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Lessons learnt from attempting to assess the evidence base for a complex intervention introduced into New Zealand general practice

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ABSTRACT

Background and context Currently, in New Zealand general practice, the introduction of new initiatives is such that interventions may be introduced without an evidence base. A critical role is to respond to the challenges of chronic illness with self-management a key component. The 'Flinders Model' of self-management collaborative care planning developed in Australia has not been evaluated in New Zealand. A study was designed to assess the usefulness of this 'Model' when utilised by nurses in New Zealand general practice. This paper describes the issues and lessons learnt from this study designed to contribute to the evidence base for primary care.

Assessment of problems Analysis of interviews with the nurses and the research team allowed documentation of difficulties. These included recruitment of practices and of patients, retention of patients and practice support for the introduction of the 'new' intervention.

Results of assessment A lack of organisational capacity for introduction of the 'new' initiative alongside practice difficulties in understanding their patient population and inadequate disease coding contributed to problems. Undertaking a research study designed to contribute to the evidence base for an initiative not established in general practice resulted in study difficulties.

Lessons learnt The need for phased approaches to evaluation of complex interventions in primary care is imperative with exploratory qualitative work first undertaken to understand barriers to implementation. Collaborative partnerships between researchers and general practice staff are essential if the evidence base for primary care is to develop and for 'new' interventions to lead to improved health outcomes.

BACKGROUND

General practice in New Zealand (NZ) recognises the importance of quality improvement through a culture of continually striving to act according to best available knowledge.[1] This is reflected in a general practice team commitment to find out 'are we doing what we should be doing?'[1] Several authors argue that research is needed to develop the evidence base for primary care[2–4] with quality patient care requiring a sound evidence foundation that can inform clinical practice.

Currently, for general practice in NZ, the rate of change and introduction of new initiatives is such that interventions may be introduced without an evidence base, and research activity is not able to keep pace with the rate of structural change. The difficulties of undertaking research in primary care have been highlighted[3–5] and include problems with recruitment of general practices and patients, practice workloads, competing demands, inadequate general practice-based research networks, lack of compensation for practices and perceived time pressures.

A critical role for primary care is to respond to the challenges of chronic illness. In NZ, chronic conditions contribute to growing health inequalities, with Maori and Pacific people tending to experience more severe disease, disability and premature death than non-Maori, non-Pacific.[6] Rigorous reviews have identified patient-centred care, shared decision-making, increased self-management support and collaborative care planning as some of the key components for improving chronic care.[7]

The NZ report 'Meeting the Needs of People with Chronic Conditions'[8] recognises self-management as a key component of chronic care and recommends incorporating self-management into chronic care frameworks with the 'Flinders Model' offered as an approach for consideration. The 'Flinders Model' is an evidence-based model developed from extensive research in Australia to address the areas of self-management support and collaborative care planning.[9] The 'Flinders Model of Chronic Condition Self-Management' utilises a set of tools and processes that enable clinicians and patients to assess self-management behaviours, with collaborative identification of the patient problems and goal setting leading to individualised patient care plans.[10]

The 'Model' has not been evaluated in NZ and the evidence base for its use has not been clarified in the NZ cultural context. Training of practice nurses and others to allow the 'Model' to be introduced into NZ primary care began in 2005. Questions were raised. Does the 'Flinders Model' require adaptation to be of value with cultural groups such as Maori and Pacific people? Additionally, what are the practical issues of implementing the 'Flinders Model' with practice nurses in NZ general practice? The Australian studies have not focused on primary care nursing in general practice.

We devised a research study aimed to assess the acceptability and usefulness of the 'Flinders Model' of patient care planning when utilised by nurses in general practice with people who have chronic conditions and specifically the acceptability of the 'Model' with Maori and Pacific patients. Our research was planned to ensure we had sufficient

numbers of Maori and Pacific patients enrolled in our study to allow this.

The planned approach was an initial feasibility study with 20 general practices enrolling 100 patients with chronic conditions. The study aimed to compare a group of patients who received assessment and care planning with nurses using the 'Flinders Model' (intervention group) with a group of patients who received 'usual care' (control group).

Primary outcome measures collected via a patient participant questionnaire at the commencement of the study and at 6 months included self-management capacity, self-efficacy, health status, quality of life and quality of care. Secondary outcome measures included psychological well-being, health service utilisation, treatment adherence and smoking status. Qualitative data focussed on the experiences of the practice nurses and the patients.

The study context was a focus within general practice for continuous quality improvement, an increasing emphasis on chronic condition management, an expanding role for nurses in primary care but also a very busy general practice environment. A feasibility study was recognised as useful before a large trial should be considered to enable outcome measures and the research design to be refined.

The aim of this paper is to describe the issues and lessons learnt that emerged from our feasibility project designed to contribute to the evidence base for the introduction of a complex intervention in primary care, and thereby contribute to quality improvement.

ASSESSMENT OF THE PROBLEMS

Assessment of the problems encountered in evaluating the benefit of a complex intervention introduced into primary care was conducted by the senior researchers involved in the project.

Interviews with the nurses from the recruited practices involved with the study were undertaken, and reflective comments from members of the research project team were recorded.

These data were analysed to identify themes and to allow documentation of the problems encountered with the feasibility study. The intent was to ensure lessons would be learnt and strategies developed for the evidence base for this intervention to be developed.

RESULTS OF ASSESSMENT

Analysis highlighted several difficulties encountered in conducting the feasibility study.

Recruitment of practices

A total of 35 general practices were approached to achieve a sample of 20 general practices. Practice workloads and competing demands were reasons given for not being willing to participate. In some cases, individual nurses expressed interest but could not convince the rest of the practice that they should participate. Securing agreement for practices to be in the control arm of the study was most difficult (practices not using the Flinders Model). Practices were reluctant to participate in a study where they perceived their patient care of the chronically ill may be shown to be of a 'lesser' quality than in the intervention practices. Personal contacts and networks proved an essential strategy in recruiting.

Recruitment of patients

Achieving a random sample of patients provided another challenge. Few practices had well-developed disease registries or coding procedures, and therefore identification of the eligible population was problematic. While it was difficult to identify patients with chronic conditions, occasionally patients were coded as having a chronic condition (asthma), yet this was many years ago, and they did not identify themselves as having a chronic condition.

The study highlighted the challenges general practice face when caring for 'high needs' populations who tend to be mobile. Maori made up 71% of the study sample, and Pacific people 48%. The number of patients with inaccurate addresses and telephone numbers was significant and added to time delays and additional costs incurred recruiting patients. A total of 430 patients were required in order to achieve the study sample of 100.

Retaining patients

Not surprisingly, people with chronic illness became sicker over the 12-month time period, and two died, thus adding to the challenge of achieving an adequate research sample size.

Practice support for 'new' intervention

The 'Flinders Model' was a new intervention for the practices, and while the nurses in the intervention practices were all trained in the Flinders care planning approach, none were using the approach in their usual work or were able to use the tools initially with confidence.

The 'Flinders Model' requires a 30–60 min consultation appointment and none of the nurses were accustomed to this length of a structured nurse appointment. The practice nurses did not routinely have patient case loads, and while all were willing and enthusiastic about the 'Flinders Method' and the opportunity to extend their role with chronically ill patients, for most, practice workloads made this difficult. Time delays for the nurses to complete the Flinders care plans caused major challenges. Only a few of the practices had team approaches to chronic care and were able to support the nurses with introduction of the new intervention.

The perceived value of research as contributing to quality improvement in general practice was not apparent in most of the practices.

STRATEGIES FOR QUALITY IMPROVEMENT

Four significant problems were identified which need to be addressed to conduct evaluation of complex chronic care interventions.

1. Understanding the practice patient population. Understanding their patient population in order to enable quality improvement is difficult for practices with standard practice management systems and requires significant vigilance and effort to keep clinical and personal patient data up to date.
2. Disease categories. Patients may not understand that they have a chronic condition. This is significant for the patient and the practice in terms of planning chronic care patient programmes—to whom should complex interventions be targeted for?
3. Introduction of a new initiative. Introducing a 'new' initiative alongside a research study designed to contribute to the evidence base for the intervention is ambitious. While wishing to improve management of chronic illness, practices may not have the structural and organisational change capacity needed for new interventions.
4. Organisational capacity. Practice workloads and demands are significant. Most nurses are already working at maximal capacity and introducing a new initiative that requires

a different approach with dedicated, uninterrupted time to spend with patients requires some practice structural change. Nurse consultation space is an issue—for example, when the intervention requires up to 60 min of nurse–patient consultation in addition to usual practice nurse work. Some practices do not have space for extensive nurse consultations. Without support to reinforce training, developing confidence in using the tools needed for new initiatives contributes to difficulties with the capacity of general practice to embrace new interventions.

LESSONS AND MESSAGES

The significant lessons learnt from this study highlight the need for a staged or phased approach to evaluation of complex interventions in primary care. Campbell *et al*[11] discuss the need for feasible and valid measures of outcomes to be determined and tested alongside development and understanding of complex interventions prior to conducting any rigorous and achievable research trials. Our feasibility study attempted to do this, but understanding the context for the introduction of the intervention more thoroughly would have been beneficial. An exploratory qualitative study to understand implementation barriers and pitfalls could have assisted planning and managing the feasibility study. Towards the end of the study, in order to understand the barriers to implementation of the 'Flinders Method,' a survey of nurses who had completed 'Flinders training' was undertaken. This would have been beneficial earlier. The introduction of the intervention and strategies to minimise barriers and the research could then have gone hand in hand.

A collaborative partnership between researchers and practice staff is essential for studies attempting to contribute to the clinical evidence base for general practice. This study highlighted the imperative of clinicians and researchers needing to work together if the evidence base for complex interventions is to be established. Practices need to remain engaged over considerable periods of time.[5]

Unlike other reports,[4] the incentives for practices in this study were accepted as being largely intrinsic. While funding can never be sufficient to be an incentive, it can reduce the cost of participating in research.[5] However, reimbursement for practices in this study was not an issue. The professional development opportunity for the nurses was highly valued, both for the new initiative but also for the opportunity to develop research capacity.

CONCLUSIONS

With an increasing shift to manage chronic conditions in primary care comes a parallel need for sound clinical research to identify the most useful and appropriate interventions. Resolving the problems encountered in this study is important if a robust evidence base is to develop. Likewise, if investment is to be made on staff training and new programmes, it is important to know if these interventions lead to enhanced health outcomes and improved quality of care.

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Competing interests None.

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