

# Designing an integrated, nurse-driven and home-based digital intervention to improve insulin management in under-resourced settings

Patrick Ngassa Piotie , Paola Wood, Elizabeth M. Webb, Johannes F.M. Hugo and Paul Rheeder

## Abstract

**Background:** In South Africa, initiating insulin for people with type 2 diabetes and subsequent titration is a major challenge for the resource-constrained healthcare system. Inadequate support systems in primary care, including not being able to access blood glucose monitors and test strips for self-monitoring of blood glucose, results in patients with type 2 diabetes being referred to higher levels of care. In primary care, initiation of insulin may be delayed due to a shortage of healthcare workers. The delayed initiation of insulin is also exacerbated by the reported resistance of both healthcare providers and people with type 2 diabetes to start insulin. In South Africa, telehealth provides an opportunity to overcome these challenges and manage insulin therapy in primary care.

**Methods:** We describe the development of a digital health intervention including the framework used, the theoretical approach and subsequent implementation strategies.

**Results:** This intervention is an innovative, nurse-driven and app-enabled intervention called 'the Tshwane Insulin Project intervention'. The Tshwane Insulin Project intervention was designed and evaluated using the framework recommended by the Medical Research Council for complex interventions. The Tshwane Insulin Project intervention was developed in four sequential phases: planning, design, implementation and evaluation. The Tshwane Insulin Project intervention followed the Integrated Chronic Disease Management framework to facilitate implementation and acceptability. The Tshwane Insulin Project comprises a facility-level intervention, where nurses evaluate patients and initiate insulin, an individual-level intervention where community healthcare workers visit patients at their homes to follow-up and provide educational information, while using telehealth to enable physician-directed insulin titration if needed, and a community-level intervention aimed at empowering community healthcare workers to support people living with diabetes and raise awareness of diabetes.

**Conclusion:** The technological advancements in digital health and telemedicine present an opportunity to improve diabetes care in resource-limited countries. This work can inform those intending to develop and implement complex interventions in primary healthcare in developing countries.

**Keywords:** digital health, implementation strategy, innovation, insulin, primary care, telehealth, telemedicine, Tshwane Insulin Project, type 2 diabetes

Received: 31 July 2021; revised manuscript accepted: 4 October 2021.

*Ther Adv Endocrinol Metab*

2021, Vol. 12: 1–11

DOI: 10.1177/  
20420188211054688

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## Background

Despite the availability of advanced analogue insulins and improved insulin delivery devices, many people with type 2 diabetes (T2D) in developing countries continue to experience suboptimal glycaemic control.<sup>1</sup> Poor glycaemic control can be partly attributed to clinical inertia or a failure to initiate or intensify insulin therapy when indicated.<sup>2,3</sup> Insulin is often initiated after years of poor glycaemic control in people with T2D,<sup>4-6</sup> increasing patients' vulnerability to long-term complications.

In South Africa, initiating insulin for people with T2D and subsequent titration is a major challenge for the resource-constrained healthcare system. Unlike other countries in sub-Saharan Africa, insulin is available free of charge in South Africa to people living with diabetes in the primary healthcare sector.<sup>7</sup> Aside from access to insulin, proper insulin management also requires consumables such as syringes, blood glucose monitors and test strips, education, information and family support.<sup>8</sup> In South Africa, blood glucose monitors and test strips for self-monitoring of blood glucose (SMBG) are inaccessible and infrequently used by people with diabetes in public healthcare settings.<sup>9</sup> In these settings, diabetes self-management education (DSME) is usually delivered to people living with diabetes on an ad hoc basis and depends on how much time the healthcare providers have for counselling.<sup>10</sup> All these factors combined result in people with T2D not knowing about the benefits of insulin therapy and lacking confidence,<sup>11</sup> which reinforces their resistance towards starting insulin.

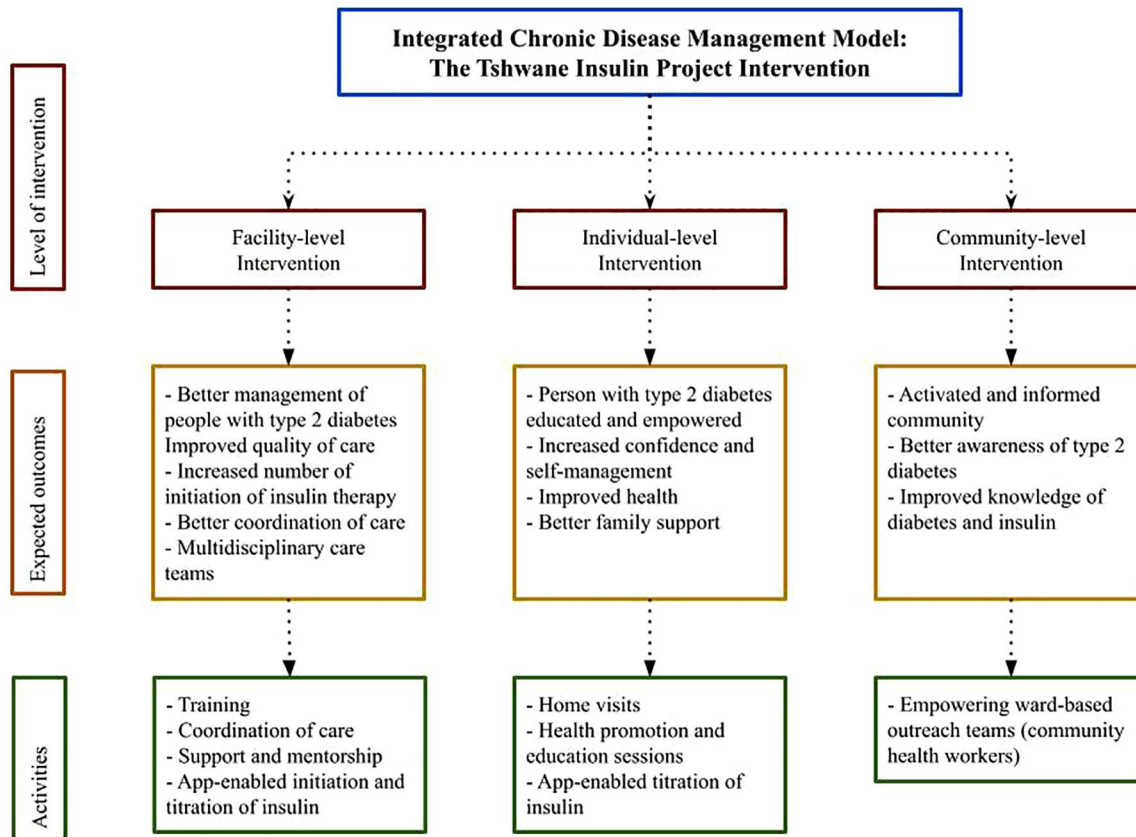
South African diabetes management guidelines recommend that insulin be initiated by a doctor.<sup>12</sup> In practice, this is not always feasible. Besides the reported resistance of both healthcare providers and people with T2D to start insulin,<sup>13-15</sup> most primary healthcare clinics lack doctors and diabetes dedicated nurses, and nurses have a heavy workload which limits their capacity to attend comprehensively to patients with T2D.<sup>9</sup> In primary healthcare, many South African doctors feel they do not know enough or have enough experience of the insulin therapy guidelines.<sup>16</sup> Consequently, people with T2D often remain on maximum oral glucose-lowering therapy despite suboptimal glycaemic control, and people who have transitioned to insulin do not often intensify their insulin therapy.<sup>15</sup> South African doctors are similar to doctors from other settings. Rushforth

*et al.*<sup>17</sup> conducted a systematic review and found that primary care clinicians struggle to meet evolving treatment targets with limited time and resources. Clinicians lack confidence in knowledge of guidelines and skills, notably initiating insulin and facilitating patient behaviour change.<sup>17</sup>

Due to the lack of support systems in primary care, people with T2D in South Africa are often referred to a higher level of care for initiating insulin, which is neither practical nor sustainable. Most patients are reluctant to go to hospital or are unable to afford the additional transport costs. District, regional and tertiary hospitals do not have the capacity to initiate insulin therapy for all patients timeously. The burden for the already resource-constrained healthcare system is expected to increase because 40–60% of the estimated 4.6 million South African adults who have T2D will need insulin to maintain glycaemic control due to the gradually declining secretion of insulin by the pancreas.<sup>18,19</sup> Referring these patients to a higher level of care is not a viable solution, and alternative solutions will have to be sought at the primary care level. Globally, insulin initiation in T2D has shifted from secondary to primary care to meet the demands of rising patient numbers and changes in health care policy.<sup>20</sup> In South Africa, primary care services are offered free of charge and cost is not a barrier to insulin initiation. For people living with diabetes, having to attend primary care facilities and clinics is synonymous with missed workdays, transportation issues and cost of follow-up appointments.<sup>21</sup>

Recent advances in digital technologies that focus on improving healthcare efficiency are providing many opportunities for diabetes care including insulin management.<sup>22</sup> Healthcare providers are using telehealth to deliver health care remotely.<sup>23</sup> Telehealth enables long-distance clinical health care and saves patients' time and money by eliminating the need to travel long distance to access healthcare services.<sup>23</sup> Telehealth has not been widely tested or used for insulin management in primary care despite the availability of digital health tools such as mobile technology.

To overcome the many challenges in initiating and titrating insulin in people with T2D in South Africa, a team of researchers designed an innovative nurse-driven and app-enabled intervention called 'the TIP intervention'. The Tshwane Insulin Project (TIP) is a 5-year translational



**Figure 1.** The Tshwane Insulin Project (TIP) intervention framework: the Integrated Chronic Disease Management model.

research programme that was developed and launched in 2019 in the Tshwane District of South Africa. In this article, we describe the development of the TIP intervention including the intervention framework, the theoretical approach and evaluation methods. We further describe the TIP intervention and subsequent implementation strategies.

### TIP intervention framework: the Integrated Chronic Disease Management model

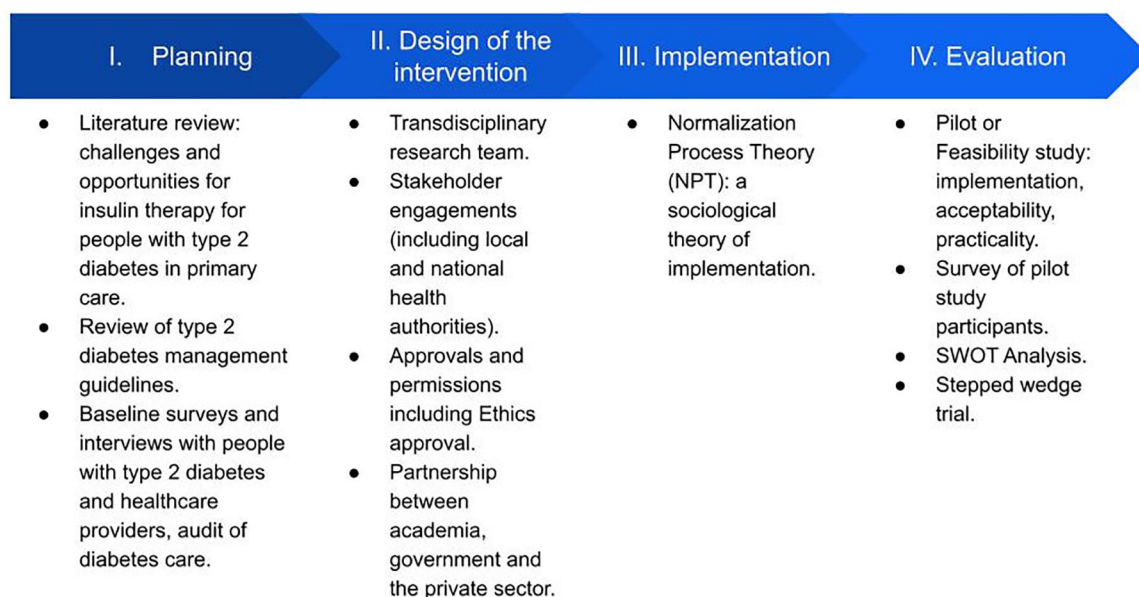
Responding to the growing burden of chronic diseases including diabetes, South Africa adopted an Integrated Chronic Disease Management (ICDM) model which aims to reduce healthcare utilisation and promotes self-management among patients with chronic conditions.<sup>24,25</sup> The ICDM goal is to achieve optimal clinical outcomes for people living with chronic communicable and non-communicable diseases.<sup>26</sup> The ICDM has four inter-related phases: (1) facility re-organisation to improve service

efficiency, (2) clinical supportive management to improve quality of clinical care, (3) ‘assisted’ self-support and management of patients through primary healthcare ward-based outreach teams (WBOT) to enhance self-care and raise awareness of chronic diseases in communities and (4) strengthening support systems and structures outside the health facility to ensure a fully functional and responsive health system.<sup>26</sup> The ICDM model integrates interventions at the facility level, community level and population level.<sup>26</sup>

The TIP intervention was developed within the ICDM framework to facilitate implementation and acceptability (Figure 1) and comprises a facility-level intervention, an individual-level intervention and a community-level intervention.

### Development of the TIP intervention

To develop the TIP intervention, the researchers used a framework recommended by the Medical



**Figure 2.** The Tshwane Insulin Project (TIP) intervention development phases based on the Medical Research Council framework.

Research Council (MRC) for designing and evaluating complex interventions.<sup>27</sup> The TIP intervention was developed in four sequential phases from I to IV (Figure 2).

#### *Phase I: planning the TIP intervention*

During the planning phase, the researchers reviewed literature on similar interventions.<sup>28</sup> They reviewed the current South African guidelines for managing T2D to identify barriers and enablers of the intervention. Finally, the researchers conducted a series of baseline surveys with primary healthcare providers and people living with T2D. The findings of the baseline surveys have been published elsewhere.<sup>13,29</sup>

#### *Phase II: designing the TIP intervention*

The TIP intervention was designed by a transdisciplinary team comprising researchers with expertise in diabetes and internal medicine, health systems and public health, nursing, family medicine, human nutrition and exercise science. After consulting with various stakeholders including local and national health authorities as well as people living with diabetes, the researchers designed the intervention following an approach best described as ‘designing for dissemination’.<sup>30</sup> Implementation was considered from the onset,

before the actual development of the intervention.<sup>31</sup> The researchers considered a set of processes and activities throughout the planning, development, implementation and evaluation of the intervention to increase potential for dissemination and implementation.<sup>30</sup> The initiative is a model of public–private partnership between academia, government and the Lilly Global Health Partnership which funded the TIP.

#### *Phase III: implementing the TIP intervention*

The implementation of the TIP intervention was guided by a sociological theory of implementation, Normalisation Process Theory (NPT), which has been previously used in similar work.<sup>31,32</sup> According to NPT, new practices become incorporated into routine clinical care resulting from individual and collective work.<sup>33</sup> Theoretically, new practices are normalised as participants make sense of the practice, engage with and invest in the practice as they work.<sup>32</sup> Consistent with NPT, the researchers developed the TIP intervention in collaboration with all relevant stakeholders from healthcare providers [medical and nurse practitioners and community health workers (CHWs)] at the clinics to people living with diabetes and health authorities. The stakeholders played distinct roles, either by actively participating in the implementation of the

intervention or by guiding or overseeing implementation.

#### *Phase IV: evaluating the TIP intervention*

Evaluating complex interventions such as the TIP intervention is difficult and challenging.<sup>27</sup> The researchers adopted a phased approach proposed by the MRC. The phased approach used a mix of qualitative and quantitative methods. Initially, the TIP intervention was piloted to assess feasibility and examine the main uncertainties that were identified during the design phase. The pilot study was registered to the National Health Research Ethics Committee (NHREC) and the South African National Clinical Trials Register (SANCTR) (Application ID: 5234). Healthcare providers and patients participated in the pilot study and were interviewed to assess the acceptability and practicality of the TIP intervention. The researchers conducted an SWOT analysis to identify the strengths (S) and weaknesses (W) of the intervention, as well as opportunities (O) that can be used and threats (T) that must be avoided to ensure the success of the intervention. Finally, a stepped wedge trial was planned for the dissemination of the TIP intervention. The pilot study and the SWOT analysis were completed. The implementation of the stepped wedge trial is ongoing, and the work should be completed in 2022.

#### **Description of the TIP intervention**

The TIP intervention is complex with several interacting components. The intervention comprises a facility-level intervention, an individual-level intervention and a community-level intervention.

##### *Facility-level intervention*

Primary healthcare providers were trained in the integrated management of T2D in primary care. The training aimed to ensure that medical officers, nurses and WBOT/CHWs were knowledgeable and confident in working collaboratively to start insulin and do adequate follow-up. The TIP intervention promotes nurse-driven insulin initiation, which is novel for South Africa. At primary care level, nurse practitioners care for patients with T2D who are on oral glucose-lowering medications and are ideally placed to know when patients need to be initiated on insulin. Nurses discuss the

initiation of insulin with qualifying patients and provide adequate counselling in preparation. Once patients are ready and consent to starting insulin therapy, nurses use a mobile app to reach out to a medical officer for a prescription for insulin. The medical officer confirms that the patient qualifies for insulin and gives the nurse a prescription. The nurse counsels the patient about insulin therapy including injection techniques and sites, SMBG, and signs and symptoms of hypoglycaemia. The patient receives a pack containing various items including a blood glucose monitor, test strips, lancets for finger pricking, a diabetes education booklet, a diary or SMBG log book and a sharp container. After initiation, patients are referred to WBOT/CHWs for follow-up based on their place of residence. Patients are also scheduled for a follow-up clinic visit a month later. In the TIP, members of the fieldwork team coordinate care at the clinic and provide ongoing support and mentorship to healthcare providers.

##### *Individual-level intervention*

CHWs visit the homes of patients initiated on insulin on a weekly basis. The CHWs reinforce health education and treatment compliance. During home visits, CHWs monitor home glucose measurements, adherence to medication and compliance with the clinic visit schedule, check for hypo- and hyperglycaemia, and check on injection sites and injection technique. The CHWs deliver individualised patient education using the diabetes education booklet based on patient needs focussing on one topic per session. The education sessions cover various topics including 'Starting and Using insulin', 'Food and Eating', 'Controlling diabetes', 'Testing blood sugar', 'Hyper- and Hypoglycaemia' and 'Emotional wellbeing'. Members of the household are encouraged to join the education sessions. Another key feature of the TIP intervention is app-enabled titration of insulin. At each home visit, CHWs use a mobile app to share the home glucose values of patients with a medical officer or doctor. The doctor indicates via the app whether the current insulin dose should be increased or decreased or remain unchanged. The CHW relays the message to the patient and ensures that he or she understands how to inject the right amount of insulin. The home visit provides an additional safety net because the CHW can refer the patient for a clinic visit if required, for example if low glucose values are repeatedly recorded.

### *Community-level intervention*

The WBOTs and CHWs are trained in the basics of diabetes and diabetes care. The TIP aims to educate WBOTs and CHWs about insulin and its role in managing people with diabetes. It is envisioned that with this knowledge, CHWs will become advocates and raise awareness of T2D in the communities, reducing resistance to insulin therapy. Communities are activated and become better informed regarding diabetes.

### **Strategy for implementing the TIP intervention**

The researchers identified potential barriers to implementing the TIP intervention by consulting with stakeholders, reviewing the literature and through past experiences, and subsequently adopted a number of strategies to ensure that the TIP intervention was successfully implemented.<sup>30</sup> These barriers or challenges and the strategies employed to overcome them are presented in Table 1.

Implementation strategies included strong engagement with stakeholders, assigning field researchers to primary care clinics and providing technical assistance to healthcare providers; providing blood glucose monitors, test strips and a SMBG log book to patients; adopting simplified algorithms for initiating and titrating insulin;<sup>34</sup> adopting an iterative approach to implementing the intervention; considering stakeholders' feedback and responding to arising barriers;<sup>31</sup> built-in safety nets such as a safe starting insulin dose,<sup>35</sup> and a 24-h helpline accessible to patients in case of emergency; titration of insulin assisted by a healthcare provider;<sup>36</sup> and timely pro-active follow-up of patients who are initiated on insulin.<sup>36</sup>

### **Discussion**

Currently, there is little literature describing the development and implementation of complex health interventions in developing countries. Digital health interventions qualify as complex interventions because they are difficult to implement due to factors such as cost, disruption to interactions between health professionals and patients, and poor implementation planning.<sup>31</sup>

In this article, we describe the development of a complex health intervention that uses digital

technology to improve insulin management in under-resourced communities.

The development and implementation of the TIP intervention was informed by dissemination and implementation science (DIS), a new area of health research that focuses on designing interventions and identifying implementation strategies that work in real life and across diverse, especially low resource, complex settings and populations.<sup>30</sup> Using DIS should ensure that the TIP intervention is well implemented, generalisable and sustainable.<sup>30</sup>

Starting insulin is a frightening event in the life of a person living with T2D and a daunting task for healthcare providers. The anxiety is exacerbated by the volume of information that a person with diabetes must absorb in a short space of time. In South Africa, these challenges are compounded by a lack of awareness or knowledge, low levels of health literacy, needle phobia, social stigma, lack of self-efficacy or confidence among patients, poor confidence in patient's abilities, lack of experience, perception of poor clinical efficacy and healthcare providers being afraid of inducing hypoglycaemia.<sup>35</sup> Starting insulin is also perceived as a time-consuming and demanding activity for already overworked and overburdened primary care staff.<sup>35</sup> The TIP intervention addresses most of these challenges and ensures that starting and titrating insulin in the primary care setting becomes a smooth journey where healthcare providers work together and the person with diabetes is empowered to play an active role in the management of his or her condition. The TIP intervention provides the necessary support to healthcare providers and to people with T2D to ensure that they get off to a good start and maintain treatment.

### *Nurse-led insulin initiation*

South African nurse practitioners are the backbone of the primary healthcare system. Nurses see most patients with chronic conditions in primary care<sup>37</sup> and routinely manage patients with T2D who are on oral glucose-lowering drugs. Many primary healthcare clinics are only visited once a week by doctors.<sup>37</sup> For these reasons, nurses are ideally placed to lead the initiation of insulin in primary care, provided they receive adequate training. While developing the TIP intervention, researchers conducted baseline surveys with healthcare providers, including

**Table 1.** Barriers or challenges identified for the implementation of the TIP intervention and strategies employed to address them.

Barriers or challenges	Implementation strategies
Resistance to change, lack of buy-in from clinic staff	Strong stakeholder engagement
Adopting a novel intervention, overburdened primary healthcare workforce	Field researchers assist primary care clinics and provide on-the-job training, mentoring and support to healthcare providers
Implementing a complex intervention	Adopting implementing the intervention, considering feedback from stakeholders and responding to arising barriers
Lack of knowledge or inexperience of healthcare providers with diabetes care	Training healthcare providers on diabetes management and care in primary care
Healthcare providers absent or unable to connect on the app	Diabetes specialists from tertiary diabetes clinics available to cover 'remotely' in case of the designated medical officer being unavailable
Community health workers do not have smartphones to use the digital app	Providing smartphones and mobile data to healthcare providers to access the mobile app
Unavailability of critical consumables for insulin therapy in primary care	Providing blood glucose monitors, test strips, SMBG log book and sharp containers to patients
Patients and healthcare providers not knowing enough about diabetes	Developing and distributing free diabetes education booklets relevant to the South African context
Healthcare providers reluctant to start or intensify insulin therapy, lack of experience and knowledge	Adopting simplified algorithms for initiating and titrating insulin
Fear of hypoglycaemia	Built-in safety nets such as a safe starting insulin dose, patient education during home visits by community health workers and a 24-h helpline accessible to patients in case of emergency
Patients' limited numeracy skills, health literacy and understanding of diabetes	Titration of insulin assisted by a healthcare provider
Discontinuation of insulin therapy, poor persistence with insulin therapy	Timely pro-active follow-up of patients who are initiated on insulin
SMBG, self-monitoring of blood glucose; TIP, Tshwane Insulin Project.	

nurses who believed that they would be able to initiate insulin provided that they were adequately trained.<sup>29</sup> Nurse-led interventions have been successful particularly when nurses followed simplified algorithms and protocols and were able to prescribe.<sup>38,39</sup> A nurse-led model of care for insulin initiation for people with T2D was tested in general practice in Australia and showed good results.<sup>40</sup> The researchers were also inspired by the expansion of primary care nurses' role to include antiretroviral therapy initiation and re-prescription which is behind the success of the South African HIV programme.<sup>41</sup>

The TIP intervention also promotes a multidisciplinary care team approach as described by Polonsky *et al.*<sup>36</sup> Nurses, medical officers, CHWs and pharmacist assistants work together to address patients' needs and provide the necessary reinforcement and support. Important tasks such as patient preparation and education, titration and follow-up are shared among one or more members of the team.<sup>36</sup> No team member has to carry all the workload alone. Task shifting or task sharing has been successfully used previously. For example, task shifting of SMBG education from doctors to nurses and other health professionals

helped improve SMBG usage in resource-limited settings.<sup>42</sup>

#### *App-enabled insulin titration*

Best practice demands that patients with T2D on insulin therapy should measure their blood glucose at least twice a day.<sup>35</sup> Currently in South Africa, most people with T2D who are initiated on basal insulin in primary care do not receive a blood glucose monitor, test strips or lancets. Contrary to the requirements of the South African diabetes management guidelines,<sup>12</sup> these patients cannot self-titrate their insulin. Furthermore, most South African patients have limited numeracy skills and lack the required education to perform self-titration.<sup>26</sup> Effective use of SMBG requires substantial numeracy skills, health literacy and understanding of diabetes.<sup>42</sup> Physician-directed titration enabled by telemedicine and assisted by a CHW (*versus* self-titration) as described in the TIP intervention is a practical solution in our context. Patients ought to receive blood glucose monitors and test strips since limited access to these vital instruments adversely affects their education and empowerment.<sup>43</sup> In developing countries, people with T2D are more likely to discontinue insulin therapy if they cannot afford test strips, are inexperienced in insulin dosing and lack support.<sup>44</sup>

Research has shown that insulin titration in patients with T2D in South Africa is vastly inadequate.<sup>34</sup> Titration of insulin is inconsistent and may occur only once a month during clinic visits. As a result, patients who are initiated remain on suboptimal insulin doses for long periods of time. Weekly home visits by CHWs allows for weekly app-enabled titration of insulin, helping patients to reach their optimal insulin dose quicker and improve glycaemic control. Faruque *et al.*<sup>45</sup> reported that telemedicine interventions that allowed healthcare providers to adjust medication in response to data from patients are associated with improved HbA1c.

#### *Assisted self-support and management*

Although the ICDM model advocates for 'assisted' self-support and management of patients through the WBOT teams,<sup>26</sup> people living with diabetes in South Africa have not benefited from this. People with diabetes are not

empowered and lack the knowledge to take responsibility for managing their own condition.<sup>11,46,47</sup> The TIP intervention presents an opportunity to fill this gap by involving WBOT/CHWs in the care of persons living with diabetes. The CHWs follow-up patients initiated on insulin at home. The CHWs help patients to adopt self-care behaviours associated with good outcomes namely healthy eating, being physically active, monitoring blood sugar, compliance with medication, and good problem-solving skills.<sup>48</sup> They also reinforce family/social support and ensure that patients receive the emotional support they need from their families.<sup>47,49</sup>

#### **Conclusion**

Here, we present the TIP, which is a digital health intervention implemented in real life. The implementation of the TIP intervention is a complex process involving interventions at multiple levels of the health system with various stakeholders. The intervention is designed to be delivered by staff typical of the South African primary care setting rather than experts in academic centres. The introduction of a digital health component should improve service efficiency when it comes to initiating and titrating insulin, and the involvement of CHWs should contribute to the empowerment of people living with T2D.

The technological advancements in digital health and telemedicine present an opportunity to improve diabetes care in resource-limited countries. This work can inform those intending to develop and implement complex interventions in primary healthcare in developing countries. We recommend a methodological approach which is evidence-based and grounded in the appropriate theory to guide the whole process from design to implementation and evaluation.

#### **Acknowledgements**

The authors thank the health facility managers and the health authorities from the City of Tshwane Metropolitan Municipality, the Tshwane district, the Gauteng Province and the South African National Department of Health for supporting the Tshwane Insulin Project (TIP); the members of the TIP technical working committee namely Prof Daniel Van Zyl, Prof Tessa Marcus, Prof Liz Wolvaardt, Prof Tanya Heyns,



Dr Jane Muchiri, Dr Celia Filmalter, Dr Gerhard Botha and Dr Zelda White for their valuable contributions; and the TIP fieldwork team: Ms Gotabeng Mohlala, Ms Amanda Segale, Ms Ntokozo Zulu, Ms Betty Manyapetsa and Mr Charles Koenaitse. Dr Cheryl Tosh for editing the manuscript.

### Author contributions

PNP contributed to conception or design of the work, drafting the article, critical revision of the article and final approval of the version to be published. PW contributed to conception or design of the work, critical revision of the article and final approval of the version to be published. EMW contributed to conception or design of the work, critical revision of the article and final approval of the version to be published. JFMH contributed to conception or design of the work, critical revision of the article and final approval of the version to be published. PR contributed to conception or design of the work, critical revision of the article and final approval of the version to be published.

### Conflict of interest statement

The authors declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

### Funding

The authors disclosed receipt of the following financial support for the research, authorship and/or publication of this article: This work was supported by the Lilly Global Health Partnership (Project Grant: A1B004/04408). The funder was not involved in the choice of study design; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit an article for publication.

### Ethical approval

The study protocol was approved by the Research Ethics Committee of the Faculty of Health Sciences of the University of Pretoria (Ethics Reference No.: 156/2019) and the Tshwane Research Council (No: GP\_201810\_049) and adhered to the Declaration of Helsinki. Written informed consent was obtained from all participants.

### Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analysed during the study.

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