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A model-based evaluation of collaborative care in management of patients with type 2 diabetes in Australia: an initial report

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Abstract

Objectives. To analyse the short- and long-term costs and benefits of alternative models of primary care for the management of patients with type 2 diabetes in Australia. The models of care reflect differential uptake of primary care-based incentive programs, including reminder systems and involvement of practice nurses in management. This paper describes our study protocol and its progress.

Methods. We are undertaking an observational study using a cluster sample design that links retrospective patient data from a range of sources to estimate costs and intermediate outcomes (such as the level of glycosylated haemoglobin (HbA1c)) over a 3-year time horizon. We use the short-term data as a basis to estimate lifetime costs and benefits of alternative models of care using a decision analytic model.

Initial report. We recruited 15 practices from a metropolitan area (Adelaide) and allocated them to three models of care. Three hundred and ninety-nine patients agreed to participate. We use multilevel analysis to evaluate the association between different models of care and patient-level outcomes, while controlling for several covariates.

Discussion/conclusions. Given the large amount of funding currently used to maintain primary care-based incentives in general practices in Australia, the results of this study generate the knowledge required to promote investment in the most cost-effective incentives.

What is known about the topic? Collaborative models of care can improve the outcomes in patients with chronic diseases such as type 2 diabetes (T2D), and the large amount of funding is currently used to maintain primary care-based initiatives to provide incentives for general practices to take a more multidisciplinary approach in management of chronic diseases.
What does this paper add? There are few model-based studies of the cost-effectiveness of alternative models of care defined on the basis of the uptake of financial incentives within Australian primary care settings for diabetes management. Using routinely collected data, this project evaluates the effectiveness of alternative models of care and estimates long-term costs and benefits of various models of care.
What are the implications for practitioners? This study explores opportunities for the use of linked, routinely collected data to evaluate clinical practice, and identifies the optimal model of care in management of patients with T2D, with respect to differences in long-term costs and outcomes.

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Introduction

Diabetes is an increasingly common chronic condition with a substantial impact on premature mortality, morbidity and healthcare resources.[1,2] Diabetes has been classified as a National Health Priority Area in Australia.[3] Diabetes affects 4% of the Australian population, with type 2 diabetes (T2D)

accounting for 88% of all cases.[4] Between 1989–90 and 2007–08, the number of people diagnosed with diabetes has more than doubled in Australia, largely driven by an increase in the prevalence of T2D.[5] In 2005, diabetes was the underlying cause of 2.7% of all deaths in Australia (with majority due to T2D).[5]

Most patients with T2D present and are treated within the primary care setting in Australia.[6] Therefore, there has been a great potential within primary care facilities to implement alternative collaborative models of care which have been rigorously shown to improve disease control and health outcomes.[7] Several clinical trials concluded that collaborative care programs (e.g. active involvement of nurses in management processes and using computerised tracking systems) can significantly improve outcomes in patients with T2D within the primary care setting.[8–11]

In recent years, several primary care-based funding initiatives have been implemented in Australia to provide incentives for general practices to take a more multidisciplinary approach. Examples include Service Incentive Payments (payments to physicians for each completed cycle of care for patients with diabetes) and financial incentives to employ Practice Nurses (PNs) and use recall systems. These initiatives have facilitated the development of new models of care in management of chronic diseases. One might view results from clinical trials as 'best case', which provides a first hurdle to be breached before the implementation of potential programs. Following implementation, there is a concomitant requirement to monitor effectiveness, and cost-effectiveness in routine clinical practice. This is particularly important in countries like Australia in which national reimbursement decisions around new health technologies (e.g. medical procedures and pharmaceuticals) are supported by economic evidence.[12]

In view of the increasing recognition of the importance of economic evaluations of alternative models of care, Beilby *et al.*[13] conducted a comparative analysis of the costs and consequences of implementation of multidisciplinary care for patients with T2D. This study used a before-and-after design, and defined different models of care based on the uptake of a register/recall system, following management guidelines and involvement of allied health professionals in management of patients. However, this study does not represent a full economic evaluation as the authors presented no cost-effectiveness ratio, although evidence of improvement in patient health outcomes was found. McRae *et al.*[14] used the United Kingdom Prospective Diabetes Study (UKPDS) Outcomes Model and evaluated long-term costs and benefits of an integrated program for the management of patients with T2D. The core of the program was a centralised database run by an Australian Division of General Practice, which was used to provide audit reports to General Practitioners (GPs) on their adherence to guidelines. Compared with the 'no-program' alternative, the program was less costly with greater improvement in quality adjusted life expectancy.

The present study, the Primary Care Services Improvement Project (PCSIP), provides a framework for evaluating system-based interventions in primary care, as applied in routine clinical practice. The application described in this paper uses linked, routinely collected data (1) to evaluate the effectiveness of alternative models of care in terms of improving glycaemic control in patients with T2D, and (2) to estimate long-term costs and benefits of various models of care in terms of the incremental cost per quality adjusted life year (QALY), using a decision analytic model.

This paper details the design of the PCSIP and describes its progress in terms of practice and patient recruitment, and data collection process.

Design/methods

The PCSIP is an observational study and uses a cluster sample design. We recruited patients from general practices within the Adelaide Northern Division of General Practice (ANDGP). Divisions are regional networks of general practices whose main role, among others, is to provide support for GPs to establish the infrastructure for chronic diseases management. ANDGP is located within the northern suburbs of metropolitan Adelaide, South Australia. In 2007, the ANDGP catchment population was ~205 000, with 11% aged over 65.[15] The population demonstrates a relatively low socioeconomic status profile, with scores well below the average for both Australia and Adelaide on the Socioeconomic Index for Australia (SEIFA).[16] Australian-born people comprised 74.8% of the Division's population, just above the Australian figure of 72.6%. Of the 14.9% of people from English-speaking countries, 14.0% were from the UK. There are 66 general practices within the Division's boundaries, and a relatively higher number of patients with T2D compared with the national figure (26.8 per 1000 population compared with 23.4 for Australia).[16]

Definition of alternative models of care

In Australia, the National Service Improvement Framework for Diabetes considers involvement of PNs in management processes, and the use of information systems to optimise the management of diabetes as the main characteristics of optimal care.[3] We evaluate three models of care which show a transition from a medical care model (in which the GP is the custodian of all care within the general practice) to a team-based approach:

(1) Model I: (No PN) + (No reminder system)
(2) Model II: (Low level of involvement of PNs in diabetes management) + (Reminder system)
(3) Model III: (High level of involvement of PNs in diabetes management) + (Reminder system)

PNs have diverse roles in general practices including clinical-based activities (e.g. patient education and self management advice), integration (networking with other healthcare providers), clinical organisation (e.g. clinical data entry), and procedural-based activities (e.g. taking blood).[17]

In order to reflect the clinical-based contribution of PNs in management processes and to evaluate its impact on patient outcomes, we measured the level of PN involvement by (1) the proportion of diabetic patients from a general practice that are seen by PNs for the management of T2D and (2) the percentage of the PN time spent on clinical-based activities. These activities include patient education and self management advice, monitoring clinical progress, and assessing and enhancing treatment

adherence. We set a threshold of 50% or more on both measures to identify a high level of PN involvement, hence allocating the general practice to model III.

We allocated all other general practices with PNs to model II. Model II includes a low level of involvement of PNs in management of patients with T2D. This model fails to reflect the complementary role of PNs in patient care, where PNs may be seen as replacements for GPs in some clinical situations rather than as professionals that can add value to patient care in their own right.[17]

A key strength of this project is our consideration of the quality of care provided by PNs, as few studies have attempted to measure this aspect. The 50% threshold has been carefully considered by the PCSIP steering committee comprising experienced primary care-based researchers, GPs and PNs, and informed by the findings of a scoping survey which was piloted with GPs and PNs working in three practices.

To inform the classification of general practices into models II or III, we surveyed PNs employed at participating practices. The survey included questions about the measures (1) and (2) as outlined above. In order to validate our two models of PN involvement, we also analysed patterns of use of a PN-led Medicare item (item number: 10997), which covers clinical services (e.g. monitoring medication compliance) provided to a patient with diabetes by a PN under the supervision of a GP in the primary care setting.[18]

Practice recruitment process

We approached all general practices within the ANDGP catchment area by an invitation letter sent to the Practice Manager or lead GP, giving information about the project. Fifteen practices agreed to participate (23% of all practices approached). In order to identify the level of uptake of primary care-based initiatives, we asked the Practice Manager or lead GP from each participating practice to complete a survey. This survey enabled the PCSIP to differentiate between practices classified as model I and those classified as models II or III.

We also undertook a survey of all participating practices with PNs, which provided details of the level of PN involvement in management processes as outlined. On the basis of these surveys, fiveparticipating practices were classified as model I, four practices as model II, and six practices as model III. This is consistent with the distribution of PN-led Medicare item claims, with 85% of all claims over the study period made by practices classified as model III.

Patient recruitment process

In each participating general practice, we used the Pen Computer Systems Clinical Audit Tool (CAT) to generate a list of eligible patients, defined as patients with at least three visits within the last 2 years, aged 18 to 75 years with T2D (based on clinical diagnosis). A patient was excluded if they were pregnant or had a severe mental disorder (e.g. psychosis) or dementia which was likely to impair their capacity to participate in the project. Patient lists were reviewed by the relevant GP to further exclude patients living in residential care facilities or those whom it would be inappropriate to contact (e.g. mentally incompetent, or those who are not mainly under their care). We assigned a random number to each patient, and sent recruitment letters to the first 75 patients on the list for each participating practice. The process was repeated to reach recruitment targets (see sample size calculation).

After a two-step process (recruitment letters mailed to eligible patients followed by a postcard reminder), 399 (41%) of the 972 eligible patients approached agreed to participate. The targeted 92 patients per model of care was achieved for models II and III, but not for model I. The process is described in Fig. 1.

Data collection and sources

We are collecting the data from a range of sources. The following sections describe the data sources, and the variables extracted from each source.

The primary outcome measure includes the level of glycosylated haemoglobin (HbA1c). The perspective for the cost-effectiveness analysis is that of the healthcare system, thus only direct healthcare costs are considered.

Medical records held at participating practices

We created an encrypted patient identification code for each participating patient. Data from patient records are being extracted directly onto a database that contains only patients' encrypted identification codes, and no patient identifiers (i.e. name, address, Medicare card number). The data collected from medical records provide information on a range of patient level variables including:

(1) Patient characteristics (e.g. age, sex, years since diabetes diagnosed, socioeconomic status, diabetes-related complications, history of other medical conditions)
(2) Intermediate outcome measures: the primary intermediate outcome in the PCSIP is HbA1c, which is an accepted indicator of glycaemic control and clinical efficacy in diabetes studies.[19] Improving glycaemic control can improve the outcomes of patients with diabetes, as it reduces the risk of developing microvascular complications (nephropathy, neuropathy and retinopathy) as well as macrovascular complications of stroke and coronary heart disease.[20,21] Secondary outcomes are blood pressure and total cholesterol level. Outcome measures were informed by evidence-based Australian guidelines for T2D management in general practices.[22]

Medicare Australia

Data requested from Medicare will provide the following cost estimates:

(1) Out of hospital services: e.g. use of GP services, preparation and review of management plans, specialist visits, use of pathology services and imaging services
(2) Pharmaceuticals: these data cover scripts that attract a government contribution, and will be used to estimate pharmaceutical costs attributable to diabetes management for each patient. The data do not include patient co-payments. This is appropriate considering the perspective chosen by the PCSIP.

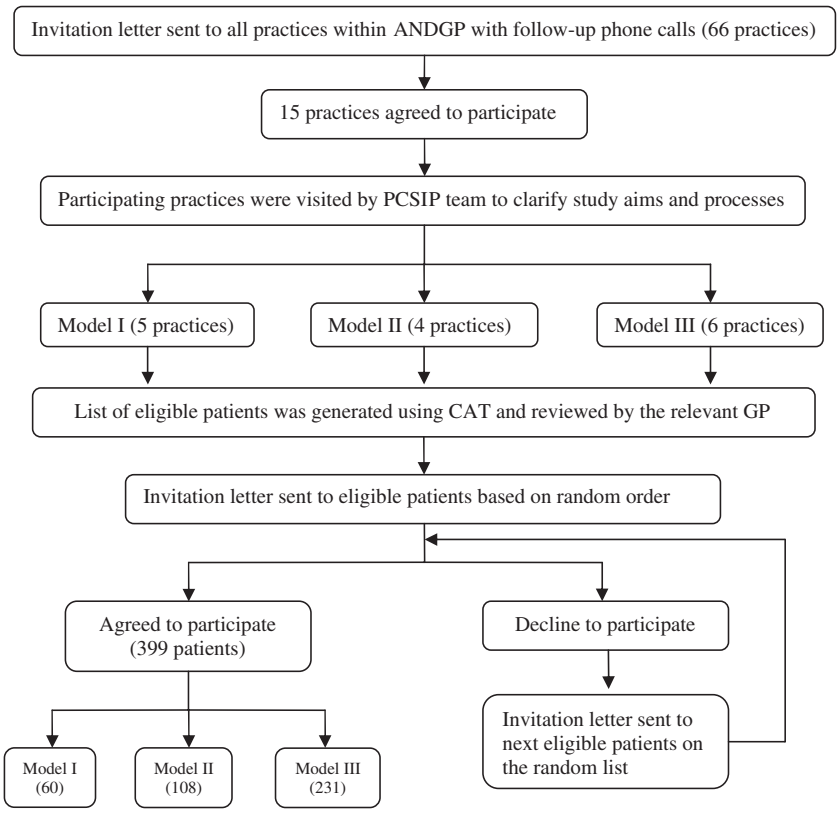

Fig. 1. Flowchart of the recruitment process.

South Australian Department of Health (SA Health)

Data will be provided by SA Health describing inpatient separations at all hospitals in SA, including diabetes specific Australian Refined Diagnosis Related Groups (AR-DRG) and length of stay. Patient level costs are available for separations at the four main public hospitals. For remaining hospitals, AR-DRG cost weights are used to estimate inpatient costs.

Surveys

Cost of the financial incentives to the government, including payment to general practices to support practices to employ PNs, and to encourage them to use register/reminder system for patients with diabetes, are being obtained from participating practices.

Other services are provided by the Division of General Practice, including:

(1) Services provided to participating patients if they are referred to the ANDGP by their GPs, e.g. self management education
(2) Costs of support to implement reminder system and on-going support to maintain the system for participating practices
(3) PN education for participating practices.

These data are being obtained from the ANDGP.

Sample size calculation

We used change in HbA1c as the primary outcome to estimate the sample size in each of the three models of care. We performed the following steps to estimate the sample size.

First, we aimed to detect an absolute 0.5% difference in mean HbA1c between models of care as the minimal clinically important difference. This led to a calculation of 42 patients required per model under an analysis of variance. This calculation was based on a standard deviation of 1.44% (on the basis of findings from recent diabetes projects in general practice in Australia),[23,24] with the 80% power and 5% level of significance. In the second step, we adjusted for the effect of the clustering design at general practice level. Based on the registry data from the ANDGP, we anticipated that the recruitment of 14–20 patients per general practice would be reasonable. Assuming an intraclass correlation coefficient (ICC) of 0.03 (based on the previous work in primary care),[25,26] the design effect was calculated to be 1.45. This inflation factor gives an adjusted number of patients per model of care of ~60. Finally, as the PCSIP is a non-randomised study, we will undertake regression-based analyses to control for potential confounding variables, including patient level factors (e.g. age, sex, duration of diabetes, baseline level of HbA1c), GP level factors (e.g. age, sex, years in practice), and general practice level factors (e.g. practice size). Allowing for

covariate effects (~5% increase per control variable[27]), a sample size of ~92 patients per model of care is required.

Data analysis: statistical analysis of effects

We use multilevel analysis to evaluate the association between different models of care and patient-level outcomes, while controlling for both general practice and patient-level covariates. Multilevel analysis allows for the simultaneous examination of the effects of both group and patient level variables on patient outcomes.[28] This method is suited to analyse data corresponding to individuals nested within groups.[29] In our project, it will be used to account for clustering of patients nested within GPs, and general practices.

Economic analysis

Within-trial analysis

The multilevel analysis will estimate adjusted mean estimates of costs and outcomes for each of the three models of care, which will be compared with estimated incremental costs and effects between the different models of care. We present confidence intervals to reflect the uncertainty around the adjusted mean parameter estimates, and the incremental results.

Lifetime extrapolation. We use the short-term data (3 years) derived from the PCSIP as a basis to estimate lifetime costs and benefits of alternative models of care using a decision analytic model. These models are now an expected part of economic evaluations, and are used to synthesise data from a variety of sources, to link intermediate outcomes to final outcomes (e.g. QALYs), and to extrapolate beyond the data observed in clinical trials.[18] These models generally represent disease progression as pathways through a series of clinical states. The aim is to estimate differences in the time spent in each state by patients receiving alternative interventions, over a defined time horizon (e.g. patients' lifetime). Costs and utility weights (representing quality of life on a 0 to 1 scale) are then attached to the time spent in each state to estimate the costs and QALYs associated with alternative management strategies (e.g. pharmaceuticals, models of care, etc.).

We use a validated model, i.e. UKPDS Outcomes Model which is used worldwide by several research groups to evaluate long-term costs and benefits of alternative interventions in diabetes. This model, described in detail elsewhere,[30] was developed from a set of risk equations using patient-level data from a subgroup of the UKPDS (3642 patients with T2D). These equations take into consideration various factors including patient baseline characteristics (e.g. age), history of diabetes-related complications, and time-varying risk factors (e.g. HbA1C). The model will estimate lifetime costs and QALYs for each model of care, which will inform incremental cost effectiveness ratios (ICERs) between the three models of care. Consistent with Australian guidelines in assessing pharmaceuticals for public funding, costs and benefits will be discounted at an annual rate of 5%.[31]

Ethics

The project protocol was approved by the Human Research Ethics Committees of the University of Adelaide, and the South Australian Department of Health.

Discussion/conclusions

Management of chronic diseases is now one of the major challenges facing healthcare systems. It has been noted that providing collaborative models of care can improve the management and control of chronic diseases such as diabetes. Given the large amount of funding currently used to maintain primary care-based initiatives in general practices in Australia, the results of studies such as the PCSIP will provide important information to optimise allocation of inevitably scarce healthcare resources.

By synthesising patient-level data with data from scientific literature (linking intermediate health outcomes to long-term health outcomes), using a decision analytic model, we will be able to analyse long-term costs and effects of initiatives relevant to management of patients with diabetes within the primary care setting. The PCSIP will generate the knowledge required to promote investment in the most cost-effective initiatives, and to improve the quality of decision making around scarce resources.

The PCSIP facilitates assessment of the impact of initiatives in a 'real world' population to which they have been applied, rather than in an ideal population, as is traditionally seen with randomised clinical trials. Real world practice is represented, which improves its generalisability. The study also explores opportunities in using linked, routinely collected data to evaluate primary care-based interventions. Furthermore, it eliminates reporting, observer and assessment bias, and is able to track patient history effectively.

The limitations of the project are inherent in practice-based research and observational studies, which require use of multilevel statistical modelling techniques to control for differences in patient, healthcare professional, and practice characteristics. The non-random selection of practices and recruitment of those GPs and patients who agree to participate may lead to self-selection bias, which may affect the external validity of the results.

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Competing interests

Authors disclose no conflicts of interest regarding this manuscript.

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