

The House of Representatives Standing Committee on Health

Aged Care and Sport

PO Box 6021, Canberra ACT 2600 30 July 2023.

September 2023

Terms of reference: New evidence-based advances in the prevention, diagnosis, and management of diabetes in Australia and internationally.

Summary: We suggest that a major percentage of the current economic and health burden of disease associated with diabetes, can be alleviated by changing the current mindset, from type 2 diabetes prevention to **prediabetes prevention**. With this in mind, we have developed a new, convenient, point of care, evidence-based insulin resistance test (IRT), for prevention of prediabetes.

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Inquiry into Diabetes

Terms of reference:

New evidence-based advances in the prevention, diagnosis, and management of type 2 diabetes in Australia and internationally.

To the Members of the Committee,

Thank you for the opportunity to provide a response to the Inquiry into Diabetes.

It's time to consider shifting the current mindset from prevention of type 2 diabetes to prevention of prediabetes.

There have been major scientific discoveries, research, education programs, public health promotions, improved healthcare, and government funding leading to effective strategies for management of type 2 diabetes (T2D), nevertheless the global burden of T2D continues to rise.

We propose that earlier detection of insulin resistance (IR), and subsequent intervention is the key to changing the trajectory of T2D as we know it. There are currently no commercially available tests to detect IR in its early stages.

From our combined and extensive clinical experience as credentialed diabetes educators, we recognise it is crucial to implement improved systems, which create a clear pathway to earlier detection of T2D, and to address gaps in our current understanding of the development and early detection of IR. Therefore, we suggest a convenient point of care self-test, which is easily accessible to urban, rural, remote, and isolated communities. Earlier detection will provide the opportunity for medication, diet and lifestyle changes, and other self-management strategies to be implemented in a timely manner, potentially preventing development of the disease with significant reduction of TD2 nationwide.

We recognise there are multiple stages in the progression of T2D. In addition, there are multiple factors, including genetics, age, diet, lifestyle, emotional and/or physical stress, that affect the development and rate of the progression to T2D. Furthermore, we understand that IR can commence up to ten years before prediabetes, or 15 years before T2D can be diagnosed. With early detection and intervention, the progression of the disease could be delayed or prevented.

With this in mind, we are currently developing, and have patented, a novel insulin resistance test (IRT), which may be of interest to the committee. It aims to overcome or ameliorate, the disadvantages of current testing, by detecting IR in its earliest stages, ideally before prediabetes develops. Earlier detection will allow additional time for appropriate medical intervention and/or lifestyle changes before the disease progresses. In combination with the AUSDRISK screening questionnaire, the IRT has potential to reach the large number of people at risk in the community.

Insulin resistance

Insulin is a vital hormone which regulates the body's blood glucose and is a major factor in the development of T2D. Insulin is required to remove glucose from the bloodstream into the body's cells, by attaching to cell receptors, thereby instigating uptake of glucose. If the cells stop responding to insulin to complete the glucose uptake process, the pancreas continues to produce more insulin, to overcome this resistance and regulate blood glucose levels. The pancreas can compensate IR for many years, avoiding high blood glucose (hyperglycaemia). Tests used to diagnose prediabetes and T2D will not detect this early-stage IR.

In the early stages, IR has often no recognisable symptoms. Only when the pancreas is unable to produce enough insulin to overcome the resistance, leading to hyperglycaemia, that symptoms develop.

IR and failure to manage hyperglycaemia is also associated with the development of pancreatic dysfunction, fatty liver disease, hypertension, PCOS and cardiovascular disease. Identifying IR early and committing to lifestyle changes can ultimately help reduce the risk of progression to TD2 and these other conditions.

Prediabetes

Prediabetes is when blood glucose levels are higher than normal, but not high enough for a T2D diagnosis. At prediabetes stage, there is decreased concentration of insulin, along with IR, and consequently blood glucose levels are elevated. If prediabetes is identified early enough, diet and lifestyle changes may prevent or prolong the trajectory to T2D. However, at prediabetes stage, damage to the body from hyperglycaemia has already occurred.

Currently, it is not general practice to detect prediabetes risk via biochemistry, since markers used to diagnose prediabetes and/or T2D only detect hyperglycaemia, (the stage where the pancreas beta cells have fatigued). At this point, decline in beta cell function is difficult or impossible to reverse, ultimately leading to T2D.

Prediabetes is considered 'borderline' diabetes, and unfortunately, many physicians wait until blood glucose levels are high enough to diagnose T2D before prescribing medication to combat IR, and/or providing a referral to the appropriate healthcare team for diabetes education and intervention.

Current tests for insulin resistance

Current laboratory tests are used to detect hyperglycaemia; they are not used to identify early-stage IR. Most are unsuitable for widespread usage, to cater for the millions of people requiring early detection.

IR has been measured by using the Homeostatic Model Assessment of Insulin Resistance (HOMA-IR), which is calculated from fasting glucose and fasting insulin levels. HOMA-IR has been used to identify IR in mild hyperglycaemia. As insulin has a very short half-life, the HOMA-IR test reflects only a moment in time.

Haemoglobin A1c (HbA1c) test is used to diagnose prediabetes and T2D. Measurement of HbA1c reflects the percentage of glucose in the blood over a three-month period. As elevated blood glucose only occurs from prediabetes stage, it would not detect the earlier stages of IR.

Another common test, usually to detect gestational diabetes, is the Oral Glucose Tolerance Test (OGTT). OGTT involves blood glucose testing at 1-hour and 2-hour post 75g glucose drink. However, the test is not routinely used to measure insulin levels alongside glucose levels to detect insulin resistance. Due to cost and length of time involved for the procedure, it is not used often.

IRT - Insulin Resistance Test

We believe our new self-test could detect changes to glucose metabolism much earlier than the current conventional tests. By connecting the latest research, we have identified biomarkers already subsidised by Medicare, which could measure the level of IR, determine between IR and insulin insufficiency, and detect IR in its earliest stages.

We envisage that the device will be a cost effective, convenient way for those at risk of developing T2D, (family history, age, gender, ethnicity, dietary intake, physical activity levels, amongst other factors), and to monitor their IR over time. It will also provide instant results to physicians, nurses, and diabetes educators, to enable intervention, education, and awareness of the condition.

A convenient self-test will not only be an early detection screening tool, but it will also promote awareness, earlier education, and instigate further investigation with a general practitioner. Perceived benefits of our newly developed IRT include:

1. Predicting the risk of development of gestational diabetes and subsequent high-risk pregnancies.
2. Screening of young people in their 20s at risk of diabetes, thereby allowing for timely prevention of prediabetes and/or T2D.
3. Screening of indigenous children who have a strong family and ethnic history of T2D.
4. Distinguishing between IR and insulin insufficiency, thereby helping identify late onset of type 1 diabetes in adults.
5. Monitoring of beta cell function and glucose metabolism over time, to determine the most suitable medication for prediabetes and T2D.
6. Early detection of IR will reduce the burden on our hospital system, the financial Government costs associated with the ongoing needs of T2D management and improve the quality of life of millions of people at risk of developing T2D.

Example 1: A male in his 20s with a family history of T2D could commence self-testing every 6-12 months to detect IR. This would provide opportunity to monitor his situation/implement changes to avoid prediabetes in his 30s, and then of course avoid the progression to T2D.

Example 2: A young woman with T2D risk factors planning a pregnancy would benefit from recognising early indications of IR. She would have the opportunity to implement lifestyle changes preconception to avoid gestational diabetes and potentially avoid a high-risk pregnancy.

Government support is needed to:

- promote change from the current diabetes health framework.
- shift the focus on prevention of T2D to prevention of prediabetes.
- conduct additional research into new, early detection technology.
- enable access to cost effective, convenient, early detection technology to all Australians at risk of developing prediabetes and T2D.

We have utilised the latest technology, scientific knowledge, research outcomes, and practical requirements for consumer use, to invent our IR device. With Government support, we can reach millions of Australians, to not only detect early signs of IR, but to prevent prediabetes, and/or T2D from occurring.

Global Diabetes Solutions would welcome the opportunity to participate further in this inquiry and can provide supplementary information at any stage to assist the Committee.