

Developing chief investigators within the NHS: the West Midlands clinical trials scholars programme

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ABSTRACT

Consecutive Royal College of Physicians' *Research for all* surveys have highlighted the challenges for doctors becoming involved in research. Local issues included under-representation of chief investigators (CIs) and reduction in dedicated research time. The West Midlands National Institute for Health Research (NIHR) Clinical Research Network (CRN) established a clinical trials scholarship (CTS) initiative in 2019 to develop research-active consultants in smaller trusts, with a dedicated day per week embedded in a local clinical trials unit. In the initial round of 41 applications from 13 partner organisations, 17 CTSs were appointed, including nine consultant physicians, with one subsequently deferring. After 2 years, the remaining 16 CTSs have been awarded 40 grants totalling £18.35 million as CI or co-CI, including 10 NIHR grants, plus >200 publications. These scholarships are a proven cost-effective way to develop CIs, provide academic leadership and promote a research culture, even in small, previously less research-active trusts.

KEYWORDS: research, chief investigator, consultant, clinical trials unit, grants

DOI: 10.7861/clinmed.2021-0606

Introduction

Previous Royal College of Physicians' (RCP's) surveys in 2016 and 2020 have highlighted the problems not only within academic research, but also in the challenges for clinicians to become

actively involved in research, despite a willingness and wish to do so.^{1,2} These surveys have also identified that the major barriers to being research active were protected time, mentorship and funding. A regional West Midlands survey of consultant contracts was performed in the (then) 26 acute trusts in 2017 to assess the potential impact on research. Just over half had a 2.5:7.5 split of programmed activities (PAs) for supporting professional activities (SPAs) to direct clinical care (DCC), with approximately a third having a 2:8 split, and the remainder with a 1.5:8.5 split. Forty-five per cent had no research included in their SPAs.

As a consequence, there were concerns that research-active clinicians, both current and future, would find it increasingly difficult to generate new research studies. This was confirmed regionally by the observation that, although the West Midlands region represents over 10% of the English population, in 2017, only 6.4% of chief investigators (CIs) for National Institute for Health Research (NIHR) portfolio studies were based in the region. As a number of portfolio studies are limited to the lead region, it was estimated that there would be a shortfall of between 3,500 and 4,000 participants each year to regional NIHR portfolio studies.

The West Midlands Clinical Research Network (CRNWM) had an initial approach from the Birmingham clinical trials unit (BCTU) to jointly develop a clinical trials scholarship (CTS) programme to generate new CIs and studies. This was subsequently matched by the CTUs in Warwick and Keele and, in 2019, the CTS development programme was launched.

The CTS development programme is designed to include both doctors and non-medics (nurses, midwives and allied health professionals (NMAHPs)) and is geared towards those at an early part of their research career, although not necessarily at an early stage of their clinical career. It provides clinicians with an effective protected space and remunerated time for developing as CIs, developing their own clinical trial ideas, leading to funding applications and, ultimately, NIHR portfolio studies in their specialty area. The aim of the programme is that successful applicants spend one dedicated day per week (equivalent to two sessions or PAs) working with a CTU or other relevant research groups to develop their grant applications and publications. Scholars also receive one-to-one personal mentoring. The CTSs are funded from CRNWM top-sliced funding for 2 years, subject to satisfactory annual review or, in exceptional circumstances and following a further additional application, for a 3rd year.

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Table 1. Essential and desirable criteria for clinical trials scholarship posts

Essential criteria	<ul style="list-style-type: none"> > Experience and participation in NIHR portfolio studies and the potential to obtain funding to support NIHR CRN portfolio research in the future. > Potential to generate substantial grant income.
Desirable criteria	<ul style="list-style-type: none"> > At application, to hold or have submitted for a higher degree (PhD/MD/DPhil) in a relevant subject area or additional qualifications eg MSc or other postgraduate training. > Evidence of commitment to research. > Demonstrable commitment and career progression in the chosen specialty. > Knowledge of health and social care research, clinical trials, research leadership and NIHR portfolio research delivery. > Presentation of work at a national or international meeting. > Publications in peer-reviewed journals. > Demonstrate the potential to develop collaborations and to meet local and national research priorities.

CRN = Clinical Research Network; NIHR = National Institute for Health Research.

Herein, we summarise the first cohort of CTSs, appointed in 2019, including the appointment process, scholar characteristics and key outcomes (funding application success and number of publications).

Methods

In late 2018 and early 2019, a series of adverts were sent out to research and development departments within the region for distribution. Applicants were asked to fill in an application form that included providing some background details, why they wished to do the scholarship, a plan of how they would spend their time during the scholarship and, ideally, a project idea or ideas (Table 1). Dependent on both geography and specialty area, applicants were asked, if successful, which one of the three CTUs they would wish to be based in. They also needed to provide a letter of support from their clinical director with confirmation that, if successful, that they would be released from clinical sessions to enable them to take up the scholarship.

Following shortlisting, applicants attended interviews that last approximately 20 minutes. The interview panel consisted of a broad range of medical and non-medical disciplines, with representatives from the CRN as well as from each of the three CTUs.

In addition to formal and allocated mentoring, CTSs are also encouraged to attend appropriate research training courses and make early contact with groups such as the research design service (RDS). They attend CTU new business meetings, where new proposals are discussed, along with other CTU meetings according to developmental need. Peer support is provided with a dedicated WhatsApp group, regular informal meetings and, during the COVID-19 pandemic, via Zoom. In addition, there are not only regular meetings with other regional CTSs appointed via the NIHR CRNWM, but CTSs within the same specialty and also same trust are encouraged to set up meetings and WhatsApp groups. The

CTSs have yearly appraisals to provide feedback and updates on progress, plus a clear plan for how the scholarship will generate future income to become self-funding at the end of 2 years.

Outcomes

In the first cohort, appointed in 2019, there were a total of 41 applications from 13 partnership organisations (NHS trusts). After shortlisting and interview, a total of 17 CTSs were appointed from 10 different NHS trusts; this included seven CTSs from non-teaching district general hospitals, three from community trusts and two from small specialist hospitals. Eleven (65%) held a higher degree (PhD or equivalent). Three CTSs chose to be based in Keele, two in Warwick and the remainder in Birmingham. Of the 17 CTSs, three were allied health professionals (AHPs): a pharmacist, a physiotherapist and an exercise physiologist. The remainder were all existing consultants, including four surgeons (whose specialty areas were ophthalmology, orthopaedics, colorectal and gynaecology) and a paediatrician. The specialty areas of the nine physicians appointed were three from anaesthesia and intensive care and individuals from cardiology, gastroenterology, rheumatology, stroke medicine, haematology and geriatrics. Three (18%) CTSs were women, and five (29%) were from a Black, Asian and minority ethnic (BAME) backgrounds.

As a result of needing to accommodate the CTS within their job plans by providing clinical backfill, there was often a delay of several months in taking up the posts. In addition, a number of the CTSs needed to take time out of their scholarship during 2020 to do patient-facing COVID-19 work. Due to workload pressures, including the COVID-19 pandemic, one of the CTSs based in intensive care at one of the smallest trusts had to defer starting their scholarship.

The breakdown of the grant income of the remaining 16 scholars in post is shown in Table 2. All but one of the CTSs have applied for a grant. Ten of the CTSs (63%) have been awarded 40 grants totalling £18,315,430, which include 10 NIHR grants: five for health technology assessments (HTAs), three for research for patient benefit (RfPB), one for programme grant for applied research (PGfAR) and one for an advanced fellowship award. There have, however, also been 45 unsuccessful grant applications, which included one scholar who has submitted 14 grants and one had submitted nine grants, although a number of these were as co-applicant. Although not all of the scholars submitted full details of their publications, the 16 scholars in post have also generated over 200 peer-reviewed articles, including 34 as first author and 46 as last author.

Table 2. Outputs of the scholarship programme

Publications	> 200 publications: <ul style="list-style-type: none"> > first author: n=34 > last author: n=46
Grants	40 including: <ul style="list-style-type: none"> NIHR: <ul style="list-style-type: none"> > health technology assessment (HTA): n=5 > research for patient benefit (RfPB): n=3 > programme grant for applied research (PGfAR): n=1 > advanced fellowship award: n=1. Medical Research Council (MRC): n=2.

NIHR = National Institute for Health Research.

Discussion

While the UK government has committed to increase the spending on research and development to 2.4% of gross domestic product (GDP) by 2027, and in the longer term to 3.0%, this still remains well below that of other Organisation for Economic Co-operation and Development (OECD) members.⁴ The various benefits of medical research are, however, already well recognised. Firstly, there is the economic benefit, with £1 of research money generating a return of 25p each year in perpetuity and £19 in total economic returns.⁵⁻⁷ A report produced by KPMG in October 2019 analysing the economic impact of the financial period 2016/17 to 2018/19 demonstrated that over this 3-year period the clinical research delivered and supported by the NIHR CRN generated £8 billion of gross value added (GVA) along with funding 47,467 whole-time equivalent (WTE) jobs in the UK. For each patient recruited into a commercial trial supported by the CRN, there was an estimated £9,200 paid to NHS Providers, along with a cost saving of approximately £5,800/patient where the trial drug had replaced standard NHS therapy.⁸

It is now also well documented that research-active hospitals have decreased mortality rates, not only for specific conditions such as colorectal carcinoma but also overall mortality.^{9,10} This improved mortality rate in research active hospitals is also associated with improved Care Quality Commission (CQC) ratings.¹¹ In addition, there is evidence that staff recruitment and retention is improved by increasing the academic component of posts.¹²

Despite the many benefits of research, there have undoubtedly been issues and challenges. A survey by the College of Deans in 2017 found that clinical academics represented only 4.2% of NHS medical consultants; this was down from 7.5% in 2004.¹³ This risks the ability to develop the chief investigators of the future, who can develop and design research that is both impactful and relevant.

In 2016, the RCP published *Research for all* based on a survey of almost 2,000 doctors representing a wide number of specialties and also career stages.¹ It was identified that over a quarter of all reported research hours were being worked by doctors who did not formally have employment in a research role. The conclusion of the report was: 'The broad message is that doctors want to be more engaged in research, but that many do not currently have the time, funding or skills support to realise their potential contributions.' The report made a total of 13 recommendations.

There was an updated report in 2020, based on responses from 1,137 RCP members and fellows.² It was, however, recognised that there had been little progress in the preceding 5 years. The major barriers to doing research were perceived as a lack of time (53%), lack of funding (16%), lack of knowledge or skills (13%), and lack of research culture (13%). Of the survey respondents, 57% wanted to be more involved in research, with this rising to 75% in those who had been consultants for less than 5 years. It was also noted that both women and physicians in rural hospitals had disproportionately low participation in research. This was despite the finding that of the non-research-active survey participants, 35% of women and 40% of physicians based in rural hospitals would like to be more involved. The RCP report recommended a targeted approach, especially in rural areas.

During this first cohort of scholars, we deliberately chose to exclude two of the larger trusts in order to provide equitable access across the region, and specifically to smaller (and by extension) often rural trusts. One of the two excluded trusts (a specialist

Table 3. Breakdown of successful scholars' details by year

Year	Scholars appointed, n	Women, n (%)	BAME background, n (%)
2019	17	3 (18)	5 (29)
2020	17	7 (41)	8 (47)
2021	20	8 (40)	8 (40)

BAME = Black, Asian and minority ethnic.

children's hospital), also separately funded a further seven CTSs, who have generated 78 publications and nine grants totalling over £4 million.³ There was also concern regarding the initial numbers of women and also those from a BAME background. Of our initial cohort of 17, only 18% were women, and 29% from a BAME background, although subsequent cohorts have had increased numbers that are now more representative: in our 2021 cohort, 40% are women and 40% are from a BAME background (see Table 3). By specifically targeted those in smaller trusts, many of which are based in rural areas, and also underserved groups, we have already successfully met some of the recommendations of the RCP report.

For subsequent rounds of scholars, we have not only included all trusts but also expanded the scholarships to include support for existing CIs who require both time and support to submit further grants; the 'accelerated trials scholars' (ATs). Although this article is primarily medically focused, it is also recognised that there are similar ongoing issues within non-medical NMAHPs.^{13,14} For the latter, we have now also devised 1-year personal development awards, with additional training and mentoring to enable them to become principal investigators.

Given that the two SPAs per scholar cost no more than £24,000 per year, a return of over £18 million for an investment of approximately £750,000 to date by the NIHR CRNWM represents an excellent return on investment. That a number were able to be awarded substantial grants within such a short period of time may well reflect the fact that a number had projects either arising from a previous higher degree (n=6) and/or an existing planned project (n=11), which already provided collaboration and mentorship. As this scholarship, however, was geared towards developing new CIs, only a small minority (n=4; 25%) were an existing CI.

These scholarships, allocating two sessions a week, were developed to complement rather than compete with the existing Health Education England – NIHR Integrated Clinical Academic Programmes, where characteristically the academic component is 50% or greater, and also provide levelling up of local schemes that aren't available in many hospitals, especially smaller ones.

In addition to publications and grant income, an additional positive effect of the CTSs has been to provide academic leadership, especially in the smaller and less research-active units, and enabling them to promote a research culture within their own trust.⁷ ■

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