What does it cost to establish a practice-nurses-led clinical trial in general practice?

Lessons learnt from the Patient Engagement And Coaching for Health (PEACH) study

Irene D Blackberry, John S Furler, Doris Young and James D Best; on behalf of the PEACH study investigators

ABSTRACT

Objective: To describe the processes and costs of engaging practice nurses (PNs) to establish a cluster randomised controlled trial (RCT) to study type 2 diabetes in general practice.

Design, setting and participants: Descriptive study of the processes and costs of engaging PNs from 59 general practices in Victoria that were participating in the Patient Engagement And Coaching for Health (PEACH) study, prior to practices being randomly assigned in the cluster RCT.

Main outcome measures: Estimated direct research costs and personnel costs for establishing a general practice-based research project involving PNs (eg, costs for approaching Victorian Divisions of General Practice and the Australian Practice Nurses Association; practice and patient recruitment; research project establishment at general practices; and PNs' training, support and engagement during the study establishment period).

Results: The estimated cost to establish our PN-led general practice-based cluster RCT was over $110 000, with an average cost of $2000 per practice. Direct research and personnel costs were considerably higher than anticipated. Lack of research skills among PNs required intensive hands-on support from the research team.

Conclusions: It is feasible to undertake a PN-led, general practice-based clinical trial in diabetes care. Future research funding needs to account for recruitment costs, including the need to build PN research capacity, and to overcome the inherent difficulties of engaging practices in complex intervention trials in primary care.

Trial registration: International Standard Randomised Controlled Trial Number Register ISRCTN50662837.

MJA 2009; 191: 492–495

Practice nurses (PNs) play an important role in supporting general practices to deliver health care.[1] A PN is "a registered or an enrolled nurse who is employed by, or ... retained by a general practice".[2] In Australia, with the introduction of the Australian Government Nursing in General Practice program, the number of PNs has doubled from around 4000 in 2003 to around 8000 in 2008.[2-4] In 2005, about half of moderate-sized general practices employed at least one PN.[3] The role of PNs varies between practices, from a focus on clinical procedures, through to health promotion and chronic disease management,[5] often delegated by general practitioners.[6]

PNs will play a key role in primary care research in the future.[7] In recent years, a number of large clinical trials involving PNs in general practice have studied the role of PNs in the management of chronic diseases, such as diabetes and cardiovascular diseases.[8-11] The difficulties of undertaking research in primary care, such as lack of GP time, lack of funding to general practice staff and workforce shortages, are well recognised,[12] yet the financial cost of engaging PNs in clinical trials in primary care, particularly during the project establishment period, has not been studied.

The Patient Engagement And Coaching for Health (PEACH) study is a cluster randomised controlled trial employing existing PNs to deliver an intensive diabetes self-management program by phone (the COACH [Coaching patients On Achieving Cardiovascular Health] program) to general practice patients with poorly controlled type 2 diabetes.[9] The study also aims to build the research capacity of PNs. In this article, we describe the costs associated with setting up the PEACH study, including recruiting and engaging PNs in these research activities.

METHODS

The overall process of establishing the PEACH study has been published elsewhere.[9] General practices participating in the study are located in urban Melbourne and rural Victoria. For the purpose of this article, general practices within 40 km of the Melbourne central business district were considered urban, with an average return travel distance to the University of Melbourne of 50 km per practice. General practices outside this area were considered rural, with an average return travel distance of 300 km per practice. Practices were eligible to be recruited if they had at least one PN.

General practices were recruited from November 2006 to August 2008. We approached all 30 Divisions of General Practice[13] in Victoria. All except two agreed to mail out study information to GPs and PNs in their area, seeking expressions of interest. Where the relevant data were available, Division mail-outs were restricted to practices with PNs. Each practice that expressed interest received a visit from the study team to explain the study in more detail and to obtain consent.

The Australian Practice Nurses Association (APNA) and the Royal Australian College of General Practitioners (RACGP) promoted the study and provided Continuing Professional Development (CPD) points for PNs and GPs who participated. A small number of PNs were Credentialled Diabetes Educators for whom CPD points from the Australian Diabetes Educators Association were obtained.

Based on the original sample size calculation, 488 patients from 30 general practices (about 16 patients per practice) were required to show an absolute reduction in mean glycated haemoglobin (HbA_{1c}) level of 0.5% or greater in the intervention arm compared with standard care. In 6 months, the study managed to recruit only 10 practices from the north and north-western areas of Melbourne, our original target area. In addition, most practices had difficulty recruiting 16 patients. Therefore, the sample

size was recalculated, and the study was expanded to other areas of Melbourne and to regional and rural Victoria. The revised required sample size was 56 practices and 336 patients (six patients per practice).

Patient recruitment

PNs at participating practices obtained a list from their local pathology laboratories of all practice patients with diabetes who had an HbA_{1c} level greater than 7.5% recorded in the past 12 months. GPs then applied inclusion and exclusion criteria.[9] Once a list of eligible patients was created, the study team assisted the PN to randomly select up to 40 patients and mail them invitations to participate in the study.

The PEACH study administrative assistant called each PN weekly to check progress and pass on details of patients who had expressed interest. Training was provided to PNs to see patients to obtain consent, administer baseline questionnaires, collect patient data from medical records, and complete pathology slips.

Costs of establishing the trial

Direct research and personnel costs for establishing the PN-led clinical trial included approaching Divisions of General Practice and APNA, recruiting practices and patients, establishing the research project within practices, training PNs, providing support and engagement during the study establishment period, and PNs' time spent in recruiting patients and obtaining consent and baseline data.

The costs we report here are based on costs estimated in 2008; we present our results showing both the original study budget and the estimated actual costs.

Ethics approval

Ethics approval was granted by the University of Melbourne Human Research Ethics Committee.

RESULTS

To allow for dropout, we recruited 59 practices and 468 patients (eight patients per practice) into the study. Thirty-four practices (58%) were located in regional and rural Victoria.

Itemised costs of approaching Divisions of General Practice and APNA to identify eligible general practices with PNs are shown in Box 1. To reach the target sample size of practices and patients, the study needed to expand recruitment from approaching two Divisions of General Practice to approaching a further 26 Divisions and the APNA. This cost almost nine times the original practice recruitment budget. Although promoting research through websites and newsletters costs nothing, this yielded very small responses.

The study spent almost four times more than the budgeted amount to recruit the 59 general practices (Box 2). Most of the extra costs were associated with recruiting an

1 Itemised costs of promoting the study and identifying potential general practices for a practice-nurse-led clinical trial

Item	Budget	Estimated costs
Recruitment through 28 of the 30 Victorian Divisions of General Practice		
Mail-out to GPs and practice nurses (average, 250 per Division at $1 each), including an invitation letter, study brochure, postage, envelope and fax-back form	$900	$7 000
Research staff cost (HEW4)	$2212	$17 208
Websites and newsletters	$0	$0
Recruitment through the Australian Practice Nurses Association		
Mail-out to practice nurses (318 at $1 each), including an invitation letter, study brochure, postage, envelope and fax-back form	$0	$318
Research staff cost (HEW4)	$0	$1 590
Websites and newsletters	$0	$0
Total	$3112	$26 116

HEW4 = Higher Education Worker Level 4. ◆

2 Detail of the original project budget and the estimated costs for recruiting the target project sample

Item	Budget (one visit to 30 metropolitan practices)	Estimated costs (one visit to each metropolitan, regional and rural practice)
Recruitment of 25 practices in the Melbourne metropolitan area		
Study information pack, including plain language statement, consent form, study outline, practice information and study manual (at $3 each)	$90	$75
Research staff cost (PSP5): an average of 2 hours practice visit and travel	$2700	$2 250
Travel cost (50 km per practice at $0.50/km)	$750	$625
Recruitment of 34 practices in regional and rural Victoria		
Study information pack, including plain language statement, consent form, study outline, practice information and study manual (at $3 each)	$0	$102
Research staff cost (PSP5): an average of 3.5 hours practice visit and travel	$0	$5 355
Travel cost (300 km per practice at $0.50/km)	$0	$5 100
Total	$3540	$13 507

PSP5 = Personnel Support Package Level 5. ◆

additional 34 practices in regional and rural Victoria. The PEACH study coordinator's visit to these practices was necessary to build a working relationship with the general practices and to train the PNs to undertake the research. Telephone, email or teleconference was used after this first in-person visit to practices. For one practice, the PN and the study team communicated via a videoconference.

The estimated cost of patient recruitment was more than double what had been budgeted (Box 3). Again, this was mainly due to the cost of recruiting patients from the 34 practices in regional and rural areas. Some of the practice recruitment tasks were delegated to research administrative staff. Additional funding was needed for the time involved in supporting PNs to engage with the research and to appreciate the importance of accurate data collection, and in supporting patients to complete questionnaires. PNs became more confident in collecting baseline data with this support.

PNs spent an average of 1 hour completing baseline data for each patient, and this matched the time allocated in the original budget. The overall cost to engage and support PNs to recruit patients and complete all baseline assessments was significantly more than what had been budgeted (Box 4), largely because of the additional number of PNs involved.

In general, direct research and personnel costs were much higher than anticipated. The PEACH study spent three times more than the original budget for practice and patient recruitment to achieve an adequate sample size. The estimated cost to establish a general practice-based clinical research project using PNs, each completing an average of eight baseline patient assessments, is nearly $2000 per practice. The lack of research experience by PNs meant more hands-on support was required from the research team.

DISCUSSION

General practice nursing is in an early stage of development in Australia compared with the United Kingdom and New Zealand.[14] The role of PNs in research was hardly mentioned in the Australian PN workforce survey conducted in 2006,[3] despite the emerging literature pertaining to PN-led clinical trials in chronic disease management.[8,9,11]

Identifying eligible practices was difficult. PNs are a highly mobile workforce,[15] and most of the Victorian Divisions of General Practice we approached did not maintain a database of PNs in general practice. To recruit practices with PNs through other databases, such as the Yellow Pages, would be costly and inefficient.

In addition, it was difficult to find enough practices willing to participate. Our estimate of costs is conservative in that all but two of the Divisions that we approached supported the study by asking us to provide only minor administrative funding. Advertising through Divisions of General Practice and APNA web-

3 Itemised costs of recruiting patients with type 2 diabetes from general practices into the study

Item	Budget for 488 patients from 30 practices	Estimated costs for 468 patients from 59 practices
Study information pack including plain language statement, consent form, study brochure, demographic survey, stamp and reply-paid envelope (at $2 each)	$1 952	$3 540
Administrative staff cost (HEW4)	$4 575	$17 995
Research staff cost (PSP5)	$6 750	$7 965
Practice nurse administrative time to identify eligible patients and mail out study invitations (at $100 per practice)	$0	$5 900
Total	$13 277	$35 400

HEW4 = Higher Education Worker Level 4. PSP5 = Personnel Support Package Level 5. ◆

4 Costs of engaging and training practice nurses to complete all baseline assessments

Item	Budget for 488 patients from 30 practices	Estimated costs for 468 patients from 59 practices
Engaging practice nurses in the Melbourne metropolitan area		
Practice nurses' time to obtain patient consent and administer baseline assessments (hourly casual rate changed from $30/h to $32/h)	$14 640	$6 400
Administrative staff cost (HEW4)	$3 660	$3 050
Research staff cost (PSP5)	$2 700	$2 250
Travel cost (50 km per practice at $0.50/km)	$750	$625
Engaging practice nurses in regional and rural Victoria		
Practice nurses' time to obtain patient consent and administer baseline assessments (hourly casual rate changed from $30/h to $32/h)	$0	$8 704
Administrative staff cost (HEW4)	$0	$4 148
Research staff cost (PSP5)	$0	$5 355
Travel cost (300 km per practice at $0.50/km)	$0	$5 100
Total	$21 750	$35 632

HEW4 = Higher Education Worker Level 4. PSP5 = Personnel Support Package Level 5. ◆

sites and newsletters was free, but yielded few responses. We had to use multiple methods, including professional teaching networks, personal contacts, snowballing, social marketing techniques, and linking with other Division events. All of these are costly in terms of staff time and resources. In addition, we did not originally anticipate the need to expand into other Divisions of General Practice and into regional and rural areas.

PNs had difficulties recruiting the anticipated number of patients (which was based on a large diabetes project in the northern and north-western area of Melbourne[16]). A major difficulty was sustaining the effort in patient recruitment over time, among other clinic demands, despite intensive help from the research team. With the smaller-than-anticipated number of eligible patients per practice, significant extra funding was required to recruit almost double the original sample size of 30 practices. The $110 000 cost of establishing the trial was well over the original budget for this part of the study (which was awarded further funding to complete the project with the increased number of practices).

Having more practices, each with fewer patients, provides statistical advantages in a cluster randomised controlled trial. However, recruiting these practices, particularly in regional and rural areas, incurred far higher costs than budgeted for based on the original sample size. Meeting with practice staff face-to-face (and the associated travel) or by videoconference was essential for building relationships and trust,[17] to engage and sustain their involvement.

Building capacity through dedicated, funded PN time was important to ensure that PNs understood the research protocol and the importance of accurate data collection, including ensuring no missing data. PNs' skills varied significantly.[18] About half of the participating PNs had never used the electronic medical record software or accessed patients' medical records in their practice. Training in using the medical record software to collect data and generate pathology laboratory requests was provided by the study team.

PNs need support to engage in research in general practice.[19] On a small scale, the Australian Government Primary Health Care Research, Evaluation and Development (PHCRED) initiative has enabled several PNs to learn research skills and develop research interests with mentorship from experienced primary care researchers.[20] On a larger scale, the PEACH study has shown that it is feasible to undertake clinical trials in general practice and engage PNs, but that this requires dedicated time and funding for training and ongoing hands-on support. Such capacity building needs to be included in budgeted costs of clinical studies involving PNs.

Recruitment is a major hurdle in any clinical trial.[12,21] Participation by PNs can improve patient recruitment.[22] Practice recruitment can also be a limiting factor, as seen in another large Australian trial in chronic disease care.[21]

A PN-led, general practice-based clinical trial in diabetes care is feasible. However, future research funding needs to be based on realistic recruitment costs, including the cost of building PN research capacity, and of overcoming the inherent difficulties of engaging practices in complex intervention trials in primary care.

ACKNOWLEDGEMENTS

We acknowledge funding and support from the National Health and Medical Research Council (NHMRC) for the PEACH study (ID 359374 and 566586) and the NHMRC Centre for Clinical Research Excellence in Clinical Science in Diabetes for support for Irene Blackberry and John Furler. We also thank all the practice nurses, patients, GPs and study investigators who participated in the PEACH study.

COMPETING INTERESTS

None identified.

AUTHOR DETAILS

Irene D Blackberry, BMed, PhD, Research Fellow in Primary Care,[1] and Fellow[2]
John S Furler, FRACGP, GradDipPubHlth, PhD, Senior Research Fellow,[1] and Fellow[2]
Doris Young, MB BS, MD, FRACGP, Professor of General Practice, and Associate Dean (Academic),[1] and Chief Investigator[2]
James D Best, FRCPath, FRCP, Chief Investigator[2] Head of School (Medicine), and Professor of Medicine[3]

1 Department of General Practice, University of Melbourne, Melbourne, VIC.
2 NHMRC Centre for Clinical Research Excellence in Clinical Science in Diabetes, Melbourne, VIC.
3 Faculty of Medicine, Dentistry and Health Sciences, University of Melbourne, Melbourne, VIC.

Correspondence: j.furler@unimelb.edu.au

REFERENCES

1 Halcomb EJ, Davidson PM, Daly JP, et al. Nursing in Australian general practice: directions and perspectives. *Aust Health Rev* 2005; 29: 156-166.
2 Australian Practice Nurses Association. About practice nursing. http://www.apna.asn.au/displaycommon.cfm?an=2 (accessed Sep 2009).
3 Australian Divisions of General Practice. National practice nurse workforce survey report. April 2006. Canberra: ADGP, 2006. http://generalpracticenursing.com.au/__data/assets/pdf_file/0004/15376/National-Practice-Nurse-Workforce-Survey-Report-2006.pdf (accessed Sep 2009).
4 Australian Divisions of General Practice. National practice nurse workforce survey 2003. Canberra: ADGP, 2003. http://generalpracticenursing.com.au/__data/assets/pdf_file/0006/15378/National-Practice-Nurse-Workforce-Survey-2003.pdf (accessed Sep 2009).
5 Annells M. Where does practice nursing fit in primary health care? *Contemp Nurse* 2007; 26: 15-26.
6 Porrit J. Policy development to support nursing in Australian general practice: an overview. *Contemp Nurse* 2007; 26: 56-64.
7 Halcomb EJ, Davidson PM, Patterson E. Exploring the development of Australian general practice nursing: where we have come from and where to from here? *Contemp Nurse* 2007; 26: 145-153.
8 Yallop J, Clark R, Chan B, et al. CHAT — a study of a nurse-led system of care. *Aust Nurs J* 2006; 14: 19.
9 Young D, Furler J, Vale M, et al. Patient Engagement And Coaching for Health: the PEACH study — a cluster randomised controlled trial using the telephone to coach people with type 2 diabetes to engage with their GPs to improve diabetes care: a study protocol. *BMC Fam Pract* 2007; 8: 20.
10 Koelewijn-van Loon MS, van Steenkiste B, Ronda G, et al. Improving patient adherence to lifestyle advice (IMPALA): a cluster-randomised controlled trial on the implementation of a nurse-led intervention for cardiovascular risk management in primary care (protocol). *BMC Health Serv Res* 2008; 8: 9.
11 Eley DS, Del Mar CB, Patterson E, et al. A nurse led model of chronic disease care — an interim report. *Aust Fam Physician* 2008; 37: 1030-1032.
12 Yallop JJ, McAvoy BR, Croucher JL, et al. Primary health care research — essential but disadvantaged. *Med J Aust* 2006; 185: 118-120.
13 Rudd C, Watts I. The industry of general practice: its infrastructure. In: Pegram R, Daniel J, Harris M, et al, editors. General practice in Australia: 2004 [rescinded publication]. Canberra: General Practice Branch, Australian Government Department of Health and Aged Care, 2005: 358-419. http://www.health.gov.au/internet/main/publishing.nsf/Content/pcd-publications-gpinoz2004 (accessed Sep 2009).
14 Jolly R. Practice nursing in Australia. Research Paper No. 10 2007-08. Canberra: Parliamentary Library, Parliament of Australia, 2007. http://www.aph.gov.au/library/pubs/rp/2007-08/08rp10.htm (accessed Sep 2009).
15 Watts I, Foley E, Hutchinson R, et al. General practice nursing in Australia. Canberra: Royal Australian College of General Practitioners and Royal College of Nursing, Australia, 2004.
16 Aylen T, Watson L, Audehm R. Nurse specialists co-managing diabetes within general practice. *Eur Diabetes Nursing* 2006; 3: 28-33.
17 Yallop JJ, McAvoy BR. The research potential of practice nurses: what contribution to primary health care research? *Contemp Nurse* 2007; 26: 117-124.
18 Halcomb EJ, Patterson E, Davidson PM. Evolution of practice nursing in Australia. *J Adv Nurs* 2006; 55: 376-388, discussion 388-390.
19 Halcomb EJ, Davidson PM, Salamonson Y, et al. Nurses in Australian general practice: implications for chronic disease management. *J Clin Nurs* 2008; 17: 6-15.
20 Walker L, Evans J. Research and development: reflections of practice nurse research fellows. *Contemp Nurse* 2007; 26: 116.
21 Perkins D, Harris MF, Tan J, et al. Engaging participants in a complex intervention trial in Australian general practice. *BMC Med Res Methodol* 2008; 8: 55.
22 Richardson A, Sutherland M, Wells E, et al. Factors affecting general practitioner involvement in a randomised controlled trial in primary care. *N Z Med J* 2002; 115: 153-155.

(Received 13 Apr 2009, accepted 14 Jul 2009) ❑