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# A review of current models for initiating injectable therapy for people with type 2 diabetes in primary care



Arti Appannah<sup>a</sup>, Toni Rice<sup>a</sup>, Rajna Ogrin<sup>a,b,c,\*</sup>

<sup>a</sup>RDNS Institute, Melbourne, Australia

<sup>b</sup>University of Western Ontario, Canada

<sup>c</sup>Austin Health, Melbourne, Australia

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## ABSTRACT

**Aims:** To systematically identify and describe models of injectable therapy initiation for people with type 2 diabetes mellitus (T2DM) in primary care.

**Methods:** Eight electronic databases and the grey literature were searched. Studies examining models of injectable therapy initiation for adults with T2DM in primary care settings were included.

**Results:** Successful models included: 1) Nurse-led one-to-one approach; 2) Nurse-led group sessions; and 3) Providing education to GPs and nurses.

**Conclusions:** Few robust studies were found. Studied models were mainly in general practices, with limited evidence documented about starting people with T2DM on an injectable in the home setting.

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## Introduction

Type 2 diabetes mellitus (T2DM) affects approximately one million Australians [18] and 422 million people worldwide [33]. Sub-optimal glycaemic management is associated with an increased risk of developing diabetes-related complications and increased longer-term health costs. Across the population of people with type 2 diabetes, a 1% reduction in HbA1c over a five year period would result in reductions in the cumulative incidence of end-stage kidney disease by 40%, in amputations by 20%, in advanced eye disease by 42% and in myocardial infarction by 15% [29]. Optimal glycaemic management, that is established early and maintained throughout the disease duration, is essential for delaying and preventing long-term complications [7,23,36,28].

Insulin is effective in optimising glycaemic levels, and the timely use of insulin for treatment of people with T2DM is clearly supported by American and European guidelines [21]. Despite this, the initiation of insulin is often delayed due to various client, General Practitioner (GP), or system level barriers. Patient barriers can include a fear of injections, negative perceptions of insulin, social stigma, lifestyle adaptations, restrictions required by insulin use and the fear of side effects and complications from use [14,4]. GP barriers can include a physician's lack of familiarity with insulin, time constraints, a lack of confidence in initiation, lack of resources

(including having practice nurses), and clinical inertia [26,30,25], amongst others. Barriers associated with the health system have been infrequently reported, but are also important and have been shown to contribute to the delay in insulin initiation in primary care [2].

In Australia, almost two-thirds of all people with T2DM have their insulin therapy initiated by a specialist rather than in primary care; with GPs initiating an injectable therapy for less than 20% of cases [3]. This is despite the 2016–2018 “General practice management of type 2 diabetes” clinical practice guidelines [37] providing clear protocols for the initiation and titration of injectable therapies in the primary care setting. Insulin initiation by specialists is also common in international settings. For example it has been shown that Diabetes Specialist Nurses (DSNs) mostly in secondary care, rather than practice nurses in primary care, initiate injectable therapy [6]. This can lead to delays in insulin initiation due to limited availability of specialist resources. A move to manage people with T2DM in primary care rather than secondary care has the potential to result in increases in insulin commencement [6], reductions in the use of more costly secondary care [12], and positive impacts on long-term outcomes for people with T2DM if it meant that insulin was started earlier [15].

For insulin initiation and titration to become successfully adopted in primary care (including general practice, community settings and domiciliary settings), there is a need for making changes in service delivery to improve diabetes management. In particular, a model of care is required that is feasible, practical and sustainable in practice. This systematic review aims to identify

\* Corresponding author at: RDNS Institute, 31 Alma Road, St Kilda, VIC 3182, Australia

E-mail address: [Rogrin@rdns.com.au](mailto:Rogrin@rdns.com.au) (R. Ogrin).

and assess current models of initiating injectable therapy for people with T2DM in primary care that are present in the literature. In doing so, the characteristics of these models and successful attributes can be described and reported on. Through this, an understanding of current practices for initiating injectable therapy in primary care can be gained, whether these practices are working, and whether any gaps in knowledge need to be addressed.

## Method

### Search strategy

A comprehensive search of the literature was conducted and included the retrieval of electronic documents and hand searching of reference lists for relevant articles. The databases that were searched included Medline, CINAHL, ProQuest, PubMed, Web of Science, and Cochrane Central register of Controlled Trials (CENTRAL). The key words used were: insulin initiation, diabetes injectable therapy initiation, insulin stabilisation, insulin titration, insulin administration and dosage, and injections subcutaneous. Searches were limited from 2000 to 2016, to capture the recent literature relevant to current clinical practice. The first author screened and assessed all titles and abstracts for inclusion, while the second author also assessed the identified articles. Any discrepancies in assessment were resolved through discussion with all authors. The reference lists of included studies were also searched for additional articles.

### Inclusion criteria

For the study selection criteria, the review was restricted to English-language studies focusing on adults with T2DM, aged 18 years and older, for whom injectable therapy for T2DM (i.e. insulins or GLP-1 mimetics/agonists) had been recommended. The review included randomised-controlled trials (RCT), quasi-RCT, uncontrolled evaluations, cross-sectional studies and qualitative research in order to gain a more complete picture of the models of injectable initiation being used. Papers excluded from the review were: studies focusing on secondary care, abstracts alone, articles that lacked sufficient information about study design, methods of analysis and findings to be able to provide adequate assessment, conceptual/methodological or advocacy papers and review articles.

### Data extraction and risk of bias

Two reviewers worked independently to extract data relevant to the review and assess the risk of bias of the studies. Data extraction forms were developed prior to the review. Information on the study purpose, setting, method, participants, sample size and main findings were extracted. Any discrepancies on data extraction and assessment of risk of bias were resolved via discussion. Two checklists developed by Kmet et al. [24] were used to assess the risk of bias for both quantitative (observational studies, cross sectional, and descriptive) and qualitative articles included in the review. These checklists addressed a range of characteristics, including study design, measures, methodology, analysis, and reporting. The risk of bias for randomised control trials (RCTs) was assessed using the Cochrane Collaboration Criteria [5].

### Data synthesis and analysis

Given the heterogeneity of the studies included, and as the systematic review aimed to identify and describe current models of initiating injectable therapy for people with T2DM, the data synthesis is largely descriptive. The findings are presented according

to the strategies identified for initiating injectable therapy for people with T2DM.

## Results

### Search results

An initial search strategy retrieved 6455 articles which fitted the inclusion criteria. After eliminating duplicates and screening titles for relevance, 118 abstracts remained for assessment. Of the 118 abstracts reviewed, 10 met all of the eligibility criteria for the systematic review. Fig. 1 shows the selection and reviewing process in greater detail.

A total of 10 articles were included in this review, of which 9 were quantitative studies and one was a qualitative study. Table 1 displays the study summaries and methodology quality.

### Study characteristics

The study characteristics are discussed separately for quantitative studies and the qualitative study.

### Quantitative study

Three of the studies were cross-sectional and self-report (2, 4, and 8), three were Randomised Controlled Trials (RCT) (1, 7, and 10) and three were longitudinal observational studies (3, 6 and 9). Sample size ranges from 20 to 20,493 participants. Response rates ranged from 11% to 95%, with one study not providing a response rate (10) because the study used purposive sampling. The outcomes assessed in the included quantitative studies varied widely, from changes in HbA1c levels with new models of care, to healthcare professionals' satisfaction with the models. Four of the studies were conducted in the United Kingdom (UK) (2, 3, 4, and 8), one in Australia (1), one each in New Zealand (6), France (9), and Canada (7) and one across four countries (Finland, Sweden, UK and Netherlands) (10). Four of the studies were conducted in general practices (1, 3, 4, and 9), one in both a general practice and using a national register of diabetes care staff (2), one in both general practices and community pharmacies (7), and two that did not specify a setting (8 and 10). Three studies involved people with T2DM (6, 9, and 10), two studies mentioned the involvement of healthcare professionals generally (4 and 8), two studies involved General Practitioners (GPs), Practice Nurses (PNs), Diabetes Specialist Nurses (DSNs) and patients with T2DM (1, 3), one study involved DSNs and PNs (2), and one involved GPs, community pharmacists and people with T2DM (7).

### Qualitative study

The qualitative study (5) was conducted in a general practice in Australia with both GPs and patients with T2DM. A purposive sampling method was used and the data collected included interviews (24 healthcare professionals and patients) and focus groups (10 patients). A thematic analysis of the data was performed, however the study publication did not state a theoretical framework.

## Narrative synthesis: initiation of injectable therapy for T2DM strategies

*Injectable therapy initiation can be successfully managed in primary care*

The majority of the studies demonstrated that injectable therapy initiation for people with T2DM can be successfully managed

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