

Implementation Scientists in Clinical Trials – an opportunity for expanding trial workforce collaborations

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Short Report

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Abstract

Background

The clinical trial sector is turning to implementation science for potential solutions to the enduring challenges of translation delays and research waste. Randomised controlled trial (RCT) teams can benefit from collaborating with implementation science experts to support innovation in trial design and outcome measures. While engagement with implementation scientists is gaining traction, their role definition in RCTs is unclear. We used a workforce survey to explore the characteristics of implementation scientists collaborating with RCT teams, the range of activities performed in this role and the perceived impact of implementation specialists contributing to the RCT workforce.

Methods

We conducted a national implementation science needs assessment survey of the Australian and New Zealand RCT workforce in 2025. We applied a descriptive, mixed methods secondary analysis that focused on data regarding the role and impact of implementation scientists in RCTs.

Results

Of the total of 353 respondents, 52 were identified as implementation scientists. Implementation scientists were experienced trialists and predominantly from an allied health or nursing background located in metropolitan settings. One third of all respondents ($n = 99$) had collaborated with an implementation scientist and reported it to be of high value. Involvement was highest at the early stages of RCT design but extended to within-trial problem solving and post-trial dissemination and translation. Implementation scientists often undertook capacity-building roles; 42% reported providing mentorship, and a third of all respondents reported desiring mentorship to upskill in implementation science. The most important impact of implementation scientists in RCTs was related to a greater and faster realisation of evidence-based practice changes.

Conclusions

Implementation scientists working in RCTs are experienced trialists within their own clinical discipline and bring additional methodological expertise in implementation science and practice. They bring valuable expertise across the lifespan of the trial that can improve the translation of trial results into practice. Investment in upskilling the trial workforce and establishing a dedicated career path for implementation scientists in the sector needs to be a priority to realise the potential research impacts of implementation scientist collaborations in RCTs.

Contributions to the literature

- Implementation scientists add value to randomised controlled trials (RCTs) by embedding theory-informed, context-sensitive strategies across the trial lifecycle, strengthening design, funding competitiveness, workforce capability, and the translation of trial outcomes in practice.
- Reinforces calls to move beyond efficacy-focused RCTs toward innovative designs that integrate implementation science and practice.
- The emerging role of implementation scientists in RCTs faces challenges related to limitations in workforce capacity and uneven access to expertise, particularly outside metropolitan centres.
- Workforce patterns support growing arguments for a distinct implementation science profession, following trajectories seen in biostatistics and health economics, requiring dedicated training, career pathways, and system-level investment.

Background

Uptake of implementation science methods and strategies within the context of randomised controlled trials (RCTs) is expanding, especially in the light of innovative trial designs and those which combine effectiveness and implementation outcomes to improve patient outcomes and healthcare delivery [1–3]. The trial sector continues to evolve with inclusion of implementation science within planning, data collection and outcomes within traditional trial designs, but uptake remains inconsistent and not well reported [4–6]. Investment in core activities of implementation such as planning implementation design and evaluation, choosing implementation frameworks, mapping implementation strategies to framework domains and testing effectiveness, creating tools to collect implementation outcome data and developing implementation management plans compatible with trial delivery and practice [7, 8] are all aimed at reducing research waste and delays in translation. This evolving trial landscape offers novel opportunities for implementation scientists to collaborate with RCT teams [9].

An implementation scientist studies and improves the processes by which evidence-based interventions are adopted, implemented, and sustained in real-world settings and contexts. Implementation scientists focus on the “know–do gap”—the lag between what research shows to be effective and what is actually delivered in practice. In Australia and New Zealand, there is no single pathway to qualify as an implementation scientist or practitioner with many obtaining formal training in a clinical discipline before specialising in implementation methodology with applied practice. Trialists may look to implementation scientists to bring leadership, knowledge, evidence translation expertise and credibility to their team capabilities [9], however, to date the current roles and value of implementation specialists in RCT teams remains unspecified and underrecognized.

We recently undertook an online cross-sectional survey of the Australian and New Zealand clinical trial workforce, [10] which showed an emerging yet superficial understanding of the application of implementation science methodologies in RCT design. Of the 353 responses, n = 201 (57%) had heard

about or seen others utilising implementation methods, but far fewer (15–26%) had direct experience using them in their own trials [10].

We aimed to extend the analysis of this survey to explore the characteristics of implementation scientists collaborating with RCT teams in Australia and New Zealand, the range of activities performed in this role and the perceived impact of implementation specialists contributing to the RCT workforce.

Methods

The survey methods are described in detail elsewhere [10]. A secondary analysis of the role of implementation scientists in RCT teams that was not reported in the original manuscript was extracted from survey results for descriptive analysis. Ethics approval in accordance with the Declaration of Helsinki (Approval: 2024/HE001682) was sought from the University of Queensland Human Research Ethics Committee and respondents provided tick box consent prior to commencement.

Respondents were eligible to complete the workforce survey if they had participated in design or delivery of a RCT in Australia or New Zealand in the last 12 months. RCTs were defined as any research study that prospectively assigns human participants to one or more health-related interventions (which may include control / placebo) to evaluate the effects on health outcomes. All respondents were asked how familiar they were with implementation science in trials with possible response of ‘not at all’, ‘somewhat familiar’ or ‘very familiar’. Those respondents who were very familiar with implementation science were then further explored to understand their professional background and role in trials, years of experience in trials, demographic characteristics and direct experience with implementation science and practice in trial design and delivery. Those who were very familiar with direct experience with implementation science methodologies and/or practice in trials were defined for the purpose of this analysis as implementation scientists.

All survey respondents were asked if they had ever worked with an implementation scientist in their role within RCTs (yes/no) and if so, what roles the implementation scientist had played in that team (multiple choice options plus free text). All survey respondents were asked to describe their views on the value of implementation scientists and what may be the impact of more implementation science and practice expertise across the RCT workforce. Free text answers underwent content analysis with Leximancer text analytics tool appropriate for knowledge discovery tasks [11].

Results

Familiarity with implementation science in trials ranged from Not at all (n = 101), Somewhat familiar (n = 200) or Very familiar (n = 52). The participants identified as being very familiar with implementation science in trials all had direct experience with one or more implementation method. The demographics of this cohort of implementation scientists are shown in Table 1. They were most likely involved with trial teams as university-based collaborators, often with an allied health or nursing background with

considerable experience in leading and collaborating in RCTs and almost all were located within a metropolitan area.

Table 1
Demographic characteristics of implementation scientists in RCT
teams (n = 52)

Demographics	Frequency
	N (%)
Trial Involvement	
Trial Conduct only	11 (21.2)
Trial Design only	9 (17.3)
Both Trial Design and Conduct	32 (61.5)
Type of Organisation	
Health Services	15 (28.9)
University	27 (51.9)
Research Institute	8 (15.3)
Commercial Industry	2 (3.9)
Professional Background	
Allied Health	16 (30.8)
Basic Scientist	6 (11.6)
Data Scientist	2 (3.8)
Health Economist	2 (3.8)
Public Health	3 (5.8)
Medical	5 (9.6)
Medical Engineering	1 (1.9)
Nursing/Midwifery	12 (23.1)
Statistician	1 (1.9)
Other	4 (7.7)
Main role in Clinical Trials	
Clinical Trials Network/Coordinating	4 (7.7)
Chief Investigator	23 (44.2)
Other Investigator	6 (11.5)
Researcher (Pre-PhD, PhD student, Early postdoc)	4 (7.7)

Demographics	Frequency
	N (%)
Trial Involvement	
Research Nurse or Health Professional	2 (3.9)
Other	13 (25.0)
Main Clinical Area of research	
Cancer and Haematology	8 (15.4)
Cardiovascular	3 (5.8)
Gastroenterology/Hepatology	1 (1.9)
Health Services	10 (19.2)
Infection and Immunity	1 (1.9)
Critical care and Anaesthetics	2 (3.9)
Kidney disease and Urology	3 (5.8)
Mental Health	1 (1.9)
Musculoskeletal	3 (5.8)
Neurological	2 (3.9)
Physical Medicine/Rehabilitation	4 (7.7)
Public and/or Preventative Health	3 (5.8)
Respiratory	1 (1.9)
Other	10 (19.1)
Regional Location	
Major City	49 (94.2)
Regional	2 (3.9)
Remote	1 (1.9)
Years of experience in clinical trials	
< 2yrs	1 (1.9)
2-5yrs	9 (17.3)
6-10yrs	10 (19.2)
11-19yrs	12 (23.1)

Demographics	Frequency
	N (%)
Trial Involvement	
> 20yrs	20 (38.5)

The types of trial design and practice related activities that implementation scientists had direct experience contributing to trial teams is shown in Fig. 1.

Of the total survey respondents (n = 353), 67% had never collaborated with an implementation scientist in their trial teams and did not know how to go about establishing a collaboration. For trialists who had experience working with implementation scientists in their team (n = 99), the collaboration was highly valued. Activities performed by the implementation scientist in RCT teams were diverse (Fig. 2). The highest proportion (76–86%) of implementation scientist roles involved early stages of RCT design, grant writing and designing outcome measures but they also participated across the life of a trial including attending investigator meetings, writing manuscripts and practically addressing implementation problems during delivery of the trial.

Implementation scientists also played an important role in workforce capacity and capability building. Around a third of the respondents to the survey were open to working with a mentor to improve their skills in implementation science and practice and 42% of implementation scientists said they provided mentoring to the teams with which they worked.

Impact of implementation scientists in RCTs

There were short responses from 175 respondents on the potential impact of more implementation scientists in RCTs (i.e. more people in the clinical trial workforce that can use implementation science). The most important theme was related to improved trial implementation and a greater and faster realisation of evidence-based practice changes.

“Clinical trial interventions that can be implemented into healthcare faster so those interventions can be utilised by the patients who they would most benefit.” [respondent quote]

“Efficiencies of a more standardised approach that would lead to improved translation and healthcare” [respondent quote]

“Better designed trials, with implementation thinking built into the design from the start, making it more likely that the trial results will impact actual practice after the trial” [respondent quote]

“Better trial design and outcomes that can be used in clinical practice more readily.” [respondent quote]

Greater trial impact, translation and practice change was considered a common consequence of implementation science and practice training with consequential improved health outcomes and reduced research waste.

“Enable trialists to consider translation at all stages of their research. It will ensure that our trials produce the greatest possible community benefit.” [respondent quote]

“So much effort is put into delivering high quality trials, and trial results - if those results are not translated, what was it all for? If we can partner with implementation science [scientists], hopefully we can design trials and associated strategies/metrics that increase the likelihood of incorporating results into practice” [respondent quote]

“a skilled workforce helps develop a future workforce that focusses on integrating research with daily health care delivery” [respondent quote]

“Connecting the dots between discovery, implementation and impact can only be done by ensuring that the workforce involved understand all steps of the process.” [respondent quote]

“What is the point in doing a clinical trial if you can't implement the findings? If you don't implement the findings, it is a waste of time and effort and money, and I think it is unethical and disrespectful to participants, study teams and the health care community if you don't.” [respondent quote]

Increased “awareness of alternative career pathways within the [clinical trial] industry” and “career development for early career researchers” were deemed beneficial. However, lack of time and resources to support training was frequently identified as a limiting factor to building capacity for implementation science and the complexity of implementation science itself made it less attractive to some clinicians and practitioners to upskill.

“This process [implementation science] is fantastic, but so complicated that no practicing clinician will be willing to engage with it. How do we simplify it without losing the benefits?” [respondent quote]

“Upskilling in implementation science has the potential to transform clinical trials from research-focused endeavours into powerful tools for systemic, real-world healthcare improvement.” [respondent quote]

“Upskilling in implementation science can transform the clinical trial landscape, making it more efficient, equitable, and impactful. This not only benefits the research community but also ultimately leads to better health outcomes for patients.” [respondent quote]

Discussion

The need to innovate RCT design and delivery to address challenges in translation has opened opportunities for broader interdisciplinary collaborations. The results of this clinical trial workforce survey indicate the emerging role of implementation scientists in trial teams which is highly valued but

currently restricted by lack of awareness of what and how implementation science contributes to trials, limited access to implementation scientists and barriers to accessing tailored workforce training opportunities across the sector.

In the Australia and New Zealand clinical trial landscape, the use of hybrid trial study methodology is developing rapidly [4] but the field of implementation science remains relatively small. Implementation scientists in this survey were early adopters of implementation science in RCT contexts and were mostly university academics with their own clinical expertise and already well-established trial experience. Allied health professionals and nurses demonstrated strong leadership and expertise in trial-related implementation science. This is unsurprising, given their frontline roles in healthcare, where they are frequently responsible for designing and implementing new innovations into practice.

There are recognised inequities of access to RCTs in non-metropolitan areas of Australia [12, 13]. This study indicated that implementation scientists working in RCTs are almost all located in metropolitan areas. This may simply reflect the density of RCT activity in metropolitan areas attracting a more diverse clinical trial workforce but could also indicate inequities in access to specialists in implementation science in regional, rural and remote locations. Facilitating collaboration with implementation scientists for trialists located outside of metropolitan areas should be a priority for the sector.

Motivations to incorporate implementation scientists into collaborative trial teams are multi-directional. Trial teams are increasingly expected to demonstrate to funders that the team has capability in implementation with robust designs for translation. Building teams with implementation expertise has potential to improve funding success [9]. There is evidence that research teams will commonly seek assistance from implementation scientists to develop and write grant applications [14] and our results indicate this is a common and valued role for an implementation scientist in trial teams.

Similarly, implementation scientists have much to gain from contributing to trial designs early to develop quality plans for translation and advance the science of implementation [15]. Application of implementation science theories, models and frameworks often suffer from a lack of empirical testing, rely on assumptions of efficacy across diverse contexts [16], rarely capture implementation costs [17] and have limited data on implementation strategy effectiveness [18]. RCTs are well placed to address these challenges. Collaboration with RCT teams brings opportunities for interdisciplinary knowledge sharing to find creative, robust solutions to the challenges facing the field of implementation science [18, 19]. Future research is needed to co-develop, test and measure how implementation scientists add value to trial teams and generate genuine translational impact for trials. Intentional efforts to promote collaboration with implementation scientists and standardise and/or mandate reporting of implementation impacts will be critical for fostering the success of interdisciplinary trial teams [14].

This survey also highlighted the important role that implementation scientists play in upskilling the broader clinical trial workforce by providing mentoring and valued support across the lifespan of the trial. Vibrant mentoring networks and implementation journey coaching has consistently been shown as an effective strategy for engaging RCT teams at different stages of trial team maturity. Mentoring can

predict success of trial implementation and translation [20–23] increasing the impact of knowledge translation projects in the health service [24–26].

Promoting implementation science as a career track rather than a skillset layered onto a clinical discipline is gaining traction [27, 28]. Australia is maturing its efforts to develop implementation science as a career pathway with emerging opportunities for training as graduate level coursework, credit bearing university subjects, short professional courses and practice-embedded programs, but there is yet to be a protected professional title, registering body or standalone degree in implementation science (and far fewer options available in New Zealand). The current trajectory of training infrastructure closely mirrors the early stages of formal professionalisation seen in fields like biostatistics in the 1990s and health economics in the 2000s. Our study indicated that currently, for implementation scientists working in RCTs, implementation science knowledge and skills are usually a methodological add-on to their existing discipline and trial expertise. There is an appetite for both greater engagement with implementation specialists with distinct competencies as well as broader workforce upskilling in foundational knowledge in the RCT sector. Implementation scientists will be increasingly expected to operate across science, policy and practice boundaries which will require dedicated training, mentoring and funding pathways to foster this as a career option.

Implementation scientists working in the Australian and New Zealand clinical trial sector are experienced trialists within their own clinical discipline and bring additional methodological expertise in implementation science and practice. They bring valuable expertise across the lifespan of the trial that can improve the translation of trial results into practice. Dedicated investment in upskilling the trial workforce and establishing a dedicated career path for implementation scientists in the sector needs to be a priority to realise the potential research impacts of implementation scientist collaborations.

Declarations

Ethics approval and consent to participate:

Ethics approval in accordance with the Declaration of Helsinki (Approval: 2024/HE001682) was sought from the University of Queensland Human Research Ethics Committee and respondents provided tick box consent prior to commencement.

Consent for publication:

Not applicable

Competing interests:

The authors declare that they have no competing interests.

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There is no funding to declare.

Author Contribution

IH, NS conceptualized the study and secured Australian Clinical Trials Alliance support; All authors [IH, MWT, JG, ML, NS, TH, NT] developed the secondary analysis research questions and methodology. IH, MWT performed statistical analysis; IH wrote the original draft. All authors reviewed and edited the manuscript and approved the final version.

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Data Availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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Figures

Activities of Implementation in Practice

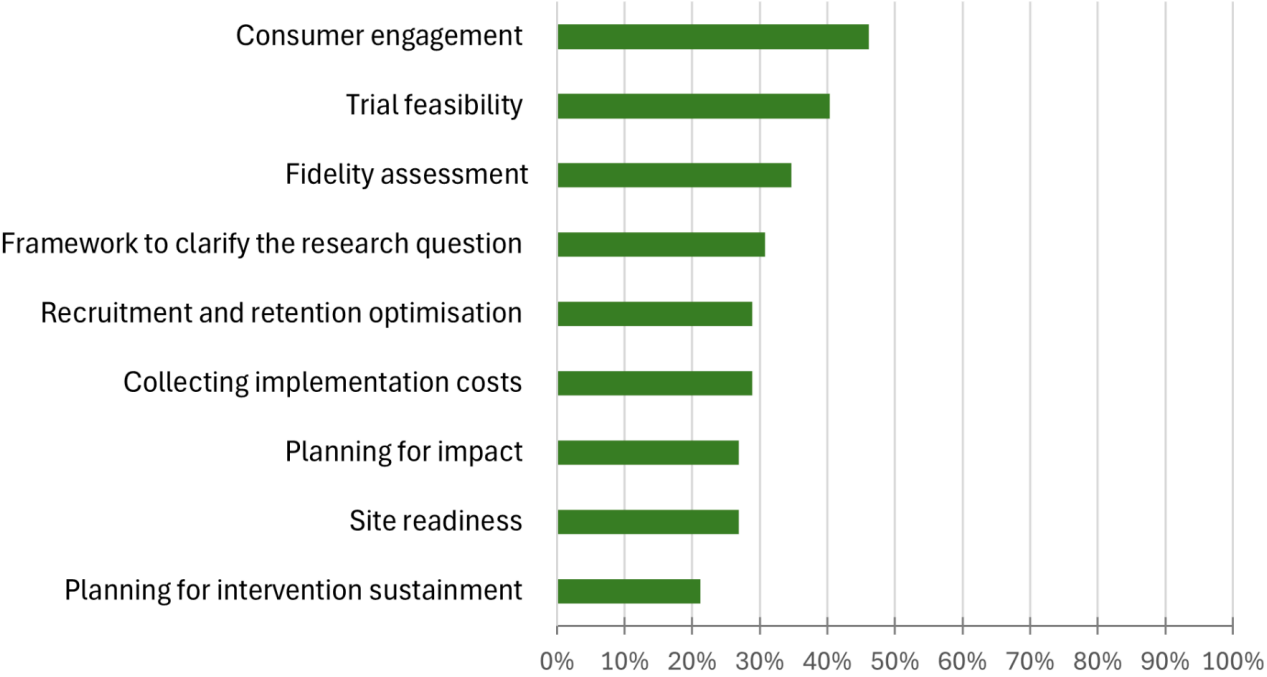


Figure 1
Frequency of Direct Experience with Implementation Science in Trial Design and Practice (N=52)

Roles of Implementation Scientists

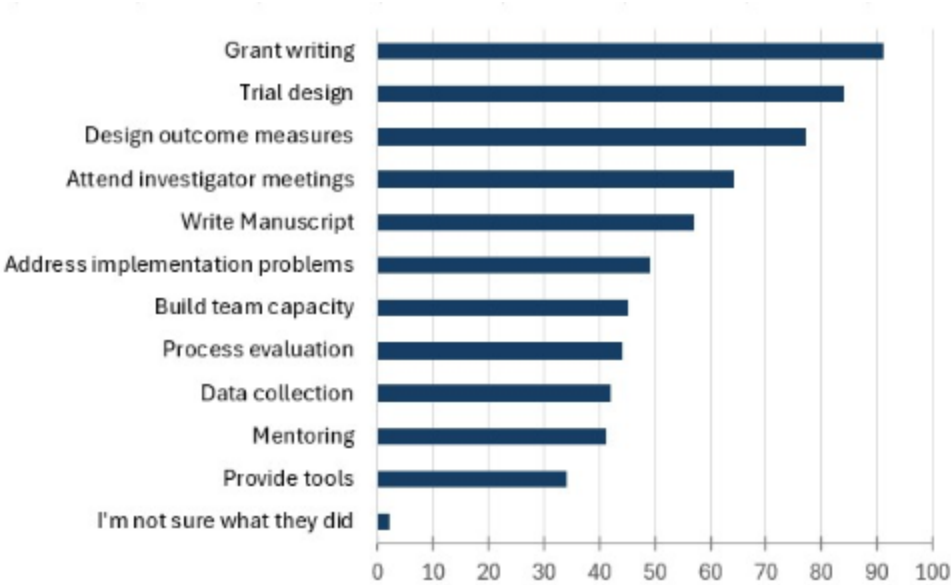


Figure 2

Roles of Implementation Scientists collaborating with clinical trial teams (data drawn from N=99 respondents with experience working with implementation scientists; multiple responses allowed)