacists play an important role in the design, delivery and dissemination of research; invention through to diffusion. Our research community has a breadth of knowledge and expertise across academic disciplines of the formal, natural, applied, social and behavioural sciences. Furthermore, as the third largest health profession, pharmacists are integral to delivering effective patient care in the NHS as front-line clinicians, managers, commissioners, educators, researchers and policy makers.

Pharmacists already make a significant contribution to the vision outlined in this strategy and the profession should be considered a key partner in delivering the aspirations outlined.
1. Do you agree with the vision outlined in the strategy? How can this be improved?

Research is often cited as “everybody’s business” in the NHS and while it is consistently referenced throughout health and social care policy it remains low on the priority list for many; a nice to do if you can fit it in. Greater efforts are required to ensure that “everybody’s business” is not merely rhetoric within the NHS and that all are committed to contributing to a strong culture of research and innovation. Therefore, we are supportive of the vision outlined in the strategy, in particular, to build a culture where all believe that “research is a primary function aligned to patient care and continuous improvement”.

However, while a national strategy is to be welcomed we believe the practical implementation of such a strategy at a local level (through, for example, leadership, culture change and system improvements) will pose the greatest challenge in realising this strategic vision.

Furthermore, it has to be recognised that the current health system is operating under significantly financially straightened times. While research and innovation in the NHS will seek to meet this challenge, the research strategy will also require significant NHS resource (including staffing) to deliver the vision. This tension must be acknowledged and addressed through prioritisation of research at national and local levels, working collaboratively and expanding research workforce capacity (across all staff in the NHS) so that research can be supported without disrupting vital patient care.

Research prioritisation should first focus on those issues where:

1. There are no solutions
2. There is limited evidence
3. There are large costs
4. There are complications
5. There is poor patient care/outcomes
6. The process is inefficient

Research priorities will then be focussed on the areas of greatest need, where a significant difference can be made.

2. Does the strategy reflect NHS England’s responsibilities? How can this be improved?

We believe that the strategy does reflect NHS England’s responsibilities and that there remains a pressing need to further change culture and remove barriers to research which seeks to improve outcomes for and experience of patients and the public.

Currently, the focus of the strategy is on research that supports commissioning and service redesign, and has not explicitly identified a responsibility for encouraging clinical research. We would hope that NHS England recognises its responsibility to support all research (evaluation and audit) which seeks to improve outcomes and experience of patients and the public. We would also stress that while RCTs are considered gold standard they might not always be the merited approach to informing the complex, multidimensional challenges in the NHS due to, for examples, issues of feasibility and affordability.

The challenge of evidence-based commissioning should not be underestimated. Local variation in population need and resource availability, coupled with the fact that there is rarely a one size fits all approach when it comes to service delivery, means that more thought should be given to how evidence-based commissioning can be supported and how it will work in practice.
Research which seeks to support service redesign should be practical to deliver, produce meaningful outcomes that can be translated into practice and, where possible, can be replicated and scalable. The patient should be at the centre, requiring research to operate across professional boundaries and care settings.

However, research which seeks to influence policy rarely offers the final word on a given topic. The NHS England strategy is currently focussed on the instrumental use of research evidence, rather than the conceptual uses. This requires addressing in the strategy as the reality is, particularly when seeking to change national or local policies, research is more likely to:

- bring an issue nearer to, or onto, the policy agenda
- translate findings into arguments and advocacy rather than revealing an uncontested ‘truth’
- boost the persuasiveness of an existing argument.

This highlights further the role that organisations such as AHSNs, CLAHRCs, NICE (through the development and implementation of quality standards) and Cochrane will play in supporting NHS England staff and commissioners to ensure research findings are adopted locally, and best practice spread nationally.

We would suggest that a further standalone objective is included in the strategy which seeks to remove barriers to research. Issues to address within this could include:

(1) education, training and flexible career opportunities (see pages 5 & 6)
(2) alleviate burdensome and inconsistent regulation (governance and ethics) - requiring working in partnership with the Health Research Authority
(3) improve information and promotion of research opportunities (see page 6)
(4) benchmarking of research incentives across clinical trials and health research

3. Are there policies or strategies you feel need to be included and reflected in this strategy? Which policies or strategies should be included?

We would like to see a stronger link between this strategy and the NHS England Pharmacy Call to Action – the aim of which is to enable community pharmacy to play an even stronger role at the heart of more integrated out-of-hospital services that support better health outcomes for patients, provide more personalised care, deliver excellent patient experience, optimise the use of medicines and secure the most efficient possible use of NHS resources. Given this aim, we believe the NHS England research strategy has a key role in informing and stimulating debate in relation to community pharmacy’s role in research and innovation to improve patient outcomes and experience.

We would also welcome reference to the Association of Medical Research Charities’ publication “Our Vision for Research in the NHS”[1] and greater recognition of their membership. Their vision outlines how a patient-centred, research friendly NHS could look and aligns well with the aspirations of NHS England’s Research Strategy, namely:

- The importance of using research evidence to inform commissioning.
- The need to design research around patients, and give patients and NHS staff access to information about opportunities to take part in research, its findings and how these can be used to improve clinical care.
- Ensuring all NHS staff can see the value of research and are encouraged and supported to take part including providing them with education and training opportunities to strengthen their research skills.
- The need to clarify responsibility for research costs and streamline regulation to tackle some of the practical challenges that can delay or prevent research projects from getting off the ground.

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4. Is patient, public and carer engagement and involvement reflected sufficiently? If not sufficient, what different input could be included?

The strategy should recognise and promote the work of the James Lind Alliance and members of the Association of Medical Research Charities (in addition to INVOLVE) by citing them as valued partners in this area.

5. i) Objective one

To identify and prioritise commissioning health services research topics and coordinate this work with the Department of Health, NIHR, Health Research Authority, research charities, industry and other stakeholders.

While we appreciate all stakeholders cannot be cited, we want to ensure that ‘other stakeholders’ includes learned societies, such as the Royal Pharmaceutical Society, Higher Education Institutes and relevant think tanks. Explicit reference should also be made to the need for engagement and collaborative working with Public Health England and social care providers.

While there is a separate objective identified that seeks to include patients in research priority setting, and that objective requires specific activities, we believe that patients and the public should be cited here and fully integrated into the annual process for identifying and prioritising emerging research priorities.

Devising a process for identifying and prioritising emerging research priorities and projects for NHS England is a worthwhile activity, but it is important that this aligns with (and does not duplicate) existing systems, such as those led by the NIHR and the James Lind Alliance.

We believe the process needs to capture and balance both local and national needs with mechanisms (local and national) to take research priorities forward.

Consideration must also be given to the limited time that stakeholders will have to engage in such a process. However, the process should not purely focus on online engagement solutions, but try to create local and national fora/networks (online and face-to-face) where people can come together. This blended approach is needed to allow patients, public, researchers, clinicians, managers, and policy makers to share knowledge and be exposed to a broad range of perspectives and expertise.

We welcome the partnership approach that NHS England will take to address research priorities, and the Royal Pharmaceutical Society is committed to working with NHS England on issues of common interest and promoting opportunities for our members to engage in the process of research priority setting.

5. ii) Objective two

To develop the evidence base in relation to models of commissioning to ensure the approach to commissioning services is based on best evidence and effectiveness?

This objective will require strong collaboration with Health Education England, learned societies and Higher Education Institutes to identify the education and training needs of NHS staff to support the proper appraisal of evidence.
In addition, working with learned societies, such as the Royal Pharmaceutical Society, would further support this objective given our role in producing professional standards and guidance, supporting the implementation of NICE guidance and quality standards and developing the evidence base to support better patient care.

Citing medical and nursing schools as the only healthcare professional academic institutions NHS England will engage with to strengthen the culture of evidence based commissioning and care is short sighted. NHS England must be inclusive of all those professions that are integral to patient care in the NHS and recognise the different perspectives and expertise they bring. Therefore, we would expect to see explicit mention of pharmacy and the allied health professions alongside medical and nursing colleagues.

Access to evidence is a focus within this objective, but we would query whether this is the core issue. We live in an age of information; there is a huge volume of evidence and numerous platforms for sharing such evidence. We believe that the more pressing issues are:

- Ensuring research findings are placed in the public domain in a timely fashion;
- Supporting NHS staff to sift through the sometimes conflicting evidence to identify what the appropriate action should be taken; and;
- Greater clarity on how evidence based commissioning decisions will be made at a local level, and the education, training and support needed to achieve this.

Cultural change (including creating space for the discussion of research evidence) alongside working with those organisations that support the adoption and diffusion of evidence, should be the primary action here. The Collaborations for Leadership in Applied Health Research and Care (CLARHCS) and Academic Health Science Networks (AHSNs) are cited and we would suggest that it is made explicit that it is their role to lead this work, with the proactive support and engagement of all constituent parts of NHS England.

We support the suggestion of establishing knowledge brokers/champions and would suggest that these roles are embedded in the Academic Health Science Networks, where they do not already exist.

5. iii) Objective three

To increase capacity amongst NHS England and commissioning staff to undertake research, and to utilise the outcomes of research, thereby increasing the quality of care and treatment.

Training and development opportunities should, where appropriate, be aligned with those opportunities already available to healthcare professionals. Bringing multidisciplinary clinicians, managers and wider NHS England and commissioning staff together through research training and development opportunities will strengthen the design of studies and aid delivery in the NHS. This should be inclusive of all those that provide NHS services. Pharmacists, particularly in primary care and community pharmacy (and their management colleagues), have previously been overlooked when research training and development schemes and incentives have been devised. Furthermore, pilot schemes often begin with medicine and nursing, rather than taking a more inclusive approach from the outset, resulting in other professions being disadvantaged if/when their opportunity comes to compete for access to these opportunities. NHS England needs to ensure that they are inclusive of all relevant healthcare professionals when developing research capacity and capability and that they use their influence at national and local level to encourage their partners to do the same.

The NIHR clinical academic training funding has, just this year, been opened up to pharmacists (at Masters and PhD level only) following the work of HEE’s newly established Clinical Academic Careers Stakeholder Group. This decision was informed by the preliminary recommendations from the ‘Pharmacy Research Workforce Task and Finish Group’ established by Health Education England in response to priorities in the Modernising Pharmacy Careers Post Registration Education and Training Review published in September 2012. We would strongly
encourage NHS England to support this ongoing work with Health Education England and the National Institute for Health Research to ensure equity of access to funding, so that research capacity and capability can be more evenly distributed throughout the NHS for the benefit of patients. Specifically, the Royal Pharmaceutical Society would like to see pharmacists have access to the full clinical-academic funding pathway (and associated developmental opportunities) that currently exists for nursing, midwifery and allied health before the 2014 year end. Without this equity of opportunity across all healthcare professions the aspiration to offer every patient the opportunity to take part in research will not be realised.

In addition to creating greater research training and development opportunities and extending these opportunities, greater efforts need to be made to raise awareness of existing opportunities (locally and nationally). Current awareness and promotion of the existing research infrastructure and opportunities therein by NHS managers is poor and NHS England needs to work with the NIHR to ensure all NHS staff are cognisant with the research infrastructure in England and proactively promote and encourage staff engagement.

We strongly support the action “Ensure the statutory responsibility to promote health and social care research funded by both commercial and non-commercial organisations (NHS treatment costs, including Excess Treatment Costs of patients involved in non-commercial research, are met).” NHS England’s interim guidance to Clinical Commissioning Groups (CCGs) on paying for experimental treatments allows CCGs to not pay excess treatment costs that they cannot afford or do not consider to represent a good use of resources. This is leading to an inconsistent approach across England, and has created a situation that researchers find challenging to appeal. Our members have identified this as a significant barrier to research in the NHS. As we understand it, NHS England will produce further guidance in 2014 to reflect that excess treatment costs associated with research on the NIHR portfolio and in Biomedical Research Centres and Units will be met by NHS England. We would welcome further clarification from NHS England on:

- How CCGs will decide whether excess treatment costs will be paid
- How this will work when a research project is taking place in more than one CCG area
- How studies where excess treatment costs have been formerly agreed by Primary Care Trusts should be dealt with.
- The funding of cancer drugs which form part of the Cancer Drugs Fund (CDF) list (e.g. if a trial includes a drug which is on the CDF list they will not be funded by the CDF, yet the patient could access the drug if not participating in the trial).

Work to address this issue should be a collaborative endeavour between HEE, NIHR, NHS England and Public Health England.

Work currently underway being led by the clinical research networks of the NIHR to improve the costing of projects at the design phase, so that the true costs of the research to the NHS are captured, will also support delivery against this objective.

We strongly support NHS England’s identified action to incentivise providers to take part in research. The Royal Pharmaceutical Society has developed a strategic partnership with the NIHR’s Primary Care Research Network to improve the opportunity for patients to be involved in NIHR CRN research studies by involving community pharmacy in the delivery of an increased number of studies. Community pharmacies can support the delivery of research through, for example:

- Raising patient and public awareness of opportunities to get involved in research
- Promoting suitable research studies to patients and the public (e.g. leaflets, posters)
- Identifying suitable study participants (e.g. opportunistically or through relevant clinics or via searches of the patient medication record)
- Recruiting to studies (e.g. obtaining valid informed consent)
- Supporting or delivering an intervention (e.g. taking samples, running clinics, managing patient data)
- Storing and dispensing clinical trial medication
- Advising on study design and feasibility of delivery in community pharmacy
- Providing expert advice on medicines use and optimization

To support this agenda the Royal Pharmaceutical Society has launched Research Ready – an online self-accreditation tool covering the basic requirements for undertaking primary care research in the UK. Developed by Pharmacy Research UK in conjunction with the Royal College of General Practitioners and the National Institute for Health Research Primary Care Research Network, it is aligned with the latest Research Governance Frameworks.

However, to accelerate the growth of this activity funding incentives, such as research site incentive schemes would be instrumental in building research capacity and commitment in this under developed sector. We would welcome advocacy at national and local level from NHS England’s staff and commissioning teams on this, particularly as Research Ready accreditation can be considered a quality marker amongst pharmacy providers.

5. iv) Objective four

i  To ensure the inclusion of patients in setting priorities for research and participation in the design, delivery and dissemination of research.

ii  To promote the ideal that every patient coming into the NHS is offered an opportunity to take part in research.

To be able to offer every patient the opportunity to take part in research will require healthcare professionals to be aware of actively recruiting studies (locally and nationally). This includes those providing NHS services in primary and community settings. The Clinical Research Networks have an important role to play here and should be explicitly cited as key partners in this area.

There are already good examples of community pharmacies supporting the delivery of clinical trials, such as the Salford Lung Study and a commercial study in Type 2 Diabetes and we would like to see the learning from these spread nationally, and further opportunities identified to build upon these examples (underpinned by Research Ready).

However, community pharmacy’s contribution to research is currently inhibited by their lack of access to patient records. For community pharmacy to fully support the NHS England research strategy and play their part in increasing patient and public access to research, they require access to patient health records:

- to help identify appropriate patients for studies
- to ensure the safe care of patients who are participating in studies, particularly those on trial medications
- to enable pharmacists to track patients and understand where the interventions they make impact upon patient outcomes; which is important for the effectiveness, cost effectiveness and improvements agendas.

2 Rivers, F. Salford pharmacists embark on groundbreaking phase III trial collaboration. The Pharmaceutical Journal 2012;288:272:  
3 Roe, N. Supporting GP clinical research: can a community pharmacy lighten the load? The Pharmaceutical Journal 2011;287:326:  
Therefore, NHS England must align their research strategy with wider work ongoing with the Department of Health exploring community pharmacy’s access to patient records.

5. v) Objective five

To increase the availability of information on current and completed research and research outcomes to the public.

NHS England must take steps to ensure patients are encouraged to ask about opportunities to take part in research, can find out about these opportunities themselves and choose how they would like to be involved. The Department of Health has proposed to introduce measures to ensure the commitments in the NHS Constitution are delivered and has also announced plans to increase awareness of the Constitution, including the NHS commitment to:

“inform you of research studies in which you may be eligible to participate (pledge)”\(^5\)

Therefore, NHS England needs to work in partnership with the Department of Health in the delivery of this objective. Furthermore, we support the Association of Medical Research Charities’ recommendations\(^6\) that NHS England should:

- work with other partners including charities to increase understanding of what the commitments mean in practice and what patients can expect; and,
- develop a measurable indicator which can demonstrate to patients and staff whether or not the Constitution pledges are being adhered to.

We would particularly welcome support from NHS England to broaden the uptake of the “OK to Ask” campaign led by the NIHR and the extension of this to the community pharmacy setting.

5. vi) Objective six

To maximise the benefits from research through innovation, income, knowledge improvement and impact.

Clearly this is a leadership role for the Academic Health Science Networks, but will require the full support of all constituent parts of NHS England. To effectively deliver on this agenda NHS England and commissioning staff need to be fully integrated in research infrastructure and processes, so that they can be equal partners in the design, delivery and dissemination of research. Traditional models of NHS England staff as “recipients” of research outputs will not achieve the knowledge mobilisation and impact that NHS England seeks to achieve.

The Royal Pharmaceutical Society, together with other Royal Colleges, are key partners in this work given our (earlier stated) role in producing professional standards and guidance, supporting the implementation of NICE guidance and quality standards and developing the evidence base to support better patient care. Working with partner organisations, and other pharmacy bodies we are aware of both clinical and non-clinical practice that have an under developed evidence base. In particular, we would draw NHS England’s attention to research priorities identified by our partner organisation Pharmacy Research UK and the recently published Research Framework of Pharmacy Voice.

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\(^5\) NHS, 2013. NHS Constitution  
http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Pages/Overview.aspx

\(^6\) Association of Medical Research Charities. Our Vision for Research in the NHS. May 2013.  
http://www.amrc.org.uk/sites/default/files/doc_lib/Our%20vision%20for%20research%20in%20the%20NHS.pdf [Last accessed: 27/01/14]
To contribute to the UK Plan for Growth (Department for Business Innovation and Skills, 2011) by supporting the retention of a world class research base and the timely recruitment of patients into trials, our partner group, the National Pharmacy Clinical Trials Advisory Group (NPCTAG) has been invaluable in providing advice and expertise. NPCTAG was established in its current form in 2011. Membership from across the NHS includes senior hospital pharmacists for whom Investigational Medicinal Product (IMP) management and clinical trial support forms a significant, permanent part of their roles as well, as a community pharmacist and representatives from the NIHR, Royal Pharmaceutical Society, Health Research Authority, Medicines and Healthcare products Regulatory Agency and the Pharmaceutical Industry. Over the last year, the Group has worked closely with the NIHR Clinical Research Network Coordinating Centre to develop online Pharmacy-specific Good Clinical Practice training resources and a pharmacy process map for commercial and non-commercial studies to help Sponsors to understand the role & functions pharmacy services and their responsibilities for IMP management, to anticipate and provide all the information Chief Pharmacists need to facilitate timely study set-up and streamlined delivery of studies. The Chemotherapy Pharmacy Advisory Service (CPAS) has also done significant work in this area through the review of clinical trial protocols at the draft stage to identify issues prior to protocols being implemented.

Finally, we would like to see NHS England’s public support for the All Trials campaign as we believe that to effectively promote the involvement of patients as participants in clinical trials, you must be committed to all trials being registered and all results being reported.