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Stepping Up Telehealth

Using telehealth to support a new model of care for type 2 diabetes management in rural and regional primary care

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Background

This Final Report is produced for an Australian Primary Health Care Research Institute (APHCRI) 2014 Foundation Grant on supporting research capacity building in primary health care. This grant focused on primary health care clinical and health services research. It is a collaboration between researchers from the Department of General Practice, the University of Melbourne and John Richards Initiative, La Trobe University. The project was conducted between November 2014 and October 2015.

THE TREATMENT GAP IN TYPE 2 DIABETES

Type 2 diabetes (T2D) is the leading cause of disease burden in Australia and costs over \$14 billion annually in direct and indirect healthcare costs (1). There are more than one million Australians with diabetes and about 100,000 people being diagnosed each year (2). The human and healthcare costs associated with T2D is expected to rise exponentially.

For people with T2D in Australia, the vast majority of their clinical care is based in general practice and primary care. In this setting, evidence-based clinical care can help people achieve glycaemic targets and improve outcomes (3). Yet many studies in Australia and internationally show a consistent failure to achieve recommended evidence-based targets for glucose and other cardiovascular risk factors in the majority of patients (4-8). This is despite significant investment over the last two decades to improve quality of clinical care and outcomes for people with T2D including the National Divisions Diabetes Program (9), the Australian Primary Care Collaborative program (10), the National Integrated Diabetes Program and targeted incentive payments to GPs and practices (11).

While increasing numbers of people with T2D are on medications for glycaemia and associated cardiovascular risk factors, many people with T2D remain out of target, without appropriate intensification of treatment (5). An international study of median time to initiate a second and third oral hypoglycaemic agents in general practice was three and seven years, respectively, when HbA1c is well out of target (12). This pattern is seen in relation to the rapidly growing list of available new oral and injectable hypoglycaemic agents as well as insulin.

Our previous work (on which this project is based) on insulin initiation focused on this challenge of treatment intensification. Early use of insulin as part of treatment intensification for people with T2D is supported by Australian and international guidelines (13, 14). Long-acting insulin analogues used with simple patient-driven algorithms are feasible, safe (low incidence of hypoglycaemia), and effective in achieving glycaemic control (15) and are associated with improved patient satisfaction (16).

Rates of insulin initiation are increasing in primary care. Prescribing rates for insulin in people with T2D increased by nearly 60% from 2003-4 to 2012-13 (17). However failure of subsequent up-titration of insulin treatment to achieve glycaemic targets remains a clinical issue (18). Clinical audits from practices in our current Stepping Up Study (19) identified that 21-32% of people with T2D and an out-of-target HbA1c (>7.5% or 58mmol/mol) are already on insulin, indicating that insulin therapy has been sub-optimally implemented once initiated.

GPs and patients face challenges in intensifying treatment to achieve glycaemic targets. Reasons for this may include: a) that GPs and patients lack a simple and reliable method for *structured self-monitoring of blood glucose* (S-SMBG), to guide decisions about insulin initiation and titration and b) lack of *access to the appropriate workforce* (i.e. the members of the T2D multidisciplinary team). These issues are the focus of our pilot study described in this report.

AN ENHANCED MODEL OF CARE: EVIDENCE FROM INITIATION AND STEPPING UP STUDIES

This treatment intensification gap is an example of a “translational gap”. Bridging such gaps between research evidence about known effective interventions and the real world of clinical care is a global issue (20, 21) and is the focus of the Research Translation Faculty in the National Health and Medical Research Council in Australia. The project described in this report builds upon and extends our translational work in developing a *new model of care* to bridge the treatment gap by supporting timely, patient centred, evidence-based treatment intensification to address hyperglycaemia in people with T2D (22).

Rethinking insulin initiation: The context for our work

Embedding insulin initiation for people with T2D in routine general practice is necessary given the majority of diabetes care occurs in this setting. This process may also be more acceptable to patients as it helps integrate diabetes care with managing other co-morbidities as a part of comprehensive, holistic, patient-centred generalist care delivery.

Bridging the treatment gap by changing clinical practice is complex. Patients and clinicians struggle with the complex, progressive nature of T2D. Constant monitoring, adjustment and intensification of lifestyle and medications are needed. For clinician and patient the challenges associated with caring for and living with such a complex and dynamic chronic condition (23) may underlie practitioner “clinical inertia” (12). Delayed initiation of insulin may also stem from patients “psychological insulin resistance” (24). Health system and organisational factors are also important. For example people with T2D are commonly referred to specialist care for insulin initiation (25, 26). Where general practice acts as a “gatekeeper”, difficulties accessing endocrinologists and registered nurse credentialed diabetes educators (RN-CDEs) due to cost and limited availability of those specialists can result in delays. Intermediate care, outreach clinics and special interest practitioners (27) have all been tried as ways to address this. Yet treatment and target gaps persist.

Our research program builds on the UK Medical Research Council framework (Figure 1) in developing a model of care intervention that is well matched to the setting of General Practice and to the experiences and priorities of patients. We undertook an exploratory qualitative study (28), leading to the development of a practice -based intervention that we pilot tested for feasibility and acceptability (22), before undertaking a larger pilot (29) and a cluster RCT (30).

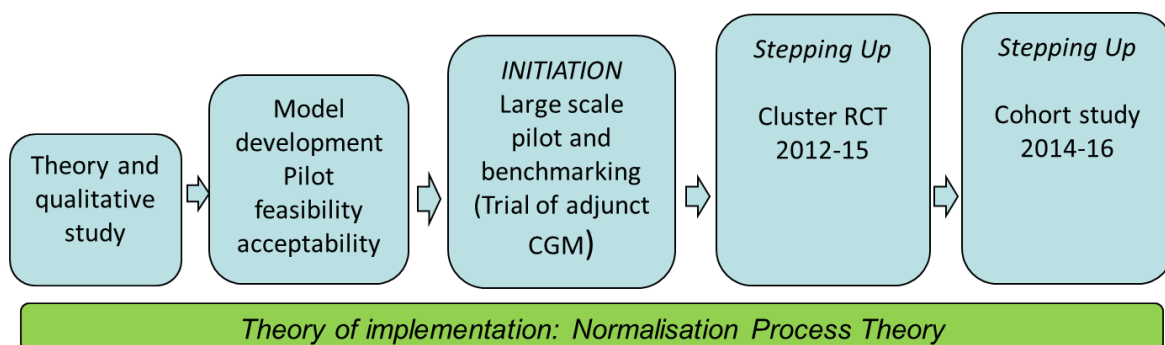


Figure 1: Program of work and underpinning theory

We based our work on Normalisation Process Theory (NPT), a sociological theory of implementation, which describes how new practices become incorporated into routine clinical care as a result of individual and collective work (31). NPT suggested that our model of care intervention would need to be patient centred and include all members of the multidisciplinary diabetes team, including Endocrinologist, RN-CDE General Practitioners (GP), and generalist Practice Nurses (PNs). All of these groups are involved in the ‘work’ of insulin initiation.

Understanding the work involved in insulin initiation in General Practice

In a qualitative study (14), we explored GP's and RN-CDE's stories of 'success' and 'failure' in initiating insulin from their own practice while patient interviews used an illness narrative approach (32). Our findings suggested that a key challenge lay in supporting the integration of the technical work of insulin initiation with the generalist work structures and relational ethos of general practice. Based on this, we developed an intervention, the *Stepping Up* model of care, which explicitly incorporated an enhanced role for the generalist PN in insulin initiation (22). This allowed GPs to delegate an active role for the PN to introduce and lead the discussion with the patient about insulin initiation. GPs retained prescribing authority. Our intervention included practitioner education using simple, understandable evidence based tools and algorithms for basal glargine insulin initiation and titration (15), and mentoring/support for the PN from a RN-CDE and endocrinologist if needed.

We piloted the model of care in 5 practices initially, and then in a larger pilot (29) in 22 practices and 92 patients. We nested a study of retrospective continuous glucose monitoring (rCGM) within this larger pilot (33). Our evaluation using a before and after design found a significant improvement in HbA1c (34). We identified the need for more intensive RN-CDE mentoring for PNs on a face-to-face basis, with additional phone support. We also incorporated more structured titration tools, including the addition of short acting insulin at one meal time if needed.

Evaluating the Stepping Up model of care

We undertook a cluster randomised controlled trial (RCT) (30) involving 74 practices and 266 patients, randomised at the practice level to receive the model of care intervention or usual general practice care. The 12-month follow up was completed in April 2015. Analysis of follow up data is being finalised and a paper is prepared for publication in 2016.

We identified important challenges from our program of work in how to personalise the intervention to provide greater patient-centred care. These included:

- > The need to incorporate the growing range of glycaemic therapies to include other oral and injectable glucose-lowering therapies
- > Allowing some flexibility in the role of the PN and RN-CDE to support tailoring the model of care to local contexts
- > Implementing the model of care in rural and regional settings to support scaling up of the model of care

DIABETES CARE IN RURAL AND REGIONAL COMMUNITIES

The prevalence of diabetes in regional and remote Australia is similar to that of metropolitan areas. In 2011-12, the prevalence rates for diabetes (based on HbA1c and self-report) in those aged 18 and over ranged from 5.3% in major cities to 5.5% in inner regional areas and 6.1% in outer regional and remote areas combined (35). However, generally people with diabetes in rural and regional areas are more socioeconomically disadvantaged and have higher rates of hospitalisation and mortality (36). In fact, mortality rates from diabetes are two to three times higher in regional and remote areas compared to major metropolitan regions (although this may reflect the larger numbers of Aboriginal people in remote areas, who have higher rates of diabetes) (37). An audit of people with T2D in rural Victoria found that only one in five achieved target levels for glycaemia, blood pressure, and lipids five years after diabetes diagnosis was made (38).

This excess need in regional and remote areas is not matched by higher levels of service provision. In 2014, there were 8,586 General Practitioners working in regional, rural and remote areas (ASGC-RA 2 to 5 locations) in Australia, with 21% working in Victoria. (39, 40). While two-thirds of the total workforce were working full time, one in six planned to leave workforce within five years. Over 60% of practices employed a practice nurse and about a third reported they had access to a diabetes educator. Most of the general practices were group practices and used a fee for service model.

GPs in rural and remote areas find effective use of insulin and other injectables challenging. This is partly due to lack of training and knowledge as well as shortage of specialists and allied health professionals in rural and remote areas despite availability of diabetes guidelines (41), but in part also related to the shortage of specialists and allied health professionals in rural and remote areas.

Lack of access to diabetes medical specialist care has also been reported by people with diabetes living in rural and regional areas registered with the National Diabetes Services Scheme (NDSS) (42). Access to dietitians and diabetes educators varies. NDSS registrants in rural areas were more likely to receive care from a diabetes educator or a dietitian compared to those living in metro regions (42). In contrast, another study in rural general practices in NSW found that almost half of people with T2D never accessed allied health services and had no understanding of the role of multidisciplinary team care (43).

Despite the lack of specialist care and geographical barriers, people with T2D from rural and regional communities show comparable health and self-care indicators against their metropolitan counterparts; suggesting rural self-reliance on primary care (42, 44).

There are huge geographic, economic, environmental and socio-demographic variations in Australian rural and remote communities that contribute to disproportionate burden of diabetes (36). Characteristics of the population, health workforce, infrastructure or support system can be vastly different between and within communities. Variation in health workforce mix, training and skills further influence how care is delivered. Any new models of care developed to address these issues has to be tailored to meet targeted population needs and capacity of the health workforce. Flexible learning via online delivery and access to specialist support via telehealth has the capacity to address some of these issues.

TELEHEALTH IN OPTIMISING T2D CARE

Addressing the higher needs and the workforce shortages in regional and remote communities and the particular challenges of delivering care in those settings requires innovation. Our aim in this project was to explore the potential for emerging eHealth technologies to extend our model of care intervention described above to those communities.

Telehealth is a rapidly expanding field. Yet the overall uptake is low, with less than one telehealth consultation for every 400 specialist consultations made in Australia (45). It may appear disruptive, that is to threaten traditional models of care, however if carefully implemented it has the potential to increase quality of care and patient satisfaction while providing professional job satisfaction and being cost-effective (46). The way that telehealth integrates with everyday life and routine healthcare, the way that it visually represents symptoms and feedback and the way that it influences the relationships among professionals and peers are known to be key factors in design and deployment of telehealth interventions to support patients with long-term conditions(47).

Professional bodies have published standards and frameworks for the implementation of telehealth in clinical practice (48, 49) and the Commonwealth supports Telehealth video-consultations under Medicare in certain circumstances to enhance access to specialist services (50). Common telehealth interventions include computerized systems for information exchange, video conferencing, and exchange of information via mobile devices,

short message service, or through the internet. Telehealth interventions can focus primarily on the patient or the provider, however a recent systematic review of quality improvement initiatives concluded “efforts to improve diabetes care in rural communities should focus on *interventions with multiple strategies targeted at clinicians and/or the health system*, rather than on traditional patient-oriented interventions.” (51). Consistent with this recommendation, our intention was to use a multi-component intervention addressing provider, system and patient factors.

The benefits of telehealth in improving diabetes outcomes are still not clear. The literature is complex and varied and interventions vary significantly making comparisons difficult and synthesis of the evidence challenging. However a systematic review of telehealth interventions in diabetes identified a statistically significant (but not clinically significant) improvement in HbA1c of -0.44% (-4.8 mmol/mol) across the 13 studies and 4207 patients they included when compared to usual care. Importantly, they noted that the improvement was most marked in diabetes where injectable treatments were involved and also that “*interventions which included changes in patient prescriptions through telehealth were associated with a greater benefit on HbA1c reduction than the ones which did not*” (52). Again this is consistent with the focus of the telehealth intervention elements we used in this pilot study.

One of the difficulties in evaluating the effect of telehealth studies is the lack of a consistent evaluation framework. In response to this we have used a framework addressing gaps identified in a review of telehealth evaluation frameworks and aligned with key indicators in the Australian National Health Performance Framework (53). The Evaluation Framework for Telehealth Implementation in Australia (54) includes four primary dimensions:

- > Patient Control
- > Clinician Quality of Care
- > Organisation sustainability and
- > Technology capability.

We use these to frame our discussion and interpretation of our findings (see Discussion section).

AIM OF THIS PROJECT

This pilot project is a ‘proof of concept’ study of an enhanced model of care supported by the use of telehealth. The project aimed to examine the feasibility and acceptability of a multi-component telehealth intervention to support intensification of treatment to achieve glycaemic targets people with out of target T2D in rural general practices. This included the capacity to initiate and up-titrate insulin and other oral and injectable hypoglycaemic agents in the primary care setting.

Methods

STUDY DESIGN

Our study was a pilot 'proof of concept' feasibility and acceptability study using a before and after study design. The focus of the study was on the use of telehealth to implement the Stepping Up model of care, modified to suit the setting and context.

Pilot feasibility studies are not designed or powered to test the effectiveness of an intervention. Pilot feasibility studies are of increasing interest in the research community for their capacity to add to the robust design of practical interventions likely to make a difference to real world practice. Pilot feasibility studies can (i) test a potential trial study protocol (ii) gather estimates for sample size calculation (iii) test data collection methods and randomisation processes (v) estimate rates of recruitment and consent, (vi) explore the acceptability of an intervention and (vii) explore appropriate primary outcome measures (55). Our study focused mainly on a potential protocol/design and the acceptability of the intervention.

The project was conducted in three phases over 12 months.

PHASE 1: ADAPTING THE MODEL OF CARE AND PROJECT MATERIALS

A Steering Committee consisting of key stakeholders and the project team was formed at the beginning of the project. This group was composed of representatives from consumer groups, health services, and policymakers. Consultation with these key stakeholders was a crucial part of adapting the new model of care and study materials to suit the local rural community (36).

During the initial meeting, the Steering Committee members discussed the scope of the project, new model of care and project materials. All the study protocol, treatment algorithm resources and training materials that have been developed in our previous studies were reviewed for their relevance for delivery via webinar (for health professionals) and in-practice (for patients and health professionals) (19, 29, 56).

The Steering Committee recommended that the clinical algorithms in the current project needed to be broadened beyond insulin to the full range of oral and injectable glucose-lowering therapies available. Furthermore, the model of care needed to be adaptable and flexible to accommodate variations in local health workforce roles, skills and capacity to deliver evidence-based diabetes care. In particular the role of the PN needed to be flexible within this adapted model of care. We used GoToWebinar for the online training.

The elements of our intervention presented in order of implementation (see Figure 2) included:

1. *GPs and PNs training via webinar*: A 90-minute education session was delivered via webinar by a GP and the study RN-CDE. The session introduced the model of care (ie with an enhanced role for the Practice Nurse), and addressed interpreting structured blood glucose monitoring data and making therapeutic changes based on simple clinical algorithms. We used GoToWebinar © (<http://www.gotomeeting.com.au/collaboration/>) for the online training.
2. *Patient education in structured monitoring (on-site)*: An educational session for patients in structured blood glucose monitoring was to be delivered in-practice with the local RN-CDE. Structured BGL monitoring involves glucose checks at set times (pre- and 2-hours post-meal) plus a check before bedtime over three consecutive days in order to generate a meaningful pattern of glucose levels. The information can be plotted on a graph or uploaded to a computer directly from the blood glucose meter and use it in a

collaborative review with their health professional to determine areas for improvement and/or treatment changes.

3. *Patient-practitioner sharing of self-monitoring data online*: Online Health Portfolio (OHP) <https://www.onlinehealthportfolio.com/> is an online service that allows patients with T2D to upload BGL data from commonly used BGL meters through a personal computer, tablet or mobile phone using a web browser or app or the iHealth PC or mobile phone applications. OHP provides the tools to upload data, receive email and SMS reminders or alerts generated from the platform, share their self-monitoring data with their doctor(s) and other health professionals as they choose, as well as observe and respond to changes and trends they see in their own data.¹ Training was planned for patients in how to register with OHP and how to upload and share BGL data with health professionals.
4. Patient and GP/PN shared consultation with specialist using video-consultation: GP and PN were instructed in the use of video consultation with the study endocrinologist and/or RN-CDE as appropriate and covered by Medicare for its use under certain circumstances². We used Skype© for the video consultations (<http://www.skype.com/en/>).

Ethics approval was obtained from the University of Melbourne Human Research Ethics Committee (HREC 1443233) and was registered with La Trobe University.



Figure 2: Elements of the telehealth intervention

¹ This was an investigator-led study. None of the investigators in this study have any commercial interest in OHP

² Under Medicare Telehealth consultations with specialists are funded for Australians in remote, regional and some outer metropolitan areas. From 1 January 2013, patient eligibility telehealth aligns with the Australian Standard Geographical Classification – Remoteness Area System. In addition, the patient and specialist are required to be at least 15 kms by road apart at the time of the video consultation. Residents of eligible Residential Aged Care Facilities and patients of eligible Aboriginal Medical Services in all areas of Australia are also eligible for specialist video consultations under Medicare. See <http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/connectinghealthservices-eligible-geo>

PHASE 2: PILOT OF THE INTERVENTION

Setting, sample and recruitment

This pilot was conducted in the rural northeast region of Victoria and southern region of New South Wales (ASGC-RA 2 region). Our aim was to recruit five practices and up to 25 patients (five patients per practice).

Eligible practices: General practices that employed a PN were identified from the University of Melbourne Department of General Practice database, Hume Medicare Local, Hume Region Department of Health and Albury-Wodonga Health Service. Each practice was sent a letter followed by a call from a Research Assistant (RA) to explain the study and practices who expressed an interest to take part received a recruitment visit from a project team member at which the GP/PN Plain Language Statement was given and consent obtained.

Eligible patients: Once consent was received from at least one GP and one PN, the project team assisted practices to identify eligible patients from an audit of the practices' electronic medical records. This involved use of a Screening Eligibility Tool. Inclusion criteria were

- > people with T2D aged 18-80 years
- > most recent HbA1c (done in the previous six months) >0.5% above their individualised target (based on age, duration of diabetes and complications)(57) and
- > on maximal doses of two hypoglycaemic agents (unless contra-indications exist) or already on insulin. GP clinical judgement was also used to define maximal oral therapy (congruent with the pragmatic, translational nature of our proposal).
- > having internet and computer access.

Exclusion criteria included debilitating medical condition (e.g. unstable cardiovascular disease, severe mental illness, end-stage cancer), proliferative retinopathy, pregnancy, lactating or planning to become pregnant during the study period, unable to speak functional English and give informed consent, unwilling to perform structured SMBG or follow study protocol, or under active diabetes care from an endocrinologist or specialist physician over the past 12 months.

Multiple methods were used to recruit patients including letters from the practice inviting eligible patients to participate, accompanied by Patient Plain Language Statement, follow-up calls from the PN and tagging of the patients electronic file for action if the patient consulted the practice. The research team member contacted patients who expressed interest, explaining the study, obtaining consent and baseline data. Final patient eligibility was determined by a repeat baseline HbA1c test. However patients with HbA1c lower than target were permitted inclusion if the patient's GP recommended that the patient would benefit from the study elements.

Piloting the elements of the intervention

An outline of the pilot study is seen in the flowchart, Figure 3.

Following training, the study RA worked with each practice to implement each of the intervention elements and to support them in implementation of the intervention as appropriate.

- > GP/PN team working in collaboration with local RN-CDE were asked to review the participating patients and if appropriate, to schedule a video-consultation with the study endocrinologist. The GP and PN were encouraged to use the resources provided in the training to deliver patient-centred intensification of diabetes therapy.

- > A patient education session was scheduled for each participating patient with the study RN-CDE to provide training in structured monitoring. Further RN-CDE patient education sessions were arranged as clinically necessary.
- > The study RA assisted practices and patients with registering as users of OHP.
- > The study RA assisted practices with establishing the necessary IT to support video-consultation by the GP and/or PN together with the patient with the study endocrinologist using skype. The patient's RN-CDE was also able to be involved in this video consultation. As a pragmatic study of real-world practice, GP and endocrinologist were free to arrange further video/telephone consultations as clinically appropriate.



Figure 3: Process Diagram of Intervention

PHASE 3: EVALUATION

We undertook a mixed methods evaluation, appropriate to a pilot feasibility and acceptability study such as this. Baseline data from patients was entered directly into REDCap (58), an electronic data capture tool, hosted at the University of Melbourne.

- > Blood and urine tests and measurement of weight and blood pressure were to be done by the practice. Follow-up data collection was planned at 3 - 6 months. This flexible follow-up window was necessary because patient recruitment occurred over a three-month period while there was a fixed end date for the study. Baseline and follow-up data were also to be collected from GPs and PNs using the online collection platform REDCap.

At the conclusion of follow-up, all health professionals and patients were invited to provide feedback via a brief questionnaire and during a brief semi-structured phone interview. The interviews explored the feasibility and acceptability, and barriers and facilitators to implementing our telehealth intervention in rural general practice. We wanted to focus on the way the intervention was adapted and optimised in practice (59), which is important for sustainability. This phase of the study was undertaken by one of the independent qualitative investigators (CW).

Table 1: Data collection

Measure		Baseline	Follow-up
Clinical	Medications, medication changes, co-morbidity, episodes of hypoglycaemia	x	x
Biometric and HbA1c	Blood pressure, weight, body mass index (BMI), waist circumference, HbA1c	x	x
Biochemistry	Lipids, eGFR, creatinine, Albumin creatinine ratio (ACR)	x	x
SMBG*	BGL upload		x
Psychosocial data	Assessment of Quality of Life (AQoL-8D), Patient Health Questionnaire (PHQ-9), Problem Areas in Diabetes (PAID)	x	x
Process evaluation	Practice and patient encounter data, Semi-structured interviews with patients and health professionals		x

*Structured monitoring of blood glucose

Data analysis:

Quantitative: Descriptive statistics were used to summarise GP, practice and patient factors. Repeated measures analysis was used to examine changes in outcome measures at baseline, and follow up. Paired t tests were used to determine if there was a significant difference in measures collected at baseline and 6 months. ³

Qualitative: We used thematic analysis for the interview data.

³ While pilot studies are small and not testing hypotheses, some include an analysis of effectiveness, exploring the possibility that “there will be a trend toward significance” (48) in a larger study (not necessarily the case). Lancaster recommends that this testing should be regarded as “secondary and the results treated with caution” 55. Lancaster G. Pilot and feasibility studies come of age! Pilot and Feasibility Studies. 2015;1(1):1.

Results

SITES: LOCATION OF PRACTICES

Of the 16 practices that were approached to participate in the study, five practice sites agreed to participate. The characteristics of the practices are shown in Table 2. Ten GPs and five PNs participated in total across the five practices.

Table 2: Practice Characteristics

Practice	Accredited Y/N	N patients registered 2014	N pts with T2D	N GPs Employed	N PNs Employed	N GPs in study	N PNs in study	RN-CDE onsite Y/N
A	Y	NS*	NS	13	7	2	1	Y
B	Y	4233	246	10	4	4	1	Y
C	Y	4851	244	6	2	1	1	Y
D	Y	4094	191	6	4	2	1	N
E	Y	7098	753	10	4	1	1	N

*NS denotes not supplied.

All five practices are classified as within the Inner Regional (RA2) section of the Australian Standard Geographical Classification- Remoteness Area (ASGC-RA). The four Victorian practices are located within the Murray Primary Health Care Network (PHN) and the NSW practice is located in the Murrumbidgee PHN. All practices were at least 50km apart from each other. The location of the practices is illustrated in Figure 4.

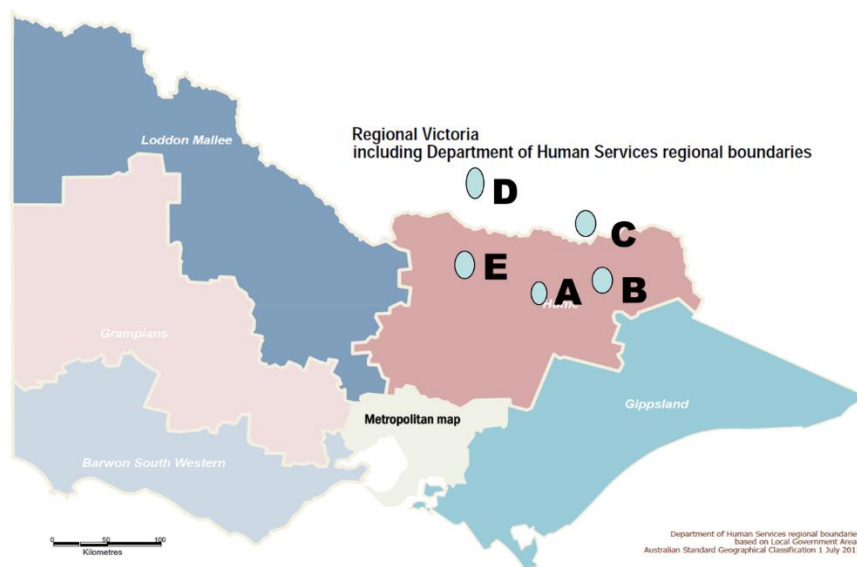


Figure 4: Location of study practices

Four of the practices were private practices and one was a bulk-billing super clinic. Three practices had a RN-CDE working within the practice in a model funded by the Murray PHN. The remaining two practices referred their patients to the RN-CDE employed in the Community Health Centre of the local health service as was their normal practice. Five practices had previously used video consultations to varying degrees although not exclusively for diabetes. Two practices had used video consultations previously with the study endocrinologist in the management with patients with T2D. While all practices had used some form of video consultation previously, not all GP's had interacted in video consultations.

TRAINING ONLINE

Figure 5 shows the various ways in which training was delivered to GPs and PNs. Of the 24 health professionals involved in the study, under half actually participated *via* the webinar as was planned. The remainder had training delivered on site (face-to-face), while in three practices a DVD of the original webinar training was provided to the GPs and PNs who were not able to join any session due to on call or roster commitments.

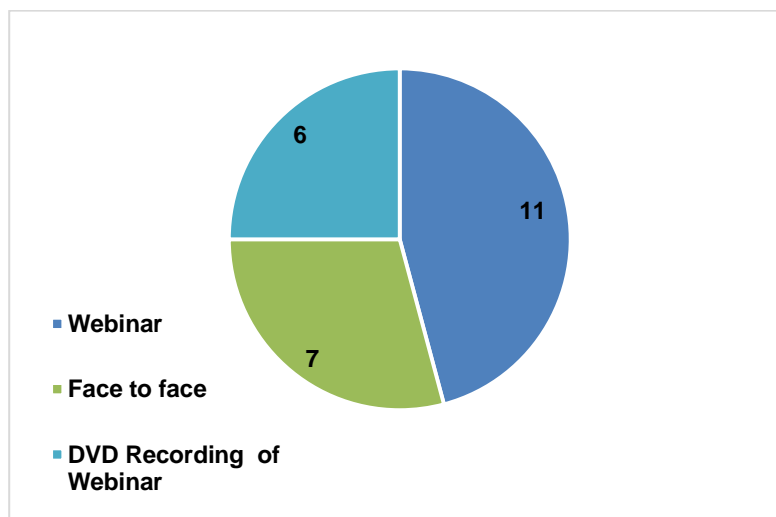


Figure 5: Method of GP and PN training

PATIENT PARTICIPANTS: BASELINE CHARACTERISTICS

Table 3 shows the number of participating patients in each practice and the number who did not complete the study.

Table 3: Patient recruitment

Practices		Patients (n)		
ID	Type	Enrolled	Lost to follow-up	Drop out
A	Private	2	0	0
B	Private	6	1	0
C	CHC	2	0	1
D	Private	6	0	1
E	Private	2	0	0
Totals		18	1	2

Two patients withdrew from the study. One patient had concurrent health issues and felt unable to commit the time needed to be involved in the study, while the other person

consented to be involved on the condition that a family member assisted through the use of their computer and IT skills to perform uploads. The family member was consequently relocated away from the area for employment and was not able to assist. This patient was offered the option of computer access and assistance through their general practice but declined the offer. One patient was lost to follow up. Two practices achieved the anticipated number of patients per practice.

Table 4 shows baseline patient characteristics and baseline and follow up data for outcome measures. Patients had a mean age of 65 years and a mean duration of diabetes of 14.7 years. The mean body mass index (BMI) was 33kg/m² showing this sample was an overweight group of patients. Levels of diabetes related distress and depression reported by participants in this study were lower than that reported by a cohort participating the Diabetes MILES study (60).

Table 4: Patient baseline characteristics

Baseline patient data n = 18	Baseline
Age (yrs)	65 (8)
Gender male (n)	9 (50)
Not employed (n)	12 (67)
Health Care Card Holder	12 (67)
Australian born (n)	12 (67)
Diabetes duration (years)	14.8 (7.1)
BMI (kg/m ²)*	33.1 (5.2)
Weight (kg)*	94.6 (21.3)
Waist circumference (cm)*	112.8 (14.3)
HbA1c (%)*	8.0 (0.9)
HbA1c (mmol/mol)*	66 (10)
Australian Quality of Life-8D (AQoL-8D) Physical	0.58 (0.22)
Australian Quality of Life-8D (AQoL-8D) Mental	0.41 (0.24)
PAID – diabetes distress*	20.1 (21)
PHQ9 – depression*	6 (5)

Mean (SD) or n (%)

PARTICIPATION IN THE INTERVENTION

Table 5 shows the frequency of which the elements of the intervention were taken up by participating practices and patients.

Table 5: Engaging with the intervention

Practices	Patients (n)	RN-CDE Sessions (n)		OHP		BGLs	Video consults (n)	
		Patients	Sessions	Active *	Not - active		Total BGL uploads	Patients
A	2	2	7	1	1	76	2	3
B	6	5	10	3	2	604	4	7
C	2	2	5	1	1	32	1	1
D	6	4	19	5	1	1143	5	6
E	2	2	0	2	0	519	2	2
Totals	18	15	41	12	5	2374	14	19

*"Active" means uploaded or entered any data and includes those whose relatives or PN performed uploads on their behalf

Figure 6 shows more detail about patients' use of OHP. While 12 patients were regarded as active in uploading BGL data, only nine were in fact able to do so independently. Three needed assistance either from a spouse, carer or the PN. Some patients dropped their glucometer at their practice and had the PN upload the data, as they had either no access to a computer or lacked the skills and knowledge to perform the upload independently.

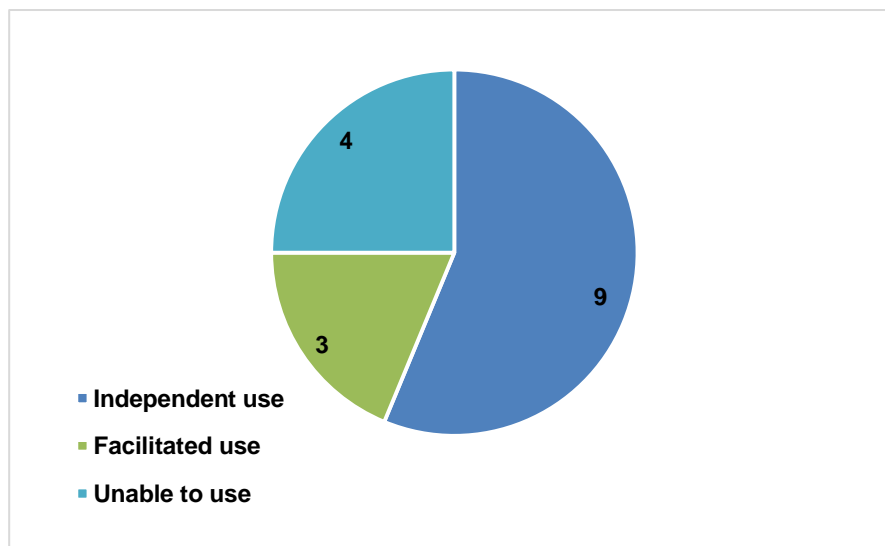


Figure 6: Patient use of OHP (n = 16)

The majority of patients were able to engage actively in using OHP to upload BGL data. A total of 2374 BGL entries were uploaded to OHP over the period of patient participation. Data outlining the number and frequency of blood glucose recordings entered on OHP is shown in Table 6.

Table 6: Number and frequency of BGL recordings uploaded to OHP

	Days in monitoring period	No. of glucose readings uploaded over monitoring period	Average readings/day (total monitoring period)	Minimum readings per day on days when ≥ 1 reading	Maximum readings per day when ≥ 1 reading	N 3-day profiles over monitoring period ¹
A	145	77	0.53	1	1	0
B	86	35	0.41	1	3	0
C	136	312	2.29	1	5	0
D	84	229	2.73	1	6	1
E	77	76	0.99	1	4	0
F	92	394	4.28	2	8	15
G	89	97	1.09	1	4	0
H	106	317	2.99	1	7	5
I	101	248	2.46	1	7	6
J	89	97	1.09	1	4	0
K	111	149	1.34	1	3	0
L	100	371	3.71	2	11	7

¹3 day profile counted if there were at least 17 readings over a 3 day period.

PATIENT FOLLOW UP DATA

While the study was not designed as an effectiveness study, at follow up we found a clinically and statistically significant reduction in HbA1c of 0.9% (10mmol/mol), weight and waist circumference in those 15 patients that completed both study time points. Levels of diabetes related distress and depression were also reduced at follow-up, although these were low overall at baseline. These outcome data are relevant for calculating sample size and power of a future effectiveness trial.

Table 7: Baseline characteristics & 6 mth results for patients that completed study (n=15)

	Baseline	Follow Up ⁺	Difference
Age (years)	64.7 (8.8)		
Gender (male)	7 (47)		
Diabetes duration (years)	15 (5.5)		
BMI (kg/m ²) [*]	34.2 (4.7)	33.2 (5.1)	-1.1 (1.6)
Weight (kg) [*]	98.4 (21.1)	95.6 (19.8)	-2.8 (4.2)
Waist circumference (cm) [*]	116.8 (13.1)	112.7 (11.1)	-4.0 (6.3)
HbA1c (%) [*]	8.1 (0.8)	7.2 (0.8)	-0.9 (0.6)
HbA1c (mmol/mol) [*]	65 (9)	55 (9)	-10 (7)
Australian Quality of Life-8D (AQoL-8D) Physical	0.57 (0.22)	0.64 (0.23)	0.06 (0.14)
Australian Quality of Life-8D (AQoL-8D) Mental	0.47 (0.24)	0.50 (0.24)	0.04 (0.13)
PAID – diabetes distress [*]	22.0 (22.6)	8.8 (12.5)	13.2 (17.0)
PHQ9 – depression [*]	6 (6)	3 (5)	2 (3.5)

Mean (SD) or n (%); ^{*} Statistically significant difference baseline to 6 mths ⁺ Denotes follow up between 3 - 6 mths

TREATMENT INTENSIFICATION

Figure 7 shows number of treatment changes made during the 19 video-consults. On 14 occasions pharmacological agents were intensified. Eleven involved a dose increase while three involved adding an injectable agent (Glargine and Actrapid insulin). One patient's prescription of Glargine was no longer required to manage blood sugar control and it was ceased.

Table 8: Medication changes from baseline to follow-up

Management Method	Baseline	Follow-Up
Lifestyle modifications	0	0
Tablets	4	4
Injectables	0	0
Injectables & Tablets	4	4
Insulin	0	1
Insulin & Tablets	1	1
Insulin & Injectables	1	1
Insulin & Tablets & Injectables	5	4
Total	15	15

BARRIERS AND FACILITATORS TO IMPLEMENTING THE MODEL OF CARE

The findings described here are based on field notes and observations of the research staff during the implementation of the study as well as on the process evaluation interviews conducted at the end of the study. In total 10 interviews were conducted by phone (three patients, two PNs, two RN-CDEs, one Endocrinologist). Where findings primarily emerged from the interviews, quotes are used to illustrate these.

Roles and relationships

Here we describe ways in which the intervention and the technology elements, predominantly the use of video-consultations, interfaced with inter-professional and patient-professional relationships in ongoing diabetes care.

Some felt that establishing inter-professional relationships prior to implementation of the model of care would have facilitated implementation of the intervention.

At times the intervention provided a platform for patients to re-engage with their diabetes self-management, with the support of the diabetes team, locally and via video consult.

The video consults, particularly when multidisciplinary, also seemed to facilitate new forms of inter-professional learning.

Most uncertainty existed about the role of the practice nurse.

One important issue we identified was the variability and uncertainty about the role of the PN in the model of care intervention. This was important, as a key intended feature of the intervention was a stronger role for the PN to manage some of the clinical work with patients around monitoring and treatment intensification.

Practice Nurses varied significantly in the extent to which they were involved in the intervention. This may in part have been as a consequence of the part-time employment many PN's had. In three practices, the PN participated in some study recruitment activities in the practice in their own time, i.e. they were not scheduled to work that day and they were not able to be released during their work hours to participate.

“...I work part-time and I didn't interact a lot with the patients because I wasn't allocated time...the doctors did that [...] I didn't sit in on any of the Skypes which from an educational point of view would have been great but as I say, time wasn't allocated to me for that...[...] it would be interesting to follow up with the diabetes educator to hear what they were suggesting...” (PN1)

Practice nurses were often performing a variety of roles and/or working across many portfolios within a practice e.g. one practice nurse fulfils the role of Aboriginal health nurse, refugee nurse and Stepping up telehealth study nurse within a 0.8 FTE. Both roles necessitated a case management approach of acute on chronic health issues that emerged on a day to day basis. Consequently this presented the PN with challenges in terms of prioritising and integrating the Stepping Up telehealth role within the workload and FTE.

Inter-professional learning emerged as an important theme. This PN extended her clinical role and benefited from the exposure to the other health professionals involved:

“... There's a lot for a PN to contribute. They (the VCs) were really good, most beneficial for myself, I built up my knowledge [...] I got interested in the new medications, I learnt a lot...” (PN2)

The mutual learning supported by the videoconferencing could help to build stronger therapeutic relationships. It was very meaningful to one patient when the GP shared at the conclusion of the videoconference how much they had learnt about managing T2D in additions to the patient's other comorbidities by participating in the video conference with the

endocrinologist. Both GP and patient had shared knowledge of the management plan for both T2D and multiple other conditions.

“...I think one of the real advantages of telemedicine is the education of the GP and PN. There’s nothing mysterious about what I do, it’s just that I do it all the time. When the GP and PN sit in they learn about it and then after two or so sessions they’ll say now I know what you are going to do and then they can do it themselves with other patients.” (Endo1)

However, there remained an uncertainty on the part of a RN- CDE about what role PNs were playing and what learning was occurring as part of the intervention:

“..It would have been good for me to be involved more with that [PN] part of the study, to know more about them [PNs] , I think they would have (learnt from the study) but I really don’t know...” (RN-CDE1)

RN-CDE support was key to bringing together patients, GP, PN and endocrinologist. Patients involved in the study found re-engaging with the RN- CDE helpful in revising their management of T2D and managing and coaching lifestyle factors to benefit their glycaemic targets.

Having an established pre-existing relationship with the RN- CDE was important. This patient had seen the RN- CDE on a previous occasion:

“... I did have a consultation with a diabetes consultant [study RN-CDE] and I took her advice about what to eat and I stuck to what she said and my levels have dropped dramatically. [BUT] it’s nothing to do with the program, it’s the advice of [study RN-CDE]. ...” (PT3).

One patient expressed that in this instance the RN- CDE had “made all the difference” to his loss of weight and reduction in HbA1c. The patient had seen the RN-CDE some years ago although prior to participating in the study had not considered that an ongoing relationship with the RN-CDE would be beneficial.

PNs who had existing care coordinating roles within the practice i.e. managing Team Care Arrangements (TCA) and General Practice Management Plans (GPMP) were able to participate more readily in the intervention as a whole, conceptualising a more patient centred approach to the intervention rather than a more task oriented approach.

The model of care potentially provided a disruptive change to “routine care”:

“...It was good because the patients I saw did need specialist input so that was good. [...] My impression was the approach was different to what they were used to and that was good”. (Endo 1)

Care coordination challenges in primary care

The intervention model of care depended on close coordination between the health professionals and patient. This was not always congruent with the busy, reactive, time-poor environment of clinical work in general practice.

Arranging appointment times for training and video consultations, and coordinating patient, GP, PN, RN-CDE and endocrinologist was challenging.

The study RA played an important role, investing a significant amount of time in this care coordination, beyond research duties.

This was made more difficult by the challenges of fragmented electronic communication that emerged.

Within practices the organisational arrangements for communication were variable, and the access of all staff, particularly the practice nurses, to communicate independently was restricted. This made the work of coordinating multidisciplinary training and video consultations more resource intensive.

Some practices had a generic email account that was used to communicate with all practice nurses (e.g. nurse@practicename.com.au) and/or channelled all communication via the practice administration email account. Emails were then directed to the appropriate practice nurse via the internal messaging system through the practice management software. This resulted in instances where communication did not reach the nurse in a timely manner and this was further complicated by a predominately part-time workforce. In fact a number of nurses preferred to communicate directly through private email accounts which they accessed on smart phones or after-hours on personal computers. In two practices the PNs had their own work email account.

GPs were similar, in that in three practices the GPs communicated with the RA with their own personal email account.

One RN-CDE working across three practices (formerly employed by the Medicare Local) only had access to patient notes when on site. Although email was accessed remotely, she chose not to access during non-working hours rather only when on site at the particular practice, and in some instances this was only on a fortnightly or monthly cycle. Again, this practitioner opted to use a personal email account for the purposes of communication with the study RA. Two other RN-CDEs who were employed within their local acute/community health service used their work emails.

Phone communication was also associated with a number of challenges. Three practice nurses preferred communication *via* telephone (although this often had to be in meal breaks) and one RN- RN-CDE preferred to make appointment times to talk *via* phone due to scheduled consultations. In four of the five practices, PNs provided their personal mobile phone numbers to ensure that communication with the RA was achievable and efficient.

Scheduling an appropriate time for delivering training GP and PN together, and coordinating involvement of the RN-CDE (as a part of building inter-professional relationships) was difficult. Webinars were delivered soon after close of business but was often delayed by consultations and on call duties. The training that occurred face-to-face did so before business hours and this was shorter than the scheduled 90 minutes planned. This was at the request of the Practice Manger (PM) in order to deliver training in their regular designated professional development timetable.

As a pragmatic pilot, the study tasks overlapped with the clinical tasks embedded within the intervention model of care. This often meant face to face meetings (again, often in meal breaks or after hours) between PN and RA, particularly during screening when PNs needed

assistance with the PEN-CAT tool to identify potentially eligible patients. PNs juggled this care coordination task within the study intervention with all their other responsibilities:

“I was the go-to person in the clinic for the study ...I had to find time in my day to do all this...I had to fit it in. [...] It could have been done by admin staff with some training.[...] lots of paper work and admin.” (PN2)

Overall the amount of administrative time can be a barrier to uptake of this new model of care:

“...it needs a facilitator to set it up and that’s usually the community nurse and they are very busy. It’s one more thing they’ve got to do. A huge barrier” (RN-CDE1)

While the observation below is about the organisational arrangements of the study, the observation is also about the challenges and uncertainties around organising multi-disciplinary care and the importance of a care-coordinator and a defined care-pathway. It also highlights the tension between protocol-driven *versus* individualised care:

“...There are no guidelines on how often they should see the DE. I sort of saw people less than normal because I thought they were seeing the specialist... there should have been guidelines on minimum times they saw the team -.... And the GPs need structure because they can let patients go too long, so if there’s a structure in the study they can learn from the titration process And the PN didn’t know what to do, maybe thinking that it was all the GP’s role because it was research, it was all going to be done for them. In one clinic, no one took on the role of referring to the specialist.... ..” (RN-CDE2)

Technology capacity issues

We encountered many issues related to the technical capacities of personal and practice IT systems and in the computer and technical skills of the health professional and patient participants. Here we describe these in relation to the webinar based training, OHP and video consultation elements of the intervention.

Webinar

We used an online platform for delivering the webinar training (Go To Webinar ©). This enabled the training to include video and audio communication, PowerPoint display, inbuilt interactive surveys, and independent registering and tracking of participation. This platform was easily usable by both presenters and participants however this was dependent on the bandwidth available and was inadequate for one participant when accessing training from home and via an iPad.

We have described above the multiple modes of training that were used. As described previously one practice requested training explicitly not via the pilot method of Webinar. One GP from this practice did participate in Webinar training and was also supplied with a DVD recording of the training as another option.

In another practice, PNs chose to join Webinars from the workplace after hours rather than from home however they encountered IT access problems (e.g. security properties of their practice logins did not permit them access to use Go To Webinar and in working around this barrier they were also unable access to the practice Wi-Fi network on personal devices).

In one area, the internet speed was such that the RN-CDE was able to only listen to the webinar, the RN-RN-CDE attempted to contribute to the online discussion and was unable to be heard.

Online Data Sharing via OHP

Online sharing of BGL data via OHP posed the most technical difficulties for participants. This was linked to the variable IT skills and experience of both health professionals and patients.

Patient participants completed a short survey at follow-up. The results are shown in Table 9 below. People particularly noted the need for additional training in OHP and that they had “technical difficulties”. Yet responses suggest that few people had problems uploading data to OHP.

People less commonly reported that they found it to be useful or intuitive or that it assisted in managing their diabetes.

Table 9: Rating of Online health portfolio

	Mean (SD) score ¹
I found the training in OHP useful	4 (2)
I needed more training in how to use OHP ²	5 (2)
OHP was easy and intuitive for me to use	3 (2)
It was easy to share blood glucose data and collaborate with my doctor and nurse ²	3 (2)
OHP helped me make treatment changes for my diabetes	3 (2)
I had technical difficulties when using OHP	6 (2)
If I had a problem with OHP, getting help was easy	3 (1)
I rarely used OHP	4 (2)
I had problems uploading data to OHP	2 (2)
I needed a lot of prompting to use OHP	3 (2)
It is likely that I will continue to use OHP in managing my diabetes	3 (2)

n=14, unless otherwise indicated; ¹On a scale of 1 to 7 where 1= strongly disagree and 7=strongly agree; ²n=13

The types of technical issues that participants (health professional and patients) encountered included computer incompatibility and security settings.

One key issue was that OHP was not integrated within the electronic medical record. Rather, it is a separate website requiring additional log-in. Others commented that this alone is a disincentive to its use due to the additional work this causes for busy health professionals:

“...you had to go on to it with the patient there so for the GP, they are already in a program and had to go out of it to look at the OHP and a GP doesn't have that time, ...It's labour intensive. ...” (RN-CDE2)

Also people commented that they found it unhelpful not to be able to get online support or feedback loops within the OHP system. This patient felt frustrated at not knowing if any health professional was looking at the BGL data that had been entered:

“...My understanding is that I chose her [GP] as my carer so she can see it all. But I have no idea if the doctor has ever looked at or not. She's never contacted me so I think she has not. [...] I've often wondered what's the point of putting it on the system if no-one's looking at it? I look at my readings and

say I must be doing the right thing. [...] but to my way of thinking the system is virtually useless because I have had no feedback..." (PT3)

Patients varied significantly in the levels of assistance needed to upload and share self-management data. Many patients continued to document in BGL diaries. Some patients seemed to have no problems with OHP:

'...we had no problems setting it up when we came home [...] it was very straightforward [...] I'd put it in manually... I did that regularly (PT1– wife speaking on patient's behalf)

A number of patients identified how important it was to have the support of their spouse in managing their illness and OHP

"Yes it was very easy to use for an old bloke like me who don't know anything about computers – my wife and I do it together and we know what to do now" (PT2)

In contrast, health professionals felt that the age of patients was potentially a barrier to engagement with this sort of online application:

"...some of [the patients] were fairly old and therefore didn't have computers themselves or their computers were old [so] they didn't use the software which was a shame. They brought the [blood glucose meter] in for me to download..." (PN1)

"...It never really worked. I logged on and went in...but then ... the clients ...they'd have to accept me as a carer and they didn't. There was only one who worked it out...Others weren't that computer literate..." (RN-CDE1)

An important enabling factor for patients was engaging early with the software. Training on how to use OHP occurred during the recruitment interview. Those participants who uploaded on the day or very soon after training in OHP had greater success and/or used the platform as opposed to those who did not look at the OHP platform for some weeks after they had received their training.

Three patients across two general practices did not have their own computer and/or email address and the practice agreed to facilitate patient uploading data and connection to a computer so that the patients had access to OHP. One of these patients withdrew from the study at the point of creating an OHP account.

A number of patients contacted the RA directly with difficulties experienced in downloading the software for use with OHP and with uploading data. One patient was using his son's computer to participate in the study; this computer was a mac and the OHP software was not compatible. During the OHP training it was highlighted that the software was incompatible to mac however it was unclear if the patient was aware of what type of computer his son had or could differentiate between a PC and a mac.

Those patients who were not able to upload and share data were directed to share their data *via* Glucometer report in pdf format, generated when connecting their glucometer *via* USB to a computer. This used software from the glucometer manufacturer. The patient was then required to email this report to the practice administration account for filing in their medical record and the attention of the PN and GP.

"...only in one patient was it set up so I could see what the uploaded BGLs were. It was all too complicated - I had to be invited but I wasn't getting the invitations to look. I had to get someone to read them out to me. I would normally look at the book. Getting the GPs to use the technology was a total failure." (Endo1)

Those GPs who used OHP with patients used a variety of methods to do so. One GP engaged well with OHP but used this quite prescriptively, asking the patient to use OHP on

specific occasions and times, following this up with a consultation. In contrast another GP developed a telephone coaching approach using the BGL data uploaded to OHP. The GP asked the patient to call in once a week to discuss down titrating the patient’s insulin. The patient achieved 9 kg weight loss and managed to eventually stop insulin therapy. It was noted that there is no Medicare funding for this telephone coaching model.

Video consultation

Patient participants were asked to complete a brief survey of their experience using video consultations (VC). The results are shown in Table 10. Patients had little experience of VC prior to the study but rated highly statements about its usefulness in managing their diabetes and their wish to continue to use this modality of access to specialist care.

Table 10: Patient reported perceived utility of video consultations

	Mean (SD) score ¹
Prior to this project I already used video consultation with my doctors	2 (2)
I found scheduling and coordinating appointments for a video consultation with my doctors is easy ²	4 (2)
Video consultations actually interfered with my relationship with my doctor	2 (1)
Video consultations helped me make treatment changes for my diabetes	6 (1)
I did not like using video consultations	3 (1)
It was hard to link video consulting with sharing my blood glucose data via OHP	4 (2)
I would like to continue to use video consultations with my doctors to help me manage my diabetes	6 (1)

n=14, unless otherwise indicated ¹On a scale of 1 to 7 where 1= strongly disagree and 7=strongly agree; ²n=13

The VCs were the element of the model of care intervention least likely to be associated with technical difficulties. Nevertheless some technical issues did still arise. Some commented on the continuing issues with slow internet speeds, a well-known issue in regional Australia that is anticipated to be resolved in the near future. In general it was felt that whilst GPs were keen to engage in VCs, they were perhaps less likely to use the technology if they encountered technical issues:

“They are struggling to get the computer on and using Skype, get the volume right and then to expect them to upload the sugars or get help via an app is too much. [...] if it’s all too complicated then that’s going to be counter-productive... (Endo1)

Practice nurses could be important in assisting GPs with technology, but these skills needed to be established through training and experience:

.....The PN was more comfortable than the GP with the technology. [...] there are some in the practices I normally work with who are really comfortable with the technology. They know about the bookings, the computer, the billings and those practice work really well” (Endo1)

In the end, the use of video consults allowed access to specialist care that might otherwise not have occurred, leading to diabetes treatment intensification:

“ A lot of the patients were not maximally treated. I optimised the use of oral drugs and emphasised the use of lifestyle changes and diet in my report back to the GP. I said this should be done before moving to insulin.” (Endo1)

For patients, the VC seemed to provide access to care that they were not previously had access to. Simply getting access to any information was important to some patients

“...the more advice, the better advice, so it’s all good [...] we appreciated the opportunity to get more information” (PT1)

On occasions it could be the “same old advice”, but having access to a specialist via VC (i.e. using technology to make more intensive health professional input possible that would not routinely be accessible) could act as a trigger for transformative behavioural change:

“...they were more than happy to see someone on-site and as people get older it’s a worry if they have to travel. And some can’t afford the trip to Melbourne. [...]... some of the patients apologised and said to me ‘you and the GP have been telling me this for years but somehow I really listened [to the specialist in the VC]...” (RN-CDE2)

A strong theme was related to how the VC were often multidisciplinary, involving GP, PN, RN-CDE and Endocrinologist. This seemed an example of technology transforming rural practice, in a way that holds lessons for practice in all geographical areas:

“We thought it excellent to have the GP and PN next to you with the specialist [...] it was a great way to access a specialist instead of traveling all the way to the city” (PT1)

“...the patients, those who have engaged they have really benefited from it. [...] they know there’s a whole team behind them” (PN1)

“...It was very good. Excellent because we were all on the same page and I could ask the endo questions...you pick on their way of thinking ...and you learn...” (RN-CDE1)

“We can talk directly too, the patient too of course and it was a two way conference with management advice of course. So I could ask questions at the time instead of just getting a letter back.” (GP2)

“...not willing to travel any distance to see a specialist. Not willing to pay for their travel. It’s a win-win. So there they were two blocks from home sitting with a GP and PN they knew well, talking to a specialist with all their past history and results at the touch of a button available and all those sets of ears listening. And it’s all bulk-billed...” (PN 2)

The multidisciplinary VC also tended to give authority and weight to an enhanced role for the PN:

“...now we are more on the same page. Especially with the PN. Those difficult patients didn’t want to see the PN before...” (GP1)

Other comments about the VC related to it being local and accessible, low cost, and allowing patients to access specialists in the context of their known and familiar practice staff:

“I’m having another [VC] in a few weeks, they are fine...if I had to travel to Melbourne it would be four hours there and back and a big expense...actually I wouldn’t go if I had to go to Melbourne” (PT2)

“...the free [Bulk Billed] VC really helped, ...an endocrinologist consult on skype can be very expensive...” (PN1)

“...she [PN] made it relaxing actually...much more relaxed” (PT2)

Practitioners reported this would be a sustained feature of their health care

“This was my first time [using VC]. I found it really positive...we have already made another appointment” (GP1)

Discussion

The Stepping Up telehealth pilot project is a 'proof of concept' of the use of telehealth modalities to support a model of care for T2D care in rural and regional primary care. The project is directly built upon our extensive research into the Stepping Up model of care to overcome clinical inertia in diabetes care in general practice. We proposed the use of technology to support wider dissemination and implementation of the model of care in rural and regional communities.

SUMMARY OF FINDINGS

Our findings suggest that, with significant support and resourcing and in particular circumstances, the new model of care supported by the use of technology is feasible and acceptable to practitioners and people with T2D and out-of-target glycaemic levels in a rural community and can facilitate intensification of treatment.

The intervention provided enhanced access to multidisciplinary care to some participants including:

- > Access to specialist care that overcame geographic and financial barriers
- > Video consultations that included Patient, GP, PN, RN-CDE-RN and endocrinologist
- > Consultations that allowed real-time enhanced access to patient clinical data (shared blood glucose monitoring data and electronic health record)
- > Shared care relationships that provided educational opportunities for GP and PN allowing generalisation of enhanced care to other patients, and
- > Improved clinical outcomes (HbA1c, weight and waist circumference).

Our process evaluation alongside project implementation shed light into how, why and the circumstances in which, the intervention works, for whom, as well as highlighting circumstances and situations where the model of care did not seem to work so well and what improvement might be made to support more effective and widespread implementation. In particular we identified some important technical issues to do with IT systems, software, training and IT capabilities of health professionals and people with T2D that are key to implementation of a complex telehealth intervention such as this.

We discuss our findings under the dimensions of the Telehealth Evaluation Framework (61).

PATIENT EMPOWERMENT: AN ISSUE OF ACCESS AND INCLUSION

Flexibility and adapting to local contexts

It is crucial that the telehealth intervention and new model of care was adapted to local context and needs (36). We consulted with local key stakeholders about the scope and intent of the project. We broadened the content of our intervention protocol and algorithm to cover a range of new diabetes therapies and injectable hypoglycaemic agents that have become available on the Australian market and included in the latest diabetes management guidelines (62). This was to ensure that both practitioners and patients could access individualised, optimal therapy and that clinical care within the model of care was patient-centred rather than protocol driven.

Patients reported positively on their experience of the use of video consultations, the ease of use, the support it gave them to manage their diabetes and their wish to continue using video consults. They commented particularly on the opportunity it provided for multidisciplinary care and to have all their providers communicating with each other. This

suggests widespread acceptance and feasibility of this telehealth platform in the setting of the study. This is important when seen in the context of the actual clinical benefit seen in participating patients, with improved glycaemic control, weight and waist circumference.

Our team also introduced a technology platform in order for patients to share their blood glucose meter data online with their health professionals. Whilst becoming more common in specialist practice to upload blood glucose meter data as a read-only pdf file, these data have rarely been shared online or in real-time among the multidisciplinary team (63). Our pilot examined the uptake, feasibility and acceptability for these data to be shared and examined in consultations between patients and their health professionals as part of their diabetes management. Nearly all patients were willing to learn and try to share BGL with their health professionals. While around half of patients managed to enter or upload blood glucose data to the data sharing platform independently after receiving training and support, others found the platform less feasible to use in practice. The study endocrinologists and RN-DCE had difficulties accessing the data possibly as patients had not selected them as nominated carers. Participants noted the difficulties of OHP not integrating with the medical record. People needed the study RA to assist with using OHP.

Telehealth interventions need to empower patients to be more autonomous, better able to self-manage and better able to access care and communicate with their health professionals. Clearly in T2D in rural communities there are issues of high patient need and demand that require “scalable innovation” in the provision of care.

Telehealth interventions, while often promising, have faced difficulties, for many reasons, in achieving widespread uptake and scalability (64). But without such up-scaling, the intervention is unable to fulfil its potential to empower broader populations. Telehealth interventions need to be more integrated in usual clinical practice and seamlessly integrate within existing work patterns and relationships, thus becoming at the same time scalable and empowering of larger numbers of people. When a telehealth intervention is not embedded as part of usual care and routines, it becomes resource intensive, costly and can place a high demand on human health care resources and become a burden to patients and their carers.

Scalability in part depends on flexibility of an intervention, leading to “dynamic sustainability” (59) in the field. A telehealth intervention needs to be both congruent with what is familiar to patients and professionals as well as discernibly different and advantageous to them in managing clinical care and self-management tasks.

CLINICIAN QUALITY OF CARE: SCOPE OF PRACTICE

The project set out to improve access to specialist care using technology.

Our team adapted our existing intervention materials into distance learning delivery via webinar. Continuing professional development, including *via* webinar education and training, is now part of the registration requirement of a number of health professional bodies to maintain skills and practice informed by latest research evidence and evidence based guidelines. Opportunities for training for the rural health workforce are more limited and distance education can provide a cost effective solution to maintain competency. Despite our intention to deliver the education *via* webinar, a practice required in practice on-site training and some health professionals accessed the education via recorded webinar. This again suggests the need for flexibility in supporting a range of learning method options.

Our project offered a clear pathway for rural general practices to be up skilled in diabetes management, more engaged with patients’ diabetes self-management and connected to specialist care. Nearly all patients received components of the telehealth interventions and engagement with local RN-CDEs who are key players in providing local diabetes specialist support within a multidisciplinary team in rural communities. Bulk billed video consultations

were embraced by patients as they facilitated timely and affordable access to an endocrinologist, minimised travel and enabled multidisciplinary care. This small pilot project resulted in clinically meaningful improvement in glycaemia among a small sample of people with out-of-target HbA1c.

However, our evaluation identified changes in the professional roles and relationships within the model of care. These were embraced in some cases but in others highlighted questions about current scope of practice of each of the diabetes team members. We also identified new roles and tasks that need to be developed if telehealth is to become part of routine practice.

In particular, we identified the significant organisational and administrative demands needed to implement the intervention in its current form (partly due to the lack of inter-operability of the intervention elements – see below). In our study this work was largely undertaken by the study RA. However in some instances this work was taken on by the PN. This new role blurred the boundaries between organisational administration and clinical case management, suggesting scope to define a new emerging clinical role within telehealth in primary care. Naming this emerging role as “nurse informatician” or “telehealth nurse” (65), captures the work of a clinically trained practice nurse who also supports the technology platforms to enable the diabetes team and patient to interact within the telehealth intervention. However, this raises the question of what is the most efficient, safe and effective use of trained health professionals’ time around the roles that telehealth interventions create. Clearly much of this work is organisational and administrative and could be undertaken by non-clinical personnel at less cost.

Other health professionals underwent change within the model of care. RN-CDEs to some extent took on a mentoring role with GPs and PNs. There is a well described tension between the specialist nurse role of RN-CDEs and the generalist medically trained role of GPs, based on historical hierarchies of power and autonomy (66). This has often focused on responsibility for clinical management of individual patients. However the structure of the model of care in the study provided a platform to recast the RN-CDE role to some extent. RN-CDEs did continue to work with individual patients but also explicitly took on a mentoring role with GP and PN and also played a key role in bringing together the whole multidisciplinary diabetes team. We also identified how the endocrinologist took on a role of educator, not just of patient but also the other health professionals in the diabetes team. PNs also commented how they learnt from the professional interactions in the multidisciplinary video consultations.

Our findings suggest that telehealth enabled professional interactions work best when based on a pre-existing established inter-professional relationship. It may be that when initiating a new telehealth enabled model of care, establishing an initial inter-professional meeting aimed at building mutual understanding is critical to the success. For example in our study it would have been helpful to reach a clear consensus on care processes, treatment and management strategies including lifestyle management as well as a shared understanding of local workforce availability, clarifying roles and relationships, possible follow-up, and local patient supports.

Clearly there are jobs and roles embedded in this telehealth model of care that push the boundaries of current professional roles. New roles need to be created, and the question remains around who is the right person to do them and how these roles should be funded. This is an issue that needs more debate and open discussion across the health care sector.

ORGANISATIONAL SUSTAINABILITY: FUNDING MODELS

We identified barriers to comprehensive engagement in this telehealth supported collaborative model of care for all members of the multidisciplinary diabetes team. In particular it emerged that fee-for-service (FFS) structures under the current Medicare

arrangements do not cover the intensive work needed to coordinate and arrange this type of collaborative care and do not incentivise GPs and PNs to engage together. While Medicare FFS does support video consultations between medical practitioners (GP and endocrinologist) in geographically restricted circumstances, this does not provide funding for PN and RN-CDE involvement unless they are nurse practitioners.

Collaborative, multidisciplinary care is possibly best supported by a blended payment system. Medicare, relying predominantly on FFS payments does not optimally support high quality, integrated, coordinated patient-centred care for chronic conditions. Rather FFS supports reactive, episodic care, which while appropriate and effective for acute illnesses, is not the most effective system for funding cost-effective chronic illness care. Chronic illness care is best provided within a continuing therapeutic relationship with a GP, informed by knowledge of the patient over a long time, and with input from specialists (medical and otherwise) across a range of disciplines who deal with the patient with multiple chronic conditions as they age. Optimal patient outcomes and coordinated and integrated care are most effectively supported by a blended payment system linked to patient enrolment supported by a judicious approach to quality of care and outcome payments (pay for performance or PFP) (67).

A blended payment system offers the structural base and opportunity to better target population groups with high need. Elements of blended payment systems include:

1. A practice-based payment. This is a payment to the practice for the provision of core set of medical services to an agreed population. It relies to an extent on some form of patient enrolment or virtual enrolment. Currently the Practice Incentive Program (PIP) uses a virtual-enrolment formula based on calculated Standardised Whole Patient Equivalent or SWPE. Practices registered for the PIP and who fulfil the criteria receive a payment per SWPE.
2. Quality related payments or Pay for Performance (PFP). The Practice Incentive Program (PIP) eligibility criteria currently include a requirement to maintain practice accreditation. Practice accreditation standards contain measures focused on process of care (i.e. quality care such as maintaining a chronic disease register, using a recall and reminder system etc.) but no measures of clinically meaningful disease outcomes; nor do they give significant weight to patient reported outcomes⁴. Enrolment in some form is necessary in PFP to attribute changes in quality and performance to a specific GP or general practice. Actual (as opposed to virtual) enrolment is stronger as incentives may be weaker if a patient visits multiple GPs each of whom may feel less “responsible” for patient outcomes(68).
3. FFS payments. A blended payment system would still contain elements of FFS payment e.g. to provide care outside of the agreed core care items (e.g. acute care, after hours care, emergency care, specific mental health or drug and alcohol related services etc.).

As a package, blended payments offer the base for funding continuous, comprehensive and collaborative care driven and incentivised to achieve clinical and other outcomes. This supports innovations in roles and relationships and practice systems and can support business models congruent with this model of care in both public and private systems.

Sustainability in the field of innovative telehealth-enabled models of care requires funding models that incentivise change from the status quo, drive quality improvement, while allowing local flexibility and autonomy in how practices organise care, delegate new roles and work (see above).

⁴ While PIP accreditation necessitates a patient survey this focuses on satisfaction. Outcome measures needs to be informed by what the priorities of patients themselves who are often managing risks across more than one condition. Patient reported outcomes and quality of life measures may have an important role in PFP.

TECHNOLOGICAL CAPABILITY

Finally, we identified significant challenges in technological capability at the patient, practice, practitioner and health system level, all potentially requiring significant investment of resources and supports to enable innovation and widespread uptake of telehealth. These include:

- > Ensuring integration of telehealth modalities with the electronic health record and the working day and billing routines of practices
- > Building IT infrastructure capacity in and across the GP and primary care sector
- > Ensuring multimodal IT support and help facilities for both patient and health professionals
- > The need to ensure telehealth interventions include the capacity for personalised feedback and reflexive monitoring by users of telehealth interventions. This is a key criteria identified in Normalisation Process Theory for embedding changed practice in routine care (69)
- > Investing in enhanced communication processes between and amongst health professionals and patients
- > Developing IT skills and capacity in the health professional workforce through training and accreditation

There has been widespread adoption of electronic health records in Australian general practice. However, while the use of the electronic health record improves documentation of diabetes care processes, this does not necessarily translate to improvement in clinical and biochemistry outcomes (70).

In particular we found that the online BGL data sharing platform we used did not currently support the domains of patient empowerment and scalability, innovation in scope of practice or organisational sustainability discussed above. OHP as a platform is not yet mature enough to enhance the organisation of administrative and clinical work involved in the model of care, and did not link well or support inter-operability with the other technologies in the model (Webinar, Video consultation, electronic health records). Nor does it address the potential to interface with the national Personally Controlled Electronic Health Record.

This is a rapidly changing field. Large health care corporations are involved in building cross-platform integrated telehealth capability. We need to ensure that the solutions they offer the field are informed by the sorts of findings we have described are patient-centred, offer real advantages that are meaningful to clinicians and patients and are supported by investment in training and capacity-building in the sector. The Australian College of Rural and Remote Medicine has developed on-line training and standards for telehealth (49). The Australian Health Informatics Society also offer some training and certification suggesting that existing training and resources could be adapted to training of health professionals.

STRENGTHS AND LIMITATIONS OF THE STUDY

Strengths

- > This study was pragmatic in nature, embedded within the real world of T2D care in rural and regional primary care practice, within current clinical practice and payment structures
- > The secured online platform that we introduced in this pilot was developed locally and has been used in other research projects and clinical care.

Limitations

- > We identified several technical and functional limitations in the online glucose data sharing platform (see Technological capability) which limited our capacity in this study to fully explore the potential utility of BGL data sharing
- > We collected our research data from electronic medical records of participating general practices. We acknowledge that the quality of the general practice data may be variable between and within general practices. It is beyond the study to audit and cross check the medical record. Our psychosocial data were self-reported by participating patients. Each of the data item was collected at baseline and at follow-up that occurred between three to six months post baseline assessment
- > Our sample size is small and aligned with the nature of a pilot project. While we observed significant improvement in glycaemia and weight over up to 6 months follow-up, this result needs to be interpreted with caution as the sample may also be subject to selection bias and hence not generalisable. Outcomes, however, will be useful for estimating power and sample size calculation for a larger trial.

IMPLICATIONS FOR POLICY AND PRACTICE

Our findings in this project suggest that the patients and practitioners in this socio-technical setting are still a long way from experiencing the disruptive influences that telehealth is capable of supporting, such as less intrusive and more closed-loop monitoring and drug-delivery systems (71) ; and less geographically constrained and more ‘just-in-time’ video consultations between patients and practitioners (72). The technology infrastructure and access, and the economic drivers of change are not in place at the points of greatest need. Further, unless greater clinical informatics expertise is nurtured in these settings the cultural beliefs and communication practices underpinning the current models of care may undergo a prolonged and suboptimal change process during subsequent implementations of telehealth.

While it is beyond the scope of this small proof of concept study to make firm recommendations, our study did identify important areas to explore further in order to support the efficient and effective uptake of telehealth interventions in management of chronic conditions in rural primary care.

Workforce development and competency

Strengthening the clinical informatics expertise of the health care workforce will provide the base for subsequent investment in telehealth in a way that will ensure maximum value and return for both Government as well as the community. This should involve embedding telehealth training and the development of core competencies to engage with a range of telehealth interventions into undergraduate and postgraduate training of GPs and Practice Nurses. This should be linked to ongoing quality improvement and accreditation programs and cycles.

- > Consider committing resources to embedding a range of telehealth competencies into undergraduate and postgraduate training for health professionals from all disciplines.
- > Incorporate telehealth training modules as part of continuing professional development to enhance the capacity to overcome geographical boundaries of care for patients in regional, rural and remote areas. Do this in collaboration with professional groups and link this to established QI and accreditation programs and cycles.

Resources for telehealth coordination and system integration

Considerable investment of human resources is needed to coordinate the range of health professionals and the patient in optimally using telehealth in a way that is advantageous to all, reduces the burden of care and treatment, and provides improved patient and provider experience. Without such coordinating work, telehealth interventions will struggle to establish themselves alongside or beyond current routines of practice and clinical care.

Consideration should be given to the piloting of new role in primary care of “care coordinator” or “telehealth nurse” aimed at supporting this care coordination work will need appropriate training as well as appropriate financial incentives. This coordination work need not necessarily be undertaken by a clinically trained person however the coordinator would need the capacity to help educate and support patients to be able to use telehealth technology in the context of their chronic conditions and to coordinate clinical appointments when multiple parties are involved.

- > Consider establishing a new coordination role in primary care to support telehealth implementation as a part of the Connecting Health Services with the Future initiative. This role, while not necessarily requiring clinical training, would encompass the capacity to help educate and support patients to use telehealth technology, to coordinate multidisciplinary care clinical appointments and to coordinate telehealth information collected from patients.

Additionally, efficiently accessing appropriately trained and online-ready specialists is an important element of a well-supported telehealth system. The Australian Health Service Directory contains fields for registering capacity to undertake telehealth consultations but is not well completed currently.

- > Consideration should be given to expanding the current national and regional directory of telehealth-ready medical specialists.

Finally integration of telehealth interventions within existing, common electronic health records will be a key factor in ensuring widespread uptake amongst health professionals. Co-operative engagement with commercial providers of electronic medical records in a national effort and approach to developing telehealth intervention will maximise interoperability and access to interventions across the patient and provider community.

- > Consider strategies for engaging commercial providers of electronic medical records in the national effort and approach to harmonise and optimise the integration of telehealth interventions.
- > Explore related opportunities to integrate seamless self-management data sharing and communication between health professionals and patients.

Funding

Widespread uptake of telehealth interventions needs to be underpinned by robust and sustainable business models in both public and private settings. Without appropriate business outcomes (combined with appropriate design and system integration to ensure human interaction and clinical care advantages as discussed above), uptake will remain low. Innovative and disruptive business models in both sectors are more likely to emerge when services and practices have some autonomy to creatively deploy financial and human resources. This sort of change and reform is least likely to emerge under restrictive fee for service models.

- > Advocate for innovative funding models that supports changed in practice, flexibility and autonomy at the local general practice level to achieve quality improvement. Consideration should be given to developing financial incentives to uptake of telehealth with a blended payment system, which can provide more local autonomy

and flexibility at the local level to change practice to achieve quality improvement and sustainability.

In the short term strategies are need to promote multidisciplinary engagement with video consultations.

- > Consider funding mechanism for PNs, RN-CDEs and other members of the diabetes team to actively participate in monitoring and responding to self-management and clinical information collected from telehealth platforms and to be able to participate in telehealth consultations.

Future research

Considerable effort needs to be put into designing telehealth interventions that are likely to be congruent with the complex human interactions of health care, particularly in the setting of complex, ongoing and often co-morbid conditions. Government has considerable incentive to be a stakeholder in this field, given the burgeoning costs of managing chronic conditions in primary care and the growing costs of health care across the country. Government is in a position to support a long term, programmatic approach to the sort of interdisciplinary research and development in telehealth that likely to deliver maximum value for investment. Within this economic evaluations will be a key component.

- > Give consideration to ways to support a long term, national programmatic approach to supporting interdisciplinary research and development in telehealth that includes economic evaluations and is likely to deliver maximum value for investment.

Conclusion

Type 2 diabetes and the epidemic of complex chronic illness are of enormous concern to funders and communities alike. It carries significant human and economic costs and solutions for making evidence-based quality care accessible to all to improve disease outcomes is rightly a focus of health policy.

We set out to undertake a proof of concept study, seeking to answer questions about the potential for a multicomponent telehealth platform to support the implementation of a model of care for type 2 diabetes in general practice and primary care. The model of care, known to be effective in a trial and known to support timely intensification of treatment to achieve better glycaemic control, faced challenges in the wider dissemination and implementation. How could the training and support for patients and health professionals be delivered widely and in particular in rural and regional centres? Was telehealth an acceptable and feasible way to bridge this implementation gap, making the model of care more widely accessible?

Telehealth is an area of rapid development in health care, driven by advances in technology and interests of governments, funders and commercial developers. It promises enormous benefits in potentially making specialist care more accessible in the right place at the right time to patients and primary care professionals. It also promises significant benefits in terms of scale, with the capacity to reach many more people via the growing ubiquity of wearable devices, smart phones and tablets. It has nevertheless been subject to slow and unpredictable uptake, in part, possibly, as it has failed to grapple with the more human and interactional elements of health care interactions.

Overall our study suggests that telehealth can play a role in making the model of care more widely accessible. The patients who participated in this small proof of concept study in 5 rural and regional practices showed significant improvements in glucose levels, weight and waist circumference. The telehealth platform did enable patients and primary care GPs to access specialist care, overcoming geographic and financial barriers. This supported novel access to multidisciplinary care involving PNs and diabetes educators, and played an educational role for both professionals and patients. Patients and GPs said they wanted to continue to use this telehealth modality. Online sharing of glucose levels was more challenging for patients and professionals suggesting the needs for greater investment in developing the user interface of this telehealth intervention. Our work suggests the need for greater integration of telehealth supports for patients and professionals with existing electronic medical records.

We also identified important issues in implementing the model of care and in the use of the telehealth platform. The PNs role in diabetes care was only partially expanded as intended. It may be that more intensive relationship building is needed between the diabetes team members to establish new roles, and that telehealth only partly provides the platform for this to occur. We also identified the significant human resources needed to coordinate in bringing together the multiple team members and the patient in a truly multidisciplinary online encounter. We suggest that funding is needed for this new work. We also suggested that this might be best achieved through a payment system that allows local autonomy for practices in how they deploy their staff and organise chronic illness care.

Finally we believe that unlocking the potential of telehealth in a country such as Australia will require a harmonised national effort that sees research and evaluation contribute progressively to more mature, usable, effective and sustainable telehealth interventions.

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