Optimising care and outcomes for people with type 2 diabetes:

*Lessons from a translational research program on insulin initiation in general practice*

John Furler, Irene Blackberry, Jo-Anne Manski-Nankervis, David O’Neal, James Best, Doris Young

STEPPING UP and INITIATION Study Groups

General Practice and Primary Health Care Academic Centre
Uncontrolled hyperglycaemia

- 62% of T2D patients above target HbA1c >7%. (ANDIAB 2004-06)
- In General Practice 44% HbA1c >7%; 19% > 8.0%. (Taggart et al 2006. http://www.cphce.unsw.edu.au)

While patient-centred education and self-management interventions are important, pharmacotherapy is a key treatment for T2D.

Delays in starting and up-titrating insulin

- Mean HbA1c prior to insulin initiation: Aust: 9.4% (Davis et al)
  UK: 9.3% (Blak et al, 2012)
- 77% T2D on insulin with HbA1c >7.0% (ANDIAB 2004-06)
**Bench**
- Basic science research
- Preclinical studies

**Bedside**
- Human clinical research
- Phase 3 clinical trials

**Practice**
- Clinical practice
  - Evidence based care to the right patient at the right time in the right place
  - Identifying new questions and gaps in care

**T1**
- **T2**
  - Practice based research
    - Phase 3 and 4 trials
    - Observational research

**T2**
- **Guidelines, systematic reviews**

**T3**
- **Dissemination & implementation research**

Why primary care based insulin initiation?

- There is a relative lack of access to specialists
- Benefits of ‘whole person’ care, continuity of care and accessibility
- Insulin initiation in general practice is safe\(^1,2\)
- How can we embed and integrate timely insulin initiation within Australian general practice?

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\(^3\) Health Workforce Australia, *Health Workforce 2025 - Volume 3 - Medical Specialties*, 2012.
\(^4\) Steele C. ADEA Conference, 2011
MRC Framework for evaluating complex interventions

1. **Theory**
   - Explore relevant theory to ensure best choice of intervention and hypothesis and to predict major confounders and strategic design issues.

2. **Modelling**
   - Identify the components of the intervention and the underlying mechanisms by which they will influence outcomes to provide evidence that you can predict how they relate to and interact with each other.

3. **Exploratory trial**
   - Describe the constant and variable components of a replicable intervention and a feasible protocol for comparing the intervention with an appropriate alternative.

4. **Definitive RCT**
   - Compare a fully defined intervention with an appropriate alternative using a protocol that is theoretically defensible, reproducible, and adequately controlled in a study with appropriate statistical power.

5. **Long term implementation**
   - Determine whether others can reliably replicate your intervention and results in uncontrolled settings over the long term.

**Continuum of increasing evidence**
- **Preclinical**
- **Phase I**
- **Phase II**
- **Phase III**
- **Phase IV**
A model of care for primary care based insulin initiation

Theory and qualitative study

Model development
Pilot feasibility
acceptability

INITIATION
Large scale pilot and benchmarking
(Trial of adjunct CGM)

Stepping Up
Cluster RCT (underway) 2012-14

Theory of implementation: Normalisation Process Theory
A model of care for primary care based insulin initiation

Interviews with 10 GPs, 4 DNEs and 12 patients

Factors important to supporting insulin initiation in GP

- Locating insulin initiation within the diverse aims of diabetes care
- Clarification of roles and expectations
- A local “in-practice” system for managing the work
- Potential role for PN

Theory and qualitative study

Theory of implementation: Normalisation Process Theory

1 Furler J, Spitzer O, Young D, Best J. Australian family physician. 2011; 40(8):617-21
2 May CR, Mair FS, Dowrisk CF, Finch TL. BMC Family Practice. 2007;8:42.
Model of care elements

- **“Micro-team”**: GP and PN in partnership identifying appropriate patients
- **“In-practice system”** to initiate and titrate insulin
- Simple protocols and tools to assist initiation/titration of insulin
- **Appropriate** Endo and DNE support: “hub and spoke”

Introducing and embedding the model of care

3 hour training session for GP and PN
- Evidence and rationale
- Clarify roles and in-practice system
- Motivating patients
- Insulin titration algorithm
- Hands on: Insulin pens

Practice and patient resource pack
DNE/Endo support as needed: Phone based
A model of care for primary care based insulin initiation

Theory and qualitative study

Model development
Pilot\(^1\)
feasibility
acceptability

Development of the Stepping Up program

Feasibility testing in 5 GP sites
- 7 GPs and 5 PNs
- 18 patients, 14 started insulin
- Qualitative evaluation at 3 and 12 mths: Focused on “workability and integration”

Theory of implementation: Normalisation Process Theory

Mobilising generalist practice to the task of initiating insulin

- **Continuity**
  - “...I think the other thing that was really good is that our PN is really well known to most of our patients, [...] rather than someone new that they didn’t necessarily trust. (TI GP5-04)

- **Comprehensive whole-person care**

- **Patient centred**
  - Dealing with other conditions and psychosocial issues
  - Information at the patients pace
  - Ready to act when the patient is

Coherent, meaningful work that GP and PN could engage with

Tools and resources supported “collective action”
Tensions, barriers and challenges

- **Negotiating clinical autonomy and accountability locally**
  - “my role was ...engaged but quite peripheral to what [PN name] was doing” (FG GP02-01)

- **Confidence to extend scope of practice**
  - “....I think generally nurses don’t see their role as going near the medication side of things or you know even dare suggesting that a patient may need to go on insulin...” (EW GP01-03)

- **Time and funds**
  - “...the amount of time and the role of the nurses because it is certainly going to be a significant feature for any practice that is going to do this.” (EW PN04-03)
A model of care for primary care based insulin initiation

Theory and qualitative study

Model development
Pilot feasibility acceptability

INITIATION Large scale pilot and benchmarking (Trial of adjunct CGM)\(^1, 2\)

- 22 practices and 92 patients who commenced insulin
- Mean $\downarrow$ in HbA1c 2.6%
- Results as good as benchmark secondary care
- $\uparrow$DNE support

Theory of implementation: Normalisation Process Theory

A model of care for primary care based insulin initiation

Theory and qualitative study

- Model development
- Pilot feasibility
- Acceptability

INITIATION
- Large scale pilot and benchmarking (Trial of adjunct CGM)

Stepping Up¹
- Cluster RCT (underway) 2012-14

Theory of implementation: Normalisation Process Theory

- 75 practices and 266 patients
- Basal +1 clinical protocol
- In practice training and significant DNE mentoring
- 12 month follow up results early 2015

Uptake of the model

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<thead>
<tr>
<th>Characteristics of teams requiring less ongoing support</th>
<th>Characteristics of teams requiring considerable ongoing support</th>
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<tr>
<td>Private clinics where the patients are ‘known’</td>
<td>Large corporate practices</td>
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<td>GP or practice nurse already had an interest in diabetes</td>
<td>Rapid staff turnover</td>
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<td>Practice nurse willing to learn and take ownership of the study</td>
<td>Practice nurse too busy, stressed</td>
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<td>Good rapport between GP and practice nurse</td>
<td>Not proactive in checking patient’s diabetes status</td>
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<td>Formal distinct role differentiation</td>
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¹Ginnivan L et al. Oral presentation at ADEA in August-September 2012.
Overall conclusions

Importance of the MRC framework for developing workable interventions that can change practice

There was a need to address inter-professional cultural differences and tensions

Intervention needed to be flexible, adaptable

Dovetailing research with day-to-day routines of practice

Intensive research support needed for decentralised networks of practices

Need for “greater investment in developmental studies prior to large scale evaluations, and in implementation research [which] will help to ensure a better return on investment in evaluation studies”.

Medical Research Council. Developing and evaluating complex interventions: new guidance.
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