

Supporting Information

Supplementary material

This appendix was part of the submitted manuscript and has been peer reviewed.

It is posted as supplied by the authors.

Appendix to: Sweeting A, Hare MJL, de Jersey SL, et al. Australasian Diabetes in Pregnancy Society (ADIPS) 2025 consensus recommendations for the screening, diagnosis and classification of gestational diabetes. *Med J Aust* 2025; doi: 10.5694/mja2.52696.

	te Consensus Reporting Document M. Sporting Document M. Chook light Itom (holin toys)				
Item No.	Section	Checklist Item (help text)	Page No.		
T1	Title	Identify the article as reporting a consensus exercise and state the consensus methods	Title page.		
		used in the title.	(methodology not stated as not a		
		For example, Delphi or nominal group technique.	report on results of a single		
			consensus study. Multiple approaches employed to develop		
			this statement.)		
11	Introduction	Explain why a consensus exercise was chosen over other approaches.	Page 4.		
12		State the aim of the consensus exercise, including its intended audience and geographical	Page 3 (scope), Page 4 (aim).		
		scope (national, regional, global).			
13		If the consensus exercise is an update of an existing document, state why an update is	Page 3.		
114	8.6 (1 1	needed, and provide the citation for the original document.	N/A (1): :		
M1	Methods Registration	If the study or study protocol was prospectively registered, state the registration platform and provide a link. If the exercise was not registered, this should be stated.	N/A (this is not a report on study		
	Registration	Recommended to include the date of registration.	findings)		
M2	Selection of	Describe the role(s) and areas of expertise or experience of those directing the consensus	Page 4.		
	SC and/or	exercise.			
	panellists	For example, whether the project was led by a chair, co-chairs or a steering committee, and, if so,			
		how they were chosen. List their names if appropriate, and whether there were any subgroups for individual steps in the process.			
M3	1	Explain the criteria for panellist inclusion and the rationale for panellist numbers. State who	Page 4.		
		was responsible for panellist selection.			
M4		Describe the recruitment process (how panellists were invited to participate).	Page 4.		
		Include communication/advertisement method(s) and locations, numbers of invitations sent, and whether there was centralised oversight of invitations or if panellists were asked/allowed to suggest			
		other members of the panel.			
M5		Describe the role of any members of the public, patients or carers in the different steps of	Page 4.		
		the study.			
M6	Preparatory	Describe how information was obtained prior to generating items or other materials used	Page 4.		
	research	during the consensus exercise. This might include a literature review, interviews, surveys, or another process.			
M7	-	Describe any systematic literature search in detail, including the search strategy and dates	As noted on Page 4, recent		
,		of search or the citation if published already.	systematic literature searches from		
		Provide the details suggested by the reporting guideline PRISMA and the related PRISMA-Search	the Scottish Intercollegiate		
		extension.	Guidelines Network and the draft		
			New Zealand national guideline		
			were utilised.		

M8		Describe how any existing scientific evidence was summarised and if this evidence was provided to the panellists.	Page 4.
M9	Assessing consensus Describe the methods used and steps taken to gather panellist input and reach consensus (for example, Delphi, RAND-UCLA, nominal group technique). If modifications were made to the method in its original form, provide a detailed explanation of how the method was adjusted and why this was necessary for the purpose of your consensus-based study.		Page 4 and see specific reports from separate meetings (Refs 20-22)
M10		Describe how each question or statement was presented and the response options. State whether panellists were able to or required to explain their responses, and whether they could propose new items. Where possible, present the questionnaire or list of statements as supplementary material.	See reports from specific meetings (Refs 20-22)
M11		State the objective of each consensus step. A step could be a consensus meeting, a discussion or interview session, or a Delphi round.	See reports from specific meetings (Refs 20-22)
M12		State the definition of consensus (for example, number, percentage, or categorical rating, such as 'agree' or 'strongly agree') and explain the rationale for that definition.	See reports from specific meetings (Refs 20-22)
M13		State whether items that met the prespecified definition of consensus were included in any subsequent voting rounds.	N/A
M14		For each step, describe how responses were collected, and whether responses were collected in a group setting or individually.	Page 4 and referenced reports from specific meetings.
M15		Describe how responses were processed and/or synthesised. Include qualitative analyses of free-text responses (for example, thematic, content or cluster analysis) and/or quantitative analytical methods, if used.	Page 4 and referenced reports from specific meetings.
M16		Describe any piloting of the study materials and/or survey instruments. Include how many individuals piloted the study materials, the rationale for the selection of those individuals, any changes made as a result and whether their responses were used in the calculation of the final consensus. If no pilot was conducted, this should be stated.	N/A
M17		If applicable, describe how feedback was provided to panellists at the end of each consensus step or meeting. State whether feedback was quantitative (for example, approval rates per topic/item) and/or qualitative (for example, comments, or lists of approved items), and whether it was anonymised.	Page 4 and referenced reports from specific meetings.
M18		State whether anonymity was planned in the study design. Explain where and to whom it was applied and what methods were used to guarantee anonymity.	See referenced reports from specific meetings. Anonymity was not used in focus groups but was in electronic surveys.
M19		State if the steering committee was involved in the decisions made by the consensus panel. For example, whether the steering committee or those managing consensus also had voting rights.	Recommendations development overseen by ADIPS Board.
M20	Participation	Describe any incentives used to encourage responses or participation in the consensus process. For example, were invitations to participate reiterated, or were participants reimbursed for their time.	ADIPS provided no incentives.
M21		Describe any adaptations to make the surveys/meetings more accessible. For example, the languages in which the surveys/meetings were conducted and whether translations or plain language summaries were available.	No adaptations.

R1	Results	State when the consensus exercise was conducted. List the date of initiation and the time taken to complete each consensus step, analysis, and any extensions or delays in the analysis.	Page 4.
R2		Explain any deviations from the study protocol, and why these were necessary. For example, addition of panel members during the exercise, number of consensus steps, stopping criteria; report the step(s) in which this occurred.	N/A
R3		For each step, report quantitative (number of panellists, response rate) and qualitative (relevant socio-demographics) data to describe the participating panellists.	Page 4 and see reports from specific meetings (Refs 20-22)
R4		Report the final outcome of the consensus process as qualitative (for example, aggregated themes from comments) and/or quantitative (for example, summary statistics, score means, medians and/or ranges) data.	See reports from specific meetings (Refs 20-22). Mixed methods employed.
R5		List any items or topics that were modified or removed during the consensus process. Include why and when in the process they were modified or removed.	N/A
<u>D1</u>	Discussion	Discuss the methodological strengths and limitations of the consensus exercise. Include factors that may have impacted the decisions (for example, response rates, representativeness of the panel, potential for feedback during consensus to bias responses, potential impact of any non-anonymised interactions).	See reports from specific meetings (Refs 20-22).
D2		Discuss whether the recommendations are consistent with any pre-existing literature and, if not, propose reasons why this process may have arrived at alternative conclusions.	N/A – pre-existing literature and consensus exercises factored into final recommendations.
01	Other	List any endorsing organisations involved and their role.	Page 12.
O2	information	State any potential conflicts of interests, including among those directing the consensus study and panellists. Describe how conflicts of interest were managed.	COI statement.
O3	Di OM 104/4	State any funding received and the role of the funder. Specify, for example, any funder involvement in the study concept/design, participation in the steering committee, conducting the consensus process, funding of any medical writing support. This could be disclosed in the methods or in the relevant transparency section of the manuscript. Where a funder did not play a role in the process or influence the decisions reached, this should be specified.	No funding received.

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Table 2. Guidelines International Network checklist for modifying a disease definition¹

Checklist item	2025 ADIPS Recommendations (compared to ADIPS 2014 Consensus Guidelines) ²
Definition: What are the differences between the previous and the new definition?	At all gestations, GDM is still diagnosed via a POGTT but the plasma glucose diagnostic thresholds have changed as follows: • Fasting: Previously ≥5.1 mmol/L, now ≥5.3 mmol/L • 1-hour: Previously ≥10.0 mmol/L, now ≥10.6 mmol/L • 2-hour: Previously ≥8.5 mmol/L, now ≥9.0 mmol/L The plasma glucose thresholds for "diabetes in pregnancy", now referred to as "overt diabetes in pregnancy", are unchanged: • Fasting: ≥7.0 mmol/L • 2-hour: ≥11.1 mmol/L HbA1c ≥6.5% (≥48 mmol/mol) was previously described as very likely representing undiagnosed type 2 diabetes. This remains true, but this HbA1c criterion is now included in the classification of overt diabetes in pregnancy, pending further investigation for diabetes post-partum.
2. Number of people affected: How will the new disease definition change the incidence and prevalence of the disease?	The new definition will reduce the incidence of GDM at all gestations. It is unclear how new recommendations clarifying advice for screening in early pregnancy will impact capture of overt DIP and GDM cases in early pregnancy. Previous ADIPS guidance stated that "women with risk factors for hyperglycaemia in pregnancy should be tested early in pregnancy". Due to a lack of evidence, the modality of testing ("ideally POGTT or HbA1c") and risk stratification was unclear. At present, many services in Australia routinely recommend POGTT in early pregnancy to women with any risk factor(s), while others do not. The new recommendations provide clear recommendations to check early pregnancy HbA1c in all women with a risk factor for hyperglycaemia, but largely limit POGTT in early pregnancy to women with prior GDM or intermediate elevation of HbA1c.
3. Trigger: What is the trigger for considering the modification of the disease definition?	The ADIPS guidance on screening and diagnosis of GDM was due for review. Debate has continued over the past decade regarding the previously recommended GDM diagnostic criteria, which have not been universally adopted and were based on observational evidence. Consumer and clinical stakeholders have been calling for consensus and consistent recommendations. Two new relevant randomised controlled trials provided new evidence to consider, including the TOBOGM trial in early pregnancy and the GEMS trial of different GDM criteria at 24-32 weeks' gestation. ^{3,4}

4. Prognostic ability: How well does the new definition of disease predict clinically important outcomes compared with the previous definition?	The new GDM definition is associated with greater risk of adverse pregnancy outcomes than the previous definition. The new thresholds are based on an odds ratio of 2.0 for a combined clinical endpoint in the observational HAPO study, compared to the old thresholds which were based on an odds ratio of 1.75.
5. Disease definition precision and accuracy: What is the repeatability, reproducibility, and accuracy (when estimations are possible) of the new disease definition?	The new GDM definition has similar precision and accuracy to the previous definition as it still relies on a single POGTT. There are limitations with regard to both the reproducibility and accuracy of plasma glucose measurements in clinical practice due to physiological, preanalytical and analytical factors. Reproducibility of the OGTT has been estimated at 65-78%. Limitations of the OGTT are likely to be less impactful with the new criteria as the diagnostic thresholds are further from the population mean, so fewer women will have borderline glucose levels.
6. Benefit: What is the incremental benefit for patients classified by the new definition vs the previous definition?	Patients classified by the new definition can have greater confidence that monitoring and management of their GDM will be of personal benefit with lesser risk of unintentional harms.
7. Harm: What is the incremental harm for patients classified by the new definition vs the previous definition?	There is unlikely to be any incremental harm for patients classified by the new definition compared to the previous definition. With the raising of diagnostic thresholds, there is rather the potential risk of harm among women who will no longer be diagnosed as having GDM. These women who previously would have been diagnosed as having GDM are at low risk of adverse outcomes but may have some relative benefit from monitoring and treatment. Nevertheless, there may also have been some risks of harm associated with monitoring and treatment in this group.

References

- 1. Doust J, Vandvik PO, Qaseem A et al. Guidance for modifying the definition of diseases: A checklist. JAMA Intern Med, 2017; 177(7): 1020-1025.
- 2. Nankervis A, McIntyre HD, Moses R et al. for the Australasian Diabetes in Pregnancy Society. ADIPS Consensus Guidelines for the Testing and Diagnosis of Hyperglycaemia in Pregnancy in Australia and New Zealand (modified November 2014). Available at: www.adips.org/downloads/2014ADIPSGDMGuidelinesV18.11.2014_000.pdf [Accessed 20th January 2025]
- 3. Simmons D, Immanuel J, Hague WM, et al, for the TOBOGM Research Group. Treatment of Gestational Diabetes Mellitus Diagnosed Early in Pregnancy. N Engl J Med. 2023;388:2132-44.
- 4. Crowther CA, Samuel D, Leslet ME, et al, for the GEMS Trial Group. Lower versus Higher Glycemic Criteria for Diagnosis of Gestational Diabetes. N Engl J Med. 2022;387:587-98.
- 5. HAPO Collaborative Research Group. Hyperglycemia and adverse pregnancy outcomes. New Eng J Med. 2008; 358:1991-2002.
- 6. Bogdanet D, O'Shea P, Lyons C, Shafat A, Dunne F. The oral glucose tolerance test is it time for a change? A literature review with an emphasis on pregnancy. J Clin Med 2020; 9(11):3451.