

# Safety and acceptability of practice-nurse-managed care of depression in patients with diabetes or heart disease in the Australian TrueBlue study

K Schlicht,<sup>1</sup> M A J Morgan,<sup>1</sup> J Fuller,<sup>2</sup> M J Coates,<sup>1</sup> J A Dunbar<sup>1</sup>

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<sup>1</sup>Department of Rural Health, Greater Green Triangle University Department of Rural Health, Flinders and Deakin Universities, Warrnambool, Victoria, Australia

<sup>2</sup>School of Nursing and Midwifery, Flinders University, Adelaide, Australia

## Correspondence to

Professor J A Dunbar;  
[director@greaterhealth.org](mailto:director@greaterhealth.org)

## 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<sup>1</sup> 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.<sup>2</sup> The complexity of chronic disease management and the increasing numbers of patients with these conditions requires a coordinated team-based approach driven by patient

## 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 PHQ-9 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.

needs. There has been considerable attention in Australia to increase the role played by practice nurses in general.<sup>3–5</sup> Primary care nurses can be effective in managing patients with chronic disease or depression.<sup>6–9</sup> 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.<sup>1</sup> 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 standard 15 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 PHQ-9 questionnaire<sup>10</sup> to decide if stepped care is required<sup>11</sup>; (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 1](#).

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 and/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 PHQ-9 be identified and appropriate action taken. In order to assess whether this protocol was being followed, we examined the PHQ-9 data being returned during the TrueBlue study<sup>1</sup> 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 appropriate action had been taken by them 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

**Table 1** Details of nurse training and support

Two-day training workshop	Depression as a risk factor in diabetes and heart disease Monitoring of depression using the PHQ-9 questionnaire <sup>10</sup> Impact of disease using version 2 of the SF36 questionnaire <sup>21</sup> 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 <sup>22</sup> 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 manager, a GP and a psychologist Peer support by participating nurses with case-study discussion

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 PHQ-9 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 2).

#### 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.

**Table 2** Acceptability of TrueBlue: themes from the focus groups and the 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

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 PHQ-9 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 PHQ-9 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 3 months. 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)

### 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 which 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.<sup>12</sup> 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,<sup>13 14</sup> but some primary care professionals find it difficult to manage simultaneously both physical and mental illness.<sup>15</sup> 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 which 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.<sup>8–16</sup> 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,<sup>17–19</sup> 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.<sup>20</sup>

### 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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**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.

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**Data sharing statement** The dataset used for the analysis and the computer codes used to produce the results are available from the corresponding author.

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**APPENDIX 1****TrueBlue Focus Group (Northern Rivers)**

1. Which parts of the project helped you (practice nurses) with your enhanced roles with the new role of being a case manager for these patients?
2. Any other people that were involved as practice nurses in the project have any other thoughts?
3. Did anyone find the manual, the handbook that went with the training program useful or not useful?
4. To what extent was the template for the GP management plan involved, useful or not useful in the way you delivered the care?
5. To what extent was the support that you had from GPs or the communication with GPs helpful for you taking on your enhanced roles of being a case manager?
6. To what extent has the nurse-led chronic disease management affected your practices as GPs?
7. Was the recall scheduling, the actual bringing people back at 3 month intervals a helpful structure or not?
8. The checklist that the patients can fill out in the waiting room before coming in to see the nurses, are you used to that or not?
9. And the PHQ-9 score and what changes. Was the actual number useful or not?
10. Did you use what had gone on in the practice nurse to generate care plans, and team care?? And mental health plans or just a proportion of those things?
11. So you added the mental health plans to what was already going on here. Is that the same with other practices?
12. I'm interested in just getting some. Seeking some opinions about communication next because chronic disease management, if it's done by a team, one of the benefits and one of the problems is communicating. Between nurses and GPs?
13. Was the GP management plan the main tool of communication or was discussion in the corridor or whatever the main tool for communication?
14. What about between nurses and allied health providers including mental health workers. Most of the communication, and this is more the case management role, was it the nurse to allied health provider or GP to allied health provider?

15. I was also wondering within the setting whether, what used to be a GP role which is doing all the referrals to any other external person have been taken over by practice nurses
16. To what extent is TrueBlue giving the patients a comprehensive management plan as opposed to a ...local aid one? Has it helped with or hindered communication with patients and their carers?
17. Would you to continue with a formalised project like TrueBlue? Would you continue including the depression screening and monitoring as part of project of disease management in a collaborative care way like this?
18. Could admin staff take more of a role or less of a role in chronic disease management? Could nurses take on even more tasks than we've asked them to in this project? Could doctors take on more tasks? What are people's thoughts getting around to that sort of balance of task sharing?
19. Are there more tasks that could make the job of chronic disease management easier for GPs by shifting more of the responsibilities to the nurses than we have in this project?
20. Do you feel like there's been a shift in the doctors' opinions of what nurses can do, or not?
21. Has there been a shift in what patients think of who their care team is?



## **APPENDIX 2**

### **GP/Practice nurse interview questions (Adelaide)**

What information was used from the risk survey to identify priorities for the visit?

- Pathology results
- Physical measures
- PHQ9 individual answers
- PHQ9 total score
- PHQ9 difficulty score (if recorded)
- SF36 answers (if done)
- Patient own ideas/concerns/expectations

How much time did you spend? How does that time break down between info gathering/measurement/recording data/discussion and planning with the patient?

What goals were set and how were they chosen?

To what extent do you, the practice nurse, suggest goals?

Was 'cycle of change' stage identified to help identify behavioural change?

Was any psycho education given?

Was any self-care information given/discussed?

- Diet
- Exercise
- Self-monitoring – e.g. blood sugars for diabetics or blood pressure
- Medication adherence
- Recall appointments
- Agenda items requiring GP attention e.g. medication changes

Were psycho education resources discussed?

Were any counselling techniques used? Were these skills developed in TrueBlue workshops and subsequent telephone support e.g. challenging fixed ideas/ventilating feelings/cognitive dissonance to encourage contemplation of a lifestyle change etc.?

How did GP respond to the GPMP draft. Was any discussion held with the GP about this patient? (Collaborative care model in action)

Were any external appointments made? Was any discussion held with the external provider? (Collaborative care model in action)

What happened in the GP consult? Any medication changes?

Why do you think the patient got better PHQ9 scored at subsequent visits?

What was your interaction with the patient's partner/carer/spouse?