

The First International Association of Diabetes and Pregnancy Study Groups (IADPSG)

Summit on the Diagnosis of Gestational

Diabetes in Early Pregnancy: TOBOGM Summit Report

14 November 2023

The First International Association of Diabetes and Pregnancy Study Groups

(IADPSG) summit on the diagnosis of gestational diabetes in early pregnancy:

TOBOGM Summit Report

Sweeting A, ^{1,2} MacMillan F, ³ Simmons D^{4,5} for the TOBOGM Summit attendees.

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Tables/Figures 2 (plus 5 supplementary)

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Introduction

While approaches may differ, there is global agreement that screening for gestational diabetes mellitus (GDM: hyperglycaemia first detected in pregnancy and below diabetes in pregnancy [DIP: likely undiagnosed type 2 diabetes]), should occur routinely at 24-28 weeks' gestation (1, 2), largely based upon two high quality randomised controlled treatment trials (RCT) (3, 4). The World Health Organisation (WHO) and International Association of the Diabetes and Pregnancy Study Groups (IADPSG) diagnostic criteria for GDM were subsequently developed based upon the large, international Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) cohort study (5). Both the HAPO study and the HAPO-Follow Up Studies (HAPO-FUS: a prospective follow up of the HAPO cohort and their offspring for 10-14 years) demonstrated continuous linear associations between maternal glycaemia during a 2-h 75g oral glucose tolerance test (OGTT) at 24-32 weeks' gestation, perinatal, and long-term maternal and offspring complications (5-7).

International guidelines now also generally recommend early testing for women at high risk of DIP (8). While glycaemic thresholds identifying DIP in early pregnancy are well established (1, 2), whether and how to define maternal hyperglycaemia below this threshold (early GDM diagnosed prior to 20-24 weeks' gestation) is unclear. Despite a physiological decrease in maternal fasting glucose in the first trimester (9), a linear relationship between early pregnancy fasting glucose levels below DIP thresholds and risk of perinatal complications also exists (10). Until recently, high-quality evidence for diagnosing and treating early GDM had been lacking. A meta-analysis of 13 cohort studies in women with early GDM demonstrated greater perinatal mortality (relative risk [RR] 3.58; 95% Confidence Interval [CI], 1.91 to 6.71) compared to women diagnosed with GDM in later pregnancy, despite treatment (11).

In the Early Gestational Diabetes Screening in the Gravid Obese Woman (EGGO) trial (12) in the United States (US), early screening for GDM among 922 women with body mass index (BMI) $\geq 30 \text{ kg/m}^2$ using the 1-h 50 g glucose challenge test (GCT), followed by a 100-g, 3-hour OGTT if the initial GCT was $\geq 7.5 \text{ mmol/L}$ (135 mg/dL), showed no difference in overall risk of perinatal complications (a composite of macrosomia [>4000 g], primary caesarean delivery, hypertensive disease of pregnancy, shoulder dystocia, neonatal hyperbilirubinemia, and neonatal hypoglycaemia). GDM was diagnosed if two or more values on the OGTT were above the thresholds: fasting $\geq 5.3 \text{ mmol/l}$ (95 mg/dL), 1-hour $\geq 10.0 \text{ mmol/l}$ (180 mg/dL), 2-hour $\geq 8.6 \text{ mmol/l}$ (155 mg/dL) and/or 3-hour $\geq 7.8 \text{ mmol/l}$ (140mg/dL). However, the trial included only a small number of women diagnosed and treated for GDM (69 women [15.0%] in the early screening group vs 56 women [12.1%] in the routine screening group, with the average gestational age at diagnosis 24.3 \pm 5.2 weeks vs 27.1 \pm 1.7 weeks, respectively), and its design did not allow a comparison of pregnancy outcomes between women with treated and untreated early GDM.

The recent Treatment of Booking Gestational Diabetes Mellitus (TOBOGM) trial (13) was the first large multicentre international RCT to test diagnostic criteria and treatment for early GDM in women with risk factors for hyperglycaemia in pregnancy. The TOBOGM study showed that immediate treatment of GDM (2-h 75g OGTT WHO 2013 criteria: fasting glucose ≥ 5.1 mmol/L [92 mg/dL], and/or 1-h glucose ≥ 10.0 mmol/L [180 mg/dL], and/or 2-h glucose ≥ 8.5 mmol/L [153 mg/dL]) (2) before 20 weeks' gestation led to a reduction in the incidence of a composite of major adverse neonatal outcomes (preterm birth < 37 weeks' gestation, birth trauma, birth weight ≥ 4500 g, respiratory distress, phototherapy, stillbirth or neonatal death, or shoulder dystocia) from 30.5% in the control group to 24.9% in the immediate-treatment group (adjusted risk difference, -5.6%; 95% CI, -10.1 to -1.2). Prespecified subgroup analyses

suggested a potentially greater effect of early intervention among women with higher glycaemic values on the OGTT, based on the 2.0 odds ratio for adverse pregnancy outcomes shown in the HAPO study (fasting glucose 5.3-6.0 mmol/L [95-109 mg/dL], and/or 1-h glucose ≥ 10.6 mmol/L [191 mg/dL], and/or a 2-h glucose level 9.0-11.0 mmol/L [162-199 mg/dL]) vs women in the lower glycaemic band, based on the 1.75 odds ratio for adverse pregnancy outcomes in the HAPO study (fasting glucose level 5.1-5.2 mmol/L [92-94 mg/dL], 1-h glucose level 10.0-10.5 mmol/L [180-190 mg/dL], and/or a 2-h glucose level 8.5-8.9 mmol/L [153-161 mg/dL]), and among women who underwent OGTT prior to 14 weeks' gestation. A potential for harm was also shown in the lower glycaemic band with more small-for-gestational-age (SGA) offspring (adjusted risk difference, +5.5%; 95% CI, 1.4 to 9.7).

The TOBOGM Summit

The TOBOGM trial sought to address the knowledge-gap in whether to diagnose and treat early GDM, following the identification of the various issues with existing GDM diagnostic criteria in early pregnancy (14, 15). The TOBOGM Summit emulated the process for defining diagnostic criteria for GDM following the publication of the HAPO study in 2008 (5), when the IADPSG ran a series of workshops and set up a writing group to gain consensus for the IADPSG criteria for GDM diagnosis at 24-28 weeks' gestation (1). A caveat to this process was that while these IADPSG criteria were adopted by the WHO and major international diabetes and obstetric organisations (2, 16-20), several national organisations either did not adopt the criteria, or proposed different criteria (15, 21-23). The rationale for not adopting the IADPSG/WHO criteria varied but largely came down to a predicted increase in workload with no RCT evidence of benefit (21, 24).

The purpose of The First IADPSG Summit on the Diagnosis of Gestational Diabetes in early Pregnancy (the TOBOGM Summit) was therefore to use the TOBOGM trial findings to scope the issues involved with early screening, to inform future discussions over possible approaches and criteria for diagnosing GDM in early pregnancy.

The TOBOGM Summit (Summit) was hosted by the IADPSG on 17th November 2022, in Sydney, Australia. Over 170 delegates from 21 countries attended, representing a range of health professionals/clinicians, academics, policy makers and consumers with lived experience. Attendees are listed in the supplementary appendix (S1). Representatives from organisations with an interest in diabetes and pregnancy included the IADPSG, International Federation of Gynaecology and Obstetrics (FIGO), International Diabetes Federation (IDF), National Institutes of Health (NIH), and New South Wales Health. The TOBOGM findings were shared with attendees, in confidence, after submission but prior to revisions and publication, but few changes were made to the results presented between the summit and the final paper. This report represents the opinions of individual delegates of the Summit and does not necessarily reflect the position of the organizations they represent. It is expected that this report will serve as a scoping review/report for nationally and internationally endorsed approaches and criteria for the diagnosis of GDM in early pregnancy.

Methodology

Format and key questions at the Summit

The Summit was divided into two parts - presentations and workshops.

Presentations by leading international experts included a global overview on the prevalence, current screening practice and diagnostic criteria for GDM in early pregnancy, as well as the

issues relating to screening, diagnosis and treatment of hyperglycaemia in early pregnancy. Presentation of the TOBOGM Study results included sessions on the primary outcomes, the pre-analytical glucose TOBOGM sub-study, consumer perspectives on potential glycaemic thresholds, and options for glycaemic thresholds and glycaemic measures from the TOBOGM study, followed by a panel discussion. The TOBOGM Summit Program is presented in **Supplementary Appendix 2**.

A series of workshops followed the presentations, where delegates discussed the following key questions:

- 1. Should we test for and treat GDM from early pregnancy?
- 2. What diagnostic criteria should we use for GDM in early pregnancy?
- 3. What are the issues over how we should screen for early GDM to decide who should have an OGTT?
- 4. What are the challenges in nomenclature/classification for GDM in early pregnancy?
- 5. What are the challenges and facilitators for translating findings from RCTs of when to test for and treat GDM from early pregnancy into practice?

The final workshop collated and presented the delegate discussions, provided international perspectives, and discussed future directions related to the Summit Report and roadmap to a framework for the diagnosis of GDM in early pregnancy.

Data collection and analysis

Feedback to the questions was collected through a pre- and post-Summit survey, sent to all delegates (**Supplementary Appendix 1**). Issues were collated using an interactive graphic polling platform (SLIDO) and audio recorded round-table discussions (with the option for

written comments), that explored perspectives on early GDM before and after presentation of the TOBOGM findings. No identifiable data were collected and delegates were aware that a summary of survey data and discussions would be disseminated via a Summit Report. Survey data were collated and descriptively analysed. Word clouds were downloaded from SLIDO with word size reflecting the degree of recurrence of any given theme (e.g. larger words for more pertinent themes). Audio recordings and written comments were manually transcribed. Transcripts and word cloud data were analysed using an inductive 6-step thematic analysis approach (25), with the identified themes summarised in the present Report.

Findings

Table 1 summarises the results of the survey prior to and following the Summit. Most delegates both prior to and following the Summit agreed that testing for early GDM should occur, that this should involve a one-step 75g OGTT, and that hyperglycaemia less than DIP occurring early in pregnancy should be called "early GDM". Following the TOBOGM presentation, there was a small increase in the proportion of delegates preferring early risk factor-based screening to decide who should perform a subsequent early OGTT. The criteria preferred by most delegates for diagnosing early GDM shifted from the WHO (based on the 1.75 odds ratio for adverse pregnancy outcomes shown in the HAPO study or TOBOGM lower glycaemic band) before the presentations, to the Canadian Diabetes Association (CDA) (based on the 2.0 odds ratio for adverse pregnancy outcomes shown in the HAPO study or TOBOGM higher glycaemic band), after the presentation.

Workshop discussion (**Table 2** includes all themes) and SLIDO data (**Figures S1-5**) showed broad support for testing and treating GDM in early pregnancy given the elevated risk shown with early hyperglycaemia and effectiveness of early treatment. Overall, delegates felt there was insufficient evidence to currently define diagnostic criteria for GDM in early pregnancy.

Financial barriers, need for consensus and resources were the most frequent issues raised in relation to testing and treating GDM in early pregnancy, defining early GDM criteria, identifying who should undergo an early OGTT and translation into clinical care. Other key issues were acceptability, the applicability of the TOBOGM findings in different populations/cohorts, which risk factors to select, equity (including access to an OGTT), the level of evidence required to revise diagnostic criteria for GDM, the need for re-testing in later pregnancy, overdiagnosis and the potential risk of overtreatment. Participants also consistently expressed that for early testing to be effective there needs to be more patient and healthcare professional education about the importance of accessing healthcare in the earlier stages of pregnancy. Major issues around nomenclature were stigma, confusion and consistency.

Conclusions and Future Directions

Despite most delegates supporting testing for early GDM using a one-step 75g OGTT approach (CDA criteria preferred to IADPSG criteria), the TOBOGM Summit thematic analysis highlights the importance of considering resources, cost, consumer perspectives and equity in translating TOBOGM results into a clinical approach to early GDM. Health economic analyses may provide further clarity. Regarding future directions, there was broad consensus for the development of a writing group comprising relevant international stakeholders in DIP to define the approach and diagnostic criteria for early GDM, ensure equity and be able to evaluate the implementation process effectively across populations and geographic regions. Further work, including more consumer perspectives, health economic analyses and modelling of the impacts of different cut-offs and risk factor approaches, are required to inform the work of the writing group. The impact on the diagnostic approach at 24-28 weeks' gestation will also need to be considered. Additional randomised controlled trials are needed including those in different populations. As such trials will take several years to fund, implement and report, consensus is

needed on how and whether, in the interim, to progress from the TOBOGM findings to clinical service implementation.

Table 1. Pre- and Post-Summit Delegate Survey Data.

| Surve | y Questions | Pre-Summit (%) | Post-Summit (%) |
|-------|---------------------------------|---------------------|---------------------|
| 1. | Should at least some women | Yes (95%) | Yes (93%) |
| | be tested and treated for GDM | n=133 | n=119 |
| | from early pregnancy? | | |
| 2. | What diagnostic criteria should | IADPSG (60%) | IADPSG (27%) |
| | be used for GDM in early | Canadian (7.6%) | Canadian (46%) |
| | pregnancy? | Other (16.8%) | Other (14%) |
| | | n=119 | n=132 |
| 3. | What test should be used? | 75g 2-h OGTT (92%) | 75g 2-h OGTT (99%) |
| | | n=115 | n=97 |
| 4. | How many blood test steps | One (89%) | One (95%) |
| | should there be? | n=113 | n=108 |
| 5. | How should we screen for | Those with DIP risk | Those with DIP risk |
| | early GDM to decide who | factors (69%) | factors (79%) |
| | should have an OGTT? | n=126 | n=113 |
| 6. | What should we call | Early GDM (76%) | Early GDM (77%) |
| | hyperglycaemia less than DIP? | Other (15.8%) | Other (11%) |
| | | n=127 | n=117 |
| | | 1 | |

Legend: SLIDO Pre- and Post-TOBOGM Summit Survey listed in Supplementary Appendix 3 (S3). n: Number of delegate responses. IADPSG: International Association of the Diabetes and Pregnancy Study Groups diagnostic criteria for GDM (2-h 75g OGTT: fasting glucose ≥ 5.1 mmol/L; and/or 1-h glucose ≥ 10.0 mmol/L; and/or 2-h glucose ≥ 8.5 mmol/L); Canadian Diabetes Association diagnostic criteria for GDM (2-h 75g OGTT: fasting glucose ≥ 5.3 mmol/L; and/or 1-h glucose ≥10.6 mmol/L; and/or 2-h glucose ≥ 9.0 mmol/L). DIP: Diabetes in Pregnancy.

Table 2. Key TOBOGM Summit Themes.

ISSUE/BARRIER IDENTIFIED AT THE SUMMIT

Issues/barriers related to testing/treating GDM in early pregnancy

Screening every woman early in pregnancy not practical

Missing later onset GDM (not retesting after initial testing)

- Primary care may stop monitoring for GDM after initial early screening
- Women perceiving they may only need testing once

Burden of OGTT on uptake and preference for shorter test

Financial barriers

Funding for early testing (competing with other types of care)

Early testing not worth the cost of additional resources/staff

Cost of education for testing in early stages

Harm of exposure to hypoglycaemia without any effective/appropriate treatments

Late development of GDM

Inequitable access to early testing

- OGTT not easily accessible for some populations
- Women cannot attend a 2-h test due to work or other obligations

Untimely access to early testing

Women do not present early for pregnancy care

- lack of knowledge in women re accessing early care

Distribution of resources

Distribution of resources based on risk

Education

Identifying who is at higher risk of GDM

Waiting lists for women to access education from health care practitioners (HCP)

Mental health of the women

Women becoming distressed from testing early in pregnancy

Insufficient diabetes educator workforce to cope with greater numbers of women requiring education in early pregnancy

Treatments available

Evidence for treatment options lacking

Women following treatment options from early pregnancy

Overtreatment

Testing early may lead to false results and/or unnecessary treatment

Overtreatment may lead to increased risk of small-for-gestational age (SGA) offspring

Issues/barriers related to choosing criteria for GDM in early pregnancy

Not enough evidence for concrete diagnostic criterion in early pregnancy

Diversity of risk in different populations

Different populations, different risk factors, different diagnosis criteria required

Risk factor criteria not relevant for high-risk ethnic populations already defined as high risk by their ethnicity-All would need early testing and to progress to late testing unless GDM is diagnosed

Those diagnosed with early GDM may not develop/correspond with later GDM diagnosis

- Misdiagnosis
- Unnecessary resource use
- Unnecessary stress for the woman

Previously established criteria

Differences in diagnostic criteria

Lack of evidence on how various diagnostic criteria translate into GDM

Limited flexibility with current criteria (e.g. early application of criteria may lead to false positive diagnosis – not corresponding to repeat positive OGTT in later pregnancy)

Two separate criteria (early vs later stages)

Indicators of GDM risk differ within ethnic groups

Inclusion of ethnicity as a criterion complicated in diverse populations

- Criteria would need to be applied to several populations with different risk factors

Not sufficient evidence to determine if two separate criteria for early and late-stage pregnancy are appropriate

Risks of two separate criteria for early and late-stage pregnancy

Difficulties arranging screening after 24 weeks' gestation

Over medicalisation of pregnancy

Medical confusion for women by using different criteria at different stages of pregnancy (e.g. woman could be told they do not have GDM at the early stage but then go on to develop it at later testing)

Issues/barriers over how to screen for early GDM to determine who should have an OGTT

Burden of testing

Burdensome (on women and the health system) and invasive testing versus precise criteria

- Too low criteria would mean potentially testing for no reason

Colonial bias

Medical bias within guidelines where non-white groups are high risk and require an OGTT

OGTT not relevant in countries where the whole population are classed as high risk based on ethnicity (precise screening required)

Nomenclature/classification

Re-education on new classification

- GDM viewed as less important than other issues
- Use of alienating, harmful & complicated terminology
- Pre-existing low levels of knowledge surrounding GDM

Impact of the term used to describe early GDM

Evidence too premature to define criteria based on TOBOGM

- Lack of follow up studies looking at impacts of confounding factors such as differences in management

Supplementary Appendix 1. TOBOGM Summit Attendees.

| First Name | Last Name | Organisation | Country |
|--------------------|-------------|---|---------------|
| Gabriela | Abrahamson | Royal North Shore Hospital | Australia |
| Marwan | Ahmed | The University of Western Australia (Telethon Kids Institute) | Australia |
| Rehena | Ahmed | The Maitland Hospital | Australia |
| Jaqui | Aikens | University of Adelaide | Australia |
| Helen | Allen | Te Whatu Ora Health NZ: Waitemata | New Zealand |
| Jane | Alsweiler | University of Auckland | New Zealand |
| Cecilia | Astorga | Liverpool Health Service | Australia |
| Helena | Backman | Region Örebro County | Sweden |
| Robyn | Barnes | Bankstown-Lidcombe Hospital | Australia |
| Helen | Barrett | Royal Hospital for Women NSW | Australia |
| Alison | Barry | Royal Brisbane & Women's Hospital | Australia |
| Amanda | Bartlett | Australian Diabetes Educators Association | Australia |
| Ashley | Battarbee | University of Alabama at Birmingham | United States |
| Amanda | Beech | Royal Hospital for Women | Australia |
| Katrien | Benhalima | UZ Leuven | Belgium |
| Anna | Bubb | Blacktown Hospital | Australia |
| Leonie | Callaway | Queensland Health | Australia |
| Amy | Castelli | Monash Health | Australia |
| Thora | Chai | Westmead Hospital | Australia |
| Ka Ian | Chan | Northern Health | Australia |
| Julie | Chemmanam | Women's and Children's Hospital | Australia |
| Angela Xun- Nan | Chen | Flinders Medical Centre/Flinders University | Australia |
| N Wah | Cheung | Westmead Hospital | Australia |
| Min Jeng | Cho | Ulsan university hospital | South Korea |
| In Young | Choi | Kangbuk Samsung Hospital | South Korea |
| Maria Hornstrup | Christensen | Odense University Hospital, Denmark | Denmark |
| Tine | Clausen | Nordsjællands Hospital | Denmark |
| Jessica | Clift | SA Health | Australia |
| Suzette | Coat | The University of Adelaide | Australia |
| Stephen | Colagiuri | University of Sydney | Australia |
| Kylie | Connor | Fiona Stanley Hospital | Australia |
| Caroline | Cook | Southern NSW Local Health District | Australia |
| Shamil | Cooray | Monash Health | Australia |
| Stephanie | Cox | Auckland District Health Board | New Zealand |
| Coralie | Cross | York and Northern Local Area Health Network | Australia |
| Caroline | Crowther | University of Auckland | New Zealand |
| Cristina | Cuenca | Roche Diabetes Care Australia Pty Limited | Australia |
| Laura | Cunningham | Royal Prince Alfred Hospital | Australia |
| Peter | Damm | Rigshospitalet, University of Copenhagen | Denmark |
| Susan | de Jersey | Royal Brisbane and Women's Hospital | Australia |
| Jessica | Deitch | Western Health | Australia |
| Difei | Deng | Campbelltown Hospital | Australia |

| Daria | Di Filippo | University of New South Wales | Australia |
|---------------------|-------------------|--|---------------|
| Edwina | Dorney | NSW Ministry of Health | Australia |
| Anna | Duke | Blacktown Mt Druitt Hospital | Australia |
| Fidelma | Dunne | National University of Ireland, Galway Ireland (NUIG) | Ireland |
| Naomi | Eastwood-Wilshere | Canterbury Hospital | Australia |
| Jade | Eccles-Smith | The Royal Brisbane and Women's Hospital | Australia |
| Alexandra | Emerton | Royal Prince Alfred Hospital | Australia |
| Joanne | Enticott | Monash University | Australia |
| Denice | Feig | University of Toronto | Canada |
| Amelia | Fernandes | Royal Prince Alfred Hospital | Australia |
| Jeff | Flack | Bankstown-Lidcombe Hospital | Australia |
| Elizabeth | Fletcher | Macarthur Diabetes Service | Australia |
| Kathy | Fu | Wollongong Hospital | Australia |
| Ian | Fulcher | Liverpool Hospital | Australia |
| Alison | Gebuehr | John Hunter Hospital | Australia |
| Emily | Gianatti | Fiona Stanley Hospital | Australia |
| Reetu | Gogna | Mercy Hospital for Women | Australia |
| Rebecca | Goldstein | Monash University | Australia |
| Akhil | Gupta | Western Sydney University | Australia |
| Kamala | Guttikonda | Northern Beaches Hospital | Australia |
| Bill | Hague | Robinson Research Institute | Australia |
| Rabbia | Haider | Blacktown Hospital | Australia |
| Rosemary | Hall | Wellington Hospital | New Zealand |
| Mohammad Monirul | Haque | Western Sydney University | Australia |
| Anandwardhan | Hardikar | Western Sydney University | Australia |
| Anna-Jane | Harding | Royal Prince Alfred Hospital | Australia |
| Matthew | Hare | Royal Darwin Hospital | Australia |
| Lorie | Harper | University of Texas at Austin, Dell Medical School | United States |
| Jürgen | Harreiter | Medical University of Vienna | Austria |
| Wendy | Hawke | POWPH/RHW Sydney | Australia |
| Kate | Hawke | Royal Brisbane & Women's Hospital | Australia |
| Susan | Hendon | University Clinic & Research Centre Blacktown | Australia |
| William | Herman | University of Michigan | United States |
| Teri | Hernandez | University of Colorado | United States |
| Emily | Hibbert | University of Sydney/ Nepean Hospital | Australia |
| Rachel | Hicks | Western Sydney University | Australia |
| Roslyn | Hogan | Westmead Hospital | Australia |
| Christine | Houlihan | Mercy Hospital For Women | Australia |
| Ruth | Hughes | Canterbury District Health Board | New Zealand |
| Jincy | Immanuel | Western Sydney University | Australia |
| Emma | Jamieson | The University of Western Australia | Australia |
| Alicia | Jawerbaum | CEFYBO-CONICET. School of Medicine. University of Buenos Aires | Argentina |
| Shan | Jiang | Campbelltown Hospital | Australia |
| Mugdha | Joglekar | Western Sydney University | Australia |
| Lynda | Jones | NSW Health, Nepean Hospital | Australia |
| | 1 | <u> </u> | 1 |

| Andrew | Kirke | The Rural Clinical School of Western Australia | Australia |
|--------------------|--------------|---|---------------|
| Jeremy | Knott | St George Hospital | Australia |
| Anna Sofie | Koefoed | Aarhus University | Denmark |
| Pooja | Kunte | Western Sydney University | Australia |
| Janet | Lagstrom | Diabetes Nurse Practitioner | Australia |
| Heena | Lakhdhir | Counties DHB | New Zealand |
| Cathy | Latino | Fiona Stanley Hospital | Australia |
| Florence | Law | Private Practice | Australia |
| Margaret | Layton | Gosford Hospital | Australia |
| Soo-Jeong | Lee | University of Ulsan College of Medicine, Ulsan University Hospital | South Korea |
| I-Lynn | Lee | Western Health | Australia |
| Cathy | Lee | North Shore Private Hospital | Australia |
| William | Lowe Jr | Feinberg School of Medicine - Northwestern University | United States |
| Matthew | Luttrell | Wollongong Hospital | Australia |
| Michele | Mack | Sunshine Coast University Hospital | Australia |
| Diana | MacKay | Royal Darwin Hospital | Australia |
| Freya | MacMillan | Western Sydney University | Australia |
| Helle Terkildsen | Maindal | Aarhus University | Denmark |
| Julia | Marley | The University of Western Australia | Australia |
| David | McIntyre | University of Queensland | Australia |
| Mark | Mclean | Blacktown Hospital | Australia |
| Ashish | Mehta | Blacktown Hospital | Australia |
| Nina | Meloncelli | Metro North Health | Australia |
| Amanthi Shamani | Mendis | Complete Health Australia | Australia |
| Yitayeh | Mengistu | Monash University | Australia |
| Boyd | Metzger | Northwestern University | United States |
| Robert | Moses | Illawarra Shoalhaven Local Health District | Australia |
| Jodie | Nema | Western Sydney University | Australia |
| Christine | Newman | Galway University Hospital | Ireland |
| Suzie | Neylon | ADIPS and SOMANZ | Australia |
| Christopher | Nolan | 1) Canberra Hospital and Health Services; 2)Australian National University | Australia |
| Jeremy | Oats | The Royal Women's Hospital | Australia |
| Karaponi | Okesene-Gafa | CMDHB & Auckland University | New Zealand |
| Ulla Kampmann | Opstrup | Aarhus University Hospital | Denmark |
| Per | Ovesen | Department of Gynecology and Obstetrics, Aarhus University Hospital, Palle Juul-Jensens Boulevard 99, DK-8200 Aarhus N, Denmark | Denmark |
| Suja | Padmanabhan | Westmead Hospital | Australia |
| Michael | Peek | Australian National University | Australia |
| Agata | Piotrowicz | Launceston General Hospital | Australia |
| Sarah | Price | Royal Women's Hospital/ University of Melbourne | Australia |
| Rohit | Rajagopal | Campbelltown Hospital | Australia |
| Uma | Ram | Seethapathy Clinic & Hospital | India |
| Gladys | Ramos | University of California, San Diego | United States |

| Sidsel Linneberg | Rathcke | Aalborg University Hospital | Denmark |
|----------------------|-------------|--|---------------|
| Yoon Ji Jina | Rhou | Westmead Hospital, Sydney | Australia |
| Michelle | Robins | Northern Health | Australia |
| Glynis | Ross | Royal Prince Alfred Hospital | Australia |
| Victoria | Rudland | Westmead Hospital | Australia |
| David | Sacks | NIH | United States |
| Joanne | Said | Sunshine Hospital, Western Health | Australia |
| Justine | Salisbury | NSW Ministry of Health | Australia |
| Carlos | Salomon | The University of Queensland | Australia |
| Cathrine | Scheuer | Nordsjællands Hospital Hillerød | Denmark |
| Christina | Scifres | Indiana University | United States |
| Anand | Shankar | Shankar Diabetes Care Centre | India |
| Alexis | Shub | Mercy Hospital for Women | Australia |
| David | Simmons | Western Sydney University | Australia |
| Leah | Snape | CCLHD | Australia |
| Georgia | Soldatos | Monash Health | Australia |
| Anne | Sørensen | Aalborg University Hospital | Denmark |
| Erica | Spry | Kimberley Aborigional Medical Services and Rural Clinical School of Western Australia | Australia |
| Louise Laage | Stentebjerg | Steno Diabetes Center Odense, Odense Universitetshospital | Denmark |
| Arianne | Sweeting | Royal Prince Alfred Hospital | Australia |
| Lee | Tan | ASHFORD Hospital | Australia |
| Nadia | Tejani | Fairfield Hospital | Australia |
| Shailja | Tewari | The Canterbury Hospital | Australia |
| Helen | Tippler | Te Whatu Ora - Health New Zealand | New Zealand |
| Nerida | Titchiner | Waikato Hospital | New Zealand |
| Huy | Tran | NSW Health Pathology Hunter | Australia |
| Hannah | Wesley | Deakin University, Geelong, Australia | India |
| Nikki | Whelan | Wesley Medical Centre | Australia |
| Barbara | White | Werribee Mercy / Specialised Diabetes Services | Australia |
| Penny | Wolski | Royal Brisbane and Women's Hospital | Australia |
| Tang | Wong | Bankstown Hospital/Prince of Wales Hospital | Australia |
| Vincent | Wong | Liverpool Hospital | Australia |
| Anna | Wood | RDH | Australia |
| Jenny (Jian Hong) | Wright | Fairfield Hospital | Australia |
| Yoko | Yamakawa | Light Touch Technology Inc. | Japan |
| Jennifer | Yamamoto | University of Manitoba | Canada |
| Myra | Yeo | University Hospital Geelong | Australia |
| Gin-Rachelle | Ynson | Westmead Hospital | Australia |
| Stephanie | Young | West Moreton Hospital & Health Service, Queensland Health | Australia |
| Lili | Yuen | Western Sydney University | Australia |
| Julia | Zinga | Royal Women's Hospital | Australia |
| | | | |

Supplementary Appendix 2. TOBOGM Summit Program 17th November 2022

Welcome and Acknowledgement to Country

8:30AM - 9:00AM

Should we treat hyperglycaemia less than over diabetes before 24 weeks gestation?

9:00AM - 10:00AM

Chairs: Fidelma Dunne & Christina Scifres

Katrien Benhalima

Where are we now? Global overview on the current screening practice and diagnostic criteria for gestational diabetes in early pregnancy. abs# 1

Lorie Harper

What are the issues relating to screening, diagnosis and treatment of hyperglycaemia in early pregnancy? abs# 2

David Simmons

Study design/sample handing/statistics abs# 3

Morning Tea

10:00AM - 10:20AM

The TOBOGM design

10:20AM - 12:30PM

Chair: Christopher Nolan

10:20 AM David Simmons

Primary Outcomes of the TOBOGM Study abs# 4

10:50 AM Helena Backman

How should we collect samples for glucose estimations Comparison of samples? TOBOGM sub-study abs# 5

11:20 AM Rachel Hicks

Consumer perspectives on potential glycaemic thresholds abs# 6

11:50 AM Arianne Sweeting

Options for glycaemic thresholds and glycaemic measures including from the TOBOGM study abs# 7

Lunch

12:30PM - 1:30PM

Workshop: Should we screen for and diagnose gestational diabetes from early pregnancy and if so how?

1:00PM - 2:15PM

Chairs: Rosemary Hall & Boyd Metzger

Workshop: How should we screen for early GDM to decide who should have an OGTT? Nomenclature/classification for GDM in early pregnancy

2:15PM - 3:45PM

Chair: Stephen Colagiuri

Workshop: Perspectives and results

3:45PM - 4:45PM

Chairs: Jeremy Oats & Denice Feig

Boyd Metzger (HAPO), LMIC (Viswanathan Mohan), David McIntyre (FIGO), Stephen Colagiuri (IDF), Fidelma Dunne (IADPSG)

Workshop: Future directions/Where to now

4:45PM - 5:30PM

Chairs: Jeremy Oats & Denice Feig

Supplementary Appendix 3 – SLIDO Questions.

- 1. Should at least some women be tested and treated for gestational diabetes from early pregnancy?
 - i. Yes/No
- 2. If yes, what diagnostic OGTT criteria should we use for GDM in early pregnancy?
 - a. What test should be used?
 - i. 75g
 - ii. 100g
 - b. How many blood test steps?
 - i. One (only an OGTT)
 - ii. Two (eg preceding 50g glucose challenge test and then OGTT)
 - c. What criteria?
 - i. IADPSG (5.1;10.0;8.5)
 - ii. Canadian (5.3;10.6;9.0)
 - iii. Carpenter Coustan if 100g; Modified carpenter and coustan for 75gOGTT=5.3;10.0;8.5)
 - iv. New Zealand (5.5/9.0)
 - v. UK (5.6/7.8)
 - vi. India (--/7.8)
 - vii. FBG 6.1
 - viii. Other
- 3. How should we screen for early GDM to decide who should have an OGTT?
 - i. Universal-everyone should have a blood test
 - ii. Those with Diabetes in pregnancy Risk factors
 - iii. Other

- 4. Nomenclature/classification for GDM in early pregnancy -what should we call hyperglycaemia less than overt diabetes in early pregnancy?
 - i. Early GDM
 - ii. Prevalent GDM
 - iii. Booking GDM
 - iv. Other
- 5. How should we adjust glucose concentrations for the use of citrate
 - i. Add difference from citrate using number from collated studies
 - ii. Can't adjust
 - iii. Other



What are the issues with testing and treating gestational diabetes from early pregnancy?



Workload agreement Women won't have a routin outcome Increased resources Access Lack of resources Unifying diagnostic crite Complicated results Patient anxiety Diagnostic criteria Criteria to use workforce Logistics Overdiagnosis Retesting who's high risk accessibility universal or not? Stigma SGA Not evident Over treatment Criteria R Over medicalisation the test used **Implementation** Anxiety Non-engaged women Cost effectiveness Workload Care burden for patients

culturally appropriate

Wordcloud poll

Varied opinion interpret

Universal applicability



What are the issues with choosing criteria?

lack of staff



Whether there is benefit Womens' experience focus Overmedicalisation consistency across labs avoiding harm universal use Prevalence Wellbeing Reliability ResourcesUniformity Complexity Ethnicity able to test workload Evidence COS1 age Consistency Timing Who to screen Criteria Consensi differing criteria at GA Overdiagnosis What is right Accuracy Population differences

Whether need all 3 values

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What are the issues associated with who should have an early OGTT?



Acceptability Missing patients Universal

Adherence

Risk factors Wording Uptake

criteria TOBOGM or ada

Overdiagnosis Unpleasant

Stigma

normalrepeat Ethnicity Cost Access
Who organises

Workload burden for people

Defining high risk

Resources

CostsValidity

What test? What targets

Awareness

What % of positives u wan Varies with population

Definition of risk factor

Wordcloud poll



What are the issues with how we name GDM occuring in early pregnancy?

How early is early patients understanding

Keep it simple! clinician understanding

pre-existing prediabetes Why complicate it Simplicity not related to pregnancy Confusing Uniformity

clear Consensus

Early GDM Stigma Consistency

Why differentiate Stigmatising Confusion Data collection

not well defined What is early

Cultural understanding Need universal term

labeling too many what gestation diagnosed



What are the top 3 issues for translation of findings into practice?





Figures S1-5. Key Issues relating to testing early in pregnancy for GDM identified via SLIDO word clouds at the TOBOGM Summit.

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