Collaborative care for co-morbid depression, heart disease and diabetes in Australian general practice

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Abstract

Patients with coronary heart disease or type 2 diabetes are at higher risk of depression. When these patients are depressed they have lower quality of life, increased disease burden and higher mortality. Depression in the presence of chronic disease is under-diagnosed and under-treated despite the recommendation of guidelines. There is a need for changed systems of care delivery in general practice to manage this problem. At the start of this story three changes were occurring in general practice that would go on to have a profound effect: practices were increasingly computerised for prescribing and recording patient data; practices were employing nurses; and incentive payments were established for chronic disease management activities. Australian general practice was primed for the introduction of a changed system of health delivery called collaborative care. This thesis describes the steps required to introduce this system of care and the outcomes of collaborative care compared with usual care in a randomised trial. The work is presented as a series of published papers.

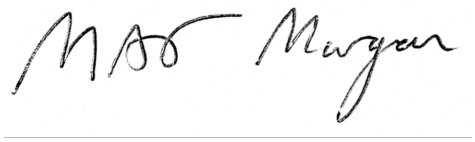
Collaborative care was both feasible and acceptable in an Australian setting for patients with co-morbid depression and coronary heart disease or diabetes, or both. Practice nurses were successfully trained to detect and monitor depression and they were able to assist patients with lifestyle modifications using goals setting and problem solving techniques. Nurses coordinated protocol-driven scheduled care for patients and assisted doctors by collating clinical information. Patients received a care plan that summarised their medical problems, personal

goals and medical management. There were improvements in depression scores, quality of life, levels of exercise, calculated 10-year cardiovascular risk and adherence to guidelines.

Collaborative care is a suitable model for delivery of primary care in Australia to better manage diabetes, coronary heart disease and depression.

Declaration by candidate

I certify that this thesis does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any university; and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text

Signed: 

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List of publications incorporated into this thesis

1. Prasuna Reddy, James A. Dunbar, Edward Janus, Alan Wolff, Stephen Bunker, **Mark A J Morgan** and Adrienne O'Neil. *Identifying depression in patients following admission for acute coronary syndrome*. Australian Journal of Rural Health (2007) **15**, 137–138

2. Prasuna Reddy, James A Dunbar, **Mark A J Morgan**, Adrienne O'Neil. Coronary heart disease and depression: getting evidence into clinical practice. *Stress and Health* (2008)**24**: 223–230

3. Adrian Elliot-Smith, **Mark A J Morgan.** How do we compare? Applying UK pay for performance indicators to an Australian general practice. *Australian Family Physician* (2010) **39**: 43-8

4. **Mark A J Morgan**, Dunbar, J. Reddy, P. Collaborative care - The role of practice nurses. *Australian Family Physician* (2009)**38**: 925-926

5. **Mark A J Morgan**, Michael J Coates, James A Dunbar, Prasuna Reddy, Kate Schlicht, Jeff Fuller. The TrueBlue model of collaborative care using practice nurses as case managers for depression alongside diabetes or heart disease: a randomised trial. *BMJ Open* 2013;**3**

6. K Schlicht, **Mark A J Morgan**, J Fuller, M J Coates, J A Dunbar. Safety and acceptability of practice nurse-managed care of depression in patients with diabetes or heart disease in the Australian TrueBlue study. *BMJ Open* 2013;**3**

7. **Mark A J Morgan**, Coates MJ, Dunbar JA. Using care plans to better manage multimorbidity. *Australasian Medical Journal* 2015;**8**(6)

Glossary

Adherence to medication	The extent to which a patient takes medications as prescribed.
Allied health	Healthcare professionals such as exercise physiologists, podiatrists, physiotherapists and diabetes educators.
Australian Medicare	Tax funded system of payments to patients to refund some or all the cost of specified medical services
Autonomic nervous system	Subconscious control system for functions such as heart rate, blood pressure, breathing and digestion
Bibliotherapy	Treatment in which patients are directed to specifically chosen texts.
Body mass index	Weight in kilograms divided by height in centimetres squared
Cardiac rehabilitation	Structured course providing education and facilitating lifestyle change provided following hospital admission for a cardiac condition.
Case management	The task of keeping track of a patients interactions with health services
Chronic Care Model	Widely regarded way to organise health systems to manage long term medical conditions (1).
Clinical indicator	Performance measure of an aspect of healthcare
Clinical pathways	Protocol for (or description of) the sequence of interactions a patient has with the health service.
Co-morbid	Depression and at least one additional chronic disease (long

depression	term medical condition)
Cognitive behavioural therapy	Psychological therapy in which patient is assisted to change unhelpful thinking and behaviour.
Cohort trial	Study design in which a group of subjects are followed over time to detect the outcomes of interest
Collaborative care	System of care in which a multidisciplinary team follows a structured plan with scheduled patient follow up and enhanced inter-professional communication (2, 3).
Coronary heart disease patients	Patients with a history of angina, myocardial infarction or coronary artery surgery
Decision support	Information collated and provided to the physician to help make clinical management choices
Depression	Persistent sadness or loss of interest lasting at least 2 weeks.
Depression care-manager	Nurse or mental health worker with the role of monitoring depression in patients enrolled in the University of Washington's model of collaborative care (4).
Diabetes Annual Cycle of Care	List of measures and procedures recommended for patients with diabetes for which there is an Australian Medicare payment on completion.
Electronic medical record	Computerised patient notes kept by a general practitioner
Endothelial	Internal lining of blood vessels

Glycaemic control	Control of average blood glucose levels usually measured as a percentage of glycosylated haemoglobin (HbA1c)
GP Management Plan	Care plan with defined minimal content for which there is and Australian Medicare payment
GP Mental Health Plan	Process of developing a written formulation of a patient's mental illness for which there is an Australian Medicare payment.
Inflammatory cytokines	Chemical signals released from cells to regulate the intensity of immune functions.
Ischaemic heart disease patients	Patients with a history of angina, myocardial infarction or coronary artery surgery
Major depression	Persistent sadness or loss of interest lasting at least 2 weeks that is moderate to severe when measured using a validated tool.
Mental Health Worker	Psychologist or social worker trained in psychological therapies or trained counsellor.
Meta-analysis	A statistical method to combine the results of several randomised trials
Meta-regression	Statistical method for identifying which components of an intervention caused an observed effect
Metabolic syndrome	Constellation of medical conditions that include obesity, raised blood pressure, raised fasting blood glucose and abnormal blood lipids.
Myocardial infarction	A condition in which some heart muscle is damaged because of blockage to the blood supply

Pathology tests	Blood tests and other laboratory measures.
Physiological measures	Physical measures such as blood pressure, weight, waist circumference.
Post hoc analysis	Re-investigation of results after completion of a trial
Practice incentive payments	Annual payments to Australian GP clinics for achieving pre-determined activity levels.
Practice nurses	Qualified nurses working in general practice clinics
Prevalence of a disease	The proportion of a defined population with the disease
Primary care	General practice and other community-based medical services that provide first point of care and longitudinal care.
Primary care collaboratives	A system in which an umbrella organisation provides training and support to medical clinics in change management principals and provides performance feedback. (Not the same meaning as collaborative care)
Problems solving techniques	Psychological therapy in which patient is assisted to define a problem, brainstorm possible solutions then choose a course of action.
Psychiatrist	Medical doctor specialising in managing mental illness
Psychologist (clinical)	A professional qualified to administer psychological therapies
Screening	Systematic testing of a defined group or population for a medical condition
Secondary care	Hospital or specialist provided care. In Australia it requires

	referral or attendance at a hospital emergency department.
Self-management support	A suite of information, education and practical measures to make it easier for a patient to monitor and improve their health.
Somatic symptoms	Physical manifestations of disease.
Stepped-care for depression	Process of care in which enhanced treatments are offered if there is insufficient response to initial treatment.
Team Care Arrangements	Process of arranging care with at least two providers for which there is an Australian Medicare payment.
Type 2 diabetes (mellitus)	A progressive condition in which the body becomes resistant to the normal effects of insulin or gradually loses the capacity to produce enough insulin in the pancreas or both (5)
UK Quality Outcome Framework	System of pay-for-performance for UK general practitioners.

Abbreviations

ACS	Acute coronary syndrome
ANCOVA	Analysis of covariance
ATSI	Aboriginal and Torres Strait Islanders
BMI	Body-mass index
BP	Blood pressure
CABG	Coronary artery bypass graft
CHD	Coronary heart disease
CONSORT	Consolidate standards of reporting trials
CVD	Cardiovascular disease
D_TECT	Depression Treatment Evaluation Care Team.
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders version 4
ECG	Electrocardiograph
eGFR	Estimated glomerular filtration rate
GGT UDRH	Greater Green Triangle University Department of Rural Health
GP	General practitioner /primary care physician
GPMP	GP management plan
HADS	Hospital Anxiety and Depression Score
HbA1c	Glycosylated haemoglobin
HDL cholesterol	High density lipoprotein cholesterol
HIV	Human immunodeficiency virus
ID	Identifier
IMPACT	Improving Mood-Promoting Access to Collaborative Treatment

	collaborative care program in USA (6)
LDL cholesterol	Low density lipoprotein cholesterol
MBS	Australian Medicare benefits schedule
MHW	Mental health worker
NHFA	National Heart Foundation of Australia
PHQ2	2-item Patient Health Questionnaire
PHQ9	9-item Patient Health Questionnaire
PN	Practice nurse
QOF	Quality Outcome Framework in UK
RCT	Randomised controlled trial
SF-36v2	Version 2 of the Short Form-36 questionnaire
SIGN	Scottish Intercollegiate Guidelines Network
SMART	Specific, Measurable, Attainable, Realistic and Time-bound
SQL	Structured Query Language
T2DM	Type 2 diabetes mellitus

Aims of this thesis

The primary aim of this thesis is to determine if the TrueBlue model of collaborative care improves depression in patients with coronary heart disease, diabetes mellitus or both.

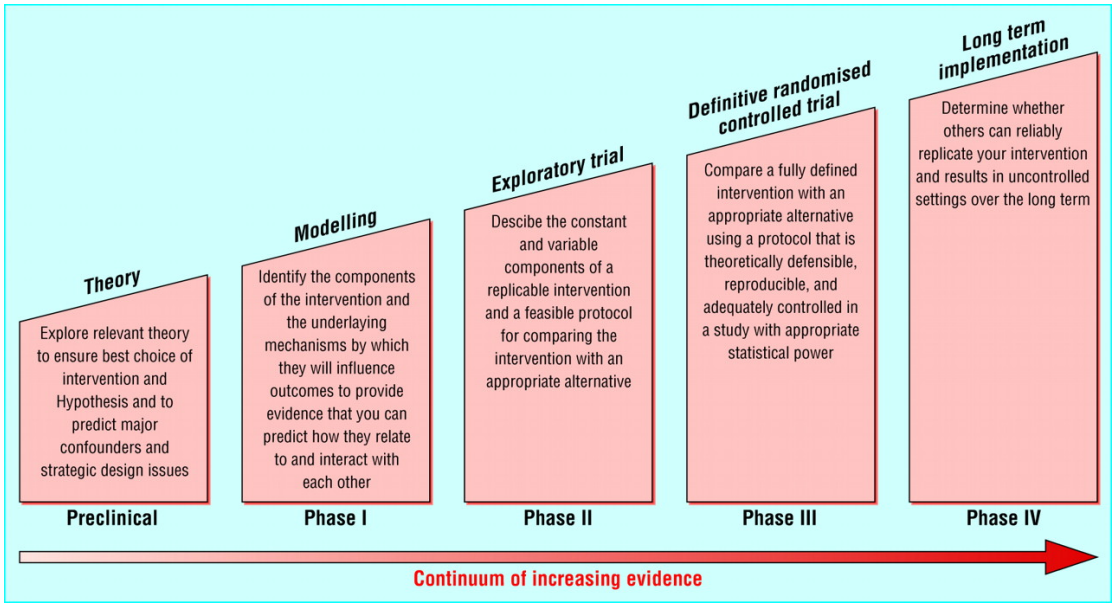
The secondary aims are:

1. To improve the detection of depression in patients who have coronary heart disease, diabetes mellitus or both.
2. To develop and test a model of collaborative care using principles of the Chronic Care Model within Australian general practice for the management of co-morbid depression, coronary heart disease or diabetes mellitus, or both.
3. To investigate if the TrueBlue collaborative care model achieves better clinical outcomes than usual care for co-morbid depression, coronary heart disease or diabetes mellitus, or both
4. To investigate whether TrueBlue care planning improves adherence to multiple disease management guidelines.

Organisation of this thesis

The primary aim of this thesis is to determine if the TrueBlue model of collaborative care can lead to better management of care for patients with depression and diabetes or heart disease, or both. Collaborative care involves a multifaceted change in the way GP clinics care for patients. In 2000, Campbell et al described a process for investigating such complex interventions where there are many interacting components leading to multiple outcome measures (Figure 1) (7). The thesis is arranged to follow the first four steps in this process from theory to modelling components of the intervention to an exploratory trial and ending with a definitive randomised controlled trial. The discussion section of the thesis will examine long-term implementation. My published peer-reviewed papers describing this body of work have been reproduced verbatim with formatting adjustments and minor edits to fit the scheme of the thesis.

(Figure 1) Development of randomised controlled trial of complex interventions (7)



Theory

Chapter 1 describes the theoretic background leading to TrueBlue collaborative care. The sections of Chapter 1 are as follows:

1. Importance of coronary heart disease, diabetes and depression
2. Interaction of coronary heart disease and depression
3. Interaction of diabetes and depression
4. Screening tool for co-morbid depression
5. Utility of screening interventions
6. Patient preference for consultation style
7. Information technology in primary care
8. Practice nurses
9. Payments to GPs for chronic disease management
10. Care plans and care planning

11. Patient self-management support for chronic disease
12. Stepped care for depression
13. The Chronic Care Model
14. Collaborative care for depression
15. Gaps in knowledge about collaborative care

Modelling components of the intervention

This step in the development of a complex intervention involves identifying components and testing them. Chapter two describes a screening intervention for depression following acute coronary syndrome. The chapter describes an investigation to explore when and where is the ideal time to screen for depression and what barriers were faced. Lastly, there is a description of a study to examine how GP computer systems can be used to identify where there are gaps between clinical guidelines and actual medical care. Published papers relating to the investigations in this chapter are reproduced in the Appendix.

Exploratory trial

Chapter 3 describes the D_TECT trial (Depression Treatment Evaluation Care Team) that explored the feasibility of introducing collaborative care in which Australian practice nurses were trained to screen for depression in the context of helping to manage diabetes or coronary heart disease.

Definitive randomised trial

Using lessons learned from D_TECT a definitive randomised trial named TrueBlue was designed. Chapter 4 contains a series of papers describing the design, quantitative and qualitative outcomes of TrueBlue and how TrueBlue care planning process was integral to its success.

Long term implementation

Chapter 5 describes the barriers and facilitators to implementation of collaborative care for co-morbid depression and international efforts to introduce this model of care.

Chapter 1. Literature Overview

This chapter outlines the rationale for this thesis and the literature that informed the design of TrueBlue collaborative intervention. In the language of complex intervention methodology this is the *pre-clinical theory*. To help provide an overview of the literature some references post-date the commencement of the pilot project in 2005 and TrueBlue randomised trials. The broad nature of this literature review meant that a systematic review would be unwieldy. This thesis is based on collected articles published in peer-reviewed journals. Each article is reproduced with its own introduction and discussion with relevant literature summarised. The search strategy for this literature overview was to use the Cochrane database of clinical reviews, Google Scholar, Medline and the United States National Library of Medicine and hand searching of reference lists. Further articles were identified in discussion with experts in each field. Search terms including collaborative care, consultation liaison, care planning, care manager, shared care, integrated care, enhanced care, complex intervention, self-care support, self management support, disease management and stepped care were used to identify examples of collaborative care. Google Scholar has been shown to provide between 92.9% and 100% of references when compared with systematic literature reviews used in the Cochrane library. Changing algorithms underpinning Google Scholar means it cannot be used for a reproducible systematic literature review. The user interface is also limited by not allowing successive filtering to make a search more precise (8-10).

1.1 Importance of coronary heart disease, diabetes and depression

The Global Burden of Disease Study in 2010 (11, 12) listed depression and diabetes amongst the leading causes of disability and ischaemic heart disease is the leading cause of death (13). Currently ischaemic heart disease is the cause of 1 in 3 deaths in Australia (14). As the proportion of the population over 65 years of age increases and with increased rates of obesity predictions for 2030 place depression as the leading burden of disease, ischaemic heart disease ranked second and diabetes ranked fifth (15, 16).

1.2 Interaction of coronary heart disease and depression

There is a two-way association between depression and coronary heart disease. A meta-analysis of randomised controlled trials published in 2006 demonstrated depressed patients had increased risk of a cardiovascular event with relative risk of 1.8 (12). Depression and stress was shown to be accountable for 32.5% of cardiovascular disease at a population level contributing more than smoking and diabetes combined (17). In the Heart and Soul prospective cohort trial in patients (n=1024) with stable coronary heart disease, major depression was associated with 41% greater risk of subsequent cardiovascular events (18). The explanations for this increased risk are not fully understood. Depression is associated with lifestyle risk factors such as smoking, insufficient exercise and reduced adherence to preventative medication (19). Biological changes are also present in depression including: increased inflammatory cytokines; changes in autonomic nervous system leading to reduced heart rate variability; increased adrenal stress hormones; and endothelial dysfunction (20, 21).

Following a cardiovascular event such as myocardial infarction or coronary artery bypass surgery there is an increased risk of developing depression with estimates varying from 15.5% to 43% depending on how soon after the event and which measurement of depression is used (22, 23).

The prognosis for patients with co-morbid depression and coronary heart disease is worse than those patients without depression. The British Whitehall II trial followed middle-aged adults for about 6 years. Participants with co-morbid depression and coronary heart disease were at much greater risk of dying (hazard ratio 5.0) compared with coronary heart disease alone (hazard ratio 1.7) or depression alone (hazard ratio 2.1) (24). A recent review of more than 50 prospective studies has corroborated this finding and led to the American Heart Association formally adopting co-morbid depression as a prognostic indicator for further cardiac events (25). Patients with co-morbid depression have poorer quality of life and greater physical limitations and fewer return to work (26, 27).

Depression and particularly co-morbid depression is under-diagnosed in primary care. One explanation of this finding is that somatic symptoms of depression such as sleep disturbance, tiredness and lack of energy overlap with symptoms of coronary heart disease (28, 29). Also, general practitioners prioritise physical symptom management over a more time-consuming exploration of psychological distress and there is a mismatch between doctor's use of the term 'depression' and use by patients (30).

There is less robust evidence for improved cardiovascular outcomes and reduced mortality by detecting and treating co-morbid depression. Treatment modalities include exercise, psychological therapies, pharmacotherapies and combined therapies. In a prospective trial of depressed patients, who were all post-myocardial infarction, self-reported regular exercising was associated with fewer future cardiovascular events (hazard ratio 0.62 after controlling for physical and social variables) (31). It was unclear whether the benefits of exercising were mediated by improvements in depression or by reductions in other cardiovascular risks factors. The converse association was made in a cohort trial of elderly patients that showed depressed patients who were inactive were at higher risk of cardiovascular death and that depression was associated with inactivity (32). Certainly, for the treatment of depression in general, participation in exercise programs has been shown to improve depression with a similar efficacy to cognitive behavioural therapy (33). A review of exercise interventions in patients with chronic disease and depression showed improved depression levels (34).

Post-myocardial infarction patients with depression or social isolation (n=2481) were allocated to group cognitive behavioural therapy or pharmacotherapy with sertraline (a selective serotonin reuptake inhibitor) failed to show improved mortality (35, 36). The authors suggest that patients either died of heart disease before depression could be adequately treated or patients had mild transient depression that diluted the impact of the intervention or patients with resistant late-onset depression might have 'vascular depression' caused by cerebrovascular damage marking these patients at increased risk of dying (37). A

Cochrane systematic review of psychological interventions published before 2010 concluded that these interventions helped reduce depression but had no effect on future cardiovascular events or mortality (38). In Sweden a randomised trial of patients with recent coronary heart disease admission to hospital compared usual care with intensive cognitive behaviour therapy intervention (20 sessions each 2 hours). The finding after 7 years follow up was 41% fewer recurrent cardiovascular events for cognitive behaviour therapy intervention but no significant effect on mortality (39). A systematic review and meta-analysis of trials of selective serotonin reuptake inhibitors in patients with depression and coronary heart disease failed to show a reduction in mortality or future cardiovascular events by pharmacotherapy but depression did improve and the treatments proved safe (40).

Guidelines from the Australian National Heart Foundation now recommend screening for depression in these patients and if present treating with a stepped-care approach using modalities such as cognitive behavioural therapy, antidepressant medication and moderate exercise at least 30 minutes duration on at least 5 days a week (41, 42).

1.3 Interaction of diabetes and depression

Patients with diabetes are more likely to have depression with estimates varying from 10.9% to 32.9% and the presence of co-morbid depression is associated with increased mortality (43, 44). These patients exercise less, eat less healthy food and are less likely to adhere to medication regimens (45, 46) with consequently poorer glycaemic control (47). Depressed patients with diabetes

have greater healthcare utilisation and costs (48) and co-morbid depression leads to greater functional disability (49).

Co-morbid depression is under-diagnosed due in part to doctors misinterpreting somatic symptoms of depression as features of diabetes and partly because patients and their doctors think it is normal to have depressed mood in the presence of a chronic disease (30, 50). Diabetes trained nurses detected only 25% of patients who subsequently scored high levels of anxiety or depression on a screening tool (51).

To break this vicious cycle current Australian guidelines recommend screening for and treating depression in patients with diabetes (52). A meta-analysis of fourteen randomised trials in 2010 reviewed the treatment of patients with diabetes and co-morbid depression (53). There were modest improvements in depression and glycaemic control for interventions using psychotherapy and for interventions using anti-depressant medication, but the greatest benefits were for those interventions that combined psychotherapy and diabetes self-management support (53).

1.4 Screening tools for co-morbid depression

There are many tools that can be used to help identify depression in patients with diabetes or coronary heart disease. An ideal tool will be quick and easy to use with high acceptability to both patients and the clinical team. It will be highly sensitive so few cases of depression would remain undetected and it will be highly specific to minimise false positives. It is particularly helpful if the same

tool is responsive enough to monitor treatment and assign severity of depression. The ideal tool will have been evaluated in the type of patients for whom it will be used. In this thesis the nine-part Patient Health Questionnaire (PHQ9, reproduced in Appendix 7.1) was selected (54).

Guidelines in USA, UK and Australia recommend the first two questions of the PHQ9 (PHQ2) to determine which patients should have further assessment. This is short and easy and it can be self-administered. In coronary heart disease outpatients it was 82% sensitive and 79% specific (cut-off score of ≥2) when compared with a gold standard psychiatric physician assessment by structured clinical interview but does not provide enough detail to monitor outcomes (18, 55, 56).

The nine-part Patient Health Questionnaire (PHQ9) uses questions that closely reflect the diagnostic criteria for depression in the DSM-IV classification (54). In coronary artery disease outpatients it was 83% sensitive and 76% specific (cut off ≥6) (55). PHQ9 cut off of ≥10 is often used as a short cut to identify 'major depression' but in a stable coronary heart disease population it was only 28% - 54% sensitive, suggesting many patients would be missed (55, 57). It is responsive to change and widely used in outcomes research both face-to-face and by postal survey. However, somatic symptoms of chronic disease may lead to some over–diagnosis (58).

Depression subscale of the Hospital Anxiety and Depression Scale (HADS-D)(59) has similar sensitivity and specificity to PHQ9 in coronary heart disease patients

despite only focusing on cognitive symptoms of depression such as anhedonia (57). In Australian patients with diabetes, PHQ9 diagnosed more moderate-severe depression (cut off ≥10) than HADS-D. Most of the difference was explained by questions relating to tiredness, sleeping problems and eating patterns. The authors suggest symptoms of diabetes might be the explanation of this apparent over-diagnosis however there was no reference gold standard test of depression used in this study to confirm there was over-diagnosis (58).

There are many other depression screening tools. A systematic review in 2012 identified 234 research papers describing the use of these tools. The popular tools were Beck Depression Inventory, Centre for Epidemiological Studies Depression Scale and Problem Areas in Diabetes Scale. Acceptability, validity and reliability were only reported in a small subset of these reports. PHQ9 had sensitivity of 82%, specificity of 68% and HADS-D was 77% sensitive and 66% specific (60).

1.5 Utility of screening interventions

The commentary above describes the interaction of depression with coronary heart disease and with diabetes, the need for screening and choice of screening tools. There is a body of evolving research describing ways to implement screening for co-morbid depression and how to organise care to best manage patients identified through screening (25, 42, 61).

On face value it seems simple to give an identified population of patients a self-administered or nurse/physician-administered depression-screening tool and

pass this information to the patient's GP. Results of this sort of intervention show little benefit in terms of patient outcomes even when primary care doctors receive copies of guidelines and educational interventions (62-67).

In the Identifying Depression as a Comorbid Condition study (IDACC) in Adelaide hospitals, depression scores were obtained for patients who had just had a coronary event (23, 68). The depression scores and some generic clinical advice was sent to each GP. Patients in the intervention arm of the trial were visited by psychiatrist or trained cardiac rehabilitation nurse and then engaged in a 10-15 minute case-conference between GP and hospital psychiatrist. Where this could not be organised, the GP received a telephone call from the psychiatrist. Patients had access to free psychology visits or fast-tracked appointments with liaison psychiatrists. Uptake of these treatment options was low at just 13 out of 331 patients in the intervention arm. In *post hoc* analysis patient specific telephone communication from consultant psychiatrist to GP was associated with a reduction in severe depression. Treatment type was not reported.

In rural south-east Australia a study of clinical pathways was undertaken to identify the points in a patient journey from admission to hospital with coronary heart disease when screening and intervention for depression can be implemented (69, 70). This study is reproduced in Appendix 1. The outcome of note here is that although conducted in a rural area where GPs work closely with a limited number of specialists and usually with only one hospital and in a defined geographical area there were communication barriers and implementation barriers. Patients who were identified as being depressed had

seen their GP, but there was no acknowledgement of depression or treatment offered.

1.6 Patient preference for consultation style

Research into primary care consultations demonstrates worrying mismatches between the doctor's agenda and patients' agenda. Consultations miss the social context in which the patient must face the illness and fail to address the patient's own ideas about the illness and its prognosis (71). It is clear that patients have a preference for 'patient-centred' consultations in which the ideas, concerns and expectations are discussed (72, 73). Medication adherence is strongly influenced by addressing patient concerns. There is a mismatch between patients' worries about side effects and the need for medication and that of their doctors. Patients also report worries about inadequate systems for monitoring long-term medications and perceived lack of consistency between secondary care and primary care (74). Patients would like longer consultations, which research shows are associated with increased chance of addressing psychosocial problems and engaging in health promotion (75). Doctors express similar concern about time pressures in consultations particularly when there are multiple chronic diseases to consider and performance indicators to achieve for each chronic disease (76). Where chronic diseases are managed in conjunction with a practice nurse there is improved satisfaction and adherence to best-practice guidelines (77). For depressed elderly patients an intervention that allowed preference for treatment modality and the addition of a nurse depression care-manager achieved improved satisfaction, self-efficacy, quality–of-life and reduced depression (78).

The TrueBlue model of collaborative care described later in this thesis gives patients additional and longer consultations with practice nurses who have been trained to follow protocols that focus on patient-centred care and national guidelines.

1.7 Information technology in primary care

For optimal management of patients with long-term medical conditions such as diabetes, coronary heart disease or depression the use electronic medical records can improve care (79). Patient clinical information, pathology results, disease guidelines reminders and prompts can be available at the time of a consultation. Patients can be invited to attend when tasks are due using recall lists. Information can be shared with specialists and allied health professionals directly from the electronic medical record (80).

During the 1990s, in Australia, there was an increase in the proportion of GPs using computers (81). Software providers kept costs down by advertising pharmaceuticals through the medium of the doctor's screen and there was government support for information technology through targeted 'practice incentive payments'. In 1998 only 10% of Australian GPs were using computers to prescribe. By 2001, 86% of GP clinics used computers with three quarters using them to retain patient demographic details and billing. Scripts were printed by 71% of GPs and about half received and stored pathology results electronically (81). By 2005, 90% of GP clinics used computers of which almost all were printing scripts and ordering pathology. Progress notes were typed by

64% of GPs but decision support within consultations was only used by 20% (82).

The full potential for use of electronic medical record software has not been reached in Australia because the software packages have been designed to mimic paper records with subsequent added functionality (83). What is missing is integration of this software with best-practice guidelines. Some attempt at 'intelligent' prompting based on recorded diagnoses and usual care pathways has been made for a narrow selection of chronic diseases. Also missing is direct access by patients to reflect on the content of their record and as a reminder of the recent consultation and to add to their own notes. Information from pathology tests, physical measures, recent external health-related visits and lifestyle risk factors are available to the user through multiple page entries rather than being pulled together to aid in the management of chronic diseases (84, 85). In the TrueBlue trial, described in Chapter 4, a self-populated template care plan was designed to overcome these deficiencies in the electronic medical records.

Electronic medical record generated prompts for physicians improve clinical care and patient outcomes, but a review of the impact suggested the effect was small (86). The most successful electronic decision support was provided at the time of consultation, fitted into the pattern of care delivery and gave treatment information for the physician and patient rather than just highlighting gaps in care (87-89). The TrueBlue trial provided the GP with a draft care plan with

imbedded guideline-derived disease management targets and a structure for achieving those targets. The completed plan was then given to the patient.

1.8 Practice nurses

In 2003 about 40% of Australian GP clinics employed a practice nurse and by 2006 this had increased to 60% of clinics with the number of practice nurses doubling between 2003 and 2007 (90-92). The roles of practice nurses in Australia have developed over the last decade. Surveys of nurse roles initially described nurses being a 'doctors' handmaiden' with tasks such as dressing wounds and assisting doctors with minor surgical procedures. Unresolved legal issues about adequate supervision, indemnity insurance and qualifications limited nurse scope of practice (91). More recently Australian practice nurses were found to spend 43% of their time doing direct clinical tasks. Their additional roles included administrative tasks, case-management for complex patients and assisting with GP care plans. Barriers to nurses performing more direct patient management in primary care include poor direct financial remuneration for nursing activities with only 3.2% of the average clinics' Medicare payments attributed to nursing (91). In an attempt to encourage more practices to employ nurses there is now direct funding via the Practice Incentives Program (93).

British practice nurses have been a much more fundamental part of GP clinics partly as a result of direct government requirements for practices to engage in health promotion (94). Funding for British general practice is based on the number of patients assigned to a particular clinic with about 25% additional

funding related to measures of quality of care. Nurses take on much of the responsibility for completion of chronic disease management tasks required by the system (95).

Practice nurses express concerns about their training and ability to manage depression (96). In UK, where many nurses are asked to screen for depression as part of the UK Quality Outcome Framework, a qualitative study suggested that the rationale for screening was poorly understood. Questions were asked in a tokenistic fashion aimed to save time and reduce the chance of identifying depression (97). There are examples of nurses with no prior mental health training successfully providing psychological therapies after brief training. In the Netherlands nurses used cognitive behavioural therapy after four days of training (98) and in UK diabetic educator nurses were trained to provide cognitive behavioural therapy and motivational interviews (99).

Patient attitude to nurse involvement in chronic disease management has been evaluated in the context of multifaceted interventions. Patients describe being able to talk more openly to nurses who are perceived to have more time to listen. Measures of patient satisfaction are at least as high as with comparable GP consultations (100-103). One German study suggested patients (and doctors) feared greater involvement by nurses because of level of expertise and dilution of contact time with doctors (104). Australian studies suggest patients fear that practice nurses might take on a gatekeeper role keeping them from seeing the doctor (105).

In this thesis practice nurses were adequately trained to feel confident in their expanded role. The collaborative care intervention in this thesis was designed to make best use of Australian Medicare chronic disease management rebates so nurse input was seen as financially beneficial to their GP clinics.

1.9 Payments to GPs for chronic disease management

Australian GPs are paid a fee-for-service with some additional 'Practice/Service Incentive Payments' for activities such as teaching, residential nursing home care and childhood immunisation programs (93, 106). In 2001, Practice Incentive Payments were made available for a completed annual cycle of care for patients with diabetes. This was a payment for minimum process of care. Examples of requirements included: recording blood pressure; weight; blood glucose control; organising foot care; and periodic eye checks. The low initial take up rate of about 10% indicates how unprepared Australian general practice was for proactive preventative care (107). The scheme was associated with a 20% rise in the probability that a patient would have a glycosylated haemoglobin test (of average blood glucose) from 13% to 32% of visits (108).

In 1999, Medicare item numbers were first introduced for writing a care plan and arranging multidisciplinary care for patients with a chronic disease or for attending a case conference (109). In 2005 the care planning tasks were separated into two components – writing the care plan (known as GP Management Plan) and arranging multidisciplinary team (known as Team Care Arrangements). Patients with one of these plans in place could access up to five Medicare funded visits to allied health team members each calendar year. Initial

uptake of care planning was poor because the time taken did not fit into the established pattern of 10-15 minute appointments (109-111). The possible income generation for general practice from claiming these item numbers is estimated to be four times the income from usual consulting by delegating the preparation of plans to practice nurses. The number of Australian Medicare rebates for the preparation of GP Management Plans more than doubled between 2007 and 2014 reflecting a reorganisation within GP clinics to access this income (112). In TrueBlue, described in Chapter 4, patient visits were timetabled every 13 weeks to fit the minimal interval for Medicare funded reviews of GP Management plans and Team Care Arrangements.

Since 2004 in UK, GPs have been paid about a quarter of their income based on performance against a range of quality indicators. In a study of diabetes indicators, involving nearly 24,000 patients, the introduction of pay-for-performance incentives accelerated year-on-year improvements in care. This effect waned by the third year in terms of incremental improvements and after removal of some of the indicators neither was there a drop off in performance (113, 114).

In a review of pay-for-performance incentives for chronic disease management there were surprisingly few studies (115). What studies there were failed to examine the optimum size of financial incentive and how high the barrier should be to achieve these incentives. Most pay-for-performance schemes were introduced as a component of a complex intervention involving health delivery re-design making the impact of financial incentives difficult to separate.

Incentive payments can be directed at process of care as in the Australian Practice Incentive Payment for completed annual cycle of diabetes care. In contrast, UK Quality Outcome Framework includes some clinical outcomes such as proportion of patients whose blood pressure is within defined targets.

In a study by the candidate reproduced in Appendix 3, an Australian practice performance was benchmarked against UK practices using the Quality Outcome Framework clinical indicators. In the absence of pay for performance the Australian practice achieved 66% of available points compared with a UK average of 97%. The TrueBlue collaborative care intervention aimed to improve performance by highlighting gaps in care and engaging the nurse, GP and patient to make changes.

1.10 Care plans and care planning

Care planning is defined as 'the process of assessing an individual's health, social risks and needs to determine the level and type of support required to meet those needs and objectives, and to achieve potential outcomes' (116). The process of care planning has long been part of nursing philosophy. Care planning is now recommended to aid chronic disease management and is supported by the World Health Organization and governments around the world (117). In respiratory diseases such as asthma and chronic obstructive pulmonary disease there is evidence that having a care plan, which includes an emergency action plan, improves self-management (118-120). Similarly, in patients with congestive cardiac failure, having a care plan reduced hospital admissions (121). For diabetes and cardiac disease care plans improve patient understanding,

hospital admission rates, adherence to medication plans and adherence to lifestyle recommendations (122-124). If the quality of plans or the level of training of the plan provider is inadequate, any measured benefits observed in clinical studies may be negated (124, 125). Provision of written care plans by primary care physicians is limited and varies from country to country. In the UK, while 84% of patients recall a care planning discussion, only 12% received any written plan (126, 127). In Germany 63% of primary care physicians routinely gave written care plans to patients, in Australia the proportion was 29% and in Canada only 14% (128) and in New Zealand 27% of nurses and 8.5% of GPs gave written plans (129).

The Australian Medical Benefits Schedule definition of a care plan requires: comprehensive assessment of the patient's health needs; formulation of agreed management goals; treatments; actions to be taken by the patient; and a review date (130). Unfortunately early examples of 'ideal' management plans missed much of the potential value. In an instructional article (131) Harris describes a plan for a fictional patient in which personal values and specific, measurable behavioural goals are missing. Also absent are health summary information, medication lists, allergies, management of co-morbidities, recent pathology results and biophysical measurements. Subsequent audit of diabetes GP management plans demonstrated similar limited content very much determined by the plan template being used (132). The focus of these GP Management Plans on medical targets for a single disease was illuminated in a qualitative review of patients in receipt of a GP Management Plan. Patients stated that the plans took little account of psychosocial problems and personal goals (110). In a qualitative

review of attitudes to diabetes care plans Shortus et al found that GPs used plans to engage patients in disease management targets but not to set personalised lifestyle goals. GPs also used the plans to help patients access Medicare subsidised allied health providers. Patients, allied health providers and specialist endocrinologists did not use the plans other than as a mechanism to access allied health services (133). This represents a missed opportunity to use care planning to coordinate a multidisciplinary approach to chronic disease management with exchange of helpful clinical information (134).

Zwar et al. conducted a retrospective, before and after medical record audit to identify the impacts on diabetes care of GP Management Plans. After approaching more than 800 GPs, 26 were able to provide data about patient care (n=230). GP Management Plans were associated with closer adherence to disease management guidelines for monitoring and patients were seen more often by allied health and this was associated with small improvements in physiological measures (135).

Chapter 4.4 reproduces a paper describing how the TrueBlue care plan was used as a multipurpose tool to direct, communicate and coordinate individualised management of multiple long-term medical conditions. To address some of the shortfalls in care planning described above, the TrueBlue care plan template prompted close adherence to recommended action to be taken by the patient and the health care team. The TrueBlue care plan included prompts to set personalised life-style and behavioural activation goals. It included health information to track changes over time and to provide relevant information for the wider health-care team.

1.11 Patient self-management support for chronic disease

Self-management can be defined as the ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes need to live with a chronic disease (136). Patients learn behavioural strategies and gain self-efficacy and empowerment to better implement lifestyle changes such as increased exercising and dietary modification. They are coached to be able to communicate better with their physicians. Self-management programs also attempt to reduce health related distress and improve both physical and mental quality of life (137). Programs have been developed and evaluated to be delivered by health care practitioners, peer-led in groups and online (138).

In diabetes care, Lorig et al demonstrated increased exercise rates, increased self-efficacy, reduced emergency department visits and reduced disease-specific distress in a variety of settings using the Stanford model with peer-supported training based around a book called "Living a Healthy Life with Chronic Conditions" (139-142). A systematic review of the Stanford model across multiple chronic diseases concluded that exercising and psychological wellbeing showed sustained improvements beyond 6 months (143). In a 2005 meta-analysis of randomised trials of group-based self-management programs for diabetes there were improvements in physical measures such as glycaemic control, systolic blood pressure and weight (144).

In Australia the Flinders model was developed from a care planning perspective in which the health care worker is trained to help individual patients identify

problems and set appropriate goals (145-147). A review of different self-management support models in Australia concluded that the greatest impact was achieved by either telephone coaching or by disease-specific self-management programs rather than the Stanford or Flinders generic models. A randomised trial of the Flinders model in community settings was beset by problems with the delivery of the model possibly related to the difficulties of imposing a time consuming structured program onto existing health delivery structures (148).

1.12 Stepped care for depression

General practice management of depression has traditionally been with prescriptions for antidepressant medications with only limited availability and affordability of psychological therapies (149-151). Up to 43% of patients stop taking medication within a few weeks of having it prescribed leading to poor outcomes (152).

Stepped care represents an alternative approach to increase access and target higher intensity treatments to those that most need it. In this system the least intrusive, simplest and most accessible interventions are offered first with additional or more intensive interventions offered to those patients who fail to respond. Low intensity therapies include guided self-help, psychological education and self-administered cognitive behavioural therapy by computer. Step-up therapies include pharmacotherapy or individual therapies by mental health workers such as problem-solving therapy (153) or interpersonal therapy (154). To implement stepped care three ingredients are required: a base-line measure of depression severity, planned follow-up for repeat measure, and

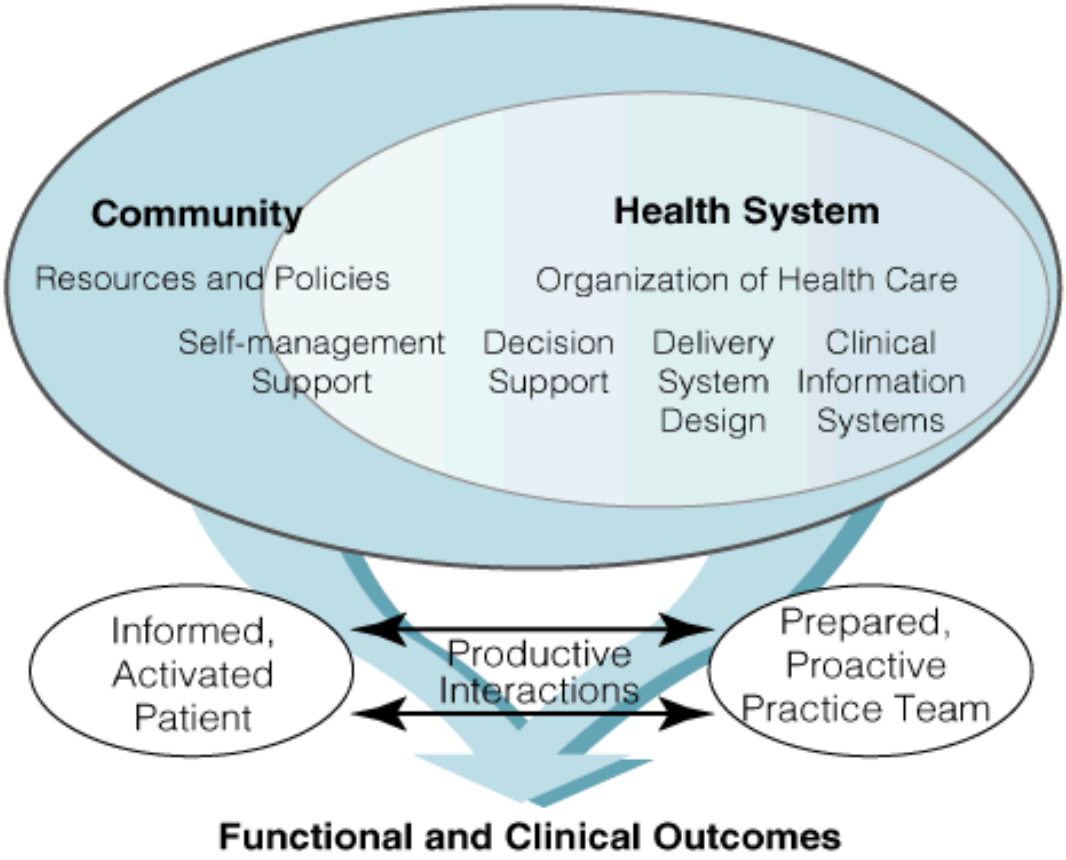
access to more intensive interventions (155). Initial scepticism of shoe-horning depression management into a system of care arose from concerns over the cost of ineffective low-intensity treatments and loss of physician autonomy to choose the best treatment for each patient (156). Reviews of the outcome of stepped care for depression have been reassuring. Acceptability is high if patients can choose between treatment modalities within each step (157). Effectiveness of low intensity care has been demonstrated including guided self-help with bibliotherapy (158) and self-administered cognitive behavioural therapy by computer (159). Even patients with major depression demonstrate improvement with lower intensity treatments with the self-correcting mechanism of review and intensification as back up (160).

1.13 The Chronic Care Model

Chronic diseases such as coronary heart disease, diabetes or depression are not a good fit for a model of episodic care where the patient makes an appointment with the general practitioner because of some acute need. These diseases need regular monitoring. There is a need for patients to make changes to lifestyle, take life-long medication and to screen for and manage the consequences of the primary disease. Patients have to adapt to the presence of the disease that might cause emotional, social and functional impacts. Wagner and colleagues described a model in which tasks are shared between a team with an emphasis on coordinated and proactive care with information made available for clinical decision making (1). In this model of care the patient is supported in self-management tasks and is educated to understand the pattern of care. The

organisation of care is aimed at meeting the needs of patients. Systems are configured to follow and audit evidence-based guidelines. [figure 2]

(Figure 2) Model for improvement of chronic illness care (1)



The Chronic Care Model components have been shown to be associated with improved management of diabetes in a systematic review as long ago as 2001 (161). In USA initially the Breakthrough Series of primary care collaboratives provided external support to primary care clinics to implement the Chronic Care Model (162). Early evaluations showed most practices could sustain changes at least for a year and that there were process improvements in patient care and improvements in intermediate outcomes (163). In a review of components of the

Chronic Care Model, improvement in clinical outcomes and quality of life were identified for care of chronic diseases including asthma, congestive heart failure and diabetes (164). In Australia Northern Territory, Aboriginal health clinics that were using the most components of the chronic care model achieved the best outcomes for measures of process of care and disease management in diabetes (165).

The six components of the Chronic Care Model (1, 74):

1. Community resources (for example, exercise programs) are utilised and patients are assisted to attend.
2. Self management support includes: building self-efficacy by achieving patient-identified short term goals (166); education to expand knowledge and improve skills; and addressing any mismatch between prescriber and patient understanding of medication (74).
3. Organisation of healthcare to encourage continuous quality improvements.
4. Decision support using evidence-based guidelines for routine clinical care with the use of reminders, education and enhanced interaction between specialists and generalists.
5. Delivery system design to use a team approach to meet the needs of the chronically ill.
6. Clinical information systems to maintain a patient registry, track follow up and to allow audit of the process and outcomes of care.

A recent review of 77 randomised trials, cohort studies and case studies reported health outcome benefits when any or several of these six components

of the Chronic Care Model were implemented (167). The authors report additional components that are rarely measured in clinical trials, but appear to lead to improved outcomes in case studies. These include engagement of clinic teams to prioritise chronic disease management, engagement of clinic leaders in the design of the intervention to increase contextual relevance, and reflective practice in which health providers make changes to health delivery as a result of understanding more about the needs of patients living with a chronic disease. Early experience using the Chronic Care Model in Australia comes from a series of coordinated care projects called SA Health Plus (168, 169). These research trials were conducted within an evolving political landscape impacting on the fidelity of the interventions, making outcomes harder to measure (170). The cost of case-management by nurses was not balanced in cost savings from reduced service utilisation. Measures of quality of life were improved and process measures such as goal setting activity were demonstrated in the intervention groups (168). Most of the positive changes reported from these trials were in terms of patient experience and provider readiness to change towards proactive population focused care (171).

1.14 Collaborative care for depression

The generic chronic disease management model described by Wagner has been further developed into collaborative care for the management of depression in a primary care setting. In a review of collaborative care trials for the management of depression a minimum of four components were identified to define collaborative care (2, 172-174):

1. Multiple professions involved – the primary care physician and at least one other.
2. Evidence–based care delivery with protocols or guidelines made available to the treating team.
3. Scheduled follow up of patients.
4. System for enhanced communication between health team members including meetings, case conferences, shared records or patient-held document.

Using this minimum set of criteria there are now more than 74 randomised trials showing consistent improvements in depression when collaborative care models are compared with usual care for the management of depression in primary care settings (173). A meta-analysis of trials of collaborative care compared with usual care published in the Cochrane library (175) demonstrated improved depression severity and increased proportion of patients recovering from depression at 6 months follow-up, 12 months follow-up and beyond. Collaborative care led to improved quality of life and patient satisfaction with treatment. Although most of the trials have been done in USA, an analysis of non-USA collaborative care trials suggest a similar effect size for these international settings. The cost effectiveness of collaborative care compared with usual care depends on the setting. Within USA, collaborative care has been shown to be cost effective (176).

There remain questions about the effectiveness of collaborative care for depression. Collaborative care introduces protocol-driven 'diligent' monitoring and treatment adjustment for depression that might account for much of the observed benefit over usual care (177). Within collaborative care interventions,

medication adherence and treatment intensification by use of medicines may also explain improved depression outcomes (2). In studies of collaborative care the control group is exposed to 'usual care' that is not defined or standardised so the effect size of collaborative care will vary according to the effectiveness of usual care (178).

Collaborative care is a complex intervention – one with multiple components. In an attempt to tease out which components of collaborative care lead to improved depression treatment meta-regression of multiple trials has been reported (173, 174). The earlier meta-regression used a broad definition of collaborative care and reviewed trials reported prior to November 2005. The components of collaborative care associated with greatest improvements in depression were found in trials that systematically screened for and monitored depression severity. Also associated with improvements were trials that engaged a mental-health trained case manager who received regular supervision. There were inherent problems in this meta-regression. The trials were poorly reported with few accounting for loss of patients (attrition bias). They were underpowered to detect remission of depression, most were focussed on increased use of antidepressant medication and there was no assessment of publication bias. Potential harms of collaborative care were not considered such as side effects of medication or problems associated with substitution of depression monitoring tasks from the primary care physician to a case manager. Meta-regression might identify factors associated with improved depression outcomes, but it cannot identify causality. Similarly, if there are essential components of collaborative care present in all the trials then meta-regression will be unable to identify the relative importance of those components. The very act of defining a minimum set

of ingredients for an intervention to be labelled as collaborative care will introduce these essential components.

A more recent systematic review of collaborative care examined ten potential components of collaborative care (173). Although antidepressant use increased in collaborative care models it was access to psychological interventions that predicted the greatest improvements in depression. This meta-regression failed to demonstrate any effect from the psychological expertise of the non-physician member of the care team be they a practice nurse or a psychologist. Likewise, there was no significant difference between collaborative care programs that offered an intense treatment program with multiple follow-up visits and those programs offering a low intensity visit schedule. Some components of collaborative care were not examined leaving questions about the importance of self-management support, the duration and intensity of psychological treatment sessions, the nature of intra-professional communication and stepped care for depression. The systematic review was also unable to distinguish which patient demographic factors were related to benefits received from collaborative care.

1.15 Gaps in knowledge about collaborative care

At the time of designing the explorative trial and TrueBlue randomised trials, there were few examples of collaborative care for depression outside of the USA. Few trials had examined the impact of collaborative care for depression in patients who also had chronic physical illness. No trials had examined collaborative care combined with a program of chronic disease management.

Collaborative care has been demonstrated for the management of depression, but is it an effective way to organise the care of patients with depression and a physical chronic disease such as diabetes or coronary heart disease? In a large (n=1801) randomised trial of collaborative care for depression (4) subgroup analysis of those with comorbid type 2 diabetes (n=417) treating depression had no impact on average blood glucose levels as measured by HbA1c (179). Similarly in an intensive collaborative care intervention, focussed on depression management in patients with major depression and type 2 diabetes, there was improvement in depression but not in HbA1c (180). This is in contrast to the findings of a small study (n=51) of cognitive behavioural therapy in patients with depression and poorly controlled type 2 diabetes which did show a significant improvement of HbA1c (181).

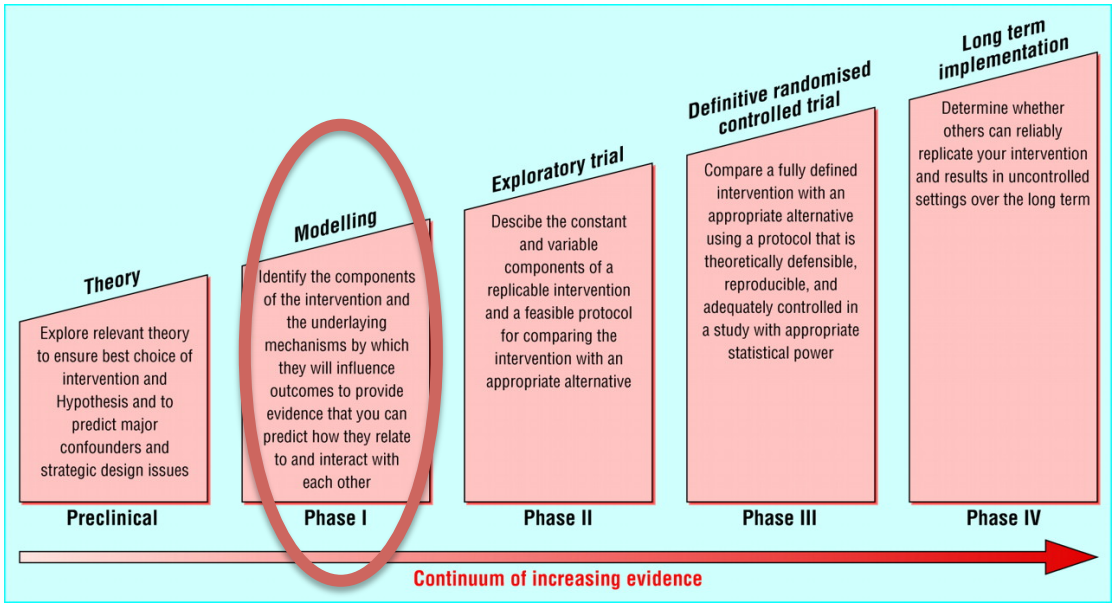
The Chronic Care Model has shown improved outcomes for the management of chronic diseases including heart disease and diabetes, but can the model be implemented alongside collaborative care to simultaneously improve the management of depression and physical co-morbidities?

Can general practice care be redesigned in an Australian setting in which GPs are paid fee-for-service with no payments for improved disease outcomes? In Northern Australian Aboriginal community centres some clinics were operating with well-developed community linkages, decision support systems, delivery system re-design and clinical information systems, which are all components of the Chronic Care Model, but these centres operate outside of fee-for-service arrangements (165).

Can Australian practice nurses step into new roles that include being part of collaborative care for depression management and is it possible to design and trial a program in which all the components of Wagner's Chronic Care Model and collaborative care are implemented with embedded stepped care for depression?

Chapter 2. Modelling components of the intervention

(Figure 3) Development of randomised controlled trial of complex interventions - modelling (7)



This chapter is based on a series of research projects that were reported in peer reviewed journal articles co-authored by the author of this thesis. These articles are reproduced in Appendix 1-3.

2.1 Identifying depression in patients following admission for acute coronary syndrome

Citation(182), reproduced in Appendix 1

Prasuna Reddy,[1] James A. Dunbar,[1] Edward Janus,[1,2] Alan Wolff,[1,3] Stephen Bunker,[1] **Mark Morgan**[1,4] and Adrienne O'Neil[1] *Identifying depression in patients following admission for acute coronary syndrome*. Australian Journal of Rural Health (2007) **15**, 137–138.

This journal article describes the outcome of a research project to explore the optimum timing to screen for depression in patients admitted to rural Australian hospitals with acute coronary syndrome. The main findings are that screening with PHQ2 identified potential depression in 46% of patients at two weeks post

admission date. At 8 weeks post admission 21% of patients still reported depression symptoms and there were 4% newly depressed patients. Most patients had seen a GP but no action had been taken to treat or manage depression. These findings led our team to investigate patient pathways through the health system after being admitted to hospital following an acute coronary event such as myocardial infarct or unstable angina.

2.2 Implementation of a guideline to screen for co-morbid depression

Citation (69) reproduced in Appendix 2

Prasuna Reddy, James A Dunbar, **Mark A J Morgan**, Adrienne O'Neil. Coronary heart disease and depression: getting evidence into clinical practice. *Stress and Health* (2008)**24**: 223–230.

This article reviewed the evidence at the time for a bidirectional relationship between depression and cardiovascular disease. The article summarised international guidelines that promoted depression screening. The gap between guidelines and implementation was identified and attributed to a combination of factors. There was a lack of knowledge of the guidelines by GPs and they lacked tools to screen for depression. Time pressures and the absence of coordination with the wider health care team were cited as additional reasons for implementation failure. Lastly there was no financial incentive to apply the guideline in everyday practice.

A clinical pathways approach was used to better understand how to construct local protocols that identify the appropriate health care worker to screen for depression and the best timing following discharge. Cardiac rehabilitation nurses

conducted screening either in person or by telephone. GPs were given the screening results and relevant information about further management.
This guideline to implementation protocol removed some of the barriers to establish screening but problems were identified. Following discharge from hospital, patients had only limited contact with hospital services so post-discharge screening at 8 weeks was an additional imposition on cardiac rehabilitation nurses. The protocol achieved the stated goal of screening but did not lead to treatment by GPs. Also, having identified the need to screen and managed depression in patients with cardiovascular disease, only the subset of those patients admitted for acute coronary syndromes were targeted in this intervention. There was an identified need to establish systematic depression screening in all patients with cardiovascular disease in primary care.

2.3 Measuring guideline implementation in Australian general practice

Citation (183) reproduced in Appendix 3:

Adrian Elliot-Smith, **Mark A J Morgan.** How do we compare? Applying UK pay for performance indicators to an Australian general practice. *Australian Family Physician* (2010) **39**: 43-8.

This article described a research project that explored how to use GP electronic medical record software to identify gaps between best practice guidelines and clinical practice. The project used the UK Quality Outcome Framework that specifies disease management targets across multiple chronic diseases. The user interface of Australian GP clinical software was designed with a rudimentary ability to create disease registries, but with limited ability to link diseases to

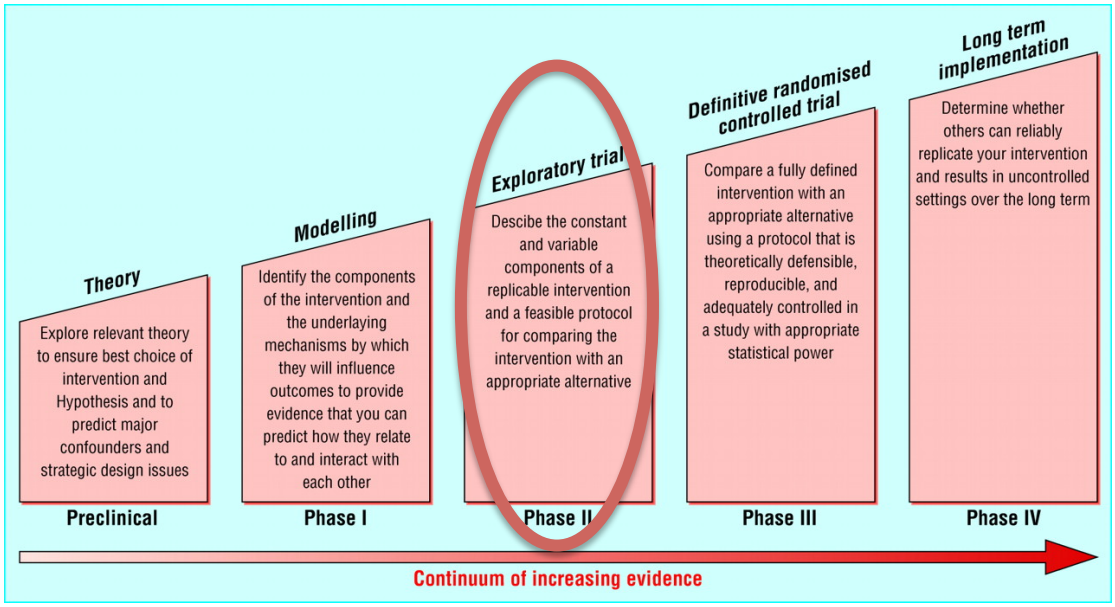
measurable outcomes. In this research project these barriers were overcome using a combination of bespoke search strategies, recreation of disease registries from disease-specific prescribing patterns and by manual sampling of electronic notes identified after a key word search.

The findings were that only 19% of patients with a diagnosis of coronary heart disease had been screened for depression. There were other significant gaps between guidelines and clinical management in both process of care and clinical disease management targets. In patients with a diagnosis of depression only 39% had used a depression severity tool. In patients with coronary heart disease or type2 diabetes 30-52% had last recorded blood pressure above threshold, which was itself above guideline recommended ideal blood pressure. Among patients with diabetes, 40% had not had urine microalbumin measured and nearly half had no recorded body mass index. These findings from a single practice are similar to those found by the Australian GP Collaboratives program across multiple practices (184, 185).

This research project demonstrated that it was possible and feasible to use the electronic medical record database to make disease registries and to identify gaps in process and outcome of care. The research project found large gaps between guideline recommended management and routine clinical care. These findings supported the development of a more systematic approach to the management of coronary heart disease, diabetes and co-morbid depression making optimum use of GP computer systems.

Chapter 3. Exploratory trial (reproduced verbatim)

(Figure 4) Development of randomised controlled trial of complex interventions –exploratory trial (7)



Segue

Citation (186):

Morgan, M. A. Dunbar, J. Reddy, P. Collaborative care - The role of practice nurses. *Australian Family Physician* (2009)**38**: 925-926.

This research article is reproduced below. It described the design and outcomes of an exploratory trial called D_TECT (Depression Treatment Evaluation Care Team). The aim was to screen for co-morbid depression in patients with type 2 diabetes or coronary heart disease. Where depression was identified collaborative care was initiated to jointly manage depression and the physical chronic disease. The setting was six rural Australian GP clinics. Additional details and background information are available in a further published article reproduced in Appendix 4.

The design of this trial incorporates the theory and modelling from chapters 1 and 2 of this thesis as outlined in table 1.

Table 1. Theory and modelling leading to corresponding features of the D_TECT exploratory trial

Theory and modelling component	**Corresponding features of D_TECT exploratory trial**
Under-diagnosed co-morbid depression in patients with coronary heart disease or diabetes.	Disease registries from coronary heart disease and diabetes were constructed and used to invite these patients to screen for depression.
Depression screening tool with adequate sensitivity, specificity, tracking over time and allowing adjustment for the influence of somatic symptoms.	Patients completed PHQ 9 and HADS questionnaires.
Personal and patient-specific communication of depression screening scores to GPs increases the chance that depression will be managed	Practice nurse protocol was to speak with the patient's usual GP for each patient identified as depressed.
Preference for patient-centred consultations that are longer, address concerns, allow choice in treatment modality, systematically monitor chronic disease and provide consistent advice.	Practice nurses spent between 30 and 60 minutes with the patient prior to usual GP consultation. Nurses used a checklist for chronic disease monitoring based on targets from current Australian national guidelines. Identifying concerns was part of the protocol.
Optimal use of information technology in primary care in which electronic records reproduce multiple pages of paper records.	Relevant parts of the electronic medical record were collated into a single draft care plan template available at the point of care.
Practice nurses need training to feel confident enquiring about mental illness	Three-day training program and six months later a two-day workshop taught nurses to use the screening tools, to understand depression treatment options, to use motivational interviewing techniques to overcome barriers and to safely manage suicidal patients.

Payments to GPs to provide a business case for collaborative care	The protocol and care plan templates were designed to allow access to Medicare chronic disease management item numbers
Comprehensive care planning	The care plan template and nurse training program ensured care plans included individualised goals, psychosocial information, summary medical information, measurements and recommended targets.
Self-management support	Nurses were trained to help patients identify short-term goals, barriers, and ways to increase self-efficacy to overcome these barriers. Diet, exercise and disease specific monitoring education was included in the protocol.
Stepped care for depression	GPs and nurses were guided to follow stepped care where PHQ9 scores remained elevated. The protocol allowed patients and GPs to select behavioural activation, psychoeducation, referral to a psychologist for brief intervention, or initiation of antidepressant medication.
Chronic Care Model	Features of the chronic care model: • Community resource folder • Self-management support • GP decision support with guidelines targets and collated measurements • Redesigned care to use additional team members – in this case the practice nurse • IT infrastructure to provide proactive scheduled care with disease registries and recall/reminders
Collaborative Care	Features of collaborative care: • Multi-professional – GP and practice nurse acting as depression care manager(4). • Evidence-based, protocol driven care • Scheduled follow up and telephone progress checks by the practice nurse to enhance continuity of patient care. • Enhanced inter-disciplinary communication using care plan

	document. There were monthly teleconferences between nurses and research team GP, psychologist and psychiatrist.
Modelling optimum place to identify co-morbid depression	In primary care by invitation and opportunistically using adequately trained and resourced nurses.
Modelling implementation of a guideline for screen-detected depression	Barriers to GP management of screen-detected depression lowered by sharing tasks with practice nurse, providing screening tools, treatment guidelines and access to Medicare chronic disease funding
Modelling of use of GP clinical software for guideline-based chronic disease management	Search strategies to construct disease registries were used to make a list of patients to invite to D_TECT

Collaborative care - The role of practice nurses (reproduced verbatim)

Morgan, M. A. Dunbar, J. Reddy, P. *Australian Family Physician* (2009)**38**: 925-926.

Abstract

Background

Comorbid depression can occur with diabetes and heart disease. This article reports on a feasibility study focusing on additional roles for practice nurses in detecting and monitoring depression with other chronic diseases.

Method

A convenience sample of six practices in southeast Australia was identified. Practice nurses received training via a workshop, which included training in the use of the Patient Health Questionnaire, to detect depression.

Results

The 332 patients who participated in the project each received a comprehensive health summary to assist with self-management. Depression was identified in

34% of patients in this convenience sample. After 18 months implementation, practice nurses were strongly in favour of continuing the model of care. General practitioners gave highly favourable ratings for effectiveness and willingness to continue this model of care.

Discussion

Practice nurses can include depression monitoring alongside systematic care of diabetes and heart disease. A randomised trial is currently underway to compare the clinical outcomes of this model with usual care.

Introduction

In patients with either type 2 diabetes mellitus or coronary heart disease the presence of depression leads to increased morbidity and mortality (45, 187). This comorbid depression is often missed in routine general practice (188). To address these problems we describe the implementation of collaborative care based on new roles for practice nurses (PNs), information technology solutions, and a shift of focus toward self-care. A similar model of collaborative care has been shown overseas to be an effective way to improve the management of depression in primary care (78).

Method

A feasibility study focusing on additional roles for PNs. Six practices in southeast Australia were selected by invitation on the basis of having PNs available to participate in the study. Patients were selected by the general practitioner from a

disease registry or opportunistically invited to attend the PN before review by the usual doctor. Regular follow up checks by the PN/doctor team were organised at 3–6 month intervals according to clinical need. The GP Management Plan template allowed de-identified collection and feedback of data, as well as prompting review appointments. Structured interviews were conducted with all PNs and GPs in the study to evaluate the usefulness of the collaborative model.

Ethics approval was obtained from the Flinders University Social and Behavioural Research Ethics Committee.

The workshops

Nurse training workshops prepared PNs for new roles including:

- Use of the Patient Health Questionnaire (PHQ9) (54) to detect and monitor depression and to assist the GP in clinical treatment of depression
- Physical checks and pathology results checklist generated from National Heart Foundation and Diabetes Australia guidelines
- Coordinating and ensuring follow up and appropriate allied health referrals
- Helping patients understand and set goals related to depression, lifestyle changes, and targets for physical and chemical measures
- Drafting a GP Management Plan
- Automated collection and feedback of results

- Ensuring completion of Medicare requirements for chronic disease item numbers.

Results

For patients

The 332 patients who participated in the project each received a comprehensive health summary to assist with self-management. Patients experienced PN led, systematic, protocol driven care. Depression was identified in 34% of patients in this convenience sample. In this model, mental health was being addressed as part of comprehensive care.

For practice nurses

Evaluation of the training workshops showed significant improvement in knowledge and confidence in the identification and assessment of depression and significant improvement in undertaking case management tasks. After 18 months implementation, nurses were strongly in favour of continuing the model of care. A supportive GP and protected time of at least 30 minutes to consult were the main enablers.

For GPs

General practitioners had to be willing to accept scrutiny of patient care by PNs using 'best practice' guidelines to highlight gaps. Despite this barrier, GPs gave highly favourable ratings for effectiveness and willingness to continue this model of care. Practices were able to claim Medicare rebates for GP Management Plans, Team Care Arrangements and completion of Diabetes Annual Cycles of Care.

Discussion

The business case did suggest that, by completing GP Management Plans or Team Care Arrangements where applicable, and Diabetes Annual Cycle of Care Medicare item numbers, practices could more than recoup the additional costs of the PN's time. It was both feasible and acceptable for collaborative care to be implemented for the management of patients with diabetes or coronary heart disease. Our training package and computer templates can equip PNs to successfully take on the role of screening for, and monitoring of, comorbid depression. A randomised trial is currently underway in three regions of Australia (urban, regional and rural) to compare the clinical outcomes of this model with usual care (189).

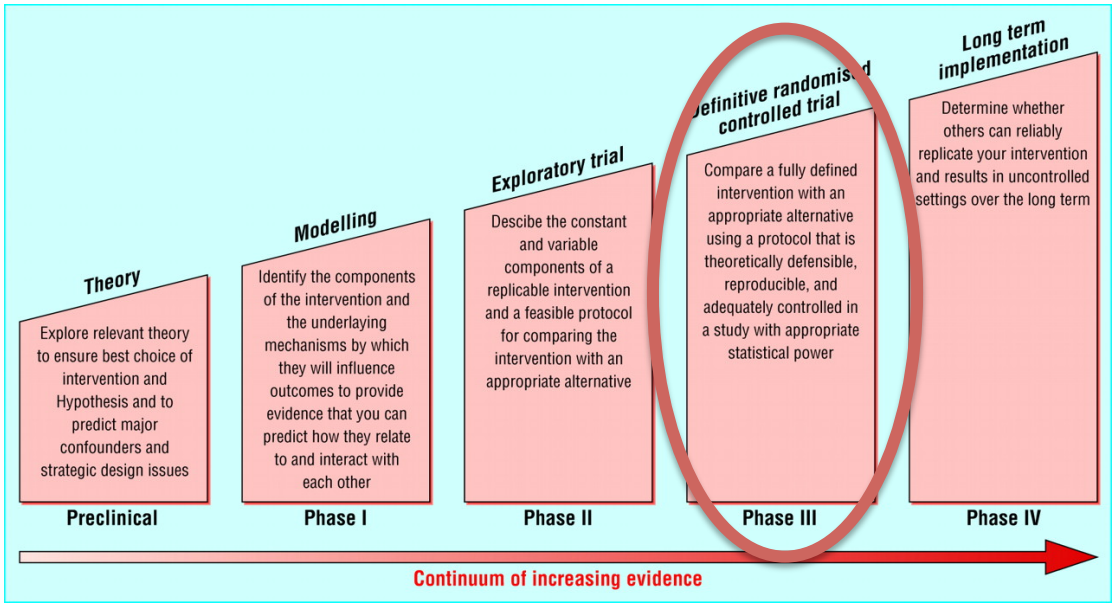
Implications for general practice

- Depression in patients with type 2 diabetes or coronary heart disease is a risk factor for poor outcome, but it is under diagnosed.
- Practice nurses can include depression monitoring alongside systematic care of diabetes and heart disease.
- Nurse-led chronic disease clinics for diabetes and heart disease are feasible, acceptable and affordable.

Conflict of interest: none declared.

Chapter 4 Definitive Randomised trial -The TrueBlue Study

(Figure 5) Development of randomised controlled trial of complex interventions –definitive randomised trial (7)



Segue

This chapter reproduces four papers based on the TrueBlue randomised trial of collaborative care for co-morbid depression.

The first paper describes the TrueBlue protocol. It links the components of TrueBlue to the generic definition of collaborative care. The paper describes how a search for suitable models of collaborative care led to the University of Washington IMPACT program in which mental health trained non-physician staff, usually psychologists, take a role as "depression clinical specialists" to lead a patient through their treatment of depression (4, 78, 190, 191). Members of the TrueBlue research team visited the authors of IMPACT to learn how they implemented the program. It was adapted in Australia to fit with existing

primary care structures in which many GP clinics employed practice nurses.

Table 2 describes some of the differences between IMPACT and TrueBlue design.

Table 2. Differences in design of IMPACT and TrueBlue interventions

IMPACT	TrueBlue	Comments
Eligible patients were over 60 years with depression	Eligible patients had depression with type 2 diabetes or coronary heart disease or both	TrueBlue examined collaborative care for co-morbid depression
Primary outcome measure was depression. Secondary outcome measures included quality of life and intensification of treatment	Primary outcome measure was depression. Secondary outcome measures included process of care and secondary prevention targets for diabetes and coronary heart disease. Changes in quality of life – both physical and mental components were measure as was intensification of treatment.	TrueBlue intervention was a combination of collaborative care for co-morbid depression and management of diabetes and heart disease incorporating the elements of the Chronic Care Model.
In IMPACT 'Depression Clinical Specialists' (DCS) were nurses or psychologists trained to a greater proficiency than a 'doctoral psychologist' (6)	Practice nurses trained in helping patients to identify behavioural activation goals alongside monitoring of physical chronic illnesses	TrueBlue was designed to be implemented in Australia where practice nurses were increasingly available but limited extra training was possible.
Randomisation at the level of individual patients so clinicians were treating some patients enrolled in collaborative care and some who were not.	Cluster randomisation at the level of each clinic to avoid GPs treating some patients differently from others.	In TrueBlue we considered it would be difficult for practice nurses and GPs to treat patients in two different ways. Changes to usual care were likely to occur lowering the measured effect of collaborative care.
Patients expressing	Patients with severe	TrueBlue safety

suicidal ideation were excluded from the trial	depression were not excluded.	protocols ensured prompt GP review of these patients.
Data collection was by telephone interview by trained lay researchers. Patients were paid to participate	Data collection was normalised as part of the intervention to guide treatment and goal setting.	Funding was not available to have data collected by external agencies. Also patient consent would need to be obtained for this further sharing of identifiable information.
Psychiatrist contributed to weekly review meetings to supervise and guide the DCS. Patients failing to respond had access to the psychiatrist	Psychiatrist were available by normal referral pathways from the GP	In Australia the availability and geographic distribution of psychiatrists is limited.
Patients choosing brief psychological therapy in the form of 'problem solving techniques' received this directly from the DCS at no charge.	Psychological therapy was accessed by referral to external psychologists after assessment by the practice nurse and GP. Psychologists could engage in a range of treatment modalities.	Practice nurses in TrueBlue were not adequately trained to conduct psychological interventions. Instead they had a role in coordinating external referrals for this service.
The use of antidepressant medication was markedly increased in IMPACT intervention patients with 78% receiving medication over the course of a year compared to usual care where 57% received medication	The use of antidepressant medication was only moderately increased within TrueBlue intervention from 17% at baseline to 21%. In control patients 27% were receiving antidepressant medication increasing to 32% during the trial.	GPs in TrueBlue were guided by patient preference, clinician preference and outcomes of PHQ9 depression monitoring. The differences might reflect a focus on medication adherence within the protocols of IMPACT and differences in physician practice.
Until stabilised patients were assessed and supported by DCS weekly or fortnightly	Protocol-driven and timetabled visits occurred at 3 monthly intervals. GPs and nurses were able to arrange additional	TrueBlue was designed to be funded by Australian Medicare chronic disease item numbers. Rebates were available for review of

	contacts with patients	GP Management Plan three-monthly and up to 5 'nurse assist with chronic disease' items annually.
Recording DCM sessions for monthly standardisation ensured the fidelity of IMPACT intervention.	In TrueBlue the intervention was determined by the availability of community resources and patient-chosen goals.	Flexibility in applying the TrueBlue intervention meant it was applicable to a wide variety of situations in rural, urban, large and small clinics. This variability reduced the ability of the TrueBlue trial to determine the effectiveness of a standardised patient experience.

The evaluative trial was successful in demonstrating the feasibility of rural Australian practices to screen and manage co-morbid depression alongside usual care of coronary heart disease or diabetes, or both. Practice nurses increased their confidence to take on new roles of monitoring chronic disease, case-management, telephone support, screening for depression, monitoring depression and helping to manage mild depression. Most of the D_TECT practices continued the model of care following the end of the research project and two of the trained nurses became peer-trainers. Nurses also reported using their enhanced skills for patients with other chronic diseases including chronic obstructive pulmonary disease and arthritis.

There were barriers to the complete implementation of D_TECT that resulted in changes to the design of the subsequent TrueBlue randomised trial described in the next chapter of this thesis. In D_TECT, of the 332 patients who had initial visit

to the practice nurse and GP only 51 attended a follow up visit. Interviews with GPs and practice nurses suggested that new patients were prioritised because they were seen as the most needy and also the financial incentives for writing a GP Management Plan exceeded the incentives for reviewing a GP Management Plan. Clinic recall/reminder systems were suboptimal because computer-based reminders were not routinely used to generate follow up appointments. There were resource limitations within practices because nurse consulting required a consulting room and dedicated time without interruption from more traditional practice nurse duties such as wound management and assisting GPs as a chaperone.

The design of the intervention in the TrueBlue randomised trial used lessons learned from D_TECT. Practices were recruited on the basis of having availability of a practice nurse to consult for 4 hours per week. Practice recruitment targeted large and small practices in urban and rural settings rather than just rural practices. Recall and reminder systems were considered in the set-up phase at each research site. Facilitators from the local Divisions of General Practice were employed in each geographical location to assist practices during this set-up phase. The research team received de-identified patient-level data from each visit so they were able to track and assist practices by highlighting any missed or overdue follow up visits. Practice nurse training was modified to reduce the duration to 2 days to reduce the impact on individual clinic workforce. D_TECT identified co-morbid depression in 34% of patients with coronary heart disease or type 2 diabetes, or both. In TrueBlue the aim was to evaluate collaborative care compared with normal care in the subset of patients with co-morbid depression so patient recruitment required prior screening for depression. In

TrueBlue there was a need to understand how the collaborative care model changed the process and outcomes of care rather than just the feasibility of the intervention so the care plan template was designed to collect de-identified data. In D_TECT most practices claimed Medicare rebates for writing of GP Management Plans. To strengthen the business case for full implementation of collaborative care TrueBlue protocols were designed to meet Australian Medicare requirements for writing and review of GP Management Plans, Team Care Arrangements and GP Mental Care Plans. Feedback from D_TECT practice nurses suggested that patients and nurses found the 9-item PHQ9 depression screening tool was effective in opening a conversation about mental health and monitoring progress. The addition of HADS depression screening tool added little value while duplicating effort so this was omitted from the design of TrueBlue intervention.

In TrueBlue a cluster randomised design was chosen to avoid the need for practice nurses and doctors to treat individual patients in different ways. There was a high likelihood that GPs and nurses trained in TrueBlue intervention would apply this training to assist all patients with co-morbid depression so randomly allocating at the clinic level rather than individual patient level was the preferred design. The cluster randomised trial design is commonly chosen for investigating health care organisation interventions(192). We chose clinics rather than geographical regions to be clusters to ensure the trial was adequately powered. Our experience from the exploratory trial suggested there was unlikely to be significant contamination between intervention and control clinics because of the need to organise new appointment systems, nurse training and GP Management Plan template in order to implement collaborative care.

Practices needed external support to achieve this. An alternative design called a stepped-wedge trial is considered in the discussion section of this thesis.

The second paper describes the outcomes of TrueBlue collaborative care (the intervention) when compared in a randomised trial with usual care (the control) over six months. This paper then describes the outcomes for the intervention group after twelve months of TrueBlue collaborative care. Participating practices agreed to be randomised to intervention or control on the proviso that after six months control practices would receive training and support to initiate collaborative care.

The third paper explores the way practice nurses managed patients expressing suicidal thoughts and the extent to which the protocol led to stepped-care for depression. Qualitative analysis of interviews with practice nurses and GPs is reported here to assess acceptability of TrueBlue.

The fourth paper describes the care plan used in TrueBlue and outlines the multiple functions of the care plan.

4.1 TrueBlue Study protocol (reproduced verbatim)

Citation (189):

Mark Morgan, James Dunbar, Prasuna Reddy, Michael Coates and Robert Leahy. The TrueBlue study: Is practice nurse-led collaborative care effective in the management of depression for patients with heart disease or diabetes? *BMC Family Practice* (2009) **10**:46.

Abstract

Background

In the presence of type 2 diabetes (T2DM) or coronary heart disease (CHD), depression is under diagnosed and under treated despite being associated with worse clinical outcomes. Our earlier pilot study demonstrated that it was feasible, acceptable and affordable for practice nurses to extend their role to include screening for and monitoring of depression alongside biological and lifestyle risk factors. The current study will compare the clinical outcomes of our model of practice nurse-led collaborative care with usual care for patients with depression and T2DM or CHD.

Methods

This is a cluster-randomised intervention trial. Eighteen general practices from regional and metropolitan areas agreed to join this study, and were allocated randomly to an intervention or control group. We aimed to recruit 50 patients with co-morbid depression and diabetes or heart disease from each of these practices. In the intervention group, practice nurses (PNs) will be trained for their enhanced roles in this nurse-led collaborative care study. Patients will be invited to attend a practice nurse consultation every 3 months prior to seeing their usual general practitioner. The PN will assess psychological, physiological and lifestyle parameters then work with the patient to set management goals. The outcome of this assessment will form the basis of a GP Management Plan document. In the control group, the patients will continue to receive their usual care for the first six months of the study before the PNs undergo the training and switch to the intervention protocol. The primary clinical outcome will be a

reduction in the depression score. The study will also measure the impact on physiological measures, quality of life and on patient attitude to health care delivered by practice nurses.

Conclusion

The strength of this programme is that it provides a sustainable model of chronic disease management with monitoring and self-management assistance for physiological, lifestyle and psychological risk factors for high-risk patients with co-morbid depression, diabetes or heart disease. The study will demonstrate whether nurse-led collaborative care achieves better outcomes than usual care.

Background

Coronary heart disease (CHD) and type 2 diabetes mellitus (T2DM) are both major causes of disability. The incidence of T2DM is now reaching epidemic proportions in Australia (193) and overseas (194), particularly as the population ages and becomes more obese (195). Within 20 years diabetes will become the leading contributor to the over-all burden of disease in Australia (196) with Australian health care expenditure projected to increase to $7 billion by 2023 (197). CHD already affects over 300,000 people in Australia and remains the most common cause of death (198). Both diabetes and heart disease are associated with a number of serious complications, each with its own cost.

There is evidence that the presence of depression in patients with CHD or T2DM leads to increased morbidity and mortality (187, 199), but co-morbid depression is often missed in routine consultations within general practices (188). One

difficulty is that the traditional model used by general practices is one in which visits to the general practitioner (GP) are initiated by patients when they feel that their needs warrant a consultation. Such visits are usually episodic and cease when the immediate symptoms are relieved. Consequently, such patients miss out on regular monitoring of their chronic disease so that risk factors go unrecognised (188).

A collaborative model is one in which the care delivery has multiple components that address these problems (78) and has been shown to have good results in treating depression (174). It relies on a case manager to coordinate that care. Hickie and McGorry summarise the planned episodes of care that include (200):

- Use of evidence based guidelines;
- Systematic screening and monitoring of risk factors;
- Timetabled recall visits;
- New or adjusted roles for team members;
- Information support for the clinician;
- Enhanced patient self-management;
- Identified case manager to coordinate care;
- A means of effective communication between all members of the care team; and
- Audit information for the practice.

The True Blue study described in this paper extends an exploratory trial to adapt the successful IMPACT model of collaborative care for depression in the USA (78) to an Australian primary health care setting. The case manager in this study

is the practice nurse (PN). The model of practice nurse-led collaborative care was demonstrated in six general practices in rural southern Australia, with 332 patients recruited (201). In this exploratory trial a practice nurse training programme was developed for chronic disease management, introducing depression screening and counselling techniques to assist with self-management. Electronically based multi-purpose tools were designed and tested to allow outcome data to be collected to inform coordinated medical care and patient self-management. The trial found depression in 34% of patients with CHD or T2DM, and demonstrated that the practice nurse-led, collaborative care model was both feasible and acceptable.

The role of practice nurses in collaborative care of chronic disease is being investigated both in Australia and overseas (202-204). The features of the True Blue study are that the programme…

- Routinely screens for depression;
- Monitors depression severity over time for participating patients;
- Uses the existing work force and funding arrangements to potentially make the model more widely applicable;
- Uses consultations with practice nurses that allow collection of physiological measurements, monitoring of lifestyle and mental health risks and setting of patient goals; and
- Is linked with appointments to the patient's usual general practitioner (GP).

The present study works with this subset of patients who have co-morbid depression and aims to demonstrate improved clinical outcomes for this higher-risk group through measurements of physiological, mental health and lifestyle parameters at regular intervals throughout the study period. It will further test and implement this collaborative care model that is focussed on the patient. An important aspect is that patients, in collaboration with the practice nurse, will develop up to three goals that they feel will be able to help reduce their risk factors, thus making patients active participants in their own health care.
The model is also intended to demonstrate how the care of co-morbid depression, heart disease and diabetes can be funded successfully using Australian Medicare Benefits Schedule (MBS) Item numbers. It will develop training programmes for PNs in screening, assessment and management of patients with co-morbid depression and heart disease or diabetes, and evaluate the feasibility of PNs to carry out screening and assessment.

Objectives of this study

The primary objective of this study is to determine whether practice nurse-led collaborative care is better than the usual method of GP-led episodic care for the management of co-morbid depression in patients with heart disease or diabetes by testing whether there is an improvement in the depression score at the end of the study. The goal is to achieve a 50% reduction in that score. It will also test whether it is a practical way to manage this complex and increasing chronic-disease burden. It will introduce an hour-long consultation with the practice nurse in which patient goal setting forms an important proactive part of the

patient care. One key strategy is that the patient outcomes will be reviewed every three months over an entire year and patient goals altered accordingly.

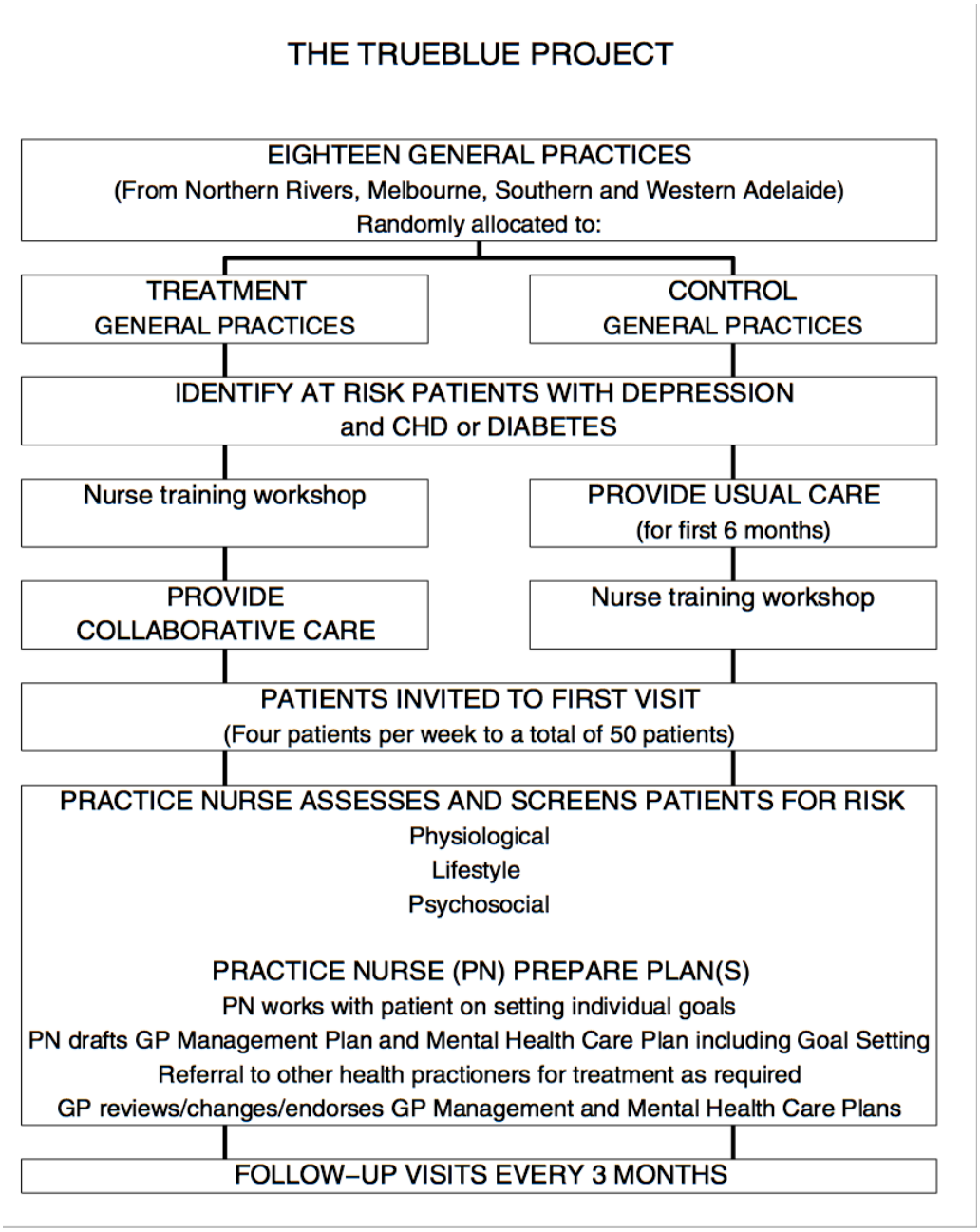
Other objectives are to demonstrate that the model of care can use existing clinical staff and be funded within current Medicare arrangements, and that it can be used in large and small practices across rural and urban settings.

Methods/design

This study is a cluster-randomised intervention trial in which general practices were allocated either to an intervention group in which nurse-led collaborative care is to be undertaken or to the control group in which usual GP- led care is to be continued.

Ethics approval for the project was obtained from Flinders University Social and Behavioural Research Ethics Committee, approval number 4164.

(Figure 6) Flowchart of the TrueBlue study



Survey forms

Patient Health Questionnaire (PHQ9)

The PHQ9 questionnaire will be used to measure and monitor depression over time. It is self-administered, suit- able for face-to-face and postal responses and for research. Its brevity and reliability as a valid measure of depression severity make it a useful clinical and research tool (54). The form has nine questions that are simply scored from 0 (no problems) to 3 (problems nearly every day). Each of these items assesses various physiological and mood indicators of depression, and are combined to form the total PHQ9 score. Scores 5–9 indicate mild depression, 10–14 moderate depression, 15–19 moderately severe, and scores above 19 indicate severe depression.

SF36 (Version 2)

Health and lifestyle will be measured using version 2 of the SF-36 questionnaire. This questionnaire is a multipurpose, short-form health survey that provides a profile of health and wellbeing as well as a psychometrically-based physical and mental health summary measures and a preference-based health utility index (205). This questionnaire provides a suite of generic measures rather than specific ones, but has proven to be useful in surveys of general and specific populations in differentiating the health benefits produced by a wide range of different treatments.

The GP Management Plan (GPMP)

Critical to collaborative care in chronic-disease management is a system that ensures the coordination of care between the GP and other health-care providers and assists patient self-management. This document, the GP management plan (GPMP), was developed by the GGT UDRH in collaboration with each of the practices in the programme. The design of this multi-purpose document enables it to serve the following functions, within the limits of current electronic medical-record applications, with minimum data entry:

- Provide a single template covering T2DM and CHD diagnoses;
- List patient medical history;
- List medication used, including prescribed medication, aspirin and antidepressant use;
- Record physiological risk factors, including blood pressure, weight, height, body-mass index (BMI), waist circumference, micro albuminuria, lipid profile and, for diabetic patients, HbA1c;
- Record lifestyle risks, including smoking, alcohol consumption and exercise regime;
- Record the psychosocial risks and PHQ9 depression scores, including referrals to and consultations with a mental health worker;
- Checklist of preventative activities and targets recommended in National Heart Foundation and Diabetes Australia guidelines;
- Individual patient goals, targets and agenda for future consultations;
- List referrals to specialists, allied health and community resources;
- Timetabled recall;

- Help practices complete the requirements to claim Medicare rebates for care planning and diabetes cycle of care; and
- Automatically generate de-identified data for research and audit.

The GPMP includes an office-use summary table containing only data that are relevant to the research. These data are identified only by a unique patient ID number assigned by the patient's practice. No personal details are forwarded to the research team. The patient information in the GPMP office-use summary is listed in the Appendix.

Sample size

Nine intervention and nine control practices, each with 50 patients, will be required to detect a minimum 2-point reduction in the PHQ9 score at the 0.05 significance level with 80% power. These patient and practice numbers were determined assuming a change in PHQ9 with standard deviation of 5.1 as observed in the pilot study (201), a drop-out of no more than 33%, and an intra-cluster correlation of 0.04. Note that detecting a 2-point reduction in the overall PHQ9 score is a more-stringent requirement than this project's objective of achieving a 50% reduction in that score.

Practice recruitment

Practices from three regions (Adelaide, inner Melbourne and the NSW Northern Rivers area) were selected to undertake the study. Practices were selected from

these regions using a range of criteria, including size and capacity, and assessable electronic medial records capable of generating an electronic registry of patients with CHD or T2DM. Practices also needed to have a PN available to lead the collaborative care.

Information about the study was circulated to these practices to explain the benefits of the True Blue project to their GPs, PNs and practice managers. These were followed up with orientation evenings that provided further detail. GPs who were interested in the project and who were able to guarantee protected time for their PN(s) to undertake the collaborative care were invited to join and their clinics included in the project, until six practices from each of the three regions had been selected.

Randomisation

Nine practices were randomly allocated to the intervention group in which nurse-led collaborative care will be undertaken. The remaining nine practices were allocated to the control group in which the usual GP-led care will continue for a period of six months. At the end of this period, the control practices will be invited to implement the practice nurse-led model of collaborative care and to send practice nurses to a training workshop (see below).

Patient recruitment

Within each general practice, a mailing list of patients with a diagnosis of CHD or T2DM is generated. Patients who are either under 18 years of age or in residential care are excluded from the study. Eligible patients are added to the master list as potential participants in the programme and assigned a unique identification (ID) number. All documentation or data forwarded to the researchers for the patient is identified only by this unique ID number. Personal details of patients, including names and addresses, are retained by the clinic concerned.

An information package is posted from the practice to each of these patients. It includes a standardised personal letter from their GP explaining the study, information brochures, a PHQ9 questionnaire, and a consent form indicating the patient's willingness to participate in the programme. Each patient is asked to complete and return the PHQ9 and consent forms. The returned PHQ9 questionnaire from consenting patients is examined to identify PHQ9 scores above 5, indicating presence of at least mild depression. These patients are invited to join the study. Patients who do not respond to the first mail-out are sent a reminder letter approximately two weeks later inviting them to participate, with further reminder letters, telephone calls and personal invitations when visiting clinics, until 50 patients have been recruited.

Inclusion and exclusion criteria

Practices with an electronic medical records system capable of generating an electronic registry of patients with CHD or T2DM and with a PN available to lead

the collaborative care are eligible to participate. Patients with either T2DM or CHD are eligible to participate, provided that they were over 18 years of age and are not in residential care.

Practice nurse training workshop

A two-day training workshop was organised for the PNs from the intervention practices to prepare them for enhanced roles in nurse-led collaborative care. This workshop introduced the rationale of the collaborative care model before presenting a range of topics to prepare PNs for their additional roles. Topics presented in the work- shop include:

• Screening for depression;

• Identification and measurement of physiological risk factors such as high cholesterol, blood pressure, blood glucose and central obesity;

• Lifestyle risk factors such as smoking, poor nutrition, alcohol and physical inactivity;

• Training to educate patients in diabetes and heart disease risk reduction;

• Training in assisting patients with goal setting and problem solving;

• Coordinating referrals and timetabled follow up; and

• Preparing the draft GP Management Plan.

Intervention programme

Each patient's session with the PN is scheduled to take approximately one hour. During their initial (baseline) session, each patient completes the SF36v2

questionnaire and a new PHQ9 questionnaire if the earlier one is more than two weeks old. Their current medication list is also updated to include over-the-counter products. The PN assesses the patient, beginning by measuring their physiological parameters, reviews the potential risk factors (biological, lifestyle, psychological) and develops up to three lifestyle goals with the patient that he/she feels are achievable in reducing his/her risk factors. The SNAP (Smoking, Nutrition, Alcohol, Physical exercise) assessment, for example, can be a useful guide (206).

The PN and patient identify possible barriers to achieving these goals and discuss enabling methods that may overcome these barriers. The PN may also suggest other professional services that may assist the patient in improving his/her outcomes, such as a dietician or counsellor. The PN may also supply educational material to assist patients in understanding their condition and meeting their goals. The PN completes the consultation by setting the review appointment date, and identifying any future tests that may be required beforehand.

Patients responding positively to the ninth question on the PHQ9, which assesses suicidal ideation, are immediately referred to their GP. The practice nurse consultation is scheduled to take about 45 minutes to complete. The remaining 15 minutes is set aside to add these data to the GP management plan (GPMP) before this is forwarded to the GP. The draft GPMP document becomes a readily accessible information support document for medication changes and referrals.

The GP completes the plan during the consultation with the patient, providing the patient with a copy of the completed GPMP document.

An important aspect of this collaborative care programme is that patients are recalled systematically to monitor the progress of their care. Another important aim is that the nurse-led care can be completely self-funded using the normal Medicare item numbers. Consequently, a thirteen-week interval was chosen as the recall period. The recall visits are booked at the time of the previous visit.

During each review, patients will complete a new PHQ9 questionnaire so that any changes to their mental health can be monitored. Additional therapies or new strategies can be considered during the consultations if the PHQ9 score has not improved by at least 50% or dropped below 5. These strategies may include changing or adding medication or referral to a mental health professional. The PN and patient then re-evaluate the goals from the previous consultation. In the second (6-month) and fourth (12- month) consultations, the patient will complete a new SF36v2 form to assess changes in quality of life.

Results

Data collection, verification and analysis

The research team includes a practice facilitator in each region to offer support to practice nurses and to monitor progress of the research programme. Monthly teleconference meetings are held to identify common issues and problems so that these can be addressed in a timely manner.

Data collection begins in the practice with the PNs entering patient data into their respective practice electronic databases, and then using these data to generate the GPMP for each patient. The GPMP includes a de-referenced, office-use-only summary table, shown in the Appendix, with the data that are relevant to the research. The PN copies the de-identified summary table from the practice database into a data-validation spreadsheet supplied by the GGT UDRH. The spreadsheet checks the GPMP summary table for completeness, consistency and accuracy. It highlights missing data and data that lie outside expected ranges that may be a result of typographical errors. These provide a warning to allow the PNs to recheck the data. Once verified, the PN forwards the validated GPMP summary data to the research team at GGT UDRH, where a final check is performed before their data are added to the master database.

Independent groups t-tests and $\chi 2$ tests will be used with baseline measures to check intervention and control for any imbalance. Clinical measures and changes (between baseline and follow-up) in outcomes of participants will be compared with measurements of controls. The difference in the change in the continuous outcome measures (particularly the PHQ9 score) between the two studied groups will be analysed using linear mixed models, treating "group" as a between-subject factor and "time" as a within-subject factor. Categorical outcome variables will be analysed using generalised estimating equations (GEE), following the same approach. The intention-to- treat principle will be adhered to, and sensitivity analysis will also be carried out. Regression analysis,

including logistic regression, will be used to identify baseline variables that predict successful outcomes and adherence.

Acceptability interviews

On completion of the programme, a series of structured interviews with PNs and GPs will be undertaken to discuss the nurse-led collaborative care model and its perceived strengths, weaknesses and barriers. We will examine how the role of the PN is changed, concentrating on confidence and expertise in leading the new model of care. We will examine how the GPs have or have not accepted the model of care and determine any problems and issues that may have arisen in implementing the model.

We will also undertake interviews with a randomly selected list of patients. These interviews will be conducted by telephone to preserve patient anonymity. We will discuss the perceived strengths and weaknesses of the collaborative care model from the patient's point of view, and examine barriers and enablers to the model.

Discussion

The strength of this programme is that it provides a full package of chronic disease management techniques, based on Wagner's chronic disease management (CDM) model (1). The programme involves reading the practice electronic medical record to generate a master list of patients who satisfy the

prescribed selection criteria. These patients are invited to begin the collaborative care process, and are systematically recalled at the prescribed review period. The collaborative care process is audited using patient feedback. Medicare funding will mean practices are remunerated for the more intense patient intervention.

The programme uses the existing workforce but involves an enhanced role for the practice nurses and so is applicable for wider roll out in using this potentially under-utilised resource. The practice nurses gain enhanced skills in the CDM set up and management that will be a useful model for patients with other chronic diseases.

A full range of outcome measures is reported and added to the electronic database. Consequently, practices will know what happens to patients (process of care) and will be able to identify changes in classic risk factors, depression symptoms and affordability within the Australian health system.

We note that practices need to be large enough to have available a practice nurse to participate in the programme. This study is only funded for 15 months of data collection but early feedback from participating practices indicates they are likely to choose to continue this nurse-led collaborative model of care beyond the lifetime of the research.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

MM designed and will implement the project. JD and PR conceived the research idea and provide strategic direction. MC manages data collection and the master database. BL manages the project, overseeing the model at each practice. All authors have read and approved the final manuscript.

Appendix

The patient information provided in the GP Management Plan office-use summary section is shown below.

Patient's True Blue Record Number

GPMP or REVIEW

Diagnosis (CHD/T2DM/Both)

Date of birth

Gender

Ethnicity (ATSI) status

Patient speaks language other than English at home Date of this service

Date of previous GP Management Plan (if prepared)

Date of last GP Mental Health Care Plan (if done)

SF36v2 completed

Smoking

Alcohol consumption

Current weight

Height

BMI

Current BP

Current waist circumference

Patient exercises 30 minutes per day, 5 days per week?

Total Cholesterol

Triglycerides

LDL

HDL

Previous episode of depression or anxiety?

Type of current treatment

Currently taking antidepressant medication?

Referred to Mental Health Worker?

Currently seeing Mental Health Worker?

Has the patient been referred to an exercise program?

Is the patient attending an exercise program?

PHQ9 total score

PHQ9 difficulty score

Proposed review date

Aspirin use

Goal 1 for the next three months

Goal 2 for the next three months

Goal 3 for the next three months

Previous goal 1 (Met/Partially met/Re-negotiated)

Previous goal 2 (Met/Partially met/Re-negotiated)

Previous goal 3 (Met/Partially met/Re-negotiated)

T2DM only

HbA1c

Micro albuminuria results (normal/raised)

Month of last professional eye exam

Date of last recorded foot check

Acknowledgements

The study is funded by *beyondblue*, the National Depression Initiative. The authors wish to thank all patients, General Practitioners, and Practice Nurses who have or will have participated in this programme.

4.2 TrueBlue Outcomes (reproduced verbatim)

Citation (207):

Mark A J Morgan[1], Michael J Coates[1], James A Dunbar[1], Prasuna Reddy[2], Kate Schlicht[1], Jeff Fuller[3]. The TrueBlue model of collaborative care using practice nurses as case managers for depression alongside diabetes or heart disease: a randomised trial. *BMJ Open* 2013;**3.**

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Article summary

Article focus

▪ To determine the effectiveness of a collaborative care model to reduce depression in primary care patients with diabetes or heart disease.

▪ To determine the effectiveness of using practice nurses as case managers of patients with depression and diabetes, heart disease or both.

Key messages

▪ The TrueBlue model of collaborative care can be introduced within the general practice workforce with practice nurses taking on the role of case manager.

▪ Practice nurses can improve the care of depression in patients with diabetes or heart disease, leading to better outcomes and reduced 10-year cardiovascular disease risk.

▪ The care of patients using the TrueBlue model is closer to 'best practice' guidelines, with substantially better levels of adherence to guideline-recommended checks than those occurring in usual care.

Strengths and limitations of this study

▪ The TrueBlue model of collaborative care overcomes many of the difficulties in implementing a guideline for the treatment of comorbid depression.

▪ The study's purpose-designed care plan gives patients and their carers, allied health professionals, specialists and general practitioners ready access to patient details, enabling them to see at a glance where improved clinical care may be needed.

▪ Clinics were able to recover the costs of the collaborative care through Australian Medicare rebates.

▪ The study could only be run in practices that had a practice nurse on staff to carry out the intervention and had access to clinical software capable of generating a disease registry from which patients could be selected to participate in the trial.

▪ Differences between TrueBlue-practice and control-practice outcomes may have been reduced by patients completing the nine-item Patient Health Questionnaire (PHQ9) depression questionnaire and reading the project description, and by general practitioners being made aware of individual PHQ9 results so that they could take action where warranted.

Abstract

Objectives: To determine the effectiveness of collaborative care in reducing depression in primary care patients with diabetes or heart disease using practice nurses as case managers.

Design: A two-arm open randomised cluster trial for 6 months. The intervention was followed over 12 months.

Setting: Eleven Australian general practices, five randomly allocated to the intervention and six to the control.

Participants: 400 primary care patients (206 intervention, 194 control) with depression and type 2 diabetes, coronary heart disease or both. Intervention: The practice nurse acted as a case manager identifying depression, reviewing pathology results, lifestyle risk factors and patient goals and priorities. Usual care continued in the controls.

Main outcome measure: A reduction in depression scores for patients with moderate-to-severe depression. Secondary outcome was improvements in physiological measures.

Results: Mean depression scores after 6 months of intervention for patients with moderate-to-severe depression decreased by 5.7±1.3 compared with 4.3±1.2 in control, a significant (p=0.012) difference. (The plus–minus is the 95% confidence range.) Intervention practices demonstrated adherence to treatment guidelines and intensification of treatment for depression, where exercise increased by 19%, referrals to exercise programmes by 16%, referrals to mental health workers (MHWs) by 7% and visits to MHWs by 17%. Control-practice exercise did not change, whereas referrals to exercise programmes dropped by 5% and visits to MHWs by 3%. Only referrals to MHW increased by 12%.

Intervention improvements were sustained over 12 months, with a significant (p=0.015) decrease in 10-year cardiovascular disease risk from 27.4±3.4% to 24.8±3.8%. A review of patients indicated that the study's safety protocols were followed.

Conclusions: TrueBlue participants showed significantly improved depression and treatment intensification, sustained over 12 months of intervention and reduced 10-year cardiovascular disease risk. Collaborative care using practice nurses appears to be an effective primary care intervention.

Trial registration: ACTRN12609000333213 (Australia and New Zealand Clinical Trials Registry).

Introduction

Management of diabetes and heart disease has been highlighted as one of the global 'grand challenges in chronic non- communicable diseases' (208) because the prevalence of these two preventable diseases is increasing (209). Along with depression, they have been identified as health priority areas in many countries. A vicious cycle exists between depression and these chronic diseases, with each being a risk factor for the other (43). Higher mortality has been demonstrated for people with depression and type 2 diabetes (T2DM) or coronary heart disease (CHD) beyond that due to the separate diseases alone (210). For patients with depression and T2DM or CHD or both, there are increased risks of adverse outcomes (211), but this comorbid depression is often missed in primary care (212). Consequently, the identification of depression has now been incorporated

into many heart disease guidelines as one of the requirements for optimal management. Meeting these challenges will require an innovative use of the existing general practice workforce, and such a reorientation of resources has been identified as one of the grand challenges (208).

Collaborative care is a system that has been shown to be more effective for chronic disease management than standard care (213). It includes a reorientation of the medical workforce through new or adjusted roles for team members, particularly using practice nurses (PNs) as the identified case manager to undertake the care of the patients (191, 200). It also includes the use of evidence-based guidelines, systematic screening and monitoring of risk factors, timetabled recall visits, information support for the clinician, enhanced patient self-management, a means of effective communication between all members of the care team and audit information for the practice. Since self-care for diabetes has been found to be suboptimal across a range of self-managed activities, particularly for patients with depression, a collaborative care model may be able to achieve better quality of care through the case manager monitoring patient progress (45, 214).

Evaluation of a change in the way general practice clinics look after patients requires complex intervention methodology (215) beyond single interventions such as the introduction of a guideline with financial incentives (216).

This methodology began with a search for potential models of care (step I), and led to adopting the University of Washington's successful IMPACT model of

Collaborative Care for depression (6, 217). In the exploratory trial (step II), our pilot project (186) adapted IMPACT by training PNs as case managers. PNs were trained to screen for depression using a patient self-report measure, the nine-item Patient Health Questionnaire (PHQ9) (54), as part of comprehensive chronic disease management. They were also trained to use a protocol for care management based on the depression scores. The depression screening and management were embedded in routine visits for patients with diabetes or CHD. The pilot demonstrated that it was feasible to detect, monitor and treat depression in routine general practice alongside the usual biophysical measures, and identified moderate-to- severe depression in 34% of participants. The TrueBlue study was a randomised cluster trial (step III) that built on and extended the pilot. It investigated whether a collaborative care model (the intervention) is better than usual care (the control) for the management of patients with depression and T2DM, CHD or both in Australian general practice. It was designed to fit into normal clinic operations, making use of practice nurses and medical software, and was able to be funded by existing Australian Medicare rebates.

Methods

Study design

The design and methodology of the study have been described in detail elsewhere (189). The study started in 2009 and was undertaken in two phases. The first phase was a cluster randomised intervention trial in which general

practices were randomly allocated to either an intervention group, in which nurse-led collaborative care was undertaken, or to a wait-list control group in which usual care led by the general practitioner (GP) was continued. At 6 months, the TrueBlue training was provided to the control practices. The key aims of the first phase were to determine whether participants with moderate-to-severe depression in the intervention group showed at least a five-point reduction from the baseline depression scores after 6 months of intervention and whether this reduction was significantly better than in the control group. A five-point reduction reflects a clinically relevant change in individuals receiving depression treatment (218). The secondary outcome was to determine whether the intervention also led to improvements in the patients' physiological measures. The second phase followed the intervention group for an additional 6 months to determine how the collaborative care model affected health outcomes over a 12-month period.

Sample size

The sample size calculation was based on detecting a 50% reduction in depression score at the 0.05 significance level with 80% power and a two-tailed test. Detecting a 50% reduction is more stringent than detecting a five-point reduction and provided some additional buffering. Using depression scores from an earlier study (a mean of 5.5 and an SD of 6.1) (214), the calculation indicated that 237 patients would be required in each group. An intra-cluster correlation of 0.04 was used (SK Lo, personal communication), with a recruitment target of 50 patients per clinic. (Fifty patients were chosen so that clinics could budget for

a nurse's time to carry out the intervention with four patients each week over the 3-month cycle of care.) To allow for difficulties in recruitment, a 50% dropout was used. On the basis of these, the study required 450 patients from nine clinics in the intervention group and the same in the control group.

Practice recruitment

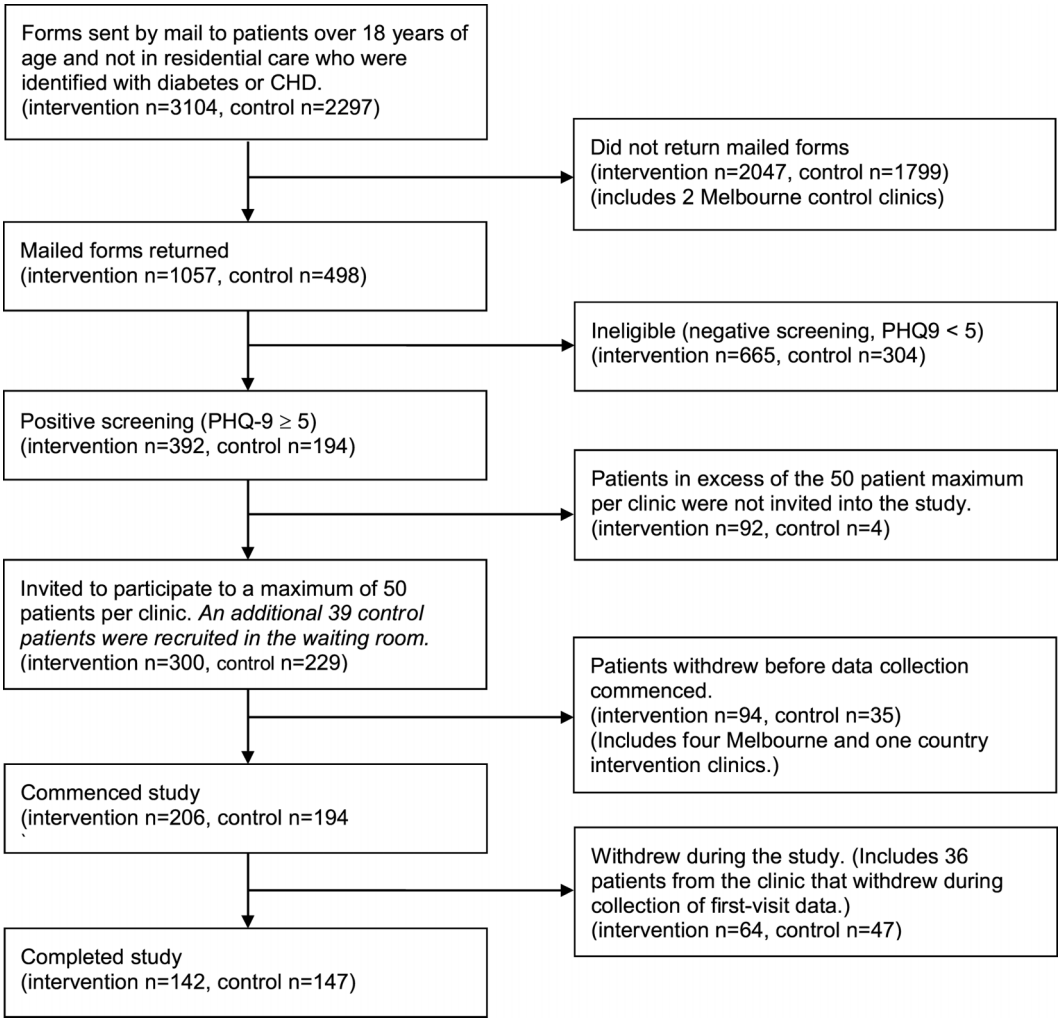
Practices were identified in city and country areas on the basis of having a PN to provide the collaborative care and being able to identify eligible patients, those with CHD or T2DM or both, from their registries; these were invited to participate in the study until the 18 clinics required by the sample-size calculation were recruited. They were allocated by a random number generator to either the intervention or control arm of the study. The unit of randomisation was the clinic. Five practices (three country, two city) in the intervention group and six (two country, four city) in the control group completed the study. One country intervention clinic withdrew while the first-visit data were being collected when its TrueBlue-trained PN left the clinic, but some (n=13) patients from it did complete the study and data were collected from them. The study team was not able to determine why the other clinics withdrew.

Patient selection

Eligible patients were sent a postal survey that included a consent form which they were asked to complete and return with the enclosed PHQ9 questionnaire, a self- report measure of depression (54). The PHQ9 has nine items, each scored

from 0 (no problems) to 3 (problems nearly every day). The sum of the scores of the nine items will lie in one of five depression categories: none (0–4), mild (5–9), moderate (10–14), moderately severe (15–19) and severe (20–27). (While it is known that responses to some of the PHQ9 items may overlap with diabetes symptoms (58), our pilot demonstrated that nurses and patients preferred using the PHQ9 because the patient's response to each of its items became the basis for the problem solving and goal setting activities that were part of TrueBlue.) Patients with scores of 5 or above, indicating some form of depression, were invited to participate in the study. A maximum of 50 patients per practice were invited. Patients in residential care or under 18 years of age were not eligible. Figure 7 presents the CONSORT diagram of the patient-recruitment process.

(Figure 7) CONSORT flow diagram of the recruitment process.



Patient safety

Participation in the intervention included a series of patient visits to their PN and usual GP every 3 months over a 12-month period. Patients in the control group continued with their 'usual care'. The control clinics were also provided with the PHQ9 depression scores to ensure patient safety during the trial. The

protocol required that PNs take action if severe depression was recorded in the returned PHQ9 or if the patient had responded to the suicidal-ideation question (question 9) on the questionnaire. This action was to be taken irrespective of whether the clinic was in the intervention or the control group.

PN training

The PN training included a 2-day workshop to prepare them for their enhanced roles in nurse led collaborative care. Topics in the workshop included identifying and monitoring depression using the PHQ9 questionnaire, and quality of life responses using V.2 of the SF36 questionnaire (219). Patient goal setting and problem solving were key components of the training with a particular emphasis on behavioural techniques to achieve improved mental health (220). The training also prepared the PNs for their role as case managers including ensuring that the Diabetes Australia and Australian National Heart Foundation guidelines were being followed and referrals were provided to appropriate services, such as allied health and mental health professionals, through discussion with the GPs.

Data collection

The research team developed a protocol-driven care plan template from which study data could be extracted automatically and sent to the research team. The template was designed to be a multipurpose document in which the patient's medical history, current medications, allergies, biophysical and psychosocial measures, lifestyle risks, personal goals and referrals were recorded. It was

designed to comply with the requirements to claim Australian Medicare rebates for care planning and to provide a checklist for 'gold standard' care. A copy of the care plan was provided to the patient as a written record of their progress.

The care plan template collected physical measures, including body mass index, waist circumference, weight and blood pressure and the latest pathology results, including lipid profile, glycaemic control (glycosylated haemoglobin, HbA1c) and renal function. Data also included lifestyle risk factors, such as smoking, alcohol consumption and level of physical activity, and depression score as measured by the PHQ9 questionnaire. Referrals to and attendance at exercise programmes and with mental health workers were also recorded, along with the patient's own goals and possible barriers to achieving these goals. The care plan template was used by the intervention-group clinics to acquire patient data at three monthly intervals over a 12-month period.

In the control group, the only complete dataset recorded using our comprehensive protocol-driven care plan template was obtained after the 6 months of 'usual care' when the TrueBlue training was offered to the control clinics. No baseline or 3-month datasets were acquired since the study was deliberately designed to avoid changing the 'usual care' that would have otherwise occurred by introducing our care plan template. The study was designed in this way to be run pragmatically in the context of the clinics' normal activities. The only baseline measure obtained was the depression score. On completion of the study, we retrospectively collected all the baseline data that

the control clinics routinely recorded in their electronic medical records in order to have data for two time points, baseline and 6 months.

Trueblue collaborative care

As part of the TrueBlue model, patients were scheduled to visit the practice every 3 months for a 45 min nurse consult followed by a 15 min consult with their usual GP, in which stepped care (psychotherapy or pharmacotherapy) was offered if depression scores had not improved or had not dropped below a value of 5. The PN used the care plan template and obtained current physical measures and reviewed recent pathology results. PNs also reviewed lifestyle risk factors. They readministered the PHQ9 and worked with the patient to identify possible barriers to achieving their goals and discussed ways to overcome the barriers. This information gathering phase of the consultation was an opportunity to assist the patient with self-management by discussing the available educational resources, such as the library of fact sheets on aspects of self-management of depression, and setting personal goals for review at the next 3-monthly visit.

Statistical analysis

Participants in this study were clustered under clinics by design. It is known that clinics are likely to be different from each other and that ignoring the nested nature of the data may lead to biased estimates of parameter SEs. However, statistical techniques for correcting for the effects of clustering tend to be overly severe and conservative (221) when a small number of higher level

units (clusters) are used, and therefore we tested whether the clinics were in fact significantly different from each other. Analysis of covariances (ANCOVAs) (222, 223) were used to adjust for baseline values and to test the significance of changes in depression scores between clinics after 6 months, using STATA V.11.1 for the statistical analyses.

Of the five clinics in the intervention (clinics 4, 5, 13, 15 and 17), only clinics 4 and 17 were significantly different from each other ($F(1,76)=9.6$, $p<0.001$). No other comparisons were significant between intervention clinics. Of the six clinics in the control group (clinics 1– 3, 6, 16 and 18), only clinics 6 and 18 were significantly different from each other ($F(1,78)=14.5$, $p<0.001$). No other comparisons were significant between control clinics. Furthermore, the intra-correlation coefficient of 0.058 for the primary outcome suggests that only 6% of the variance could be attributed to the clinic's level. Given this lack of difference between the clinics in each arm coupled with the sample-size requirements for reliable multilevel modelling (224), we analysed our data at the patient level.

In order to compare the effectiveness of the TrueBlue care model to the usual care control, ANCOVAs were used to adjust for baseline values and test the significance of changes in continuous variables between the two groups after 6 months. A multilevel mixed-effects logistic regression (STATA's xtmelogit) was used to test the significance of changes in the binary (categorical) variables between the two groups after 6 months, with time and group as the independent variables and with random effects at the patient level. (We used the mixed-effects logistic-regression model since the pairs of observations over time are

not independent, i.e., observations at 6 months would be expected to be related to the initial baseline observations.) Within each group, changes between the two time points (baseline and 6-month visits) were tested using paired t tests for the continuous variables and matched-case–control McNemar $\chi 2$ tests for the binary variables.

The longer-term effects of the intervention were evaluated over the 12-month period using multilevel mixed-effects linear regression (STATA's xtmixed) for the continuous variables and multilevel mixed-effects logistic regression (xtmelogit) for the binary variables. All the 3-monthly data available in the intervention group over the 12 months were used. Note that the study design could not collect such 'usual care' data from the control clinics since the data collection protocol was part of the intervention. In addition, TrueBlue training was provided to these clinics at 6 months after which they ceased to be a control.

Patients from the clinics who withdrew before or during collection of first-visit data were excluded from the analyses. (Data for the 13 patients from one of these clinics who did complete the study have been included.) Characteristics from available clinics were compared between early dropouts and participating clinics and addressed in terms of their possible impact on the generalizability of the results. Missing 6-month data were replaced with their baseline values using the 'no change' formulation of intention-to-treat by assuming that no change occurred between baseline and 6 months. The underlying assumptions of the statistical tests used were assessed.

Results

Demographics

A total of 5401 invitations (3104 interventions and 2297 controls; see figure 1) were posted to patients with either T2DM or CHD (or both) identified in the clinics' registers. Approximately 30% (1057 interventions and 537 controls, including 39 additional patients invited in the waiting room) of the invitations were returned with completed consent forms and PHQ9 questionnaires. This proportion is typical in studies of this type reported in the literature. Of these, 34% (300 interventions and 229 controls) were eligible (a depression score or 5 or more) and were invited to participate. However, 25% of these (94 interventions and 36 controls) did not start when their clinics withdrew before data collection began.

Of the 206 patients in the intervention who started the study (figure 7), 17% (n=36) were forced to leave when their clinics withdrew the study. A further 14% (n=28) of patients withdrew as the study progressed, with 4% leaving after 6 months, 5% after 9 months and 5% after the full year. Reasons included leaving the area, going into residential care or becoming too ill to continue, but no consistent pattern could be identified. (The exact numbers for each reason are not known.) In the control group, 24% (n=47) of the 194 patients who agreed to participate had forgotten about the study by the time the 6-month review was to be undertaken and did not want to proceed.

Table 2 presents the characteristics of the patients in both the intervention and control groups who started the study. It shows that these characteristics were similar across both groups. There were no significant differences in patient characteristics between the intervention and control at baseline.

Table 3. Patient characteristics at the baseline visits

Characteristics	**Intervention group (n=170)**	**Control Group (n=147)**
Male(%)/female (%)	51.8%/48.2%	55.2%/44.8%
Age (year)	68.0 ±11.7	67.6 ±11.2
Aboriginal or Torres Strait Islander (%)	0.0%	0.7%
Diagnosis Type 2 Diabetes CHD Both	 37.6% 45.3% 17.1%	 47.6% 35.8% 16.6%
Body mass index (kg/m^2)	31.4 ± 6.0 (n=170)	30.8 ± 6.0 (n=103)
Systolic blood pressure (mmHg)	134.1 ± 19.0 (n=169)	133.5 ± 19.6 (n=112)
Total cholesterol (mmol/l)	4.21 ± 0.94 (n=165)	4.41 ± 1.06 (n=110)
Triglycerides (mmol/l)	1.73 ± 0.88 (n=165)	1.92 ± 1.37 (n=105)
LDL (mmol/l)	2.22 ± 0.74 (n=159)	2.37 ± 0.88 (n=89)
HDL (mmol/l)	1.23 ± 0.36 (n=159)	1.18 ± 0.33 (n=97)
HbA1c (%)	7.00 ± 1.21 (n=94)	7.19 ± 1.42 (n=69)
PHQ9 score	10.7 ± 4.7 (n=164)	11.6 ± 5.5 (n=146)
PHQ9 score range at baseline	5-24	5-27
There were no significant differences between the intervention and control at baseline.		

CHD, coronary heart disease; HbA1c, glycosylated haemoglobin; HDL, High-density lipoprotein; LDL, Low-density lipoprotein; PHQ9, nine-item Patient Health Questionnaire

Phase 1: comparison of outcomes between the control and intervention groups after 6 months

Table 3 presents the baseline and 6-month data for markers used to monitor control of chronic disease for both the intervention and control groups. While the 6-month depression scores for all 310 patients (164 interventions and 146 controls) were significantly lower than those at baseline in both the intervention group (10.7±0.7 reducing to 7.1±0.8, $t(163)=8.38$, $p<0.001$) and the control group (11.6±0.9 reducing to 9.0±0.9, $t(145)=6.01$, $p<0.001$), the ANCOVA,

adjusting for the baseline scores, showed that the improvement was significantly better in the intervention group than in the control group ($F(1,309)=6.40$, $p=0.012$). (The 95% confidence ranges are indicated by the plus–minus sign.)

Half of the patients had only mild depression at baseline (PHQ9 scores between 5 and 9). Because the reported score for many of these patients may be due to their diabetes rather than depression (58), the intervention is unlikely to be able to change these scores. This is one reason why Katon et al (217) used a score of 10 or more as an inclusion criterion in their study. Consequently, we examined the change to baseline PHQ9 scores for the 164 patients (81 interventions and 83 controls) with moderate-to-severe depression (PHQ9 scores of 10 or more) at baseline. These patients showed significant improvement, with the mean depression score in the intervention group dropping by 5.7±1.3, from 14.4±1.1 down to 8.7±1.3 ($t(80)=9.00$, $p<0.001$), a clinically significant change (218). The improvement in the intervention group for these patients was significantly better than in the control group ($F(1,161)=4.02$, $p=0.047$) where the depression score dropped by 4.3±1.2, from 15.1±1.1 down to 10.8±1.4 ($t(82)=6.88$, $p<0.001$).

Except for the high-density lipoprotein (HDL) measurements, there were no significant changes in biophysical measures after 6 months in either group. Smoking rates were low at baseline in the patients with established cardiovascular risk factors. Recording of alcohol was suboptimal, although it was better than in other Australian primary care surveys (225).

The intervention group also showed a significantly greater number of patients exercising, referred to and attending an exercise programme, and referred to and attending a mental health worker after 6 months of collaborative care. In the control group, there were no significant changes observed after 6 months, except that referrals to a mental health worker increased significantly ($p<0.001$) from 9% to 21%, consistent with the action being taken by the nurses as required by the protocol. Neither group showed any significant changes in the number of patients taking antidepressant medication.

Table 4. Health and process related outcomes for the TrueBlue trial at six months

	Intervention				Control				
	n	**Baseline**	**6 months**	**Within group[1]**	**N**	**Baseline**	**6 months**	**Within group[2]**	**Between groups**
PHQ9 depression score	164	10.7±0.8	7.1±0.8	p<0.001	146	11.6±0.9	9.0±0.9	p<0.001	p=0.012
SF36v2 mental health score [3]	71	37.3±34	41.1±3.4	p=0.034		Not recorded			
SF36 physical health score[3] ¶	71	39.9±2.2	42.5±2.6	p=0.023		Not recorded			
Body mass index (kg/m^2)	162	31.3±1.0	31.2±1.0	NS	103	30.8±1.2	31.0±1.0	NS	NS
Waist (cm)	161	104.7±2.4	105.0±2.4	NS	80	104.2±4.0	105.8±3.2	NS	NS
Systolic blood pressure (mmHg)	161	134.2±3.0	132.4±2.8	NS	112	133.5±3.8	131.2±3.4	NS	NS
Total Cholesterol (mmol/l)	158	4.21±0.16	4.22±0.14	NS	109	4.41±0.2	4.44±0.2	NS	NS
LDL (mmol/l)	154	2.23±0.12	2.17±0.14	NS	86	2.37±0.18	2.29±0.20	NS	NS
HDL (mmol/l)	154	1.23±0.06	1.29±0.06	p=0.023	93	1.17±0.06	1.27±0.08	p=0.011	NS
Triglycerides (mmol/l)	158	1.72±0.14	1.66±0.12	NS	104	1.84±0.22	1.75±0.18	NS	NS
HbA1c (%)[4]	89	6.97±024	6.90±0.26	NS	67	7.22±0.34	7.40±0.36	NS	p=0.049
10-year CVD risk[5]	61	26.9±3.2	26.1±3.2	NS	46	26.3±3.6	24.7±3.2	NS	NS
Smoking	162	15(9%)	13(8%)	NS	110	13(12%)	13(12%)	NS	NS
Alcohol	104	47(45%)	51(49%)	NS	42	27(64%)	27(64%)	NS	NS
Exercise 30min/day, 5 days/week	162	66(41%)	97(60%)	p<0.001	75	22(29%)	22(29%)	NS	p<0.001
Referred to exercise programme	162	32(20%)	58(36%)	p<0.001	111	15(14%)	10(9%)	NS	P<0.001
Attends exercise programme	162	12(7%)	23(14%)	p=0.041	79	12(15%)	9(11%)	NS	NS
On antidepressant medication	162	27(17%)	34(21%)	NS	113	31(27%)	36(32%)	NS	P=0.025
Referred to mental health worker	162	47(29%)	58(36%)	p=0.022	114	10(9%)	24(21%)	p<0.001	p<0.001
Attends mental health worker	162	10(6%)	37(23%)	p<0.001	109	14(13%)	11(10%)	NS	p=0.44

The 95% confidence ranges are indicated by the ±sign. Note that lower scores indicate improvement for all items except the SF36v2 and HDL results, where higher scores indicate improvement.
Unit of alcohol is 10g of ethanol
The values in brackets are the percentages of the total n
[1]Significant difference between baseline and 6 month values within the intervention clinics
[2]Significant difference between baseline and 6 month values within the control clinics
[3]SF36v2 questionnaires were not collected by all clinics
[4]HbA1c results were only available for patients with T2DM
[5]CVD risk could only be calculated for patients with T2DM only
CVD, cardiovascular disease; HbA1c, glycosylated haemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein; NS, no significant difference; PHQ9, nine-question Patient Health Questionnaire; SF36v2, version 2 of the Short Form 36-Question health survey; T2DM, type 2 diabetes.

Phase 2: chronic disease outcomes over 12 months using TrueBlue collaborative care

Table 4 presents data at baseline and 12 months for the intervention group for markers used to monitor control of existing diabetes and CHD. The improvement in mental health observed after 6 months was maintained at 12 months, with a significant reduction in the mean depression score being maintained (10.7±0.7 to 6.6±0.7, $t(163)=9.92$, $p<0.001$) and nearly 70% of patients having lower depression scores than at baseline after 1 year. Patients with moderate-to-severe depression at baseline showed an even greater improvement after 12 months of collaborative care, with the mean depression score dropping by 6.4±1.2, from 14.4±0.8 to 8.0±1.2 ($t(80)=10.41$, $p<0.001$). A significant improvement in the mean SF36v2 composite mental health and physical health scores, which was observed after 6months, was also maintained at 12 months.

Physiological measures showed a trend, although not significant, to improvement in weight, systolic blood pressure and HDL. Mean baseline lipids and HbA1c were close to guideline targets. The 10-year cardiovascular disease (CVD) risk calculated with the Framingham risk equations (226) suggests a small but significant ($p=0.015$) reduction in risk from 27.4% to 24.8% for patients with only T2DM. (The Framingham risk equations cannot be used for those patients who have CHD.)

The most notable change in lifestyle after 12 months of the intervention was a significant increase in the number of patients who reported taking regular

exercise or being referred to an exercise programme. Reported referrals and visits to a mental health worker and numbers taking antidepressant medication were also significantly greater at 12 months.

The TrueBlue protocol also included goal setting so that patients could become more proactive in their own care. An analysis of participant goals revealed that two-thirds of the visits resulted in at least one behavioural activation goal being set and, over the course of the study, 86% of patients identified a behavioural activation goal.

Table 5. TrueBlue outcomes at 12 months within the intervention clinics only

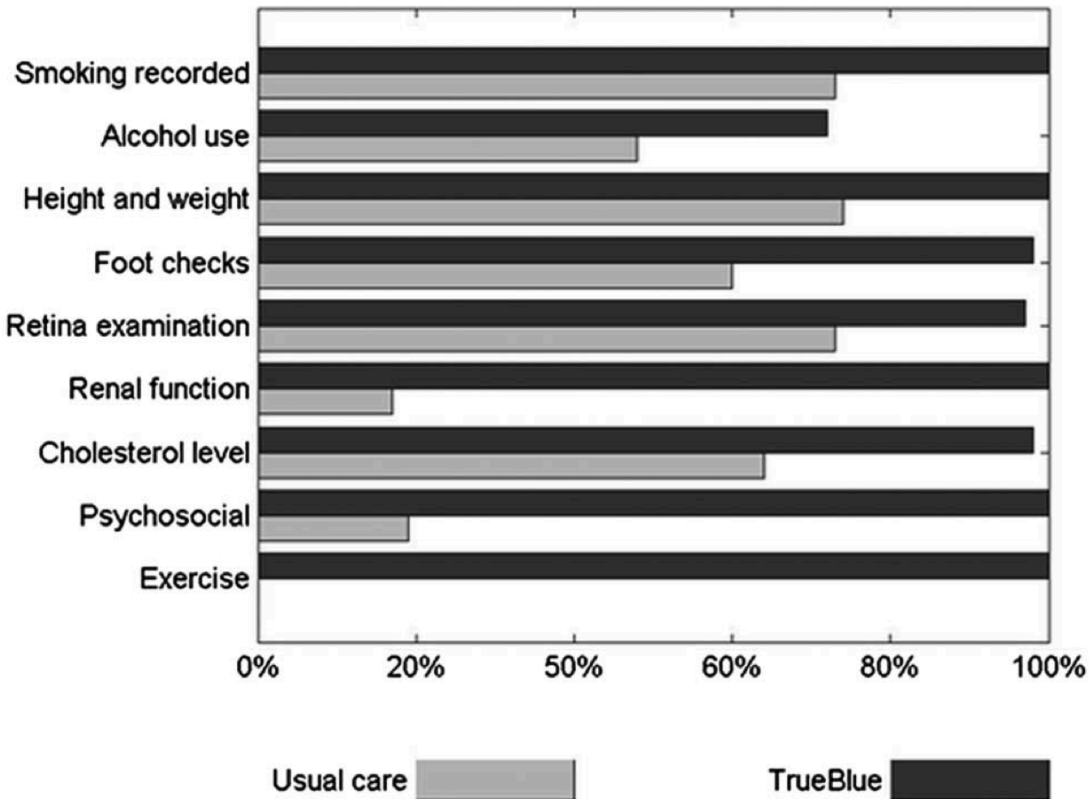
	Intervention			
	n	**Baseline**	**12 Months**	**Within group[1]**
PHQ9 depression score	164	10.7±0.7	6.6±0.7	p<0.001
SF36v2 mental health score[2]	70	36.0±3.2	41.3±2.8	p<0.001
SF36v2 physical health score[2]	70	40.6±2.2	44.3±2.8	p<0.001
Body mass index (kg/m^2)	142	31.4±1.0	31.1±1.0	p=0.006
Waist (cm)	141	105.0±2.4	105.2±2.6	NS
Systolic blood pressure (mmHg)	141	135.2±3.2	130.2±3.0	p=0.016
Total cholesterol (mmol/l)	138	4.18±0.16	4.28±0.16	NS
LDL (mmol/l)	135	2.19±0.12	2.24±0.20	NS
HDL (mmol/l)	135	1.22±0.06	1.36±0.08	p<0.001
Triglycerides (mmol/l)	138	1.73±0.16	1.63±0.14	p=0.004
HbA1c (%)[3]	79	7.01±0.26	7.04±0.28	NS
10-year CVD risk[4]	55	27.4±3.4	24.9±3.6	p=0.015
Smoking	142	15(11%)	11(8%)	NS
Alcohol	95	45(47%)	47(47%)	NS
Exercise 30min/day, 5 days/week	142	57(40%)	83(58%)	p<0.001
Referred to exercise programme	142	26(18%)	53(37%)	p<0.001
Attends exercise program	142	10(7%)	17(12%)	NS
On antidepressant medication	142	22(15%)	33(23%)	p=0.001
Referred to mental health worker	142	40(28%)	59(42%)	p<0.001
Attends mental health worker	142	8(6%)	25(18%)	p<0.001

The 95% confidence ranges are indicated by the ± sign. Lower scores indicate improvement for all items except SF36v2 and HDL results, where higher scores indicate improvement.
The values in brackets are the percentages of the total n.
Unit of alcohol is 10g ethanol.
[1]Significant difference between baseline and 12-month values
[2]SF36v2 questionnaires were not collected by all clinics
[3]HbA1c results were only available for patients with T2DM
[4]CVD risk could only be calculated for patients with T2DM only
CVD, cardiovascular disease; HbA1c, glycosylated haemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein; NS, no significant difference; PHQ9, nine-question Patient Health Questionnaire; SF36v2, version 2 of the Short Form 36-Question health survey; T2DM, type 2 diabetes.

Adherence to guidelines

Figure 8 shows the percentage of TrueBlue patients who had psychosocial and biophysical checks undertaken as recommended by the Australian National Heart Foundation and Diabetes Australia guidelines, with the corresponding percentages for usual care being taken from a study of a large sample of Australian general practices (225).

(Figure 8) Recording of checks recommended by the National Heart Foundation and Diabetes Australia guidelines. Data for 'usual care' were adapted from Wan et al (225). No usual-care data were available for exercise.



Outcomes of phase 1

Depression scores were significantly lower at 6 months for patients in the intervention group compared with those in the control group, and the improvement was clinically significant for patients with moderate-to-severe depression (218), with patients moving one depression category. Patients experienced increased nurse contact time through the nurse consultations. They were provided with information about mental health and their physical health through psychoeducation resources and had their treatment intensified when required. Modalities included behavioural activation, antidepressant medication and referrals to mental health professionals and exercise programmes. Similar improvements in depression scores and stepped care were observed in the collaborative care model of Katon et al. (217). The reduction in depression scores observed in the control group could be explained, in part, by control practices being provided with each patient's entry-level depression score during the recruitment process as part of the study's safety protocol. Usual care could have been influenced by drawing attention to comorbid depression (217) as the protocol required that PNs take action if severe depression was recorded or if the patient had responded to the suicidal-ideation question. Referrals to mental-health workers by the control clinics had increased significantly, consistent with the clinics taking action where warranted. It is also known that recruiting interested patients (those who wanted to participate) from interested clinics (those that agreed to join) can affect the representativeness of the study

population (227). GPs with a particular interest in the study may be more likely to participate and manage their patients more effectively, irrespective of whether they are in the control or intervention arm. Consequently, a reduction in depression scores in the control group was expected, but the structured TrueBlue model did produce a significantly better reduction in depression. While the effect size may be small (Cohen's f=0.15), it is important to note that TrueBlue was designed to be implemented easily within general practices, with running costs funded by existing Australian Medicare rebates, and to make better use of their existing resources. These features mean that TrueBlue could be easily applied to patients across general practices at a population level, making the benefits clinically important.

Outcomes of phase 2

The key clinical outcomes over a 12-month period in the intervention group (Table 4) were a sustained improvement in mental health, demonstrated by symptom severity score (PHQ9 total score) and by the patient's function and subjective evaluation of mental health (SF36 mental health composite score) and physical health (SF36 physical health composite score). Regular physical exercise has been shown to be important for reducing depression (228). The self-reported exercise rates showed significant improvement over the 12 months of collaborative care intervention. The biophysical measures reported in Table 4 showed modest improvements after 12 months and the Framingham risk equations (226) suggest a small but significant reduction in the 10-year CVD risk for the T2DM patients. These improvements were achieved despite the fact that

we did not specifically select patients whose physiological parameters exceeded guidelines. Rather, our recruitment process was selected from the practice's disease registry on the basis of only the presence of depression and T2DM or CHD, and consequently, many patients were already being treated to target on measures such as cholesterol and HbA1c, leaving little room for improvement.

Limitations

We were able to run TrueBlue only in practices that used clinical software, which we used to generate a disease registry from which participants could be selected, and had a PN on staff. Clinics that chose to take part in the study may not have been representative of wider general practice. Operational limitations further reduced the number of practices over the duration of the study. Patient response rates to the mail-out (28%) may reflect anxiety over the new model of care where the patient discloses depression and visits the PN first rather than only the GP. Usual care in the control clinics may have been changed by patients completing the PHQ9 and reading the project description. GPs were made aware of individual PHQ9 results and took action where warranted. GP awareness of these biophysical and lifestyle risks may be expected to change clinical management. By design, TrueBlue practices needed to incorporate all research activities within the context of their busy clinics, and so only research data that could be extracted automatically were collected. The data dropout resulting from these two factors contributed to the observed small effect size. We were not able to obtain multiple data sets at three monthly intervals over 12 months of 'usual care' because the act of inviting patients and measuring depression scores and

biophysical measures would in itself change the nature of usual care. In addition, practices would not have been willing to join the study if there was a chance of being randomly allocated to 12 months of being in such a control arm (227).

Collaborative care

A recent UK study has shown the difficulties of disseminating a guideline without guidance on how to implement collaborative care. Organisational barriers included GPs finding the PHQ9 awkward to use, nurses not feeling confident or competent due to lack of training and no guidance on stepped care (216). The TrueBlue model of collaborative care overcame many of these difficulties. Its successful components were (200, 229):

- *Use of evidence-based guidelines*. The National Heart Foundation and Diabetes Australia Guidelines determined the disease management targets and frequency of monitoring.

- *Systematic screening and monitoring of risk factors*. Patients attended three monthly visits in which a care plan with its checklist was completed. By providing a comprehensive collation of all necessary information, this document made clinical management by the patient's GP easier, quicker and more accurate.

- *Timetabled recall visits*. The date of the next appointment was set during each visit. PHQ9 was re-administered and, if improvement was insufficient, stepped

care was followed by initiating drug therapy or increasing the dose or by referral to a mental health worker according to the guidelines.

‣ *New or adjusted roles for team members*. PNs took responsibility for organising and monitoring the outcome of referrals, goals and targets. They used a depression questionnaire (the PHQ9) to open a discussion with patients about their depression symptoms.

‣ *Information support for the clinician*. GPs were provided with the care plan by the PNs.

‣ *Enhanced patient self-management*. Patients received their own copy of the care plan with personalised goals, current measurements, targets and safety advice. A component of each visit was to discuss and update their plan and receive education material on depression.

‣ *Identified case manager*. PNs became case managers, but the GP remained the key clinician.

‣ *Means of effective communication between all members of the care team*. The care plan was designed to provide relevant clinical information in a succinct format while still being comprehensible to patients.

‣ *Audit information for the practice*. De-identified data were provided automatically through the care plan.

Applicability of TrueBlue

TrueBlue used existing clinical software and improved the focus of the GP consultation by delegating some tasks to the PN. Higher levels of adherence to guideline-recommended checks were also reported for TrueBlue. Patients and their carers, allied health professionals, specialists and GPs gained ready access to patient details provided in TrueBlue's care plan, enabling them to see at a glance where improved clinical care may be needed. The study achieved improved outcomes with the potential for prevention of heart attack and stroke through reduced 10-year CVD risk. The care plan template also allowed the practice to collect high quality audit data without taking up clinical time. While it was not possible to obtain complete financial data from the clinics specifically relating to the TrueBlue visits, the data that are available suggest that clinics did indeed cover their costs in implementing TrueBlue through Australian Medicare rebates.

The success of TrueBlue and Team Care (217) demonstrates that collaborative care is feasible in routine general practice in Australia and the USA, and could lead to improved outcomes for patients with depression and other chronic diseases (213, 230).

Acknowledgements

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Contributors

All authors have full access to the complete study dataset, contributed to the design, implemented the project and co-wrote and approved the manuscript. MAJM, MJC, JAD and PR analysed the data. MAJM, PR and KS developed and ran the practice nurse training programme. JAD and PR conceived the TrueBlue model during a visit to the IMPACT team. JAD is the guarantor.

Funding

Funding was provided by *beyondblue*, the National Depression Initiative in Australia (grant 172), but it had no other involvement in any phase of the study. All researchers were independent of and not influenced by *beyondblue*.

Competing interests

None.

Ethics approval

Ethics approval was obtained from Flinders University's Social and Behavioural Research Ethics Committee. All patients gave informed consent to participate in the study.

4.3 Safety and acceptability of TrueBlue (reproduced verbatim)

Citation (231):

K Schlicht[1], **M A J Morgan[1]**, J Fuller[2], M J Coates[1], J A Dunbar[1]. Safety and acceptability of practice nurse-managed care of depression in patients with diabetes or heart disease in the Australian TrueBlue study. *BMJ Open* 2013;**3.**

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Article summary

Article focus

- To determine whether practice nurses could utilise stepped care, problem solving and goal setting for patients.
- To determine whether practice nurses managed suicidal ideation safely in the primary healthcare setting.
- To determine the acceptability of TrueBlue collaborative care by the practice nurses and GPs.

Key messages

- Practice nurses can manage mental health risk in conjunction with diabetes and heart disease.
- Practice nurses can identify suicidal ideation on the PHQ9 and follow a protocol-driven response.

Strengths and limitations of this study

- The study's purpose-designed care plan template provided protocol-driven criteria to deliver treatment.
- The focus group contained both GPs and practice nurses and the presence of the GP may have influenced the responses of the practice nurses.

Abstract

Objectives

To determine the safety and acceptability of the TrueBlue model of nurse-managed care in the primary healthcare setting.

Design

A mixed methods study involving clinical record audit, focus groups and nurse interviews as a companion study investigating the processes used in the TrueBlue randomised trial.

Setting

Australian general practices involved in the TrueBlue trial.

Participants

Five practice nurses and five general practitioners (GPs) who had experienced nurse-managed care planning following the TrueBlue model of collaborative care.

Intervention

The practice nurse acted as case manager, providing screening and protocol-management of depression and diabetes, coronary heart disease or both.

Primary outcome measures

Proportion of patients provided with stepped care when needed, identification and response to suicide risk and acceptability of the model to practice nurses and GPs.

Results

Almost half the patients received stepped care when indicated. All patients who indicated suicidal ideations were identified and action taken. Practice nurses and GPs acknowledged the advantages of the TrueBlue care plan template and protocol-driven care, and the importance of peer support for the nurse in their enhanced role.

Conclusions

Practice nurses were able to identify, assess and manage mental health risk in patients with diabetes or heart disease.

Introduction

The TrueBlue project (207) was conceived to better meet the needs of general practice patients with depression and comorbid chronic illness as these cannot be met through normal episodic care alone (232). The complexity of chronic disease management and the increasing numbers of patients with these conditions requires a coordinated team-based approach driven by patient needs. There has been considerable attention in Australia to increase the role played by practice nurses in general (90, 92, 233). Primary care nurses can be effective in managing patients with chronic disease or depression (161, 234-236). TrueBlue was a randomised-control trial undertaken in eleven Australian general practices in country (three intervention and two control) and metropolitan (two

intervention and four control) areas (207). It was undertaken from 2009 to 2011 and enrolled 400 patients with depression and chronic disease (diabetes, coronary heart disease or both). TrueBlue followed the existing practice nurses employed in the general practices.

Nurses undertook scheduled 45 min consultations on a 3 monthly basis, immediately followed by a standard15 min general practitioner (GP) consultation. The nurse consultation consisted of four tasks: (1) recording of pathology results and physical measurements; (2) using depression severity scores from the PHQ9 questionnaire (54) to decide if stepped care is required(155); (3) identifying barriers to improved physical and mental health and reviewing appropriate goals for the next 3 months and (4) care coordination between the GP, patient and other healthcare professionals. The TrueBlue multipurpose care plan template was a checklist for the practice nurses to review and monitor progress, to provide decision support for the GP and to provide information for patients, patient carers and the wider healthcare team. The content of the nurse-training package and external support to the nurses are summarised in table 5.

Table 6. Details of nurse training and support

Two-day training workshop	Depression as a risk factor in diabetes and heart disease
	Monitoring of depression using PHQ9 questionnaire
	Impact of disease using version 2 of the SF36 questionnaire
	Identifying barriers and enablers for better lifestyle choices
	Goal setting and problem solving using Specific, Measurable, Attainable, Realistic and Time-bound (SMART) goals
	Behavioural activation
	Diabetes Australia and Australian Heart Foundation guidelines
	Case management with other health professionals
	Use of care plan as a communication tool, checklist and data collection for research
Local facilitator support	Patient selection and recruitment
	Information technology support
Monthly teleconferences	Expert supervision from the project managers, a GP and a psychologist
	Peer support by participating nurses with case-study discussion

TrueBlue confirmed the effectiveness of nurse-managed care by demonstrating improvement in depression, mean body mass index, systolic blood pressure, high-density lipoprotein cholesterol and 10-year cardiovascular-disease risk. Adherence to the 'best practice' guidelines recommended by the Australian Heart Foundation and Diabetes Australia for the monitoring and care of patients with diabetes and heart disease was considerably better than the Australian norms.

Many of the tasks required by the TrueBlue collaborative-care model were enhanced roles for practice nurses. This study examined the extent to which practice nurses initiated stepped care for depression, whether they followed the patient-safety protocols related to suicidal ideation, and whether nurses and GPs found the TrueBlue model to be acceptable.

Design

Initiating stepped care

Stepped care was indicated when the patient's depression severity score had not dropped below a score of five (indicating no depression) or had not dropped by at least five points between the 3-monthly visits. An instance of stepped care was considered to have occurred when the patient was (1) referred to a mental-health worker, (2) started on antidepressant medication, (3) started exercising or (4) set at least one new behavioural activation goal. Data indicating stepped care were extracted from the database created during the TrueBlue trial.

Safety

The study's safety protocol required that patients who self-reported a non-zero score on the suicidal-ideation item of the PHQ9 be identified and appropriate action taken. In order to assess whether this protocol was being followed, we examined the PHQ9 data being returned during the TrueBlue study(207) after the first contact with the patient or from the returned postal questionnaires. Any patients who indicated thoughts of self-harm were identified and their study IDs submitted to the four practice nurses who had worked with these patients. Interviews were conducted with these nurses to determine that they had taken appropriate action and that the study's safety protocol was being followed.

Acceptability

Acceptability of the TrueBlue model of care to the practice nurses and the GPs was assessed qualitatively through two focus groups held on the completion of the study. The first focus group involved four nurses (N1– N4) and four GPs (GP1–GP4) from different country practices. The second focus group involved one nurse (N5) and one GP (GP5) from a metropolitan practice. Structured prompts were used by the group facilitator (MM) with the discussions recorded, transcribed verbatim and thematically analysed by two of us (KS and JF). The second focus group was conducted by a psychologist and one of us (MM), transcribed verbatim and then analysed for themes (KS and JF).

Results

Stepped care

Of the 206 patients in the intervention arm in the study database, 63% met the criteria for needing stepped care at some point during the study. There were 257 instances identified where the criteria were met, and in 48% of these, stepped care occurred. Actions included starting of medication (13%), referral to mental health worker (15%), starting exercising (17%) and negotiation of at least one new behavioural activation goal (24%). However, no data were collected to identify where the GP increased the dose or changed antidepressant medication. At the start of the study, only 20% of those referred to a mental health worker were attending but, after 12 months of the intervention, this had doubled to

42%. These combined results suggest that practice nurses were able to initiate and deliver stepped care according to the patient's psychological/clinical needs.

Safety

During the early stages of the trial, confirmation of the adherence to the study's safety protocol was undertaken. From the study database, 23 patients (11%) were identified with suicidal ideation. The records and practice nurse interviews demonstrated that:

1. All patients who had returned a non-zero score for the suicidal-ideation item on the PHQ9 questionnaire were identified by the practice nurse.

2. The practice nurses informed the GP according to protocol and confirmed that appropriate follow-up had occurred.

3. The main actions were either to make a referral to a mental health professional or for the GP to treat the presenting condition.

Acceptability

Three major themes were identified from the concepts that participants described (Table 6).

Use of the TrueBlue template

The TrueBlue model appeared to be acceptable to practice nurses and GPs because of the structure that it provided for teamwork and communication between healthcare providers and patients. Having a care plan template meant that the nurse was prompted to undertake a comprehensive approach to care as one nurse (N1) stated

> the way that it was set out, plus all the other stuff [it outlined] all that it needed to.

The care plan template was a protocol about what information was needed to guide the nurse's action, as a GP described

> There should be a template for all of these care plans ... The TrueBlue template I think is by far the best one that kind of exists on the system. It's kind of all encompassing ... It includes the mental depression sides of things as well which again, unless you ask the question, sometimes you never know. (GP2)

In addition to the care plan template, the use of the PHQ9 provided further structuring of care through assessment of depression, where the patient's score to each of its items became the cue for a longer discussion between the nurse and the patient. A nurse and GP described

> Patients that took part in the TrueBlue project were relieved to be asked the question about how they were feeling. A lot of them said things to me like, "the doctor's always too busy and I've only got 15 minutes with him and by the time he does the script and gives me the pathology request and we talk about the blood results, I'm out the door". (N1)

> They [nurses] have the time to do it, we [GPs] don't have the time ... All of us are so busy that sometimes you don't ask them if they're depressed. (GP1)

Practice nurses reported that the training in using the PHQ9 and how to manage risk enabled them to discuss topics that they would not normally have raised during their appointment with the patient. Although the numbers of nurses interviewed were limited, all the nurses indicated that they felt more confident about managing risk in a primary healthcare setting because of the protocols in place.

Not all practices preferred the TrueBlue template. In one location the nurse reported that the GPs had their own and so that practice had continued to use their existing process but with the addition of the TrueBlue items. Another clinic GP also reported a mixed response to the care plan template, but this was related to the style of working in that practice, which differed according to the preferences of individual GPs rather than as a whole of practice system

> In our practice it's very patchy and it was driven by the individual GPs, not systematized. There's been a general trend to doing more of it and it's a very patch variable quality when they are done. It's not embedded in the nurse's domain so it's not done well. (GP3)

The work style of the practice, such as the existence of team meetings, may well influence the use of a care plan template. One nurse described how meetings were used to communicate about the TrueBlue model as an important way to get the team 'on board':

> At ... Clinic, we went to great lengths to make sure everybody in the practice knew what it was about and we had staff meetings where I was able to relay everything that we learned in initial meetings in Melbourne ... getting everyone on board made a big difference to the way it all worked in the practice. (N4)

Goal setting

A key component of TrueBlue's care plan was the setting of patient goals and the subsequent use of motivational interviewing by the practice nurse. Nearly all (96%) of the intervention patients elected to set a personal goal and, of these, 81% were achieved or partially achieved. For the 19% of goals that were not achieved, the practice nurses renegotiated most of them (14%) with the patient. These results demonstrate that the practice nurses were able to work collaboratively with patients to identify and review patient centred/initiated

goals. Three nurses reported that this was a rewarding aspect of the model, and changed care towards a greater patient focus and hence patient motivation to 'move forward and be in control'

> Some of the doctors who were setting the goals for the patients ... I think they tend to get the goals now from the patients a bit more than they did in the patient's own words. (N2)

> Setting their own goals, which weren't necessarily getting the HbA1c under 7 or whatever, it was more lifestyle goals ... so that they could achieve what they wanted ... I found that then that helped them to move forward and to just help them to problem solve. (N1)

> It's just that little bit of empowerment allows them to go on and then achieve other things. So it wasn't about maybe losing 2 kilos in 6 weeks it was about being in control and knowing that you could actually be in control. (N4)

Nurses' roles

Communication between nurses and patients was enhanced through generation of a care plan and review of that plan every 3months. This was seen as an extended role by practice nurses as one nurse described

> It's become a bit of a shared role because we are often now enlightening doctors to things that we've picked up in a conversation that may not have time to be discussing otherwise with the patient. (N4)

There was also a change in the communication between nurse and GP, which one GP described

> If the [nurses] found a problem, we see the patient usually after they've had their plan done, so if the [nurses] are worried they'll walk in and say "here's Mary, look I'm a bit worried about blah blah and then off you go." (GP1)

An additional enhanced role was the organisation of external referrals for the management of depression

> At ... Clinic we [nurses] pretty much generate all the referrals ... The doctors are happy and sign them. (N1)

> Yeah. We [GPs] always read them and sign them. (GP1)

This changed role did need support and an incident was described where a nurse had started to get involved in mental health counselling to which the focus-group facilitator commented that would be challenging to a psychologist with the most difficult patients and the [nurse] got into strife.

Peer support and role definition were suggested as ways to help nurses extend their role within scope. Peer support enabled the identification of problems that were also experienced by others which could then be jointly solved. Such support was provided by TrueBlue:

> The monthly telephone conference that we [nurses] took part in as a group was really supportive because we could swap stories about what was working ... and what we were having trouble with and we could [then] find a solution to our problems (N2)

The peer review process also highlighted the importance of being part of a group and the benefits of the normalising of the common problems experienced by other practice nurses

> It was only everyone else on the end of the phone that understood what we were going through. For me that really got me through. (N2)

Table 7. Acceptability of TrueBlue: themes form the focus groups and concepts related to them

Use of the TrueBlue template	Goal setting	Nurses' role
Structured communication	Patient focus	Enhanced communication
Protocol for nurse and patient discussion	Motivation	Extended practice
Style of practice	In control	Support

Discussion

This study has demonstrated that the TrueBlue collaborative care model was effective, safe and acceptable from the nurses' and GPs' point of view. It provided a protocol-driven structure for practice nurses to expand their role in the primary healthcare setting, and the training that enabled the practice nurses to embrace the expanding role and to feel confident in dealing with mental health issues. Protocols and communication processes have been found elsewhere to be important enablers to service linkages in primary healthcare (229). The practice nurses were able to identify and manage depression (according to the protocol) in conjunction with the GP in a primary healthcare setting. This is an important development for primary healthcare for two reasons.

First, untreated depression is a major risk factor for morbidity and mortality in diabetes and cardiovascular disease (210, 211), but some primary care professionals find it difficult to manage simultaneously both physical and mental illness (30). Early identification and treatment of depression is important for

better outcomes for the patient. If patients are not being screened for depression when they come to the GP then this diagnosis may be missed, as one GP noted

> I didn't know she was depressed. (GP2)

Second, the TrueBlue model of care is a change from the existing model that is episodically driven and medically focussed. TrueBlue highlights the collaboration between the GP, the nurse and the patient. GPs are renowned for not having enough time for patient consultations. TrueBlue in fact encourages patients to have an in-depth conversation with a practice nurse, which is seen by patients to be beneficial (236, 237). The practice nurse is then able to inform and work with the GP to determine the best treatment for the patient.

Similar to other studies (4, 238, 239), our study demonstrated the benefits of peer support and expert advice in order to maintain professional boundaries, as highlighted in the focus group. It also highlighted the enhanced opportunity for the patient to be involved in treatment decision-making. The practice nurses instigated a change in the focus of goal setting from a medical focus, such as cholesterol, to a lifestyle-focused goal. There is enough literature to support the notion that the more involved in the decision making and the greater understanding the patient has about their treatment the better the outcome for the patient (240, 241).

Limitations of the study

The qualitative data in this study are from a small number of nurses and GPs who agreed to attend and so the findings cannot be generalised, but they do show that safe and acceptable nurse-managed care for depression and comorbid chronic disease is possible. As the focus groups consisted of both nurses and GPs, the presence of the GPs may have influenced the response by the practice nurses because of the perceived power difference between them. The only indication of patient acceptance was the low drop out (16%) of patients over the course of the study and the positive anecdotes related by the study nurses. TrueBlue was designed to fit into routine procedures in the general practices and interviewing patients would have intruded into these normal procedures. Further studies would be needed to determine patients' perspectives. The follow-up for the patients who returned a non-zero score on the suicide-ideation item was ascertained only by interviewing the practice nurses concerned to maintain patient confidentiality.

Conclusions

Traditional episodic GP-led care of patients is in sharp contrast to TrueBlue nurse-managed collaborative care. In this latter system of care delivery, there are scheduled follow-up visits, protocol-driven monitoring in line with current evidence-based guidelines and systematic monitoring of depression severity leading to stepped care when appropriate. The nurse consultations provide an opportunity for patients to set personalised goals.

The study demonstrated the practice nurses' ability to identify, assess and manage mental health risk in a primary healthcare setting when it is associated with diabetes or heart disease. Managing risk involved informing the GP and providing ongoing referrals for the patient. Therapeutic psychological interventions were not part of the protocol. Training in mental health, goal setting and problem solving and the screening tools appear to have been key elements in the success of this collaborative care model. The success of TrueBlue demonstrated that practice nurse-managed collaborative care is effective, acceptable and safe in routine general practice in Australia and could lead to improved outcomes for patients with depression and other chronic diseases.

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The authors wish to thank the patients, practice nurses, general practitioners and support staff of the participating clinics Evans Head Medical Centre, Lennox Head Medical Centre, Keen Street Clinic, Tintenbar Medical Centre, Health on Grange, Warradale Medical Centre, Seaton Medical and Specialist Centre, Woodcroft Medical Centre and Southcare Medical Centre. We would also like to thank David Ekers and Tim Keneally for their useful comments, Bob Leahy for managing the project and Vicki Brown for her assistance during the first focus group.

Contributors

JAD conceived the TrueBlue model during a visit to the IMPACT team. KS, MAJM, MJC, JF and JAD contributed to the design and implementation of the project. MAJM and KS undertook the focus groups. KS, MAJM, MJC and JF analysed the data. KS, JF, MAJM and MJC prepared the draft manuscript. All authors edited and approved the manuscript.

JAD is guarantor.

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Competing interests None.

Ethics approval

Ethics approval was obtained from Flinders University's Social and Behavioural Research Ethics Committee. All patients gave informed consent to participate in the study.

4.4 Using care plans to better manage multimorbidity (reproduced verbatim)

Citation (242):

Morgan MAJ, Coates MJ, Dunbar JA. Using care plans to better manage multimorbidity. *Australasian Medical Journal* 2015;**8**(6).

Abstract

Background

The health care for patients having two or more long-term medical conditions is fragmented between specialists, allied health professionals, and general practitioners (GPs), each keeping separate medical records. There are separate guidelines for each disease, making it difficult for the GP to coordinate care. The TrueBlue model of collaborative care to address key problems in managing patients with multimorbidity in general practice previously reported outcomes on the management of multimorbidities. We report on the care plan for patients with depression, diabetes, or coronary heart disease, or both that was embedded in the TrueBlue study.

Methods

A care plan was designed around diabetes, coronary heart disease, and depression management guidelines to prompt implementation of best practices and to provide a single document for information from multiple sources. It was used in the TrueBlue trial undertaken by 400 patients (206 intervention and 194 control) from 11 Australian general practices in regional and metropolitan areas.

Results

Practice nurses and GPs successfully used the care plan to achieve the guideline-recommended checks for almost all patients, and successfully monitored

depression scores and risk factors, kept pathology results up to date, and identified patient priorities and goals. Clinical outcomes improved compared with usual care.

Conclusion

The care plan was used successfully to manage and prioritise multimorbidity. Downstream implications include improving efficiency in patient management, and better health outcomes for patients with complex multimorbidities.

Key Words

Multimorbidity, care plans, collaborative care, diabetes, heart disease, depression

Implications for Practice:

1. What is known about this subject?

Medicare-funded care plans generally fail to deal with multiple diseases, track changes over time, omit personalised goals, miss supporting self-management, and don't provide specific prompts for recommended checks.

2. What new information is offered in this report?

A care plan template developed from multiple disease guidelines was successfully used to manage multimorbidity, summarising information from multiple sources and involving patient participation in disease management.

3. What are the implications for research, policy, or practice? GP practices should consider a combined care plan approach similar to the plan reported here with its automatic prompts to ensure better adherence to the recommended checks.

Background

Multimorbidity, the co-occurrence of multiple medical conditions in an individual (243), is becoming the norm for older people. One-third of 65-year-olds have three or more chronic conditions (244). Patients with multimorbidity have poorer quality of life, greater loss of physical function, and are prescribed multiple drugs with consequent difficulties with adherence. These patients are more likely to be admitted to and have longer stays in hospital (79). They already form the majority of GP workload in primary care, with more than half of patient encounters dealing with managing chronic conditions (245), and this will increase as the population ages (246, 247). Recent articles have highlighted that it is both timely and important to examine practical ways to better manage the healthcare of patients with multimorbidity (248, 249).

One difficulty is that treatment guidelines are based on research focused on single diseases that specifically exclude patients with multimorbidity. This can lead to conflicting management guidelines—such as using non-steroidal anti-inflammatory medication for the treatment of osteoarthritis pain (250) while avoiding the same medications in the presence of heart failure (251)—that do not account for the complexities of living with overlapping medical conditions (79). As a result, patients undergo multiple investigations and find their health care fragmented between multiple specialist clinics, allied health providers, and general practice. The location of these services adds an additional travel burden, especially in rural or regional areas. With the fragmentation of health care, important comorbidities can be missed, such as depression, which is overrepresented and under diagnosed in patients presenting with other chronic diseases (211). Individual preferences are often overlooked with targets being

simply medical ones without the patient's wishes and lifestyle preferences being considered.

The key question for patients with multimorbidity is how high quality and coordinated care can be achieved in healthcare services in the face of such fragmentation of care (252). The TrueBlue model of collaborative care (186, 189, 207, 231), in a large, multicentre study undertaken in Australia, provided a means to address this question.

The TrueBlue study

Collaborative care has been recognised as a successful systematic approach to the management of depression (175). The TrueBlue model of collaborative care used the principles of chronic disease management (1) that call for timetabled reviews, a single case-manager, new roles for practice nurses, a way to exchange information between all members of the healthcare team, and a combined guideline for type 2 diabetes, coronary heart disease (CHD), and depression. The TrueBlue model is described in detail elsewhere (189, 207); a brief description is provided here.

Patients were screened for depression by completing the Patient Health Questionnaire 9 (PHQ9) (54) in the waiting room before attending a 45-minute nurse consultation, followed by a 15-minute GP consultation. In each nurse consultation, pathology results, clinical measurements, and lifestyle risks were documented and referrals to allied health, specialist services, or mental health workers were arranged. Patient priorities, goal setting, and problem solving were key components of the TrueBlue model. Nurses worked with patients during the consultation to enable them to think about their personal priorities and the barriers to and enablers of better lifestyle choices. Nurses used problem-

solving techniques to help patients set personal SMART (specific, measurable, attainable, realistic, and time-bound) goals that patients felt were achievable to assist in reducing their risk factors. Nurses reviewed and updated these goals with patients during each subsequent consultation. GP clinical decisions were based on these patient priorities. Importantly, this entire process was repeated every three months by automatically timetabling recall visits. The costs for the nurse time were covered through Australian Medicare rebates for chronic disease management.

Care plans are known to be important in managing chronic disease (131) and lead to improved patient outcomes (253) and reduced hospitalisation (121). However, typical Australian GP management plans (GPMPs), such as a suggested blank GPMP template (254), do not report the patient's wishes and lifestyle preferences, focusing instead on medical targets and management goals, nor do they track the achievement or partial achievement of personal lifestyle goals. Such GPMPs only contain a snapshot of information taken at the time of the consultation and do not track the changes over time that allow progress to be easily reviewed. Many such GPMPs are disease-specific and do not incorporate the varied requirements of multiple diseases that follow multiple guidelines. They do not have built-in prompts that guide the clinician through the various guideline- recommended checks. A new care plan template was designed to address these issues as part of the TrueBlue study to assist in the management of multimorbidity. We report here on the implementation of that care plan, and provide details of its integration into clinical practice.

Methods

The care plan template (Figure 9) was specifically developed to acquire all necessary information and provide it in a single document. It was designed around the overlapping management tasks, targets, and lifestyle changes recommended by the National Heart Foundation of Australia, Diabetes Australia, and the MacArthur Foundation for Depression so that it could act as a guide for the clinician through routine scheduling of tests and activities required for each patient.

The care plan was designed to be capable of summarising clinical data, identifying clinical priorities, recording patient's personal goals, coordinating the broader healthcare team, and providing de-identified audit data that could be used for research or for feedback to the clinic. It allowed tracking changes over time enabling the clinicians to monitor medication, referrals, adherence to the treatment plan, and attendance at external referrals. The care plan recorded patient's personal goals and preferences, and the barriers and enablers to achieving these. It allowed depression to be monitored and whether stepped care was occurring through medication management and mental health worker referrals and attendance. The care plan incorporated an automatic recall visit rather than relying on patients making the next appointment on an ad-hoc basis. Importantly, it incorporated automatic prompts to the health professionals to make sure that all this information was acquired.

The care plan was tested in the D_TECT trial in six rural Australian general practices (186) before being used in the TrueBlue randomised trial with usual GP care as a control (207).

Results

Four hundred patients (206 in the intervention and 194 in the control) with depression and one or both of diabetes and CHD from 11 general practices in regional and metropolitan settings commenced the TrueBlue trial. Practices ranged from small, single GP practices to large, multi-GP clinics, with five (three intervention, two control) of the practices coming from a regional area and six (two intervention, four control) from a metropolitan area (207). Data collection commenced in 2009 and was completed in 2011. Approximately 72 per cent of patients (142 in the intervention and 147 in the control) completed the study. Table 7 presents the comparison between the control and intervention groups of the checks recommended by the National Heart Foundation and Diabetes Australia that were included in the combined guideline for CHD, diabetes, and depression management. Near-perfect recording occurred when the care plan was used. The intervention data were those recorded at the end of the 12-month study. The usual-care data from the control group were retrospectively extracted at baseline before their nurses were trained in the TrueBlue model and started using its care plan. Usual-care depression and exercise rates were not available because there was no system for recording exercise rates in usual care and patients were specifically screened for depression as part of their recruitment into the TrueBlue RCT.

Table 8. Comparison between the control and intervention groups for the guideline-recommended checks

	Control group			TrueBlue		
Item recorded	N*	n§		N	n	
Smoking	114	110	96%	142	142	100%
Alcohol	114	42	37%	142	107	75%
Height & weight	114	103	90%	142	142	100%
Blood pressure	114	112	98%	142	142	100%
Foot checks	94	34	36%	80	80	100%
Eye checks	94	30	32%	80	79	99%
Renal function	75	64	85%	80	80	100%
Lipids	114	110	96%	142	141	99%
HbA1c	75	67	89%	80	80	100%
Depression†	–	–	–	142	140	99%
Exercise‡	–	–	–	142	142	100%

†Usual-care depression scores were not available for the control group because patients were screened for depression as part of the recruitment process. ‡ Baseline exercise rates were not available for the control group. * The total number of patients for whom checks could be performed (N) varies as not all checks were required for patients without diabetes. § n is the number of patients for whom checks were performed.

Discussion

The TrueBlue model was successful in its primary aim that patients using its model of care showed a clinically- significant improvement in depression (207). Improved 10-year cardiovascular risk, exercise rates, and referrals to exercise programmes and mental health workers were also observed. Personal lifestyle goals were set by almost all (96 per cent) of intervention patients. Nurses, GPs, and patients found that the care plan provided a structure for teamwork and communication between the healthcare providers and patients, and the information and prompts within it ensured a comprehensive approach to care (231).

The prompts in the care plan ensured that the practice nurses were able to successfully perform the combined- guideline-recommended checks for CHD, diabetes, and depression management, with a near-complete reporting of the recommended checks in the intervention group (Table 7). This contrasts with the reduced level of reporting observed in the usual care undertaken by the control group, especially for eye and foot checks. This may be simply due to control clinics not reporting existing data but our "usual- care" rates are consistent with those reported for blood pressure (93 per cent), renal function (69 per cent), HbA1c (82 per cent), and lipids (90 per cent) observed in a recent study of patients with diabetes (255) prior to an audit cycle with training in the management of diabetes.

Rates of depression screening in usual care could not be obtained in the control clinics because their patients were screened and their scores recorded as part of the recruitment phase. However, rates as low as 19 per cent in usual care have been reported (256).

Multimorbidity shifts the focus from an index disease to the cumulative combination of many diseases (257). Consequently, patient priorities will be a greater part of the decision- making process. Our care plan ensured that patient priorities and goals were identified for almost all patients.

Care plans can be generated online (256), but there are difficulties because online systems must be general enough to encompass all likely variations in data, leading to complex data entry. Consequently, the care plan used in the TrueBlue study was deliberately incorporated into the letter-writer component of each practice's clinical software that automatically populated the care plan with existing data from the electronic medical record and additional measures obtained during each patient's visit. It also generated a table of de-identified data that could be exported to the research team. Automating these tasks made time available to the practice nurses to build therapeutic relationships with their patients.

To allow patients to be more proactive in improving their health, it was important that the care plan be kept short and non-technical with a view to being readable by the patient so that they had an overview of all their medical conditions. However, it was also important that it still remain a useful summary for the patient's clinical team.

When designing a care plan where multiple guidelines conflict in their advice, GPs will need to use clinical judgement to determine which targets should be followed (246, 248). However, a well-constructed care plan developed using clinical judgement can assist GPs to undertake these tasks. GPs will need to use their skills as generalists and their expertise in longitudinal care together

with their unique knowledge of each patient's history to best manage the complexities of multimorbidity.

Several components should be considered when developing the care plan. The following items were found to be necessary to achieve the improvements that were observed in the TrueBlue study:

- Multiple guidelines need to be formulated into a single care plan into which practice nurses collate and enter information. GPs will need to use clinical judgement to determine which targets should be followed.
- Patient priorities need to be determined and SMART goals developed and written into the care plan to assist GPs to make appropriate clinical decisions. This requires that nurses be trained in effective goal setting and problem solving.
- Patient goals and priorities need to be reviewed and updated in the next appointment and the care plan updated.
- The care plan should automatically timetable recall visits to ensure ongoing continuity of chronic disease management.
- The care plan should assist with case-management tasks by documenting referrals to other healthcare specialists, acting as a communication tool between the healthcare teams, and allowing referrals to be monitored over time.
- The care plan should provide a succinct summary of healthcare information, management targets, and personal goals to enable patients to proactively self- manage their care, while simultaneously providing important information useful for emergency hospital visits or for visits to external health providers.

- The care plan should contain automatic prompts so that all recommended checks are performed and data entered into the clinic's medical records.

The next steps are to extend the care plan and the TrueBlue model of care to cover a broader range of co-existing chronic diseases while still using the practice nurse as case manager and the care plan as the communication tool. Practice nurses will continue to play a central role in collating information from multiple sources and coordinating referrals. The extension of the TrueBlue training package will equip practice nurses to help patients set effective goals and identify priorities. GPs will be assisted with protocols for de-prescribing to reduce the harm from polypharmacy and align medications with identified patient priorities rather than following a range of separate single-disease guidelines. Patients will continue to receive the individualised care plan that provides an overview of all their medical conditions and clearly states their priorities and the steps to be taken to achieve them. Monitoring will be focused on reducing harms, maintaining function, and achieving the patient's priority outcomes.

Conclusions

A care plan was designed to contain automatic prompts to ensure that all recommended checks formulated from separate chronic-disease guidelines were performed during the consultation. The care plan was designed to be a patient-readable summary of their medical conditions, while still remaining a suitable summary for the health team of information coming from multiple sources. It involved the participation of patients in the management of their diseases and

summarised their priorities. The care plan was used successfully in the management and prioritisation of depression, diabetes, and heart disease during the TrueBlue study.

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PEER REVIEW

Not commissioned. Externally peer reviewed.

CONFLICTS OF INTEREST

The authors declare that they have no competing interests.

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ETHICS COMMITTEE APPROVAL

Ethics approval was obtained from Flinders University's Social and Behavioural Research Ethics Committee, approval number 4164.

(Figure 9) The care plan template used by TrueBlue

This template can be adapted to include other guidelines and relevant local information as required. Items in double-angle brackets were populated automatically from each practice's electronic medical record and from data entered during the consultations.

<<Practice Name>>

<<Practice Telephone>>

<<TRUEBLUE Care-plan/Review>> (<<Diagnosis>>)

This plan should help you to better understand diabetes and heart disease. It should help plan your preventative care. Leaflets about diabetes, diet, exercise, foot care, and heart disease can be attached to this record.

Patient's Name: <<Patient Full Name>> **Date of Birth:** <<Patient DOB>>

Goals to help minimise my risk factors, with help from the practice nurse and my GP:
<< Guideline based clinical and lifestyle targets>>

Patient goals for the next three months:

Goal – what change do I want to achieve and why?	Barriers – what will make it difficult?	Enablers – what will help?
<<Goal 1>>	<<What makes it difficult 1>>	<<What will help 1>>
<<Goal 2>>	<<What makes it difficult 2>>	<<What will help 2>>
<<Goal 3>>	<<What makes it difficult 3>>	<<What will help 3>>

Three-month review:

Previous goal 1	<<Previous goal 1? Met/partially met/renegotiated>>
Previous goal 2	<<Previous goal 2? Met/partially met/renegotiated>>
Previous goal 3	<<Previous goal 3? Met/partially met/renegotiated>>

Measures	Last Recorded	Previous result -Comments
Weight	<<Current Weight>> kg	
Waist	<<Waist size>> cm	Target <94 (men), <80 (women)
BP	<<Current BP>> mmHg	Target less than 130/80
HbA1c	<<Current HbA1c>>%	Target less than 7.0
Total cholesterol	<<Total cholesterol>> mmol/L	Target less than 4.0
LDL	<<LDL>> mmol/L	Target less than 2.0
HDL	<<HDL>> mmol/L	Target more than 1.0
Triglycerides	<<Triglycerides>> mmol/L	Target less than 2.0
Urine microalbuminuria	<< Normal/raised>>	
Last ECG	<<Date of last ECG>>	
Last professional eye exam	<<Last professional eye test>>	
Doppler checks of circulation in feet	L <<Doppler left Yes/No>>	
	R <<Doppler right Yes/No>>	
Foot exam (pulses, fine touch, skin and nails)	<<Date of foot exam by podiatrist, nurse or doctor>>	
Exercising	<<Exercise at/above guideline>>	Target 30 min per day, 5 days pw

Depression

Depression can be hard to detect in people with long-term medical conditions, but it can have a big impact on their diabetes and heart disease. The Patient-Health Questionnaire (PHQ-9) score helps identify those who might be at risk.

PHQ-9 score for depression	<<PHQ-9 Score>>
Previous episode of depression or anxiety	<<Previous depression/anxiety? Yes/No>>
If there were previous episodes how were they treated?	<<Treatment? None/medication/therapy/both>>
Currently taking anti-depression medication?	<<Taking anti-depression medication? Yes/No>>
Currently seeing a mental health worker?	<<Attending mental health worker? Yes/No>>

MEDICAL HISTORY << Medical history>>

MEDICATIONS <<Current Medications>>
Other medications <<Over-the-counter medications>>

ALLERGIES <<Clinical details: allergies>>

ALCOHOL <<Clinical details: alcohol>>

SMOKING STATUS <<Clinical details: smoking>>

REVIEW DATE: <<Proposed review date>>

REFERRALS: <<List of referrals and area of expertise>>

Doctor signature
Doctor name: <<Doctor Name>>
Date: <<GPMP date>>

MORE INFORMATION
www.heartfoundation.org.au
www.diabetesaustralia.com.au
www.beyondblue.org.au

Quitline call 131848

Chapter 5-Discussion

5.1 Developing TrueBlue based on theory for an Australian setting

TrueBlue was developed out of a desire to improve the management in primary care of patients living with diabetes or coronary heart disease. In Chapter 1.1-1.4 an overview of the literature described how many of these patients have co-morbid depression that often goes unrecognised despite being a major risk factor for poor self-care, increased morbidity and disability. In TrueBlue, co-morbid depression was identified using a simple and reliable self-administered depression-screening tool, PHQ9 (54).

Chapter 1.5 explored how identifying depression and informing GPs does not adequately improve outcomes. Therefore a system of care delivery is needed that supports the management of co-morbid depression (64). This holds true despite identifying optimum points in a patient's journey through the health system, informing GPs of the depression screening result and guidelines for action. This problem is described in published articles that are reproduced in Appendix 1 and 2 of the thesis.

Chapter 1.6 presented evidence that patients with long-term conditions have a preference for patient-centred care in which their problems are addressed rather than just disease-specific targets. TrueBlue identified needs and problems using a comprehensive assessment protocol that included: medical records; pathology results and physical measures; responses to individual questions in

the PHQ9; and psychosocial enquiry. Nurses were taught to enquire about: problems with activities of daily living; problems adhering to the medical plan; attendance at external appointments; and barriers experienced following lifestyle advice.

Patients with chronic disease have a preference for more contact time with their health providers. In TrueBlue each visit was scheduled for 45 minutes with the practice nurse then 15 minutes with the GP. Additional telephone support from the practice nurse was made available. GPs could bring the patient back for further appointments according to need. Usual care involves episodic *ad hoc* 15-minute GP appointments. Qualitative review of TrueBlue in chapter 4.3 suggested this additional time was welcome.

Chapter 1.7 explored the use of computers in Australian general practice. Computerised medical records that use searchable disease labels allow primary care clinics to generate disease registries. These registries can be used for a population approach to disease management. They enabled patients with diabetes and heart disease to be identified in both the exploratory trial described in Chapter 3 and TrueBlue trial described in Chapter 4. Medical software programs used by Australian GPs also enabled the generation of clinical summaries that were built into the care plan templates used in TrueBlue. Chapter 2.3 (and Appendix 3) presents a more detailed exploration of the functionality of GP computer systems in one GP clinic. Hidden behind the user interface, clinical information is contained in an extensive spreadsheet. Inbuilt search tools allowed this spread sheet to be interrogated to reveal the clinic's

performance against chronic disease management indicators. It was clear that there was room to improve the management of diabetes and coronary heart disease. Only 19.2% of patients diagnosed with diabetes or coronary heart disease were being screened for depression. The results demonstrated a need for changed systems of care. The techniques for conducting electronic audit described in Appendix 3 were used to monitor performance in TrueBlue.

Chapter 1.8 reviewed the role of practice nurses in primary care. Nurse involvement in chronic disease management programs was both feasible and acceptable. In Australia, any new model of care for chronic disease needed to be designed with existing members of the workforce because of funding and workforce constraints. Practice nurses were working below their scope of practice as GP 'handmaidens'. TrueBlue was designed to train nurses for new roles as care coordinators capable of monitoring depression and assisting patients with lifestyle interventions. The exploratory trial described in Chapter 3 examined the feasibility of this approach.

Chapter 1.9 discussed the evidence and experience of incentives and payments to fund and encourage proactive chronic disease management. In TrueBlue funds were not available to pay for practices to be part of the study. In order for any system redesign to be sustainable the project needed to be cost-neutral or better for the clinics. GPs in Australia work on a fee-for-service basis. TrueBlue intervention was specifically designed to maximise the opportunity for GP clinics to claim Australian Medicare fees for chronic disease management. Initial visits enabled clinics to claim for completion of GP Management plans, Team Care

Arrangements, completion of annual cycle of diabetes process of care and direct fees for contribution of practice nurses to chronic disease. Clinics were able to claim fees for electrocardiographs, assessment for peripheral vascular disease with Doppler and fees for conducting influenza and pneumococcus immunisations. Review appointments were timetabled at three months to fit with the shortest interval allowed under Medicare for review of chronic disease plans. Although economic assessment was not part of the evaluation of TrueBlue the theoretical sum of these claimable fees more than covered the cost of additional nurse and administrative time. In the TrueBlue study there were no direct payments for improving clinical outcomes such as control of blood pressure. The expectation was that a systematic approach to highlighting, within the patient-held care plan, where action was needed to achieve guideline-based 'best practice' would be sufficient. Currently the Royal Australian College of General Practitioners does not support pay for performance (258).

Chapter 1.10 described the use of care plans in chronic disease management. Worldwide, care plans are used in only a minority of primary care patients with chronic disease. Where care plans are in use, they rarely reflect patient priorities, goal setting or psychosocial aspects of disease management. In TrueBlue the care plan template was written with multiple purposes in mind. These are described in Chapter 4.4. The care plan was designed to provide: clinical summary information; check list of 'best practice' guideline-based care requirements; direction and written summary of a patient's personalised goal setting; record of progress over time in achieving these goals; and summary data for the research team.

Chapter 1.11 reviewed the literature for patient-self management support. In TrueBlue nurses used a library of patient information leaflets and a network of local allied health and community resources to help patients achieve their goals. Patients received information about disease management targets, monitoring frequency and lifestyle recommendations that were built into the care plan. Barriers were assessed and achievable, realistic goals set.

Chapter 1.12 reviewed the evidence for stepped care management of depression in which there are regular reviews of depression using a validated tool. When there has been insufficient response to treatment, action is taken to either increase the dose of treatment or add in a further treatment modality. This approach has been shown to be more effecting than the 'set-and-forget' model of depression management in which patient adherence to the treatment plan is low (175). The most effective treatment of depression occurs with stepped care when patients have a choice of treatment modality. Within the protocol for TrueBlue, patients were reviewed every three months using PHQ9. If depression had not improved or if there was a positive answer about suicidal thoughts, the GP was alerted. In TrueBlue, patients, together with their GP and practice nurse, were able to choose behavioural activation activities, referral to a mental health worker or change in medication. Self-reported adherence to the chosen plan was recorded. Practice nurses facilitated referral to a mental health worker by assisting GPs to write a GP Mental Health Plan that is required to access Medicare rebates for seeing a psychologist. The results of TrueBlue in Chapter 4.2 show that at baseline only one fifth of patients referred to a mental health

worker had attending in the previous three months. After six months of collaborative care, 64% of referred patients were attending.

Chapter 1.13 described the ingredients and evidence for the Chronic Care Model (1) for the management of long term medical conditions in primary care. True Blue protocol was designed to incorporate all the ingredients of this model of care:

- Use of community resources. Practice nurses in TrueBlue established referral pathways to allied health services. Nurses enquired about attendance at subsequent appointments and made the necessary arrangements for the patient to be able to claim Medicare rebates for allied health. As part of the training for TrueBlue, nurses established a local resource folder with options for behaviour activation such as walking groups.
- Self-management support. Within TrueBlue patients set goals, explored barriers and facilitators to these goals and at follow up appointments, achievement and appropriateness of these goals were reviewed. The patient-held care plan outlined results of pathology testing and physical measures in relation to disease-specific clinical targets. The plan also outlined recommended frequency of testing and other health maintenance tasks. Patients reported to nurses that they used this information to be 'on the same page' as their GP.
- Continuous quality improvement. In TrueBlue this was achieved by submission of de-identified patient level data through a data-checking program. Any missing data or misplaced decimal point within the data

was fed back to practice for correction. Practices were also informed if patients were overdue for follow up visits. In this way the process of care was standardised.

- Decision support for clinicians. At each quarterly visit, GPs received a draft care plan from the practice nurse in which pathology results, physical measures and recommended activities were collated. The care plan listed disease specific targets and recommendations from evidence-based guidelines.
- Team approach to care delivery. In TrueBlue there was a shift from episodic care triggered by patients making appointments with their GP when the need arose to scheduled care by practice nurse followed immediately by a GP visit.
- Clinical information systems. In TrueBlue practices were aided to develop disease registries to use for patient recruitment. They were helped to set up systems of reminders and recall to provide scheduled follow up visits. Pathology testing was arranged prior to patient appointments and then results were collated to make it easier for the GP to make clinical decisions.

Chapter 1.14 and 1.15 described the nature of collaborative care for depression and the wealth of evidence for its effectiveness in the treatment of depression. The chapters also explored the remaining questions about the effectiveness of collaborative care and its applicability in patients with physical co-morbidity and in settings outside the USA.

TrueBlue was designed to incorporate all of the ingredients contained in the most accepted definition of collaborative care (2):

- Multi-professional: in TrueBlue practice nurse and GP worked together with external referral to a psychologist when appropriate. Nurses were also supported by having access to a monthly teleconference attended by the research GP and a psychologist.
- Structured system of care using guidelines or protocols. In TrueBlue the care plan template was used as a tool to encourage protocols to be followed. There was a project manual that described the theoretical underpinnings of TrueBlue and details about organising clinics.
- Scheduled follow up. This occurred every three months.
- System for enhanced communication. The care plan again became the tool for enhanced communication as a patient-held summary, record of progress and a place where collated information could be recorded.

5.2 Outcomes of TrueBlue

Chapter 4 reproduces papers describing the outcomes of TrueBlue. The primary outcome was improved mean depression score at six months in the collaborative care intervention group compared with usual care control group. Secondary outcomes in the intervention group included: reduced cardiovascular risk for diabetes patients; intensification of stepped care treatment; closer adherence to best-practice guidelines; improved quality of life in both physical and mental health domains; enhanced goal setting; development of a multipurpose multi-disease care plan; high levels of acceptability amongst GPs and practice nurses;

and safe management of patients with suicidal thoughts uncovered by use of PHQ9 questionnaire.

5.3 Limitations of TrueBlue

Limitations of TrueBlue design

This thesis describes the steps taken to introduce and evaluate a complex intervention. These steps follow the model complex intervention design adopted by the Medical Research Council in 2000 (7). There was a subsequent model that describes how the design of complex interventions could evolve (259). Rather than a linear progression through design stages, the outcome of subsequent steps might require further modelling of components or a further evaluative trial. For example, in the exploratory trial (Chapter 3) few patients were seen for follow up visits leading us to use recall and reminder systems in the definitive randomised trial. Ideally this approach would have been tested in a re-run of the exploratory trial. Funding of our trials did not allow further evaluation of components. In the 2008 Medical Research Council recommendations for complex intervention research, it was suggested that implementation would be more practical if local circumstances were allowed to alter the delivery of the intervention (259, 260). In TrueBlue, nurses and doctors engaged available community resources, allied health and mental health workers so the intervention experienced by patients varied from site to site.

TrueBlue was a cluster-randomised trial with a comparison between outcomes of the intervention and usual care after six months. When recruiting practices to the trial, doctors were concerned that their site might be randomised to the

control arm of the study. The doctors had a preconceived notion that TrueBlue would be beneficial for their patients and perhaps also financially beneficial. It was a condition of their agreement to participate that the maximum delay before starting collaborative care would be six months. It is a weakness of the design of TrueBlue that the comparison between intervention and control was after this relatively short-term exposure to collaborative care. Primary care research commonly faces this dilemma where the prior belief of doctors and patients has an effect on the decision to participate (227). One approach to this problem is the 'stepped-wedge' trial that allows staged introduction of the intervention. Sites are randomly allocated to a commencement time. Outcome measures then occur at pre-determined intervals after commencement. One advantage is that likely beneficial interventions can be investigated without subjects running the risk they will be allocated to a control group. Another advantage is that staged commencement might be logistically easier to deliver than simultaneous commencement (261). Problems can arise with stepped-wedge trials if the intervention fidelity is not maintained causing a drift in effect size over time (262). Stepped-wedge design would have allowed baseline data to be collected prospectively for each staged commencement. In TrueBlue, control site baseline data was collected retrospectively. Differences in baseline data might have occurred because of differences in the collection method.

The control arm of the TrueBlue randomised trial was usual care enhanced by informing the doctors the results of the patient's postal PHQ9 score. Patients and doctors in the control group had read the study rationale and protocol. It is possible that awareness of the importance of co-morbid depression and the

presence of co-morbid depression would influence usual care. Chapter 1.5 of this thesis explores how simply screening for depression has limited impact. In one of our modelling trials there was little action taking by general practitioners for depressed patients recovering from acute coronary syndromes (Appendix 2). Usual care in TrueBlue was not defined. Measurements were limited to retrospective collection of patient data. It is a common fault of trials reporting the outcomes of collaborative care that usual care is inadequately defined (213). Without a precise description of usual care, trials such as TrueBlue cannot inform doctors whether or not their patients would be better off if the collaborative care intervention was implemented. It is not known whether TrueBlue is better than excellent usual care.

Limitations of TrueBlue outcome measures

The outcome measures of complex health care interventions ideally include: clinical outcomes; patient reported outcomes; patient experience outcomes; health economic outcomes; impact on stakeholders; harms; and unintended consequences (263). Process evaluation will identify: barriers and enablers; how the intervention works; and why the intervention works (264, 265). The potential to implement the complex intervention will depend on: where it works; for which patients; how well the processes can be normalised; and what are the maintenance requirements to keep it working (266, 267).

In TrueBlue, health related quality of life, assessed in the intervention group only using SF36, was the only patient reported outcome measure (268). There was no measurement of patient empowerment or self-efficacy. The components of self-

efficacy include: setting of personalised lifestyle goals; recognising the impact of behaviour on health; the skills and confidence to manage the health condition; and the ability to adhere to disease management over time (269). Practice nurses addressed these components so ideally an assessment tool should have been used to measure their effectiveness.

TrueBlue was inadequately resourced to interview patients or to hold focus groups to gather the patient perspective of the intervention. Patient reported experiences of care could have been assessed using self-reported tools to assess: satisfaction; patient-provider interactions; and the extent to which care followed the Chronic Care Model (270, 271).

TrueBlue was not resourced to run an economic evaluation of the intervention. Part of planning for implementation of a complex intervention requires the financial impact on stakeholders and the health system (2). We were able to assess the nurse time to conduct research tasks to confirm, at a clinic level, the intervention was adequately renumerated from Australian Medicare chronic disease items numbers.

The impact of TrueBlue collaborative care on clinics was only addressed by questions asked during structured interviews and the focus group reported in Chapter 4.3. No measure was made to determine if there were benefits or harms to the usual running of clinics. For example, practice nurse protected time for the TrueBlue intervention might have meant less availability for other tasks. Enhanced nurse-GP collaboration for TrueBlue patients might have improved

team working within the clinic. A more comprehensive qualitative analysis of doctors and nurses would ideally have been based on grounded theory and continued until saturation point (272, 273). No data was collected about the impact of TrueBlue on allied health, community resources, mental health workers or specialists who all form part of the extended health care team.

Harms of collaborative care were not recorded so, for example, it is not known if treatment intensification led to increased medication side effects.

Process evaluation of the collaborative care intervention was limited in scope. We examined the adherence to best-practice guidelines. We also identified which patients were referred to and which patients attended mental health workers and exercise providers. The details of what happened during consultations with these external providers or the duration and frequency of appointments were not established. We were able to capture limited information about how TrueBlue patients were managed by their doctors. Starting a new antidepressant medication was noted but changing from one antidepressant to another, or increasing the dose was not. There was no assessment of medication changes to achieve better disease control for the physical co-morbidities. It was not possible to trial many different versions of the intervention and then analyse which components are most likely to have resulted in the measured outcomes. This means there are gaps in knowledge about which components form the core requirement for the intervention to be implemented.

Sources of bias in TrueBlue

The Cochrane Collaboration has developed a tool for assessing bias in randomised trials that provided the following framework for assessing risk of bias in TrueBlue (274).

Selection bias between intervention and control clusters (clinics) was reduced by the use of a random number generator. Once selected, clinics were made aware to which arm they were allocated with no attempt at allocation concealment because planning was required for staff training. There was additional risk of selection bias in the subsequent recruitment of patients (275). Patients may have become aware whether their clinic was in the intervention arm or the control arm of the trial. With this information patients could self-select whether to participate or not. Since no detailed information was collected about non-responders, who did not consent to be part of the trial, it is unknown if they differed between intervention and control clinics.

Performance bias may have occurred in TrueBlue because both the patients and clinic staff were aware of their allocation to either intervention or control. Members of the health care team and patients may have responded differently to individual components of the intervention because of the lack of allocation concealment. Patients vary in the extent to which they wish to present themselves in a positive light. This 'social desirability' responding bias could have affected outcome results for self-reported measures in TrueBlue such as exercise rates. We did not attempt to verify exercise rates with objective

measures (276). There was no attempt to stratify patients into high or low social desirability categories to determine the impact of this source of bias (277).

Detection bias was a risk in TrueBlue because we relied on practice nurses to record outcome measures. For control clinics outcome measures were collected from routinely recorded data retrospectively. If data was favourably recorded by nurses this would introduce bias in favour of the intervention. Patients may have responded to questions in a way to maximise approval of the practice nurse. This 'social approval' bias might have favoured the intervention for all non-physical measures (276).

There was a potential for attrition bias in TrueBlue because some data could not be collected from patients who dropped out of the study so it is not known if these patients differed between intervention and control. The impact of this bias was reduced by using 'intention to treat' analysis in the statistical examination of results of those patients who commenced the trial. The loss of the Melbourne cluster after randomisation but prior to patients commencing the trial was not included in the intention to treat statistical analysis.

Reporting bias was minimised by tabulating the results of multiple measures for each participant. There has been a call for collaborative care trials to report remission rates in depression but in TrueBlue this was not calculated (2). Subgroup analysis of patients who had moderate to severe depression was reported. This retrospective subgroup analysis was performed to allow

comparison of TrueBlue outcomes to other trials but ideally this sort of analysis should be part of the study protocol from the start.

Other sources of bias include regression to the mean. We selected patients who returned a PHQ9 suggesting depression. Ideally this base-line test would have been repeated several times to minimise the statistical tendency for subsequent repeated measures to approach the mean. By selecting outliers with high depression scores for inclusion into TrueBlue, improved scores can be partly attributed to this effect (278). The effect of regression to the mean was controlled for by having randomly allocated control arm of the trial. Using analysis of co variables (ANCOVA) statistical tools also helped to reveal the differences between intervention and control.

Limitation of TrueBlue trial to inform implementation of collaborative care

Trueblue was designed and tested in small single-GP practices and large group practices in both rural and urban areas of Australia. There were selection criteria for practices that would influence the applicability of the results to other settings. All the practices were in Australia where patients can access Medicare items for chronic disease management sufficient to fund 45-minute nurse consultations followed by 15-minute GP consultations every three months. Not all GP practices have access to a practice nurse. The use of GP clinical software program was required in order to generate care plans. Not all GP clinics have computers containing patient health summaries.

Although TrueBlue collaborative care used existing workforce there was external support provided to train practice nurses for their new roles, to assist clinics

with setting up appointment schedules, sending recruitment letters to patients and installing the TrueBlue care plan template. Any implementation of TrueBlue would need to consider reproducing these external supports.

Melbourne practices recruited very few patients and then withdrew from the project. It is not known why the recruitment strategy that worked elsewhere failed in Melbourne. When the research team visited Melbourne practices, GPs and practice nurses were positive about the rationale for TrueBlue, but stated that their patients were not interested in joining the project.

TrueBlue recruited some patients with mild to moderate depression, scoring greater than 4 on the PHQ9 but less than 10. The change in mean depression score in this subgroup of patients who had mild to moderate depression was not statistically different between intervention and control group so it is not possible to claim that mild-moderate depression is better treated by TrueBlue care.

Lastly the TrueBlue care plan template specified disease management targets for depression, type2 diabetes and coronary heart disease. Many patients will have additional long-term medical conditions. To formulate a comprehensive management plans for these multimorbid patients required practice nurses and GPs to add additional management targets. It would have been convenient to have pre-formulated management targets for the common long-term medical conditions that could have been added to the care plan automatically. In order to maintain patient confidentiality comprehensive lists of patient medication and medical history was not made available to the research team. It is not known if

there are particular combinations of co-morbidities that impede or enhance the outcomes of TrueBlue collaborative care.

5.4 Where TrueBlue now fits in an international context

Since TrueBlue commenced there have been international examples of the use of collaborative care for depression and chronic diseases. In 2014 Atlantis systematically reviewed trials of collaborative care for diabetes and depression, identifying TrueBlue and six USA trials (3). Two additional trials conducted outside of USA have been recently reported (64, 279). The standardised mean difference in collaborative care for depression was -0.32 and HbA1c was improved -0.33%. In TrueBlue the effect size for depression was -0.35 and for HbA1c was -0.5%. Table 8 describes the trial included in the meta-analysis and the additional two trials reported subsequently.

Table 9. Randomised trials of collaborative care for depression and diabetes

Author	Study description	Key findings	Comment
Katon (180) (Pathways study)	N=329, USA primary care clinics, based on IMPACT model. Stepped care by specialist nurses and GP. Offered problem solving, antidepressants and step up to psychiatrist.	Depression improved. HbA1c (diabetes) did not.	Moderately intense depression-focused intervention but not managing physical chronic disease.
Williams (179), IMPACT	N=293. USA. Intervention as above. Average 9	Depression scores improved. Exercising	Intense depression collaborative care had little impact on

study diabetes subgroup	visits and 5 telephone contacts over 12 months.	improved. HbA1c did not.	self-care activities and no impact on diabetes.
Piette (280)	N=291 USA. Telephone cognitive-behavioural therapy (average 13 contacts) and pedometer-monitored walking.	Improved depression remission rates. Improved systolic blood pressure and increased walking. No impact on HbA1c	Nurse to GP communication related to depression management only. (This study was omitted from Atlantis systematic review)
Ell (281)	N=387 USA. Hispanic patients. IMPACT model delivered bilingual by depression and diabetes trained social worker	Depression remission rates and scores improved. Improved social and physical functioning, emotional and physical quality of life. No impact on self-management or HbA1c	Collaborative care for depression can be tailored for low social economic groups in USA. No specific diabetes management component and no diabetes outcomes.
Katon (217) TEAMcare study	N=214. USA. Poorly controlled diabetes &/or coronary heart disease. Nurse delivered guideline-based physical disease and depression. Average 10 visits and 11 calls over 12 months	Depression improved. HbA1c improved. Cholesterol improved slightly. Treatment intensification was noted.	High intensity intervention achieved depression and diabetes improvements in high-risk patients.
Bogner (282)	N=58 USA. African Americans from a single practice. Self-management support 3 visits and 2 calls in 12-week intervention.	Adherence to depression and diabetes medications improved. Depression and HbA1c improved.	Short-term intervention that lifted medication adherence from a low 10% (depression) and 24% (diabetes).
Bogner (283)	N=180. USA. Self-management support for diabetes and depression. 3 visits and 2 calls over 12 week.	Adherence to medication improved. Depression remission and mean scores improved and HbA1c improved	Short-term intervention addressing barriers to taking medication. Approximately doubling adherence that might be the

			only explanation for clinical outcomes.
Johnson (64) Non-randomised comparison trial	N=157. Canada. Nurse developed care plans following TEAMcare model of contacts every2-4 weeks.	Depression scores improved. No biophysical changes or quality of care changes were seen.	Comparison trial of moderately intense self-management support that did not replicate positive outcomes of TEAMcare
Coventry (279) COINCIDE trial	N=387 UK. Diabetes &/or coronary heart diseases and major depression. Choice of brief psychological therapies,8 sessions. Liaison to practice nurse.	Depression scores improved at 4 months. Quality of life and disability scores were unchanged.	Trial focussed on improving mental health and patient-centred care. Biophysical measures were not reported.

In 2015, Tully conducted a systematic review of collaborative care for depression and coronary heart disease identifying TrueBlue and five USA trials (284). These have been collated and described in table 9. The standardised mean difference for collaborative interventions was -0.31 similar to the effect size in TrueBlue of -0.35. Some trials also reported remission rates in depression. In the meta-analysis the Odds ratio of remission was 1.77 when compared with usual care. The rate of new cardiac events was reduced for collaborative care early after the collaborative care intervention but this was not sustained for long-term follow up.

Table 10. Randomised trials of collaborative care for depression and coronary heart disease

Author	Study Description	Key Findings	Comment
Rollman (285) Bypassing the Blues study	N=302. USA. Patients recruited at time of CABG. Nurse-led care plans, close liaison with GP. Average 10	At 8 months, Depression severity, mental and physical quality of life had improved.	Depression focused collaborative care with emphasis on case-management

	telephone contacts.	Biophysical measures not reported	to ensure follow up.
Davidson (286) COPES trial	N=157. USA. Persisting depression after acute coronary syndrome. IMPACT model of problem solving &/or medication stepped care. 6-19 contacts depending on treatment modality.	Depression scores improved. There were 3 new cardiac events in the intervention, 10 in the usual care controls.	Depression focused intervention that might have also reduced new cardiac events.
Davidson (287) CODIACS vanguard trial	N=150. USA. Intervention similar to COPES trial	Depression improved. Healthcare cost neutral at 6 months.	Described as a feasibility study of collaborative care.
Huffman (288) SUCCEED trial	N=175. USA. Cardiac patients hospital-based collaborative care to design depression care plans for discharge	Primary endpoints were adequacy of depression plan. At 12 weeks depression was adversely associated with poor adherence to medication and lifestyle changes.	Although this intervention was collaborative care it was a short term intervention in hospitalised patients.
Huffman (289) MOSAIC trial	N=183. USA. Patients admitted with a cardiac diagnosis. Most advised to chose antidepressant medication. Low intensity cognitive behavioural therapy by social worker 1 visit, average 3 calls.	Depression scores reduced and mental health component of quality of life improved.	Low intensity intervention that ensured in-patients were discharged with an adequate depression treatment plan.

Randomised trials of collaborative care for depression and other chronic diseases

A systematic review by Ekers in 2013 of collaborative interventions using nurses for long term physical conditions identified TrueBlue and 13 other trials of which 11 were conducted in USA (172). The trials of depression and other long term physical conditions are listed below.

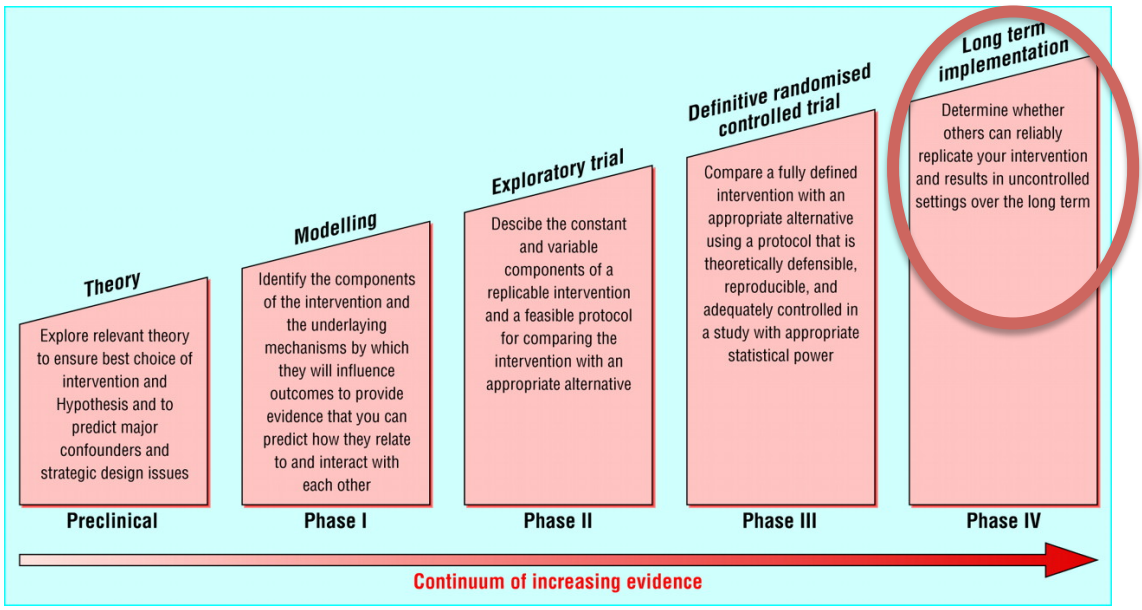
1. Lin (290) examined outcomes in a subset of patients with arthritis from one of the seminal collaborative care studies of depression called IMPACT (6). Pain reduced on average by half a point on a 10-point scale and there was an increase in functional status and quality of life.
2. Williams (291) conducted a trial of post stroke patients and demonstrated a 12 week collaborative care intervention improved depression scores.
3. Strong (292) showed collaborative care using cancer nurses could improve depression in Scottish patients with cancer.
4. Kroenke (293) conducted a trial in veterans with chronic pain that examined the impact of collaborative care depression management followed by pain self-management support. Depression and pain were both improved.
5. Mitchell (294) used an 8 week intervention for post stroke patients that showed lasting benefits for depression.
6. Kroenke (295) reported telephone delivered nurse intervention for cancer patients with pain. Both pain and depression improved.
7. Lamers (98) examined the impact of 4 hours of cognitive behavioural therapy on over 60 year olds with chronic obstructive pulmonary disease or diabetes in the Netherlands. Depression and both mental health and physical domains of quality of life improved.
8. Pyne (296) reported collaborative intervention for patients attending HIV clinics. Disease impact was reduced and depression improved at 6 months but not 12 months.

These trials of collaborative care for co-morbid depression mostly used PHQ9 for depression diagnosis and monitoring. Psychological interventions varied including cognitive behavioural therapy, problem solving, psycho-education and behavioural activation. The effect size of a meta-analysis reported by Ekers et al was 0.43 in favour of collaborative care compared with usual care (172). The effect size of the two trials of collaborative care for patients with painful conditions (290, 293) was greater than other co-morbidities possibly because chronic pain and depression are co-dependent (297). The effect size in TrueBlue, which was included in the meta-analysis, was similar to other trials at 0.35.

The conclusion that can be drawn from this extensive literature is that collaborative care can achieve improved depression outcomes and some improvements in physical co-morbid conditions. Integration of depression care with management of the chronic physical diseases helps both.

5.5 Implementation and sustainability of collaborative care

(Figure 10) Development of randomised controlled trial of complex interventions –implementation (7)



Recruitment and retention of GP clinics

Recruiting GPs to be involved in research projects is notoriously difficult because GPs have multiple conflicting calls on their time and attention (298). Consultation patterns are repeated so frequently that they become habitual and any change in pattern of consulting comes at an increased effort (299). Research into maximising recruitments and retention of GPs in clinical trials is often an afterthought to salvage some insights from a difficult process. Dormandy reported that there were three factors that led to successful recruitment (300). Firstly the topic of study had to be of interest to the GPs. Secondly the invitation information for GPs needed to be clear and concise. Thirdly, targeting GPs who already had an interest in research was beneficial. In the evaluative trial and TrueBlue the research was focused on ways to help the most difficult subset of patients with coronary heart disease or diabetes. These patients were failing to achieve disease management targets and using increased resources so the topic of research was of interest. Secondly invitation was multifaceted using succinct brochures and short evening or lunchtime meetings with the GP researcher from the team leading the discussion with his peers. Similarly, nurses who had worked in clinics during the evaluative trial were engaged to recruit and train nurses in TrueBlue in a model of peer-to-peer learning. The research team employed local facilitators in each geographic region who had working experience of the practices through Divisions of General Practice. This is a strategy that was subsequently successfully employed by Reed et al. (301). In the evaluative trial practices were approached who had successfully completed the first wave of the Australian Primary Care Collaboratives. These practices were

therefore experienced at methods for improving population health by use of disease registries and computer generated performance indicators. They were used to using plan-do-study-act change methodology and they had some experience of team approach to care. The biggest difficulty encountered was gaining acceptance from practices that they might be randomly allocated to the control group. This was made harder after explaining the theoretical underpinnings of collaborative care and the potential benefits for the patients and clinics. Control practices were offered the training package and assistance implementing TrueBlue at the end of data collection comparison period.

Retention of GPs in clinical trials depended on three factors (300). Firstly there was a need for ongoing communication with the research team. Secondly it was important that data collection was kept simple and thirdly payments were recommended for reaching agreed targets. TrueBlue research team communicated with GP clinics via monthly teleconference with the practice nurse and more frequent contact with local facilitators. Feedback of missing data or incorrectly entered data or patients late for follow up was also provided. Data collection in TrueBlue was designed to minimise duplication. Within the care plan template data was self-populated from the clinical record as much as possible. Manual entry of measurements and some pathology items and external appointment information was prompted. A copy of all data points was automatically reproduced and added into a spreadsheet using a unique patient identifier. TrueBlue practices were not paid directly for their work but they were facilitated in claiming Medicare items. In a survey of Australian GPs

contemplating involvement in research direct payments were the least important facilitator (299).

Recruitment and retention of patients enrolled in TrueBlue

Patient recruitment into clinical trials can also be difficult, particularly for patients who have established patterns of accessing care (302). In TrueBlue successful strategies included a plain language statement describing the project and its aims. This appealed to the twin drivers of recruitment – altruism and personal benefit (303). Invites were personally addressed and endorsed by the patient's usual GP to improve recruitment rates (304). Reminder postcards were sent following invite letter. The practice nurse who had completed TrueBlue training was available to answer questions from prospective patients.

Retention of patients within a trial depends on perceived value of the service compared to the cost, effort and time to attend (305). The service cost was covered by Medicare rebates so participation did not increase out-of-pocket expenses for patients. Patients valued contact with the nurse and the patient-centred approach to care as well as provision of a folder with self-management and psycho-education materials. In contrast to the exploratory trail (Chapter 3) follow up appointments were made at the time of each visit.

Dissemination of TrueBlue

Wider implementation of collaborative care for comorbid depression requires dissemination of the outcomes to physicians, local health care organisations and national policy makers. TrueBlue outcomes have been published in widely cited peer review journals. The outcomes have been presented at conferences in Australia, UK and North America. Meetings with policy makers in Australia and submissions to National reviews of chronic disease management have helped disseminate the evidence of effectiveness. Outcomes of this dissemination in terms of policy changes are still awaited.

Facilitators and barriers to sustainable collaborative care

Sustainability of collaborative care beyond the duration of research trials depends on having local champions prepared to maintain the fidelity of the intervention once accountability to the research team has ceased. It requires willingness of organisations to fund and support the intervention (238, 306) Collaborative care involves new roles for practice nurses for which they are trained so there will be an attrition rate when these key personnel leave the organisation (307). To counterbalance this attrition there is also the potential for diffusion of innovation. Practice nurses trained in collaborative care as part of the evaluative trial and TrueBlue report using their new skills to assess depression and to use goal setting for a variety chronic diseases beyond diabetes and coronary heart disease. Nurses also report adapting TrueBlue templates for other chronic diseases such as stroke and osteoarthritis. Nurses trained in the evaluative trial (Chapter 3) and in TrueBlue volunteered to be peer trainers for subsequent nurse training workshops.

In a study of sustainability of collaborative care in seven sites in the USA, those sites continuing were also found to have relaxed their participant criteria but lost some fidelity. For example, there was less liaison with the supervising psychiatrist (238). In a study of state-wide implementation of collaborative care for depression in the USA, anticipated improvements in depression outcomes failed to eventuate. Adoption of collaborative care was incentivised with payments but the introduction of this multifaceted intervention seemed to require ongoing external support (308). At the time of designing and conducting the TrueBlue trial it was thought that external inputs for broader implementation of collaborative care would be supported by meso-level GP organisations such as the Divisions of General Practice (and subsequently Medicare Locals then Primary Health Networks). These organisations have roles such as supporting GP clinics to improve care of chronic diseases and collation of aggregate patient outcome data for chronic diseases. The size and structure of these organisations has changed frequently limiting their effectiveness (309, 310).

5.6 Future directions

Collaborative care has been shown to be a system that can achieve improved outcomes in patients with co-morbid depression with coronary heart disease, diabetes, or both. The next phase of this research is to trial a system of collaborative care for patients with a much broader range of long-term medical conditions. Multimorbidity is defined as the co-occurrence of two or more

diseases within one person (311). In over 75 year olds the prevalence of multimorbidity is estimated to be 83% (245)

There are difficult challenges to overcome in the care of multimorbidity:

- Guidelines for disease management are written on the basis of research that has often excluded patients with multiple long-term medical conditions (246).
- Multimorbidity increases with age, many guidelines are based on evidence that excluded the elderly from trials.
- Guidelines for specific diseases can be discordant so that recommended treatment for one disease is harmful for the next (312).
- Multimorbidity often leads to polypharmacy with attendant concerns over adverse effects, drug-drug interactions, drug-disease interactions, adherence difficulties, costs to the health budget, costs to patients, increased monitoring requirements and potential for prescribing errors (313).
- Medication lists held by GPs and reproduced in summaries and referral letters differ from the list of medication being taken by patients so there is a need for medication reconciliation. In one study of patients presenting to emergency departments in Australia there were errors in 87% of GP referral letters (314).
- Coordination of care becomes more difficult when patients attend multiple specialist clinics and allied health providers.
- Complexity of GP appointments overwhelms the time available for those appointments.

- Addressing the psychosocial needs of patients, particularly co-morbid depression, becomes less likely with increasing complexity of physical needs (315).
- Gaps exist in the skills and knowledge of GPs to de-prescribe long-term medication (316). There are no clear guidelines that state which medicines can be ceased and in whom. Nor is it easy for GPs to cross reference primary evidence to inform these patients of the benefits and harms of ceasing (or starting) a medicine.

Chapter 6 Conclusion

TrueBlue collaborative care is a complex intervention that was successfully tested in a randomised trial. This thesis has examined need for better detection and treatment of co-morbid depression. The theoretical underpinnings and testing of components of the intervention have been described. A pilot project was undertaken to examine the feasibility and acceptability of TrueBlue collaborative care and outcomes from the pilot project informed the final design of TrueBlue. Collaborative care for co-morbid depression has now been tested in a variety of settings and for a variety of chronic diseases. It has yet to be widely implemented because organisational change requires external support that is not currently in place outside of clinical trials. Some GP practices engaged in the TrueBlue collaborative care model have continued the model of care because the model is funded within Medicare, uses existing clinic workforce and is highly acceptable to patients, nurses and doctors.

Managing complex chronic disease requires teamwork. There are two definitions of teamwork juxtaposed by Pearson in 1994 (Pearson and Jones 1994):

Beasts of burden yoked together

A small group of people who relate to each other to contribute to a common goal

I would like to hope that we work within the second of these definitions.

Dr Mark Morgan

Appendix 1 – Identifying co-morbid depression (reproduced verbatim)

Citation (182):

Prasuna Reddy,[1] James A. Dunbar,[1] Edward Janus,[1,2] Alan Wolff,[1,3] Stephen Bunker,[1] **Mark Morgan**[1,4] and Adrienne O'Neil[1] *Identifying depression in patients following admission for acute coronary syndrome*. Australian Journal of Rural Health (2007) **15**, 137–138.

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Introduction

Cardiovascular disease and its relationship with depression is supported by considerable evidence (317, 318). The presence of anxiety symptoms, either with or without depression, is common. A recent study of patients with coronary heart disease found 50% exhibited symptoms of depression, 70% symptoms of anxiety and 48% symptoms of stress (319). Untreated depression also results in a poorer prognosis for patients with cardiovascular problems (320). Despite the evidence connecting depression with chronic disease, there is poor recognition

and under-treatment of depression in both primary care and hospital medical practice.

Method

The purpose of our study was to trial four screening questions to identify depression and anxiety in patients admitted for acute coronary syndrome (ACS) in two rural hospitals in Victoria and South Australia. Participants included 21 women and 32 men who were interviewed at two time periods: within two weeks of discharge from hospital (Time 1), and eight weeks after the initial interview (Time 2). Participants were between 40 and 71 years of age at the time of the first interview. The screening questions assess primary symptoms of depression (dysphoria and anhedonia) (321) and anxiety (tension and fearfulness).

Results

The results show overall, within two weeks of discharge from hospital (Time 1), in response to the screening questions: 25% (n = 13/53) reported both depression and anxiety, 21% (n = 11/53) reported depression but no anxiety, and 11% (n = 6/53) reported anxiety but no depression. Only two of these patients were receiving treatment for depression.

At two months post discharge, of the 24 patients reporting depression symptoms at Time 1, nine had improved showing neither depression nor anxiety, four

showed depression only, four showed anxiety only, and the remaining seven patients showed both depression and anxiety. Two patients who showed neither depression nor anxiety at Time 1 reported depression at Time 2. None of the patients reporting depression or anxiety was receiving treatment.
Only 13 patients who had been admitted for ACS had attended cardiac rehabilitation programs; four of these patients reported depression or anxiety at two weeks post discharge. All but five of the 53 patients interviewed said they had seen their GP at least once since leaving hospital. None had been screened for depression on GP visits.

Our results show that 55% of patients who report depression within two weeks of admission to hospital for treatment of ACS improve over the next two months. However, for 45% of patients, symptoms of depression persist at two months post discharge, and 9% of those who do not show depression at admission do report depression about 10–12 weeks post discharge.

Conclusion

It might not be worthwhile to screen for depression while a patient is in hospital, but it is useful to do an assessment at two months post discharge. At this time, patients have less regular contact with specialist health professionals in hospitals. As uptake of cardiac rehabilitation programs is generally low in rural areas, partly because of distance, the other main resource for patients needing help is primary care. This is especially true for patients living in rural areas, where they are treated only by their GP. Depression is often missed in primary

care settings because of the overlap of somatic symptoms such as changes in sleeping and eating patterns, lethargy and fatigue. Patients are also reluctant to report depression because of the stigma attached to mental health problems. Using screening questions that assess the cognitive and emotional symptoms of depression will enable general practitioners and other health professionals to quickly identify patients at risk. The identification and management of depression in chronic disease needs to be routinely undertaken when reviewing these patients.

Acknowledgements

We thank the National Heart Foundation (Victoria) for funding this research, and the Department of Health and Ageing for providing funding for a research assistant through the Primary Health Care Research Evaluation Development Strategy.

Appendix 2 Implementation of a guideline to screen for co-morbid depression (reproduced verbatim)

Citation (69):

Prasuna Reddy, James A Dunbar, **Mark A J Morgan**, Adrienne O'Neil. Coronary heart disease and depression: getting evidence into clinical practice. *Stress and Health* (2008)**24**: 223–230.

Summary

Clinical guidelines based on systematic reviews of the evidence recommend identification and treatment of patients with coronary heart disease and depression. The evidence shows that depression is an independent risk factor for heart disease, and when present after an acute coronary event, is a predictor of poor prognosis. This paper will describe our experience of getting that evidence into practice using change management based on mapping the processes of the patient's journey through the healthcare system. This allowed identification of the points in the journey where screening and intervention could take place. Cardiac rehabilitation is the intervention point for acute presentation, and primary care has the role in long term follow up of risk factors including depression. Overall, comorbid depression is best managed within a system of collaborative care based on chronic disease management principles.

Key Words

Depression, coronary heart disease comorbidity, collaborative care, clinical pathways, chronic disease management

Introduction

Cardiovascular disease and depression will continue to make the major contribution to the global burden of disease for the foreseeable future. In most countries, cardiovascular disease (CDV) is responsible for more deaths than any other disease, and contributes to significant illness, disability, poor quality of life and premature death (322, 323). Depression carries significant risks of death and disability, and its relapsing nature accounts for one of the highest levels of disease burden of any condition (323-325). These two conditions will become more prevalent as rates of obesity and metabolic syndrome rise in the population (326). An ageing population combined with global competition for health professionals will create pressure for effective management of comorbid coronary heart disease (CHD) and depression. This article examines the links between these two conditions and how they can be better managed in clinical practice.

Depression as a risk factor for CHD

Depression is associated with traditional risk factors for CHD such as smoking and diabetes as well as behavioural and lifestyle risk factors such as physical inactivity and unhealthy diets (327-330). Depression predicts poor adherence to prescribed medication regimens and prescribed therapies, which can have a negative impact on CHD outcomes (199, 331). There is now a substantial body of evidence for depression as an independent risk factor for the development and progression of CHD after adjusting for other risk factors. Much of this evidence is based on cross-sectional studies, although there are some longitudinal

prospective studies that arrive at similar conclusions (329, 332). The results of many studies suggest that depression confers a unique risk above and beyond any association with disease severity. Some researchers (333) have noted that cognitive and affective components of depression may be associated with increased risk for morbidity and mortality for people with CHD.

Many reviews of the relationship between depression and CDV have argued that although there may not be clear evidence that treatment for depression directly reduces cardiac risk (36, 334, 335), given the disproportionate prevalence of depression in this population, and the impact of depression on adherence and other risk factors, as well as quality of life concerns (57, 199, 336), screening and treatment for depression is warranted (329, 337-339).

From research to clinical guidelines

A report on outcomes research in CVD noted there is little research that assesses the quality of care and health outcomes of populations with CVD or at risk for CVD (340). Critical to improving healthcare is defining best practice through systematic review of the evidence, which is usually set in clinical practice guidelines produced at national and international levels by medical associations and government bodies. The purpose of clinical guidelines is to guide clinicians in specific areas of healthcare. Ideally, clinical guidelines identify, summarize, and evaluate the evidence about prevention, diagnosis, prognosis, treatment, risk, benefit and cost effectiveness.

A major difficulty in seeking guidelines for comorbid CHD and depression is that while the validity of guidelines for single conditions can be evaluated by an international shared frame- work such as The AGREE Collaboration (2001), there are none that consider the integrated care of multiple conditions. In our translational research, described below, we have relied on guidelines of international standard for management of CHD that acknowledge the role of depression.

The Scottish Intercollegiate Guidelines Network (2002) produced a guideline (SIGN57) that lays out psychological and educational interventions for patients who have had a heart attack or revascularisation procedure (341). In particular, SIGN57 advocates screening all CHD patients for depression at 6 to 12 weeks after the event, repeated thrice monthly if appropriate. The guideline outlines the evidence for various therapies, and other aspects of management for these patients. The 2004 and 2007 guidelines produced by the National Heart Foundation of Australia (NHFA) provide detailed recommendations for management of biomedical, lifestyle, and behavioural risk factors (342). The guidelines recommend that all patients with CHD be assessed for depression and receive appropriate psychological and medical management.

Although there are clinical guidelines for depression (343), these are less well developed for comorbid conditions. We have not been able to locate clinical guidelines for comorbid depression that provide a logarithm for choice of treatment, based on scores on specific diagnostic or screening instruments, and that have been produced to the international standard of AGREE. In our

implementation research, described below, we have found that the Depression Management Tool Kit developed by the MacArthur Foundation Initiative on Depression and Primary Care (2004) is easiest to use for this work (344). This clinical practice guideline provides tools for recognising and diagnosing depression, patient education, evidence-based guidelines for treatment and management of depression, and monitoring patient response to treatment.

Guidelines to practice

Although clinical practice guidelines may provide recommendations for best practice, few identify optimal strategies for implementation. The authors of a review of care gaps in chronic CDV note that the translation of research evidence into clinical practice is unpredictable, inconsistent and complex (345). Assuming the guidelines have been well produced, barriers to implementation can include: structural factors such as lack of time or financial incentive; organizational factors such as poor teamwork or skill-mix, lack of facilities or equipment; and individual professional factors such as lack of knowledge and skills.

In our study of implementation of guideline recommendations for depression of patients with CDV (346), we found a large gap between recommended best practice and what happens in routine practice. We interviewed 57 patients and their adult carers at 8 weeks post discharge from hospital for treatment of acute coronary syndrome, and 36 health professionals including 18 general practitioners involved in the care of these patients. Of the few who were aware of the guidelines, most did not follow them. Barriers to depression screening

included lack of awareness of assessment tools, lack of time during consultations, lack of funding for mental healthcare, and lack of staff resources to screen and follow-up patients. Particularly striking was the lack of continuity of care between hospital, cardiac rehabilitation, and primary care.

The results of our study are consistent with previous research on barriers to guideline adherence (347-349). Grol and Jones (2000) suggest that too much hope is placed on clinical guidelines for improving quality of healthcare (350). They note that clinical guidelines may be useful when practitioners are unclear about appropriate practice or where scientific evidence can provide an answer, but multidisciplinary collaboration is required to implement change in practice.

Methods

Identifying depression following acute coronary syndrome

Clinical pathways link evidence to practice for specific health conditions with the aim of optimising patient outcomes and maximising clinical efficiency, and support the translation of clinical guidelines into local protocols and clinical practice. Clinical pathways are an example of a protocol, which coordinates the activities of different professionals who need to collaborate in the care of a single patient. They are documented multi- disciplinary plans that outline the sequence and timing of actions necessary to achieve effective patient outcomes with optimal efficiency.

In our study (182) identifying depression following hospitalisation for acute coronary syndrome (ACS) or revascularisation procedures, our intervention built on an existing high-quality clinical pathway for ACS (351). We trialled the

intervention in two hospitals in Victoria and South Australia using the NHFA 2004 guidelines. Given that we were attempting to identify best ways of screening for depression in existing systems of healthcare, we realized that multi-faceted approaches were most likely to succeed.

The features of our intervention were:

- Recruitment of the medical director and senior cardiologists as champions;
- Assessment of the baseline which showed that patients were not screened for depression;
- Multi-disciplinary educational sessions on the guidelines and evidence for identifying depression;
- Intensive work with cardiac rehabilitation staff with monitoring of their screening rate for depression; and
- Feedback of results to the wider multi- disciplinary group.

Results

Coronary heart disease and depression

We will focus here on the results of screening for depression. Cardiac rehabilitation nurses were trained to screen for depression using the Hospital Anxiety and Depression Scale (HADS) (59), and the Two-Question Screen (MacArthur Foundation Initiative on Depression and Primary Care) (344). The results for each patient were transmitted, along with a treatment protocol, to the patient's general practitioner (GP). Patients who did not attend cardiac rehabilitation programs were administered the questionnaire by telephone. Treatment and follow-up was left with the GPs.

The results show that of the 53 ACS patients screened for depression, within two weeks of discharge from hospital, 25 per cent reported both anxiety and depression, and 21 per cent reported depression only. Follow-up of these patients at two months post-discharge showed that depression persisted for 45 per cent of those who reported depression at first screening, and another 9 per cent reported symptoms of depression that were not evident at the first screening.

Discussion

Our study demonstrated that cardiac rehabilitation nurses in hospital settings can conduct screening for depression, and the results can be provided to primary care physicians. We understand that our system of screening has continued in one of the hospitals as part of their established clinical pathway for ACS (Wolff, personal communication, August, 2007). But we also recognize limitations of this approach, the major ones being the low uptake of cardiac rehabilitation programs, and patients' lack of contact with hospital staff post-discharge.
Over 90 per cent of all ACS patients in our study (182) said they had seen their GP at least once since leaving hospital, but none had been screened for depression on GP visits. Clinical pathways for identification and management of comorbid depression and heart disease clearly need to consider the link between hospital care and primary healthcare.

Chronic disease management

Rothman and Wagner place management of chronic disease firmly in primary care (352). They argue that the defining features of primary care— continuity, comprehensiveness, and coordination—match the care needs of people who are chronically ill. The chronic care model developed by Wagner (353) has six inter-related components: self-management support, clinical information systems, delivery system redesign, decision support, health- care organization and community resources. It is a way of redesigning the organization of individual primary care practices to produce a system in which informed activated patients interact with prepared, proactive practice teams.

Achieving guideline-based outcomes in the treatment of depression are based on system changes directed at activating trained multi-disciplinary primary care teams, clinicians, and patients (324, 354, 355). There is growing evidence that collaborative models of patient care are effective for chronic disease management, and are preferred models for management of most people presenting with depression in primary care (174, 200, 213, 356). Collaborative care includes components at patient, provider, and system levels based on a chronic disease model. Central to collaborative care models are multi-disciplinary primary care teams who assist the primary care provider in delivering evidence-based treatment.

Appendix 3 Measuring guideline implementation in Australian general practice (reproduced verbatim)

Citation (183):

Adrian Elliot-Smith, **Mark A J Morgan.** How do we compare? Applying UK pay for performance indicators to an Australian general practice. *Australian Family Physician* (2010) **39**: 43-8.

Abstract

Background

United Kingdom general practitioners receive payment based on their performance in multiple clinical indicators. We set out to apply the same indicators in an Australian general practice to benchmark our performance and to see how much work was required to obtain the data.

Methods

Clinical indicators for the 2008–2009 UK Quality and Outcomes Framework (QOF) cycle were examined and achievement levels measured in a large rural Australian general practice, mainly by computer searching of the clinical database.

Results

Outcome measures were obtainable for 79 out of 80 indicators. Manual perusal of computer records was required for 16 indicators. Data collection takes approximately 130 hours. The Australian general practice achieved 66% of available pay for performance points compared with the UK average of 97%.

Discussion

United Kingdom QOF clinical data is obtainable relatively easily in a well-computerised Australian rural general practice. The exercise identified significant areas in which clinical performance could be improved.

Keywords

Health care quality assessment; clinical audit; health policy; health care economics

Introduction

In 2004, as an attempt to improve and measure the quality of primary care and as part of a new contract with general practitioners, the United Kingdom government introduced a voluntary pay for performance scheme for general practices called the 'Quality and Outcomes Framework' (QOF). This provided a potential extra 25% income for GPs and has now been almost universally adopted. The 2008–2009 scheme comprises 138 separate indicators outlining targets within chronic disease management, practice organisation and patient experiences of primary health care. Evidence is emerging that this approach accelerated existing general practice care for key conditions specified (although the rate of improvement has now peaked) (357). Such a model might be worthy of consideration in the health systems of other countries.

The Australian health system shares with the UK a structure of GP led primary care responsible for much of chronic disease management. There are nevertheless significant organisational differences that make it harder to

measure the quality of chronic disease management in Australia. In the UK all patients are registered with a single general practice of their choice, whereas Australians are free to choose at any time a doctor willing to see them. Parallel to this is the existence in the UK of a single general practice record (which follows the patient if they change the practice in which they are registered), whereas each practice involved in the care of an Australian patient maintains a separate unlinked record.

This study explores the potential for a large, computerised, rural Australian general practice (Hawkins clinic in Mount Gambier, South Australia) to collect clinical data used for the UK QOF clinical indicators (80 categories) for the years 2008–2009.

Methods

Setting

Hawkins clinic is currently a 17 doctor (14 full time, three part time) practice with 16 314 patients. Mount Gambier is the second largest town in South Australia (population approximately 25 000) about 5 hours drive from Adelaide. The practice is paperless and uses Best Practice clinical software. Clinical summaries use the software coded disease index wherever possible. Incoming pathology is entered electronically and is automatically coded.

Defining the practice population

For the purposes of this project a patient of the practice was defined as a patient in whom there exist three separate progress note entries in the records in the 2 years between 1 April 2007 and 31 march 2009.

Obtaining Hawkins Clinic data for each clinical indicator

The UK clinical indicators for the years 2008–2009 were chosen (358). A 'snapshot' of practice data on 31 march 2009 was used to compare with UK practices that all report on this same date. The Best Practice clinical software search tool was modified by inserting specifically designed Structured Query Language (SQL) directly into the search pane. This made it possible to construct relevant disease registries and assess performance precisely for most of the clinical indicators. For some indicators it was necessary to manually check a random sample of clinical records.

Analysis

Disease prevalence for Hawkins clinic were compared with UK national averages. Performance of Hawkins clinic for each clinical indicator was determined by reference to the UK QOF points allocation system. For each clinical indicator (apart from those simply requiring the existence of a disease register) points are awarded in proportion to the number of patients who fulfil the criteria of that clinical indicator. Some indicators are given greater importance by the awarding of more points. For most indicators maximum points are awarded once 80 or 90% of patients have achieved the criteria. There are defined circumstances where a patient refuses or is unsuitable for the clinical indicator and is therefore excluded from the count. The average UK 'exception

rate' across all practices is published for each indicator (359). We calculated our percentage achievement of points for each UK QOF indicator applying the UK exception rate to each indicator to make the benchmarking exercise more meaningful (the mean adjustment across all indicators was 5.26%). Figure 1 illustrates how QOF points are awarded for blood pressure control in patients with type 2 diabetes. In this example practices start gaining points when 40% of their patients fulfil the criteria, reaching maximum points once 60% or more have fulfilled the criteria. By performing these calculations for each of the clinical indicators it was possible to derive the financial reward that Hawkins would have received in the UK.

All 80 UK clinical indicators were examined in the Australian GP context. Apart from an adjustment for the southern hemisphere winter for flu immunisation items, clinical entities matched exactly for all except four indicators (Table 1).

Flinders university social and behavioural Research ethics committee approved the study.

(Figure 1) Calculation of UK QOF points for DM12 indicator

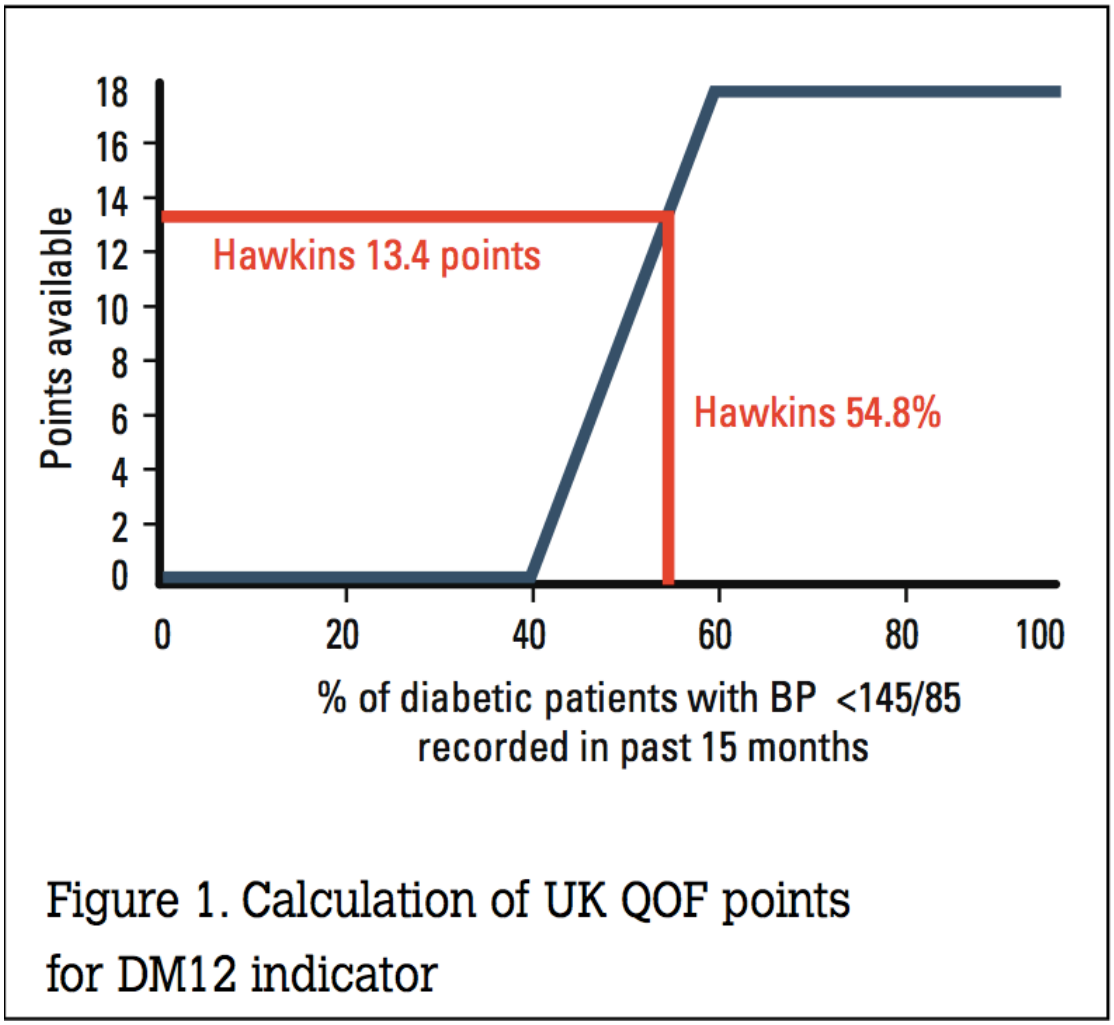

Figure 1. Calculation of UK QOF points for DM12 indicator

Table 1. Clinical indicators changed for use in Hawkins Clinic	
UK QOF indicator	**Hawkins Clinic approximation**
Practice has a register of palliative care patients	Local palliative care service register of practice patients
Recorded multidisciplinary case reviews of palliative care patients	Weekly meetings between palliative care service and GPs
Annual review including routine health promotion of patients with psychotic or bipolar disorders	Up-to-date with RACGP preventive screening guidelines (eg. the 'red book')[4]
Recording of follow up contact for patients with psychotic or bipolar disorders failing to attend annual health promotion visit	No Australian equivalent (opportunistic health promotion instead of planned annual visit)

[4]RACGP preventative screening guidelines (Red Book) (360)

Results

Disease prevalence

Disease prevalence data was found to be similar to average UK figures (Table 2) for all conditions with the exception of diabetes, palliative care and obesity.

Table 2. Disease register prevalence as percentage of population (Hawkins Clinic and UK data)		
Register	**Hawkins Clinic**	**UK 2007–2008**
Coronary heart disease (CHD)	4.1	3.5
Heart failure (HF)	0.81	0.8
Stroke and transient ischaemic attack (STROKE)	1.8	1.6
Hypertension (BP)	15	12.8
Diabetes mellitus (DM)	6.5	3.9
Chronic obstructive pulmonary disease (COPD)	1.5	1.5
Epilepsy (EPILEPSY)	0.92	0.6
Hypothyroid (THYROID)	2.3	2.7
Cancer (CANCER)	0.59	1.1
Palliative care (PC)	0.048	0.1
Mental health (MH)*	1.1	0.7
Asthma (ASTHMA)	6.5	5.7
Dementia (DEM)	0.41	0.4
Chronic kidney disease (CKD)	2.8	2.9
Atrial fibrillation (AF)	1.6	1.3
Obesity (OB)	3.4	7.6
Learning disabilities (LD)	0.22	0.3
* Refers to schizophrenia and other psychotic illness and bipolar disorder		

Clinical indicator performance

For each indicator Table 3 has a brief description. The next two columns show the percentage of Hawkins clinic patients fulfilling the indicator criterion for the relevant disease and the percentage required to achieve all of the UK QOF points for that indicator. The final column shows what proportion of available points Hawkins clinic achieved. For example the 'DM12' indicator shown in Figure 1, Hawkins clinic attained 54.8% (base rate of 48.3% with addition of 7.5% UK exception rate) which achieves 13.4 of the 18 points available, i.e. 74%).

Hawkins clinic achieved more than 95% of available points for about half the indicators but in the remainder there were less satisfactory achievements that are discussed below. In total, Hawkins clinic achieved 66% of the available 650 clinical UK QOF points.

Table 3. QOF clinical indicator achievements (Hawkins Clinic and UK data)				
Indicator	**Description**	**Hawkins Clinic % of patients with each disease who meet QOF criterion**	**UK minimum % required to be awarded full QOF points**	**Hawkins Clinic QOF points awarded (% of total available)[#]**
Coronary heart disease				
CHD 1	Register			100
CHD 2	ETT in angina diagnosed after 1 April 2009	89.0	90	100
CHD 5	BP measured	88.1	90	99
CHD 6	BP <=150/90 mmHg	70.1	70	100
CHD 7	Cholesterol measured	87.4	90	100
CHD 8	Cholesterol <=5 mmol/L	75.8	70	100
CHD 9	On anti-platelet medication	89.0	90	100
CHD 10	On B-blocker medication	50.6	60	100
CHD 11	Patients with myocardial infarction diagnosed after 1 April 2003 on ACEI medication	83.3	80	100
CHD 12	Influenza immunisation	71.3	90	89
Chronic heart failure				
HF 1	Register			100
HF 2	Echo in patients with HF diagnosed after 1 April 2006	68.3	90	78
HF 3	On ACEI medication	68.9	80	93
Stroke				
STROKE 1	Register			100
STROKE 13	CT in diagnosis after 1 April 2008	79.2	80	100
STROKE 5	BP measured	78.9	90	80
STROKE 6	BP <=150/90 mmHg	55.4	70	68
STROKE 7	Cholesterol measured	83.9	90	100
STROKE 8	Cholesterol <=5 mmol/L	62.4	60	100
STROKE 12	On antiplatelet medication	83.3	90	100
STROKE 10	Influenza immunisation	71.5	85	100
Hypertension				
BP 1	Register			100
BP 2	BP measured in previous 9 months	78.4	90	77
BP 3	BP <150/90 mmHg in previous 9 months	57.7	70	59
Diabetes mellitus				
DM 19	Register			100
DM 2	Body mass index measured	51.3	90	30
DM 5	HBA1C measured	86.0	90	97
DM 20	HBA1C <=7.5	65.3	50	100
DM 7	HBA1C <=10.0	81.8	90	95
DM 21	Retinal screen performed	72.6	90	80
DM 9	Peripheral pulses checked	60.4	90	53
DM 10	Neuropathy testing	60.4	90	53
DM 11	BP measured	83.5	90	90
DM 12	BP <145/85 mmHg	48.3	60	74
DM 13	Microalbuminuria checked	60.6	90	53
DM 22	eGFR measured	86.7	90	97
DM 15	On ACEI medication if albuminuria present	81.0	80	100

Table 3. QOF clinical indicator achievements (Hawkins Clinic and UK data) (continued)				
DM 16	Cholesterol measured	89.4	70	100
DM 17	Cholesterol <5 mmHg	73.7	70	100
DM 18	Influenza immunisation	54.7	85	66.7
Chronic obstructive pulmonary disease				
COPD 1	Register			100
COPD 12	Spirometry in new diagnosis	63.6	80	40
COPD 10	FEV1 measured	18.1	70	0
COPD 11	Inhaler technique checked	4.4	90	0
COPD 8	Influenza immunisation	68.7	85	93.3
Epilepsy				
EPILEPSY 5	Register			100
EPILEPSY 6	Seizure record	65.3	90	58
EPILEPSY 7	Review	75.5	90	78
EPILEPSY 8	Seizure free for 12 months recorded	43.9	70	66.7
Hypothyroidism				
THYROID 1	Register			100
THYROID 2	Thyroid function measured	80.7	90	82
Cancer (excludes nonmelanotic skin cancer)				
CANCER 1	Register			100
CANCER 3	Review of new diagnosis in previous 18 months	81.6	90	90
Palliative care				
PC 3	Register			100
PC 2	3 monthly multidisciplinary review meetings			100
Schizophrenia, psychosis and bipolar disorder				
MH 8	Register			100
MH 9	Health promotion performed	28.4	90	5.2
MH 4	Lithium patients – TSH measured	79.2	90	80
MH 5	Correct lithium level in previous 6 months	54.2	90	45
MH 6	Care plan in place	14.6	50	18.3
MH 7	Follow up if not attended health promotion	0		0
Asthma				
ASTHMA 1	Register			100
ASTHMA 8	Reversibility measure in diagnosis after 1 April 2006	44.2	80	40
ASTHMA 3	Smoking status age 14–19 years	42.2	80	13
ASTHMA 6	Review	20.0	70	0
Dementia				
DEM 1	Register			100
DEM 2	Review	83.6	60	100
Depression				
DEP 1	DM/CHD depression screen	19.2	90	0
DEP 2	Severity tool in new diagnosis in previous 12 months	38.7	90	24.4
Chronic kidney disease* (stage 3–5 CKD)				
CKD 1	Register			100
CKD 2	BP measured	88.4	90	98
CKD 3	BP <140/85 mmHg	50.3	70	72.7
CKD 4	Patients with proteinuria on ACEI medication	100	80	100

Workload

For those indicators that required manual perusal of the electronic record (for the most part by a suitably trained clerical officer of the practice) the estimated time required was 112 hours (Table 4). To obtain the rest of the data (and generate the lists of patients for the manual record check above) required the use of 89 separate searches using the Best Practice search engine but with extensive SQL code addition. Designing the searches was a time consuming exercise but once formulated the SQL code can be used in any practice using Best Practice clinical software. Running the searches and calculating the data took about 16 hours.

Table 4. Clerical time for data collection for indicators that required manual search of records

Indicators	Total Hawkins Clinic patients	Sample	Time to examine sample (hours)	Estimate for all notes to be examined (hours)
CHD 2	73	73	3	3
HF 2	41	41	2	2
STROKE 13	24	24	1.5	1.5
DM 21, 9, 10	1060	106	4	40
COPD 11	249	69	2.5	9
EPILEPSY 6, 7, 8	151	151	4	4
CANCER 3	87	87	4	4
MH 9	178	88	5	10
MH 5	24	24	1	1
ASTHMA 3	64	64	3	3
ASTHMA 6	1066	100	3	31.5
DEM 2	67	67	3	3
Total hours			**36**	**112**

Discussion

This project demonstrates that it is possible to collect the UK QOF data in an Australian practice. The practice population definition provided a reasonable method for obtaining disease prevalence data and for obtaining the denominator for many of the activity targets outlined in UK QOF. The actual practice

population (people who would regard themselves as patients of the practice) might differ – some infrequent attendees will have been missed while others who have subsequently moved away will have been included. Most QOF targets relate to the proportion of patients in a particular disease register who are receiving recommended care so there is no absolute requirement to follow the UK example of registering patients with only one practice. The population definition probably works well for a large general practice in a small town, or a one-practice town, but it might not work well in urban areas where patients have a greater tendency to use more than one general practice.

The remarkable similarity of Hawkins clinic and UK prevalence data is an encouraging vindication of the methodology for the most part. The higher rate of diabetes in our population was a surprise. The obesity rate (about half that in the UK) is likely to be explained by under recording.
In the UK there was a significant lead-in time before the first QOF targets were assessed. Practices could adjust their clinical and organisational systems well in advance to maximise their performance from the outset of the scheme (e.g. by making sure relevant clinical measurements and data had been recently recorded and by identifying patients eligible for exception reporting). It is hardly surprising therefore that an unprepared 'snapshot' of an Australian practice fails to achieve anything like the levels of achievement of UK practices (66% for Hawkins clinic compared with the UK average of 97%).

Implications for Hawkins Clinic

Aside from the UK QOF comparison this work has been valuable in highlighting some aspects of chronic disease management where Hawkins clinic should improve. Blood pressure targets that are by no means stringent are only met for about 50% of our stroke patients (≤150/90), hypertensive patients (≤150/90), diabetic patients (≤145/85), and chronic kidney disease patients (≤140/85). For patients with diabetes, routine checks of retina, feet and micro albuminuria were disappointingly low (60%) despite being part of the Australian Diabetes cycle of care Medicare Australia protocol. These results indicate to us the potential benefits of protocol driven chronic disease management with the assistance of our practice nurses.

Other areas for similar attention include:

• Annual spirometry for asthma and chronic obstructive airways disease

• Recording of seizure frequency in epilepsy (which might increase the percentage of identified seizure free epileptic patients)

• Recording of smoking advice and cessation

• Formal health promotion checks for patients with psychotic or bipolar disorders

• Annual depression screening of patients with diabetes or coronary heart disease

• Use of severity tool for new diagnoses of depression.

The UK QOF measures seem to be a suitable starting point for measuring our future performance.

To efficiently measure and reward performance in this way requires accurately summarised and maintained computerised clinical records. This involves high initial and ongoing investment (361). Achieving targets would be greatly benefited by software tools such as Doctors Control Panel which can highlight QOF requirements for individual patients during consultations (362). Sophisticated software for identifying where practice targets are being missed already exists in Australia, but would need a much wider scope to include the range of QOF clinical measures (363). Such tools were made available to UK practices with substantial government financial support.

Pay for performance might fund supplementation of GP care by practice nurses within protocol driven chronic disease management clinics. However, the value of regular contact between a patient and their GP might be undermined by this drive to meet performance targets. It is possible that working toward narrowly focused targets could direct attention away from care of medical conditions that are not included in the scheme.

Conclusion

Applying UK-style pay for performance clinical indicators to an Australian general practice is feasible in a well computerised practice and can identify significant areas for improved clinical care. If this practice had volunteered for the UK pay for performance system then an increase of $296 000 (out of a

possible $465 000) would have been earned by the current level of performance in the clinical indicator component of the UK QOF.

Conflict of interest: none.

Acknowledgments

This work was supported by a Primary Health Care Research, Evaluation and Development bursary administered through the Greater Green Triangle University Department of Rural Health (Warrnambool, Victoria). Thanks to Hawkins Medical Clinic administrative staff and Laura Elliot-Jones in particular.

Appendix 4 D_TECT Exploratory Trial (reproduced verbatim)

Citation (69):

Prasuna Reddy, James A Dunbar, **Mark A J Morgan**, Adrienne O'Neil. Coronary heart disease and depression: getting evidence into clinical practice. *Stress and Health* (2008)**24**: 223–230.

Introduction

Our research team embarked on an ambitious project in 2005 called D_TECT (Depression Treatment Evaluation Care Team) to test the feasibility of a collaborative care model for depression in adult patients with existing CHD or diabetes on the databases of six general practices in southern Australia. The region has a disproportionately high rate of CHD (364), and like many rural areas, limited access to specialist mental health services (365). The D_TECT methodology sought to implement the key elements of IMPACT (4), a successful collaborative care model for treatment of older adults for depression in primary care. D_TECT is a complex intervention involving multiple sites, different primary care teams, and different health- care services across two states. This paper presents preliminary results from one part of the study: training practice nurses to screen, assess, and review progress of patients listed on the practice registers as having a diagnosis of CHD or diabetes in the preceding 5 years.

Hickie and McGorry have summarized many of the key elements of collaborative care models for management of common mental health problems (200):

• A structured and multifaceted approach based on chronic disease management principles;

• A greater role for non-medical specialists using nurses as care managers, clinical psychologists and other mental health professionals; and
• Inclusion of some key organizational and professional components.

Our collaborative care model for management of comorbid depression, CHD and diabetes in primary care had these key elements. We followed a structured and multifaceted approach based on chronic disease management principles shown to be effective in management of heart disease and diabetes, and extended to comorbid depression. We ensured a greater role for practice nurses, who were central to the collaborative care model, from conducting assessments through to acting as care managers. The nurses worked closely with the general practitioners and psychologists in the management of severe-moderate depression. Key organizational and professional components that have been shown to be effective in chronic disease management in primary care settings were included in the model. These are detailed below.

Methods

Clinical education

We held a 3-day residential training program for practice nurses and general practitioners from participating practices focusing on screening, assessment, and review of depression as a fundamental part of the collaborative care model for management of heart disease and diabetes. Six months later, we held another 2-day residential programme to train practice nurses in basic counselling skills and use of psychological strategies to help patients achieve behavioural and lifestyle changes to manage psychosocial risks and mild depressive symptoms. In these

training sessions, we reviewed case management procedures for identification and management of moderate to severe depression. Training included information on how depression was managed in the IMPACT model, identification of suicidal risk, use of GP Health Plans and GP Mental Health Plans.

Dissemination and implementation of treatment and management guidelines

The NHFA 2004 guidelines and clinical guidelines for management of depression were distributed during the first training session. Practice nurses and corresponding GPs were trained in and asked to write a protocol for implementation in their individual practices.

Use of case finding questionnaires

In most general practices, clinicians rely on patient self-report or their general impression to recognize symptoms of depression, and some use screening tools. Since we were focusing on practice nurses to do the initial screening for depression, and assessment had to fit alongside other tasks in brief clinic visits, we selected the 9-item self-report Primary Health Questionnaire (PHQ9) (366), as the major screening instrument for depression. We included the HADS (59), as a supplementary instrument to identify cognitive and affective symptoms of depression and anxiety that present with medical conditions.

Reconfiguration of roles within the primary care team

Practice nurses allocated about 45 minutes to review blood test results, patient measurements, lifestyle modifications, mental health, and a 'best practice'

checklist for secondary prevention. Doctors allocated about 15 minutes to complete a medication review, address issues raised by the nurse, and complete the GP Management Plan. Nurses were trained to manage mild depression, and act as case manager for moderate to severe cases to ensure adherence. Prior to the training program, the nurses did not have identified roles in developing GP Management Plans. In this project, the GP Management Plans were initiated by the nurse, substantially adding to the practice income.

Earliest appropriate use of specialised psychological or psychiatric assessment

Where the nurse identified a patient with moderate to severe depression, the protocol stated that the nurse would bring it to the attention of the GP, who would decide on clinical management. The guideline recommendations were: watchful waiting, with supportive counselling; prescribing antidepressants; referral to a mental health specialist; or combination of antidepressants and psychological counselling.

Case management, reminder systems and other active follow-up schemes to enhance continuity of care and adherence to treatments

The project used a computerized reminder-system to identify patients with high depression scores, and trigger patient recall. Results of depression screening were also recorded in patients' progress notes. The nurses were trained to re-administer the PHQ9 at 3 months for patients who had initially been identified with moderate-severe depression (PHQ9 scores > 10). The nurses were also trained to follow-up these patients by telephone ensuring adherence with treatment. The increased use of GP Management Plans in itself led to better team coordination.

Consultation-liaison to improve working relationships between primary and specialist services

Regular telephone case conferences were held with the participating nurses and a team of specialists including a GP, a psychiatrist, a psychologist, and a community psychiatric nurse. In these case conferences, the nurses were able to report on progress in screening and management of depression in their practices. The GP and psychologist on this team were also the key professionals in the training programmes.

Support for patient education and consumer-based decision tools

A copy of the GP Management Plan was given to the patient as part of self-management. The practice nurses were issued with and shown how to use patient self-management materials. These ranged from fact sheets and recommendations to decision tools and activities to manage aspects of depression such as sleep problems and negative thinking. A list of Web-based materials on depression and self-management were provided for patient dissemination.

Key findings

Collectively, 332 patients from the six practices were screened for depression, and 51 patients have been recalled for review. The proportions of mild, moderate, and severe depression on the PHQ9 measure at initial assessment

were 19, 10 and 5 per cent respectively, and 20 per cent reported a past history of depression.

Recent follow up interviews with participating practice nurses and GPs in 2007 indicated that the training enhanced nurses' skills and gave them greater confidence in their role. At the time of the interviews, which were conducted about eight months after the second training session, nurses were actively engaged in consulting independently with patients, assessing risk factors, using depression screening tools and generating action plans for patients with chronic disease. They noted that the screening instruments also had the benefit of opening discussion with patients about depression, specific depressive symptoms, and treatment options. The nurses saw support from other practice staff, particularly the treating GP, as the essential enabler for continuing a collaborative care model. Interestingly, while the nurses rated effectiveness and willingness to continue this care model in the moderate to high range, the GPs gave highly favourable ratings for the implementation.

The main barriers to full implementation of this model are resource constraints. Practice buildings do not have sufficient space to allow an increase in the nursing workforce necessary for this intervention, even though the business model for funding practice nurse time is a sound one. The major barrier to implementation of the model was lack of time, especially in recall of patients for initial screening and ongoing monitoring. Successful features of the intervention were the confidence and competence engendered in the nurses through the training programs and consult-liaison process. Most practice teams are willing to continue with the intervention, despite the system difficulties and barriers.

Conclusion

While there is clear recognition that the clinical care of patients with multiple conditions is complex and needs integration of specialists and primary care (367), there is little guidance about how to improve outcomes in patients with multi-morbidity (368). The problem becomes even more complex when we consider the management of co-occurring chronic medical illness and psychological conditions (180, 337, 369). In the case of CHD, as difficult as it may be to identify comorbid depression and other psychological risk factors, it is even more difficult to identify methods of improving psychosocial health and reducing overall CHD risk at the same time.

Despite the great burden that comorbid depression places on individuals, families, and the healthcare system, it remains a condition that is not managed well in tertiary or primary care. Deficiencies in healthcare relate to under-diagnosis, inadequate treatment, and lack of patient follow-up after treatment is initiated.

Our results suggest the collaborative care model that we developed for comorbid depression can transform the way that the GP and practice nurse team take an integrated view of depression management in primary care. We have demonstrated, to some extent, that it is feasible for practice nurses to screen, assess, counsel and monitor patients with CHD or diabetes and depression. We

believe that this collaborative care model for comorbid depression in primary care can be adapted to developed healthcare systems.

Acknowledgments

The studies were supported by grants received from the National Heart Foundation of Australia Victoria, and *beyondblue*: the National Depression Initiative.

Appendix 5 – Additional published articles

Appendix 5.1 Practice nurses as case managers in a collaborative care model for managing depression among patients with heart disease or diabetes: The D_TECT and TrueBlue studies in primary care

Citation (370):

Mark Morgan, Prasuna Reddy, Michael Coates, Robert Leahy, Kate Schlicht, James Dunbar. Practice nurses as case managers in a collaborative care model for managing depression among patients with heart disease or diabetes: The D_TECT and TrueBlue studies in primary care. In *A Bright Future for Rural Health. Evidence-Based Policy and Practice in Rural and Remote Australian Health Care*; 2010, Chapter 10 P48-52.

Article Summary

Rural researchers found that more than one-third of patients seeing a general practitioner (GP) for diabetes or coronary heart disease also have depression. In a

typical busy general practice, mental health conditions may go undiagnosed or unaddressed. This was the motivation to develop a new model of care using existing general practice health teams and taking advantage of Medicare funding opportunities for complex care. Practice nurses (trained in assessment, patient education, and patient-centred goal setting and problem solving) held individual sessions with patients and attended consults with the GP and patient. Preliminary results from a randomised controlled trial show significantly greater reduction in depression among patients receiving collaborative care.

A successful feasibility study called D_TECT (Depression Treatment Evaluation Care Team) used a collaborative approach to detect, monitor and treat depression among patients with existing type 2 diabetes mellitus (T2DM) or coronary heart disease (CHD) in primary care. It was developed by the Greater Green Triangle Department of Rural Health and conducted in general practices in rural areas.

The model mobilised existing resources and funding paths available in general practice, including general practitioners (GPs), practice nurses (PNs) and existing Medicare- funded enhanced primary care items. PNs received additional training in detecting and managing depression, as well as use of electronic medical recording, which up skilled them to take on a case manager role for individual patients. Participants in the program attended regular appointments with both the nurse and their usual GP.

The D_TECT pilot study showed that the collaborative model was feasible, acceptable and affordable in rural settings. More than one-third of patients were assessed as having depression, and patients described positive attitudes and relief that their mental health concerns were being addressed as part of a comprehensive care package. PNs and GPs were in favour of continuing the model of care.

As a pilot study, D_TECT was not designed to investigate the clinical benefits of the collaborative model. A randomised control trial called TrueBlue was developed for this purpose. The trial is still in progress but preliminary results are available.

Relevance to rural and remote health

It is anticipated that within 20 years, diabetes will become the leading contributor to the overall burden of disease in Australia (196). As the population ages and the trend toward obesity continues (195), general practice will deal with more cases of the many resulting conditions, including diabetes and heart disease.

Depression is increasingly being recognised as a major factor that leads to poor clinical outcomes. In patients with either diabetes or heart disease, the presence of depression leads to increased morbidity and mortality (45, 187). Unfortunately, this depression is often missed in routine general practice (188)

and it remains under diagnosed and under treated, especially when in the presence of diabetes and heart disease.

There is a particular need for new approaches to this problem in rural and remote areas where the shortage of health professionals means that GPs have less access to specialist and allied health services for their patients. Across Australia, there is an increasing number of PNs being employed in general practices. The Australian Practice Nurse Association (APNA) reports 60% of general practices employ at least one PN. Models of care that expand the role of PNs provide one method of alleviating the shortage of health professionals, particularly in rural areas.

The research

Eleven practices in South East Australia employing PNs are participating in the TrueBlue trial. Six practices were randomly assigned to the intervention group and five to the control (usual care) group. Approximately 150 patients were recruited to each group.

Before implementing the model, the PNs attended a two-day workshop to prepare for their new role. The workshop introduced the rationale of the collaborative care model before presenting a range of topics, including screening for depression, and identification and measurement of physiological and lifestyle risk factors, such as high cholesterol, blood pressure, blood glucose, central obesity, smoking, alcohol and physical inactivity. Training to educate patients in

diabetes and heart disease risk reduction and to assist patients with goal setting and problem solving was undertaken. Administrative activities, such as coordinating referrals, timetabling follow-ups, and preparing the draft GP management plan, were also covered.

An important aspect of the model is goal setting, in which the patient (guided by the PN) develops up to three goals that the patient feels are achievable to help reduce the risk factors. This means that patients become more active participants in their own care. Patients are recalled automatically and systematically every 13 weeks so that the progress of their care can be monitored and their goals can be reassessed to ensure that they remain timely and relevant. Special tools and protocols were put into place to identify and manage patients at risk of suicide or self-harm.

Because the study was still in progress at the time of writing, no final results were available. However, the preliminary results suggested a mean reduction in depression score of 33% after six months of collaborative care compared with a 16% reduction after six months of usual care. (The 95% confidence limits are a 23% to 39% reduction for the intervention clinics, and an 8% to 26% reduction for the control clinics.) These observations are supported by anecdotal comments from the PNs who report a visible improvement in appearance and manner of many of their TrueBlue patients. Case review and qualitative interviews with the PNs have demonstrated clearly that the protocols put in place to deal with positive responses to the self-harm question and worsening depression scores have been followed.

Lessons learned

The pilot study and preliminary results of the TrueBlue trial indicate that collaborative models of primary care for diabetes help to identify and successfully address depression and other mental health issues of patients with diabetes. Up-skilling nurses and providing a structured way for them to take on more responsibility and work closely with a GP assists rural heath professionals to work effectively as a team. A supportive GP, training for the PNs and protected time of at least 30 minutes for the PN to consult were important requirements for the model's success. By completing GP management plans or team care arrangements, and diabetes annual cycle of care Medicare item numbers, practices could more than recoup the costs of the PN's time.

These studies are an excellent demonstration of the value of rural research capacity building. The 18-month trial of D_TECT was conducted entirely in rural areas, demonstrating the value of rural research capacity to develop and test innovative ideas in partnership with local health professionals. After demonstrating the feasibility of the model, the rural-based research team was able to launch a randomised control trial to rigorously test clinical outcomes in urban and rural sites across three states.

Wider relevance

The strength of this collaborative care model is that it provides a sustainable way to manage chronic illness with particular attention to monitoring and self-management of mental health. Sustainability comes through building on the skills of existing health care workers and systematically accessing funding opportunities available. The model can be used readily in any primary care setting with PNs and GPs.

Appendix 5.2 Use of chronic disease management plans in rural practice

Citation (371):

Mark Morgan. Use of chronic disease management plans in rural practice. *Australian Journal of Rural Health* (2009) **17**, 173.

Editorial

Use of chronic disease management plans in rural practice

The traditional model of general practice in Australia is one of episodic visits to the doctor initiated by the patient. Within these consults, GPs struggle to deal with presenting problems, ongoing chronic disease needs and a myriad of administrative tasks. As the population ages, more and more patients will be living with a chronic disease (198). Guidelines for 'best practice' management of these chronic diseases become more detailed with each evidence-based update requiring ever more monitoring and the initiation of additional medication. With the dual pressures of increasing numbers and increasing complexity, the gap between achievable care and best-practice care will widen unless the work can be shared. The introduction of enhanced primary care Medicare item numbers provides a financial incentive to change the delivery of primary care to one in which care can be effectively shared. Patients are given a management plan detailing their needs, personalized goals and the tasks of each health care provider.

Initial uptake of care planning Medicare item numbers was hampered by their complexity. In this report, the authors describe an initiative to identify the barriers to wider use of care planning in rural practice (372). An educational intervention was attended by practice nurses, managers and doctors. Following this intervention, there was an expected increase in confidence and knowledge

about the process of using Medicare item numbers, but we are not told whether it was these participants who were responsible for increased numbers of items claimed.

In rural areas, workforce shortage often demands innovative solutions to problems, such as dealing with increasing chronic disease burden. It is feasible for practice administrative staff to take a significant role in organising patient recall visits, pathology testing and completion of waiting room checklists. Practice nurses can successfully take on new roles to lead the assessment of patients and coordination of referrals to allied health. Nurses can work with patients to define personalised goals, screen for comorbid depression and collect bio- physical and pathology measures. Practice nurses are also well placed to provide self-management advice and resources for patients, thus freeing up the GP to concentrate on diagnosis and clinical management (201). Medicare item numbers are a potential financial engine to fund this enhanced service for our patients. Research in Australia is currently under way to compare the clinical outcomes of nurse-led collaborative care using GP management plans with usual care.

Mark Morgan

Hawkins Medical Clinic and Greater Green Triangle University Department of Rural Health

Appendix 5.3 Quality outcomes in general practice. How do we compare?

Citation:

Morgan, M. Quality outcomes in general practice. How do we compare? in *Snapshot of Australian primary health care research 2010*. (2010): **7**,18-19.

Quality outcomes in general practice – how do we compare?

Strengthening preventive and chronic disease care and improving performance and accountability are priorities for reforming the Australian primary health care system. Measuring and rewarding quality care in a workable way is a challenge. Since 2004, a proportion of UK GP income has been based on performance against a framework of quality indicators. These indicators emphasise reward for clinical outcome, in addition to activity.

How do Australian GP outcomes compare with the UK? A group practice in regional South Australia undertook this original study to find out how an Australian practice would perform under the UK policy model, and whether it could use its clinical software program to obtain relevant clinical outcome data. A search of 16,314 patient records at the practice was undertaken and showed it was possible to examine the quality of chronic disease management using almost all of the UK indicators. This research demonstrated, for the first time, that it is possible to examine the quality of chronic disease management in an Australian practice by identifying important clinical outcomes using a series of computer searches. Of the available UK scheme points, 66 per cent were achieved – equal to a bonus payment of $296,000. Gaps in care were also uncovered. These can now be easily monitored by the same computerised searches. The methodology also allows international benchmarking and provides significant new knowledge

about practice and policy activities to influence the quality of medical care provided.

"...it is possible to examine the quality of chronic disease management in an Australian practice by identifying important clinical outcomes using a series of computer searches."

Appendix 6 Selected presentations

1. Conference presentation RACGP annual meeting, Perth, 2009. Benchmarking an Australian general practice using England's pay-for-performance indicators – how do we compare?

2. Keynote presentation to PHCRED Tristate conference, Warrnambool, 2010. Primary Health Care Research to Better Manage Diabetes, Heart Disease and Depression – the True Blue Study (373)

3. Conference presentation to PHC Research Conference, Brisbane, 2011. TrueBlue collaborative care for the management of depression, heart disease and diabetes (374)

4. Conference presentation to 41st annual meeting of North American Primary Care Research Group annual conference, Ottawa, Canada, 2013. Outcomes of a randomised trial for multimorbidity (375).

5. Conference presentation to RCGP Annual Conference, Harrogate, UK, 2013. Collaborative care for multimorbidity. The TrueBlue trial and beyond (376).

Appendix 7 Materials used in clinical trials

Appendix 7.1 PHQ9

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use "✔" to indicate your answer)*	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
☐	☐	☐	☐

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.

Appendix 7.2 HADS

Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week.
Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

Please check you have answered all the questions

Scoring:
Total score: Depression (D) _____ Anxiety (A) _____
0-7 = Normal
8-10 = Borderline abnormal (borderline case)
11-21 = Abnormal (case)

Appendix 7.3 Waiting room survey

We are checking that our records are correct.

Please tick if you are you taking any over the counter or complimentary medications including the following?

☐ Aspirin you buy over the counter
☐ Aspirin that Dr has prescribed for you
☐ St John's Wort
☐ Other over the counter medications?
……..
……

Have you had a flu vaccination recently? Yes ☐....No... ☐
Have you had a pneumonia vaccination recently?.Yes.... ☐.. No... ☐

Your Name……..Your Doctor……

Please give to your Practice Nurse when you go in to see him/her

Appendix 8 – Authorship declarations

Co-author declaration by: Dr Stephen Bunker

Declaration by Dr Mark Morgan ('the candidate') regarding contribution to the published papers presented in this PhD thesis.

Prasuna Reddy, James A. Dunbar, Edward Janus, Alan Wolff, Stephen Bunker, **Mark Morgan** and Adrienne O'Neil. Identifying depression in patients following admission for acute coronary syndrome *Australian Journal of Rural Health* (2007) **15**, 137–138	I was part of the writing group and contributed to the design and implementation.

I certify that:

1. The above declaration correctly reflects the nature and extent of the candidate's contribution to this work;
2. They meet the criteria for authorship in that they have participated in the conception, execution or interpretation, of at least that part of the publication in their field of expertise;
3. They take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. There are no other authors of the publication according to these criteria.

Signature:  **Date: 15 March 2016**

Name: Dr Stephen Bunker

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Declaration by Dr Mark Morgan ('the candidate') regarding contribution to the published papers presented in this PhD thesis.

Adrian Elliot-Smith, **Mark A J Morgan.** How do we compare? Applying UK pay for performance indicators to an Australian general practice. *Australian Family Physician* (2010) **39**: 43-8	I was co-author and contributed extensively to the concept, design, implementation and analysis of the trial.

I certify that:

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Prasuna Reddy, James A. Dunbar, Edward Janus, Alan Wolff, Stephen Bunker, **Mark Morgan** and Adrienne O'Neil. Identifying depression in patients following admission for acute coronary syndrome *Australian Journal of Rural Health* (2007) **15**, 137–138	I was part of the writing group and contributed to the design and implementation.
Prasuna Reddy, James A Dunbar, **Mark A J Morgan**, Adrienne O'Neil. Coronary heart disease and depression: getting evidence into clinical practice (part 1). *Stress and Health* (2008)**24**: 223–230	I was part of the writing group and contributed extensively to the design, implementation and analysis of the trial.
Morgan, M. A. Dunbar, J. Reddy, P. Collaborative care - The role of practice nurses. *Australian Family Physician* (2009)**38**: 925-926	I was lead author and contributed extensively to the design and implementation and analysis.
Mark A J Morgan, Michael J Coates, James A Dunbar, Prasuna Reddy, Kate Schlicht, Jeff Fuller. The TrueBlue model of collaborative care using practice nurses as case managers for depression alongside diabetes or heart disease: a randomised trial. *BMJ Open* 2013;**3**	I was lead author and contributed extensively to the concept, design, implementation and analysis.

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Mark A J Morgan, Michael J Coates, James A Dunbar, Prasuna Reddy, Kate Schlicht, Jeff Fuller. The TrueBlue model of collaborative care using practice nurses as case managers for depression alongside diabetes or heart disease: a randomised trial. *BMJ Open* 2013;**3**	I was lead author and contributed extensively to the concept, design, implementation and analysis.
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Morgan MAJ, Coates MJ, Dunbar JA. Using care plans to better manage multimorbidity. *Australas Med J* 2015;**8**(6)	I was lead author and contributed extensively to the concept, design, implementation and analysis.

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3. They take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
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Mark A J Morgan, Michael J Coates, James A Dunbar, Prasuna Reddy, Kate Schlicht, Jeff Fuller. The TrueBlue model of collaborative care using practice nurses as case managers for depression alongside diabetes or heart disease: a randomised trial. *BMJ Open* 2013;**3**	I was lead author and contributed extensively to the concept, design, implementation and analysis.
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12. There are no other authors of the publication according to these criteria.

Signature: **Date: 13 March 2016**

Name: Dr Michael Coates

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