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The workforce delivering translational and applied health research: A cross sectional survey of their characteristics, studies and responsibilities

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ABSTRACT

Background: Translational and applied health research, and the workforce needed to deliver it, have grown substantially in the last 10 years and this growth is likely to continue. However, there are few good empirical studies of the workforce and only limited evidence on which to base future policy and practice.
Aim: To provide a better understanding of the workforce that delivers translational and applied health research by exploring who delivers studies, what types of studies are delivered and what delivering them entails and whether this varies across employment contexts.
Methods: A link to an on-line questionnaire was sent to 280 non-medical researchers in England funded by the National Institute for Health Research to deliver translational and applied health research; 168 (60%) responded. Responses were analysed quantitatively.
Findings: Participants were from 11 occupational groups, with nurses (77%) the most common. Most (82%) had worked on clinical trials and almost as many (73%) on observational studies. A fifth had conducted studies outside hospital settings. Participants recruited from Community sites more often reported taking a medical history ($p = 0.022$) and carrying out initial assessments ($p = 0.028$) and less often reported managing other staff ($p = 0.036$). Those recruited through the University Hospital more often reported contributing to development of new studies ($p = 0.000$); to research governance ($p = 0.001$) and protocols ($p = 0.000$); and to writing publications ($p = 0.005$).
Discussion: There is greater diversity in the workforce than previously identified, more variation in types of studies delivered and a wider range of settings. Responsibilities vary across employment contexts.
Conclusions: This diversity needs to be acknowledged in educational, training and career planning to sustain capacity for delivering translational and applied health research in the future.

Problem

Little is known about the workforce that delivers clinical research, where they work and what they do.

What is already known

Research nurses are fundamental to the delivery of clinical trials in hospitals. The recent growth in clinical research has led to an increase in demand for a workforce to deliver more studies.

What this paper adds

The workforce is more diverse, and the types of studies and settings in which they are delivered are more varied, than previously reported. The institutional contexts in which research nurses work offer varying degrees of challenge and scope for developing further skills and experience.

1. Introduction

In the UK, translational and applied health research has grown substantially following the publication in 2006 of the Department of Health's research strategy, *Best Research for Best Health*. This document identified health research as playing 'a key role in the knowledge economy of our country through its contribution to

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international competitiveness and economic growth' and as providing a centrepiece for the UK government's determination 'to raise the level of research and development (R&D).' (Research and Development Directorate, 2006: 1). Later in 2006 the National Institute for Health Research (NIHR) was established to provide the framework through which this strategy could be implemented. In addition to funding high quality peer-reviewed research through its Research Programmes, NIHR supports translational and applied health research through an extensive research infrastructure which provides practical assistance in the design and conduct of commercial and non-commercial studies, a range of research training programmes which build research capability and capacity, and research information systems which ensure integration across the National Health Service (NHS) and partner organisations (http://www.nihr.ac.uk/about/). This extensive and multi-layered support has created a context in which translational and applied health research has thrived.

As in other countries (e.g. Bell, 2009; Rickard and Roberts, 2008; Wilkes, Jackson, Miranda, & Watson, 2012), the growth of translational and applied health research in the UK has seen a corresponding growth in the workforce needed to deliver it. 'Translational research' aims to turn the discoveries of basic science into new treatments, technologies, diagnostics and other interventions which will provide benefit to patients. It involves, for example, pre-clinical and early phase clinical trials and proof-of-concept studies in humans. 'Applied health research' addresses specific clinical, health services, public health or policy questions. It includes, for example, epidemiological studies, case series and case-control studies, cohort studies, later phase clinical trials, outcomes research and health services research (Rubio, Schoenbaum, Lee et al., 2010; University of California San Francisco, n.d.). 'Delivering' (or 'supporting') a study, whether translational or applied health research, entails implementing the study protocol on behalf of the Chief and/or Principal Investigators and their collaborators so that the study can be completed successfully and on time. Key features include recruiting the minimum number of participants agreed for the study and collecting and entering research data, all in keeping with Good Clinical Practice (https://www.crn.nihr.ac.uk/can-help/funders-academics/). 'Implementing' results is also an important aspect of translational and applied health research but the time taken to establish study results and to test their robustness through publications and peer review means that putting findings into practice is largely outside the scope of research nurses.

The NIHR has been a major funder of those who deliver research in England: in 2015 the NIHR Clinical Research Network alone provided funding for almost 10,000 posts (J. Patterson, personal communication, 13 January 2016) while many more posts were funded through NIHR Biomedical Research Centres, NIHR Clinical Research Facilities and other NIHR infrastructure organisations (http://www.nihr.ac.uk/about/nihr-infrastructure.htm). The continued growth of translational and applied health research, reinforced more recently by the UK government's Plan for Growth (Department for Business, Innovation and Skills, 2011), is likely to create a continuing demand for this workforce in order to deliver studies 'to time and target' in both the commercial and non-commercial sectors (Spilsbury, 2008). However, there are few good empirical studies of this workforce and only limited understanding of what they do.

2. Literature review

Nurses have been by far the largest group employed to deliver research, although studies have reported other health professionals as also employed in this role (Eastwood, Roberts, Williams, & Rickard, 2012; Rickard, Roberts, Foote, & McGrail, 2006; Rickard et al., 2011; Scott, White, & Roydhouse, 2013; Wilkes et al., 2012). There is now a substantial body of literature on research nurses, also commonly referred to as clinical trials nurses, clinical research nurses or research co-ordinators (e.g. Barthow, Jones, Macdonald et al., 2015; Castro, Bevans, Miller-Davis et al., 2011; Hill and McArthur, 2006; Rickard et al., 2011; Spilsbury, Petherick, Cullum et al., 2008). While this literature has provided valuable information on the workforce delivering health research, it has a number of limitations. Much is comprised of commentaries rather than empirical studies (e.g. Bird and Kirshbaum, 2005; Gibbs & Lowton, 2012; Gordon, 2008; Hastings, Fisher & McCabe, 2012; Ledger, Pulfrey, & Luke, 2008; Stephens-Lloyd, 2004) and most of the empirical studies have focused on those who work on clinical trials (e.g. Spilsbury et al., 2008; Wilkes et al., 2012; Yanagawa, Akaishi, Miyamoto et al., 2008) in a hospital setting (e.g. Hill & MacArthur, 2006; Rickard et al., 2011; Roberts, Eastwood, Raunow et al., 2011) or on research within a single specialist area (e.g. Catania, Poire, Bernardi et al., 2012; Eastwood et al., 2012; Nagel, Gender, & Bonner, 2010; Rickard et al., 2006; Roberts et al., 2011). Translational and applied health research, however, encompasses a much wider range of studies than clinical trials and studies may be undertaken in settings other than hospitals. In addition, as the number of studies continues to grow, the demand for research nurses may exceed the supply available and it may become more difficult to recruit experienced nurses to deliver research (Pharmaceuticals & Biotechnology Branch, 2006). Relatively little is known about these developments and their implications for the composition of the future research workforce and the nature of their roles and responsibilities. In addition, there are significant methodological limitations to the research nurse literature, with most studies based on small scale convenience samples that have been recruited through a single organisation (e.g. Catania et al., 2012; Nagel et al., 2010; Rickard et al., 2006; Spilsbury et al., 2008), or through snowball sampling (e.g. Eastwood et al., 2012; Rickard et al., 2011; Wilkes et al., 2012).

Clearly, only limited evidence is available on which to base future policy and practice in the delivery of health research. This paper presents a study intended to provide a better understanding of the workforce that delivers translational and applied health research. It addresses three main questions: who delivers studies; what types of studies are delivered; and what does delivering them entail? In addition, it explores whether their responsibilities vary across the different contexts in which they are employed.

3. Study design, ethics and participants

3.1. Study design

The study was designed as a cross-sectional, mixed methods study comprising a questionnaire and focus groups. However, topics discussed in the focus groups were not relevant to the questions addressed in this paper and are not presented here.

3.2. Ethics and Approvals

The research protocol was reviewed and approved by the University Research Ethics Committee of Oxford Brookes University (UREC Registration Number 130703). NHS Trust approvals were sought and received from their R&D Department. The work described in this paper was carried out in accordance with the Code of Ethics of the World Medical Association's Declaration of Helsinki (World Medical Association, 2001).

3.3. Participants

The population of interest was defined by the following criteria:

3.3.1. Inclusion criteria

Non-medical researchers who deliver (rather than lead) translational and applied health research and have direct contact with research participants; funded by an NIHR infrastructure organisation; and employed by a NHS Trust, Primary Care practice or, in the case of a Biomedical Research Centre/Unit only, a University.

3.3.2. Exclusion criteria

Those who lead (rather than deliver) research (e.g. Chief or Principal Investigators); those who do not have direct contact with research participants (e.g. Clinical Trials Unit Directors)

3.3.3. Funding and employing organisations

The employing organisations included the following: the University Hospital, a large, research active hospital on four sites incorporating a major research intensive Medical School as well as a Biomedical Research Centre and Biomedical Research Unit and providing a wide range of secondary and tertiary hospital services; four Other hospitals in urban centres across the area, providing a range of acute and follow-up hospital services for their communities, commonly on several sites; two Community healthcare providers delivering care for mental and physical health from bases in the community, hospitals, specialist clinics and people's homes, one of which incorporated a Clinical Research Facility; and 11 GP Practices which were largely small independent businesses, funded by the NHS to provide primary care to their practice population of registered patients.

The NIHR infrastructure organisations (http://www.nihr.ac.uk/about/nihr-infrastructure.htm) included the following: a Biomedical Research Centre (BRC) which is a partnership between the University Hospital and University, funded to conduct translational research; a Biomedical Research Unit (BRU), similar to a BRC but with a focus on a specific therapeutic area of disease; a Clinical Research Facility (CRF), which is a partnership between one of the Community sites and University, also funded to facilitate translational research; two generic Clinical Research Networks (CRN), covering hospital, primary care and community settings, and three Topic Specific Research Networks, covering cancer, dementias and neurodegeneration, and diabetes, which deliver studies adopted onto the NIHR Portfolio (ie high quality studies that are of clear value to patients or the NHS; funded through a nationally competitive, peer-reviewed process; and reviewed by a Clinical Research Network or a Network Industry Adoption Panel) (https://www.crn.nihr.ac.uk/can-help/funders-academics/).

Those identified through the BRC and BRU were employed to work on studies for which the BRC or BRU had received funding directly from NIHR. Those identified through the Clinical Research Networks were funded to support studies adopted onto the NIHR Portfolio along the last three stages of the 'Research Delivery Pathway', including supporting the set-up and start-up of studies, study recruitment and follow-up and study closure.

4. Methods

4.1. Recruitment of participants

All those who met these criteria were contacted between June and October 2013. To meet data protection requirements, the participating infrastructure organisations identified those eligible and sent their names directly to the relevant Research and Development (R&D) Manager in their employing Trust, or to the Operations Manager at the BRC and BRU or to their Research Network manager, as appropriate. At the same time, MB sent each manager an email invitation with a weblink to the on-line questionnaire specific to their organisation and a participant information sheet as an attachment, for them to forward to the list of individuals identified by the NIHR infrastructure organisation. Two reminder emails were sent out to all those initially contacted.

4.2. Data collection

The questionnaire was developed by MB, an experienced social science researcher, on the basis of a literature review and an earlier small scale study of research nurses. A weblink to the draft questionnaire was sent to three research nurses, a research occupational therapist, and two research physiotherapists in another area of England as well as two senior research nurses and three NIHR Clinical Research Network managers. Eight individuals completed the questionnaire and provided written feedback; the questionnaire was revised to take account of their comments. Questions either asked participants to write in their response, offered options for them to choose from or provided a list of items where they could choose all that applied. Most included 'other' as an option and where further information was specified the response was recoded to one of the options provided or a new response option added. Those who indicated 'not applicable' were excluded from the analysis. Questionnaires were completed on-line between June and December 2013; completion was taken as indicating consent to take part in the study.

4.3. Data analysis

Data from the on-line questionnaires were downloaded into IBM SPSS (Version 19) for analysis. Descriptive statistics were produced using totals and percentage for categorical variables and mean, standard deviation and range for interval variables. To examine associations between categorical variables, a Pearson chi square was first calculated as a measure of statistical significance, with p values of 0.05 or less regarded as significant. Where a statistically significant difference was found, Cramer's V was used to determine strength of association between the variables. An association of between 0.20 and 0.25 was considered a moderate association, between 0.25 and 0.30 a moderately strong and above 0.30 a strong association. Missing data were excluded when examining associations.

5. Findings

Completed questionnaires were received from 168 of the 280 individuals invited to take part, a response rate of 60%.

As the number of participants from each of the 14 recruiting organisations was quite small, they were combined into three larger groups according to their employment context: University Hospital (109, 65%), Other hospitals (36, 21%), and Community (including primary care) (23, 14%). The response rate was higher for those recruited through the University Hospital (109/165, 66%) compared with those recruited through Other hospitals (36/74, 49%) and the Community (23/41, 56%).

5.1. Who delivers translational and applied health research?

The socio-demographic characteristics of the sample are shown in Table 1. All but 7 participants were female, more than 80% were between the ages of 25 and 54, and three quarters had qualifications at Bachelor's degree level or above, including 6 who had a PhD or Professional Doctorate.

Nurses (121, 77%) were the largest professional group; the remainder comprised individuals from 10 other backgrounds. A higher proportion of those recruited through the Community came from backgrounds other than nursing while those recruited through the University Hospital included the greatest variety of professional backgrounds.

Table 1
Socio-demographic characteristics and professional background of sample by recruitment sites.

	University Hospital n (%)	Other hospitals n (%)	Community n (%)	Total n (%)
Gender				
Female	98 (90)	28 (78)	21 (91)	147 (88)
Male	5 (5)	1 (3)	1 (4)	7 (4)
Data missing	6 (6)	7 (19)	1 (4)	14 (8)
Total	109 (100)	36 (100)	23 (100)	168 (100)
Age				
18 to 24	1 (1)	0	3 (13)	4 (2)
25 to 34	13 (12)	7 (19)	5 (22)	25 (15)
35 to 44	43 (39)	8 (22)	4 (17)	55 (33)
45 to 54	32 (29)	10 (28)	7 (30)	49 (29)
55 to 65	14 (13)	5 (14)	2 (9)	21 (13)
Data missing	6 (6)	6 (17)	2 (9)	14 (8)
Total	109 (100)	36 (100)	23 (100)	168 (100)
Highest Qualification				
Certificate, Diploma or Foundation degree	20 (18)	8 (22)	3 (13)	31(18)
Registered nurse/midwife	7 (6)	1 (3)	3 (13)	11 (6)
Bachelor's Degree	50 (46)	13 (36)	8 (35)	71 (42)
Post-Graduate Diploma, MSc	21 (19)	8 (22)	8 (35)	37 (22)
PhD or Professional Doctorate	6 (6)	0	0	6 (4)
Data missing	5 (5)	6 (17)	1 (4)	12 (7)
Total	109 (100)	36 (100)	23 (100)	168 (100)
Professional Background				
Assistant Practitioner	0	0	2 (9)	2 (1)
Health care assistant	1 (1)	0	3 (13)	4 (2)
Midwife (without nursing)	4 (4)	0	0	4 (2)
Nurse	84 (77)	26 (72)	11 (48)	121 (72)
Nutritionist or Dietician	1 (1)	0	0	1 (1)
Optometrist or Orthoptist	1 (1)	0	0	1 (1)
Physiotherapist	4 (4)	0	0	4 (3)
Psychologist/Qualified mental health practitioner	2 (2)	0	7 (30)	9 (5)
Radiographer	2 (2)	2 (6)	0	4 (2)
Clinical or other Scientist	3 (3)	0	0	3 (2)
Other	3 (3)	1 (3)	0	4 (2)
Data missing	4 (4)	7 (19)	0	11 (7)
Total	109 (100)	36 (100)	23 (100)	168 (100)

Table 2
Employment characteristics of sample by recruitment sites.

	University Hospital n (%)	Other hospitals n (%)	Community n (%)	Total n (%)
Current posts				
Clinical research post only	87 (80)	18 (50)	11 (48)	116 (70)
Clinical research post plus clinical practice or teaching	22 (20)	17 (47)	12 (52)	51 (31)
Data missing	0	1 (3)	0	1 (1)
Total	109 (100)	36 (100)	23 (100)	168 (100)
Contracted hours				
Full-time (30 h or more)	71 (65)	20 (56)	12 (52)	103 (61)
Part-time (20 to 29 h)	23 (21)	3 (8)	5 (22)	31 (18)
Part-time (19 h or less)	9 (8)	7 (19)	5 (22)	21 (13)
Data missing	6 (6)	6 (17)	1 (4)	13 (8)
Total	109 (100)	36 (100)	23 (100)	168 (100)
Experience in Current Post				
Less than 1 year	26 (24)	7 (19)	10 (44)	43 (26)
1 to 2 years	34 (31)	16 (44)	5 (22)	55 (33)
3 to 5 years	36 (33)	7 (19)	6 (26)	49 (29)
More than 5 years	13 (12)	6 (17)	2 (9)	21 (13)
Total	109 (100)	36 (100)	23 (100)	168 (100)

The employment characteristics of the sample are shown in Table 2. Two thirds of participants were employed solely in research posts. However, this proportion is significantly higher amongst those recruited through the University Hospital compared to those recruited through Other hospitals and Community sites (Pearson chi-square = 15.951, 2 df, p = 0.000, Cramer's V = 0.309). The majority were employed full-time.

A quarter of participants had worked in their current post for less than a year and a further third for only 1 to 2 years. The total number of years worked as a researcher (including all posts) ranged from 0 to 23 years (mean 4.7, standard deviation 4.7).

5.2. *What types of studies are 'delivered' and in what context?*

Table 3 shows the characteristics of the studies on which the participants worked. Although all studies had been funded by the NIHR and/or adopted onto the NIHR portfolio, the potential diversity amongst them was nonetheless considerable.

Table 3
Characteristics of the studies on which participants worked by recruitment sites.

	University Hospital n (%)	Other hospitals n (%)	Community n (%)	Total n (%)
Types of Studies (tick all that apply)				
Drug trials	66 (61)	21 (58)	15 (65)	102 (61)
Other clinical intervention studies	60 (55)	20 (56)	18 (78)	98 (58)
Non-intervention studies (e.g. epidemiological studies, biobank)	79 (72)	26 (72)	13 (57)	118 (70)
Data missing	2 (2)	4 (11)	1 (4)	7 (4)
N =	109 (100)	36 (100)	23 (100)	168 (100)
Study Settings (tick all that apply)				
Hospital	107 (98)	32 (88)	5 (22)	144 (86)
General practice	6 (6)	2 (6)	10 (43)	18 (11)
Community (e.g. day centre, primary care, community hospital)	8 (7)	0	7 (30)	15 (9)
Data missing	2 (2)	3 (8)	1 (4)	6 (4)
N =	109 (100)	36 (100)	23 (100)	168 (100)
Study Sponsor (tick all that apply)				
University	91 (83)	25 (69)	16 (70)	132 (79)
NHS Trust	67 (61)	26 (72)	11 (48)	104 (62)
Commercial	54 (50)	14 (39)	13 (57)	81 (48)
Uncertain	9 (8)	1 (3)	4 (17)	14 (8)
Data missing	2 (2)	3 (8)	1 (4)	6 (4)
N =	109 (100)	36 (100)	23 (100)	168 (100)
Number of Studies (Grouped)				
0–1	11 (10)	2 (6)	1 (4)	14 (8)
2–5	40 (37)	9 (25)	10 (43)	59 (35)
6–10	31 (28)	16 (44)	7 (30)	54 (32)
11–15	13 (12)	2 (6)	3 (13)	18 (11)
16–20	4 (4)	0	0	4 (2)
21–40	7 (6)	3 (8)	0	10 (6)
Data missing	3 (3)	4 (11)	2 (9)	9 (5)
Total	109 (100)	36 (100)	23 (100)	168 (100)

5.2.1. Types of studies

Almost two thirds (102/168, 61%) of participants had worked on a clinical trial involving an investigational medicinal product (CTIMP), with remarkably similar proportions across the three recruitment sites. Most had worked on Phase 2 trials (43/102, 42%) designed to assess how well the drug works and to continue safety assessments begun in Phase 1 trials, and/or on Phase 3 trials (70/102, 69%) designed to affirm the safety and efficacy of the drug and assess its clinical effectiveness in relation to the current gold standard. A quarter had worked on post-marketing Phase 4 trials (25/102, 25%). Only 10/102 (10%) had worked on Phase 1 trials, which look at optimum dose levesl and side effects, while a similar proportion (12/102, 12%) were uncertain of the type of trial they had worked on.

More than half (98/168, 58%) the participants had worked on other types of clinical trials or intervention studies, most commonly studies involving a medical device (46/98, 47%), a surgical intervention (31/98, 31%) or an exercise or physical therapy (25/98, 26%). Less than a fifth (18/98, 18%) had worked on psychological or behaviour change interventions, though this rose to half (9/18, 50%) amongst those recruited through the Community sites.

Overall, 132/168 (79%) had worked on some type of clinical trial or intervention study.

More than two thirds (118/168, 70%) had worked on observational studies, including genetic/genomic (61/118, 52%), bio-bank, (58/118,49%) and/or registry or database studies (57/118, 48%). Nearly half the participants (53/118, 45%) had worked on questionnaire based studies with a significantly higher proportion (11/13, 85%) of those recruited from Community compared to University Hospital (26/79, 33%) or Other hospitals (16/26, 62%) sites ($x^2 = 8.583$, 2 df, $p = 0.014$, Cramers V = 0.226).

The majority of those who worked on a CTIMP (61/102, 69%) had also worked on studies involving another type of intervention and three quarters (77/102, 75%) had also worked on observational studies.

5.2.2. Study settings

Hospitals were the most common setting for research studies, though this varied from almost all those recruited through the University Hospital to a quarter of those recruited through Community sites. About a fifth of participants (31/168, 18%) carried out studies in either General practice or other community settings: this varied from about one in eight of those recruited through the University Hospital and Other hospitals to three in four of those recruited through Community sites.

5.2.3. Study sponsor

More than three quarters of participants had worked on studies that were sponsored by a University, almost two thirds by an NHS Trust and half by a commercial organisation.

5.2.4. Number of studies

Most participants had worked on multiple studies in the previous 12 months: less than one in ten had worked on just one study while one in five had worked on more than 10 studies (mean 7.9, standard deviation 7.26, range 40).

5.3. What does 'delivering' translational and applied health research entail?

5.3.1. Main duties and responsibilities

A list of duties and responsibilities was drawn up based initially on job descriptions and a review of the literature on research nurses, and revised following piloting of the questionnaire. Participants were asked to indicate which had been their main duties in delivering research studies over the last 12 months. These responsibilities were then divided into three groups, according to the proportion of participants who had indicated that they had been among their main duties: those identified by 75% or more were labelled 'core responsibilities', those identified by 50% to 74% were labelled 'common responsibilities' and those identified by less than

50% were labelled 'specialist responsibilities'. Responsibilities identified by less than 10% of participants were excluded.

Responses are shown in Table 4. *Core responsibilities* entailed liaising with clinical staff; identifying, recruiting and consenting participants; and collecting and entering clinical data. Interestingly, obtaining written informed consent was reported by a significantly *smaller* proportion of those recruited through the University Hospital (Cramer's V = 0.199, p = 0.043).

Common responsibilities included assessing patients and providing and/or co-ordinating care; further aspects of collecting and managing research data; and contributing to research governance. A significantly larger proportion of those recruited through Community sites reported carrying out initial assessments and physical examination (Cramer's V = 0.211, p = 0.028) while a significantly higher proportion of those recruited through the University Hospital reported contributing to research governance (Cramer's V = 0.302, p = 0.001).

Specialist responsibilities were diverse. They included liaising with external organisations, reported by just under half of participants across the recruitment sites as well as processing biological samples, reported by about a third of participants across the recruitment sites. By contrast, a significantly higher proportion of those recruited through the University Hospital reported contributing to or amending protocols (Cramer's V = 0.316, p = 0.000) as among their responsibilities while of those recruited through the Community a significantly higher proportion reported taking a medical history (Cramer's V = 0.218, p = 0.022) and a significantly lower proportion reported managing other staff (Cramer's V = 0.204, p = 0.036).

5.3.2. Responsibilities outside the research delivery pathway

A minority of participants reported responsibilities outside the Research Delivery Pathway, including data analysis, dissemination activities and development of new studies. Over a third of participants reported presenting posters or giving talks on their studies, with similar proportions across the recruitment sites, and more than a quarter reported contributing to data analysis. Less than a fifth reported contributing to publications, with a significantly higher proportion of those recruited from the University Hospital doing so (Cramer's V = 0.259, p = 0.005). A quarter reported contributing to the development of new studies, almost all recruited through the University Hospital (Cramer's V = 0.378, p = 0.000).

4. Discussion

Research nurses and others who 'deliver' studies make a significant contribution to the success of research, providing 'care work' while implementing study protocols on behalf of the (usually medical) lead researchers. In the UK, this workforce has grown substantially over the last decade in the context of substantial government funding (Department for Business, Innovation and Skills, 2011), an explicit commitment to research in the NHS constitution (Department of Health, 2015) and the support of NIHR infrastructure organisations (http://www.nihr.ac.uk/about/). This paper has explored three key questions regarding this workforce. The findings are discussed below in relation to previous studies and their implications for the future of this workforce are considered.

4.1. Who delivers translational and applied health research?

As in previous studies, almost all those in this study were female, most were between the ages of 35 and 54 and the great majority were nurses (Eastwood et al., 2012; Rickard et al., 2006, 2011; Roberts et al., 2011; Wilkes et al., 2012). However, this study has documented greater diversity in the workforce than earlier studies. Previous studies have reported individuals from other backgrounds as employed in delivering research (Rickard et al., 2006, 2011; Wilkes et al., 2012), but with one exception (Eastwood et al., 2012), numbers have been small. In this study, almost a quarter were from backgrounds other than nursing and of those recruited through community sites, this rose to more than half. The reasons for this greater diversity are not clear, but could reflect both difficulties in recruiting nurses to research posts as well as a recognition that, for some studies, individuals from different backgrounds may bring appropriate skills (Rickard & Roberts, 2008). Whatever the case, in the context of the growing shortage of nurses generally (Centre for Workforce Intelligence, 2015; Imison, 2015) it is likely that recruiting nurses to, and retaining them in, research posts will become more challenging in the future.

The longer term implications of the widening range of professional expertise among those who deliver research are also unclear. While it may be appropriate in order to meet the demands for a workforce to deliver a growing body of research, it could also mark the start of a process of progressive differentiation among types of applied health research, for example with nurses specialising in interventional studies where clinical care and patient safety are of greatest concern, while observational and other studies are delivered by those with other relevant qualifications. If this is the case, it will be important to ensure that *all* those who deliver research prioritise the principles of Good Clinical Practice and that they put the rights, safety and wellbeing of participants are at the heart of their relationship. In some cases, for example Clinical Trials of an Investigational Medicinal Products (CTIMPs), it will be essential to employ a trained nurse so that research participants are appropriately safeguarded. Where this is not the case, it will be important to set out competency frameworks, to provide appropriate training and supervision and to develop professional identities for those recruited from other backgrounds.

4.2. What types of studies are delivered and in what context?

In contrast to much of the earlier literature where the assumption, implicit or explicit, has been that research nurses conduct clinical trials in hospitals (e.g. Catania et al., 2012; Gordon, 2008; Raja-Jones, 2002; Spilsbury et al., 2008; Stephens-Lloyd, 2004), in this study nearly three quarters of participants had engaged in observational studies and a fifth carried out studies based in the community. Almost half had worked on both clinical trials and observational studies, a finding consistent with recent studies (Rickard et al., 2006, 2011; Roberts et al., 2011). Furthermore, the majority worked on more than five studies in the same year and one in ten on more than 15 studies. While this is also consistent with previous research (Eastwood et al., 2012; and Roberts et al., 2011) it suggests a demanding workload and further research is needed on how such workloads are determined, experienced and managed.

4.3. What does 'delivering' research entail?

The range of responsibilities reported in this study are broadly consistent with those previously described in the UK (Bird and Kirshbaum, 2005; Gibbs & Lowton, 2012), Australia and New Zealand (Rickard et al., 2011; Wilkes et al., 2012), and other countries (Eastwood et al., 2012; Nagel et al., 2010), though there are differences in details. While assessing and consenting patients and collecting data are the 'cornerstone of research' (Eastwood et al., 2012: 843), and were reported by the great majority of participants, this study also provides further evidence of the wide-ranging activities undertaken by those who deliver health research (Hill & MacArthur, 2006; Spilsbury et al., 2008; Stephens-Lloyd, 2004)

In recent years, attention has turned from describing the *range* of activities undertaken in delivering research to identifying *clus-*

Table 4
Responsibilities in clinical research post by recruitment sites.

	University Hospital (n = 106)	Other hospitals (n = 32)	Community (n = 22)	Total (N = (160)
a) Core Responsibilities:				
Liaising with members of the multi-disciplinary team	97 (92%)	32 (100%)	19 (86%)	148 (93%)
Informing potential participants of what to expect in a study	91 (86%)	29 (91%)	19 (86%)	139 (87%)
Identifying and recruiting participants	90 (85%)	26 (81%)	20 (91%)	136 (85%)
Entering data onto a Case Report Form (CRF)	88 (83%)	26 (81%)	19 (86%)	133 (83%)
Participating in the process of informed consent	83 (78%)	30 (94%)	19 (86%)	132 (83%)
Entering data onto other research databases	84 (79%)	29 (91%)	17 (77%)	130 (81%)
Collecting clinical data (e.g. ECGS, BP, Barthel Index)	80 (76%)	28 (88%)	20 (91%)	128 (80%)
Liaising with ward, clinic or community staff	83 (78%)	24 (75%)	13 (59%)	120 (75%)
Obtaining written informed consent	73 (69%)	28 (87%)	19 (86%)	120 (75%)a
b) Common Responsibilities				
Resolving data queries	76 (72%)	24 (75%)	14 (64%)	114 (71%)
Collecting biological samples (e.g. blood)	73 (69%)	22 (69%)	15 (68%)	110 (69%)
Co-ordinating patient care (e.g. organising tests, follow-up)	72 (68%)	18 (56%)	17 (77%)	107 (67%)
Liaising with representatives of collaborating organisations	70 (66%)	20 (62%)	13 (59%)	103 (64%)
Providing patient care (e.g. giving treatments, carrying out tests)	65 (61%)	19 (59%)	12 (55%)	96 (60%)
Carrying out initial assessments or conducting a physical examination	55 (52%)	16 (50%)	18 (81%)	89 (56%)c
Contributing to research governance (e.g. SOPs, ethics)	65 (61%)	14 (44%)	4 (18%)	83 (52%)f
c) Specialist responsibilities				
Liaising with representatives of funding/sponsoring organisations	52 (49%)	16 (50%)	10 (46%)	78 (49%)
Managing other research or support staff	55 (52%)	13 (41%)	5 (23%)	73 (46%)b
Taking a medical history	39 (37%)	18 (56%)	14 (64%)	71 (44%)d
Processing biological samples	49 (46%)	11 (34%)	7 (32%)	67 (42%)
Contributing to or amending protocols	47 (44%)	5 (16%)	2 (9%)	54 (34%)g
d) Outside the Research Delivery Pathway				
Presenting posters and giving talks	40 (38%)	15 (47%)	8 (36%)	63 (39%)
Contributing to data analysis	36 (34%)	7 (22%)	4 (18%)	47 (29%)
Contributing to the development of new studies	44 (42%)	3 (9%)	0	47 (29%)h
Contributing to publications	26 (25%)	1 (3%)	1 (5%)	28 (18%)e

aPearson Chi-square = 6.308, 2 df, p = 0.043, Cramer's V = 0.199.
bPearson Chi-square = 6.647, 2 df, p = 0.036, Cramer's V = 0.204.
cPearson Chi-square = 7.125, 2 df, p = 0.028, Cramer's V = 0.211.
dPearson Chi square = 7.604, 2 df, p = 0.022, Cramer's V = 0.218.
ePearson Chi-square = 10.764, 2 df, p = 0.005, Cramer's V = 0.259.
fPearson Chi-square = 14.639, 2 df, p = 0.001, Cramer's V = 0.302.
gPearson Chi-square = 16.001, 2 df, p = 0.000, Cramer's V = 0.316.
hPearson Chi-square = 22.844, 2 df, p = 0.000, Cramer's V = 0.378.

ters of activities which may constitute potentially distinct roles. The *core responsibilities* identified in this study align with the five domains of activities that Wilkes et al. (2012) suggested as a cluster concerned with the recruitment to and day to day running of clinical trials which could be distinguished from a cluster concerned with other activities. In the USA, Bevans, Hastings, Wehrlen et al. (2011) drew a similar distinction between the role of the research nurse co-ordinator (RNC), who was oriented to a specific study or PI and engaged in activities such as recruitment, informed consent, and preparing research data for analysis and that of the clinical research nurse (CRN), who focused on direct clinical and research care to individual patients. For most participants in the present study, the balance of their activities was similar to that of the RNC. This contrasts with the findings of Bevans' own study, where only 18% of the sample were classified as RNCs, and suggests differences in the ways that the research nurse workforce is deployed in the UK and in the USA.

Only rarely did the responsibilities of study participants extend beyond those of recruitment to and day to day running of their studies to include activities such as analysing data, writing publications and developing new studies. Previous studies (Eastwood et al., 2012; Hill & MacArthur, 2006; Rickard et al., 2006; Roberts et al., 2011; Wilkes et al., 2012) have reported similar findings. Bevans et al. (2011), for example, reported that none of the RNCs in their study contributed to study grant development and only a minority to presentations, publications or other dissemination activities. Other authors, however, have suggested that the role of research nurses often extends more widely, to encompass 'academic, financial, managerial and administrative boundaries' (Stephens-Lloyd, 2004: 20). Rickard, Williams, Ray-Barruel et al. (2011), for example, reported that 54% of their participants identified preparing grant submissions as one of their responsibilities, Roberts et al. (2011) that 30% carried out their own research studies and Wilkes et al. (2012) that 30% had at least once been identified as a Principal or Co-Investigator. Barthow et al. (2015) suggested that 'research nurses *should* [emphasis added] be involved in all aspects of a study including inception, design, testing, fieldwork, analysis and interpretation, and dissemination of results.'

These differences in expectations of the nature and scope of responsibilities point to uncertainties around the identity of those who deliver research and their position within nursing and research. Rickard et al. (2006) reported that a large variation in job titles led to confusion as to how to differentiate between roles and Scott et al. (2013) also noted that unclear role definitions complicated the identification clinical trials nurses and made estimates of the size of the workforce difficult. While a distinction is commonly drawn between 'research nurses' who deliver research and 'nurse researchers' who lead research of interest or concern to nurses (Johnson & Stevenson, 2010; Watmough, Flynn, Wright, & Fry, 2010), further distinctions may need to be drawn between different types of 'research nurses'. Bevans et al. (2011) distinguished between CRNs and RNCs; however, a further distinction could usefully be made between 'research nurse co-ordinators' who are employed to deliver studies on behalf of (potentially many) CIs commonly based elsewhere and 'research nurse officers/fellows' who are employed directly by the grant holders to work as a mem-

ber of their research team. While specific responsibilities of both research nurse co-ordinators and research nurse officers/fellows may vary according to the studies they work on, differences in their relationship with those who lead the study are likely to give rise to differences in the nature of their involvement across the whole research process.

4.4. Do their responsibilities vary across employment contexts?

Compared to those who worked in either Other hospitals or the Community, those who worked in the University Hospital were more likely to engage in activities at the extremes of or outside the Research Delivery Pathway. That is, they were significantly more likely to be involved in the very early stages of research, including the development of new studies and preparation of documents such as protocols and research ethics forms needed in applying for the required approvals, and in the later stages of research including contributing to publications. The fact that they were more likely to be employed solely in research posts may have facilitated their ability to engage in these activities. Also important, however, were the opportunities afforded by a large, research active organisation with a regular flow of new research studies. The University Hospital was well placed to offer continuous employment to those who delivered studies and support their integration into a clinical team which both provided clinical care and developed and led their own research. The experience they gained and the working relationships they established in this context may contribute to longer term career development within research nursing and, for the minority who are so inclined, facilitate the transition from research nurse to nurse researcher (Watmough et al., 2010).

Community sites employed the widest variety of research staff, with a lower proportion of nurses and a higher proportion of psychologists and of those without a degree. This may be related to the significantly higher proportion of questionnaire based studies and the higher proportion of psychological and behaviour change studies carried out in community and primary care settings. Compared with the University Hospital and Other hospitals, participants recruited from Community sites were significantly more likely to report taking a medical history and carrying out initial assessments or conducting a physical examination as among their responsibilities. This may reflect the particular demands made on those who deliver research based in the Community where, as Barthow et al. (2015) suggest, their isolation from an academic environment and often from the community or primary care team means that they must draw on their professional skills and make their own decisions. This isolation may also account for the finding that participants recruited from Community sites were significantly less likely to manage other staff than those in either the University or Other hospitals.

5. Strengths and limitations

Major strengths of this study were the use of a clearly-defined sampling frame, a good response rate and a relatively large sample size. The final sample size of 168 is considerably higher than those of previous studies with the exception of Bevans et al. (2011) in the USA. A further strength was the development and piloting of the questionnaire with research nurses and AHPs in a different area, to ensure it was meaningful and acceptable to participants and covered what they considered important topics.

Research nurses and others employed by the study NHS Trusts and primary care practices to deliver research but who were not funded through NIHR infrastructure facilities were excluded from this study as it was not possible to identify the relevant population. This means it is not possible to generalise the findings to this wider population and nor to compare the two populations. Others have reported similar constraints: Wilkes et al. (2012) noted that the Clinical Trials Nurses should be considered a hard to reach population as there is no national register nor professional organisation which could provide a comprehensive sampling frame and Rickard et al. (2011: 168) reported that 'the lack of organisational recording of research nurse positions made it impossible to determine a response rate'.

Further limitations include the self-report format of the questionnaire, the difficulties that some had in using the survey platform, and the length of the questionnaire which meant that not all who started it completed the questionnaire. The response rate from those employed in Other hospitals was lower than in the University Hospital and Community, and the proportion of missing data was higher, which limits the generalisability of the findings to similar hospital contexts.

6. Conclusion

This paper provides evidence from a multi-site study with a clear sampling frame and good response rate of the nature of the workforce that delivers translational and applied health research in England. While the majority are nurses, there is greater diversity in the workforce than has previously been reported. In the context of a growing shortage of nurses generally, and the high proportion of studies which do not involve a clinical intervention, the number of those from other professional backgrounds is likely to increase.

It also makes clear the diverse range of types of study delivered, with varying degrees of challenge and scope for initiative and expertise, and the wide range of settings in addition to the traditional hospital, which provide differing opportunities and demands. This diversity also needs to be acknowledged in educational, training and career planning to sustain capacity for delivering translational and applied health research in the future.

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