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# Overcoming clinical inertia in insulin initiation in primary care for patients with type 2 diabetes: 24-month follow-up of the Stepping Up cluster randomised controlled trial

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ABSTRACT

*Aim:* To examine the two-year impact of Stepping Up, a general practice based model of care intervention for insulin initiation and titration in Australia.

*Methods:* 266 participants from 74 general practices participated in the Stepping Up cluster randomised controlled trial between 2012–2014. Control practices received training in the model of care on completion of the 12-month trial. Patients were followed for 24 months. Participant baseline characteristics, insulin and non-insulin medication use were summarised for each study group. Linear mixed-effects models with random intercepts were used to estimate differences in mean outcome (HbA1c and weight) between the study groups using restricted maximum likelihood estimation.

*Results:* At baseline 61% of patients were male, mean (SD) age 62 (10) years, diabetes duration 9 (5, 13) years and mean (95% CI) HbA1c was 8.9 (8.8–9.1)% (74 (73–76) mmol/mol) for both groups. There was a significant between group difference at 6 months which was sustained at 24 months; Mean (95% CI) HbA1c at 24 months in the intervention group was 7.6 (7.5–7.8)% (60 (58–62) mmol/mol) and 8.0 (7.7–8.4)% (64 (61–68) mmol/mol) in the control group. At 24 months 97 (71.3%) of the intervention group and 26 (31.0%) of the control group were prescribed insulin; there was no significant difference in weight. Use of non-insulin anti-hyperglycaemic agents was similar in both groups with the exception of dipeptidyl peptidase-4 inhibitors which were prescribed more frequently in the control group (30(36%) vs 21(16%)).

*Conclusion:* Stepping Up was associated with improved glycaemic control compared to usual care for 24 months, suggesting that the model facilitated more timely treatment intensification. Ongoing RN-CDE support may be needed to facilitate ongoing treatment intensification.



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## 1. Introduction

Diabetes is a prevalent condition, affecting 415 million people globally [1]. In Australia, over one million people have been diagnosed with type 2 diabetes [2] and an additional 1 in 34 adults are estimated to have undiagnosed diabetes [3]. Diabetes costs the Australian economy at least $14 billion annually and this is likely to rise with the increasing prevalence of this condition, which is expected to double in the next 20 years [3,4]. Effective management of type 2 diabetes (T2D), including assisting people to achieve optimal glycaemia, is vital to reduce the development of complications and to contain the associated human and economic burden. The majority of people with T2D will receive care in general practice.

Ten years after diagnosis approximately 50% of people with type 2 diabetes will require insulin injections because their pancreatic beta cells are not able to produce sufficient insulin to maintain optimal glycaemia despite the use of non-insulin anti-hyperglycaemic agents [5]. Whilst rates of prescribing of insulin to people with T2D appear to be increasing in Australia [6,7], evidence suggests that the initiation of insulin therapy is often delayed in general practice [8–11]. Data also indicate that primary care physicians are more likely to demonstrate therapeutic inertia in relation to insulin initiation when compared to their specialist colleagues [12]. Therapeutic inertia refers to a "providers' failure to increase therapy when treatment goals are not met" [13] and is relevant to the pharmacological management of glycaemic control in T2D where therapeutic targets are clearly defined and there are benefits to attaining those targets [14]. Reasons for therapeutic inertia include overestimating the level of care provided, soft reasons (such as the belief that the patient is close enough to target), lack of training and organisation in the practice [15], clinical uncertainty (for example, GPs may not be confident in making treatment decisions if they feel they have insufficient or conflicting information) [16] and competing demands when patients have more than one condition that requires management [17].

The Stepping Up model of care, described in detail elsewhere [18], was developed to address therapeutic inertia in insulin initiation. We recently reported the findings of a cluster randomised controlled trial (RCT) evaluating this model of care [19]. Intervention practices received an in-practice lunchtime training session for general practitioners (GPs) and practice nurses (PNs), followed by mentoring and ongoing support by the Stepping Up Registered Nurse-Credentialed Diabetes Educator (RN-CDE) to initiate and titrate insulin. In control practices, participating patients were managed according to usual care over 12 months. The model of care was effective in overcoming clinical inertia, with 69.5% compared to 21.7% of patients commencing insulin, a 0.6% (8 mmol/mol) reduction of HbA1c favouring the intervention arm, and 35.8% compared to 20.9% achieving an HbA1c ≤7% (53 mmol/mol) [19], which is the general target for HbA1c in Australia [20]. Continued improvement in HbA1c after insulin initiation in general practice appears difficult to achieve. Observational studies in Germany and the United Kingdom have demonstrated improvements in HbA1c at nine and six months respectively which have been maintained, but not further improved upon, for up to two and a half years [21,22]. However, it should be noted that in contrast to Schreiber et al. and Dale et al., not all patients for whom insulin was indicated commenced this medication in the pragmatic 12 month Stepping Up study [19].

## 2. Aim

The aims of this study were to:

a) Examine the two-year impact of the Stepping Up model of care on a range of measures, including glycaemia, insulin dosage, prescription of non-insulin anti-hyperglycaemic agents and weight.
b) Determine whether a training intervention without RN-CDE support resulted in improvement in glycaemia in the control group following participation in the Stepping Up RCT.

## 3. Methods

### 3.1. Setting

74 general practices in Victoria, Australia.

### 3.2. Practice eligibility and recruitment

General practices must have employed a practice nurse to be eligible to participate in the study. Practices were recruited using our University Department of General Practice database (the VicReN practice based Research Network) and through Medicare Locals (primary health care organisations tasked with coordinating primary health care delivery and improved access to primary care; now called Primary Health Networks).

### 3.3. Randomisation in the Stepping Up cluster RCT

The unit of randomisation in this cluster randomised controlled trial was the general practice. The study statistician generated stratified block randomisation sequences with varying block size (4, 6 and 8); practices were stratified by size, setting (private vs community health centre) and whether they had participated in type 2 diabetes quality improvement programmes. Practices were randomised after recruiting at least one eligible patient [18].

### 3.4. Patient eligibility

Patients were eligible to participate in the study if they were adults with type 2 diabetes with above target HbA1c (≥7.5% (58 mmol/mol)) in the past six months who were already prescribed maximum oral treatment (at least two oral hypoglycaemic agents at maximum doses) or if their GP judged that insulin would be clinically appropriate. Patients were ineligible if they were aged more than 80 years, were already using insulin, had an estimated glomerular filtration rate <30 mL/min/1.73m$^2$, were unable to give informed consent, or had a complex debilitating medical condition, such as severe mental illness, end stage cancer, or unstable cardiovascular disease.

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