EVERY PATIENT A RESEARCH PATIENT?

Evaluating the current state of research in the NHS

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CANCER RESEARCH UK

A REPORT FOR CANCER RESEARCH UK

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EXECUTIVE SUMMARY

Modern medicine is built on the foundations of medical research. From understanding how to prevent cancer, discovering new drug treatments, new ways of delivering radiotherapy and new surgical techniques, research has driven the improvements in cancer services witnessed in the UK. Patients today are reaping the benefits of medical research undertaken in the past.

Cancer continues to affect millions of people in the UK each year - more than 331,000 people were diagnosed with cancer in 2011, and this is set to increase. The fact that two in four cancer patients will survive their disease (for 10 years or more) - compared to half that number 40 years ago, is testament to the progress made through all forms of cancer research. However, UK survival rates remain lower than some of the top performing countries, and there are some cancer types where we have made much less progress. Research therefore continues to be the answer to the health challenges presented by the disease leading to a better future for patients. Indeed, to sustain progress in combating not just cancer but all diseases, improvements must continue to be made through acquiring and delivering evidence through research.

Supporting research delivers further benefits. Evidence suggests that clinical research activity is a driver for high quality cancer care with there being better outcomes for patients who are treated in research-intensive hospitals (National Institute for Health Research (NIHR), 2014a). Patients appreciate the opportunity to participate in clinical research. When asked, 89% of people said they would be willing to take part in clinical research and 95% of people said it is important to them that the NHS carries out clinical research (NIHR, 2014). The economic benefits of investment in research are also considerable. Government and charity funders spend over £500m per year on cancer research annually (National Cancer Research Institute (NCRI), 2012) with estimates suggesting that each pound invested returns around 40p to the UK every year in perpetuity (RAND Europe, 2014).

Day-to-day service pressures dominate the NHS, as highlighted by the report 'Measuring Up? The Health of NHS Cancer Services' (Cancer Research UK, 2014). These pressures squeeze out time for research activities. It is important, therefore, to restate the importance of research in supporting the health system, and to acknowledge the benefits it will bring in the future.

FINDINGS AND RECOMMENDATIONS

There was universal praise for the progress made in cancer clinical research during the last decade, and in particular progress made following the establishment of the NIHR. In 2000, only around one in 26 cancer patients took part in cancer research. Now, the UK recruits around one in five cancer patients to cancer research studies, higher than any other comparable nation. This transformation is credit to the work of the NIHR and research networks.

However, we have found mounting and pressing concern about whether there is capacity and capability within the NHS to continue this progressive journey. A range of constraints were identified including:

- **the ability of people to commit time to research, in the face of mounting service pressures;**
- **the availability of key skills and experience within the workforce;**
- **financial pressures that impact in two ways - firstly in the robustness and continuity of the research infrastructure, and secondly in the close scrutiny by organisations of additional and unfunded research costs;**
- **the changing nature of clinical research.**

The following key themes were identified as critical to providing a research-active culture in the NHS. This report covers aspects of research culture that are important to achieve and relevant across all UK health services. Evaluation of the recent changes to the health system effects on research, focused solely on England.

LEADERSHIP OF RESEARCH IN THE NHS

Leadership at all levels within the research community is critical in driving the research agenda and maintain progress. This was seen to be particularly the case within NHS organisations. The role of a Trust Chief Executive as an active champion of research was felt to be a powerful means to develop a research-rich culture. In those organisations with a real sense of this, the role of research in delivering high quality care and achieving better patient outcomes was emphasised.

There is a significant degree of variation in how research is managed and undertaken within the NHS, with examples of highly motivated and highly research-active 'pockets' of clinicians within organisations, as well as organisations that have a broader coverage of research activity across teams and departments. Further growth and subsequent sustainability in research terms is likely, however, to require an approach where research activity is distributed at all levels more. i.e. more individuals, more departments and more organisations are involved in undertaking research but under the guidance of strong leadership.

Complicated and over burdensome regulation and governance of clinical research has traditionally been a barrier to running studies and trials. Progress has been made to improve these aspects under the leadership of the Medicines and Healthcare products Research Authority (MHRA) and Health Research Authority (HRA). However, there appears to be a lack of awareness and there is a potential in this area to do more to promote their work.

The Health & Social Care Act's legal duty to promote research throughout the NHS provides the necessary legislative backing to bring about a paradigm shift in the way research is interwoven into everyday care. NHS England has yet to take decisive leadership using this power by producing a research strategy, therefore leaving the NHS without a clear vision for how to achieve its legal duty.

1. **Government should maintain investment in the NIHR recognising its importance in delivering a healthcare infrastructure that has accelerated clinical research in the UK.**
2. **A comprehensive health research strategy should be produced incorporating all relevant partners, including NHS England, Department of Health, NIHR and other relevant bodies. It should set out how the Excess Treatment Costs of trials will be met.**

CAPACITY FOR RESEARCH IN THE NHS

The main concern for interviewees and survey respondents is the perceived lack of organisational capacity for sustaining current research activity and undertaking further research, specifically in relation to the time constraints on clinicians. Doctors interviewed spoke of the need for them and their colleagues to be very highly motivated to do research, in order to overcome the barriers. In addition, the core skills required for effectively managing research activity appear to be in limited supply.

There have been significant developments in the research infrastructure during the last decade and this was acknowledged by participants in the study. However, the uncertain nature of funding for research posts created logistical difficulties and was time-consuming to manage. Our study also indicates that because of service pressures, there are capacity constraints in other key areas such as a lack of chemo chairs, or limited pharmacy and radiography capacity, all of which have knock-on effects on research activity.

At a system level, interviewees commented on the reorganisation of Clinical Research Networks. Though it was felt to be too soon to comment on the impact of this reorganisation, there were concerns raised about the potential reduction of resources for, and dilution of focus on, cancer research.

3. **Within one year of full transition, NIHR should review the Clinical Research Networks to ensure that cancer research continues to be delivered effectively.**
4. **Department of Health, through the NIHR, should review the ability of Trust Boards to influence consultant contracts in order to enable research time to be set aside.**

THE RESEARCH WORKFORCE

The enthusiasm for research and the recognition of its place in improving healthcare should be nurtured at the earliest possible stage in the careers of both clinicians and non-clinicians. Pre-registration training could provide a better sense of what research involves, while post-graduate education and training could provide more meaningful opportunities for research activities to be undertaken. In addition, the importance of mentors and infrastructural support

for early career researchers was highlighted. More recognition and rewards for early endeavours could also encourage people to pursue a more research-orientated career.

The role of the clinical research nurse is clearly central to research activity. It was suggested by many of those interviewed that, in reality, the success or otherwise of research rested with this group of staff and their ability to manage the necessary processes, recruit patients and maintain their involvement, and develop effective relationships with those staff that would be required to facilitate research activity. However, current career structures and the ambiguity of their role in the wider health team can present difficulties for these staff members.

5. **Health Education England should establish a national training programme and increase the development of career opportunities for clinical research nurses. Similarly, there should be a review of the opportunities that can be offered to develop national training programmes and development opportunities for research managers, trial co-ordinators, etc.**

6. **NHS England and Health Education England should seek to incentivise and develop the profession and the research career development prospects for both clinical and non-clinical staff.**

METRICS AND INCENTIVES

The measures currently used to monitor research performance have provided organisations with a means to raise the profile of research activity. However, the dominance of patient recruitment as the primary marker of success, does not recognise the differing types of research in different disease area, or the nature of the study.

Cancer clinical research usually involves a smaller number of patients than other studies but the effort to undertake it is reported to be equivalent to other studies recruiting larger numbers. The financial reward for institutions undertaking cancer clinical research is therefore not seen to be as advantageous as clinical research in other areas. There are also potentially disadvantageous financial implications for organisations that undertake cancer clinical research, if the research requires additional costs that are not currently met by funders or the NHS.

7. **NHS England should review what new metrics are needed to measure clinical research activity so that a wider range of study types can be incentivised and rewarded. They should also identify possible disincentives in the commissioning model which can prevent certain studies taking place.**

AWARENESS OF RESEARCH

It was generally felt that the impetus for driving recruitment to trials came from researchers rather than patients themselves and that this could be improved with better communication of opportunities and awareness raising about research in general.

If cancer clinical research becomes increasingly focused on studies that are tailored to specific genetic profiles, fewer patients will be recruited, and these patients will need to be identified. In general, there was optimism about the possibilities of such research, though the logistical challenges were acknowledged.

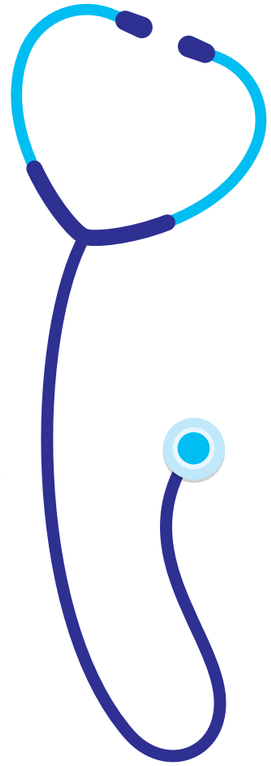
8. **NHS England, NIHR and research active healthcare sites should consider developing more strategic relationships with media channels to improve the level of awareness of research among the general public.**

RELATIONSHIP BETWEEN FUNDERS AND RESEARCHERS

The relationship between researchers and funders appears to be generally good, but there are specific areas that participants felt could be improved. It was suggested that funders and researchers could do more together to develop the research questions for the future and to ensure that the portfolio of research covers those aspects of cancer care that are seen to be of most interest and advantage to patients, service providers and commissioners of care. It was also felt that funders could work with researchers and the NHS in different ways in disseminating findings in order to speed up knowledge, and hence improve and accelerate adoption.

9. **Funders should continue to review the way in which they manage relationships with clinicians, patients, service providers and commissioners to ensure a productive and collaborative research culture.**

THE PIECES NEEDED TO BRING CLINICAL RESEARCH TO LIFE



IDEA GENERATION

- Clinical Trials Support Unit
- NHS clinicians and nurses
- National Cancer Research Institute (NCRI) Clinical Study Group

WHERE DO I GET FUNDING FROM?

- Research councils
- National Institute for Health Research (NIHR)
- Cancer Research UK
- Other charities
- Industry

WHAT DO I DO TO GET MY STUDY APPROVED?

- NHS England commissioners approve excess treatment costs
- Health Research Authority (HRA) and National Research Ethics Service (NRES) provide ethical and research governance approval
- NHS Trusts provide NHS R&D approvals
- Human Tissue Authority/Human Fertilisation and Embryology Authority (HTA/HFEA) for tissue and embryo research
- Medicines and Healthcare Products Regulatory Authority (MHRA) provide regulatory and scientific approvals

HOW DOES MY IDEA GET PUT INTO PRACTICE?

- Collaborations for Leadership in Applied Health Research and Care
- National Institute for Health Research (NIHR) Human Tissue Authority (HTA) programme
- The National Institute for Health and Care Excellence (NICE)
- Academic Health Sciences Networks (AHSNs)
- Clinical Reference Groups in NHS England

WHERE DO I GET PRACTICAL SUPPORT TO RUN MY STUDY?

- Clinical Trials Units provide regulatory support and data collection
- NHS Trusts provide clinical time to recruit and run trials
- National Institute for Health Research (NIHR):
  - Clinical Research Network provides nurses to administer treatments, supports patient recruitment
  - Biomedical Research Centres and Units
  - Experimental Cancer Medicines Centres (ECMC) provide nurses and data analysis for early stage cancer trials

WHERE DO I GET DATA TO DO MY RESEARCH?

- National Cancer Intelligence Network (NCIN) in Public Health England
- Health and Social Care Information Centre (HSCIC)
- Medicines and Healthcare Products Regulatory Authority (MHRA) responsible for Clinical Practice Research Datalink (CPRD)

INTRODUCTION

Research has driven the improvements in cancer services witnessed in the UK over the last 40 years. It has led to new drug treatments, a better understanding of lifestyle factors that can prevent cancer, new ways of delivering radiotherapy and new surgical techniques. A great deal more is also now known about the genetic changes in different types of cancer and how every patient's disease is unique. There is also evidence that clinical research activity is a driver for high quality cancer care with better outcomes for patients who are treated in research-intensive hospitals, (NIHR, 2014a).

The economic benefits of investment in research are considerable. The government and charity funders spend over £500m per year on cancer research (National Cancer Research Institute (NCRI), 2012) with estimates suggesting that each pound invested returns around 40p to the UK every year in perpetuity (RAND Europe, 2014).

However, there is still much more that is not understood about the disease, its causes and its effects. There are also huge opportunities to personalise treatment by identifying who will respond well to a particular treatment.

Investment in and commitment to, research must therefore continue in order to increase knowledge, develop more precise, effective and less aggressive treatments, and to continue to deliver the significant return on investment that cancer research provides for the UK population as a whole. The National Institute for Health Research (NIHR) is the major provider of research infrastructure and faculty that enables research to take place in the NHS. Under the NIHR banner, Clinical Research Networks (CRNs) provide the means to set up clinical studies, support patient recruitment and provide training.

The term 'clinical cancer research' can cover a broad spectrum of disciplines including not just oncology, haematology, surgery and radiology; but also pathology, molecular and cell biology, biochemistry, immunology, epidemiology, and toxicology. About 40% of the cancer research portfolio in the UK consists of research targeted at one or more particular types of cancer (NCRI, 2012a). The cancer research portfolio as a whole doubled between 2002 and 2010 and during this period the National Cancer Research Network[1] increased the proportion of patients entering clinical trials across the UK five-fold, from less than 4% in 2001/02 to 22.8% in 2011/12 (NCRI, 2012b). It has been calculated that over 330,000 people have taken part in NIHR network-supported cancer research studies since 2001. In England, more than one in every five newly diagnosed cancer patients is now participating in a trial (www.crn.nihr.ac.uk).

Responses to the 2013 national cancer patient experience survey (NHS England, 2013a) clearly demonstrate a willingness on the part of cancer patients to take part in research. However, while 85% of patients said they had seen information about research, only 32% of patients said that taking part in research had been discussed with them. There was significant variation between Trusts ranging from just 11% of patients in the lowest scoring Trust having their involvement in research discussed with them, to 62% in the highest scoring trust. Of those patients who were asked to take part in research, 64% went on to do so.

Although there have been many positive developments in recent years, there is still concern that embedding a truly research-based culture is a major challenge for the NHS. A recent report by the Association of Medical Research Charities (AMRC, 2013) identified a number of barriers which prevent clinicians taking part in research. These include; the pressure of clinical work, a lack of necessary skills and role models, a lack of practical support, burdensome regulation and a lack of information about research opportunities. The AMRC's recommendations focused on three main areas; ensuring that every patient has the opportunity to take part in research, that all NHS staff appreciate the importance of research, and that the NHS conducts high-quality research and adopts new treatments. Reducing the amount of time it takes between investment in research and its eventual impact on patients is also seen as a priority by the research community – at present it is estimated that the average time lag is around 15 years. (RAND Europe, 2014).

[1] The National Cancer Research Network (NCRN) provides researchers with practical support. It comprises the National Institute for Health Research (NIHR) Cancer Research Network in England, the Scottish Cancer Research Network, the Wales Cancer Research Network and the Northern Ireland Cancer Trials Network.

REPORT METHODS

Cancer Research UK commissioned an independent research team from the University of Birmingham's Health Services Management Centre and School of Health and Population Sciences to explore how best to embed a culture of research in the NHS. This evaluation focuses on:

- **To what extent there is a culture of clinical research within the NHS?**
- **What is currently done well in research within the NHS?**
- **What the barriers are to research within the NHS?**
- **How are NHS England and Clinical Commissioning Groups meeting their duty to promote research?**
- **What steps need to be taken to promote a stronger culture of research in the NHS?**

The evaluation takes a predominately qualitative approach synthesising data from a rapid evidence assessment (REA), expert interviews, Appreciative Inquiry events and an online survey. Semi-structured telephone interviews were undertaken to explore the views and experiences of cancer experts at a national level and from NHS staff in five case study sites. In total, 46 in-depth interviews were carried out between May and August 2014 with a wide range of participants. In order to ensure anonymity, quotations from the interviews have been attributed using only the interviewee's role. To complement the in-depth insights gleaned through the qualitative interviews, two Appreciative Inquiry (AI) events were undertaken to add to our understanding of the factors that support an embedded research culture and to generate a more nuanced and realistic account of how and why things have worked well in particular areas. The online survey was conducted to access a broader range of views on clinical research in cancer. The survey gathered quantitative evidence using fixed response questions but also contained open ended questions to elicit free text responses. It was distributed to Research and Development Departments, Clinical Research Networks, Clinical Trials Units, Experimental Cancer Centres, and CR-UK-funded Research Centres.

Further details about the research methodology can be found in Appendix 1.

DEFINITION OF TERMS RESEARCH

The term 'research' can be interpreted in different ways and with significant differences in scale and scope. In more recent years, the term 'innovation' has also been used widely, certainly within policy documents, to refer to the introduction and spread of new ways of working, which may include new treatments and processes (DH, 2011a).

The Research Activity Codes used by the UK Clinical Research Collaboration describe broad areas of research as follows: Research that underpins investigations into the cause, development, detection, treatment and management of diseases, conditions and ill health (underpinning research); the identification of determinants that are involved in the cause, risk or development of disease, conditions and ill health (aetiology), prevention; detection, screening and diagnosis; treatment development; treatment evaluation; disease management and health services research. Nearly 70% of funding in all areas of health in the UK is spent on research which is 'underpinning' or aetiology-related (UKCRC, 2012).

Given the scope of possible research activities and the ambiguities in interpretation of the term research, in this study the term research applies specifically to the conduct of clinical research within the NHS. Clinical research is dominated by clinical trials, [2]both observational and interventional[3], and also incorporates general population research using patient data which is vital in understanding cancer's effect on the general population. The findings presented here tend to reflect the former type of research activity.

CULTURE

It is also helpful to provide a definition of culture within the context of this study. Schein (1985) suggests that culture is evident at different levels within an organisation: at the most obvious level, in terms of observed actions, rituals and outcomes, that he terms 'cultural artefacts'; the second level is 'espoused values' i.e. those used to inform and

[2] Clinical trials are studies in which participants are assigned to receive one or more interventions (or no intervention). This enables researchers to evaluate the effects of the interventions on biomedical or health-related outcomes.

[3] Observational trials are those in which data are collected during standard management, while interventional studies are those in which participation in the study may alter the patient's management

justify behaviour, and the third level of culture is 'basic assumptions' i.e. the unspoken and unconscious beliefs and expectations shared by people.

In health organisations, Gale et al. (2014) also distinguish between three domains of culture: the people-culture, i.e. who is involved in decision-making and change; the patients'-culture, i.e. how patients are involved in their care, and the place-culture, i.e. the physical environment and organisational structures. Though observers may doubt whether creating an enduring set of shared beliefs is possible, the underlying assumption of this study is that it is possible to foster an environment in which research is valued, encouraged and supported, and it is this concept of culture which this study adopts. It seeks to capture what needs to be in place so that research becomes part of 'the way things get done around here' (Deal and Kennedy 1982).

The executive summary and structure of this report sets out the constituent elements of a research active culture in the NHS.

POLICY CONTEXT

NHS England has a statutory responsibility to promote research (NHS Constitution DH, 2013, Health and Social Care Act 2012 HMSO, 2012). This new responsibility, enshrined in legislation, presents a significant opportunity to build on the work of the NIHR and to transform the nature of research within the NHS, ensuring that it becomes embedded within the service. The Department of Health Mandate to NHS England (DH, 2012) requires it to: "...ensure that the new commissioning system promotes and supports participation by NHS organisations and NHS patients in research funded by both commercial and non-commercial organisations". As a result, Commissioners must ''...actively seek out research opportunities, understand where research is taking place within the providers with whom they contract and support that activity wherever possible, through their commissioning decisions,'' (DH, 2013b). While the NHS Constitution (2013) has a commitment to inform patients ''...of research studies in which you may be eligible to participate."

NHS England's latest business strategy (NHS England, 2013b) provides a list of key deliverables in relation to research and innovation including the publication of a research and development strategy for NHS England which was originally due to be published in September 2014[4].

The draft research strategy prepared by NHS England – Research is Everybody's Business (NHS England, 2013c) sets out a vision of a culture which values and promotes research and innovation, whereby, ''...all the constituent parts believe that research is a primary function aligned to patient care and continuous improvement. All stakeholders will recognise and understand the role that research plays in increasing and delivering good quality care. Managers and clinicians will share a wish for their organisation, staff, and patients and their families, to participate in research to improve the quality of services and improve outcomes,'' (p7.)

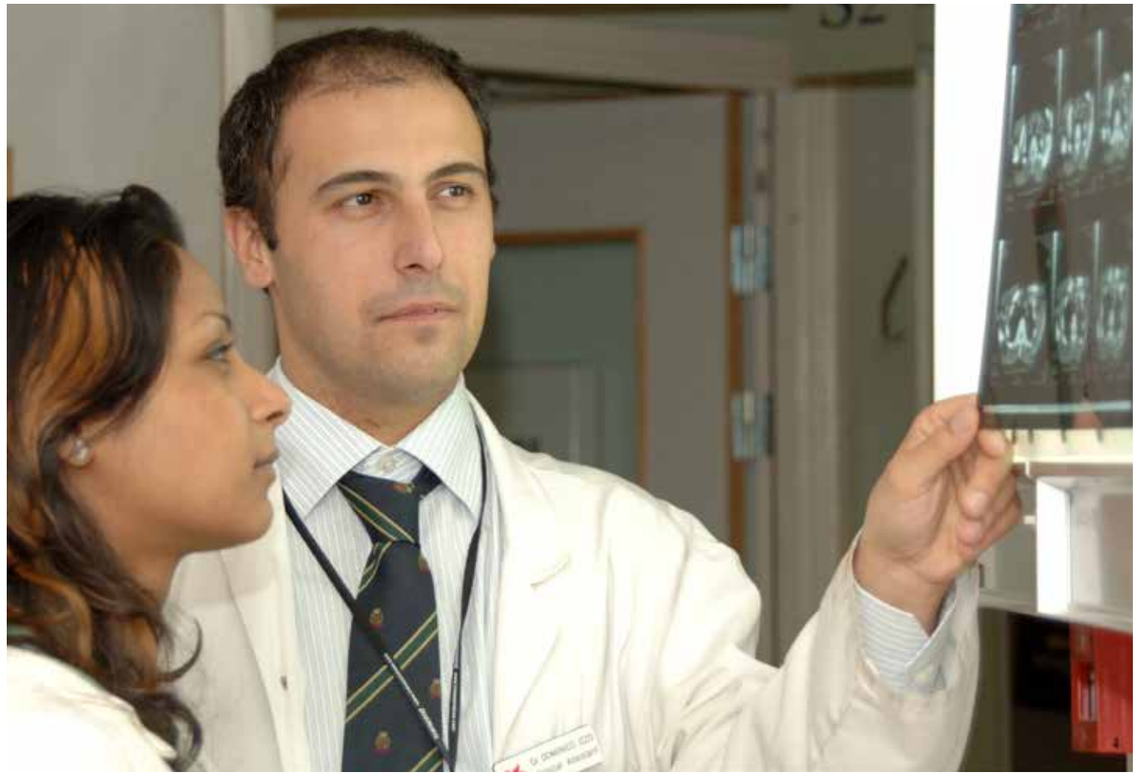
A significant amount of time has now passed since consultation on this research strategy was concluded. At the time of publication, a finalised research strategy has not yet been produced, although the Five Year Forward View document by NHS England's Chief Executive Simon Stevens sets out a vision for how research will provide the evidence needed to transform services and improve outcomes (NHS England, 2014). As this report demonstrates there is a need for clear leadership from all levels of the NHS to drive change in the system – it is important therefore, that this vision is articulated into a practical plan for all organisations involved in research activities.

More widely, the Government's "Plan for Growth" (HM Treasury, 2011) which covers the Parliamentary term up to 2015, highlights "healthcare and life sciences" as a sector to grow in the UK. The Prime Minister's Life Sciences Strategy (DBIS, 2011) similarly puts an emphasis on the need for the NHS to be research active in order to support patients and the economy. When launching the strategy, the Prime Minister declared that he wanted to make "every willing patient a research patient." [5]

The infrastructure to fund, develop, support and deliver research in the NHS is comprehensive and complex making it difficult to navigate, particularly for the lay person who is not part of the research community. A summary of the roles, responsibilities and functions of relevant research organisations is therefore presented in Appendix 2 in order to provide the context for the findings of the study.

[4] The final strategy document was still not available at the time of publication

[5] David Cameron, PM speech on life sciences and opening up the NHS, 5 December 2011



FINDINGS

LEADERSHIP OF RESEARCH IN THE NHS

The Prime Minister's commitment to make "every willing patient, a research patient" and the Health and Social Care Act's commitment to promoting research, provide a unifying force to foster a stronger culture of research within the NHS.

In order to meet these goals the health service needs to address the increasing demands on clinicians' time while strengthening the contribution to be made by the range of organisations that now play a part in commissioning and delivering NHS services. While different models emerge for how best to promote research at a local level it is clear that both strong leadership at senior levels of the health system and a commitment towards research by individuals at a local level are critical in fostering a strong research culture.

The UK is fortunate in starting from a strong research base, with the establishment and development of the NIHR receiving much of the credit for the progress made to date.

THE DELIVERY OF HEALTH RESEARCH SINCE 2006

Our research elicited universal praise for the progress made by the National Institute for Health Research (NIHR) in its work funding and supporting research since its inception in 2006. In general, the capability of the UK to undertake high quality clinical research was seen as 'exceptional' and 'ahead of the game' compared to other countries; while research in cancer was seen as a 'trailblazer' compared to research into other disease areas and conditions.

"NIHR has been transformative in changing culture – bridging the gap between basic science and translational research. It has provided lots of research funding and given academic kudos to all forms of research."
– Clinical Academic

"With the formation of the NIHR, things have got a thousand times better than they were and I think now it's more organised, there's a sense of purpose, people know what is expected of them and I think that it's much more cohesive."
– Director of R&D at NHS FT and clinical academic

Though there was universal praise for the progress made, one of the most striking observations arising from this study is that there is a great deal of variation across the country in how clinical research is managed and supported, and in the precise roles of organisations, departments and individuals. Firstly, the way in which research is conducted varies considerably between a large teaching hospital and a District General Hospital for example, where the internal infrastructure to support research is more limited in the latter.

"We are very limited by the resource made available to us from the NIHR and xx LCRN. Funding becomes more of a challenge year on year. Despite having the motivation, experience and expertise, being a DGH can be an obstacle to research expansion as we may not be the first choice of research partner for academic and industry researchers."
– Director, R&D Department

What is perhaps more surprising, however, is the extent to which there is variation among large teaching hospitals. This is often reflected in differences in the role and function of Research and Development (R&D) Departments and differing relationships with academic institutions. This appears to be the result of a combination of historic contextual factors, the influence of key individuals, and serendipitous arrangements with the funding of specific posts and/or units. There is no blueprint for how things should happen. Instead, an infrastructure develops to suit local circumstances. There was recognition among many of those interviewed that while the organic 'bottom-up' approaches have worked so far, further growth and subsequent sustainability in research terms will require an approach where research activity is more distributed at all levels i.e. more individuals, more departments and more organisations are involved in undertaking research.

"The research culture of the Trust has tended to revolve around specialities that show an interest in delivering research through links with Universities or individual clinicians who enjoy research. Plans are now being developed to extend research delivery across all Trust specialities with the aim that the whole Trust will be 'research active'."
– R&D Director

In addition to leadership at the organisational level, a number of interviewees talked about the importance of system-wide leadership to reinforce a research culture.

"We are committed to actively increasing the research opportunities to our patients. However, conflicting priorities with delivery, other targets and financial constraints mean that research doesn't have the priority we would like. To date, external bodies - CCGs, NHS England appear to have little demonstrable commitment to promoting / supporting research."
– R&D Director

There was also a plea for more clarity over the role of different stakeholders and organisations and calls for better co-ordination of the different parts of the research community to gain maximum advantage and impact from all the research activity taking place. Coupled with this, there was a feeling that the strategic direction for clinical research in the UK could be clearer.

"...there's an awful lot of stuff that the NIHR is throwing out, you've got CLAHRCs, you've got this, you've got that, you've got academic health networks. And it's an awful lot of administrative stuff going on out there, which creates more and more layers of research and 'activity' but, actually, where does it take you?"
– Clinical academic

"It's not as joined up as it could be I think is part of the problem. We've got excellent islands of basic research. We've good islands of translational research and we've got good islands of clinical trial activity and then to complete the circle, we've also got some very good people looking at implementation research. It's a question of sometimes bringing all those together and realising potential, which I think is sometimes a problem."
– Clinical academic

As well as NHS organisations coming together to provide system-wide leadership, there was also an appetite expressed for opportunities for different stakeholders such as academics, the pharmaceutical industry and funders to come together in fora to encourage more joined up thinking and creativity to flourish.

FUNDING AND SUPPORT OF RESEARCH IN THE NHS

The costs associated with research can be an issue when it comes to an organisation making decisions about the research it is able to undertake. The Government has worked closely with the academic sector in order to produce costing templates that support academic research such as Attributing the Costs of Health and Social Care Research and Development (AcoRD), but there is still a need for organisations to work better together to reconcile the tensions caused by the potential overheads associated with research. A stronger leadership steer could help to better articulate the long term benefits of research in terms of the clinical care delivered and the improvements to patients' lives.

"There is stronger support throughout the trust for research now, than at any time in the last 15 years. Finance is the limiting factor. NHS standing financial instructions prohibit using service monies for research, research network funding is static, pharmaceutical funding is limited, and clinical staff workload is immense."
– R&D Director

"The way service support and excess treatment costs are being handled, with the definition and funding for service support being constantly narrowed ...is an additional threat. It appears that funding organisations such as the NIHR are increasing pushing the support costs of research onto an NHS that is on the brink of breaking point."
– Survey respondent

Evidence suggests that in the longer-term, savings can outweigh costs for an organisation undertaking research (NIHR, 2014b), but in the shorter term, in a financially constrained NHS, extra costs can be difficult to negotiate with commissioners, or to get approved by Trust Finance Directors. Even when costs are not prohibitive, the negotiation between parties around who pays for what can mean it is difficult to get trials off the ground and delays can occur. This might prove particularly problematic with costs that are likely to be recurring for several years.

"There are many patients being treated for whom best standard of care is actually enrolment in clinical trials and research studies, and they may be on such studies for years... those of us who are

required to fund the research, we really don't have the resources for dealing with people whose care is managed in that way."
– National interviewee

However, the view was also expressed that the impact of these costs might be being magnified unnecessarily.

"We don't want to be out of pocket but if you're breaking even and you're attracting the best clinicians because you're research active and you're enhancing future patient care in a way why wouldn't you do it ... the issue of excess treatment costs ...it's made a bigger issue than it needs to be."
– AHSN, Ex-Chair, NHS Trust

Nevertheless, there was a clear distinction between the financial impact of covering the Excess Treatment Costs of enhanced NHS care for people in research trials and covering the costs of unfunded 'research' activity such as the screening of patients to determine eligibility for recruitment into trials. It was suggested that the costs associated with this particular type of activity could restrict an organisation's ability to be involved in trials that would require this sort of approach.

"If you're going to do screening, which is a sort of branch of bio banking, it's not portfolio- funded... why isn't it recognised that actually collecting samples ... is an activity we should be supporting and recognising."
– Clinical Academic

RESEARCH INFRASTRUCTURE AND PROCESSES

The infrastructure to support research emerged as an important area of interest both within the Rapid Evidence Assessment, and the empirical research. For example, Stead et al (2011) compared the accrual rates to clinical trials before and after the establishment of the National Cancer Research Network in 2001. They found that the target of doubling the number of cancer patients recruited to clinical studies in England within three years, set in 2001, was met ahead of schedule. Much of this success was attributed to the provision by the Network of over 700 staff and funded personnel whose roles focussed on the support and delivery of cancer clinical research.

Responses from the survey continue to recognise the important role of Research Networks with regards to promoting cancer research to clinicians and potential participants. There were slight differences of opinion between R&D Department respondents and respondents from other research organisations as to which organisation plays the major role in these activities, however with respondents from the latter group putting more emphasis on Clinical Trials Units, than the former.

The infrastructure that currently supports research in England and the processes that are undertaken can appear complex and labyrinthine. Add to this the variation in approach and local arrangements and it is not surprising that navigating this takes time and effort.

"...there's stuff there, but you do need to be fairly astute to access it, and there is a complexity around it... it's a bit like The Crystal Maze...it's quite a lot of time and effort, and as an active NHS clinician, that's quite difficult... I've got a trials nurse and a data manger/administrator and a data analyst person ... I'm dead in the water without them."
– Consultant surgeon

There is variation in the way R&D Departments are organised, with differences in the numbers and kinds of staff employed; the roles they fulfil and the funding streams to support the department. In one example given of a Trust where research was seen as a core activity, the support provided by the R&D Department was focused on achieving a high success rate in terms of study recruitment. In another, there was pump priming money available specifically for new researchers to get started. Departments, therefore develop in quite organic, opportunistic ways rather than in a necessarily planned, strategic way. In some areas Joint Research Departments have been established between Universities and Trusts, in other areas these are co-located, if not formal joint enterprises.

It has already been suggested that current arrangements for getting clinical trials up and running, "...continue to hinder the UK's potential for being the country of choice to carry out such studies," (The Academy of Medical Sciences, 2014). The Health Research Authority (HRA) also reports that feedback from researchers describe inconsistency in information governance processes, clinical support services and non-commercial agreements across NHS organisations. Interviewees' and survey respondents' comments reinforce these frustrations quite powerfully. Although the survey also showed that other research organisations were far more concerned with the challenge of administrative processes than R&D Departments, possibly flagging up more frustrations with internal NHS processes.

"I think a single permission centre on behalf of organisations is what we require. It's laborious, it's time consuming, it's unnecessary... I think you can save a lot of money if you have permission centres on behalf of other organisations."
– Clinical academic

To address this, work has already started to simplify procedures and the HRA is currently developing a more streamlined process to align the Research Ethics Committee approvals process with local NHS R&D approvals, reducing duplication by creating a single HRA assessment. This was cautiously welcomed, however, and concerns were expressed about the difference it would make in practice.

"I'm not terribly sure that the HRA are going to make it any more swift in the sense that OK you can have one approval but it will still be up to me to argue with my finance director that we can afford to do this ...."
– Director, Joint Research Office.

And, for smaller providers, there may still be specific logistical difficulties in linking with other organisations that may provide specific elements of activity within a research study, for national multi-site trials. This kind of collaborative working will still require negotiation and formal approval processes to be chartered.

"... we have the enthusiasm and the experienced teams, but we do rely on neighbouring Trusts for radiology, imaging, and specialist laboratory services. These co-dependencies do not infringe on our ability to get involved and deliver research as such but when approached to participate in national trials, it can make contracting a little complex."
– Director, R&D Department

For trials involving primary care providers, it is difficult to navigate the approvals process. Due to the 2012 reforms, Primary Care Trusts (PCTs) have been replaced with Clinical Commissioning Groups (CCGs) and these new organisations are working hard to understand and develop their role. Research capability and capacity have therefore not been the priority so far.

"Some of the processes are still quite laborious... and particular problems with sponsorship approvals at the moment for primary care studies... It's not clear who's going to sponsor them. Under the PCTs they had processes and systems, people in place to provide the approvals and the sort of legal status...that's not the case with CCGs."
– Director, CTU

Comments were also made about the different processes commercially-funded and non-commercially funded trials might operate when getting trials up and running and monitoring their performance.

"I know that there are contracts that have been developed at the national level, the model agreements, but actually very often if you're doing a clinical trial with a company, they'll pay lip service to the model agreement and then send you their own one anyway."
– Director, Joint Research Office

"Sometimes getting contracts in place is slower than it needs to be, that's more often driven by the sponsor not wanting the ABPI model than anything else. As soon as you get any lawyers involved it does slow down...."
– CTU Director and Chief Investigator

The sometimes disproportionate nature of the effort expended versus the risk involved was put in sharp focus by one interviewee who commented on the analysis that had been undertaken nationally of claims that had gone through the NHS Litigation Authority. Of those claims relating to patients involved in research, it was reported the number was so low as to be almost negligible.

Further frustrations were expressed about the limitations imposed by data sharing restrictions and the lack of electronic care records.

"You say, 'Oh, I wonder if they're dead or alive. I wonder if the cancer came back.' Then you say, 'Ooh, let's ask that question', and then it's a bit like a hurdle race to get through all the barriers and get permissions and to find out."
– Consultant surgeon

THE LEADERSHIP ROLE OF CLINICAL COMMISSIONING GROUPS

Clinical Commissioning Groups (CCGs) have a specific duty to promote research and the use of evidence obtained from research, as part of their

function. This duty to "promote research" can be interpreted in different ways and is not necessarily as strong a driver to foster a culture of research as some observers may believe it to be. Indeed, only 5% of all survey respondents agreed that CCGs have a major role to play in promoting cancer research to clinicians, and only 10% agreed CCGs have a major role to play in promoting cancer research to potential participants.

These results strongly suggest that commissioners of services have not yet connected with the research community in a meaningful way, perpetuating the separation between research and service delivery.

It is clear from our interviews however, that some CCGs have responded to their statutory duty positively with a number appointing an R&D lead. This role appears to be quite wide-ranging Although with responsibility for both developing the commissioning aspects and encouraging more research activity to take place within primary care.

"…. It looks at …the CCG as an organisation to see how we can make R&D more central to how we work, and how we can demonstrate that our commissioning is more evidence based than it currently appears to be."
– GP and CCG Lead for R&D

The promotion of research does not necessarily have to be the preserve of clinicians however, one CCG R&D lead discussed the potential for staff involved in commissioning activities to use the skills they might already have gained in other areas of research to develop 'research-based commissioning.

"…people have … got MAs and sometimes PhDs… but those talents and resources are not being used … so we're exploring with senior management how we could … introduce some sort of training programme/organisational awareness raising, and trying to raise the focus and priority on research based commissioning."
– GP and CCG Lead for R&D

There appears to be an appetite to influence the research agenda from within primary care, partly because there is a sense that what matters to primary care is not necessarily reflected in the kind of research questions being addressed by the main research funders.

"… that's partly why we've got involved in the CLARHC at the CCG - we want to influence the agenda. I think sometimes not only do academics take an awful long time to produce results, but it's sometimes quite difficult to see what relevance they have to day to day lives."
– GP and CCG Lead for R&D

RELATIONSHIP BETWEEN NHS AND ACADEMIC INSTITUTIONS

Relationships between NHS provider organisations and academic institutions are variable. There are inherent tensions as a result of the different drivers and goals of each organisation. Success in the clinical-academic world is judged on the amount of research income generated for the academic institution and the number of high quality research publications generated. This can cause some tension between collaborating parties in research studies, as the end goals of clinical academics and NHS clinicians may not always be aligned.

However, even within an academic institution, the attitude of the most senior figures can significantly affect the prominence given to academic clinical research and set the tone for all subsequent interactions with the NHS.

"And if the big university strategy is not to promote academic clinical research, then it seriously affects the way the NHS works. So that is a particular problem at the moment where the leadership of the university and the Faculty is actually antagonistic to clinical academic leaders."
– Clinical academic

Academics are judged by the quality of their research outputs, usually in the form of peer-reviewed articles in high impact journals. These outputs are used to determine an individual academic's REF rating (Research Excellence Framework) which at an aggregate level will ultimately affect the amount of funding Universities receive from the Government. The requirement to produce publications of high academic value can present a number of issues for the development of clinical research in the NHS.

At an organisational level, some academic institutions may appear to be quite elitist, favouring alliances with those NHS partner organisations which have a higher profile in research terms, because this is seen as being the best way to achieve a high REF rating across the organisation. At an individual level, there is a professionally competitive culture in academia which can result in behaviour which is counter-productive to effective team-working among academics and between academics and NHS practitioners.

"It's fuelled by how universities judge the success of their employees. How researchers judge the success of their peers, and the culture is one that encourages unhealthy competition."
– Clinical academic

"Universities are totally ambivalent about teamwork, they go on about it but actually when it comes to the REF, it's all about the individual, nothing at all about teamwork really. Which is why I actually think the idea of impact becoming important is helpful, because it may enable some of that really good teamwork to be recognised properly."
– Clinical academic

There were also suggestions from some interviewees that given the need to deliver high-value academic papers, some clinical academics may be selective about the sort of clinical research they undertake. It was suggested that this could have a particular impact on commercially-funded research, if the research questions were not seen to be of great academic importance, and might deter clinical academics from contributing to studies if they were not the Chief Investigator.

"…clinical academics say 'well we'll do the clinical academic research but we don't do studies where we're a participating site', so nobody does it… if everybody took the same attitude to your study in other trusts, you'd never get it done, so if you're expecting them to contribute to your multicentre study, you know, we have to repay the favour"
– Director R&D, NHS Trust

However, there were examples of strong partnerships between Universities and NHS Trusts, often signalled by a joint research function or joint committees. It is recognised, that these partnership arrangements take time and effort to establish.

"The JRE (Joint Research Executive) … has the faculty pro vice Chancellor, the Dean of Research … the great and the good from the faculty are on the committee. And from the trust point of view, … we have the chief executive, the medical director, the clinical director of R&D, so it's quite a high powered committee…."
– Director, Joint Research Office

While Academic Health Science Networks (AHSNs) are intended to provide leadership in this arena and to broker and develop relationships between academia, the NHS and industry; the way each operates varies and each AHSN has its own priority projects. AHSNs were not on the radar at all for many interviewees and those that did refer to them were sceptical about their potential to bring partners together in a more meaningful way. There appears to be a general lack of clarity across the community of what is being delivered by the AHSNs and little indication from NHS England policy documents of their achievements to date or ongoing policy projects. Promoting the work of the AHSNs nationally as well as locally is clearly important, therefore, in encouraging engagement with the clinical research community and fostering the collaboration that they were intended to deliver.

"To me the Academic Health Science Networks are absolutely critical because it is very much ensuring buy in from the senior leadership of all of the partner organisations…So that the Chief Execs and the Medical Directors have a responsibility for steering the network and therefore, a responsibility for taking it back the other way and ensuring that research becomes increasingly embedded within their organisation."
– National interviewee

KEY ATTRIBUTES OF ACHIEVING LEADERSHIP IN THE NHS

Following the Francis report, there has been much discussion about culture in the NHS and the changes that are necessary to ensure that a high quality patient experience is consistently achieved. Despite widespread acknowledgement of the importance of culture change however, there is little agreement about how it can be achieved.

Davies and Mannion (2013) suggest that we need to be cautious that top down interventions will change culture and that the "emphasis needs to be on careful local nurturing….Local contexts provide for organic, home grown approaches that are sensitive to local histories and preoccupations, and real change requires detailed and sustained work on the ground." The role of local leadership is key in developing culture, provided not only by senior managers and clinicians, but by a range of leaders. If research is to be routinely part of 'the way things are done around here', local leadership will hold the key, supported by actions to make the infrastructure and processes more supportive.

DEVELOPING A STRONG CULTURE FOR RESEARCH

There was a strong sense from the interviewees that while the NIHR was to be applauded for developing the current research infrastructure, culture could not be imposed on an organisation but would develop organically and be driven initially, at least, by a few key individuals who were passionate about research.

"... in the end it's down to individual clinicians to change their units and their practice ... in my own unit in four or five years we've gone from entering no patients at all into clinical trials to last year entering 250 major cases into clinical trials ...it's largely due to my consultant colleagues working very hard to deliver the patients."
– Clinical academic

There were examples from interviewees of Chief Executives of Trusts who were particularly pro-research and endeavoured to make strong links with academic institutions. Although even where this is the case, it is apparent that little can be achieved without the engagement of clinicians within the Trust.

"You need a managerial culture in the hospital that says, 'We are interested in research. This is important for us.' You then need a head of R&D and clinical R&D lead for the trust who's both keen and active. But then, within any given cancer and any given multidisciplinary team, you also need someone who is going to be a research or trials champion...."
– Consultant surgeon

However, interviewees were clear that the Chief Executive of a Trust has definite responsibilities as regards to setting the research agenda for organisations, and that they, together with their Executive team, have a responsibility to enable people to become involved in research.

"Everyone's kind of saying the same thing, 'We know a bit about research, we'd like to know more, we're keen on research, but we haven't got enough time. And that's where the management and trust board comes in, because if that's the perception, then it's up to the people up the top to change that...You know, people want to do it and they've got to be facilitated to do that."
– Clinical academic

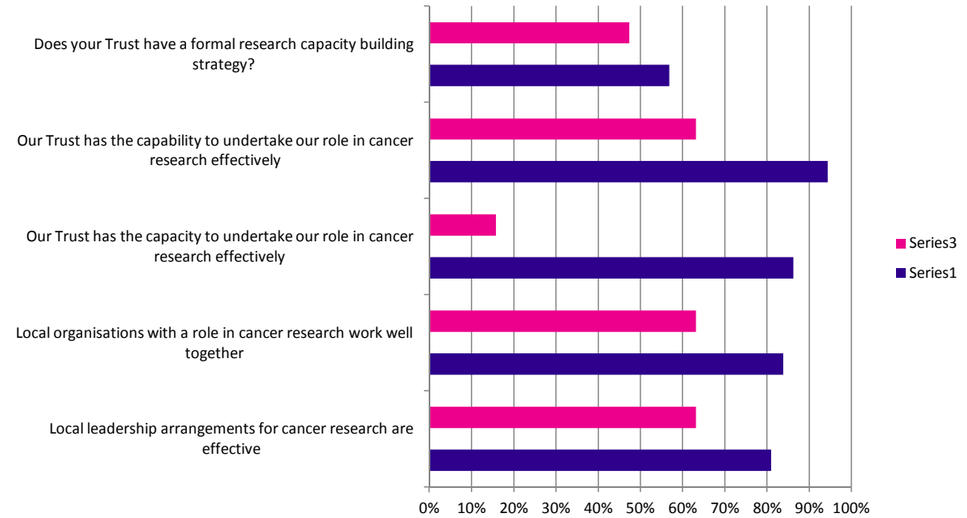
"I do have an exec lead for research and, you know, I have my one to ones with our chief exec, so I sit quite high up in the organisation because they've recognised that research is absolutely key to the organisation and so that gives me that sort of stature within to drive that strategic direction."
– R&D Director, NHS Trust

Interviewees talked about a range of initiatives or developments within their organisations that they believe had helped to foster a stronger research culture, all of which require a commitment from the leadership of the organisation to deliver or facilitate. These included Board performance reports and other communications demonstrating research activity and success, ensuring that support was in place in R&D Departments, and recruiting people who were pro-research.

"Our CE is very supportive and comes to research collaboration meetings, R&D forum. Research is frequently mentioned in monthly CE roadshow meetings. We have a monthly magazine which goes out to all staff...- this is a great way to inform all our staff about research activity within the Trust. We report recruitment as a KPI to the board."
– R&D Director

Survey respondents from R&D Departments were generally positive about their organisation's approach to promoting research, with 87% agreeing that research activities were communicated throughout their Trust and 70% agreeing that research success was celebrated.

Graph 1: Survey respondents views on the capacity and capability of their Trust's ability to undertake research.



Legend: **Series 1: NHS Trusts**
Series 2: Research organiations*

* Clinical Trials Units, Clinical Research Networks, Experimental Cancer Medicine Centres, and Cancer Research UK - funded Research Centres.

THE RELATIONSHIP BETWEEN RESEARCH AND SERVICE DELIVERY

One of the key attributes of a strong research culture for people was the clear link between research and the delivery of services, a relationship that also requires leadership to articulate and promote.

"If you look at our outcomes for cancer, we are in the top performing trusts for our outcomes... the fact we are research active is helping our mortality or morbidity...And it's getting that story over to our clinicians as well, so this isn't just a numbers game, this is also how you improve your quality of care that you can offer patients."
– Director of R&D, NHS Trust

"The more it (research) can drive service improvement I think the more likely it is to get mainstreamed within organisations like mine, and the more likely that chief executives like myself are likely to champion it."
– Chief Executive, NHS FT

Organisations employed a range of strategies to make this link clear. These involved the management team at Directorate level receiving activity reports or being accountable for aspects of research activity, and in some organisations, developing Operational Directorates into Research Directorates.

"We've done a lot of work to integrate research as part of service. We've engaged with our directorate managers of each of the areas... And they get monthly reports of the research work that's going on in their area, who's doing it, how they're performing against their targets of recruitment...."
– R&D Director

"What we're trying to do is to take the clinical directorate structure and identify ones that want to become known as academic clinical directorates, so that the research prowess of the university is reflected back into the trust and vice versa...we've got about 22 directorates, and so far we've got 15 that are clearly identified as academic clinical directorates."
– Director, Joint Research Office

It was noted that this relationship between research and service has to go hand-in-hand with an acknowledgement that research is what makes the difference to patient care.

"... there's always pressures in terms of beds, in terms of time, in terms of priorities and so you need to ...create that culture where delivering clinical research is part of proper clinical care. And if you're not doing research, you're not giving proper care."
– Clinical academic

In addition, a strong research culture will help to raise the reputation of the organisation and attract high calibre staff who, in turn, will have an impact on patient care.

"So one of the reasons we want to encourage the research culture is that we think a learning culture is a healthy one, and (is) helpful in terms of attracting the best calibre applicants for jobs. So, it's good for its own sake but it's also good in terms of the knock-on benefits for service to patients."
– Chief Executive of NHS FT

The centrality of the role of a clinical research nurse and their contribution to establishing a strong research culture within organisations, was referenced by interviewees from all disciplines. The centrality of the role of clinical research nurses was particularly clear in one NHS Trust that had recently created a Chair of Nursing in order to provide a clear leadership role, raising the visibility of research for nurses and hopefully attracting the best research nurse talent to the organisation.

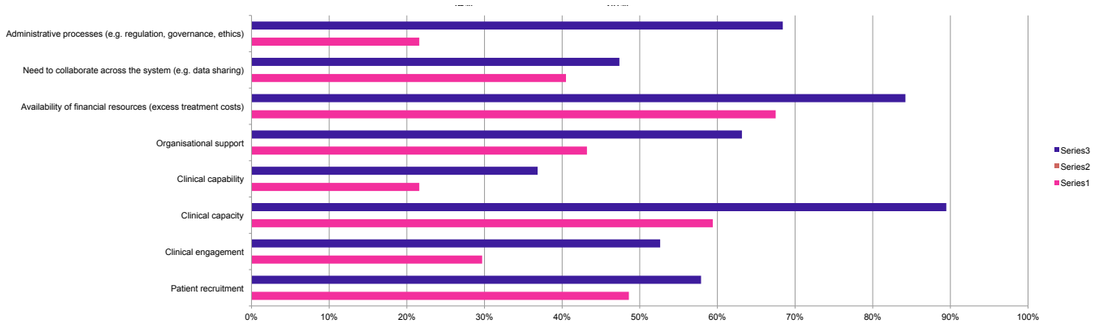
1. **Government should maintain investment in the NIHR recognising its importance in delivering a healthcare infrastructure that has accelerated clinical research in the UK.**
2. **A comprehensive health research strategy should be produced incorporating all relevant partners, including NHS England, Department of Health, NIHR and other relevant bodies. It should set out that the Excess Treatment Costs of trials will be met.**

CAPACITY FOR RESEARCH IN THE NHS

The NHS in England is under considerable pressure. Not only has it recently been through the biggest re-organisation in its history, but the NHS has also been tasked with ensuring £20bn in efficiency savings by 2014-15. On top of this, a £30bn funding gap between 2013/14 and 2020/21 is predicted if current funding levels stay as they are. These are clearly challenging times, as set out in our earlier report "Measuring up? The health of NHS cancer services" (2014a).

The findings of the report indicate that too often research is still seen by many commissioners and senior staff as an extra on top of existing service provision. As NHS capacity to deliver services continues to be squeezed, ensuring research is an integral part of care delivery and supported by adequate resources continues to be paramount.

Graph 2: Survey respondents were asked to identify the major challenges in successfully completing cancer trials in their Trust



Legend: **Series 1: NHS Trusts**
Series 2: Research organiations*

*** Clinical Trials Units, Clinical Research Networks, Experimental Cancer Medicine Centres, and Cancer Research UK -funded Research Centres.**

ORGANISATION OF RESEARCH IN TRUSTS

In spite of major advances in recent years in developing the NHS research infrastructure, none of those interviewed felt the system was perfect and there were many examples of the challenges and difficulties that remain. The most pressing of these challenges and the one mentioned most often was the capacity of the NHS for people to commit time to research. Though this might be expected within a smaller Trust such as a District General Hospital, there was consensus that all providers would find it difficult to prioritise research given their clinical commitments and current service pressures on both people and physical capacity.

The weekly Multidisciplinary Team meeting (MDT) provides clinicians with the opportunity to identify eligible patients for clinical trials in cancer but capacity is an issue here specifically, with the sheer volume of patients being discussed proving to be a barrier.

"... the amount of time per individual patient is relatively constrained and there are some patients who take longer in discussion than others, which means that inevitably there is pressure on the clinical aspect of that meeting that can make keeping in mind the clinical research questions more of a challenge...."
– Consultant surgeon

A further point of concern with regard to capacity is the perceived lack of priority given to research activities over 'normal care' activities when the research requires specific interventions or tests. An example of this was the difficulty faced in one organisation with arranging diagnostic tests for research participants when the overriding priority was providing 'normal care' for other patients. This example might indicate a particular cultural issue within this organisation but might also reflect the increasing pressure on diagnostic services for cancer care in general (Cancer Research UK, 2014a).

Service pressures were also apparent when patients receiving 'normal care' needed to be seen in dedicated research facilities because there was no clinical capacity available elsewhere.

''We've got separate clinical research facilities... but part of the problem with that is on occasions, it's getting more difficult to get research in there because we are needing to treat just normal patients, rather than patients signed up to research projects, just because of pressure on the main wards...''
– Director, Joint Research Office

Survey responses reveal a mixed picture of views between NHS provider organisations and the other research organisations surveyed, regarding the capacity of the NHS to undertake research. 86% of R&D departments that responded agreed their Trust had the capacity to undertake their role in cancer research effectively, while other research organisations were less equivocal with only 16% agreeing that the NHS organisations they worked with had the capacity to do so. What is clear, however, is that almost two in five Trusts that responded do not have a formal research capacity building strategy. It is possible therefore, that in responding to this particular survey question, R&D Departments are confident they have the capacity for current activity, rather than projected or potential activity.

CLINICAL CAPACITY

In spite of the more positive response from R&D Departments in the survey regarding overall capacity, there was universal recognition that there was not adequate time allocated for clinical research activities in consultant job plans. Only 8% of R&D department respondents and no respondents from other research organisations believed there was either adequate time, or appropriate backfill arrangements.

There is a clear distinction between clinical academics, who are doctors employed by Higher Education Institutions in a research and/or teaching capacity and who also provide services for NHS patients as part of honorary NHS contracts; and non-academic clinicians, who are employed on substantive contracts by the NHS and who might be co-investigators in research studies within their organisations. Clinical academics have protected, dedicated time for undertaking research, though working arrangements vary, with some managing their time by alternating their research and clinical activities on a week by week basis, and others managing their split commitments within their working week, with sessions dedicated to clinics, or theatre lists, administrative duties, teaching and research.

''It is different for NHS consultants and academics, so ... we're employed to see patients and operate on patients so we tend to do the research as a side-line of it...so the people who are research active, you know, they're all the people who reply to emails at 10 o'clock at night. It's different for every academic, their main focus and what they're measured on is their research output.''
– Consultant Surgeon

''A lot of medical directors are quite sceptical/ cynical about research in job plans, they regard it as an easy session I think...The joint appraisal scheme for jointly appointed clinical and university staff works very well, having two appraisers sitting down with a person because then both parts of the equation are considered and there's a nice little kind of arm wrestling ... over allocation of time and that's usually pretty healthy. But if you've just got an NHS director and an NHS member of staff, I think research would just get nodded through or blocked...''
– Clinical Academic

While theoretically not subject to the same encroachment on their research time from service requirements as non-academic clinicians, the clinical academics who were interviewed still reflected on the pressures on their time too.

''...the research time often spills out onto the evenings and weekends ...I would say that twenty percent of my time is spent doing clinical activities, twenty percent of my time is spent doing NHS administration ... and sixty percent of my time is spent doing research of which much is undertaken in my own time.''
– Clinical Academic

THE CONSTRAINTS OF NHS CONSULTANT CONTRACTS

The current consultant contract was introduced in April 2004 and is based on a full-time work commitment of 10 Programmed Activities (PAs) a week. Each consultant has a job plan that sets out the number of PAs they undertake and the duties they are expected to perform. A number of interviewees talked about how the introduction of these contracts and the use of PAs had resulted in a much sharper focus on justifying any non-clinical time, and a consequent reduction in research activity.

''Our major problem is that clinicians now are totally pressurised by NHS priorities - the time taken to attend multi-disciplinary team meetings, revalidation, all the bureaucracy now is absolutely outstanding as well as doing all your clinical work. So the thing that gets squashed, because obviously their primary job is looking after patients, is research and it's very difficult to get clinicians involved.''
– Clinical Academic

''Basically people are very worried that they're going to lose sessions, with the Trust saving money they're going to cut sessions, they're putting nurses running clinics, they regard doctors as very expensive, so obviously one way of cutting the salary bill is to reduce sessions and so ...all doctors are sort of subliminally or liminally aware of this and they therefore sort of work hard to try to justify every session.''
– Clinical Academic

Though there are means by which PAs can be 'bought out' by research monies, in order to allow consultants the time to undertake research, these mechanisms are not without attendant considerations.

''Xx is a BRC (Biomedical Research Centre – funded by the NIHR), so we're very lucky on that respect ...we ought to be able to buy sessional activities for research active clinicians but my experience in cancer is that that is not very popular because once you've lost an NHS session, you're then at the mercy of the BRC and there's no guarantee that's going to go on and then when you try and buy it back from the NHS, you know, they say they haven't got the money.''
– Clinical Academic

There was a counter-view advanced however, that these kinds of constraints could be overcome if people were really willing and enthusiastic about undertaking research.

''If you set out with the attitude that you want to recruit and develop clinicians who research then you find that they actually go the extra mile to do that research because they want to. My experience is you can make it a barrier but it doesn't need to be''.
– Chair, Academic Health Science Network, and ex-Chief Exec

Although, it was also recognised that a high level of enthusiasm and willingness to be research active was needed in these circumstances and that being broadly positive about research was unlikely to be enough of a driver.

''So if you consider a straight line, and if you consider that as neutral – (with) people on that straight line who are broadly positive about clinical trials and would wish to be helpful ... then those people are never going to be active participants ... to be an active participant, you need to get way above that line and say, 'Right, I'm really, really keen.''
– Consultant Surgeon

RESEARCH INFRASTRUCTURE

Constraints on the exact nature of the research infrastructure available to organisations and individual researchers are imposed by different business and funding models. For example, some Clinical Trials Units (CTUs) are funded in part or completely by organisations such as the NIHR, Cancer Research UK, MTC or RCS, and in universities where the number of undergraduate students is high, CTUs can in effect, be subsidised by this income source in a way that cannot happen in other academic institutions with lower student numbers. Where CTUs receive no other funding stream, they are reliant on the income generated from research projects to cover their overheads.

''It takes a lot of effort to work up grants, and it's the funding for that that we have the most trouble with... we're trying to do it by generating enough from grants to be able to reinvest, and that's not an easy economic model. NIHR put some money in so there is stuff around but ... I spend probably almost more time juggling that side of it sometimes than thinking about the science.''
– Co-Director of Clinical Trials Unit

Depending on their business model, some CTUs charge for advice and assistance before a grant is won and awarded, meaning that this can be too expensive for researchers to use speculatively and therefore the expertise and experience within the CTU is not accessible to them. Funding constraints also create additional complexities, with CTUs recruiting people to work on specific studies, only as and when they are funded. This can create some logistical difficulties and problems with cash flow.

''We don't always have somebody just sitting waiting to take up the reins of a particular study. And that can cause delays in getting people into posts and being able to crack on with the approvals process, it's further complicated by the fact that most funders don't actually release the grant until ethical approval and R&D approval are in place, but you need people to do those applications.''
– Director of CTU

CTUs specialise in certain kinds of research such as early or late stage trials, certain disease or condition areas, and certain methodologies. This means that they are not always able to support their local NHS Trusts, if the research study they want to do is outside of the area of expertise or specialisation of the CTU. There was also a view expressed that CTUs were less responsive to early career researchers, who hadn't yet built up a reputation and a profile and were unable to secure high level funding from grants.

''... you require a lot of time with new investigators to get them from A to B ... I don't think there is sufficient funding in the whole system outside of the academic health science centres for clinical trials units to help new investigators develop their skills''
– Clinical Academic

Though there is no statutory requirement for trials to be conducted through CTUs, many funders require this and therefore the capacity of units to respond to researchers has to be managed by some process of prioritisation, as one CTU Co-Director commented.

''We have a formal adoptions process and ... we practically stopped adopting because we had a bit of a backlog... not all of those are worth supporting. Some of them the basic idea is there but they need an awful lot of work and we judge we can't do that, but actually there's some which ought to be straightforward and we just can't do all of those.''
– Co-Director Clinical Trials Unit

The ability of the NHS to manage its research activities strategically at the system-level was a cause for concern for some interviewees, particularly given recent changes to the Research Network structure. The previous Cancer Research Networks no longer exist in the same form and instead Local Clinical Research Networks combine the full range of conditions and topics, with cancer now one of six divisions. This transition has yet to bed in but concerns were raised about the level of resource that might be available to cancer in the new structures.

''I think we'll have to see how all the new structures settle down, and ...we'll have to see how the resource works out for cancer. ... cancer has been very well resourced through the cancer research networks and now that resource is going to have to be shared with others as well...''.
– Consultant Surgeon

It was also reported that the perception in the cancer field is that the generic emphasis is starting to dilute the attention on cancer which might have an impact on attracting researchers.

''It's starting to erode the feeling that it's easy to bring people into the cancer field because it's starting to become a much more generic research workforce which I think is less attractive to people.''
– National interviewee

This reorganisation also meant that research staff had to re-establish who had taken on the roles and responsibilities within the new networks and re-establish relationships – all of which was time consuming and frustrating.

''...our region has changed in size and shape and has changed vastly in nature with the new clinical director and the new COO, which has had a direct impact on our research delivery staff, ... so if you're a researcher out in the patch ...it has had a knock on effect just trying to play catch up. ''
– Head, Joint Research Office

3. **Within one year of full transition NIHR should review the Clinical Research Networks to ensure that cancer research continues to be delivered effectively.**
4. **Department of Health, through the NIHR, should review the ability of Trust Boards to influence consultant contracts in order to enable research time to be set aside.**

THE RESEARCH WORKFORCE

The workforce involved in research covers many different roles and responsibilities, requiring a broad range of skills and experience. These include clinical researchers, such as doctors and nurses but also pharmacists, radiographers and therapists; data analysts and statisticians; and research managers and directors, responsible for overseeing specific research projects from inception to completion. Any strategic developments should therefore take into account the need to ensure the research workforce in its broadest sense has capacity and is equipped with the skills to sustain increased demand and to meet new research challenges.

DOCTORS' MOTIVATIONS FOR UNDERTAKING RESEARCH

Interest in and motivation to undertake clinical research is, to some extent, embedded in undergraduate training, but medical schools vary in terms of the amount of exposure students have to research at undergraduate level. In addition, there was little confidence that research was adequately covered in postgraduate training for doctors with fewer doctors now undertaking doctorates – this was particularly the case for surgeons, where in the past all surgeons undertook a doctorate. And if less research was undertaken throughout training then research would be less embedded in doctors' minds when qualified.

The nature of postgraduate training was also seen as hampering early engagement with research, and hence future motivation, as the rotational arrangements prevented junior doctors from seeing the research process through for most studies, (which take years, rather than months). In addition, moving around the country to take up training posts was not seen as conducive to building and maintaining research contacts.

"So there's this national appointment system ... it's very difficult for them to go where they want to be. So we've got a very good reputation for xx research... One of our trainees wants to come back and is finding it almost impossible...there isn't a tick box which says 'I want to go to xx because that fits in with my research and that's what I want to do'."
– Clinical academic

The attitude of the Postgraduate Deaneries is critical in this regard and there were suggestions that in some instances there might be a level of antipathy towards academic career paths, which in turn could influence how trainees viewed these opportunities.

"... there is quite a strong anti-academic culture promoted particularly by the postgraduate deaneries... So you've got your academic clinical fellowships, you've got the NIHR and so on, all of these are helping but that's against a background of a non-supportive academic environment for trainees."
– Clinical academic

One interviewee commented on the fact that as a research portfolio is not required for appointment to consultant grades, there was less motivation or inclination for juniors to become involved in research. Another suggested that if jobs were scarce, doctors may think differently about undertaking research in order to gain a competitive advantage.

"I think that's been down to the job market and how short people are of consultants. So if they get to a consultant post, it's very, very competitive and you need something to give you an edge, then people will perhaps do some full-time research. If, on the other hand, you know, there's a shortage of consultants, people perhaps tend to do that less."
– Consultant surgeon

Conversely, doctors discussed a range of incentives that might increase their personal commitment to research. For some, the kudos that taking part in research brought to their department was enough of an incentive. While for others, the opportunity to do something different from routine clinical work and to feel they were making a contribution to delivering better care were seen as powerful motivators.

"As a consultant you gear up for research as it's what you've trained for all your life,"
–Consultant Haematologist

There were also suggestions that other incentives such as peer recognition could prove helpful, although the logistics of freeing up time to conduct research would still need to be addressed.

"One of the things we suggested to our network was that we could involve our clinicians in the publications.... But that needs ...the consultant... in the district general hospital who's working flat out to deliver on their clinical care to be able to devote time to this. So, in their job plan they need to have a session or two devoted to research."
– Clinical Academic

In the career trajectory for clinical academics, individuals talked about the importance of having access to the support and guidance of more senior colleagues working in the same field to avoid feeling professionally isolated. A view that it was difficult to get a research career off the ground in an environment where existing success was given preference was also expressed.

"Trials units are interested in research that is fundamentally going to be phenomenally successful and a huge blockbuster... it was really difficult for me to set up in the early stages of my career - took a good seven years to get where we are today. "
– Clinical academic

Within the NHS, there is a system of recognising and rewarding achievement by consultants financially. The administration of the scheme rests with the Advisory Committee on Clinical Excellence Awards. Applicants are assessed in five areas, one of which is Research and Innovation. Evidence is sought to demonstrate how applicants 'have made a contribution to research over and above their contractual obligations.' However, the nature of the scheme tends to reward clinical academics who can more readily produce evidence of a strong track record in research.[6] There is also some uncertainty about the future of this scheme in the minds of doctors and what the implications of the scheme's cessation might mean.

"I do worry that if and when they do stop those, that goodwill for research will just evaporate in people who ...are basically doing it in their own time 'cause they're passionate about it and they believe in it and they think it makes a difference.."
– Clinical Academic

THE ROLE OF CLINICAL RESEARCH NURSES

Research nurses provide the day-to-day contact with patients recruited into trials and work to develop a trusting and supportive relationship with them so that they can continue their involvement in the study. Their value was recognised across the broad spectrum of those interviewed.

However, in spite of the obvious enthusiasm for the contribution a research nurse makes, the role is not without its challenges and ambiguities. The rewards for involvement in research, both in terms of financial remuneration and career prospects, are nowhere near as clear as they are for medical staff. In addition, the identity of clinical research nurses within the wider nursing community is not always easy to manage.

"I felt that immediately the nurses in chemo clinic started to view me differently and distanced themselves from me to an extent. It was as though by taking the research nurse post I had snubbed them and was no longer part of their community. I also felt that leaving to do research was viewed as an easy option by the ward."
– Clinical Research Nurse

As well as the relationship with the wider clinical team and their place within it, clinical research nurses interviewed for the study talked about a range of other issues they had faced in practice. These included the practical and physical difficulties of undertaking research activities in areas that were not suitable for their purposes, either because they were cramped, or because they lacked basic facilities such as power sockets for equipment.

The difficulty of getting diagnostic tests booked for patients within the timescales set down in research protocols was also reported. This was felt to be because research participants were viewed as less of a priority than patients receiving standard care.

[6] Nearly two-thirds of clinical academics in each country held an award in 2010, a higher proportion than NHS consultants. The share of national awards held by clinical academics increases with the level of award, so that over half of the highest awards (platinum Clinical Excellence Awards and A+ Distinction Awards) are held by that group," (Review Body on Doctors' and Dentists' Remuneration - Review of compensation levels, incentives and the Clinical Excellence and Distinction Award schemes for NHS consultants, 2012)

Research was seen by non-research staff as interfering with the 'day job'. This was felt to counter-productive as one interviewee explained.

"Nurses need to recognise that research and practice go hand in hand firstly, to promote best practice so that high standards of care can be delivered, and secondly, because, if nursing is going to develop as a profession we need to be more forward thinking about combining academic and clinical skills."
– Clinical Research Nurse

Research nurses more than any other member of the research team, build a bond with participants. This can be mutually beneficial, but it can also prove to be difficult emotionally and the research nurses interviewed for this study discussed the problems that arise when such an attachment becomes a relationship of dependency.

"The formation of these relationships was really rewarding ...however, it could at times create difficulties.... often patients would continue to phone up and rely on me for advice and support weeks and months after they had come off their trial... it is very difficult to make a clean break, when your patients have come to rely on you and trust you."
– Clinical Research Nurse

Potentially, the duties of a research nurse can vary from organisation to organisation and from study to study, depending on the infrastructure in place to support the study and the nature of the organisation.

"There are some people who ... are working in DGHs where they have a mixed portfolio, but they are in the minority and a lot of the clinicians don't like it (they) want their nurse to be a cancer nurse and so they don't want a generalist research nurse." – Research nurse

In some organisations, it is possible that a research nurse will undertake a much broader range of roles than those operating in an environment supported by a large trials unit. Views expressed argued that research nurses should concentrate on the patient interaction and should not have to become 'bogged down' with administrative duties.

"...in some centres they do all the set-up... meeting with the pharmaceutical company; they do the feasibility; they'll do the costing... None of my nurses do that. Then one of the other things which the nurses will do is the Electronic Case Report File, which is the data collection tool, none of my nurses enter any data. We have admin people who enter the data...So basically the nurse's time is set for recruiting patients..."
– R&D manager, NHS Trust

However, it was also reported that some research nurses fear they will become de-skilled as a result of the development of expertise within trials units, presenting a further challenge to their professional identity.

"The main issues now that I've heard from research nurses when we have a discussion is previously research nurses are involved with everything in setting up studies, like being involved in costing, liaising with the sponsor, but nowadays with loads of positions like clinical trial practitioner, clinical trials coordinator, portfolio manager, finance manager, it's very specialised now...we feel that it's going towards that way and we feel that we're going to be deskilled."
– Clinical Research Nurse

Some developments in research practices have presented a different kind of challenge for research nurses, such as the requirement of some studies to enter data within a short time period – such as 48 hours or 72 hours after seeing patients. In addition, it was suggested that the ability to work with monitoring technology will become an increasing requirement for research staff - particularly research nurses.

"We are going to become more electronic savvy, there's going to be more that's monitored remotely. We have a huge issue in cancer around managing follow-up and how we can do that from more of an electronic perspective and that's evolving but that will only get greater. So, I guess, it is more there will be cancer specific training that will be required..."
– National interviewee

THE CAREER PROGRESSION OF CLINICAL RESEARCH NURSES

From a career perspective, clinical research nurses saw themselves falling in a gap between a clinical and an academic career, with the former becoming increasingly distant from their experience as a nurse undertaking research, and the latter seen by some as moving too far away from contact with patients. There were also suggestions that the skill sets at each end of this continuum were quite different.

"People who've got good personal skills and can encourage people to consent and put them at their ease and inform them appropriately so they're not worried – so they understand – I think that's a real skill... and writing a grant application's a real skill, but often the two people who would do those things have different skill sets."
– Clinical academic

There were efforts being made in some organisations to foster research interest amongst nursing staff.

"We also do work very closely with the Faculty of Health Science and their clinical academic scheme for nurses and AHPs, so if we have a research nurse who is showing interest and capability to actually become more academic and a clinical academic in their own right, then we also have that career path that they can go down as well."
– Director of R&D, NHS Trust

Many organisations have recognised and attempted to address the issues of career progression, job security and continuity for research nurses, as well as other research staff.

"...there was no career structure there, they were Band 6 nurses, they had nowhere to go...we've created a structure where we can appoint at Band 5, then they have the career progression to be a Band 6 research nurse and they have the career progression to go to Band 7 team leader and then we have a couple of 8As in the structure, an 8B and now an 8C..."
– Director of R&D, NHS Trust

"We've got a year's money and then it stops. And that's difficult because if you want to make a career out of it as a nurse ...if you've only got one year and then... the money runs out and if you commit to it then you can get left stranded. We thought very hard about it and said, 'Well, the only way we can change that is to make the posts permanent.' Which puts pressure on us because we've got to deliver to be able to pay the salaries, but I think we should have the pressure and they shouldn't."
– Clinical academic

THE WIDER RESEARCH WORKFORCE

A number of interviewees raised concerns about their ability to meet their research aspirations because of shortages in specific clinical skills or expertise in their own organisations. These included areas such as pharmacy, pathology, and radiography. These shortages, or difficulties in releasing staff time for research purposes, were reported across the case sites, and were not therefore limited to one particular geographical area.

"The pharmacy is everybody's bottleneck...."
– Director CTU and Chief Investigator

"I have quite a lot of dealings with the pathology department and their research is extremely low on their list of priorities... they suffer from the problem that ... if they're not keeping up with their numbers they've got someone breathing down their necks, so the ability to squeeze in some research is extremely limited.."
– Clinical academic

Staff in one organisation discussed their approach to managing the shortfall in research nurse capacity by introducing a different kind of role.

"Clinical trial practitioners (is) a role that we are looking at, so it's not an administrator, but it's a practitioner who is able to do some things with patients, but is not a fully qualified nurse."
– Director of R&D, NHS Trust

In addition, statisticians, database managers and trial managers were also mentioned as being hard to come by in CTUs.

"...when it comes to recruiting statisticians we're fishing in the same pool as a lot of other people... nationally there are issues with statisticians through

junior roles through to chair roles... there are things in place, there are more people coming through the Masters courses now... it's just that the need is expanding."
– Co-Director, Clinical Trials Unit (CTU)

"Once we get into sort of senior trial managers, QA managers, we're fishing in a much smaller pool and there's far fewer well qualified and experienced people."
– Director, CTU

Often posts specifically related to research are not permanent and are funded on fixed-term contracts. This creates career uncertainty for people, which has an impact on retention.

"There is the issue about attracting high quality people, but there is a big issue about retaining them. And very good people are like gold dust and they will go where the next opportunity exists."
– Clinical Academic

EDUCATION AND TRAINING

As we move towards a future where increasingly all aspects of the healthcare system need to be research active, the need for training and development of staff becomes critical. Research itself is becoming increasingly multi-disciplinary so it is necessary to consider a much broader range of careers as relevant to research and to take into account these requirements when considering the education and training of all those working within the healthcare sector.

Many of the interviewees talked of the need to instil a culture of research within all clinicians, whether doctors, nurses, or Allied Health Professionals (AHPs), in their pre-registration training.

"The more experience during training clinicians have of research and the better understanding they have, the more likely they are to contribute, even if they're not chief investigators...."
– Clinical academic

It was suggested by some interviewees that education should be focused on the centrality of research within the day-to-day treatment and care of patients, in order to make the relationship explicit.

There were also calls from interviewees for better mentoring for medical students who might become future research leaders, ensuring that any undergraduate experience of research was positive as a negative experience could colour future clinicians' perceptions of the attractiveness of research for the rest of their career. An example was given of one medical school that expects all its medical students to undertake a year-long research project, to develop their skills and knowledge of the research process. This was seen as a positive development, as it gave the research component of their degree a higher profile.

The introduction of the clinical fellow role in one organisation was described as an effective way of giving doctors a taste of research early on in their careers. It was felt this would pay dividends later.

"I've got some clinical fellows who are going from SHO to registrar level and they just want a year out to decide what they want to do... they might just leave and go back into clinical practice, but at least they've been exposed to research on the way and maybe they'll be a research active consultant one day."
– Director R&D, NHS Trust

Beyond initial study and training, interviewees talked of the need to nurture and inspire early career researchers, providing them with better training in specific skills such as trial design and statistical analysis and providing them with opportunities to develop their academic profile.

There were mixed views as to whether research activity should feature in revalidation processes, and what the value of this might be.

"I think revalidation is tiresome enough already without adding layers of complexity to it. And what revalidation should be about is making people effective practitioners in medicine."
– National interviewee

"One of my many mantras is that if I turn up to be appraised and revalidated as a clinician, I should be able to say 'I've put these patients into clinical trials, I'm delivering frontier new breakthrough care and providing evidence to support it and all of my patients are being independently evaluated in these clinical trials. So yes, I'm providing a very high quality health service' and I think that's a really smart way of embedding clinical research into clinical practice and that's one that we're trying to put across into revalidation and appraisals and the like."
– Clinical academic

Formal training for clinical research nurses is generally limited to the Good Clinical Practice Training (GCP)[7], with further development activity then provided in-house and 'on the job'. A number of interviewees expressed an interest in exploring what more could be done to support clinical research nurses in their training and developmental needs, with suggestions that a national programme, or some national provision would be helpful.

"The only formal training I got as a research nurse was Good Clinical Practice Training which was updated every two years via a one day refresher course. Apart from that all my research skills were learnt on the job."
– Clinical Research Nurse

The recognition of the contribution of research trial and project managers was seen as an indicator of the importance of research in an organisation. However, the training for these staff and professional and academic recognition is currently limited.

"... if you don't invest in good research management, you're shooting yourself in the foot ...that's an underfunded and underdeveloped area... the career development in research management is somewhat neglected and we struggle to recruit staff with the adequate knowledge and skills set, so we're having to grow them and it's not easy."
– Director R&D, NHS Trust

"Be good to see a Professor of Trial Management appointed in the future. Trial managers are superb project managers and this should be recognised as a worthwhile career."
– CTU Director

As with clinical research nurses, the only formal training provided for trial and project managers in research management currently is the GCP course. This might change however, as the NIHR has been working closely with Health Education England (HEE) recently to consider the kinds of skills that the research workforce will need. As a result, the HEE's strategy and commissioning policy now makes specific references to research requirements. Interviewees from non-clinical backgrounds who are working in research posts would certainly recognise the need for a more systematic and co-ordinated way of providing training and education.

"Coming at it from a non-clinical point of view, it's taken me quite a while to get up to speed. There aren't training courses I can go on to try and understand this ...you pick this kind of thing up indirectly ... but it is getting more complicated and it's how you skill people up"
– Co-director, CTU

The literature also highlights the positive impact on the conduct of cancer clinical trials that having appropriately trained non-clinical staff can make. In their evaluation of the Clinical Trials Officer (CTO) a new role at the time, Cox et al (2005) found that once established, the CTO could make a difference to trial recruitment rates and improve the patient experience of participating in research through effective communication with patients and maintaining continuity in contact. Training and a career structure were highlighted as areas of concern at the time of this study, and little appears to have changed significantly in the intervening years.

[7] Good clinical practice is a set of internationally recognised ethical and scientific quality requirements for designing, conducting, recording and reporting clinical trials. The Clinical Trial Regulations (Regulation 12) effectively require anyone involved in a clinical trial to receive this training. It is compulsory for those involved in commercial research to have GCP training.

5. Health Education England should establish a national training programme and increase development of career opportunities for clinical research nurses. Similarly, there should be a review of the opportunities that can be offered to develop national training programmes and development opportunities for research managers, trial co-ordinators, etc.
6. NHS England and Health Education England should seek to incentivise and develop the research professional. It should look to support the research career development prospects for both clinical non-clinical staff and the research career development prospects for both clinical and non-clinical staff.

METRICS AND INCENTIVES

In order to embed research in every day practice it is crucial that the right incentives are in place to promote research activity in the same way as incentives are in place to improve regular service delivery. Despite the obvious presence of altruistic motivations for undertaking research and the overall benefits that research brings to organisations, it is important that staff and departments are recognised and rewarded for their efforts.

In order to distribute incentives fairly it is necessary to measure activity in a suitable way. As new types of research emerge and trial designs evolve it is important that the metrics for measuring research activity reflect the complexity of such research, particularly for complex cancer trials.

RESEARCH PERFORMANCE MEASURES

Provider organisations are paid according to the number of patients recruited into trials – known as 'accruals' in the research community. The unintended consequence of this however, is that organisations may see the cost benefits of recruiting large numbers into simple population-based or observational studies, as more advantageous than recruiting patients for more complex, interventional trials which require fewer participants but which need as much time and energy, if not more, to recruit patients to.

''It actually takes as much effort to get your ethical and MHRA and R&D approval for a study of ten patients as it does for one of a hundred or a thousand patients. But yet the sort of budgets that people see fit for these smaller scale studies are much smaller.''
– Director, CTU

''Our Trust's model is built on the more activity within your clinical academic group, the more money you get at the end of the year, which is quite difficult for cancer... it is more difficult to recruit (to) cancer trials... you get your recruitment money in year 1 but then you have to do follow-ups and everything probably 10 or 20 years, and there's no further funding ''
– R&D Department Manager

The possibility that a conflict could exist between the need to recruit patients for the sake of increasing numbers, and what was in a patient's best interests, was also raised by a number of the interviewees. In particular, one research nurse commented that it was her job to make sure patients were completely aware of what they were consenting to and that this could lead to patients withdrawing from trials.

''...sometimes doctors try to recruit patients into trials to get the recruitment numbers up, but they haven't made the patient aware about the potential time commitments or the difficult treatment regime this will involve.''
– Research Nurse

However, as it stands at present, the number of patients recruited is how Trusts are assessed and where the money flows from. According to the survey, only a third of all respondents agree that these measures are appropriate.

FUTURE RESEARCH QUESTIONS AND RESEARCH DESIGN

The nature of clinical research is changing as a result of advancements in stratified medicine. These developments offer huge opportunities for patients.

''Surgical research isn't necessarily about doing bigger, bolder operations, it might be selecting the right patients to do smaller, safer operations...and this is really exciting because we're reducing the amount of harm we're doing patients,''
– Clinical academic

''... we can start more accurately identifying which

sub-groups of patients need what drugs ...we can start doing modelling how we're treating cancer as a kind of integrated care pathway instead of these packages of care that we're giving at the moment.''
– Clinical academic

However, these changes can also bring a number of research challenges in relation to the design of clinical trials, patient recruitment and research timelines. Trials might use an adaptive design with multiple arms, and multiple comparators in the first stage. These can be dropped or new arms can be introduced as the research progresses. This is an efficient design in terms of recruiting patients and not progressing with research on interventions that aren't effective.

''We stratify patients before surgery...that puts enormous pressure on the team to deliver this new test but not delay the patient's operation and treatment plan ...once you've identified the right patient to try out the right treatment on you should be able to get more information faster because you're actually going to get more events happening in that patient population.''
– Clinical academic

These developments can have financial implications however, as they may be more expensive than more traditional trial designs. Funders are therefore cautious about how to ensure sustainable funding for the future if these kinds of trials become the norm. Such a targeted approach might also have unforeseen consequences in terms of the likelihood that provider organisations would be prepared to support these kinds of trials because of the financial implications.

''... it'll be more difficult ... for me to sell to the trust because you could fund me to get five patients into one trial but actually it might be better ... if we could do something with the vast number of patients on diabetes...we'd be able to get lots of bums in beds and score points with the CRN for our recruitment, (and) it might have a wider impact on a greater number of patients.''
– Director, Joint Research Office

Stratification was also seen as causing a challenge in terms of the availability of an appropriate pharmacological response in certain circumstances.

''...that only really works if that stratification maps onto drugs ... and for many cancers, that isn't really the case ...I think it puts patients and clinicians into a very difficult position wherein they're saying, you know, 'drug A won't work for you but there is no drug B','
– National interviewee

There is also the challenge of cancer as a disease entity evolving and there was recognition from interviewees that targeted therapies might only prove to be part of the answer.

''More problematic is the biology of the tumour... the worry is that ... if we give very targeted therapies, that's what cancer's very good at avoiding ... jumping ship and adapting itself...a targeted therapy by itself is not likely to be the way to go, it's going to have to work in combination with other things or multiple targets at the same time.''
– Clinical academic

Interviewees were also beginning to think about other future opportunities, such as the ability of personalised medicine to develop better treatments for cancer patients with co-morbidities.

''...it would be interesting to have more trials that target cancer patients who also suffer with diabetes or cancer patients who also have problems post stroke or whatever it is because it's the combination of disease types that we're seeing...stratified medicine or personalised medicine it's got to be the way forward.''
– Director, Joint Research Office

The set-back of the Care.data programme was disappointing for those interviewees who commented on this specifically, as they discussed the increasing importance of 'unlocking' the clinical data that was held within the NHS for the advancement of stratified medicine.

''It's really important that we get the right balance around the duty to protect confidentiality absolutely within the NHS but really to twist that as well to be a duty to use that data responsibly to inform advances in care.''
– National interviewee

Survey respondents across the board were cautious about the future of cancer clinical research, with less than a third agreeing their organisations were prepared for the challenges that might arise.

7. **NHS England should review what new metrics are needed to measure clinical research activity so that a wider range of study types can be incentivised and rewarded. It should also identify possible disincentives in the commissioning model which can prevent certain studies taking place.**

AWARENESS OF RESEARCH IN THE HEALTH SERVICE

To best promote research throughout the health service it is vital that staff, patients and the public are aware of research opportunities and feel informed enough to promote participation in the case of the former, and to demand participation for the latter.

STAFF ENGAGEMENT WITH RESEARCH

Many interviewees talked of the need to demonstrate to all staff that research should be seen as part of the 'day job' and not an 'add on', with the contribution of research to the care of patients and to the value of the organisation as a whole being seen and understood. There was a range of initiatives and developments recalled by interviewees that were increasing the visibility of research activity and providing a powerful symbolic representation of the importance of research within organisations. These included research staff having joint university and Trust email addresses; the names of Trusts, or their branding, referring specifically to research activity; staff briefings on research activity; and newsletters and website reports on research activities.

"Because research is one of the strategic objectives of the organisation, it's within all our literature that we aim to be world class in research..."
– R&D Director

In one organisation, the R&D Managers talked about their department's 'open door policy' one day a week. This enabled anyone to go and visit the department and ask questions – either about research in progress, research they wanted to do, or just to know more about the department. Other initiatives to raise awareness of research activities more broadly across organisations were reported by interviewees and survey respondents.

"We want to get ... as many staff members as possible thinking that research is part of their job as opposed to, 'I don't have to worry about research 'cause that's what other people do'... we've appointed research nurses to do the main recruit, and ... part of their role, is to encourage others ... to be involved ... identifying what we call 'champions'."
– Clinical academic

In some NHS organisations, the message regarding the importance of research was delivered as a matter of course to new staff through induction sessions. In other NHS organisations, research activities were promoted through roadshows or other regular events. A number of interviewees also mentioned the boost that research award schemes could give an organisation - creating a sense of pride in the research work carried out.

"We have annual showcase events. We're very proud of what we do here, and I think a lot of the research that goes on here isn't publicised. People don't tend to know about it ... So we try to blow our own trumpet a little bit, ... so it's going to be an annual event – where we get researchers... talking about their research and everyone in the trust is invited."
– Clinical academic

Interviewees suggested that to really embed research, organisations need to demonstrate its relevance to patient care. It was acknowledged that there may be issues in this regard if research activity and further research opportunities were limited to a few specialities.

"...it's answering questions that are clinically relevant... that's important to the staff... and they think, 'Well, we need to know more about that.' If you inform the team...explain why you're doing what you're doing and involve them in that way... they just might think, 'Well, it's important that I remember, the next time I've got someone who's got this problem, to phone the team or to let the ... patient know about the study."
— Clinical academic

It was also suggested that in order to build momentum in research, getting a critical mass involved and engaged was more important initially than the exact nature of the research undertaken.

"I would prioritise quantity over quality ... because I think in order to change culture you have to have a critical mass of activity and at the moment ... the level of research activity is too low to create that culture change...we can then start saying are we really focusing on the best questions and the most important questions."
– Clinical academic

Examples were given by interviewees of the importance of all staff in an organisation being research-aware, in order to ensure that any interactions with patients could be used as an opportunity to raise awareness of research and to ensure patients were not given unhelpful or misleading information.

"We did have an instance at xx where they asked the receptionist and she said 'we don't do that here,' ... if you've got people in key customer based positions that don't know about it, people would be put off."
– AHSN and ex-Chief Exec of NHS Trust

Developing a greater awareness of research among staff includes those in primary care. It appears that there is a knowledge gap with primary care not always aware of what is happening within its own arena in research terms, let alone elsewhere in the system. An example was given of one university that was recruiting to the post of a GP Research Champion, specifically to raise the profile of research at a practice level, and to try and encourage primary care to recruit more research participants. There was also a tacit acknowledgement that research is not generally seen as the preserve of primary care, which appears to be a cultural issue.

"It's not really seen as the role of primary care to get directly involved...there's that cultural issue. I think primary care would definitely see it as important that they use the evidence in their clinical practice but to actually be doing the research I think they would generally feel that they haven't got the skills and haven't got the time, don't know how to get the resources."
– GP and CCG Lead for R&D

There is also some potential difficulty in getting people interested in research when the perception is that most research questions do not seem relevant to primary care's role in service delivery.

" I suppose things that interest me are how are we going to do the secondary to community care shift, how are we going to pull resource towards prevention, how are we going to integrate health and social care... (its) a far more important consideration than whether drug x or drug y is slightly better for hypertension or not."
– GP and CCG Chair

However, in relation to cancer services, there was recognition that primary care has a legitimate role in research at key stages in the patient pathway – specifically early diagnosis and follow-up care.

"There is a big question currently about early diagnosis and how you achieve that... So I think there are definitely things that we could be doing...I think a lot of care that is delivered in hospital with cancer patients could actually be delivered in primary care, particularly around the survivorship agenda." – GP and CCG Lead for R&D

The infrastructure to support primary care to undertake, contribute to, and promote research is an important element of its involvement. A couple of examples were given by interviewees of the use of technology to identify potential trial participants and promote research to patients, though these were still embryonic initiatives.

"(It) is basically an electronic IT solution to recruitment of patients for appropriate trials ... it will download all our clinical and patient data onto a server which can then be interrogated by researchers to see how many patients are available to answer their specific questions."
– GP and CCG Lead for R&D

"We have got a section on the CCG website...and we have talked about having a list of potential trials where patients could go and have a look and see if there's anything they were interested in."
– GP and CCG Lead for R&D

PATIENT AND PUBLIC INVOLVEMENT IN RESEARCH

It is recommended that the public and patients should be involved in all stages of the research process (DH 2006, 2005) and not just as research subjects. Whilst unable to proffer definitive conclusions, the literature highlights the potential benefits of public involvement in research. These include a greater awareness of the nature and importance of participating in clinical trials, increases in recruitment rates, and improvements in the quality of the studies themselves.

From the interviews conducted, arrangements for public and patient involvement vary considerably between R&D departments and CTUs. Some tap into existing resources that may reside elsewhere in their organisations, whereas others have dedicated Patient and Public Involvement (PPI) groups for research purposes. These arrangements are by and large opportunistic, rather than strategically planned and a number of interviewees talked about their aspirations to do this type of work in a more planned way.

"I think the big thing for me is I would like to get more at the front end in terms of the actual research protocol design to make sure that we're asking the appropriate questions."
– Director, Joint research Office

"We try to get them involved as much as possible ... so: 'Have you got any ideas? Is there anything you think we should be researching?' The formulation of the protocol and the grant and the information sheet and then how we actually deliver it...that's work in progress."
– Clinical academic

There was also concern expressed by some interviewees that the proliferation of different groups undertaking PPI activities might lead to some confusion for patients and an over-reliance on a few patients who wished to be involved in this way. It was felt organisations therefore needed to think a little more carefully about how this was carried out, with better co-ordination of PPI efforts across the board.

"...everyone tries to develop their own PPI programmes. So you have the clinical study groups, you have the networks, you have local trusts, and ... the so-called consumers often sit on ten different kinds of boards and become professional consumers ...."
– Clinical academic

The literature identifies a number of other barriers that can hamper public involvement in the design and conduct of research (Boote et al 2010 and Fudge et al 2007). These include:

- **Tensions between different stakeholder groups, patients and researchers having conflicting views concerning which outcomes should be measured**
- **Scepticism concerning the difference involvement would make**
- **Practical issues such as securing the use of suitable venues**
- **The time commitment and costs of involvement**
- **The alienating nature of research 'language' and jargon**
- **The ill-health of participants.**

ORGANISATIONAL STRATEGIES TO PROMOTE RESEARCH TO PATIENTS

Historically, only a small proportion of eligible patients became involved in clinical trials (Hutchinson et al 2007, Charlson and Horowitz 1984). Most trials in the UK failed to meet their recruitment targets (Prescott et al 1999), in fact some trials failed to recruit any patients at all (Jack 1990, Peto 1993). As noted earlier, the National Institute for Health Research (NIHR) has significantly improved this picture in recent years, but if this growth in recruitment to trials is to continue then more needs to be done to recruit patients - this is likely to become more complex and challenging with further developments in stratified medicine. Indeed, reservations about patient recruitment to clinical trials continue to be expressed by our survey respondents, with just over half agreeing that it was a major challenge in successfully completing cancer trials in their organisations.

Several interviewees noted that their organisation states explicitly within its appointment letters and elsewhere that patients can expect to be approached by researchers asking them if they would like to take part in a trial.

"our policy is that when we send out information to patients about attendance at clinics or inpatients coming into hospital, there is a separate sheet which tells them that they can expect to be approached by researchers to discuss clinical trials."
– Clinical academic

A number of organisations had particular processes in place to increase patient recruitment to trials.
One Trust has a means by which all ongoing research in a particular disease area is available at the press of a button for the consulting clinician, so that patients can be informed of anything relevant straight away.

"So when ... they press the code, it will then pull through to all the research which is ongoing. And then the doctor can call for the research nurse via the iPad in his clinic room for that particular research project. And if there's no research project associated with that disease area or the patient is not eligible, then they're asked if they would like to be contacted for future research."
– R&D Manager, NHS Trust

Other initiatives were cited by interviewees from organisations that appear to have embraced a research culture.

"We've got a programme called Consent to Consent, which is around consenting patients up front...to consider being part of research should we find a project that we think may be suitable for them and that goes from healthy volunteers through to the patient population as well."
– R&D Director, NHS Trust

A culture of treating patients as partners in the research process was described by one interviewee as the state to which they aspired, recognising that this would require a different approach to recruitment and communication with patients.

"... it's really important we get our informed consent right and that we recognise this as a process rather than a box that needs to be ticked... (a) conversation with patients as partners needs to be an ongoing one rather than a single process .... make them feel part of the research culture so that even if ... the chances are something won't come up for them ...at least they're then left with a feeling they've participated ... moving away from the idea that it's your sample I'm interested in but you, as a partner, I think is important."
– Clinical academic

PATIENT ATTITUDES TO RESEARCH

Although the literature suggests that altruism is a determining factor for many patients choosing whether or not to participate in a clinical trial (Cox and Mcgarry, 2003, Comis et al., 2003, Garcea et al., 2005), patients can be deterred if they do not understand the terminology and concepts involved (Comis et al., 2003, Jenkins and Fallowfield, 2000, Buss, Du Benske, Gustafson et al., 2008). One of the more difficult concepts to grasp with regard to clinical trials is randomisation.

The randomised controlled trial (RCT) is generally accepted as the 'gold standard' methodology for evaluating the effectiveness and efficacy of interventions (Brueton et al 2013), if patients are to participate in RCTs they need to understand what randomisation means in this context so that they can give informed consent. A survey study by Jenkins et al. (2010) suggests that a clearer explanation of the randomisation process and study design is required by potential participants to enable them to make informed choices about whether or not to participate in clinical trials

RCTs rely on participants being in a state of equipoise - that is the belief that in a trial, no arm is known to offer greater harm or benefit than any other arm (Alderson 1996). It has been argued that randomisation only becomes a rational and ethical course for individuals when they are informed and in equipoise (Chard and Lilford, 1998). However, maintaining equipoise can be challenging. Letting chance decide treatment is a difficult barrier for patients to overcome and the literature suggests that clinicians use a number of strategies to make it more acceptable to patients, including extra consultations to discuss the study in question, emphasising the potential benefits to patients in the future and ensuring explanations do not include words such as 'lottery' or any others with associations with gambling to remove any concerns about winners and losers (Wade et al. 2009).

The reasons why people participate in clinical trials will differ between specialties and conditions and this was noted as being of particular relevance for cancer research by interviewees in our study. For cancer clinical trials, participants are already patients and interviewees perceived their motivations as being both altruistic and self-interested – given that there was a likelihood that by taking part in the research study they might receive treatment or care that would be better than 'normal' care. The issue of incentivising patients to take part in clinical trials was therefore seen as unnecessary and for many interviewees unethical.

"I'm privileged to be working with breast cancer patients. They are some of the most altruistic people I know... they want to give something back... do you need to incentivise patients? In my experience I've never even had to go near (that) because patients have always willingly offered to be part of something."
– Clinical academic

The view was expressed by several interviewees that the extra attention participants receive is particularly appreciated, and that there is a therapeutic benefit to patients from simply taking part in a trial.

"So I think ... when they go on a clinical trial ... they feel they get good care because they've been on a clinical trial, so that bit of it really could be promoted." – Research nurse

This is borne out by the literature with Tolmie et al (2004) noting that the provision of health checks as part of the study design, and positive interactions with the study team - characterised by discussions with caring research nurses who were friendly, competent and efficient and staff who kept participants fully informed about the progress of the study - were powerful motivators for patients' continuing participation in trials.

Interviewees thought that in general patients wait to be asked to be involved in trials, rather than actively asking to do so, but are enthusiastic to participate once asked.

"My own experience ... is they're very, very keen to take part...it's one of our great assets in this country, relative lack of cynicism about research and taking part in it."
– Clinical academic

A view was expressed however, that investigators often overestimate the numbers they can recruit into trials and that this was a reason why some trials were unsuccessful.

As noted previously, only 32% of patients who completed the 2013 National Cancer Patient Survey (NHS England, 2013a) said that taking part in research had been discussed with them. Clearly more work needs to be done to encourage staff to discuss opportunities with patients, but it is also important to develop the 'push' factor from patients in tandem, so that more patients are aware of research and will ask to be involved in suitable trials. The NIHR launched its 'OK to Ask' campaign, precisely to address this issue. Though interviewees were aware of the initiative, its impact was not known.

It was reported that publicity surrounding research was influential in potential participants coming forwards. A number of interviewees had experienced occasions when a particular news item had resulted in patients contacting their Trust directly to ask to take part in a specific clinical trial.

".... And it was on (the) news on television and it was in the (paper). The very next day we had a patient who called us to say "I'm coming in for my operation, can you please tell me whether I'm eligible for this trial because I want to be part of it". That was a real eye-opener to me of the power of the media in terms of being able to influence and inform patients that these trials are ongoing."
– Clinical academic

PARTICIPANT INFORMATION

Getting the participant information right was seen as crucial to recruiting patients. The need for this to be simple and user friendly was emphasised, with current literature criticised as being too lengthy and too legalistic in tone.

"And there are trial information leaflets that are not done for the benefit of the patients. They're done for the benefit of the regulators and to cover people's backs, and they're unhelpful, they're obstructive...!"
– Consultant surgeon

Interviewees commented on the kinds of messages that patients ought to be hearing and the complexity of these messages, with some interviewees suggesting that the likelihood that a new kind of treatment would be better for patients can sometimes be over-estimated. Figures were quoted by one clinical academic that suggest only 25% of trials result in a new treatment that is better for patients, with 25% resulting in a less effective treatment, and 50% showing no difference.

"...that's the sort of starting point that we should be presenting to people. We've been treating this disease in this way and it works pretty well but we've got another treatment and we want to see if it's any better, it may be better, it may be worse and you know this is your choice...that's an extremely difficult message to get across."
– Clinical academic

It is evident that staff involved in recruiting participants to trials need to be fully prepared and this may require extensive face to face discussion with research teams to ensure methods and processes are fully understood (de Salis et al 2008a,b). A number of studies suggest that using multi-media approaches to provide clinical trial information may be helpful in enabling potential participants to make informed decisions when consenting or declining to take part in trials.

BARRIERS TO PATIENT PARTICIPATION IN TRIALS

Time demands and a lack of flexibility of appointment times often serve as a deterrent to participants who are considering taking part in clinical trials (Hall et al. 2010 and Nair et al. 2014). In addition, if patients do not have a positive experience during a hospital stay, it can reduce their propensity to participate (Agoritsas et al 2011).

It is also important to note that barriers to recruitment may be influenced by the age and/or ethnicity of participants. Jenkins et al (2010) found that younger people expressed a greater willingness to participate in clinical trials research than older people, though other studies have found no significant age related relationship (Solomon et al 2003, Madsen et al 2002). It is reported that Black and Minority Ethnic (BME) populations are underrepresented in UK health research studies (Netuveli et al., 2005, Sheldon and Rasul, 2006) – this raises questions of equity in health provision, since studies have suggested that people who participate in clinical trials have better health outcomes than those who do not (Brawley, 1998, Killien et al., 2000, Edwards et al., 1998).

Some researchers have investigated differences between ethnic groups in their willingness to participate in research, but it is unclear whether observed differences are primarily the result of intrinsic values held by different cultural groups, or the perceptions and stereotyping of healthcare practitioners about different cultural beliefs, or a mixture of both. For example, health professionals may display a 'passive lack of inclusion' of BME participants because it is felt more time and cost are needed to secure their inclusion, whilst others are 'cherry-picked' if they are thought to be easy to recruit, fluent in English and easily approachable (Hussain-Gambles et al. 2006), while family issues, language barriers, concerns about modesty, cultural taboos and religious restrictions, may all reduce trial participation rates too. These issues highlight the need for strategies designed to recruit BME communities to clinical trials which are culturally sensitive (Talaulikar et al. 2014; Hussain-Gambles et al. 2004) and to challenge preconceptions.

In the interviews conducted for this study, two other potential barriers were raised – one was the issue of inequality of access to trials depending on where people live:

"... not all trials will be done locally ... nobody should be disadvantaged as a result."
– Clinical academic

"It becomes absolutely essential that patients, wherever they are treated, ...are not disadvantaged ... the majority of patients are treated in the district general hospitals, not in the big teaching hospitals."
– Clinical academic

While the second concern related to the potential for competing trials to over burden patients if they were approached multiple times for different trials. The need to plan ahead to avoid this was cited, with clinicians proactively prioritising participation by assessing which trial would be in the best interests of the patient.

8. NHS England, NIHR and research active healthcare sites should consider developing more strategic relationships with media channels to improve the level of awareness of research among the general public.

THE RELATIONSHIP BETWEEN FUNDERS AND RESEARCHERS

A productive and healthy relationship between research funders and the clinicians, investigators and nurses undertaking the research is as important as the relationship between researchers and the health service as a whole. Continuing to improve the nature of communication and collaboration between funders and researchers should be a priority as a means by which clinical research can be accelerated.

A number of interviewees discussed the issue of the nature of the dialogue between funders and researchers and suggested that a more constructive one could be established. This was raised quite forcibly in relation to the provision of feedback on grant applications that are ultimately unsuccessful. For some interviewees the experience of submitting applications for funding and having these subsequently rejected with either limited, or extremely critical feedback, had been a difficult experience and was potentially a serious de-motivator for submitting future applications.

The need for more dialogue between funders and researchers was also felt to be important to broaden the range of research that should be funded, the means of funding it, and the recipients of funding. It was suggested that funding bodies were often too focused on instant impact, rather than considering the longer term benefits, and that more funding could be made available for developing scoping or feasibility studies or more exploratory research, as well as more grants to support early career researchers.

"... the clinical studies group are the country's experts and the country's innovative thinkers .... if they had a budget to run or at least to pump prime clinical trials to feasibility, etc., ... asking those people rather than other grant award committees, who may not necessarily be experts in the field and may not necessarily understand the need... would be a really good way of speeding up delivery."
– Clinical academic

Interviewees felt there were gaps in the portfolio of cancer studies, most notably in those aspects of care at the beginning and end of the patient pathway, and that research funders ought to develop a better means of ensuring comprehensive coverage between them.

"... who takes responsibility for the trials that have to do with quality of life, with psychological wellbeing, with survivorship, with early diagnosis, with screening, prevention? I know of top notch researchers ... who have no idea where to go to for their grant funding now because there are gaps in the portfolio....they (MRC) need to start talking to partner organisations and say..., 'look you fund cancer, we fund cancer...can we look critically and see what domains we want to cover?', so that they could be overlapped, but the key thing that they should avoid is have a gap because if they have a gap, patients are disadvantaged."
– Clinical academic

Another aspect of a constructive dialogue that could be developed between researchers and non-commercial funders was the approach of the latter for checking on the progress of studies. Interviewees suggested that non-commercial funders could follow the example set by commercial funders and put in place a more rigorous approach to progress checking.

"...you know, a real push ... that there is an expectation of chief investigators to deliver the research as effectively and as efficiently as possible and an expectation of how ... findings are disseminated and embedded into clinical care."
– Clinical academic

Some criticism was also levied at smaller charitable funders that had unrealistically high expectations of what could be achieved for the funding available and that were potentially diluting the focus of research by awarding a number of smaller grants, without the rigour of approach established by the larger funding organisations.

"If there's a gripe...it really is with the plethora of small charities that often are competing and that sometimes do not use, for example, peer review in decision making about where the funding goes. And the funding tends to be small packages around which there is a very great expectation of what's going to be delivered."
– National interviewee

RELATIONSHIP BETWEEN RESEARCHERS AND THE PHARMACEUTICAL INDUSTRY

It was generally perceived by interviewees that the requirement for commercial trials was a quick response rate, and that industry were more limited in the kinds of questions asked compared to non-commercial research. They were seen to be driven by a business imperative which affected the continuation of the trial, as findings emerged.

"In commercially funded research the company has a very clear view of what they want normally... they have very defined parameters, and timescales that they want you to stick to. So there's much less opportunity to be creative but there's a great opportunity to drive things through.... and of course the other thing is if it doesn't work then they just drop it...as an academic, you have to get used to that."
– Clinical academic

Funding arrangements, contractual clauses, the level of scrutiny, and governance processes may also differ from those of non-commercial trials, commercial trials being more onerous and less advantageous to the exploitation of academic capital.

"... in London alone, around £3 million a year was spent, you could say, wasted on legal advice on changes to contracts."
– National interviewee

"The funding model is different so typically with the research branch ...once you've got the money it's agreed up front it's yours to manage. The commercial ones are much more, 'you'll get it if you recruit this number of patients'.... And then with the commercial ones it depends on what you negotiate...if you negotiate to have the IP you might be free to publish. If you do it on a contractual basis you may not be. "
– Co-Director, CTU

It was suggested that commercial funders can be as elitist about the organisations they work with as universities, and that this may be hampering the ability to spread clinical research across the country in a more distributed way.

"From a commercial contract study perspective it's been hard to get research moved out of the big sites really...a company will come with preconceived ideas that they only want to deliver their oncology research in The Marsden, The Christie, latterbridge..."
– National interviewee

A number of interviewees were cautious about the ability of the NHS to respond to commercial and scientific developments.

"... we need to really bite the bullet about who's going to pay for all this because they're developing therapies that we're not going to be able to afford. So there needs to be a rethink about how we do drug trials and a rethink how we work with pharmaceutical industry and how both parties contribute to that process."
– Clinical academic

9. **Funders should continue to review the way in which they manage relationships with clinicians, patients, service providers and commissioners to ensure a productive and collaborative research culture.**

CASE STUDIES – WHAT LESSONS CAN BE LEARNT FROM AREAS OF GOOD PRACTICE?

The purpose of the Appreciative Enquiry Events was to obtain more 'fine grained' detail of what an effective research culture might look like. The material is presented within a framework of 'People, Patients, and Place', which recognises different aspects of culture (Gale et al, 2014). The case study sites were selected on the basis of their commitment to research, and their willingness to participate. It was also a feature of the research design that the two case study sites should present a comparative picture - providing examples of different approaches to nurturing a research culture – the first case study provides an illustration of a more organic, bottom-up approach, and involves a single department within a Trust; the second is an illustration of an approach that combines elements of the top-down as well as the bottom-up, and is therefore concerned with the organisation as a whole. Both approaches have resulted in significant research success – one lesson therefore being that no single approach or model is necessarily better than another when it comes to developing and embedding a culture of research.

EAST KENT HOSPITALS UNIVERSITY FOUNDATION TRUST

The success of the haematology research team at East Kent Hospitals University Foundation Trust (EKHUFT) has been the result of steady growth since the late 1990s. EKHUFT is a district general hospital based in the south east of England. Its catchment area of 725,000 people is the 6th largest in the UK. Rather than being attached to a specific university, the department receives clinical trial proposals from universities and trial centres all over the country and carries out an equal number of commercial and non-commercial trials.

RESEARCH CULTURE: THE PEOPLE

The arrival of a new haematology consultant, from his previous post in a research intensive hospital, strengthened the drive for research. The research team has subsequently grown from two research-active consultants, one research nurse and a handful of trials, to a situation where all the consultants are research active. There are now six research nurses, two trial administrators, and a large research portfolio with a mixture of both commercial and non-commercial studies. Despite this growth, the team has remained close and socialize regularly outside of work. They describe themselves as 'a bit like a family ... respectful but straight with each other'.

RESEARCH CULTURE: PATIENTS

For most of the research team, it is the ability to provide the optimum care to their patients by accessing the best treatments available, that is their most important value. Often trials are selected because both arms offer a new drug intervention, rather than the current NHS 'gold standard', meaning that the control arm is likely to be better than standard care. There was a recognition that within their catchment area (a largely middle class and older population), there is a lot of positivity about research and that it was easy to engage and recruit.

The research nurses describe their relationship with the patients as one of the most valued parts of their job. They are able to provide continuity of care and feel they can be the patients' advocates, providing emotional and taking a holistic approach - something they feel can be missing from modern nursing care. The whole team feel that the care they provide and the ability to offer the latest trials meant that the patients have 'faith' in them, and are therefore extremely tolerant when there are any problems, such as delays in treatment or changes to appointment times.

RESEARCH CULTURE: PLACE

The spatial organisation of the department is a key part of the culture. The research offices are situated alongside the chemotherapy wards and the day-case unit. This provides the team with good resources as they are close to everyone. Additionally, haematology patients who are on clinical trials are treated in the same area as non-trial patients and are treated by a mixture of research and chemotherapy nurses. This integration of trial and non-trial staff and patients seems to work well here, providing a sense of community practice and camaraderie, as opposed to the 'us and them' attitude that can exist.

Although it was acknowledged that the haematology research team work 'pretty independently' from the rest of the hospital, good relationships exist with other departments such as R&D, laboratory medicine and radiology. The research team built up these connections through interpersonal contact and maintain goodwill by offering financial support to those they work with, such as offering to pay for courses they are not able to access through their own study leave budgets. They feel that their work is valued at Board level meetings, and they are regularly mentioned in Trust newsletters when they have successes.

THE FUTURE

The team is looking to strengthen its links with colleagues in Kent, Surrey and Sussex, to facilitate cross-referrals within a larger catchment area, allowing more people access to trials. The team is also looking into ways in which they can improve retention of research nurses and administrators by moving towards permanent contracts and by facilitating promotion, as recognition for the highly specialised, autonomous work that research nurses frequently undertake. As the lead consultant is approaching retirement within ten years, and not intending to take on further new Principle Investigator responsibility within five years, there is a lot of consideration going into succession planning to ensure continued leadership.

At a strategic level within the Trust, it was reported that efforts are being made to strengthen the research culture across other departments. For instance, they are developing research workshops for clinicians who haven't previously been involved in research to try and promote their interest in it.

It was felt that one of the most important things that policy-makers could do was to increase exposure to research for all clinical professions at the undergraduate level to help embed it in the clinical culture, rather than it being something that was locked away in an 'ivory tower'. The team's view was that if you weren't exposed to research early on you could go through your career without realising you were missing it and that if you were treating patients without putting them into trials (either locally or at other centres) it was like working in 'the dark ages.' .

KEY POINTS:

- Operating relatively independently, the haematology department has succeeded in attaining a national reputation in terms of its high recruitment rate to clinical trials.
- Bottom-up approach driven by a consultant passionate about research.
- Strong, collaborative research team passionate about research, with excellent research nurse capacity and administrative support.

BLACKPOOL TEACHING HOSPITALS NHS FOUNDATION TRUST

The success of the research culture at Blackpool Teaching Hospitals NHS Foundation Trust has been the result of a combination of passionate staff and a systematic approach to supporting research activity throughout the organisation, including the development of a new Clinical Research Centre (CRC). The Trust serves a population of approximately 440,000 people across Blackpool, Fylde, Wyre, Lancashire and South Cumbria and the North of England. Currently, almost all the trials that take place at the Trust are portfolio studies and, over the last few years, there has been a steady increase of commercial trials, which now make up about a third of the trial portfolio.

RESEARCH CULTURE: THE PEOPLE

There has been research activity in pockets for many years at the Trust, but six years ago there was a big push, supported by the then Chief Executive, to increase the hospital's research profile. This coincided with the development of the research networks and with the North West Exemplar Programme which fast-tracked the opening of industry trials. In 2009, they undertook two large 'Exemplar' studies (in haematology and cardiology), which gave the research team more of a lever to work with the general managers and facilitated processes for getting studies approved quickly. Now, all new trials in the Trust are subject to "feasibility meetings" where members of the

multi-disciplinary team discuss upcoming trials and get any problems ironed out at these early stages. This streamlines the trial set up process and ensures everyone is clear on their role and the resources needed for the trial.

At the heart of the research activity is the Clinical Research Centre, a dedicated research facility which has over 30 research staff including a research nurse manager, senior research nurses, research nurses & midwives, a research management and governance team, a clinical trials coordinator, clinical trials administrators, a clinical trials pharmacist, senior / pharmacy clinical trials technicians as well as patient and public involvement (PPI) representatives. There are efforts to build in a career structure and development within the team with different banded posts available.

A number of approaches have been used over the years to increase the profile of research in the Trust amongst staff more widely, including questions on research in the appraisal system, leaflets and marketing. However, levels of knowledge about what research is involved are generally low and with time and financial pressures, research is felt to be low on the priority list for many people. The Research Team is aware that maintaining a high profile for research in the Trust requires constant renewal of the messages going out and particularly those emphasising the importance of research for clinical quality, quality of care and efficiency of the service. Despite the feeling that younger consultants are taking a more active role in research, there is recognition that as consultants became more senior their research input could get pushed aside due to other responsibilities. As new managers and consultants came into post, the research team arranges to meet with them as soon as possible to discuss the role of the CRC. In addition, they run stakeholder events, work closely with practice development nurses and clinical nurse specialists and give presentations to promote research to ward nurses. Student nurses and new starters at the Trust spend time during their induction with the research team and there is a drive to ensure all staff have Good Clinical Practice (GCP) training, allowing them to get involved in research.

RESEARCH CULTURE: PATIENTS

There is a strong culture of PPI at the Trust that has grown and become embedded over the years. At the point six years ago, when the Trust sought to develop its research activity, the trust owl logo was perceived to be too distant and academic an image and was replaced with more patient-focused images as part of a 'rebranding' exercise. Some patients who had previously been involved in research studies were invited to be part of a photo shoot for leaflets and posters around the Trust. PPI representatives from the research team note there has been a shift from feeling like they were 'foisted' upon research teams to feeling that their contribution is genuinely valued. The CRC team feel that in some ways it is easier to engage patients than staff because patients feel that 'something good is coming out of something not so good'.

The research nurses feel they are able to provide study patients with extra care, support and advice through trial entry, something which helps their relationship with other clinical staff.

RESEARCH CULTURE: PLACE

In 2012, after spending some time looking for a suitable location within the hospital, the CRC was established in a centralised space within the hospital, bringing together the research staff previously dispersed across the Trust site. The CRC has offices for the nurses and administrators and some clinical space for trial activities, including sleep studies. While this initially caused some tension among Principal Investigators who sometimes saw research nurses as belonging to the department rather than the broader research efforts, the nurses feel they have benefitted from better peer support and a strong identity. More recently, the research nurse teams have been restructured to reflect the NIHR research speciality divisions. This has enabled the Trust to standardise research systems and processes, as well as improving patient safety and the quality of care provided as best practice is shared and there is more staff cover, shared electronic information, training and support. Most research nurses still have a base in their own clinical area, so they are able to spend time there as well as in the hub. The trial nurses and non-clinical admin staff work in 'cluster' teams, which are assigned on the basis of trial complexity and the capacity of the nurses.

THE FUTURE

Although patient recruitment figures had steadily increased until 2012, there has been a dip recently, largely due to changes in the trial portfolio, with fewer observational studies and more complex studies for rarer diseases coming through. The Trust is looking to address this by further integration of research into Trust 'core business' and by supporting clinicians within the Trust to develop their own research ideas and become Chief Investigators. The CRC is working with local higher education institutions such as the University of Lancaster and the University of Central Lancashire to develop joint clinical academic posts and to develop research funding applications. The Trust is a founder member of the Lancaster Health Hub at Lancaster University - the purpose of which is to bring together clinical staff and academic colleagues to develop research which is relevant to the local population.

At a national policy level, the research team recognises how important it is that the Department of Health give clear messages about the importance of research and that these top-down messages can have a bigger impact on Chief Executives and Boards than messages bottom up from the research team. The issue of Excess Treatment Costs was raised as an example of something that could delay trials from opening for months and would more easily be resolved by being resolved at a national level and earlier in the trial set-up process, rather than leaving it down to individual trusts to negotiate.

The importance of better undergraduate training in research for nurses and medical students is felt to be vital for the future of clinical research. Although within the Trust itself, the new training lead for medicine insists that all medical students engage with the CRC and new nurses are given time to shadow a research nurse, they feel strongly that a research culture within the clinical professions needs to begin earlier than this.

A final area that the research team feel would have a big impact on clinical research is greater awareness among the public. Many patients initially perceive trial participation as like being a 'guinea pig', and the research team feel that there is a role for national education campaigns. Other patients want to find out about the outcomes of the research trials they've taken part in and feel that there is a need for better engagement by academics or commercial companies running the trials.

KEY POINTS:

- The research culture within the Trust thrives from the intersection of bottom-up passion from individuals and a strategic approach to supporting research across the Trust.
- The location of all the research staff in a central facility with appropriate desk and clinical space provides an environment where individual nurses and administrators are well supported by peers and best practice can be shared across clinical areas.
- Patient and public involvement in research is central to the ethos of the research team and PPI representatives feel that their input is genuinely valued by principal investigators.

CONCLUSION AND RECOMMENDATIONS

It is clear from this study that strong research cultures exist in pockets within the NHS - this is generally reflected in the existence of a specific team or department within an organisation that has made conscious and concerted efforts to develop its research activity; less apparent is a strong research culture within whole organisations, though there are some examples where this is the case. In order to ensure the NHS is developing a sustainable research base for the future, and to address concerns that saturation is being reached in some areas of the research portfolio, capacity needs to be developed in a more planned and distributive way and it is therefore the latter that needs to be encouraged. This requires a more rigorous assessment of capacity and capability across the NHS and a willingness from commercial and non-commercial funding bodies to adopt an approach which is geared towards spreading research activity and expertise more widely, where it is appropriate to do so, rather than concentrating it in a small number of centres.

In order to facilitate this, academic institutions and individual clinical academics, need to consider their relationships with the full range of NHS organisations within their reach, and take a more flexible attitude to joint enterprises and partnerships. In return, NHS organisations should endeavour to accommodate staff requests for dedicated research time, though service constraints are a challenge in this respect. Given the nature of the performance regime that the NHS is subject to, it may prove helpful to consider whether the provision of dedicated research time for those who wish it, is a target against which an organisation might be measured.

There are, nonetheless, potential tensions in seeking to disperse research work and the tendency to centralisation. It is expected that post REF, research funding will be allocated to a smaller group of 'centres of excellence'. How this will affect the conduct of cancer clinical research on the ground is not yet known, but there are likely to be challenges in balancing the centralisation of expertise and critical mass with growing new centres and building new partnerships. This tension needs to be addressed at a policy level.

Having in place the necessary resources to undertake research effectively is clearly a central message from this study, though given the financial constraints faced by the service, it is also clear that simply requesting more money is not a particularly helpful strategy. It is perhaps therefore more productive to consider how existing resources can be best deployed, and their impact maximised.

The clinical research community in the UK is fortunate to have a body of highly dedicated and passionate people, striving for excellence. As a result, clinical research in cancer has thrived and patients are benefitting every day from the progress made in discovering and improving treatments. Efforts should now be made to ensure that these advances can be sustained and that the infrastructure and expertise already developed is further enhanced and strengthened.

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APPENDIX 1. METHODOLOGY

OVERVIEW

Although there have been many positive developments in recent years, there is still concern that embedding a truly research-based culture is a major challenge for the NHS. A recent report by the Association of Medical Research Charities (2013) identified a number of barriers which prevent clinicians taking part in research. These include; the pressure of clinical work, a lack of necessary skills and role models, a lack of practical support, burdensome regulation and a lack of information about research opportunities. The AMRC's recommendations were based on three main areas; ensuring that every patient has the opportunity to take part in research, that all NHS staff see the importance of research, and that the NHS conducts high-quality research and adopts new treatments. Reducing the amount of time it takes between investment in research and eventual impact to patients is also seen as a priority by the research community – at present it is estimated that the average time lag is around 15 years. (RAND Europe, 2014)

Cancer Research UK therefore commissioned an independent research team from the University of Birmingham's Health Services Management Centre and School of Health and Population Sciences to explore how best to embed a culture of research in the NHS. This evaluation focuses on:

- To what extent there is a culture of clinical research within the NHS
- What is currently done well in research within the NHS
- What the barriers are to research within the NHS
- How NHS England and Clinical Commissioning Groups are meeting their duty to promote research
- What steps need to be taken to promote a stronger culture of research in the NHS?

In order to address the questions set, a mixed methods approach was taken comprising of four main elements as detailed below:

1. Literature and evidence review
2. Exploration of the experiences and perceptions of local and national stakeholders regarding the research culture in the NHS through semi-structured qualitative interviews
3. A mixed methods online survey reporting stakeholders' views of specific elements of the research infrastructure and processes
4. Appreciative Inquiry (AI) events

LITERATURE AND EVIDENCE REVIEW - RAPID EVIDENCE ASSESSMENT (REA)

An REA is a tool developed from the systematic review method which involves comprehensive electronic searches of appropriate databases, internet sources and follow-up of cited references. Given the timeframe of the project, the use of REA is appropriate as it can be completed in a shorter period of time than a systematic review. This can range from three weeks to six months (Ganaan et al 2010). In order to do this, some concessions are made, for example hand searching of journals and textbooks is not undertaken to the same extent as would be the case in a full systematic review, and searching of 'grey' literature is curtailed. The shortened timeframe for producing results, whilst useful in a rapidly changing practice and policy environment, increases the risk of publication bias, which is the tendency for studies that find significant relationships between variables of interest to have a higher chance of acceptance in academic journals than studies that find no such relationships (Davies 2006). However, if the framework recommended by Davies (2004) below is adopted this risk can be minimised:

- Search the electronic and print literature as comprehensively as possible within the constraints of a policy or practice timetable
- Collate descriptive outlines of the available evidence on a topic
- Critically appraise the evidence
- Sift out studies of poor quality
- Provide an overview of what the evidence is saying.

They provide timely information to inform practice, however they are not a quick fix, nor should they compromise on the quality of searching, critical appraisal or analysis. The only concession made with these evidence assessments is on the comprehensiveness and sensitivity of searching in the time available (Davies 2006). Expert librarians based at the Health Services Management Centre, University of Birmingham provided the technical expertise necessary to undertake this phase of the project.

Two main aims underpinned the evidence and literature review: 1) to produce an understanding of how research is being conducted within the NHS and 2) to gather insights and examples from the theoretical and empirical literature about how a research culture can be embedded and promoted within the NHS.

QUALITATIVE INTERVIEWS

Views and experiences of undertaking clinical research in cancer were explored through interviews with cancer experts at a national level and in five case study sites, determined by a broad geographical coalescence of research activity. The selection of sites was based on the principle of maximum variation sampling, a purposive approach which seeks to select 'cases' to include the widest possible range of characteristics, thereby maximising diversity in the sample. Sampling is guided by an understanding of the likely factors that might affect experiences and perspectives, and seeks to include as many of these as possible. For this research, these factors included the following area characteristics:

- Socio-economic characteristics: e.g. areas with more and less affluent populations
- Demographic characteristics: e.g. inclusion of areas with more and less homogeneous and heterogeneous populations
- Environmental characteristics: e.g. areas with differing urban: rural population ratios
- Service-related characteristics: e.g. inclusion of areas with specific research infrastructure such as Academic Health Science Centres and those without such resources

A total of 46 people took part in telephone interviews between May and August 2014 – 11 at a national level and 35 from local case study sites. Interviewees were selected to ensure a variety of different roles and perspectives and the final sample from the case study sites included the following; Chief and Principal investigators, clinical academics, non-academic clinicians, clinical research nurses, Directors of Clinical Trials Units and Research Centres, Directors and Managers of Research and Development Departments within NHS organisations. National interviews included one scoping interview with a key figure in each of Scotland, Wales and Northern Ireland in order to provide an overview of clinical research and its organisation and delivery in that country (three interviews in total).

The interview topic guide comprised an introductory, five general and one closing questions, supplemented with additional questions to clarify responses and explore issues in greater depth (see Appendix 3). Interviews lasted on average 45 minutes and, with participants' permission, were digitally recorded; they were then transcribed verbatim.

Thematic analysis of the interview data was carried out, guided by the principles of Ritchie and Spencer's (1994) Framework Approach. This involves the initial identification of analytical themes derived from the research questions and existing literature, to which additional themes are added as new insights emerge from the data. The value of this approach is that it is particularly well suited to the problem-oriented nature of applied and policy-relevant research, whilst also allowing for an analytical process which remains grounded in and driven by participants' accounts.

ONLINE SURVEY

A complementary element of the study was an online survey to provide further insights into research activity and the research infrastructure within organisations. A mixed-methods survey was created, combining closed response questions (quantitative) and free text (qualitative) questions. It was distributed to Research and Development Departments within NHS provider organisations, Clinical Trials Units, Clinical Research Networks, Experimental Cancer Medicine Centres, and Cancer Research UK-funded Research Centres. A total of 56 responses were received from across the five categories of organisation, of which 37 were from Research and Development Departments. This represents an approximate overall response rate of 25%. Within organisations,

the person completing the questionnaire was usually the Director, or Manager, demonstrating a high level of seniority.

APPRECIATIVE ENQUIRY

An Appreciative Inquiry (AI) study was carried out in two sites. Two NHS provider organisations, identified through the interviews and survey, as examples of good practice in embedding research into their culture, were approached to participate on a voluntary basis.

An AI seeks to support and enhance good practice, while drawing out transferable lessons about what works and how. It also provides a positive framework to think forward towards further improving an organisation or project, (Cooperrider and Whitney, 2007 and Cooperrider, Whitney and Stavros, 2007). The method involves asking a series of positively framed questions to encourage the teams involved to put energy into finding out what went well, and why, rather than spending too much time focusing on (and therefore reinforcing) problems or failures. The approach was semi-structured, focusing on the three domains of culture identified by Gale et al (2014) of people, patients and place. Problem areas are framed in a way that makes them more accessible to change and the facilitator explores with the teams creative ways in which improvements could be made.

The aim of our analysis was to add to our understanding of the factors that support embedding research (from previous methods) in order to generate a more nuanced and realistic account of how and why things have worked well in a particular service. This enabled the research team to add significant value to the overall findings, by drawing on the positive experiences of people working in services where research is highly embedded, while also exploring aspirational ideas about what would be opportunities for the future.

APPENDIX 2 - RESEARCH INFRASTRUCTURE IN THE UK

Within the UK, there are four government bodies and four research councils involved in the funding of health research as follows:

- Department of Health (England)
- Chief Scientist Office, Scottish Government Health and Social Care Directorates (Scotland)
- National Institute for Social Care and Health Research (Wales)
- HSC R&D Division of the Public Health Agency (Northern Ireland)
- Medical Research Council (MRC)
- Biotechnology and Biological Sciences Research Council (BBSRC)
- Economic and Social Research Council (ESRC)
- Engineering and Physical Sciences Research Council (EPSRC)

In addition, four of the largest medical research charities in the UK (Arthritis Research UK, British Heart Foundation, Cancer Research UK and the Wellcome Trust) are estimated to fund more than 70% of UK charitable health related research.

The vast majority of the DH's funding of healthcare research (£992m in 2010-11) is allocated to the National Institute for Health Research (NIHR) which was established in 2006 with a specific remit to increase the volume of clinical and applied health and social care research. The NIHR manages its health research activities through four main work strands supported by co-ordinating centres: the commissioning and funding of research, the provision of facilities and staff, the support of faculty members and the provision of systems for managing research and its outputs.

The NIHR's infrastructure incorporates 15 Local Clinical Research Networks (LCRNs), with a Co-ordinating Centre, established in April 2014. Prior network arrangements consisted of six topic specific networks, which included cancer, a primary care research network and a comprehensive research network, each of which comprised of a number of local networks (LRNs). The new arrangements are more streamlined with each of the 15 LCRNs encompassing 30 Clinical Research Specialties, of which cancer is one. Clinical leadership for each of these 30 specialities is provided by the national co-ordinating centre. The catchment areas of the 15 LCRNs are based on the footprint of the 15 Academic Health Science Networks[8]. Each LCRN is hosted by an NHS provider organisation.

The NIHR also incorporates Biomedical Research Centres and Units, Clinical Research Facilities for Experimental Medicine, including Experimental Cancer Medicine Centres (funded in partnership with Cancer Research UK), Healthcare Technology Co-operatives – to develop new medical devices and healthcare technologies, Diagnostic Evidence Co-operatives to improve the way diseases are diagnosed, and the MRC/NIHR Phenome Centre which enables researchers to better understand how the environment interacts with genes to cause disease.

In addition, the NIHR funds the Collaborations for Leadership in Applied Health Research and Care (CLAHRCs) – partnerships between universities and surrounding NHS organisations. Nine CLAHRCs were established in 2008 in order to undertake applied health research and to support the translation of research evidence into routine clinical practice in the NHS.

The NIHR's approach to increasing the amount and efficiency of research in the NHS is to promote unified, streamlined and simple systems for managing research and its outputs and improving patient participation in research. The NIHR is currently working with the Health Research

[8] There are five accredited academic health science systems in the UK – the purpose of these partnerships between universities and the NHS is to translate cutting edge research and innovation into measurable gains for patients and populations.

Authority to simplify approval processes for research in the NHS. The NIHR also provides a range of information systems. Developments include: the Clinical Practice Research Datalink (CPRD) which provides a secure and safe access point to patient electronic health records; the UK Clinical Trials Gateway – a website and mobile app, that provides patients with easy to understand information about research studies; the NIHR Portal, which tracks programme and project awards for research funding applications; and the NIHR Dashboard, that provides information about funded research.

Clinical Trials Units (CTUs) are the specialist organisations that co-ordinate clinical trials. They are involved in the design and management of trials including the provision of statistical and analytical support to researchers. The funding for these units is derived from a range of sources including the NIHR, the MRC, Cancer Research UK, the Royal College of Surgeons and NHS Trusts. Many CTUs are self-financing, using income generated from research activity to support the employment of key staff. Some CTUs specialise in particular kinds of research or specific disease areas, so that the CTU geographically closest to an NHS provider organisation is not necessarily the one that supports its research activities.

There are a number of regulatory bodies and procedures that operate within the UK research context. These include the – the Medicines and Healthcare products Regulatory Agency (MHRA) - the Government agency responsible for regulating all medicines and medical devices in the UK and the Health Research Authority (HRA). The HRA was established in December 2011 in order to protect and promote the interests of patients and the public in health research. Within the HRA in England, there are a number of Research Ethics Committees (RECs) with equivalent appointing authorities in Scotland, Wales and Northern Ireland. The role of these committees is to review research applications in order to ensure the rights, safety, dignity and well-being of people participating in research are maintained, as well as facilitating and promoting ethical research that is of potential benefit to participants, science and society.

NHS Research and Development Approval (or NHS Permission) is required before any research involving NHS patients, staff, data or facilities can take place within an NHS organisation. In most NHS provider organisations, an R&D office is responsible for carrying out these checks before permission is given by the Chief Executive or a delegated senior person. In addition to providing a governance and assurance function, R&D Offices or Departments also provide a range of other functions to support NHS researchers. These include maintaining a database of all clinical research being conducted in the Trust, costing research studies and administering study funds, negotiating and drawing up study contracts and agreements, and providing advice and support for researchers on the design and conduct of research and research training.

There are also a number of independent organisations that offer support and advice to the research community. These include: The UK Clinical Research Collaboration (UKCRC), established in 2004 with the aim of enabling the UK to become a world leader in clinical research; The Academy of Medical Sciences (AMS) founded in 1998, with a Fellowship of over 750 of the UK's leading medical scientists from hospitals, academia, industry and public service; and the Association of Medical Research Charities - a national membership organisation of medical and health research charities which together support over one third of all publicly-funded medical research in the UK (Its members invested over £1.3 billion in health research in 2013) (RAND Europe, 2014). The AMRC helps its members by interpreting and influencing the regulatory, policy and research environments. The All-Party Parliamentary Group on Medical Research also brings together participants from a range of organisations including the Medical Research Council, the Association of Medical Research Charities, the Academy of Medical Sciences, Cancer Research UK, the Wellcome Trust, and Arthritis Research UK. Finally, the Association of the British Pharmaceutical Industry (ABPI) represents research-based biopharmaceutical companies and is the negotiating body for the pharmaceutical industry. Its members supply 90% of all medicines used by the NHS.

CANCER RESEARCH INFRASTRUCTURE

The infrastructure supporting cancer research is less complex but its interface with the overarching research system nonetheless can be a cause of confusion, particularly given the recent changes that have occurred in research network arrangements.

The UK's National Cancer Research Network (NCRN) brings together cancer research networks within the NHS in England, Wales, Scotland and Northern Ireland, each of which is funded by the relevant government health department. Within England, Cancer is Division 1 of the NIHR-funded Clinical Research Network, with a Coordinating Centre based in Leeds. The Cancer Co-ordinating Centre works with each of the 15 Local Clinical Research Networks in England to ensure they have a well-balanced cancer research portfolio that reflects national and local priorities and needs[9]. In January 2014, the NIHR Clinical Research Network Cancer portfolio had over 620 open studies in progress and in excess of 170 in set-up.

Specific objectives have been set for cancer research for 2014-15. These include a minimum level of recruitment for participation in cancer studies (15% overall of cancer incident cases, with 7.5% recruited to intervention studies), and 100% of NHS cancer care providers recruiting patients into cancer studies, (NIHR, 2014b).

The cancer research portfolio is subdivided into 21 disease areas which map onto the 21 National Cancer Research Institute (NCRI) Clinical Studies Groups (CSGs). The National Cancer Research Institute was established in 2001 and is hosted by Cancer Research UK. It is a non-statutory partnership organisation comprising of seven government partners, 14 charities and the Association of the British Pharmaceutical Industry (ABPI). The NCRI's Clinical Studies Groups maintain an overview of the current research portfolio in their area and provide advice and guidance on the development of the portfolio. For example, when grant proposals are received by Cancer Research UK they are sent out to clinical study groups which provide advice on questions such as whether the trial design is viable and likely to recruit. A CSG may also share its knowledge and experience with applicants in order that they might improve their research.

A framework to measure the quality of cancer services within the NHS is set out in The Manual for Cancer Services - an integral part of Improving Outcomes: A Strategy for Cancer (DH, 2011b). The Manual supports the National Cancer Peer Review quality assurance programme for cancer services. It includes national quality measures for site specific cancer services, cross cutting services such as chemotherapy and radiotherapy and cancer research measures. It is intended that research is embedded into the delivery of care in the NHS, through the Multi-disciplinary Team (MDT) infrastructure within provider organisations, and through these to regional groups[10]. These regional groups are responsible for reviewing local portfolios and determining which studies they will participate in, determine targets for recruitment, and engage with the clinical community to support research in their area, (NIHR, 2014b).

Cancer Research UK provides core funding for a number of clinical trials units. This funding is for five years in order to provide some sustainability and stability with the provision of research posts, such as data analysts and functions such as pharma co-vigilance etc. Some clinical trials units work across the country in a particular scientific discipline i.e. Cambridge, while others work in a more geographically bounded way across a range of disciplines.

[9] Public Health England (PHE) is now the repository for, and provider of, all cancer datasets – work previously managed by the National Cancer Intelligence Network (NCIN).

[10] These may be known by a variety of names such as Network Site Specific Groups, (NSSGs), Tumour Site Specific Groups (TSSGs), or Expert Advisory Groups (EAGs).

APPENDIX 3 – LOCAL INTERVIEWS TOPIC GUIDE

QUESTION 1. (10 MINS)

Aim: Capture background information about the interviewee.

Main question: Can you start by telling me a bit about your current role and main responsibilities with regards to clinical research?

Possible probes:

- How long have they been in current position?
- How much contact do they have with day-to-day clinical research in cancer?
- How much involvement in research is expected of you and your position?

QUESTION 2. (5 MINS)

Aim: Explore views of participants concerning their local infrastructure for research.

Main question: Do you believe the local research infrastructure is working well to support organisations and individuals undertaking research?

Possible probes:

- Understanding of local infrastructure – who does what?
- Capacity and capability to support proposals?
- Capacity and capability to support trials? Including trial design and statistical support?
- Relationship between different organisations?
- Local leadership?

QUESTION 3. (15 MINS)

Aim: Explore key components of a strong research culture.

Main question: What do you think are the key components of a research receptive culture within the NHS? What are the barriers to developing a research receptive culture within the NHS?

Possible probes:

- To what extent is research a core activity within your Trust? (only applies to providers)
- How do you personally promote research in your organisation/to other organisations?
- To what extent are all staff aware of research activities within your organisation?
- Do the current career structures for health professionals reward/recognise involvement in clinical research?
- Are there any conflicts in balancing the role of the health professional, having a duty of care, and a responsibility to recruit patients into clinical trials?
- Are job plans for medical staff useful in managing the research component of the role?
- Is there a role for financial incentives to increase staff involvement?
- How should research participants be compensated for their time and cost?
- Are there any differences in managing/ undertaking commercially-funded research to non-commercially funded research?
- What is your experience of EU/International cancer research?

QUESTION 4. (15 MINS)

Aim: Exploring the potential to improve current working practices

Main question: How can we improve the quality, speed and co-ordination of cancer clinical research?

Possible probes:

- What are the main reasons for delays or failures in cancer clinical research studies?
- How important is participant information in recruiting patients?
- Is specific training provided for staff which enables them to explain principles and processes of research to potential participants i.e. randomisation? Control groups?
- Is the portfolio wide enough?
- How common is it that patients ask to be involved in clinical research, rather than waiting to be invited? (the 'push', rather than the 'pull' factor)
- What is your experience of recruiting participants from specific demographics (i.e. literature suggests lower numbers of people from ethnic minorities are recruited into trials)? Are there particular cultural issues which have proved difficult for researchers recruiting particular participants?
- How are members of the public/patients involved in the design stage of clinical research?
- Collaboration with other parts of the system i.e. GPs sharing data, negotiation of Excess Treatment Costs with commissioners
- Administrative procedures?
- Ethical approval, regulation and governance?
- Dissemination processes?

QUESTION 5. (5 MINS)

Aim: Gather suggestions about the factors that will continue to drive clinical research in cancer in the future

Main question: How would you like to see clinical research in cancer develop nationally over the next five years? What support / help do local researchers need to achieve this vision?

Possible probes:

- Where are the gaps in terms of support? What more is needed?
- What are the main challenges to realising this vision? Multi-arm trials? Stratified medicine?
- What are the priority areas for future cancer clinical research?

QUESTION 6. (5 MINS)

Aim: Gather any further suggestions/insights that may add to the research

Main question: Is there anything else you would like to add that you think may be helpful or informative to this study?

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