Improving Opportunities for Research Training for Specialist Registrars in Australasia

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Research is an important, and formally assessed, component of physician training in Australasia. Experience in the development and implementation of clinical research is a crucial aspect of professional development in medicine. In order to continue to improve clinical practice, and hence patient outcomes, there must be an ongoing commitment to clinical research, and education to enable specialist registrars to develop their own research programs and develop the skills to critically analyse the results of research published by others. However, the interface between clinical practice and clinical research is inherently complex. There exist a plurality of stakeholders involved in the funding, design and implementation of a clinical trial, and the eventual utilization of the intervention being investigated. The transition from clinical practice to clinical research is challenging for many specialist training registrars, but ultimately, is crucial for their professional development.

The issue of promoting professional development for specialist registrars in Australia has hitherto received very little attention within the medical literature. With the exception of a number of descriptive studies addressing broad issues of satisfaction[1], little attention has been paid to the professional trajectories of specialist registrars. Specialty-specific studies in surgery have found that doctors in specialist training programs may not feel that they have an adequate knowledge of scientific method,[2] but little is known about physician training and differences that may exist between specific medical specialist training programs. In the following discussion, utilizing a case of a trial initiated and organized by an Infectious Diseases specialist registrar, we examine some crucial issues faced by specialist registrars in developing and implementing clinical trials including: financial constraints; inter and intra-professional dynamics; and role-based restrictions. It is argued that addressing these issues would improve research quality, increase interest in research, and potentially improve patient outcomes through the promotion of high quality clinical research.

Context - Specialist registrar training in most medical specialist training programmes under the Royal Australasian College of Physicians includes a formally–assessed research component. This involves specialist registrars submitting research projects as a requirement for the completion of specialist training. In Infectious Diseases, registrars are required to submit three projects (e.g. audit, case series, clinical trial) over a three year period of specialist training.

At the time of their specialist registrar training in Infectious Diseases, JB designed and implemented a non-randomised clinical trial to assess the efficacy of a simple intervention. The basics of the trial background and design are listed in Table 1. Ethanol lock therapy was an intervention that had been used with anecdotal success at a previous hospital that JB had previously worked.[3]. There are two published retrospective case series demonstrating potential efficacy of the technique[4],[5] but no prospective studies of the intervention had been published. As an intervention ethanol was cheap, available and unable to be patented. The intervention, if proven to be effective, was likely to save time, decrease patient morbidity, and result in cost savings for the hospital. This was quite unique in the sense that most improvements in patients' outcomes incur additional costs. Moreover, staff already had the necessary skills to implement the intervention. Patient numbers required were low (n=47), a relatively small number compared to the number of potential candidates at the hospital concerned per year

Factors which have been observed to hinder the progress of the trial are discussed. It is hoped that this will draw attention to difficulties that are encountered in clinical research at a registrar level and provide some constructive suggestions to countering these problems.

Table 1: Design of the trial: Ethanol lock therapy to treat infected tunneled central venous catheters.

Trial design:

Inclusion criteria:

1. tunneled central venous catheter
2. central venous catheter associated blood stream infection
3. treating team and patient consent to trial entry

Exclusion criteria:

1. history of allergy or intolerance to ethanol
2. evidence of a tunnel or exit site infection
3. pregnant or breast feeding
4. evidence of metastatic infection

All patients received:

A. Ethanol lock therapy for four hours per day for five days to each lumen of their tunneled central venous catheter
B. Antibiotic therapy appropriate in choice and duration for the microbial pathogen isolated.

Outcome measures:

A. Blood cultures performed from each lumen of the central venous catheter one day after completion of ethanol lock therapy (day six).
B. Time the catheter was retained following ethanol lock therapy

Blood cultures performed as clinically indicated subsequent to day six.

Funding Issues

Institutional supports - Institutional funding for specialist registrar research is crucial if projects are to be successfully developed and implemented. However, the provision of such support is largely ad hoc, and at times insufficient, presenting a major barrier to professional development. Clinical trials are predominantly funded by drug companies who seek to benefit from the sale of new drugs once the trial is completed. This tendency toward economically profitable intervention has considerable implications for trials like that presented here. Internal institutional funding is usually limited and hence specialist registrars will not be in the strongest position to successfully draw on this source of support, as was the case in this study. Despite anecdotal success of the intervention and potential cost-saving to the hospital, the hospital did not have the resources available to support the trial. Weighted allocation of institutional internal funding according to stage of training would create a more democratic process and give early researchers a greater chance of success in securing financial support for research.

Commercial support - Receiving drug company support in clinical research is a useful means of lowering costs to the institution. However, drug company funding for small studies of non-patented, cheap interventions can be difficult. After considerable negotiation, minimal drug company funding was obtained for the study presented here, which allowed for the employment of a research nurse for one day a week for sixteen weeks. Although extremely limited, this funding provided much needed support for data collation and patient recruitment. This facilitated the development of a database with records of patient outcomes; without which the results would potentially have been inadequately collated as a result of time constraints. However, many specialist registrars do not get access to funding from drug companies (nor internal funding support) and this can severely limit the scope and quality of their research programs.

Research nurse support - The practical difficulties of trial design and implementation would be somewhat offset by adequate research nurse support. Unfortunately, research nurses are commonly employed by departments from resources sourced from drug companies for large nationwide or international trials, and hence are not available to assist in institutional trials that do not attract funding. Access to help of this form is usually not freely available to specialist registrars, and hence a large proportion of the burden of running a clinical trial will fall on a registrar who already has extensive additional responsibilities including patient care, teaching, presentation preparation, and administrative tasks within their department.

Inter and Intra-professional Issues

Negotiating adverse cases and anecdotally-informed clinical practice - The issue of clinicians adhering to the treatment protocol is not merely a problem for specialist registrars. Clinical judgment is often preferred by clinicians even when presented with the highest level of scientific evidence.[6] For a registrar, the process of implementing a clinical trial is likely to be the first time

in which they have had to address the issue of non-adherence on the part of their colleagues. In the current trial it was clear in certain cases that doctors were reluctant to refer patients for entry into the trial because they had individually decided that the intervention did not work. This was enhanced after one case in which the intervention failed. We know from the preliminary results that the intervention is likely to be highly successful, however, doctors are strongly influenced by observed complications or cases. The flow-on effect of this is mediated by the status of the person running the study.

Intra-professional hierarchies and power dynamics as shaping trial implementation - Seniority is a significant barrier when registrars attempt to run clinical trials. In cases where researchers are junior to key decision makers (consultants), power dynamics can influence the degree to which the study protocol is effectively implemented. In hospitals, patients under a medical team will have a primary treating team who will consult other specialties for opinions, but ultimately make the final clinical decisions themselves. Complying with clinical trial protocol requires; belief of the treating team that the intervention being investigated has merit, understanding by the treating team of the clinical trial process, and acceptance of the judgment of the investigators. Registrars have a lower status in the hospital system than consultants. This dynamic can result in practical difficulties in ensuring clinical concordance with trial protocols.

The practical implications from this are that a registrar contemplating a clinical trial should first of all ensure that he/she has the full support of his senior staff. Consultants in the department from which the trial is being run should be proactive in promoting the trial with an awareness of the influence that their status can have on patient recruitment and clinician concordance.

Trial implementation in a consultative-based specialty - The complexities of being a primarily consultative specialty are well known in Infectious Diseases and other consultative specialties, and will not be expanded on here, except to point out that this adds to the difficulties in organizing a trial as an Infectious Diseases registrar or physician.

Role-based Issues

Training and professional development - Education should be provided to specialist registrars allowing them to develop the skills required for collation of data (database design) and the need for administrative support should be recognized and funded.

Clinical service requirements place limitations on the time doctors can allocate to research. As a specialist registrar, workloads will vary between specialties and between hospitals. An average specialist registrar might work 55 to 60 hours per week. A minority of hospitals have protected time for research and ongoing education. If registrars are required to complete research projects for their specialist training, dedicated research time is necessary given the time commitments needed for the various elements of the research process (i.e. preparation of a proposal, gaining ethics approval, applying for funding, collating data etc…)

Conclusion

Amongst the points raised here, we identify the following as key changes that would facilitate more effective specialist registrar research in Australia:

- Tertiary referral hospitals should consider providing research funding directly promoting research at a registrar level
- Regular multi-disciplinary and inter-specialty meetings to communicate research plans and progress
- Promotion of the trial by consultants
- Provision of research nurse support for advanced trainees
- Education in study design, data collation, statistical analysis, and grant writing
- Protected research time
- Administrative support

The study described above is ongoing, two years from initial design. The preliminary data indicates that the intervention is likely to be highly effective with few complications. A multi-site prophylactic trial is now in development. If conditions are improved for specialist registrars, more studies like the one described here will be performed, leading to improved outcomes for patients, and clinicians with more experience in research.

Research identifying impediments to research in physician training throughout Australasia and under physician training schemes internationally would give useful information as to changes that could be implemented.

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