

## Underestimation of risk for large babies in rural and remote Australia:

### Time to change plasma glucose collection protocols

#### What do we already know?

Gestational diabetes mellitus (GDM) means high blood sugar in pregnancy. It causes problems in pregnancy and childbirth, like big babies and complicated births. GDM mums and babies are more likely to have Type 2 Diabetes later as well. Women living in rural areas are at higher risk of developing GDM than their urban counterparts because of the higher rates of obesity. It is important to screen for GDM so that it can be treated. The recommended screening test is a fasted 75g oral glucose tolerance test (OGTT), also known as the sugar drink test, which involves three blood samples to be collected over two hours.

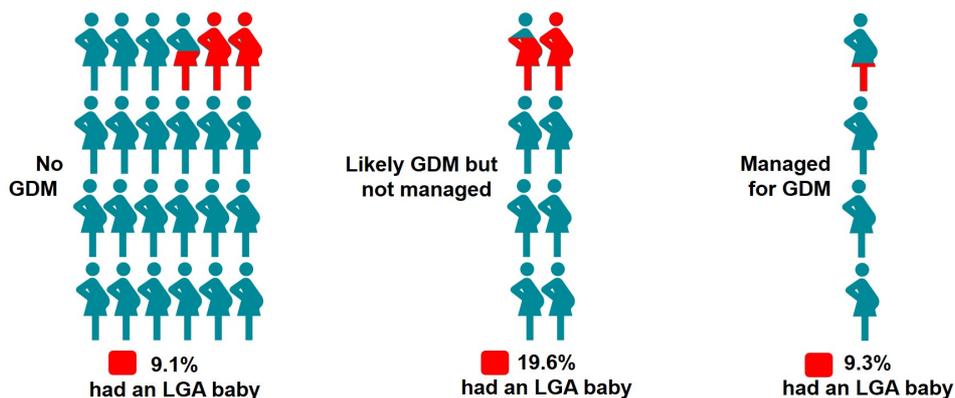
Following a large international study on Hyperglycaemia and Adverse Pregnancy Outcome (HAPO), new OGTT diagnostic criteria were introduced in WA in 2015. The **ORCHID Study** (Optimisation of Rural Clinical and Haematological Indicators of Diabetes in pregnancy) was designed to help simplify screening for GDM in rural and remote WA. Our [first paper](#) showed that it can be difficult to get everyone to do this test. Our [second paper](#) showed that two-thirds of women with GDM who do the test are missed due to blood glucose sample instability.

The HAPO study used ice to help stabilise blood glucose samples and made sure that samples were measured within one-hour of test completion. This is impractical for rural and remote clinics where tests are often done in the clinic rather than a dedicated collection centre. FC Mix tubes offer a practical alternative by stabilising glucose without ice and keeping it stable for at least two-days. However, they give slightly higher readings to the HAPO study ice-method (+0.2 mmol/L), raising concerns of overdiagnosis of GDM.

#### What does this research show?

In a follow-up to the second paper we wanted to know what impact glucose stability issues had on identification of large-for gestational age (LGA) babies. Similar to the second paper we adjusted the ORCHID study OGTT results of 495 women based on delay to laboratory and estimated how much glucose was lost if the HAPO study ice-method or FC Mix tubes had been used. We found that:

- Correction for glucose loss using the HAPO study ice-method doubled the rate of women with GDM (from 9.7% to 22.7%) and improved the prediction of risk for an LGA baby (from 1.1 to 1.8 relative risk for an LGA baby compared to women without GDM).
- Correction for glucose loss using the FC Mix tube method resulted in a 4-fold increase in rate of GDM (44.6%).
- When using the FC Mix tube correction we needed to increase the GDM diagnostic criteria by +0.2 mmol/L to get similar results to the HAPO Study ice-method (GDM 29.3%, 1.8 relative risk for LGA babies compared to women without GDM). The higher risk for an LGA baby remained in women with GDM after mum's weight, age, and smoking were considered.
- One in five women who probably had GDM but were not managed had an LGA baby (they were missed because of blood glucose sample instability). This may have been avoided if GDM had been detected using FC Mix tubes and increasing the GDM diagnostic criteria by +0.2 mmol/L:





## Changes to clinical practice

- Kimberley Aboriginal Community Controlled Health Services implemented FC Mix tubes in September 2019. Please refer to [Greiner Bio-One](#) for more information. If other clinics are interested in obtaining these tubes please contact [Interpath](#), the Australian distributor for Greiner Bio-One. For further assistance with your enquiries please contact ORCHID Study coordinator, [Emma Jamieson](#).
- In collaboration with Diabetes WA we have submitted a position statement to the Royal College of Pathologists of Australasia (RCPA) recommending acceptance of FC Mix tubes across Australia and to develop pragmatic methods for interpretation of results. [Julia Marley](#) is part of the *Pre-analytical glucose group*, formed last year to progress national changes to laboratory practice. Our reasons for promoting the use of FC Mix tubes were discussed as part of a [Letter to Diabetes Care](#) in 2020.

## Future research

We think this is an important finding. From our first paper we know that half of women are not screened for GDM in rural and remote WA. We now know that in the women who are screened we are missing GDM because of how the test is done and that these women are at high risk of having an LGA baby. To improve detection of GDM in rural WA we are:

- Assessing the use of FC Mix tubes in Kimberley ACCHS and the impact on the number of women managed for GDM and if this improves birth outcomes.
- Comparing the OGTT using FC Mix tubes to other tests that are easier to give to the pregnant women.

We would like to thank all health service staff who assisted in completing this project and the health services that agreed to participate. This project is a collaboration between Rural Clinical School of WA, Kimberley Aboriginal Medical Services, WA Country Health Services and this part was funded through grants from RCSWA, Lishman Health Foundation and Diabetes Australia.

If you have any questions or comments please direct them to ORCHID Study Chief Investigator, [A/Prof Julia Marley](#).

## Website links

- Greiner FC Mix™: <https://shop.gbo.com/en/row/products/preanalytics/venous-blood-collection/vacurette-tube/glucose/fc-mix-glucomedics/>
- Interpath: [https://www.interpath.com.au/interpath\\_contact.html](https://www.interpath.com.au/interpath_contact.html)
- [Webinar on ORCHID findings: https://youtu.be/GqK1PJ9bxdk](https://youtu.be/GqK1PJ9bxdk)

## ORCHID publications

1. Kirke AB, Atkinson D, Moore S, Sterry K, Singleton S, Roxburgh C, Parrish K, Porter C, Marley JV. Diabetes screening in pregnancy failing women in rural Western Australia: An audit of oral glucose tolerance test completion rates. [Aust J Rural Health. 2019; 27\(1\): 64-69.](#)
2. Jamieson EL, Spry E, Kirke AB, Atkinson D, Marley JV. Real-world gestational diabetes screening: problems with the oral glucose tolerance test in rural and remote Australia. [Int J Environ Res Public Health. 2019; 16\(22\): 4488.](#)
3. Jamieson EL, Spry E, Kirke AB, Roxburgh C, Atkinson D, Marley JV. Underestimation of risk for large babies in rural and remote Australia: Time to change plasma glucose collection protocols. [J Clin Transl Endocrin; 2020: 100247.](#)
4. Jamieson EL, Spry E, Kirke AB, Roxburgh C, Atkinson D, Marley JV. Variations in the Prevalence of Gestational Diabetes Mellitus With Remote Testing and a Pragmatic Solution to Improve Accuracy. [Diabetes Care; 2020: 09: 09.](#)

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