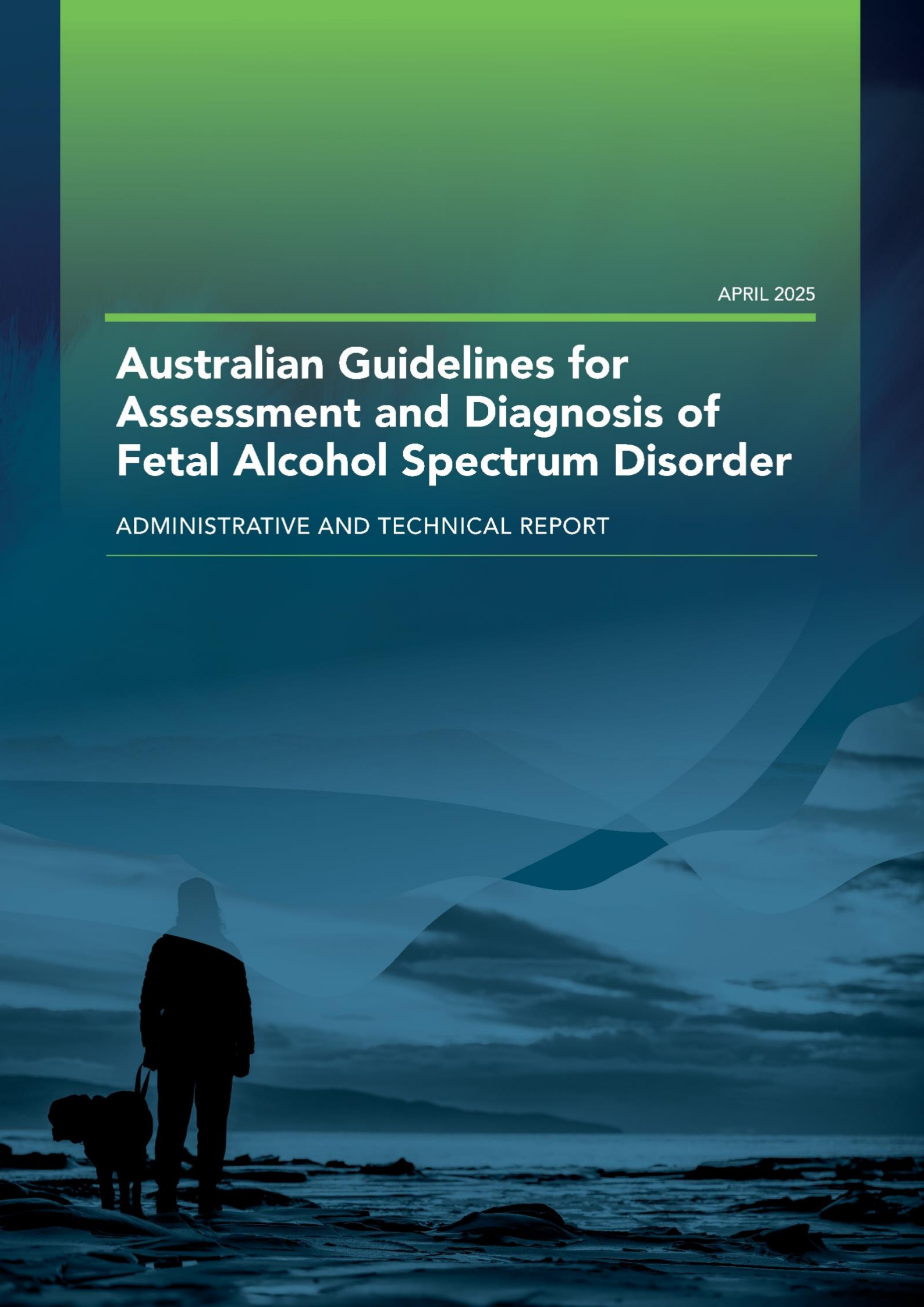
APRIL 2025

Australian Guidelines for Assessment and Diagnosis of Fetal Alcohol Spectrum Disorder

ADMINISTRATIVE AND TECHNICAL REPORT



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Abbreviations

AGREE-II	Appraisal of Guidelines for Research & Evaluation Instrument
ARBD	Alcohol-related birth defects
ARND	Alcohol-related neurodevelopmental disorder
ASD	Autism spectrum disorder
AUDIT	Alcohol Use Disorders Identification Test
CDC	Centers for Disease Control and Prevention
CNS	Central nervous system
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, 5th Edition
FAS	Fetal alcohol syndrome
FASD	Fetal alcohol spectrum disorder
GRADE-CERQual	Grading of Recommendations Assessment, Development and Evaluation - Confidence in the Evidence from Reviews of Qualitative research
IOM	Institute of Medicine
NDIS	National Disability Insurance Scheme
NHMRC	National Health and Medical Research Council
OFC	Orbitofrontal cortex
PAE	Prenatal alcohol exposure
pFAS	Partial fetal alcohol syndrome
PFL	Palpebral fissure length
TBI	Traumatic brain injury
WHO	World Health Organisation

1. Background

1.1 Rationale for the review

Recognising the critical need for enhanced assessment and diagnosis of fetal alcohol spectrum disorder (FASD), the Australian Government funded the development and distribution of The Australian Guide to the Diagnosis of FASD in 2016 (Bower & Elliott, 2016). The Guide was designed to provide clinicians a standardised diagnostic framework, along with tools to support or refer individuals and their families. The Guide was adapted from the Canadian National Guidelines (Cook et al., 2016), and incorporated updates based on a literature review, consultation of stakeholders, and elements from the University of Washington's 4-Digit Diagnostic Code (Astley, 2004). Since its release, there have been improvements in the uptake and consistency of diagnostic practices across Australia (Reid et al., 2020). A priority aim identified in the 2018–2028 National Action Plan for FASD in Australia (Australian Government, 2018) was to review and update the Guide, to ensure it remains aligned with international best practices and current knowledge in the field.

1.2 Objectives of the review

Aim: Revise, update and disseminate Australian clinical practice guidelines for the assessment and diagnosis of FASD.

Objective: Integrate the best available evidence, living experience voices, cultural knowledge, and clinical expertise to develop Australian clinical practice guidelines for the assessment and diagnosis of FASD.

1.3 Guidelines procedures, standards, and reporting

The Australian Government National Health and Medical Council (NHMRC) has specific procedures and requirements for meeting the standard for clinical practice guidelines (NHMRC, 2020). These requirements largely align with the AGREE-II (Brouwers et al., 2010), an internationally recognised instrument for assessing the quality and reporting of clinical practice guidelines. For a detailed overview of the AGREE-II and NHMRC standards applied to this project, please refer to Appendix A.

2. Guidelines Governance Structure

Genuine inclusion and collaboration with stakeholders has been pivotal to the development of these guidelines. Significant time was dedicated to the process of stakeholder involvement, incorporating a wide range of perspectives in a meaningful way to strengthen the guidelines. Research supports that stakeholder engagement leads to increased uptake and implementation of clinical practice guidelines (NHMRC, 2018). Stakeholders include anyone who may be impacted by the guidelines. To maximise collaboration and inclusion of a diverse range of stakeholders, three key groups were established: Project Steering Committee, Advisory Groups, and Guidelines Development Group (Figure 1).

Figure 1. Key stakeholder groups involved in guidelines review and development process

2.1 Steering Committee

The Project Steering Committee comprised representatives from each organisation that was part of the consortium funded by the Department of Health and Aged Care for the review of the guidelines. The Steering Committee's role was to provide strategic direction, support the success of the project, and ensure project completion aligned with the funding objectives. For an overview of the primary and proxy representatives of the Project Steering Committee, see Table 1.

Table 1. Membership of the Guidelines Steering Committee

Organisation	Primary representative	Proxy representative
The University of Queensland	Dr Natasha Reid, Senior Research Fellow, Clinical Psychologist (Chair)	Professor Karen Moritz, Associate Dean Research
University of Sydney	Professor Elizabeth Elliott, Paediatrician	Dr Melissa Cheung, Research Fellow
Telethon Kids Institute	Dr Amy Finlay-Jones, Senior Research Fellow, Psychologist	Dr Rochelle Watkins, Senior Research Fellow
La Trobe University	Dr Kerryn Bagley, Senior Lecturer, Social Worker	Dr Jo Spong, Senior Lecturer
Griffith University	Professor Dianne Shanley, Clinical Psychologist	Dr Erinn Hawkins, Senior Lecturer, Clinical Psychologist
Gold Coast Hospital and Health Service – Child Development Service	Dr Haydn Till, Clinical Neuropsychologist	Dr Francoise Butel, Paediatrician

National Organisation for FASD (NOFASD)	Ms Sophie Harrington, Consumer	Ms Nicole Hewlett, First Nations Cultural Representative
Patches Paediatrics	Ms Rowena Friend, Forensic Psychologist	Ms Serena Cribb, Clinical Neuropsychologist
Monash – VicFAS	Dr Alison Crichton, Clinical Neuropsychologist	Dr Katrina Harris, Paeditrician
West Moreton Health	Mr Andy Webster, Clinical Nurse Consultant	Mr Alan White, Clinical Nurse Consultant
FASD CARE	Dr Raewyn Mutch, Paediatrician	Dr Robyn Williams, Senior Research Fellow

2.2 Advisory Groups

Four types of Advisory Groups were established: (1) clinicians; (2) researchers; (3) cultural representatives; and (4) individuals with living experience. The purpose of these groups was to enable broad consultation with key stakeholders regarding the revision, updating and dissemination of the guidelines. Meetings were held either as separate groups or combined sessions, depending on the topic for discussion. Separate group meetings provided a safe space for members to discuss their specific values, needs, and preferences, ensuring comprehensive input and feedback from all stakeholder types. In combined group meetings, sessions were recorded, and slides and recordings were disseminated afterward. All members had opportunities to provide written input or verbal feedback at any stage throughout the process.

2.2.1 Selection process

Terms of reference and an expression of interest (EOI) form were developed in consultation with the Steering Committee (Appendix B). Steering Committee members were asked to distribute copies of these documents to all key stakeholders in their networks who possessed relevant expertise. Additionally, the terms of reference and EOI form were also emailed to relevant professional associations, inviting them to nominate members or circulate the EOI form to their members for self-nomination.

2.2.2 Membership

Table 2 provides an overview of the members of all Advisory Groups.

Table 2. Members of the Guidelines Advisory Groups

Name	Qualifications/position	Organisation Representing	Institutional Affiliation	Location
Dr Honey Heussler	Associate Professor & Developmental Paediatrician	-	Queensland Health; The University of Queensland	QLD
Dr Tamara Tulich	Associate Professor in the Law School	-	The University of Western Australia	WA
Dr Carmela Pestell	Professor & Clinical Neuropsychologist	-	The University of Western Australia	WA

Dr Delyse Hutchinson	Associate Professor & Clinical Psychologist	-	Deakin University	VIC
Ms Angelene Bruce	Parent	-	-	VIC
Ms Amanda Mulligan	Carer, Board Member for RFFADA	-	RFFADA	QLD
Ms Cheryl Dedman	Carer; Chair of Board for NOFASD Australia	NOFASD Australia	NOFASD	VIC
Ms Sophie Harrington	Parent; COO NOFASD Australia	NOFASD	NOFASD	WA
Mr Max Naglazas	Speech Pathologist	-	WA Health	WA
Ms April Wilson	Carer	-	-	
Dr Ian McCracken	Child & Adolescent Psychiatrist	-	Allambi Care	NSW
Ms Lorelle Holland	Lecturer	-	The University of Queensland	QLD
Dr Gareth Baynam	Clinical Geneticist	-	WA Health	WA
Dr Jamie Berry	Clinical Neuropsychologist	-	Advanced Neuropsychological Treatment Services	NSW
Dr Alina Iser	Paediatrician	-	Alice Springs Hospital & Central Australian Aboriginal Congress	NT
Dr Karen Clunies-Ross	Clinical Neuropsychologist	-	WA Health	WA
Ms Storm Anderson	Speech Pathologist	-	Child Development Service, QLD Health	QLD
Ms Sarah Goldsbury	Clinical Neuropsychologist	-	Sarah Goldsbury Psychology Services	NZ
Ms Brianna Hollis	Clinical Neuropsychologist	-	Child Development Service, Gold Coast Hospital and Health Service	QLD
Dr Dianne Shanley	Professor & Clinical Psychologist	-	Griffith University	QLD
Dr Carmel Lum	Clinical Neuropsychologist & Clinical Psychologist	-		NT
Dr Natalie Kippin	Speech Pathologist, Researcher		Curtin University	WA
Ms Jessica Doak	Clinical Psychologist	-	Grassroots Psychology	QLD

Dr Robyn Williams	Senior Research Fellow	-	Curtin University	WA
Dr Vanessa Spiller	Clinical Psychologist	-	Jump Start Psychology	QLD
Dr Carolyn Ng	Paediatrician	-	QLD Health	QLD
Ms Jess Styles	Director, Programs	NACCHO	NACCHO	ACT
Kate Cooper	Education consultant	-	VicFAS	VIC
Ms Jessica Birch	FASD Advocate	-		
Ms June Riemer	Deputy CEO	First Peoples Disability Network	First Peoples Disability Network	NSW
Dr Jane Halliday	Professor & Principal Research Fellow	-	Murdoch Children's Research Institute & University of Melbourne	VIC
Dr Rochelle Watkins	Senior Research Fellow	-	Telethon Kids Institute	WA
Dr Lorian Hayes	Elder & FASD Educator	-	National Indigenous Corporation for FAS Education Network	QLD
Ms Rowena Friend	Forensic Psychologist, Senior Lecturer	-	Private Practice, Charles Darwin University	NT
Dr Hester Wilson	General Practitioner & Addiction Medicine Specialist	RACGP	RACGP	NSW
Ms Linda McSherry	Kimberley Supports Senior Manager	-	Kimberley Aboriginal Medical Services	WA
Dr Erinn Hawkins	Lecturer & Clinical Psychologist	-	Griffith University & private practice	QLD
Mr Gilberto Spencer	FASD Advocate	-	Life Coach School	NSW
Ms Susan Burns	Manager NDS	National Disability Services	National Disability Services	NT
Dr Ali Crichton	Clinical Neuropsychologist	-	VicFAS	VIC
Dr Kristy Nicola	Physiotherapist	Australian Physiotherapy Association	Private Practice and	QLD
Ms Hannah Blaine	Clinical Neuropsychologist	-	Central Australian Aboriginal Congress	NT

Dr Heidi Webster	Paediatrician	-	Coastal Developmental Paediatrics	QLD
Dr Kelly Jeng	Clinical Neuropsychologist	-	NSW CICADA	NSW
Ms Ellaina Anderson	Clinical Neuropsychologist	-	QLD Health	QLD
Dr Fiona Kay	Paediatrician	-	NT Health & PATCHES Paediatrics	NT
Dr Haydn Till	Advanced Clinical Neuropsychologist	-	Child Development Service - Gold Coast Hospital and Health Service	QLD
Mr Andy Webster	Registered Nurse	-	QLD Health	QLD
Ms Kristina Barisic	Senior Clinical Neuropsychologist	-	Child Development Service - Gold Coast Hospital and Health Service	QLD
Dr Michael Doyle	Senior Research Fellow	-	The University of Sydney	NSW
Ms Maree Maloney	Occupational Therapist	-	The University of Queensland	QLD
Dr Marcel Zimmet	Paediatrician	-	Royal Far West	NSW
Ms Sarah Hill	Occupational Therapist	-	SA Health	SA
Ms Emma Johnston	Speech Pathologist	-	NSW Health	NSW
Ms Carol Jewell	Occupational Therapist	Occupational Therapy Australia	Occupational Therapy Australia	VIC
Ms Amelia Paterson	Paediatric Clinical Neuropsychologist	-	Central Australian Aboriginal Congress	NT
Dr Sharynne Hamilton	Senior Research Fellow	-	Telethon Kids Institute	WA
Dr Karen Liddle	Paediatrician		QLD Health	QLD
Dr Manjula Kannangara	Paediatrician	-	QLD Health and Murri School	QLD
Dr Kerryn Bagley	Social Worker	Australian Association of Social Workers	La Trobe University	VIC
Ms Brooke Shakspeare	Social Worker	-	QLD Health	QLD
Dr Seth Sivaydganathan	Paediatrician	-	QLD Health	QLD

Ms Lynda McDowall	Registered Nurse	-	SA Health	SA
Dr Amanda Wilkins	Paediatrician	-	WA Health	WA
Dr Kate Highfields	Researcher and early childhood specialist	-	Early Childhood Australia	NSW
Dr Gavin Cleland	Paediatrician	RACP	QLD Health	QLD
Dr Suparna Chakrabarty	Paediatrician	-	QLD Health	QLD
Dr Deepa Jeyaseelan	Paediatrician & Medical Unit Head	-	Child Development Unit, SA Health & Flinders Medical Centre	SA
Dr Seema Padencheri	Psychiatrist	-	Hornsby Child and Youth Mental Health	NSW
Dr James Stewart	Clinical Neuropsychologist	-	WA Health	WA
Mr Tim Smith	Psychologist	-	Department of Communities	WA
Mr Alan White	Registered Nurse	-	QLD Health	QLD
Dr Sharon Dawe	Professor & Psychologist	-	Griffith University	QLD
Dr Sara McLean	Psychologist	-	Emerging Minds	SA
Ms Jade Houghton	Speech Pathologist	-	The Murri School	QLD
Ms Aimee MacGougan	Senior Clinical Neuropsychologist	-	Child Development Service - Gold Coast Hospital and Health Service	QLD
Dr Brenton Maxwell	Senior Clinical Neuropsychologist	-	Mindlink Psychology	WA
Dr Harry Blagg	Professor & Senior Honorary Research Fellow	-	The University of Western Australia	WA
Ms Alana Muir	Senior Occupational Therapist	-	Child Development Service - Gold Coast Hospital and Health Service	QLD
Dr Carol Bower	Senior Principal Research Fellow	-	Telethon Kids Institute	WA
Dr Heather Douglas	Professor of Criminal Law	-	University of Melbourne	VIC
Ms Susan Evans	Social Worker	-	NSW Health	NSW

Ms Maria Koupos	Speech Pathologist	-	VicFAS	VIC
Dr Tracy Tsang	Senior Research Fellow	-	The University of Sydney	NSW
Dr Karen Moritz	Professor, Associate Dean of Research. Faculty of Medicine	-	The University of Queensland	QLD
Dr Hayley Passmore	Lecturer	-	The University of Western Australia	WA
Ms Nirosha Boaden	Senior Specialist in Mental Health Social Worker	-	NT Health	NT
Ms Erin More	Senior Speech Pathologist	-	Child Development Service - Gold Coast Hospital and Health Service	QLD
Ms Chantele Edlington	Senior Speech Pathologist & Senior Advisor for Justice and Mental Health	Speech Pathology Australia	Monash Health	VIC
Ms Mary Woodward	Speech Pathologist; Senior Advisor Justice	Speech Pathology Australia	Speech Pathology Australia	NSW
Ms Shanon Whiting	Carer	-	-	QLD
Ms Tracey Biehn	Social Worker	-	QLD Health	QLD
Ms Jane Stewart	Special Projects	-	Legal Aid	WA
Dr Barbara Lucas	Specialist Paediatric Physiotherapist; Post-doc research fellow	-	NSW Health & University of Sydney	NSW
Ms Sharon Wallace	Carer	-	-	QLD
Ms Stella Martin	Speech Pathologist	-	Youth Justice	QLD
Ms Diane Mayers	Team Leader	-	Youth Justice	NT
Dr Tracey Harbour	Parent of child with FASD	-	FASD Advisory Committee and Telethon Kids Institute	QLD
Ms Geraldine Kirkcaldie	Parent of child with FASD	-	Education Queensland	QLD
Ms Hannah Mawbey	Principal Practice Officer	-	Youth Justice	QLD

Ms Heather Jones	Senior Manager FASD Projects	FASD Hub	Telethon Kids Institute	WA

2.3 Guidelines Development Group

The Guidelines Development Group was established to review the evidence summarised by the research team, collaborate to develop the actionable statements, and contribute to the drafting, review, and finalisation of all guidelines documents.

2.3.1 Membership Selection Process

Terms of reference and an EOI form were developed in consultation with the Steering Committee (Appendix C). Steering Committee and Advisory Group members were invited to self-nominate and were asked to distribute the terms of reference and EOI form to all key stakeholders in their networks who possessed relevant expertise.

2.3.2 Chair and Methodological Expert Selection Process

The Steering Committee took recommendations from a range of methodological and content experts in the field regarding potential Chairs. Options were discussed during Steering Committee meetings, leading to the recruitment of Professor Phillipa Middleton as an independent Chair of the Guidelines Development Group. Additionally, the Steering Committee consulted various sources, including the NHMRC Guidelines team, to identify potential methodological experts. After discussion in Steering Committee meetings, Professor Zachary Munn was selected as the preferred candidate to serve as the methodologist for these guidelines.

2.3.3 Membership

Table 3 provides an overview of the Guideline Development Group members.

Table 3. Guideline Development Group Members

Name	Discipline/Content Expertise	Role	Institutional Affiliation	State
Professor Philippa Middleton	Perinatal Epidemiologist	Independent Chair	South Australian Health and Medical Research Institute	SA
Dr Natasha Reid	Clinical Psychology	Content Chair	University of Queensland	QLD
Ms Nicole Hewlett	Indigenous Health	Cultural Advisor	QUT/Menzies/UQ	QLD
Professor Zachary Munn	Public Health	Methodologist	University of Adelaide	SA
Dr Andi Crawford	Clinical Psychology	New Zealand Guidelines Project team	University of Auckland, Te Ara Manapou	NZ
Dr Raewyn Mutch	Paediatrics	New Zealand Guidelines Project team	Refugee Health Service and General Paediatrics, Perth Children's Hospital	WA
Associate Professor Matthew Gullo	Clinical Psychology	-	Griffith University	QLD

Ms Sophie Harrington	Living Experience	-	NOFASD	WA
Professor Elizabeth Elliott	Paediatrics	-	University of Sydney Clinical School; Children's Hospital Westmead	NSW
Associate Professor Delyse Hutchinson	Clinical Psychology	-	Deakin University	VIC
Ms Rowena Friend	Forensic Psychology	-	Private Practice, Charles Darwin University	NT
Dr Katrina Harris	Paediatrics	-	VicFAS Service - Monash Children's Hospital	VIC
Mr Max Naglazas	Speech Pathology	-	Neurosciences Unit, Western Australia Department of Health	WA
Professor Carmela Pestell	Clinical Neuropsychology	-	University of Western Australia & Private Practice	WA
Professor Doug Shelton	Paediatrics	-	Child Development Service, Gold Coast Hospital and Health Service	QLD
Dr James Stewart	Clinical Neuropsychology	-	North Metropolitan Health Service	WA
Ms Prue Walker	Social Work	-	Private Practice; LaTrobe University; VicFAS Monash Children's Hospital	VIC
Dr Natalie Kippin	Speech Pathology	-	Curtin School of Allied Health, Curtin University	WA
Dr Haydn Till	Clinical Neuropsychology	-	Child Development Service, Gold Coast Hospital and Health Service	QLD
Dr Seema Padencheri	Psychiatry	-	Child and Youth Mental Health Service, Hornsby Hospital Northern Sydney	NSW
Dr Fiona Kay	Paediatrics	-	Royal Children's Hospital, Darwin Children's Clinic; PATCHES Paediatrics	NT
Ms Diana Barnett	Occupational Therapy	-	Children's Hospital Westmead	NSW
Ms Storm Anderson	Speech Pathology	-	Child Development Service, Gold Coast Hospital and Health Service	QLD
Dr Kelly Skorka	Occupational Therapy	-	On Call Children's Therapy; The University of Queensland	QLD
Megan Crowe	Speech Pathology	-	NT Health	NT
Dr Robyn Doney	Occupational Therapy	-	PATCHES Paediatrics	WA

2.3.4 Conflicts of Interest Policy and Declared Interests

A Guidelines Development Group Conflicts of Interest Policy was drafted in consultation with the Project Steering Committee (Appendix D). All members of the Guidelines Development Group reviewed the policy and completed the declarations of interest form. Members were provided multiple opportunities to ask questions and discuss any potential interests they were unsure about, both during meetings and individually as needed. Appendix E provides a summary of all members' declarations of interest.

2.3.5 Guidelines Development Group Guiding Principles

The following guiding principles (Table 4) were developed by the Guidelines Development Group to inform the processes of the group and preparation of the guidelines document.

Table 4. Guidelines Development Group Guiding Principles

Solidarity	Collaborating with a shared purpose to advance assessment and diagnostic care for individuals, families and communities living with FASD.	**Cultural Responsiveness** Ensuring Aboriginal and Torres Strait Islander ways of knowing, being, and doing are intrinsic to the principles, processes, development, and implementation of these guidelines.
Inclusivity	Regardless of background and experience, all voices are equal, and all people are provided with the opportunity to express themselves. All voices are genuinely listened to and respected to create a safe space for open dialogue. Fundamental to the spirit of inclusivity is understanding how increased diversity translates to a richer, more innovative guidelines that resonate with more clinicians and health professionals.	
Importance of living and lived experiences	Acknowledging and respecting the unique perspectives of people with living experiences and the privilege this voice brings in ensuring assessment and diagnosis is accessible and that the recommendations are client and family centred.	
Continuous improvement	Establishing and documenting information transparently, to facilitate a process of continuous improvement for current and future guidelines.	
Quality	Collaborating to produce guidelines that are of a high standard and open to evolving in accordance with new evidence.	
Impact	Ensuring these guidelines are accepted by, and builds the capacity of, the FASD diagnostic workforce to increase uptake and implementation in Australia.	

3. Guidelines review and development components

Three key components informed the guidelines review and development process, as summarised in Figure 2. An overview of each of these components is provided below, with further details expanded upon in the relevant Appendices and associated reports for each of the systematic and scoping reviews.

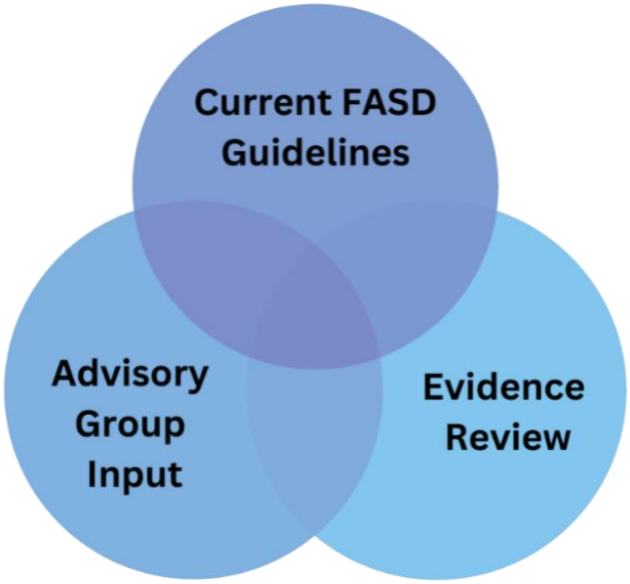

Figure 2. Key components of the review and development process

3.1 Current FASD Guidelines

A review of all published international FASD guidelines was conducted. Tables 5 provides an overview of the current FASD guidelines reviewed, while Table 6 details the diagnostic outcomes presented in each. Appendix F offers an overview of the content, reasoning, and evidence cited to support the decisions made in these guidelines. Further detailed data extraction of the evidence cited across the relevant guidelines documents was also undertaken and utilised as required in the evidence review process. However, but for brevity, this is not presented here.

3.2 Advisory Group Input

Various strategies were employed to collect input and feedback from Advisory Group members. These included Advisory Group meetings, a priority setting survey (Figure 3; Table 7; Appendix G; Hayes et al., 2022), an evidence-to-decision framework survey for the diagnostic criteria (Appendix H), and the opportunity for individual feedback on the initial draft documents. Appendix I provides a summary of the feedback received on the draft documents and how it was considered. High quality and comprehensive input and feedback was obtained through each of these mechanisms.

Table 5. Overview of current international FASD Guidelines

Diagnostic System	Original Development Agency	Date of Publication	Country of Origin	Diagnostic Setting	FAS Only	Spectrum
4-Digit Diagnostic Code, 3rd Edition	University of Washington	2004	United States	Multidisciplinary Team		X
Australian Guide to Diagnosis	Australian Department of Health	2016	Australia	Multidisciplinary Team		X
Canadian Guideline for Diagnosis	Public Health Agency of Canada	2015	Canada	Multidisciplinary Team		X
Centers for Disease Control Guidelines for Referral and Diagnosis	Centers for Disease Control and Prevention	2004	United States	Multidisciplinary Team	X	
DSM-5	American Psychiatric Association	2013	United States	Individual Providers		X
German Clinical Practice Guideline	German Society of Neuropediatrics	2013	Germany	Multidisciplinary Team	X	
Revised Institute of Medicine Clinical Guidelines	Institute of Medicine	2016	United States	Multidisciplinary Team		X
Scottish National Clinical Guideline	Scottish Intercollegiate Guidelines Network	2019	Scotland	Multidisciplinary Team		X

Table 6. Summary of the main diagnostic outcomes for current guidelines

Guideline	Diagnostic outcomes			
Canadian	FASD with the three sentinel facial features	FASD with less than the three sentinel facial features		
Australian	FASD with the three sentinel facial features	FASD with less than the three sentinel facial features		
Scottish	FASD with the three sentinel facial features	FASD with less than the three sentinel facial features		
Revised IOM	Fetal Alcohol Syndrome	Partial Fetal Alcohol Syndrome	Alcohol-related neurodevelopmental disorder	
4-Digit Diagnostic Code	Fetal Alcohol Syndrome	Partial Fetal Alcohol Syndrome	Static Encephalopathy	Neurobehavioral Disorder
German Guideline	Fetal Alcohol Syndrome	-	-	
CDC Guideline	Fetal Alcohol Syndrome	-	-	
Proposed DSM Criteria	Neurobehavioral Disorder Associated with Prenatal Alcohol Exposure			

Note. Revised IOM also includes a diagnostic outcome of Alcohol-Related Birth Defects: one of more specific major malformations without any neurodevelopmental impairment.

Figure 3. Overview of Advisory Group priority setting survey results. *Note.* Blue circles represent the first level themes, green circles represent the 2nd level themes and orange represents the third level themes.

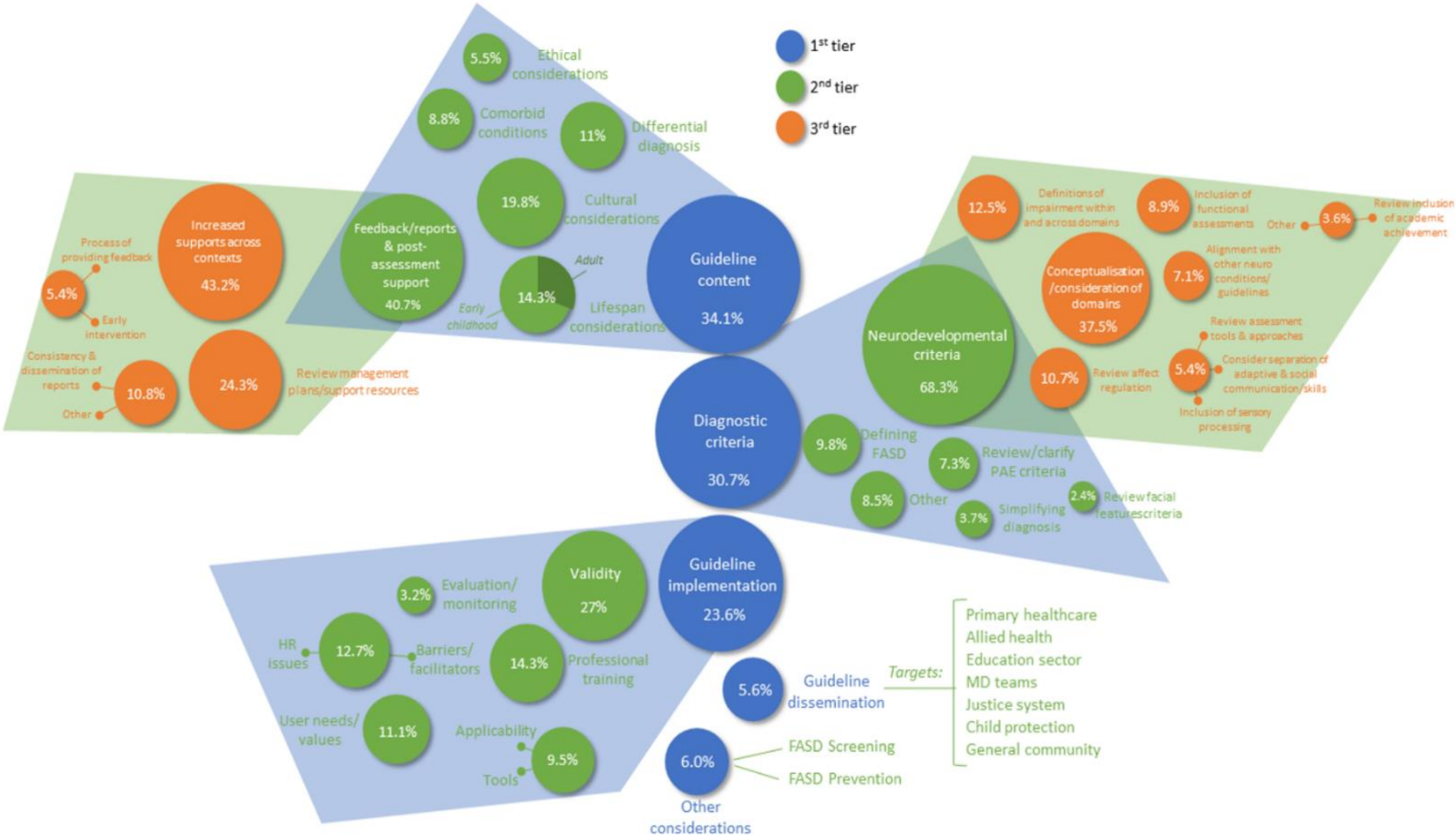

Table 7. Summary of content analysis findings of priority setting survey results

Priorities	Frequency (%)	Example Participant Quotes
Diagnostic criteria	**82 (30.7)**	
Neurodevelopmental criteria	***56 (68.3)***	
Conceptualisation of domains	21 (37.5)	"Acknowledge the overlap of symptoms and that impairment in three of the 10 domains may not reflect widespread brain injury…The guideline needs to urge the use of clinical judgment in such situations."
Definitions of impairment	7 (12.5)	"I wonder if the use of cut-off scores for FASD diagnostic determinations is appropriate and should be reviewed. Some individuals can score above -2SD and have significant functional impairment."
Inclusion of functional assessments	5 (8.9)	"Direct functional assessment is not currently required when considering a FASD diagnosis. Informant reports might be provided, which can give some insight into functioning, and inform the adaptive functioning/social communication domain. However, many difficulties and the impact of them can be invisible, even to people within the direct circle of care…"
Review assessment tools and approaches	3 (5.4)	"Update example tests under each domain. Including indirect measures. Update of Considerations for each area."
Inclusion of sensory processing	3 (5.4)	"Inclusion of sensory processing in the neurodevelopmental domains for assessment. Sensory processing is important for development in motor, attention, executive functioning, affect and adaptive behaviours as a self-regulatory factor but could be unrecognised as a major contributor to impairments."
Review inclusion of academic achievement	2 (3.6)	"Academic achievement domain—if a person's language and cognitive are severe, then their academics are also going to be severely affected—should this be a stand-alone domain?"
Review inclusion/conceptualisation of affect regulation domain	6 (10.7)	"Consideration/justification and evidence in including affect regulation in the diagnostic criteria."
Consider separation of adaptive and social communication/skills	3 (5.4)	"I'm unsure if adaptive functioning and social communication should be the one domain."
Alignment with other neurodevelopmental condition standards/guidelines	4 (7.1)	"Referencing other diagnostic guidelines such as Developmental Language Disorder under Language, and Developmental Coordination Disorder under Motor for consideration within domain rankings may be useful."
Individual recommendations	2 (3.6)	"Re-labelling "cognition" as intellectual functioning. Cognition is all thinking abilities; IQ is only one cognitive domain. Referring to IQ as cognition is misleading and leads to confusion."

Prenatal alcohol exposure	***6 (7.3)***	
Review/clarify prenatal alcohol exposure criteria	6 (100)	"Specificity: ensuring that there is adequate guidance/guardrails for clinicians so that the diagnosis of FASD is only given when antenatal exposure to alcohol is very likely to be a primary cause of the identified impairments."
Sentinel facial features	***2 (2.4)***	
Review facial features criteria	2 (2.4)	"Review of the assessment of facial features, selection of normative charts referred to across different ages and also for different ethnicities (including Aboriginal)."
Defining FASD	***8 (9.8)***	
Clarifying the definition of FASD	5 (62.5)	"Clarify if FASD is/will be intended to impute causal status to prenatal alcohol exposure (by way of title). Current Australian guide appears to require causality. But this varies in research and practice. To ensure nomenclature matches intention to convey accurate messages to empower others decision making for optimum outcomes + to avoid misdiagnosis and misnomers akin to this."
Consideration of 'the spectrum' of FASD	3 (37.5)	"Exploring the diagnosis as a spectrum disorder, as opposed to only including the severe end of the spectrum of people (i.e., acknowledging people living with mild to moderate impairments)."
Simplifying diagnosis	***3 (3.7)***	
Simplifying assessment and diagnostic process	3 (100)	"To make the diagnosis more straight forward."
Other	***7 (8.5)***	
Other individual diagnostic/assessment considerations	7 (100)	"Look at current diagnostic criteria for FASD and where it is falling short and what needs to be altered for better diagnostic clarity."
Guideline content	**91 (34.1)**	
Lifespan considerations	***13 (14.3)***	
Increased consideration of adults	4 (30.8)	"Clearer guidelines for adult assessment."
Consideration of how assessment is completed in young children/early detection	9 (69.2)	"Review the neurodevelopmental domains in relation to new research on features in young children under 6 years old."
Cultural considerations	***18 (19.8)***	

Cultural sensitivity/ safety/inclusivity	9 (50)	"Inclusion of an individual's cultural perspective/understanding of health and development. For First Nations peoples, this should involve a process of co-design to ensure the cultural safety of the Guide. Doing so will contribute to decolonising the Guide and the diagnostic methodology underpinning it."
Assessment tools/clinical decision making	9 (50)	"Consider alternative assessment processes (and recommended assessment battery/tools) that are more culturally safe and appropriate for Aboriginal and Torres Strait Islander people."
Formulation/differential diagnosis/comorbid conditions	***18 (19.8)***	
Formulation/differential diagnosis	10 (55.6)	"Expand on Section E: Formulating a diagnosis—points about excluding other causes or conditions and assessing potential influence of other exposures and events."
Consideration of comorbid conditions	8 (44.4)	"Additional advice/reminders regarding the importance of screening for child maltreatment/trauma and sleep disorders during FASD diagnostic assessments."
Feedback/reports and post-assessment support	***37 (40.6)***	
Process of providing feedback/diagnosis	2 (5.4)	"Include in the guidelines recommended protocols and processes to reporting and feeding back assessment results to individuals and families."
Consistency and dissemination of reports	4 (10.8)	"That diagnosis reports be uniform across clinics in Australia and other diagnostic groups."
Review management plans/supports and resources	9 (24.3)	"Provide more guidance on developing an effective management plan, with reference to evidence-based practice where possible."
Increased support/coordination for individuals and families	17 (44.7)	"Ensure that all clients who receive a FASD diagnosis have available support services that are easy to access, free of cost, accurate and knowledgeable…"
Early intervention	3 (8.1)	"Early intervention where possible."
Follow-up	2 (5.4)	"Follow up on children diagnosed to provide insight into better practices for managing FASD."
Ethical considerations	***5 (5.5)***	
Potential implications of diagnosis and misdiagnosis	3 (60)	"Addition of a section on the common consequences of misdiagnosis and encouragement that clinicians consider these negative consequences when weighing up the accuracy of diagnosis, e.g., poorly targeted interventions, stigma, blame and shame for communities, disempowerment, reinforcing systemic racism, misuse by the legal system."
Consent for referral/assessment	2 (40)	"Consent is not regulated. FASD is stigmatising diagnosis and warrants control of what constitutes informed consent..."

Dissemination considerations	**15 (5.6)**	
Widespread dissemination, including health, education, justice, child protection and the general community	12 (80)	"To disseminate this amongst both professional people and the community."
Targeted dissemination to MD teams	2 (13.3)	"Dissemination of guidelines to most useful clinical groups—encouragement of multi-disciplinary teams."
Specific strategy for primary health	1 (6.7)	"To get this onto health pathways, supported with education through established educational pathways –Royal Australian College of General Practitioners, Public Health Networks, etc."
Implementation considerations	**63 (23.6)**	
Validity	***17 (27)***	
Consideration and presentation of up-to-date research evidence	8 (47.1)	"Update and revise based on recent research, particularly reviews and meta-analyses, where available."
Consideration/harmonisation with international diagnostic approaches	6 (35.3)	"Consideration of harmonisation of available diagnostic guides/criteria internationally." "Ensure it's in line with best practice internationally."
Individual recommendations	3 (17.6)	"The guide needs to include acknowledgement of the current significant limitations in the literature in this area, e.g., no clearly established dose-effect relationship between alcohol and impairments, no Aboriginal Australian norms for facial features, no established cognitive phenotype of FASD."
Applicability	***6 (9.5)***	
Applicability	6 (100)	"Patient centred language, non-judgemental, provide better words and ways to express concerns, also centred on hope for the future and maximising outcomes for affected children."
Accommodation: User needs/values	***7 (11.1)***	
Incorporation of lived experiences	4 (57.1)	"Involvement of people with FASD and their families."
Individual recommendations	3 (42.9)	"Consulting with clinicians, families, sub-populations...to maximise acceptability and usefulness of revised guidelines in different settings."
Accommodation: Human resources	***8 (12.7)***	

Consider alternatives to multi-disciplinary teams to expand access	4 (50)	"Consider alternatives/additions to multi-disciplinary team process, and collection of assessment information that can be completed via non-clinicians."
Focus/review multi-disciplinary team approach	4 (50)	"Further highlighting the needs for multidisciplinary teams (and not single clinicians)."
Accommodation: Professional	***9 (14.3)***	
Recommendation regarding level of training required	3 (33.3)	"Minimum training requirements for any health practitioner (Registered Discipline or not) to be eligible to make the FASD diagnosis."
Increased general awareness and training across contexts	6 (66.7)	"Training in FASD awareness for those working in the health, mental health, justice, and other relevant sectors. Aboriginal trainers should be used in Aboriginal organisations."
Implementation: Barriers/facilitators	***8 (12.7)***	
Access to prenatal care information	2 (25)	"Sharing of information from antenatal to postnatal service providers."
Pathways of care	2 (25)	"Pathways are developed for children who show atypical development where there has been known exposure to prenatal alcohol."
Individual recommendations	4 (50)	"Resources to allow regional and rural clinicians to better assess as usually significant time constraints utilised."
Implementation: Tools	***6 (9.5)***	
List of clinics/practitioners	2 (33.3)	"Forming a register of practitioners and clinics who can diagnose FASD."
Individual recommendations	4 (66.7)	"Case examples where space permits."
Evaluation: Monitoring	***2 (3.2)***	
Evaluation and monitoring	2 (100)	"Monitoring and evaluating implementation."
Other	**6 (16)**	
Prevention	8 (50)	"Focus on need for prevention, i.e., engaging with women of childbearing years, their partners, opportunistic interventions, i.e., as part of consultation regarding sexual health, contraception, lifestyle, nutrition, etc."
Screening	8 (50)	"Consider adding recommendations regarding screening."

3.3 Evidence Review

3.3.1 Clinical questions informing the evidence review

The following research questions were developed in consultation with the Project Steering Committee to guide the evidence review:

1. What is the available evidence for each of the components of the diagnostic criteria (i.e., prenatal alcohol exposure, dysmorphology, neurodevelopment and physical size)?
2. What are the experiences of individuals with FASD and their families of the assessment and diagnostic process?
3. What broader factors (i.e., in addition to the diagnostic criteria) should be considered as part of a holistic assessment when considering FASD as one possible outcome?
4. What are the costs, other resource implications and models of care to be considered when undertaking assessments that consider FASD as one possible outcome?

3.3.2 Searching

Comprehensive systematic literature searches were undertaken for each of the review questions. Specific search dates and strategies are provided in each of the review reports. The following databases were searched:

- PubMed
- Web of Science
- EMBASE
- CINAHL
- PsycINFO
- Cochrane Library

3.3.3 Selection of the evidence

For all research questions, the titles and abstracts of the retrieved records were screened for eligibility by two independent reviewers. Publications at the full text level were also assessed by two independent reviewers, with any discrepancies resolved by a third reviewer.

3.3.4 Data extraction

Data were extracted for each research question using pre-formulated standardised data extraction forms designed specifically for the review question. Data extraction was performed by one reviewer and checked by a second reviewer. Any discrepancies were resolved through discussion.

3.3.5 Risk of bias and quality appraisal

3.3.5a Risk of bias – quantitative studies included in the systematic review of the components of the diagnostic criteria

An amended version of the RTI Item Bank for Assessing Risk of Bias and Confounding for Observational Studies of Interventions or Exposures (Viswanathan et al., 2013) was used to assess study risk of bias. Assessments were performed independently by two reviewers and verified by a third reviewer. Ten items evaluating detection, performance, selection, and attrition bias, as well as confounding in each

study were considered and scored as 'yes', 'no', 'partially', 'cannot determine', or 'not applicable'. Risk of bias rated as low, moderate, serious, or critical.

If a study did not assess and control for confounding, it was rated as having a critical risk of bias and was excluded from the meta-analysis. Studies with a major methodological flaw or multiple minor flaws were rated as having serious risk of bias. Studies with minor methodological flaws were rated as having a moderate risk of bias. Studies without methodological flaws were rated as low risk of bias. Risk of bias was assessed independently by two reviewers and checked and summarised by a third reviewer. For detailed results, see the Technical Report for the systematic review of diagnostic criteria components and associated Supplemental Files for all results.

3.3.5b Qualitative appraisal – qualitative studies included in the systematic review of lived experiences of the assessment process

The Critical Appraisal Skills Programme (CASP) Checklists for Qualitative Studies (CASP, 2018) was used to assess the quality of included qualitative studies. The CASP Checklists include factors including aims, recruitment, data collection and analysis, participant-research relationships, ethics, outcomes, and research value. Items were evaluated as 'Yes', 'Partial', 'Unsure' and 'No'. Assessments were performed independently by two reviewers with discrepancies verified by a third reviewer. See the Technical Report of the systematic review of lived experiences of the assessment process for the full results.

3.3.6 Assessment of the available evidence

3.3.6a GRADE (Grading of Recommendations, Assessment, Development and Evaluations for quantitative studies

The Grading of Recommendations, Assessment, Development and Evaluation (GRADE; Schunemann et al., 2013) approach was used to assess the certainty of evidence. This assessment considered several factors, including methodological limitations (risk of bias), imprecision, inconsistency, indirectness, and publication bias. Based on these factors, the overall certainty in evidence was categorised as high, moderate, low, or very low. A prognostic factors approach (Foroutan et al., 2020) was employed, whereby bodies of evidence started as high and were rated down based on the domain assessments. Assessments and overall GRADE ratings were completed using GRADEpro (McMaster University & Evidence Prime, 2022). For detailed results, see the Technical Report for the systematic review of diagnostic criteria components and associated Supplemental Files.

3.3.6b GRADE – CERQual (Confidence in the Evidence from Reviews of Qualitative Research) for qualitative studies

The GRADE CERQual was used to assess confidence in qualitative evidence (Lewin et al., 2018; Noyes et al., 2018). Similar to the GRADE system, CERQual provides an assessment of the degree to which each review finding is an acceptable representation of the finding of interest. Assessment methods incorporated a number of factors including: Methodological limitations of studies (i.e., the degree to which there are concerns about study conduct or design), coherence (i.e., how clear and convincing or well supported the fit is between data from the primary studies and review syntheses) adequacy of data (i.e., the overall determination of the extent of richness and quantity of data illustrating a finding), relevance (i.e., the extent to which the primary studies support a review finding is appropriate to the setting detailed in the review question).

Concerns regarding each component were rated as either no/very minor, minor, moderate, or serious. Based on these factors, the overall confidence in evidence was categorised as high, moderate, low, or

very low. For the full results, see the Technical Report of the systematic review of lived experiences of the assessment process.

3.3.7 Development of evidence summary visuals and figures

Figures were developed to present the findings of each of the systematic and scoping reviews. Figure 4 provides an overview of the outcomes included in the systematic review of the components of the diagnostic criteria. Figure 5 illustrates a summary figure for the systematic review of the components of the diagnostic criteria. Figure 6 provides an overview of the theme areas identified in the systematic review of the lived experiences of the assessment process (Hayes et al., 2023). Figure 7 summarises the content analysis results from the scoping review of broader factors that could be considered as part of a holistic assessment for FASD (Reid et al., 2023). Figure 8 offers an overview of the content analysis results of the scoping review examining the costs, other resource implications, and models of care (Kent et al., 2023).

3.3.8 Development of Evidence-to-Decision Frameworks for the Diagnostic Criteria Components

To summarise the findings from the systematic review and meta-analyses of the diagnostic components transparently and support the development of GRADE-based recommendations, evidence to decision frameworks (EtDFs) were generated for each component of the diagnostic criteria. An adapted EtDF structure was developed to suit the specific purpose of these guidelines. Summarised versions of the EtDFs are provided in Appendix J.

The process of populating the EtDFs involved several steps:

1. The research team inputted the review findings and draft content of the EtDF domains.
2. The Guidelines Development Group reviewed and discussed of the draft EtDFs.
3. The group discussed and agreed on the EtDF domain ratings.
4. The group discussed and agreed on the resulting recommendations.

Given the number and variability of outcomes assessed in each component of the diagnostic criteria, a decision was made to provide a certainty range for each of the EtDFs to offer more detailed information about certainty of the evidence.

4. Development of an Indigenous FASD Framework

Key findings from the Advisory Group input, including the initial priority setting survey (Hayes et al., 2022) highlighted the importance of further work to inform culturally responsive assessment and diagnostic practices. This led to the Cultural Advisory Group leading the development of an Indigenous FASD Framework (Hewlett et al., 2023). Strategies from this framework have been integrated throughout the main Guidelines document and detailed further in an additional Framework document. Figure 9 provides a visual overview of the Framework. For more details on the development and application of the framework, please refer to the associated framework document, publication (Hewlett et al., 2023), and Foundational Considerations Chapter of the main guidelines document. Additionally, a letter from the Cultural Advisory Group is included at the beginning of the Main Guidelines document, offering critical contextual information and considerations for clinicians.

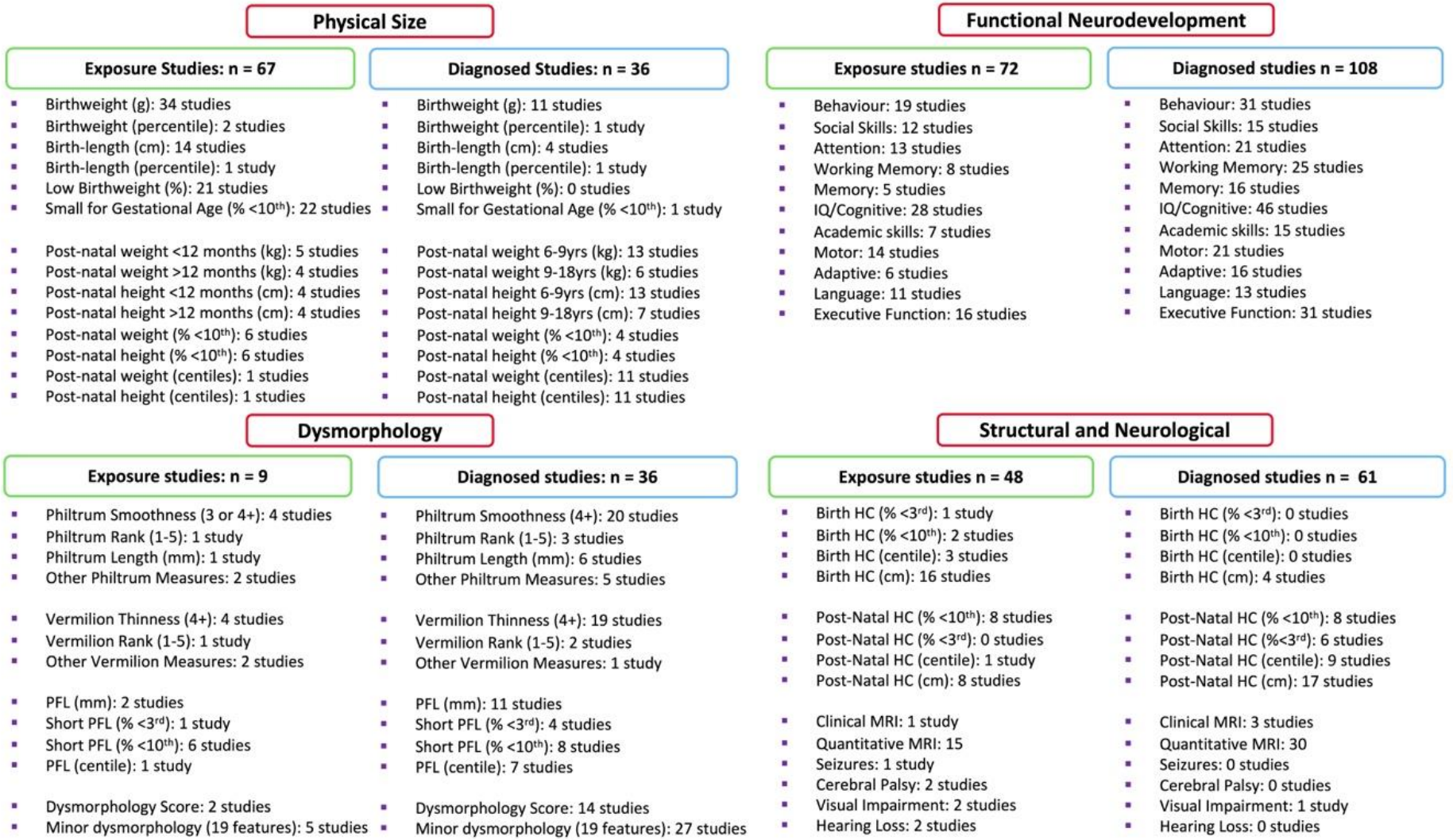

Figure 4. Overview of outcomes included in the systematic review examining the components of the diagnostic criteria. *Note.* g = grams, cm = centimetres, mm = millimetres, PFL = palpebral fissure length, IQ = intelligence quotient, HC = head circumference, MRI = magnetic resonance imaging.

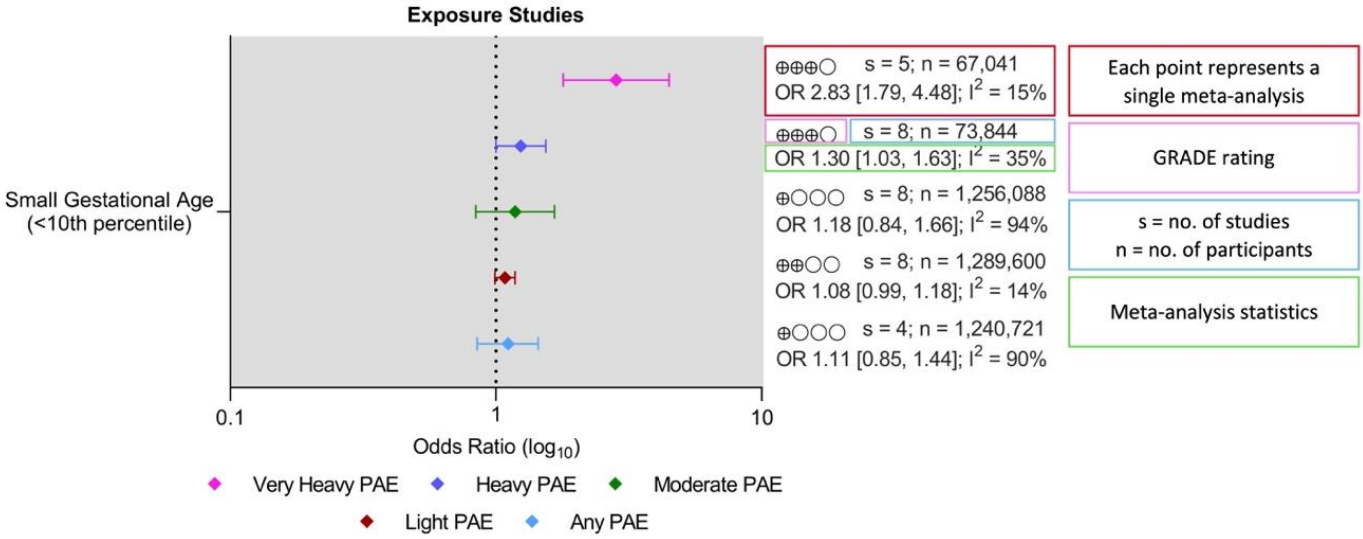

Figure 5. Example and explanation of a results summary Figure for the systematic review examining the components of the diagnostic criteria. *Note.* PAE = prenatal alcohol exposure; Light PAE = 1-20 g of alcohol per week or up to 2 standard drinks per week; Moderate PAE = 21-100 g per week or up to 10 drinks per week; Heavy PAE = 101-200 g per week or up to 20 drinks per week; Very heavy PAE = > 200 g per week or greater than 20 drinks per week.

Figure 6. Overview of the theme areas of the systematic review of lived experiences of the assessment process (Hayes et al., 2023)

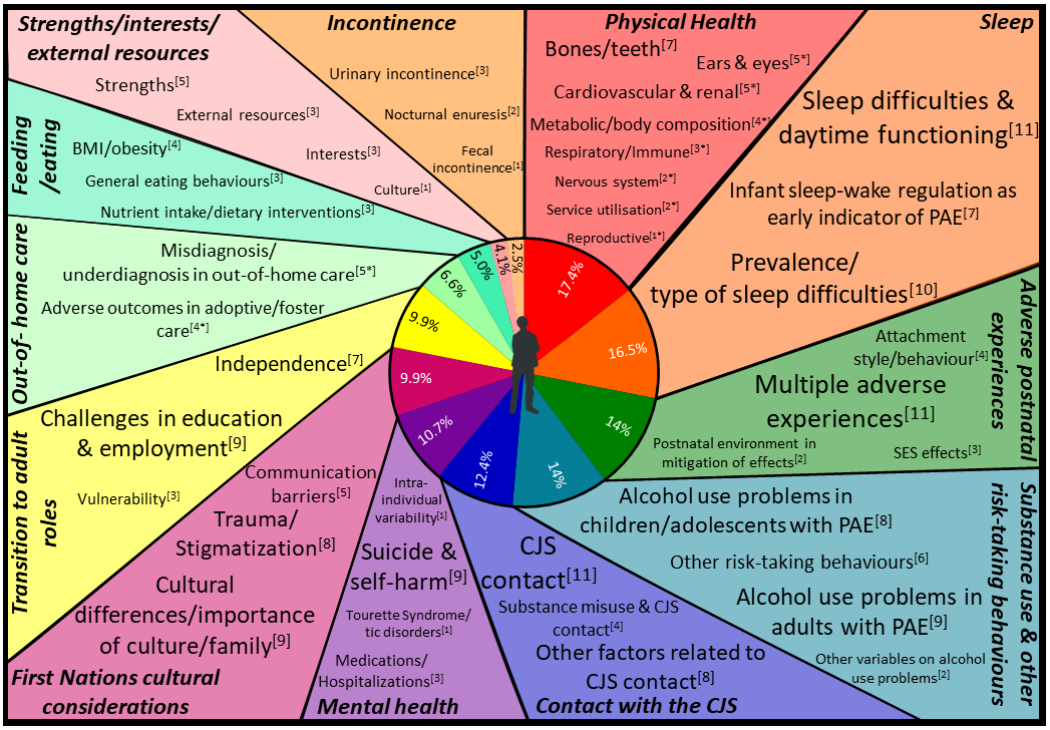

Figure 7. Results of the content analysis for the scoping review of broader factors that could be considered as part of a holistic assessment (Reid et al., 2023). *Note.* The size of the font and number in superscript brackets depict the number of studies that addressed each sub-area. *=sub-areas that included systematic reviews, PAE=prenatal alcohol exposure, BMI=body mass index, CJS=criminal justice system, SES=socio-economic status. Note: some studies were included across 2-3 key areas of interest and therefore the sum of the percentages does not equal 100%.

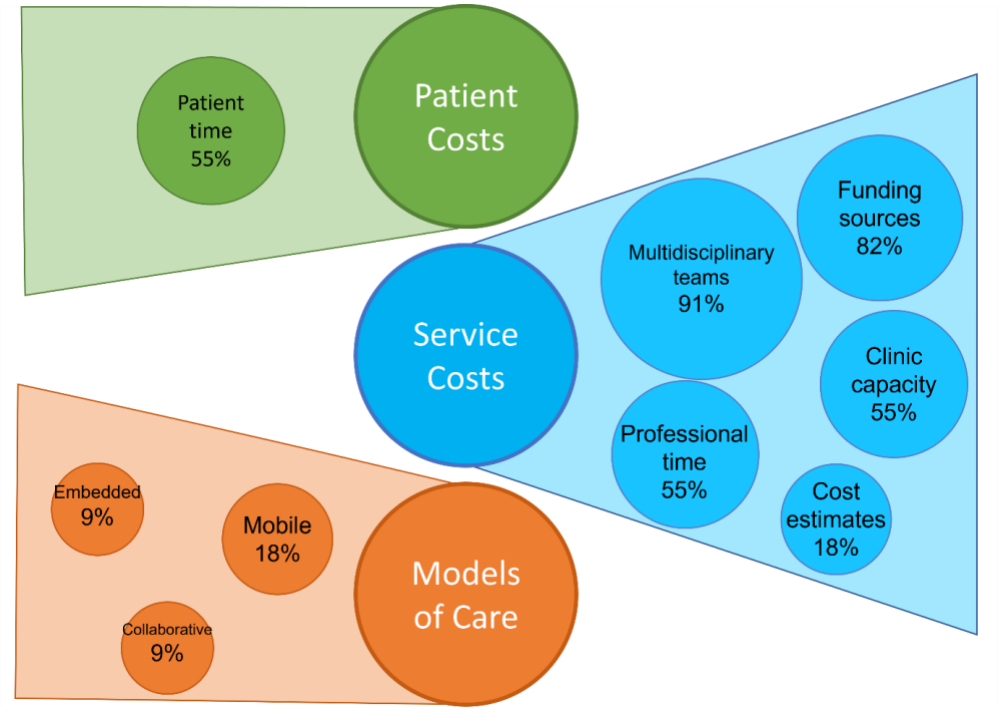

Figure 8. Results of the content analysis for the scoping review of the costs, other resource implications and models of care (Kent et al., 2023). *Note.* The size of the bubble represents the percentage of papers that addressed each sub-topic relative to the total number of papers included in the scoping review.

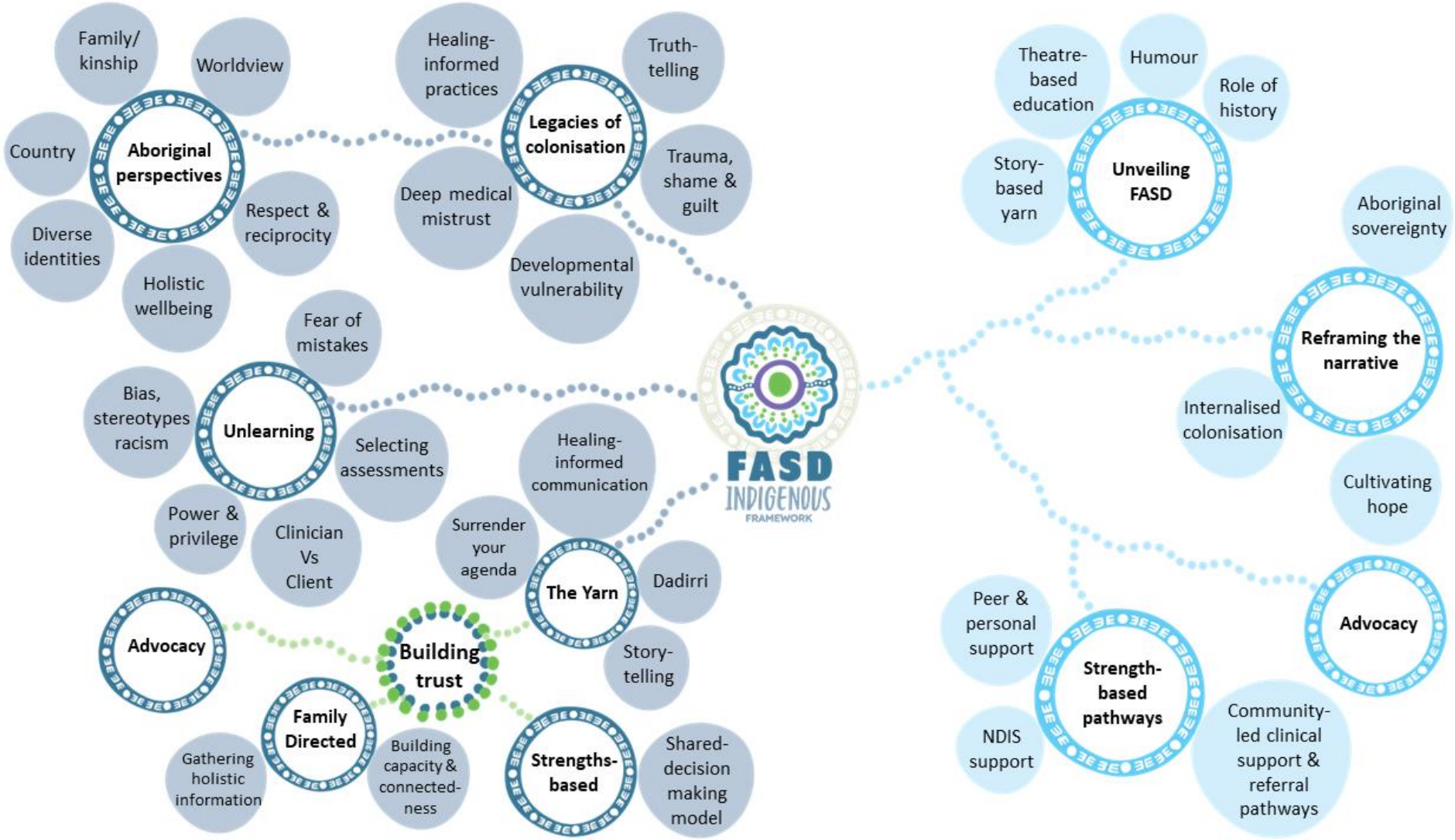

Figure 9. Overview of the Indigenous FASD Framework (Hewlett et al., 2023).

5. Developing Actionable Statements

Different formats and approaches for actionable statements were discussed with the Guidelines Development Group and Steering Committee. For clarity and consistency, the framework proposed by Lotfi et al. (2022) was applied, with some adaptations made for these specific guidelines. Table 8 provides an overview of the different types of actionable statements. Each type of actionable statement is identified and colour-coded in the Main Guidelines document, with this colour coding aligning with the artwork from the Indigenous Framework.

5.1 GRADE-based recommendations

GRADE-based recommendations were developed from the systematic review of the diagnostic criteria components using EtDFs. These EtDFs were reviewed, discussed, amended, and approved by the Guidelines Development Group. Summarised versions of the EtDFs are provided in Appendix J. The recommendations were categorised as 'Strong' or 'Conditional.' Notably, for these guidelines, the term 'Strong' was used when there was insufficient evidence to recommend inclusion of a particular component in the diagnostic criteria.

The Guidelines Development Group also created an overarching EtDF for the diagnostic criteria to examine the potential downstream implications. This overall EtDF is included as an Appendix in the main guidelines document and was also informed by a survey completed by Advisory Group members (Appendix H).

5.2 Lived experience statements

Lived experience statements were derived from the results of the systematic review of lived experiences of the assessment process (Hayes et al., 2023). The wording of these statements was reviewed and refined by the Guidelines Development Group. Additionally, results of the systematic review were also presented and discussed with the Lived Experience Advisory Group to ensure they accurately reflected the experiences of individuals and families in the Australian context.

5.3 Good practice statements

Good practice statements were firstly developed from the content of the current Guide for Diagnosis of FASD. The Guidelines Development Group aimed to maintain effective clinical practices and avoid suggesting unnecessary changes. Feedback from the priority setting survey (Hayes et al., 2022), Advisory Group and Guidelines Development group meetings, and the results of the two scoping reviews (Kent et al., 2023; Reid et al., 2023) were subsequently used to refine and develop additional good practice statements. Two full day workshops were held with the Guidelines Development Group to inform the development of the good practice statements and Main Guidelines document content. Consensus was achieved through discussion, revision, and approval of the statements.

5.4 Implementation considerations, tools, and tips

Implementation considerations, tools, and tips were developed from the priority setting survey, Advisory Groups, Guidelines Development Group meetings, and the Indigenous Framework. While a wide range of additional implementation tools suggested by Advisory Groups, the development of these resources additional funding.

Table 8. Framework for actionable statements (i.e., recommendations)

Statement type	Definition
GRADE-based recommendations	These are the result of a formal deliberation process and contain an explicit and direct link to the bodies of evidence resulting from a systematic literature search and appraisal process underpinning the recommendations. In the context of the current guidelines, these recommendations apply to the clinical features included in the diagnostic criteria. The strength of these recommendations is reflected by the two categories of 'strong' and 'conditional.' • Strong recommendations: "The Guidelines Development Group recommends." • Conditional recommendations: "The Guidelines Development Group suggests."
Lived Experience Statements	Actionable statements derived from an evidence synthesis of lived experience and reviewed by the Guidelines Development Group. They provide important guidance for health care providers to consider when providing assessment and diagnosis of FASD/ND-PAE.
Good Practice Statements	These actionable statements are those that are considered necessary to support clinical decision-making. They have not been based on synthesised summaries of the evidence and do not have formal ratings of certainty of evidence or strength of the recommendation. The following criteria were considered in whether to issue a good practice statement: 1. Is collecting and summarising evidence a poor use of a guideline panel's limited time and energy? 2. Is the message necessary to inform actual health care practice? 3. After consideration of all relevant outcomes and potential downstream consequences, does implementing the good practice statement result in a large net positive consequence? 4. Is there a well-documented, clear, and explicit rationale connecting the statement with the indirect evidence? 5. Is the statement clear and actionable?
Implementation considerations, tools, and tips	Contain supporting information to enhance implementation of recommendations/good practice statements. Often describe the how, who, where, what and when related to implementation. May be made available in separate documents.

5.5 Overall reviewing and approval process

Once all the statements and content of the documents were drafted, the Guidelines Development Group was provided extensive opportunities to review and edit the statements and document content through OneDrive. Subsequently, members of the Advisory Groups were provided with the opportunity to review all the draft documents and provide feedback through meetings and via a feedback form (Appendix I).

6. Public consultation

Public consultation is a mandatory requirement of the NHMRC procedures and requirements, and this process was conducted accordingly. The draft documents were made available on the FASD Hub website for a 6-week period (11th March – 22nd April 2024), with an additional 1-week provided following requests from stakeholders. The public consultation was advertised on the NHMRC website and in the NHMRC Tracker. Invitations were also sent to wide range of key stakeholders, including all Director Generals, Chief Executive or Secretaries of each state, territory and the Commonwealth health department, as well as other relevant government departments (i.e., all Director Generals, Chief Executive or Secretaries of each state and territory education, child protection and justice departments).

The Guidelines Development group met multiple times to consider all submissions. Table 9 provides a summary of the main areas of suggestions and key actions taken. Appendix K provides the full summary of all public consultation suggestions and responses provided.

Table 9. Summary of main suggestions and key actions taken by the Guidelines Development Group

Main areas of suggestions	Key actions
Lengthy main guidelines document	An abridged version of the main guidelines document, a plain English Summary, and Frequently Asked Questions document were developed to support understanding of the main document.
Diagnostic terminology	The terminology of FASD was applied throughout the document for clarity and consistency, while still allowing flexibility for different diagnostic terminologies based on individual preference. This aligns with the human-rights and shared decision-making principles of the guidelines. An additional section has also been included in the Introduction providing more contextual information regarding diagnostic terminology.
Minimum prenatal alcohol exposure threshold (Criterion A)	The wording of Criterion A and relevant sections of the document were revised to aid interpretation and application of this criterion.
Public health messaging	Additional information was added to the Introduction section to provide more information about how these guidelines are aligned with current public health messaging. Visual supports and wording throughout the document were also revised where relevant to further clarify this point.

Information regarding use of standardised tools	The wording in Criterion B was revised aid interpretation and application. Sections of the document were re-structured to make information regarding percentile ranges easier to find. Additional information was provided to support practitioners in this area.
Clarification about assessment of infants and young children	Relevant information was revised to help clarify this section for practitioners.
Incorporation of additional information to the dissemination, implementation and evaluation report	A range of excellent suggestions from various organisations were included, such as the need for targeted implementation resources for different sectors, and capacity building to support the proposed assessment process, including for general practitioners, rural and remote practitioners and Aboriginal Community Controlled settings.

7. Independent Expert Review

NHMRC commissioned an independent methodological and clinical review and coordinated feedback from one methodological expert and six clinical experts in the field. Table 10 provides an overview of key areas of feedback and actions taken. Appendix L provides a summary of all feedback received and responses to the independent review.

Table 10. Summary of expert review key feedback areas and actions taken

Key feedback	Key actions
Organisation of information- range of information suggested to be included in the main guidelines document that was covered in other documents.	Information was copied across from other documents so as to also be covered in the main guidelines document.
Adding information regarding public consultation.	Information was added to the Administrative and Technical Report, including dates of the public consultation.
Additional information regarding the body of evidence underpinning the guidelines.	An additional chapter was added to the main guidelines document providing an overview of the body of evidence, with links to the evidence summaries provided in the Technical Reports and supplemental materials.
Formatting issues and inconsistencies across documents.	A range of formatting issues and inconsistencies across documents were addressed.
Document accessibility and navigation.	Colour contrast was updated to improve readability. Alt text was added to all visuals. Bookmarks, section numbers, and an index were added to the main document. Hyperlinks will also be added between documents once available online.

Wording of Criterion A (i.e. prenatal alcohol exposure minimum threshold).	Revised wording regarding Criterion A and associated sections of the documents was undertaken to aid interpretation and implementation.
Diagnostic terminology.	Additional information was included in multiple sections throughout the document (e.g., Introduction, adding diagnostic terminology section after the diagnostic criteria, which includes all the relevant terminology and coding options).

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9. Appendices

Appendix A: AGREE-II and NHMRC Criteria

Procedures and Requirements for Meeting NHMRC Standards for Clinical Practice Guidelines

AGREE-II criteria	Mapping NHMRC requirements	Location
Domain 1: Scope and Purpose		
OBJECTIVES Report the overall objective(s) of the guideline. The expected health benefits from the guideline are to be specific to the clinical problem or health topic.	**B.1** The purpose of the guideline is stated, including the clinical questions issue or problems the guideline addresses.	Introduction of main document and Technical Reports.
QUESTIONS Report the health question(s) covered by the guideline, particularly for the key recommendations.	**B.2** The health care setting to which the recommendations apply is described, including the health system level and clinical stage.	Assessment process section of main document.
	C.1 Clinical questions addressed by the guideline are stated in a structured a consistent format to define the boundaries of the topic.	Introduction of main document and Technical Reports.
POPULATION Describe the population (i.e., patients, public, etc.) to whom the guideline is meant to apply	**B.4** The population to which the guideline recommendations will apply is defined and population subgroups for which specific information is required are identified and described.	Background section of main document.
	B.5.1 Issues relevant to special-needs groups such as culturally and linguistically diverse communities or groups with low socioeconomic status are identified and described.	Main document where relevant.

AGREE-II criteria	Mapping NHMRC requirements	Location
	B.5 Issues relevant to Aboriginal and Torres Strait Islander peoples are identified and described.	Main document and Indigenous Framework.
Domain 2: Stakeholder Involvement		
GROUP MEMBERSHIP Report all individuals who were involved in the development process. This may include members of the steering group, the research team involved in selecting and reviewing/rating the evidence and individuals involved in formulating the final recommendations	**A.5** A complete list of all the people involved in the guideline development process is provided, including the following information for each person: name, profession or discipline, organisational affiliation and role in the guideline development process.	Administrative and Technical Report.
	A.8 The guideline development process includes participation by representatives of Aboriginal and Torres Strait Islander peoples and culturally and linguistically diverse communities and the processes employed to recruit, involve and support these participants are described.	Administrative and Technical Report & Indigenous Framework document.
TARGET POPULATION PREFERENCES AND VIEWS Report how the views and preferences of the target population were sought/considered and what the resulting outcomes were.	**A.3** A multidisciplinary group that includes end-users, relevant disciplines and clinical experts is convened to develop the purpose, scope and content of the guideline, and the process for selecting members is described. **A.4** Consumers participate in the guideline development, and the process employed to recruit, involve and support consumer participants is described.	Administrative and Technical Report.
TARGET USERS Report the target (or intended) users of the guideline.	**B.3** Intended end users of the guideline are clearly defined, and any relevant exceptions are identified.	Background of main document.
Domain 3 Rigour of Development		
SEARCH METHODS Report details of the strategy used to search for evidence.	**C.2** Systematic searches for evidence are undertaken and the search strategy is documented, including the search terms and databases searched.	Technical Reports
	C.3 The population groups specified in the search strategy include Aboriginal and Torres Strait Islander peoples and any population subgroups that have been identified.	Holistic and Cultural

AGREE-II criteria	Mapping NHMRC requirements	Location
		Framework review.
	C.4 The publication period covered by the searches is stated and the latest date is within 12 months of the first day of public consultation and within 20 months of submission of the final draft guideline to NHMRC for approval.	Technical Reports – confirmed date of searches with NHMRC.
	C.3.1 The population groups specified in the search strategy include groups such as culturally and linguistically diverse communities or other groups for whom specific sociocultural factors should be considered.	Holistic review
	C.3.2 Search strategies include search terms to identify evidence related to consumer perceptions and experiences.	Lived experiences review.
	C.3.3 Dependent on the guideline scope, the search strategy is designed to identify evidence of all relevant alternatives for diagnosis of the condition.	N/A
	C.3.4 Search strategies include search terms to identify evidence relevant to cost effectiveness and resource implications of practice.	Resources and models of care review.
EVIDENCE SELECTION CRITERIA Report the criteria used to select (i.e., include and exclude) the evidence. Provide rationale, where appropriate.	• The inclusion and exclusion criteria used to select studies for appraisal are described.	Technical Reports
STRENGTHS & LIMITATIONS OF THE EVIDENCE Describe the strengths and limitations of the evidence. Consider from the perspective of the individual studies and the body of evidence aggregated across all the studies. Tools exist that can facilitate the reporting of this concept.	**C.8.1** If gaps in the evidence are identified during the evidence review, these are described in the guidelines and areas for further research are noted.	Technical Reports and main document.
	• The strengths and limitations of the body of evidence reviewed are described in the guideline text and areas of uncertainty are acknowledged.	Technical Reports and main document.

AGREE-II criteria	Mapping NHMRC requirements	Location
FORMULATION OF RECOMMENDATIONS Describe the methods used to formulate the recommendations and how final decisions were reached. Specify any areas of disagreement and the methods used to resolve them.	**D.4** Recommendations formulated in the absence of quality evidence are clearly labelled as such. The preferred term for this type of recommendation is a consensus-based recommendation.	Framework provided for labelling of statements.
	D.5 Any further recommendations included in the guideline, where the subject matter is outside the scope of the search strategy are clearly labelled as such. The preferred terminology for this type of recommendation is a practice point.	Lotfi et al framework used – good practice statements.
	D.6 The method used to arrive at consensus-based recommendations or practice points (e.g., voting, or formal methods such as Delphi) is documented.	Admin & Technical Report
	D.7 Areas of major debate about the evidence and the recommendations are identified and the various significant viewpoints are outlined in the guideline text (even if the guideline development group eventually reached a decision).	Main document
	D.8.1 Recommendations that are likely to be affected by new evidence after the guideline has been approved are identified and the implications for the guideline recommendations are explained in the guideline text.	N/A
	D.9 The guideline acknowledges current national guideline recommendations approved by NHMRC or endorsed by major authorities and any deviations from these are explicitly noted in the guideline text and the rationale is provided.	N/A
	D.10 Where a guideline makes any recommendation/s that are not available or restricted in Australia the text clearly indicates this and the developer has consulted with relevant authorities.	N/A
	D.9.1 Clinical recommendations that deviate from current practice are identified.	N/A
	D.11 Where evidence is identified showing that Aboriginal and Torres Strait Islander peoples or other population groups have specific prevention or treatment outcomes, this evidence is clearly identified and considered in the formulation of recommendations.	Included where relevant in main document and Indigenous

AGREE-II criteria	Mapping NHMRC requirements	Location
		Framework document.
	D.11.1 Where evidence is identified showing that sociocultural factors affect treatment or prevention outcomes, this evidence is clearly identified and considered in the formulation of recommendations.	Evidence to decision framework and main document where relevant.
	D.16 If evidence for complementary and alternative medicine options is identified, the risks and benefits for these are stated in the guideline test and appropriate recommendations included.	N/A
	D.17 If there is a lack of rigorous evidence for a complementary and alternative medicine/therapy commonly used in practice, this is explicitly stated in the guideline text.	N/A
	D.18 Recommendations that consider consumer self-management options are included, where relevant.	N/A
	D.19 Recommendations emphasise consumer and carer involvement in treatment and care decisions, where relevant.	Main doc.
CONSIDERATION OF BENEFITS AND HARMS Report the health benefits, side effects, and risks that were considered when formulating the recommendations.	**D.12** The harms (risks or side effects) and benefits of each recommended intervention are identified and described in text.	N/A
	D.12.1 Absolute measures of both efficacy and harm are stated for each management option where available.	N/A
	D.13 Any safety, legal or potential misuse issues related to the clinical recommendations are identified and described in the guideline text.	Described in main document where relevant.
	D.13.1 Ethical issues are considered when formulating the recommendations and any such issues identified and described.	Evidence to decision framework and

AGREE-II criteria	Mapping NHMRC requirements	Location
		issues highlighted from priority setting survey also highlighted in the document.
LINK BETWEEN RECOMMENDATIONS AND EVIDENCE Describe the explicit link between the recommendations and the evidence on which they are based.	**D.3** For each evidence-based recommendation, the supporting references are listed and the grade of recommendation is indicated according to an NHMRC-approved method.	Technical Reports
EXTERNAL REVIEW The Guideline has been externally reviewed by experts prior to its publication.	**D.15** The guideline and recommendations have been assessed by at least two reviewers, independent of the guideline development process, using the AGREE-II instrument.	Admin and Technical Report
	F.1 The process for public consultation on the draft guideline complies with Section 14A of the Commonwealth National Health and Medical Research Council Act 1999 and accompanying regulations.	Admin and Technical Report
	F.2 Details of submissions received during public consultation and the responses of the guideline development group to the submissions are provided as a separate document to NHMRC.	Admin and Technical Report
	F.2.1 A version of the public consultation submissions summary is publicly available, with submissions de-identified.	Admin and Technical Report
	F.3 During the public consultation period, the developer has undertaken and documented consultation with: • The Director General, Chief Executive or Secretary of each state, territory, and Commonwealth health department. • Other relevant government departments as appropriate to your guidelines topic.	Admin and Technical Report
	F.4 The developer has identified and consulted with key professional organisations and consumer organisations that will be involved or affected by the implementation.	All key professional organisations

AGREE-II criteria	Mapping NHMRC requirements	Location
		invited to be involved and many have representatives on the Clinical Advisory Groups.
UPDATING PROCEDURE Describe the procedure for updating the guideline.		Dissemination, Implementation and Evaluation Report
Domain 4: Clarity of Presentation		
SPECIFIC AND UNAMBIGUOUS RECOMMENDATIONS Describe which options are appropriate in which situations and in which population groups, as informed by the body of evidence.	**D.1** The wording of recommendations is specific, unambiguous, clearly describes the action/s to be taken by users and matches the strength of the body of evidence. **D.2** The wording of the recommendations is written in plain English and is consistent throughout the guidelines. **D.2.1** Recommendations are formulated using consistent grammar, syntax and wordings, so they can be readily adapted for electronic implementation strategies (e.g., electronic decision support systems and automatic data collection).	All completed in main document.
IDENTIFIABLE KEY RECOMMENDATIONS Present the key recommendations so that they are easy to identify.	**E.4** The guideline includes an executive summary that lists all the recommendations and their grade using an NHMRC-approved method.	Summary of statements provided in the main document.
	E.7 The document design and layout enables recommendations to be identified easily within the text.	Colour coded and boxed throughout main document.
Additional NHMRC requirements for clarity of presentation	**E.2** The guideline title page includes NHMRC required information. **E.2** The guideline is easy to navigate and includes a table of contents or index with hyperlinks or bookmarks to facilitate navigation.	All complete in main document.

AGREE-II criteria	Mapping NHMRC requirements	Location
	E.5 A glossary of technical terms, acronyms and abbreviations is provided, and terms are used consistently throughout the guideline. **E.8** References in the text are clearly identified and the citations clearly listed. **E.9** Chapter and heading levels are consistent, clearly distinguishable by the document design and layout and assist with the navigation throughout each topic of the guideline. **E.10** The guideline information is sequenced in a logical manner which is applicable to the intended end user.	
	E.11 The technical report is ether included in the guideline document or provided in a readily accessible location, which is indicated in the guideline. **E.12** The administrative report is either included in the guideline document or provided in a readily accessible location, which is indicated in the guideline.	A combined Admin & Technical Report is provided.
	E.6 Where medicines are mentioned, generic names are used and brand names are avoided	N/A
Domain 5: Applicability		
IMPLEMENTATION ADVICE/TOOLS Provide advice and/or tools on how the recommendations can be applied in practice.	**A.7** A list of organisations that will be approached to endorse the guideline is provided	Dissemination, implementation, and evaluation report provided.
	G.1 A plan for dissemination of the guideline is submitted as a separate document from the clinical practice guideline.	Dissemination, implementation, and evaluation report provided.
	G.3 A practical implementation plan is provided as a separate document, based on considerations of the Australian health care context and identification of appropriate organisations where the key recommendations may be directed.	Dissemination, implementation, and evaluation report provided.

AGREE-II criteria	Mapping NHMRC requirements	Location
	E.3 The guideline includes a brief (e.g., 1 page) plain English summary.	Plain English Summary
	G.2 Key recommendations that are most likely to lead to improvements in health outcomes are highlighted for consideration in implementation.	Dissemination Report
	G.4 Resources to support implementation of the guidelines are developed, such as summaries and other tools for different health care professionals and the guideline indicates where these can be obtained.	Initial clinician support tools included as Appendix to the main document
	G.5 Accompanying consumer information is provided.	Plain English Summary & FAQ document
	G.6 Versions of plain English summary and consumer information are available in different languages, if appropriate.	To be completed
	G.7 Suggestions for local adaption and adoption of the guideline are provided.	Main document
FACILITORS AND BARRIERS		Clinician Determinants questionnaire used to gather specific information.
RESOURCE IMPLICATIONS Describe any potential resource implications of applying the recommendations.	**D.14** The potential impact of each recommendation on clinical practice or outcomes in described in text. **D.9.2** The resource implications and cost effectiveness of any recommended practice, compared with current or established practice are explicitly stated in the guideline text.	Evidence to decision frameworks and further consideration required in text.

AGREE-II criteria	Mapping NHMRC requirements	Location
MONITORING/ AUDITING CRITERIA Provide monitoring and/or auditing criteria to measure the application of guideline recommendations	**G.8** Measures are developed for determining the extent to which key guideline recommendations are implemented. **G.9** An evaluation strategy is developed and described to assess the extent to which guideline recommendations are adopted into routine practice.	Dissemination and implementation report and database form.
Domain 6: Editorial Independence		
FUNDING BODY Report the funding body's influence on the content of the guideline.	**A.2** Sources of funding for guideline development, publication and dissemination are stated.	Reported inside cover of all documents.
	A.2.1 The amount and percentage of total funding received from each funding source is stated	Reported inside cover of main document.
COMPETING INTERESTS Provide an explicit statement that all group members have declared whether they have any competing interests.	**A.1** The organisation/s responsible for developing and publishing the guideline are named.	Reported inside cover of main document.
	A.6 Potential competing interests are identified, managed and documented and a competing interest declaration is completed by each member of the guideline development group.	Admin & Technical Report

Appendix B: Advisory Group Terms of Reference and Expression of Interest Form

Key Stakeholder Advisory Groups

Terms of Reference

Purpose

A consortium led by The University of Queensland has been funded by the Australian Government Department of Health to review, update and disseminate the National Clinical Guideline for the Assessment and Diagnosis of Fetal Alcohol Spectrum Disorder (FASD; 2016), commencing August 2020. The purpose of the Key Stakeholder Advisory Groups are to gather valuable stakeholder input and consultation on the development and implementation of updated FASD guideline. At the completion of the project, the overall aim is that clinicians throughout Australia caring for children, adolescents and adults will have access to evidence-based clinical practice guidelines to support best practice and guide decision making in the assessment and diagnosis of FASD.

Roles and Responsibilities

The role of the key stakeholder advisory groups is to:

Provide input regarding the guideline scope and areas to consider for each clinical question to be addressed in the guideline

Provide feedback regarding the feasibility and acceptability of the recommendations

Provide input and feedback on the content of the draft guideline and supporting documentation

Provide input and feedback on the implementation plan

Membership

Five different types key stakeholder advisory groups will be established. Where required (e.g. due to different cultural groups and size of the groups) multiple groups of each type will be established. This will include:

Clinician Advisory Group

Members will include: paediatricians, psychologists, occupational therapists, physiotherapists, speech pathologists, and social workers. This will include invitations to all relevant health professional associations.

Research Advisory Group

Members will include: national and international researchers.

Cultural Advisory Group

Members will include representatives from a variety of cultural groups and representatives from relevant associations.

Consumer Advisory Group

Members will include: carers of individuals with FASD, young people and/or adults with FASD and consumer group representatives.

Other Key Stakeholder Group

Members will include: Education, Justice, Child Protection and NDIS representatives

Advisory Group Members will:

Have general knowledge regarding FASD assessment and diagnosis.

Have a genuine interest in improving the diagnostic approaches for individuals with FASD.

Be an advocate for individuals with FASD and their families.

Participate respectfully in group discussions.

Advisory Group Members will be selected through consultation with the Steering Committee members, advertisements sent to the Australian and New Zealand FASD Clinical Network and posted on relevant FASD organisations and invitations sent to all relevant professional bodies.

Meetings

The key stakeholder advisory groups are time-limited groups established for the duration of the project. Each group will meet a minimum of four times over 2021 - 2022, via tele/video conference. Meetings will normally be of one hour duration.

Confidentiality

Members will not reveal any confidential or proprietary information entrusted in the course of their involvement in the stakeholder advisory group, and may not use, or attempt to use any such information, documents or data, other than for fulfilment of work with the stakeholder advisory group.

Upon cessation of the stakeholder advisory group membership, and thereafter, the members shall not reveal any confidential or proprietary information which they obtained while a member of the stakeholder advisory group, and may not use or retain, or attempt to use or retain, any such information, documents or data.

Key Stakeholder Advisory Groups

EXPRESSION OF INTEREST

ABOUT THE PROJECT

Across 2020-2023, a consortium of 12 organisations, led by the University of Queensland are undertaking a comprehensive review and update of the Australian Guide to the Assessment and Diagnosis of FASD, which was first released in 2016.

To undertake this work we are establishing a number of **key stakeholder advisory groups** to guide the development and implementation of the revised FASD guideline.

The project aims to ensure clinicians throughout Australia caring for children, adolescents and adults will have access to evidence-based clinical practice guidelines to support best practice and guide decision making in the assessment and diagnosis of FASD.

Key Stakeholder Advisory Groups

The purpose of the key stakeholder advisory groups is to provide valuable stakeholder input and consultation on the development and implementation of the guideline. Five key stakeholder advisory groups are sought,

including clinicians, researchers, cultural advisors, consumers, and representatives for education, justice, child protection and disability.

The roles and responsibilities of the Key Stakeholder Advisory Groups are outlined in the '*Key Stakeholder Advisory Groups Terms of Reference'*.

WHO ARE WE LOOKING FOR?

Clinicians with experience in assessment and diagnosis of FASD, including:

Paediatricians

General practitioners

Psychologists

Occupational therapists

Physiotherapist

Speech pathologists

Social workers

Researchers with knowledge and expertise in prenatal alcohol exposure and FASD

Expert Cultural Advisors

Consumers, including:

Parents/Carers of individuals with FASD

Young people and/or adults with FASD

Consumer group representatives

Other key stakeholders, including representatives from:

Education

Justice

Child protection

Disability/NDIS

APPLICATION AND APPOINTMENT PROCESS

Members will be appointed by expression of interest. The Project Steering Committee will review all the applications and work to ensure an appropriate balance of members in the groups.

Expression of Interest Form

Review and Dissemination of the Australian Guide for Assessment and Diagnosis of Fetal Alcohol Spectrum Disorder (FASD)

Key Stakeholder Advisory Groups

Personal Details	
Applicant Name:	
Mailing Address:	
Email:	
Telephone:	

Background Experience		**N/A**
Qualifications:		☐
Current role and employer:		☐
Expertise relevant to FASD:		☐

Please indicate which advisory group you would like to be a member of:				
Clinician	**Researcher**	**Expert Cultural Advisor**	**Consumer**	**Other specialist**
☐	☐	☐	☐	☐

Please indicate your preferred meeting times:						
	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**
Morning	☐	☐	☐	☐	☐	☐
Afternoon	☐	☐	☐	☐	☐	☐
Evening	☐	☐	☐	☐	☐	☐

Please return this form to nicole.hayes@mater.uq.edu.au

If you have any questions, please contact n.reid1@uq.edu.au

Appendix C: Guidelines Development Group Terms of Reference and Expression of Interest Form

Guideline Development Group

Terms of Reference

Background and Purpose

A consortium led by The University of Queensland has been funded by the Australian Government Department of Health to review, update and disseminate the National Clinical Guideline for the Assessment and Diagnosis of Fetal Alcohol Spectrum Disorder (FASD; 2016), commencing August 2020. In accordance with the *2011 NHMRC Standard for Developing Clinical Practice Guidelines*, a Guideline Development Group will be established. The purpose of the Guideline Development Group is to act as an expert advisory group for the development and implementation of the updated FASD Guideline. At the completion of the project, the overall aim is that clinicians throughout Australia caring for children, adolescents and adults will have access to evidence-based clinical practice guidelines to support best practice and guide decision making in the assessment and diagnosis of FASD.

Roles and responsibilities

The role of the guideline development group will be to oversee and lead the development of the guideline. This will include:

Refining the guideline scope and identifying the key clinical questions to be addressed in the guideline

Reviewing the research evidence using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) methodology

Reviewing input and feedback gathered from the key stakeholder advisory groups

Developing appropriate evidence-based and consensus-based recommendations

Reviewing the acceptability, feasibility, potential risks and benefits of recommendations

Developing the content and reviewing a draft of the guideline (including additional resources)

Developing and reviewing a draft of the implementation plan

Considering and deliberating on public consultation submissions

Finalising the draft guideline and implementation plan for NHMRC approval

Reviewing prepared responses following feedback from NHMRC reviewers and/or NHMRC council members

Membership

The guideline development group will be chaired by TBA, an independent expert in TBA. The group will consist of up to 15 members and will include:

Content experts that have clinical experience in the assessment, treatment and management of FASD in children, adolescents and/or adults;

Content experts that have knowledge and expertise in pre-clinical and/or clinical research on prenatal alcohol exposure and/or FASD;

Consumers representatives of individuals with FASD and their carers;

Cultural representatives

GRADE Methodology expert

The guideline development group is a time-limited group established for the duration of the project across 2021-2022. Appointment on the guideline development group will be an honoraria position only. Out-of-pocket expenses to attend workshops for consumer and cultural representatives will be provided.

A summary table detailing the members of the guideline development group and their areas of expertise will be published as part of the final Guidelines documents.

Meetings

The group will meet via tele/video conference quarterly in 2021 and 2022. Meetings will normally be of one hour duration. One/two face-to-face workshops will be held in late 2021 and early 2022. The specific location and dates are yet to be confirmed. GRADE training (via video conference) will be provided to members, planned for early 2021. Additional meetings can be scheduled at the request of the Chair or at the request of a majority of the members of the Committee.

Members of the Committee may nominate a proxy from the organisation they are representing to attend a meeting if the member is unable to attend. The proxy must also have substantial knowledge of the FASD diagnosis process, be committed to representing the collective perspective of the organisation and comply with this Terms of Reference. The Chair must be informed of the substitution at least one working day prior to the scheduled nominated meeting. The nominated proxy shall have all rights afforded to committee members at the attended meeting. A quorum will be a majority of the members, including proxy members, present by teleconference/workshop attendance.

Members of the committee will agree to participate respectfully in group discussions and read and provide feedback on any associated documents between meetings in a timely manner.

Confidentiality

Members will not reveal any confidential or proprietary information entrusted in the course of their involvement in the guideline development group, and may not use, or attempt to use any such information, documents or data, other than for fulfilment of work with the guideline development group.

Upon cessation of the guideline development group membership, and thereafter, the members shall not reveal any confidential or proprietary information which they obtained while a member of the guideline development group, and may not use or retain, or attempt to use or retain, any such information, documents or data.

Conflict of Interest

Members will be asked to disclose all relevant interests (financial and non-financial) upon acceptance into the group so that conflicts of interest can be identified and managed. Members will also be asked to inform the Chair of any new conflicts of interest that may arise prior to all meetings

during the guideline development process. The Conflict of Interest policy and associated Conflict of Interest Declaration Form provide information on the appropriate disclosure and management of potential conflicts of interest.

A summary of members' conflicts of interest will be published as part of the final Guidelines documents.

Guideline Development Group

EXPRESSION OF INTEREST

ABOUT THE PROJECT

Across 2020-2023, a national consortium of 12 organisations, led by the University of Queensland are undertaking a comprehensive review and update of the Australian Guide to the Assessment and Diagnosis of FASD, which was first released in 2016.

To undertake this work we are establishing a **Guideline Development Group**. The purpose of the guideline development group is to act as an expert advisory group that will oversee and lead the development and implementation of the guideline.

The group will include up to 15 expert members that have clinical experience in the assessment, treatment and support of FASD for children, adolescents and/or adults; knowledge and expertise in research on prenatal alcohol exposure and/or FASD; consumer representatives of individuals with FASD and their parents/carers; cultural representatives and members who have expertise in broader clinical practice guideline development.

The roles and responsibilities of the Guideline Development Group are outlined in the '*Guideline Development Group Terms of Reference*'.

APPLICATION AND APPOINTMENT PROCESS

The EOI will be sent to all members of the Project Steering Committee and Advisory groups who will be invited to disseminate further to relevant people in their network who they think could be an appropriate group member.

Members will be appointed by expression of interest. The Project Steering Committee and Guideline Development Group Chair will review all the applications and work to ensure an appropriate balance of members.

For those interested, please complete the expression of interest form and return to email: nicole.hayes@uq.edu.au.

Applications close **30 June 2021.**

If you have any questions, please contact Dr Natasha Reid: n.reid1@uq.edu.au, 07 3069 7511.

Guideline Development Group

EXPRESSION OF INTEREST FORM

Personal Details	
Applicant Name:	
Work Address:	
Email:	
Telephone:	

Background Experience:	
Qualifications:	
Current role and employer:	
Expertise relevant to FASD and/or clinical practice guideline development more generally:	
What is your interest in being involved in this group:	

Conflicts of Interest: Members will be asked to complete a formal COI that will be published in the final guideline document. At this stage we were just wanting to get an indication of any potential conflicts to inform the selection process.	
Please list any potential COIs:	

Please indicate your preferred meeting times:						
	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**
Morning	☐	☐	☐	☐	☐	☐

Afternoon																	
Evening																	

Do you have any significant periods of leave planned during the project?

Could you please provide information regarding your general availability/capacity to provide input to the Guideline Development Group for us to take into consideration when selecting group members.

☐

By ticking this box, you confirm your agreement with the Terms of Reference and commit to attend and participate respectfully in meetings, and review, comment and contribute to relevant documents between meetings in a timely manner.

Please return this form to nicole.hayes@uq.edu.au by 30 June 2021

If you have any questions, please contact Dr Natasha Reid, n.reid1@uq.edu.au, 07 3069 7511.

Appendix D: Guidelines Develop Group Conflict of Interest Policy and Declaration Form

Conflicts of Interest Policy

Conflicts of interest could bias guideline recommendations and therefore need to be identified and managed. As stated by the National Health and Medical Research Council (NHMRC):

> *"It is important for you to understand that having a conflict of interest does not in itself imply improper motivation or individual wrongdoing. Also having a conflict does not necessarily preclude your involvement in a guideline development group. However, it is widely understood that conflicts can directly influence decision making and this is often an unconscious act."*[1]

A conflict of interest involves:

- A **perceived conflict** where it could be reasonably perceived or give the appearance that a competing interest or obligation, whether personal or involving a third party, could improperly influence a member's duties and responsibilities.
- A **potential conflict** where a member has an interest or obligation, whether personal or involving a third party that could conflict with the member's duties and responsibilities.
- An **actual conflict** where a member has a competing interest or obligation, whether personal or involving a third party, that directly conflicts with the member's duties and responsibilities.[2]

NHMRC[1] provides the following examples:

Non-financial interests to declare could include:

- Publishing research that may be used in a guideline
- Having personal or family experience (i.e., lived experience) of a condition considered in a guideline
- Holding positions or convictions (political, intellectual, religious, ideological or other) relevant to the guideline.

Financial conflicts of interest to declare could include:

- Fees paid for service to a company (e.g., consultancy payments, speaking fees, panel memberships).
- Indirect payments (e.g., funding of travel, accommodation, professional development)
- Company stock
- Royalties
- Directorships
- Support for a researcher's clinical or research infrastructure (e.g., funding of data managers, scientists, equipment, and clinical staff).
- Personal relationships with those who may have the above interests.

[1] https://www.nhmrc.gov.au/guidelinesforguidelines/plan/identifying-and-managing-conflicts-interest
[2] https://ppl.app.uq.edu.au/content/1.50.11-conflict-interest

Organisational conflicts of interest to declare could include:

- Representing, or having roles in, organisations with financial links or affiliations with industry groups that stand to benefit from or be affected by guideline recommendations.
- Representing, or having roles in, organisations that advocate industrial or policy positions.
- Having personal relationships with those who may have the above interests.

Disclosure of conflicts of interest

All members of the Guidelines Development Group will be required to disclose conflicts of interest (i.e., perceived, potential or actual) prior to their involvement with the group. In line with the guidance provided by NHMRC[1], a summary will be published as part of the Guidelines documentation (see Appendix A for a copy of the summary table).

It is the responsibility of each member to disclose any conflicts by accurately completing the required forms (declaration form attached). Any conflicts will be discussed the Chair of the Development Group and if required a decision made regarding involvement.

In addition to disclosure of conflicts prior to their involvement with the Development Group, members are required to declare any relevant interests as they arise. This will be facilitated by a standing agenda item in the group meetings, which will allow for regular disclosure and discussion of interests.

Management of conflicts of interest

Final decisions on membership will be made through consultation between the Steering Committee and the Development Group Chair. Decisions will take into account information disclosed in the relevant forms and will:

- Consider whether there could exist perceived, potential, or actual conflicts that could influence a person's expert judgement or erode the integrity of a group decision.
- Determine whether or not the disclosed interests will be managed by a range of measures (e.g., exclusion from certain discussions; divestment of financial interests; resignation from membership of entities whose interests could be affected by any recommendations; excluding conflicting members from writing or approving recommendations associated with the conflict; removing a conflicting member from the group).
- Ensure the Development Group is chaired by someone who has no conflicts of interest that could, or could be perceived to, erode the integrity of a group decision.

Questions

We are happy to answer any questions or discuss anything regarding the conflicts of interest policy or disclosure process. Please feel free to send through any questions to fasdguidelines@uq.edu.au

Conflicts of Interest Disclosure and Declaration Forms

Financial Activities

Type	No	Yes: Benefits to you (received or expected)	Yes: Benefits to immediate family (received or expected)
In relation to 1 below: Over the past three years, have you been employed by an entity having a commercial or other interest in the subject of the guidelines to be developed?			
1. Employment			
In relation to 2 and 3 below: Do you, or, as far as you are aware, any immediate family members have any ownership interests in any entity that has commercial interests in the subject of the guidelines under development (including where stock in the entity is not publically traded)?			
2. Ownership interests*			
3. Board membership			
In relation to 4-10 below: Have you or, as far as you are aware, any immediate family members been paid consultancy fees or honoraria, received meals and beverages, travel, accommodation, entertainment, remuneration, educational event attendance, gratuities, grants or gifts. Disclosures are required of all financial interests and the NHMRC CEO or their Delegate will determine whether or not a management strategy is required in relation to these interests. Disclosure is required in relation to disbursements over the three years preceding and any anticipated disbursements in the twelve months following, appointment to the Development Group.			
4. Consultancy fees/honorariums			
5. Grants			
6. Support for travel or accommodation			
7. Meals/beverages			

8. Entertainment			
9. Gifts or gratuities			
10. Other**			

*Ownership interests include stock options, but exclude indirect investments through mutual funds and the like

** Any other relevant information, including institutional interests

Relevant Professional and Organisational Experience

Have you published or spoken on or advocated or publicly debated the topic of concern in the guidelines (including the provision of expert testimony)?			
Type	**No**	**Yes**	**Details (attach example if required)**
Publications*			
Speeches/lectures			
Expert testimony			
Development of related guidelines, standards, educational material or fact sheets			
Other (e.g. unpaid advisory roles)			

* The requirement is for material on published positions (including any in the media) relevant to the issue being considered by the committee. If the same position has been expressed in multiple publications, the requirement is only for an illustrative sample rather than a full listing of all publications.

Other Relationships or Activities

Type	**No**	**Yes**	**Details (attach example if required)**
Relationships			
Activities			

Conflicts of Interest Declaration Form

_____ _____

Given name *Surname*

Fetal Alcohol Spectrum Disorder Assessment and Diagnostic Guidelines

Guideline name

Declaration:

I declare that the information was correct on the date entered below.

I declare that I have read the Project Conflict of Interest Policy Document and the NHMRC recommendations regarding Identifying and Managing Conflicts of interest and agree to comply with the requirements.

In signing this form I hereby agree to:

- Update this information throughout my involvement with the development of these guidelines in the event that my circumstances change, or otherwise in response to the Project Steering Committee requests to update this information.

- Comply with any conflict of interest management plan.

Allow the publication of a summary of any interests I have disclosed in this form and any interests declared after I complete this form, and any management plan in the final guideline

Appendix E: Summary of Guidelines Development Group Declarations

Name	Discipline/Content Expertise	Organisational/Institutional Affiliations	Conflicts declared
Prof Philippa Middleton	Perinatal Epidemiologist	South Australian Health and Medical Research Institute	Publications – Co-author of FASD guidelines paper. Supervision – Supervising a PhD student whose topic is FASD.
Dr Natasha Reid	Clinical Psychology	University of Queensland	Employment – University of Queensland. Publications, speeches/lectures and grants related to FASD.
Prof Zachary Munn	Public Health	University of Adelaide, Joanna Briggs Institute	Consultancy fees and travel – Support for speaking at conferences and running workshops related to guideline and evidence synthesis; Grants –related to guidelines and evidence synthesis.
A/Prof Matthew Gullo	Clinical Psychology	University of Queensland, Centre for Youth Substance Abuse	None declared
Ms Nicole Hewlett	Indigenous Health	QUT/Menzies/UQ/NOFASD	Employment – Casual employment developing guidelines; Consultancy fees and travel – Paid by FARE and Vichealth to speak to the development of NHMRC Alcohol guidelines, Travel to attend NOFASD board meetings; Publications – Co-author of FASD guidelines papers, undertaking PhD related to development and implementation of the FASD Indigenous Framework; Speeches – APSAD pre-conference workshop (2022), key note ADAANT, APSAD 2023 and Paediatrics conference.
Dr Andi Crawford	Clinical Psychology	University of Auckland, Te Ara Manapou	Related guidelines – Development of NZ diagnostic guidelines for FASD
Ms Sophie Harrington	Lived Experience	NOFASD	Employment – National Organisation for FASD, NOFASD; Grants – Ongoing Dept of Health funding to provide NOFASD helpline Relationship – Parent of child with FASD
A/Prof Delyse Hutchinson	Clinical Psychology	Deakin University	Related guidelines – National Clinical Guidelines for the Treatment of Alcohol Use Disorders (2021)
Ms Rowena Friend	Forensic Psychology	PATCHES Paediatrics	Employment – Clinical Manager at Patches; Grants – National grants delivered to Patches to expand services; Speeches – FASD assessment training through Patches; Related guidelines – Completing PhD related to guideline development for court reports (FASD); Other – Testimony to court on young people or adults with FASD
Prof Carmela Pestell	Clinical Neuropsychology /Clinical Psychology	University of Western Australia & Private Practice	Employment – Previously employed by Patches Paediatrics, currently in private practice at Robin Winkler Clinic; Consultancy fees and travel – Northern Territory Australian Aboriginal Justice Agency; Grants – Multiple Commonwealth; Supervision and teaching of students conducting FASD research and studies; Publications and speeches – numerous FASD related; Related guidelines – Input into first FASD diagnostic guidelines, current development of FASD related employment resources; Other – provided expert testimony for Royal Commission into NT Child Detention, member of National FASD Advisory Group.
Dr James Stewart	Clinical Neuropsychology	North Metropolitan Health Service	Publications – Effective approaches to prevent, diagnosis and support for FASD senate inquiry.

Dr Haydn Till	Clinical Neuropsychology	Gold Coast Hospital and Health Service	Publications – Multiple relating to FASD clinical outcomes and guidelines; Speeches and testimony – Related to clinical neuropsychology and FASD
Dr Seema Padencheri	Psychiatry	Child and Youth Mental Health Service, Hornsby Hospital Northern Sydney	None declared
Prof Elizabeth Elliott	Paediatrics	University of Sydney Clinical School; Children's Hospital Westmead	Grants – Multiple from NHMRC and philanthropic groups Publications – Numerous on related matters Speeches and testimony – Numerous on related matters, Government inquiries on FASD, mental health services, disability services; Related guidelines – Developed 2016 Australian Guide to Diagnosis as well as educational resources with NSW Health, FARE and others; Other – Board Member NOFASD, Chair Australian Government FASD Advisory Board, Chair FASD Hub Advisory Board; Activities – Involvement in FASD Hub, Registry, Surveillance.
Dr Katrina Harris	Paediatrics	VICFAS Service - Monash Children's Hospital	Employment – Head of the Victorian Fetal Alcohol Service (VicFAS); Consultancy fees and travel – To support regional outreach clinics; Grants – Funding provided to support VicFAS; Speeches and lectures – Regularly give FASD lectures.
Dr Fiona Kay	Paediatrics	Royal Children's Hospital, Darwin Children's Clinic; PATCHES Paediatrics	Employment – Darwin Children's Clinic, Royal Children's Hospital and Patches; Speeches and lectures – Medical teaching.
Dr Raewyn Mutch	Paediatrics	Refugee Health Service and General Paediatrics, Perth Children's Hospital	Consultancy fees and travel – National Judicial College of Australia conference (2023); Grants – Out of home care grant; Speeches – FASD guideline updates; Related guidelines – NZ FASD Guidelines; Other – Previous board member of FASD Care, carried out assessments for children before the courts, representative for Health Department intergovernmental panel on age of criminality.
Dr Doug Shelton	Paediatrics	Gold Coast Hospital and Health Service	Teaching – Regular teaching about FASD diagnosis generally as it pertains to current guidelines, as well as a need for improvements in current methods.
Ms Storm Anderson	Speech Pathology	Child Development Service, Gold Coast Hospital and Health Service	Employment – Child Development Service
Dr Natalie Kippin	Speech Pathology	Curtin School of Allied Health, Curtin University	Publications and PhD that includes reference to FASD guidelines; Other – court-ordered assessments related to FASD; Related guidelines – input into first FASD diagnostic guidelines.
Mr Max Naglazas	Speech Pathology	Neurosciences Unit, Western Australia Department of Health	Publications – Effective approaches to prevent, diagnosis and support for FASD senate inquiry.
Ms Diana Barnett	Occupational Therapy	Children's Hospital Westmead	Speeches – Poster on OT and Motor skills at FASD Conference and National OT Conference (2018).
Dr Robyn Doney	Occupational Therapy	PATCHES Paediatrics	Employment – Patches, FASD-related publications, lectures/speeches
Dr Kelly Skorka	Occupational Therapy	On Call Children's Therapy; The University of Queensland	Employment – Casual research assistant with Child Development Clinic completing OT assessments for FASD project; Publications – Completing PhD related to interprofessional interventions for child with FASD and their caregivers, multiple publications related to lived experiences of children and adolescents with FASD; Speeches – Conference presentations for PhD-related topics (lived

			experiences of FASD, interprofessional practice framework).
Ms Prue Walker	Social Work	Private Practice; LaTrobe University; Monash Children's Hospital	Employment – VicFAS diagnostic clinic, Australian Childhood Foundation; Speeches and lectures – Discussion of FASD diagnostic guidelines in conference presentations and training workshops; Related guidelines – Work with NOFASD to develop factsheets and a carer guide, as well as my own training materials that cover using the guidelines.
Ms Megan Crowe	Speech Pathology	NT Health	Speeches and teaching – Regular teaching about FASD diagnosis as it relates to current guidelines.

Appendix F: Additional results of the review of current FASD diagnostic criteria/guidelines

Appendix F Table 1. Prenatal Alcohol Exposure Criteria and Reasoning

Inclusion of a specific level of prenatal alcohol exposure required for diagnosis			
Guideline	**Relevant guideline content**	**Reasoning provided**	**Supporting citations[a]**
4-Digit Code (2004)	Full spectrum**: No specific level of** PAE is required for diagnosis. However, diagnostic outcomes vary based on the exposure level (i.e., different 4-Digit Codes reflecting absent, unknown, confirmed, confirmed high). FAS: **unknown PAE accepted**	"The case-definitions for the four Ranks address two important issues: 1) that exposure information in a clinical setting can be of limited availability or of unknown accuracy and 2) a clear consensus is not available concerning the amount of alcohol that can actually be toxic to each individual fetus" (p. 43).	Astley, 2004; Astley, 2010; Astley, 2011; Astley et al., 2009; Chasnoff et al., 1985; Klein de Licona et al., 2009; Sood et al., 2001; Stratton et al., 1996; Streissguth et al., 1993
Australian (2016)	Full spectrum**: No specific level** of PAE is required for diagnosis. FASD with sentinel facial features**: unknown PAE accepted**	"It is likely that multiple mechanisms are involved in damage to the brain from PAE and no 'safe' threshold for alcohol consumption during pregnancy has been established" (p. 8).	Sampson et al., 2000; Chudley et al., 2005 (Canadian Guidelines); Astley, 2011; Bertrand et al., 2005; Stratton, 1996; Feldman et al., 2012; Interagency Coordinating Committee on FASDs, 2011; O'Leary et al., 2012; NHMRC, 2009.
Canadian (2015)	Full spectrum: **Threshold** of 'estimated dose at a level known to be associated with neurodevelopmental effects' (7 or more standard drinks per week, or 2 or more episodes of drinking ≥ 4 drinks on the same occasion) is required for diagnosis of FASD without sentinel facial features. FASD with sentinel facial features**: unknown PAE accepted**	"At this time the threshold of alcohol exposure known to be associated with adverse neurodevelopmental effects is 7 or more standard drinks per week, or any episode of drinking 4 or more drinks on the same occasion. Because the effect size with a single binge episode are relatively small a threshold of 2 binge episodes is recommended as a minimum for diagnosis" (Appendix, p. 16).	Cites for inclusion of a threshold: Flak et al., 2014; Guerri et al., 1999; Jacobson & Jacobson, 1994; Kaminski et al., 1976; May et al., 2013. Cites for ≥ 7 standard drinks per week: Eckstrand, et al., 2012; Greene, et al., 1991; Jacobson et al., 1993; Jacobson & Jacobson, 1994; Jacobson et al., 2013; O'Leary et al.,

			2010; O'Leary & Bower, 2012; Streissguth et al., 1983. Cites for ≥ 4 standard drinks per occasion: Abel & Sokel, 1986; Chang et al., 2011; Eckstrand, et al., 2012; Ernhart et al., 1988; Feldman et al., 2012; Flak et al., 2014; May et al., 2013a; May & Gossage, 2011; Paintner et al., 2012.
CDC (2004) ***FAS Only**	FAS: **unknown PAE accepted**	"Every effort should be made to obtain the necessary information, but lack of confirmation of alcohol use during pregnancy should not preclude an FAS diagnosis if all other criteria are present. This would be considered "unknown prenatal alcohol exposure." In very rare instances, there will be confirmed absence of exposure. Documentation that the birth mother did not drink any amount of alcohol from conception through birth would indicate that the FAS diagnosis is not appropriate."(p. 18)	No citations
DSM-5 (2013)	Full spectrum: **Threshold** of 'More than minimal' PAE is required, defined as ≥ 13 drinks per month during pregnancy (i.e., any 30-day period of pregnancy) or ≥3 drinks on any one drinking occasion.	"The 'more than minimal' criterion is not intended to denote a threshold for safe consumption of alcohol during pregnancy. It is simply an acknowledgement of ongoing controversy about low levels of exposure and an attempt to make sure the diagnosis was not overused because the base rate of drinking any alcohol among women of childbearing years is relatively high" (p. 6).	Cites for inclusion of a threshold: Riley & McGee, 2005; Henderson et al., 2007; Flak et al., 2014; Tan et al., 2015. Cites for ≥ 13 drinks or ≥3 drinks: No citations.
German (2013) ***FAS Only**	FAS: **unknown PAE accepted**	"In cases where maternal alcohol consumption could not be confirmed, sensitivity for the diagnosis FAS was higher (unconfirmed 89%, confirmed 85%), while specificity was lower	Burd et al., 2010

		(71.1% versus 82.4%). … Given the existence of estimates that a large proportion of children with FAS in Germany do not have their disorder diagnosed, the guideline group accepted the low specificity of the diagnostic criterion "unconfirmed intrauterine alcohol exposure"" (p.708)	
Revised IOM (2016)	ARND and ARBD: **Threshold** of 'documented prenatal alcohol exposure' which can be indicated by: • ≥ 6 drinks/wk for ≥ 2 wks during pregnancy • ≥ 3 drinks per occasion on ≥ 2 occasions during pregnancy • Documentation of alcohol-related social or legal problems in proximity to (before or during) the index pregnancy • Documentation of intoxication during pregnancy by blood, breath, or urine alcohol content testing • Positive testing with established alcohol-exposure biomarker(s) during pregnancy or at birth • Increased prenatal risk associated with drinking during pregnancy as assessed by a validated screening tool of, for example, T-ACE or AUDIT FAS and pFAS: **unknown PAE accepted**	"These criteria for maternal drinking are based on large epidemiologic studies that demonstrate adverse fetal effects from ≥3 drinks per occasion and others that indicate 1 drink/day as a threshold measure for FASD" (Table 2, p. 5).	Cites for inclusion of a threshold: No citations. Cites for ≥ 3 drinks per occasion: May et al., 2008; May et al., 2013a; Maier & West, 2001. Cites for ≥ 6 drinks/wk for ≥ 2 wks: Day et al., 1991; Robles et al., 1990; Larkby et al., 2011. Cites for alternative documentation or test results: Bryanton et al., 2014; Manich et al., 2021; May et al., 2013a; May et al., 2013b; May et al., 2014; May et al., 2015; Wurst et al., 2008.
Scottish (2019)	Full spectrum**: No specific level** of PAE is required for diagnosis. FASD with sentinel facial features**: unknown PAE accepted**	"As most of the published data relating to drinking alcohol during pregnancy are collected from mothers either prospectively or retrospectively, they may be inherently flawed. Studies have shown that women tend to under-report (or not report) their alcohol consumption during pregnancy. The presence of all three facial	Ernhart et al., 1988; Jacobson et al., 1991; Morrow-Tlucak et al., 1989

		features has such high specificity to prenatal alcohol exposure and FASD that confirmation of alcohol exposure is not required when they are present. The presence of fewer than three facial features does not have the same degree of specificity and therefore requires other confirmation."	

Appendix F Table 2. Sentinel Facial Features Criteria and Reasoning

Clinical cut-off for palpebral fissure length and which lip/philtrum guide is used			
Guideline	**Relevant guideline content**	**Reasoning provided**	**Supporting citations[a]**
4-Digit Code (2004)	FAS = PFL **≤ 2.5th** percentile[3]/2 SD below the mean; Lip **and** Philtrum Rank 4 or 5 **UW lip-philtrum guide** pFAS = Two of PFL, lip, and philtrum ≤ 2 SD below the mean, and the other feature >-2 SD and ≤ -1 SD	Facial features and clinical cut-offs: "A series of analytic studies conducted 20 years later confirmed the sensitivity and specificity of these features to FAS, and served to case-define the magnitude of expression required to maximize sensitivity (100%) and specificity (99%). Relaxation of these criteria substantially reduced sensitivity and specificity" (p. 27). "Rank 4 FAS facial phenotype is > 95% sensitive and specific to FAS and prenatal alcohol exposure. Sensitivity and specificity were confirmed to be unaffected by race, gender, and age." (S. Astley, 2013, pp. 429–430) When the definition of a "short" PFL was relaxed to < 10%, no correlations were found with any pattern of prenatal alcohol exposure. When the definition of a "short" PFL was set back to < 2% (the criteria used by the 4-Digit Code), strong, significant correlations were found with quantity, frequency, and duration of alcohol exposure (Figure 4B) (S. Astley, 2013, p. 431) PFL Normative Charts: **Canadian (Clarren) charts[4]**; Normal PFL charts adjusted for race should be used if available and confirmed valid.	Astley, 2004; 2010; 2011; Astley & Clarren, 1995; 1996; 2000; 2001; Astley et al., 1992; 1999; 2002; Clarren et al, 2010.

[3] Astley, 2013 includes reference to cutoffs of both 2.5th percentile and 2nd percentile for PFL.
[4] Astley and colleagues recommended use of the Stromland charts in a 2006 publication (S. Astley, 2006).

		Lip/Philtrum Guide: "As the FAS facial phenotype increases in severity of expression from Rank 1 to Rank 2 to Rank 3 to Rank 4, the prevalence of underlying brain damage/dysfunction also increases linearly. The FAS facial phenotype, including partial expressions of the phenotype, serves as a sensitive marker of brain damage/dysfunction" (p. 27).	
Australian (2016)	FASD with the three sentinel facial features = PFL **≤ 3rd** percentile/2SD below the mean; Lip **and** Philtrum Rank 4 or 5. **UW lip-philtrum guide**	Facial features: "Although these facial features may also occur independently as normal variations in the general population (unrelated to prenatal alcohol exposure), when seen in combination, these facial features are pathognomonic of and highly specific to prenatal alcohol exposure" (p. 33). PFL Normative Charts: "**The Canadian (Clarren) charts** are based on a multi-racial population considered to be a better representation of Australian children, although this has not been qualified by research. As the charts start at 6 years of age, Scandinavian (Stromland) charts need to be used in children under 6 years of age" (p. 34). Lip/Philtrum Guide and clinical cut-offs: University of Washington guide without specific rationale for this choice.	Reference to UW FAS Prevention and Diagnostic Network (FAS DPN). No citations given for choice of PFL charts.
Canadian (2015)	FASD with sentinel facial features = PFL **≤ 3rd** percentile/2SD below the mean; Lip **and** Philtrum Rank 4 or 5. **UW lip-philtrum guide**	Facial features: "There is evidence to support the recommendation that the simultaneous presentation of the three characteristic facial features that discriminate individuals with PAE include short palpebral fissures, indistinct philtrum and thin upper lip" (p. 17). "Collectively, it is clear that there is emerging evidence to suggest the diagnostic utility of additional facial and/or physical features that in some (yet unspecified) combination may be unique to prenatal alcohol exposure. However, the decision to reduce the number of facial features (to 2 of 3) required for the diagnosis of FASD with Sentinel Facial Feature did not appear sufficiently supported by the evidence, and further investigation is needed before a formal recommendation can be made" (p. 19). PFL Normative Charts: "Since the publication of the 2005 Guidelines, research conducted in **Canada (Clarren)** has provided current norms for palpebral fissure length for children age six years and older… Standard deviation values can be conveniently computed using University of Washington software" (p. 20)	Facial features: Astley, 2006; 2013; May et al., 2010; Moore et al., 2007; Fang et al., 2008; Foroud et al., 2012. Lip/Philtrum Guide: No citations.

		Other suggested charts: Thomas, et al., 1987; Jones et al., 1978 (infants and very young children); Stromland et al., 1999. Lip/Philtrum Guide and clinical cut-offs: "The University of Washington Lip-Philtrum Guides continue to be the standard for an objective evaluation of lip and philtrum development" (Appendix p. 19).	
CDC (2004) ***FAS Only**	FAS = PFL **≤ 10th** percentile; Lip **and** Philtrum Rank 4 **UW lip-philtrum guide**	Facial features and clinical cutoffs: "Based on these scientific findings and the extensive clinical experience of the SWG [scientific working group], the following facial dysmorphic features were determined to meet the dysmorphia criteria essential for FASD (based on racial norms" (p. 9). "Specific criteria were chosen by the SWG to maximize inclusiveness of potential cases on this diagnostic parameter and, therefore, might differ somewhat from other systems currently in use… Review of available diagnostic systems seems to indicate that the dysmorphic criteria agreed upon by the SWG provide a balance between conservative and overly inclusive diagnostic systems" (p. 10). PFL Normative Charts: No specific charts suggested. Lip/Philtrum guide: University of Washington without specific rationale for this choice.	Facial features: Astley & Clarren, 1997; 2001; CDC, 2001; Coles et al., 1985; 1991; Graham et al., 1988; Johnston et al., 1996; Moore et al., 2002. Clinical cut-offs: Astley & Clarren, 1997; Coles, et al., 1985; Graham et al., 1988; CDC, 2001. Lip/Philtrum guide: No citations
DSM-5 (2013)	*DSM-5 does not include guidelines for the diagnosis of FAS or other conditions on the fetal alcohol spectrum with dysmorphia.*	N/A	N/A
German (2013) ***FAS Only**	FAS = PFL **≤ 3rd** percentile; Lip **and** Philtrum Rank 4 or 5 **UW lip-philtrum guide**	Facial features: "Regardless of ethnicity and sex, the most powerful dis- criminating characteristics for FAS proved to be smoothing of the philtrum, a thin upper lip, and short palpebral fissure length. These facial screening criteria for FAS showed sensitivity of 100% and acceptable specificity of 89.4%" (p. 706). PFL Normative Charts and clinical cutoffs: "**Clarren** et al. developed percentile curves for palpebral fissure length based on measurements in 2097 healthy	Facial features: Astley, 2011; Astley & Clarren, 1995; Jones et al., 1976; Clarren et al., 1987. Lip and Philtrum: Astley & Clarren, 2000; Astley, 2004

		Canadian girls and boys ranging in age from 6 to 16 years (explorative cohort study, LoE2b). … Astley et al. showed that the mean palpebral fissure lengths of children with FAS (n = 22) were at least two standard deviations lower than the corresponding values in healthy Canadian children" (p. 707). Lip/Philtrum Guide: UW Lip-Philtrum Guide without rationale for choice.	(4-Digit Code); 2011; Clarren et al., 2010.
Revised IOM (2016)	FAS/pFAS = ≥ 2 of the following: PFL **≤ 10th** percentile; Lip **or** Philtrum Rank 4 or 5. **IOM lip-philtrum guide**.	Facial features and clinical cut-offs: "Similar to others, our goals in the formulation of FASD diagnostic guidelines have been improved sensitivity and greater inclusion of children in the complete continuum of FASD; thus, we have set cut-off levels for growth deficiency, head circumference and palpebral fissure length at ≤10th centile and required 2, rather than 3, cardinal facial features for a diagnosis of FAS and PFAS" (p. 8). PFL Normative Charts: Advocate use of **Thomas, et al., 1987** and live measurement versus photographs citing "Avner et al found palpebral fissure lengths measured from photographs to be consistently smaller than those measured live. Similarly, Astley found the norm for palpebral fissures measured from 2-dimensional photographic software to fall 1.6 SDs below the mean on a palpebral fissure chart derived from live examinations" (p. 6). Lip/Philtrum Guide: Revised IOM Lip-Philtrum Guide without rationale for choice.	Facial features and clinical cutoffs: Hoyme et al., 2005; CDC, 2004 (CDC Guideline); Astley 2016; Hoyme et al 2015. Palpebral Fissure Length: Astley, 2011; 2015; Avner et al., 2014; Cranston et al., 2009. Lip and Philtrum: Astley, 2016; Hoyme et al., 2015.
Scottish (2019)	FASD with the three sentinel facial features = PFL **> 2** SD below the mean; Lip **and** Philtrum Rank 4 or 5. **UW lip-philtrum guide**	Facial features: "There is evidence to support the recommendation that the simultaneous presentation of the three characteristic facial features that discriminate individuals with PAE include: short palpebral fissures, indistinct philtrum, and thin upper lip" (p. 18). "FASD diagnostic data revealed that the presence of all three sentinel facial features and microcephaly … was always associated with significant neurodevelopmental impairment." (p. 18) PFL Normative Charts: **Clarren** et al., 2010; Thomas, et al., 1987; Jones et al., 1978 (infants and very young children); Stromland et al., 1999. Lip/Philtrum Guides and clinical cut-offs: "The University of Washington Lip-Philtrum Guides continue to be the standard for an objective evaluation of lip and philtrum development" (p. 18).	Facial features: Astley, 2013; Astley, 2006; Foroud et al., 2012; Fang et al., 2008; Moore et al., 2007. Lip/Philtrum guides and clinical cut-offs: reference to UW FAS Diagnostic and Prevention Network (FAS DPN).

		"The percentile threshold has been removed from the PFL criterion due the lack of standardized norms for this measure in the UK" (p. 19).	

Appendix F Table 3. Growth Criteria and Reasoning

Inclusion of growth impairment and definition			
Guideline	**Relevant guideline content**	**Reasoning provided**	**Supporting citations[a]**
4-Digit Code (2004)	FAS: Prenatal **or** postnatal height and/or weight ≤ 10th percentile.	"Key updates to the 3rd edition include… modification of the growth deficiency case-definitions to harmonize with the U.S and Canadian diagnostic case-definitions for growth deficiency. This modification allows one to document and differentiate growth deficiency at both the 3rd and 10th percentiles" (p. iii). "Inter-correlations between growth, face, brain, and alcohol, confirmed to exist in laboratory-based studies of alcohol teratogenicity" (p.426). Growth charts: CDC	Astley et al., 1999; Astley et al., 1995.
Australian (2016)	Not included.	"In some study populations, children exposed to prenatal alcohol exposure have growth deficiency which is relatively consistent over time and correlates with severity of neurodevelopmental impairment. However, *growth impairment is no longer considered diagnostic of FASD* due to the range of factors which can influence growth in an individual in combination with prenatal alcohol exposure. Recent evidence and clinical experience suggest that growth impairment is neither sensitive nor sufficiently specific to indicate a FASD diagnosis" (p. 37).	Cook et al., 2016 (Canadian guideline); Astley, 2004 (4-Digit Diagnostic Code); Astley, 2013.
Canadian (2015)	Not included.	"The predictive value of growth deficiency especially in the absence of documented prenatal alcohol exposure has been queried. Recent evidence, plus clinical experience suggest that growth is neither sensitive nor sufficiently specific to indicate an FASD diagnosis. Other contemporary diagnostic approaches have relaxed the criterion for growth deficiency in making the diagnosis, although not removing it entirely. Following an analysis of historical clinical reports, basic science, and clinical research, the committee supported the recommendation to remove growth as a diagnostic criterion" (p. 45).	O'Leary et al., 2009.

CDC (2004) ***FAS Only**	FAS: Prenatal or postnatal height **or** weight or both ≤ 10th percentile, documented at any one point in time.	"The SWG reviewed available literature, clinical expertise, and practical issues to arrive at benchmarks for each of these three aspects [parameters, severity, timing] of growth abnormalities" (p. 10). "However, because multiple organic factors can lead to growth deficiencies (e.g. brain structure abnormalities leading to poor skeletal growth or disruption of endocrine function leading to poor weight gain), and because most children with FAS are symmetrical for height and weight, it was determined that deficiencies in *either* height or weight, but not height for weight, should be included as growth parameters that might be affected by FAS" (p. 10). "For public health reasons of capturing the largest number of children who might need services, the 10th percentile was chosen by the SWG" (p. 11). Growth charts: None suggested.	Coles et al., 1991; Jacobson & Jacobson, 2002.
DSM-5 (2013)	*DSM-5 does not include guidelines for the diagnosis of FAS or other conditions on the fetal alcohol spectrum with growth restriction.*	N/A	N/A
German (2013) ***FAS Only**	FAS: Birth weight or body weight ≤ 10th percentile, **or** Birth length or body length ≤ 10th percentile **or** Body mass index ≤ 10th percentile.	"The recommendations of the guideline group regarding abnormalities of growth are predominantly based on these two studies" (p. 441). Growth charts: None suggested.	Klug et al., 2003; Day et al., 2011.
Revised IOM (2016)	FAS: Height **and/or** weight ≤ 10th percentile.	"We define growth deficiency as ≤ 10th percentile" (p.6). Growth charts: WHO growth charts for 0-2 years; CDC for 2-19 years; Oken et al. (2003) for prenatal growth restriction.	Hoyme et al. 2005; CDC 2004.
Scottish (2019)	Not included.	No statements/summary of research provided.	No citations.

Appendix F Table 4. Neurodevelopmental Impairment Criteria and Reasoning

Guideline	Relevant guideline content	Reasoning provided	Supporting citations[a]
Definition of impairment in neurodevelopment – structure and function			
4-Digit Code (2004)	*Brain structure and neurology:* Rank 4: Microcephaly = OFC **≥ 2 SD** below the mean **or** Significant brain abnormalities of presumed prenatal origin (i.e., hydrocephaly, heterotopias, change in shape and/or size of brain regions) **or** Seizures not due to a postnatal insult or other postnatal process **or** Other hard neurological signs of presumed prenatal origin. *Brain function:* Rank 3: Significant impairment (**≥ 2 SD** below the mean) across **three or more domains** including, but not limited to: executive function, memory, cognition, social/adaptive skills, academic achievement, language, motor, attention, or activity level. Scores must come from standardized psychometric tests. Rank 2: Evidence of delay/dysfunction that suggest the possibility of CNS damage, but data to this point do not permit a Rank 3 classification. Evidence can come from standardized psychometric tests, observational data, and/or caregiver interview. FAS, pFAS, Static encephalopathy = Rank 3 or 4. Neurobehavioral disorder = Rank 2.	Microcephaly and cutoffs: "Head circumference 2 or more standard deviations below the mean has been associated with mental deficiency in the literature" (p.36). Brain function domains and cutoffs: "It was important to establish a method that quantified the breadth and magnitude of dysfunction (e.g., the number of domains of function 2 or more SDs below the mean as measured by standardized psychometric tools administered by a clinician) without unduly constraining which domains must be impaired" (p. 440). "The 3 CNS Ranks in the 4-Digit Code were case-defined to predict increasing likelihood of underlying structural brain abnormality… Many significant correlations were identified between CNS dysfunction and brain region volumes, but perhaps most striking was the significant, inverse, linear correlation between increasing CNS dysfunction (CNS Ranks 1,2 and 3) and decreasing caudate volume" (p. 440).	Microcephaly and cut-offs: Astley, 2010; Dolk, 1991; Pryor & Thelander, 1968. Brain function domains and cutoffs: Astley, 2010; 2011; Astley & Clarren, 1997; Astley et al., 2009.
Australian (2016)	*Brain structure and neurology:* OFC = < 3rd percentile or **≥ 2 SD** below the mean **or** Structural brain abnormalities associated with PAE (i.e., overall brain size, corpus callosum agenesis or hypoplasia, reduced gyrification or surface area of the cerebral cortex, reduced volume in cerebellum, hippocampus, basal ganglia) **or** Seizures not due to a postnatal insult or other postnatal process **or** Significant	Domains: "In FASD, ten domains of neurodevelopment have been identified that reflect areas of brain function known to be affected by PAE, based on evidence from human and animal research and clinical experience" (p. 13). "A FASD diagnosis requires objective evidence of *severe impairment* of brain function in *at least 3* of these 10	Domains: Cook et al., 2016. (Canadian Guidelines) Clinical cut-offs: American Psychiatric Association, 2013; Sparrow et al., 2006;

	neurological diagnoses (i.e., cerebral palsy, visual impairment, etc.) without other etiological cause. *Brain function:* Severe impairment (**≥ 2 SDs** below the mean, or less than the 3rd percentile) on a global or major subdomain score on a validated neurodevelopmental scale required in 3 areas of: brain structure/neurology; motor skills; cognition; language; academic achievement; memory; attention; executive function (including impulse control and hyperactivity); affect regulation; adaptive behavior, social skills, or social communication **or** A significant discrepancy (seen in less than 3% of the population) between major subdomain scores on language, memory, or cognition testing, or for academic achievement in relation between cognition and any subject All diagnoses: Severe impairment in at least 3 neurodevelopmental domains (brain structure/neurology or functional)	specified neurodevelopmental domains. The rationale for this is that PAE may cause widespread fetal brain injury and result in pervasive brain dysfunction" (p. 13). Clinical cut-offs: "The 2 standard deviations cut-off is the usual standard for defining a severe level of impairment" (p. 17).	Wechsler, 2016; Bruininks & Bruininks, 2005.
Canadian (2015)	*Brain structure and neurology:* OFC = < 3rd percentile or **≥ 2 SD** below the mean **or** Structural brain abnormalities associated with PAE **or** Seizures not due to a postnatal insult or other postnatal process *Brain function:* 9 domains considered. Severe impairment (**≥ 2 SDs** below the mean) required in 3 areas of: brain structure/neurology; motor skills; cognition; language; academic achievement; memory; attention; executive function (including impulse control and hyperactivity); affect regulation; adaptive behavior, social skills or social communication **or** A significant discrepancy (seen in less than 3% of the population) between major subdomain scores on language, memory, or cognition testing, or for academic achievement in relation between cognition and any subject.	Domains: "There is no single neuropsychological measure, nor pattern of neuropsychological profiles that are specific to all individuals with FASD…However, the most common neurodevelopmental disabilities include attention, executive function, spatial working memory, mathematics, communication, and adaptive behaviour" (Appendix p. 22-23). "The domains in the current list are impacted by prenatal alcohol exposure, can be reliably measured and are not redundant or easily confused with one another" (Appendix p. 37). Clinical cut-offs: "The committee considered comments that the 2 SD was a conservative cut-off for the FASD diagnosis… The 2 SD cut-off is the standard for defining a severe level of deficit in other guidelines (i.e., for	Domains: Abele-Webster et al., 2012; Alvik et al., 2011; Archer, 2011; Astley, 2010; 2013; Burd et al., 2003; Carr et al., 2010; Chudley et al., 2005; Davis et al., 2013; Fjeldsted & Hanlon-Dearman, 2009; Hansen & Jirikowic, 2013; Franklin et al., 2008; Fryer et al., 2007; Grossman et al., 2003; Haley et al., 2006; Hellemans et al., 2010; Kodituwakku, 2007; Manning & Eugene, 2007; Mattson et al., 2013; McCarthy & Eberhart, 2014; Nash et al., 2008; O'Connor & Paley,

	All diagnoses: Severe impairment in at least 3 neurodevelopmental domains (brain structure/neurology or functional)	Intellectual disability in DSM-IV and 5)" (Appendix p. 23). "Using 2 SD as a clinical cut-off for severe deficits corresponds closely to the criteria used by the DSM-5, ICD-10 and guidance from the American Association for Intellectual and Developmental Disabilities. As well, many commonly used scales, including the Wechsler and Stanford-Binet intelligence scales and the Vineland Adaptive Behavior Scales define 2 SD as significantly below the population average and in the range of severe impairment" (p. 23). "A diagnosis of FASD implies that alcohol is a causative factor, not just "associated with" the deficits and there is no empirical data that would support relaxing the clinical cut-off to 1.5 SD. Statistical models of changes to a cut-off score on a battery of neuropsychological tests suggests that small changes in the threshold for diagnosis may have a very large effect on prevalence rates. Finally, this would reflect a major change from the 2005 guidelines without sufficient data to support the change." (p. 24).	2009; Paintner et al., 2012a; 2012b; Pei et al., 2011; Rasmussen, 2005; Riley et al., 2011; Schlotz & Phillips, 2009; Ungerer et al., 2013; Zhang et al., 2005. Clinical cut-offs: American Psychiatric Association, 2013; WHO, 1992; Schalock et al., 2010; Ingraham & Aiken, 1996
CDC (2004) ***FAS Only**	*Brain structure and neurology:* OFC at or **below 10th percentile or** Significant brain abnormalities observable through imaging **or** Neurological problems not due to a postnatal insult or fever **or** Other soft neurological signs *Brain function:* Global cognitive or intellectual deficits representing multiple domains of deficit (or significant developmental delay in younger children) with performance below the **3rd percentile OR** functional deficits below the **16th percentile** (**1 SD** below the mean) in **at least 3** of: cognitive or developmental; executive functioning; motor; attention or hyperactivity; social skills; other, such as	Domains: "Early brain damage is usually generalized rather than specific, with increased specificity of abnormalities revealed as development progresses. The functional abilities affected by prenatal exposure to alcohol vary greatly from person to person, depending on the amount of alcohol exposure, timing of exposure, and pattern or exposure. Despite this inherent variation of effects, several areas of significant functional vulnerability have been observed consistently by clinicians and clinical researchers with particular damage to corresponding structures reported (e.g., corpus callosum, cerebellum, or basal ganglia). (p. 14).	Microcephaly and cut-offs: Jones, et al., 1973; Samson, 1986. Structural: Harris-Collazo, et al., 1998; Johnson, et al., 1996; Jones, et al., 1973; Mattson et al., 1992; Mattson et al., 1994; Mattson et al., 1996; Riikonen, 1994; Riley et al., 1995; Sowell, et al., 1996. Domains: Aaronson, et al., 1985; Brody, 1976;

	sensory problems, pragmatic language problems, memory deficits, etc. FAS: Structural, neurological or functional abnormality as defined above	"For functional deficits, it is generally accepted that multiple locations in the brain (and corresponding functional capability) are affected by prenatal exposure to alcohol. To address this issue, functional deficits that fulfil the CNS abnormality can be met in two ways: (1) Global cognitive deficit or significant developmental delay in children too young for an IQ assessment. (2) Deficits in three or more specific functional domains. … Decreased performance on a standardized measure of cognition/intelligence or development assumes deficits in multiple domains. In the absence of such a measure, several specific domains need to be assessed individually to determine that multiple functional domains have been affected. The specific domains most often cited as areas of deficit or concern for individuals with FAS are described below, although other domains and abilities can be affected and this list is not exhaustive." Clinical cut-offs: "Previous research indicates that approximately one-quarter of individuals diagnosed with FAS perform at the most conservative level of below the 3rd percentile (2 standard deviations below the mean) on standardized measures. In keeping with this finding, and to adequately capture the full spectrum of effects, the SWG adopted two levels of functional deficits that would meet the criteria for a CNS abnormality..." (p. 16-17).	Carmichael-Olson, et al., 1998a; 1998b; Church, 1996; Coles, 1993; Coles et al., 1991; 1997; 2002; Coles & Platzman, 1993; Conner et al., 1998; 2000; Conry, 1990; Goldschmidt, et al., 1996; Goodman et al., 1998; Jacobson et al., 1993; 1994; Janzen et al., 1995; Kaemingk & Paquette, 1999; Kelly et al., 2000; Kerns et al., 1997; Kodituwakku et al., 1995; Kopera-Frye et al., 1996; 1997; Kyllerman et al., 1985; Little et al., 1982; Mattson & Riley, 1998; Mattson et al., 1997; Marcus, 1987; Nanson & Hiscock, 1990; Oesterheld & Wilson, 1997; O'Malley & Nanon, 2002; Pennington et al., 1996; Prifitera et al. 1998; Riley, 1990; Roebuck et al., 1998; 1999; Simmons et al., 2002; Smith et al., 1986; 1987; Stratton, et al., 1996; Streissguth, 1997; Streissguth et al., 1980; 1984; 1986; 1991; 1994; 1995; 1996; Thomas, 1993; Thomas et al., 1998. Clinical cut-offs: Streissguth et al., 1996.

DSM-5 (2013)	*Brain structure and neurology:* not included *Brain function:* Neurocognitive deficits manifested by deficits in one or more of global intellectual performance, executive functioning, learning, or memory **and** Self-regulation deficits manifested by deficits in one or more of mood or behavior regulation, attention, or impulse control **and** Adaptive behavior impairments manifested by deficits in two or more of communication, social communication and interaction, daily living skills, or motor skills, one of which must be communication or social communication and interaction. No specific cut-offs are provided. ND-PAE: 1 or more neurocognitive deficits **and** 1 or more self-regulation deficits **and** 2 or more adaptive function deficits, one which must be in the areas of communication or social communication and interaction.	Domains: "Although these broad domains overlap with other disorders of childhood, specific deficits within them are indicative of ND-PAE" (p. 2). Clinical cut-offs: "However, for diagnosis, it is important to recognize that not all affected children perform in the range of intellectual disability. Clinical research has found that 86% of individuals with FASDs have an IQ in the low average or borderline ranges. The important point is that the child under consideration is functioning below what would be expected relative to his or her peers" (p. 4-6). "Even if global delay or impairment is not present, specific deficits can indicate neurocognitive impairment consistent with ND-PAE" (p. 6).	Domains: Bertrand & Dang, 2012; Burden et al., 2005; Church et al., 1997; Coles, 2011; Crocker et al., 2011; Disney et al., 2008; Kable et al., Kodituwakku et al., 1995; Kooistra et al., 2009; Novick et al., 2012; Oberlander et al., 2010; O'Connor & Paley, 2009; Olson et al., 2007; O'Malley, 2007; Pesonen et al., 2009; 2016 Riley et al., 2011; Riley & McGee, 2005; Scher et al., Steinhausen, 1996; Steinhausen & Spohr, 1998; 1988; Streissguth, 1997; Vaurio et al., 2008; Whaley et al., 2001. Clinical cut-offs: Streissguth et al., 1996.
German (2013) ***FAS Only**	*Brain structure and neurology:* "The guideline group was unable to achieve consensus on this criterion. Thus head circumference **≤ 3rd percentile and ≤ 10th percentile** were both judged to fulfil the criteria." *Brain function:* Global intelligence **≥ 2 SDs** below the mean or significant combined developmental retardation in children under 2 years of age **OR** Performance **≥ 2 SDs** below the mean in at least 3 areas or in at least 2 in combination with epilepsy of: speech, fine motor skills, visuospatial perception or spatial-constructive skills, learning ability or retentiveness, executive functions, arithmetic skills, attention, social skills or behavior.	Structural CNS abnormalities: "Early injury of the brain by alcohol toxicity may be primarily manifested by pathological restriction of growth (microcephaly)." (p. 707) "There is no agreement in the literature of the past 10 years regarding a recorded cut-off value for microcephaly in children with FAS. The guideline group was unable to achieve consensus on this criterion. Thus, head circumference ≤ 3rd percentile and head circumference ≤ 10th percentile are both adjudged to fulfill the criteria for the diagnostic category 'structural abnormalities of the CNS'" (p. 707). "Owing to the limited evidence on structural abnormalities of the CNS such as volume reduction of	Structural CNS abnormalities: Archibald et al., 2001; Astley et al., 2009; Bjorkquist et al., 2010; Day et al., 2002; Geuze et al., 2005; Handmaker et al., 2006; Sowell et al., 2008; Yang et al., 2011. Functional CNS abnormalities: Aragon et al., 2008; Astley, 2010; Astley et al., 2009; Bell et al., 2010; Coles et al., 2002; Fagerlund et al., 2011; Mattson et al., 2010; Pei et al., 2011; Nash et al., 2011;

	FAS: functional or structural abnormality as defined above	the cerebellum and thickening of the cortex, the guideline group agreed that structural CNS abnormalities other than microcephaly cannot currently be used as criteria for the diagnosis of FAS." (p. 707) Functional CNS abnormalities: "The determination of the affected functional brain domains is based on the studies shown in ePub: Table 4" (p. 442). "In summary, no specific neuropsychological profile of children with FAS can be defined because of methodological weaknesses of the available studies" (p. 442). "Because the alcohol-induced damage of the brain may be either general or multifocal, the patient should show deficits in at least three domains to establish the diagnosis of FAS (expert consensus)" (p. 443). "Although there were no control groups in these studies these prevalences for epileptic activity are considerably higher than in the normal population. Therefore, for the diagnosis of FAS, epilepsy combined with deficits in two neuropsychological domains fulfils the criteria "Functional CNS abnormalities" (p. 443).	Rasmussen et al., 2010; Russ et al., 2012; Thorne & Coggins, 2008; Vaurio et al., 2011.
Revised IOM (2016)	*Brain structure and neurology*: Head circumference **≤ 10th** centile **or** Structural brain abnormalities **or** Recurrent nonfebrile seizures (other causes ruled out). *Brain function*: Cognitive: Global intelligence (or performance, verbal or spatial IQ) **≥ 1.5 SD** below the mean **or** Deficit in at least 1 (for FAS/pFAS) or 2 (for ARND) neurobehavioral domain(s): executive functioning, specific learning, memory or visual-spatial **≥ 1.5 SD** below the mean **– OR –** Behavioral: Deficit in at least 1 (for FAS/pFAS) or 2 (for ARND) domain(s) **≥ 1.5 SD** below the mean in self-	Structural CNS abnormalities: "we have added documentation of recurrent nonfebrile seizures to the potential assignment of children to the diagnostic categories of FAS or PFAS… This modification was prompted by a growing body of research that indicates that epilepsy is a frequent accompaniment of FASD. More commonly observed in children with FASD, a small head circumference is a reliable, easily obtained proxy for decreased brain volume. Finally, a number of structural brain anomalies have been observed in	Structural CNS: Bartholomeusz, 2002; Bell et al., 2010; Mattson et al., 2001; Nicita et al., 2014; Treit et al., 2015. Domains: Aragon et al., 2008; Brown et al., 1991; Ceccanti et al., 2014; Coles et al., 1985; 1991; 1997; 2002; 2010; Connor et al., 2000; Hannigan et al., 2010; Howell et al.,

	regulation (mood or behavioral regulation, attention, or impulse control) **– OR –** (for FAS/pFAS only) For children <3 y of age, evidence of developmental delay **≥1.5 SD** below the mean. FAS: 1 or more deficit of brain structure and neurology **AND** Cognitive **or** Behavioral **or** Developmental delay (for children <3 y of age) pFAS with documented PAE: Cognitive **or** Behavioral **or** Developmental delay (for children <3 y of age) pFAS without documented PAE: 1 or more deficit of brain structure and neurology **or** delayed height and/or weight **AND** Cognitive **or** Behavioral **or** Developmental delay (for children <3 y of age) ARND: Cognitive **or** Behavioral impairment	imaging studies in animals and human subjects with FASD" (p. 9). Domains: "because neurocognitive impairment and abnormal behavior are the principal sources of disability in FASD, assignment of children with prenatal alcohol exposure into an FASD category without neurobehavioral impairment has no practical utility for either the child or the child's family" (p. 9). "These functional domains were selected based on the empirical evidence of deficits in children prenatally exposed to alcohol and/or have been given a diagnosis of FASD" (p. 11). "the cognitive and neurobehavioral phenotype of affected children evolves predictably over time and can be correlated with areas of brain vulnerability" (p. 7). Clinical cut-offs: "Our previously published data confirm that because the dysmorphology score has the highest correlation with confirmed diagnoses in the FASD continuum, confidence in an FAS or PFAS diagnosis can be ensured with impairment in fewer neurobehavioral domains" (p. 11).	2006; Hoyme et al., 2005; Kodituwakku, 2009; Mattson et al., 1996; 2010; 2013; May et al., 2011; 2013; Olson et al., 2007; Stratton et al., 1996; Streissguth, 1986; Ware et al., 2013; Willoughby et al., 2008. Clinical cut-offs: May et al., 2011; 2013.
Scottish (2019)	*Brain structure and neurology:* OFC = < 3rd percentile or **≥ 2 SD** below the mean **or** Structural brain abnormalities associated with PAE **or** Seizures not due to a postnatal insult or other postnatal process *Brain function:* Severe impairment (**≥ 2 SDs** below the mean) required in 3 areas of: brain structure/ neurology; motor skills; cognition; language; academic achievement; memory; attention; executive function (including impulse control and hyperactivity); affect regulation; adaptive behavior, social skills or social communication **or** A significant discrepancy	Domains: "It is well established that learning disabilities, inattention, social, and executive function deficits can occur regardless of facial dysmorphology. There is no single neuropsychological measure, nor pattern of neuropsychological profiles that is specific to all individuals with FASD" (p. 9). "Canadian guidelines from 2005 and 2016 consistently recommend that significant deficits in at least three CNS areas of assessment are required for a diagnosis or descriptor of FASD" (p. 19).	Structural CNS: Glass et al., 2014; Mattson, et al., 2001. Domains: Chudley et al., 2005; Cook et al., 2016; Davis et al., 2013; Greenbaum et al., 2002; Kodituwakku, 2007; Kully-Martens, 2012; Malisza et al., 2012; Manning & Hoyme, 2007; Mattson et al., 2011; Nash et al., 2008; Paintner et

	(seen in less than 3% of the population) between major subdomain scores on language, memory, or cognition testing, or for academic achievement in relation between cognition and any subject. All diagnoses: Severe impairment in at least 3 neurodevelopmental domains (brain structure/neurology or functional)	Clinical cut-offs: No statements/summary of research provided.	al., 2012; Rasmussen, 2005; Riley et al., 2011.

Appendix G: Advisory Group priority setting survey

Advisory Group Input

Please complete the survey below.

Thank you!

Thank you for agreeing to take part in an Advisory Group for the Review of the Australian FASD Assessment and Diagnostic Guideline.

We are collecting the information in this survey from all Advisory Group members. The information will be collated and summarised, provided back to you and used to facilitate discussions during the Advisory Group sessions. We are also planning to use the responses to these questions for research purposes.

Study Information Sheet

[Attachment: "Advisory Group Online Survey Information Sheet V3 23.2.21.docx"]

If you have any questions about the research after reading the information sheet please email n.reid1@uq.edu.au

CONSENT FORM

.) By clicking this box, I voluntarily consent to participate in the above research project.

- I have read, or had read to me in my first language, the information statement version listed above and I understand its contents.
- I believe I understand the purpose, extent and possible risks of my involvement in this project.
- I understand that I am free to withdraw at any time during the research project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that this project has been approved by Children's Health Queensland Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007) - updated May 2015.

◯ Yes I consent

The next couple of questions are to gather some basic information about you.

!) Please indicate which Advisory Group/s you are a member of?

☐ Clinician/Other Specialist
☐ Researcher
☐ Cultural
☐ Lived Experience

3) Which state/territory do you reside in?

- ◯ New South Wales
- ◯ Victoria
- ◯ Queensland
- ◯ Western Australia
- ◯ Tasmania
- ◯ Australian Capital Territory
- ◯ Northern Territory
- ◯ South Australia

4) What is your gender?

- ◯ Male
- ◯ Female
- ◯ Non-binary

5) What is your primary discipline area and/or work role?

_____

6) How many years of experience do you have in this area?

_____

7) How many years experience do you have working with individuals with FASD?

_____

For the next questions, please list and describe up to five priorities that you think are important for the review of the Australian FASD Assessment and Diagnostic Guide.

8) Priority 1:

_____

9) Priority 2:

_____

10) Priority 3:

_____

11) Priority 4:

_____

12) Priority 5:

_____

13) Are there any other topics or ideas at this stage that you would like to raise for discussion during the Advisory Group meetings?

_____

Appendix H: Advisory Group evidence to decision framework survey

Advisory Group Input: Overarching Evidence to Decision Framework

Thank you for taking the time to complete this survey.

The information from this survey will be used to create an overarching Evidence to Decision Framework for the diagnostic criteria. Your suggestions will be used to improve wording in the Guidelines document and support clinicians with implementing the diagnostic criteria in practice.

The results of this survey will also be used for research purposes to describe the methodology that has been used to develop the diagnostic criteria.

If you have any questions about this survey please free free to email fasdguidelines@uq.edu.au

Advisory Group Member Type	☐ Lived Experience Advisor ☐ Cultural Advisor ☐ Clinician Advisor ☐ Research Advisor (Please select all options that apply. Please note questions will be tailored based on your response to this question.)
State/Territory you are based in	◯ Northern Territory ◯ Australian Capital Territory ◯ Victoria ◯ New South Wales ◯ Western Australia ◯ Queensland, ◯ Tasmania ◯ South Australia
Is assessment and diagnosis of FASD a priority in Australia? (i.e., based on consequences of not diagnosing or inaccurate diagnosis, urgent need, recognised as a priority based on political or policy decisions?)	◯ Yes ◯ No
Why is diagnosis of FASD a priority in Australia?	_____
Why is diagnosis of FASD not a priority in Australia?	_____
As a person with lived experience of FASD, do you feel the diagnostic criteria are aligned with your personal values and preferences for how you would like to experience assessment and diagnostic services?	◯ Yes ◯ No
Please describe any changes we could make to better suit your personal values and preferences in how you would like to experience assessment and diagnostic services	_____
Please provide any information about how you feel the diagnostic criteria align with your personal values and preferences	_____

What would be the increased resource requirements?	_____
How would resource requirements decrease?	_____
Are there groups or settings that might be disadvantaged in using the diagnostic criteria?	◯ Yes ◯ Probably yes ◯ Probably no ◯ No ◯ Varies
Please describe any groups or settings that may be disadvantaged by the new diagnostic criteria	_____
Would the new criteria result in an increase or decrease in health equity compared to the current criteria?	◯ Increase ◯ Decrease ◯ No change
How would the new criteria result in an increase in health equity?	_____
How would the new criteria result in a decrease in health equity?	_____
What considerations should be made when implementing the diagnostic criteria in order to ensure inequities are reduced?	_____
Is the new criteria acceptable to use in clinical practice?	◯ Yes ◯ Probably yes ◯ Probably no ◯ No ◯ Varies
What changes would need to be made for it to be acceptable for you to use?	_____
Are there key stakeholders that would not accept the distribution of the benefits, harms and costs resulting from use of the diagnostic criteria?	◯ Yes ◯ Probably yes ◯ Probably no ◯ No ◯ Varies
Please describe what would not be acceptable in terms of the distribution of benefits, harms and costs of using the diagnostic criteria	_____

Would the proposed criteria negatively affect people's autonomy (i.e., rights of people attending for assessment and their family/support network to make their own decisions)?	◯ Yes ◯ Probably yes ◯ Probably no ◯ No ◯ Varies
Please describe how the criteria could negatively affect people's autonomy	_____
Would the proposed criteria positively affect people's autonomy?	◯ Yes ◯ Probably yes ◯ Probably no ◯ No ◯ Varies
Please describe how the criteria could positively affect people's autonomy	_____
Are there key stakeholders that would disapprove of the diagnostic criteria for reasons other than its effects on people's autonomy (i.e. in relationship to ethical principles such as non-maleficence, beneficence or justice)?	◯ Yes ◯ Probably yes ◯ Probably no ◯ No ◯ Varies
Please describe any concerns people may have about the criteria	_____
Is the new criteria feasible for you to use in practice?	◯ Yes ◯ Probably Yes ◯ Probably No ◯ No ◯ Varies
What changes would need to be made for it to be feasible for you to use in practice?	_____
Are there important barriers that are likely to limit the feasibility of implementing the proposed criteria?	◯ Yes ◯ Probably yes ◯ Probably no ◯ No ◯ Varies
Please describe any barriers that limit feasibility that we should take into consideration	_____
Is the diagnostic criteria sustainable for you to use in practice?	◯ Yes ◯ Probably yes ◯ Probably no ◯ No ◯ Varies

What changes do we need to make to ensure the diagnostic criteria is sustainable for you to use in practice?	_____
What are the potential downstream implications of adopting these new criteria? (e.g., likely to result in net benefit or harm? any potential unintended consequences?)	_____
Are there additional key assessment principles that should be included?	◯ Yes ◯ No
What additional assessment principles should be considered?	_____
Is there additional information that we haven't covered in this survey that should be included in the diagnostic criteria?	◯ Yes ◯ No
Please describe any additional information that should be included in the diagnostic criteria	_____

Appendix I: Advisory Group Feedback Summary

Australian Guidelines for Assessment and Diagnosis of FASD/ND-PAE

Advisory Groups Feedback Summary

Feedback has been combined across people/organisations and ordered by page numbers where possible.

Feedback on the main guidelines document: Introduction & Foundational Considerations sections	
Comments/suggestions	*Responses - highlighted in green for minor changes completed; highlighted in blue where comments have been provided and no responses were required.*
Question re.: TITLE – Australian Guidelines for..... Should it be Australia Guideline for ..... – as to speak to the full document (singular) rather than the guidelines (plural) included within the document. This would be across all document titles and within each report/document.	We initially used the word 'guideline' but through discussion with Guidelines Development Group this was decided that guidelines was the most appropriate title. This is also consistent with NHMRC https://www.nhmrc.gov.au/guidelinesforguidelines
Dedications page 5: wonderful women deserving of respect. A couple of grammar errors are a distraction.	
Minor change: Pg 7. Should it read 'including *the* late Dr Janet Hammill'?.	
The message from the cultural advisory group is extremely moving, page 7-8	
p.7, para. 1: 'The guidelines arising from the 2020-2024 review has intentionally...' should be 'The guidelines arising from the 2020-2024 review have intentionally...' (guidelines is plural, as opposed to guideline).	

P .8: Questioning use of mainstream "We assert that all mainstream guidelines should embed – Could this read "We assert all guidelines should embed.... - although understand this is a message from the Cultural Advisory Group – so are their words.	
P12 point 7 Feedback and support planning – can this be expressed in a more strengths-based way; eg. strength-based pathways is also mentioned regarding First Nations people. Service provision planning is mentioned in the intro for example. Resource planning is another option (that could cover anything from education to parents to specific school programs and healthcare) (clearly pushes responsibility back to services). I note support planning occurs through the document.	
p.14: Suggested reword – However, this lack of consistency and standardisation complicates research and diagnostic processes, in turn impacting individuals and their families.	
p.14: Suggested edit: The current guidelines [or guideline] put[s] forward an approach to advancing the diagnostic criteria for FASD/ND-PAE.	
Minor change Pg. 15, final paragraph: instead of 'in the current project' could it be 'in the development of these guidelines'?	
p.15: Add comma: The diagnostic criteria are described in such a way that all the relevant features of the condition can be documented for each individual attending for assessment, regardless of the diagnostic nomenclature. (sentence length comma required).	
P16 'intervention' pathways – would it better to use words like support and development pathways. Intervention among First Nations people has certain connotations but also 'intervention' is not really what we are looking for from service providers? The word 'intervention ' is used often in the document, it may be unavoidable but could be checked at each point it is used to see whether something else could be used instead that is less infused with state and expert power and control.	

P16 similarly 'children's language problems' – could we say something to make this more neutral /solvable and not located in the child as a problem and also pushes responsibility back to society's response possibly 'language development' could be used in some places – this could be consistent with the general approach to diagnosis – linked to assessment against age development etc. (A problem is only a problem when it's not responded to appropriately -even difficulty may be better).	Changed wording to 'language impairments'
p.16: Suggested reword: In developing the diagnostic criteria and actionable statements (i.e., recommendations), the Guidelines Development Group aimed to balance the level of detail and structure that clinicians need, with the flexibility to support appropriate implementation of the guidelines at the individual client level.	
p. 17, 1st paragraph last line delete 'the' before….. 'cut offs'	
p.17: Overall objectives: Should this be in present tense – aims to rather than were developed to – see below. These clinical practice guidelines aim to support clinicians in undertaking assessments across the lifespan when one possible outcome may be a diagnosis of FASD/NDPAE.	
p.18: in the list of disciplines, could it please say 'speech pathology' (not 'speech-language pathology')	
*Typo in the quote on page 20. Should read "… diagnostic *and* nosological…"	
P21 I really liked the discussion of history regarding Indigenous people/alcohol and the human rights framework. However, I was left with the idea that Aboriginal people were the only ones being soaked in alcohol as a result of colonisation process. I wondered whether there should be something about how much non-Indigenous people in Australia drink too, and how much of a part of Australian culture alcohol is. While Indigenous people are overrepresented in diagnoses of FASD this is obviously not to say	This feedback was discussed and the GDG felt it would not be appropriate to discuss the role alcohol plays in the broader Australian culture in this particular section where the history of colonisation and its ongoing impacts on Aboriginal and Torres Strait Islander peoples is unpacked. The letter introducing the guideline from the Cultural Advisory Group captures this

there are many other non-Indigenous people who are affected by FASD but may not have that diagnosis (may seek a less stigmatising diagnosis of ADHD etc.)	point and acknowledges that FASD and alcohol harms are not "Aboriginal problems" but speak to a societal issue.
- p27, paragraph 2 – the wording of "yarning... enables... improved understanding for *clinicians, individuals with FASD/ND-PAE, and their families*" seems to imply that there is a presumption of a diagnosis if an assessment is considered warranted. We think it is important to capture that many individuals who undergo assessment for FASD/ND-PAE will *not* meet the criteria, and while they may have other issues/conditions/strengths, they too will benefit from shared decision-making in cases of non-diagnosis. Suggested change to include "individuals undergoing assessment for FASD".	Wording has been updated to "individuals attending for assessment." Please note we have tried to avoid using wording of "assessment for FASD/ND-PAE" throughout the document, as we do not want to suggest that assessment should only be focused on FASD/ND-PAE. Rather we want to encourage clinicians to have an open mind and consider all possible outcomes as part of any assessment. Thus, wording of "assessment where one possible outcome may be a diagnosis of FASD/ND-PAE" or assessment and diagnosis of FASD/ND-PAE has been used where appropriate.
- p27, paragraph 3 – 'informed consent' could be elaborated to include explicit recommendation to discuss both the pros and cons of assessment (including some of the diagnostic challenges such as no specific phenotype) and a FASD diagnosis. Given the harms from misdiagnosis, or even from correct diagnosis (e.g. shame/blame), open discussion as part of informed consent is essential in FASD assessments, and the guide needs to reinforce this, given observed over-diagnosis in the sector (WA) with apparent little regard for the consequences of mis/over-diagnosis.	Due to this being the Introductory section of the document, this has not been elaborated on here. The informed consent and shared-decision making framework sections of the document include information about the importance of openly discussing potential harms and risks of assessment and diagnosis.
P29 re dot point Dysfunction – I would bold impairments in that para too given that language is also used often and it is used in next dot point so helps to understand it's defined.	Italized the impairments and functional impacts as the common terms that are used.
The use of quotes throughout the documents from clinicians/stakeholders/ individuals with lived experience is a great addition to the document.	
The introduction is well written and clearly states the premise/ethos of which these guidelines have been developed including acknowledgement of past researchers/communities who have been foundational in advocating for the FASD communities and how their work has been beneficial to developing pathways that are strength based and inclusive. It enables the reader to appreciate the effort and	

evidence over time across diverse groups/communities that have informed the new diagnostic document. It is positive that Person level factors are emphasised– client's values, need, preferences and cultural context – as we can minimise their importance at times especially in health care due to parameters in which we are required to work – more evidence around this would be good to see as an economical way to meet health outcomes and client safety. Nice clear objectives, noting desired users and the aim to be an inclusive approach relevant to a wide range of settings beyond clinical. Love the 4 key research questions – encompasses all things that we question in this area across all stakeholders.	
This whole section is excellent. Complex processes and approaches are described in clear and precise language, providing readers with an understanding of the nuances around the diagnostic processes.	
The second paragraph under "Indigenous Framework" is a compelling overview of the impact of trauma experienced by Aboriginal and Torres Strait Islander peoples since invasion and I'm sure I'll be referring to this paragraph in many other contexts.	
I respect the Aboriginal culture and their unique ways of knowing, being and doing and the Framework is excellent in supporting aboriginal communities and enabling clinicians. The focus should be on this framework with the premise there has been a great injustice since colonisation. Great to see there is a document specifically informing clinicians to accompany the guidelines that gives more specific details.	

These sections are long and there may be some negative feedback in this regard, however I think that the principles explained here are central to the diagnostic process and are not necessarily well understood by clinicians or other stakeholders and I would resist any pressure to reduce the content here.	
Love the explanation around risk and disease and developmental psychopathology – ie applying a wider lens	
I strongly support the decision to include the alternate options of diagnostic terminology FASD and ND-PAE.	
Multi-culturalism that we find in Australia and how culturally and linguistic diversity needs to be considered is mentioned further in the document but wondering if we also need to include this in the foundational considerations?	We have included additional information at the end of the Indigenous Framework section regarding how improving accessibility of services for Aboriginal people will improve accessibility of services for all Australians. As you have noted, we include cultural and linguistic diversity throughout the document. It is critical to acknowledge that these Guidelines were developed on the stolen ancestral lands and waterways of Aboriginal and Torres Strait Islander peoples, where ongoing colonial attitudes, practices and policies continues to undermine equitable access to Australia's Traditional custodians. In the spirit of truth-telling, solidarity, and healing, the FASD Indigenous Framework shares an equal and important platform with the Guidelines.
Thank you for the opportunity to provide feedback on these documents. The documents and the information and guidance they provide is very comprehensive. It is clear that there has been extensive consultation with a range of stakeholders, and I particularly value the shift from a bio-medical focus of diagnosis to the consideration of a more holistic focus including the use of disability language and frameworks, human rights conceptualisations, First Nations worldviews and the inclusion of wisdom from lived experience.	

I have not come across the term 'actionable statement' before and was initially a bit confused about what these were and that this was the first thing the reader comes across after the dedications. Is this term analogous to 'recommendations' or 'recommendations for practice'? If so, perhaps more plain language could be used for this section, which comes right at the start?	Have included the word 'recommendations' in brackets for many of the first uses of this terminology throughout the Introductory section of the document.
Feedback on the main guidelines document: Assessment Principles & Diagnostic Criteria sections	
Assessment Principles – nice and clear and easily accessible – all makes sense and relevant across disciplines approaches to assessment and clinical decision making. The further guidelines for regarding PAE level is very useful. Love emphasising the point that clinicians need to be competent and seek discipline specific supervision and interprofessional collaboration to support clinical impressions and decisions around diagnosis and not to rely solely on standardised scores – especially when current tools are not normed across all populations and that we need to be provide person centred and culturally responsive assessments.	
Assessment Principles: Excellent again. Great that this allows for professional judgment and shared decision making to determine the most appropriate assessment tools in a given context, and the focus on professional assessment and consideration rather than arbitrary cut-offs on standardised tests. This reads like a text-book on best practice in developmental assessments. Working in remote Aboriginal and Torres Strait Islander communities, we're continually frustrated by approaches that require us to perform standardised assessments that we know are not appropriate for our clients in order for them to have disabilities recognised by NDIS or Education providers. This guideline gives us freedom to provide what we know is best practice. This approach will both increase the access to diagnosis for people in resource-poor settings, while also reducing the number of inappropriate diagnoses based purely on meeting arbitrary diagnostic thresholds without a full consideration of the whole picture.	

Really appreciate having the actionable statements embedded in the guidelines.	
P30 should dot point say 'we' or 'clinicians are' - its sounds like it is about the authors?	
Page 31: thank you for specifying reassessment is not required.	
As noted at the start of this section, as noted earlier in this document – could different wording be used to reference previously highlighted/ discussed information. Maybe refer to the section title you are referencing.	
p.31: For individuals already with a diagnosis of FASD under previous criteria, reassessment is not required, unless clinically indicated. (suggest deleting *please note*).	
- p31, paragraph 1 – PAE can result in a wide range of whole-body outcomes from subtle to severe – 'subtle' should be changed to 'negligible'. We aren't aware of any definitive evidence that PAE *always* results in some impairments or adverse outcomes, despite the obvious needs to recommend no alcohol in-utero as risk reduction for health messaging.	We have used wording of 'can result' in this sentence to indicate that PAE does not always result in adverse outcomes.
-p31, paragraph 4 – [suggested addition] In line with a 'developmentally informed approach' clinicians should also consider whether there are other diagnoses, conditions or factors that can explain the neurodevelopmental impairments reported or observed on testing. Correct attribution of these impairments to their true causes increases the likelihood for accurate understanding of the individual and thus enabling targeted interventions.	Due to space limitations for this section this information is not repeated. This point is addressed in detail in Criterion E. Further information has also been added to the additional information section for Criterion B regarding this point.
-p31, paragraph 5 – 'assessment and diagnosis of FASD/ND-PAE can and should take place across the lifespan, especially at times of transition" – it should also be noted here that times of transition (such as becoming involved with the Justice system) are stressful and difficult for many individuals, and these reactions (i.e. may be developmentally expected) need to be carefully considered as potential explanations for observed cognitive and behavioural impairments, particularly in the social-emotional domain.	

Page 32-34: The formatting for the diagnostic criteria could be altered to aid readability. For example, having the A,B,C,D,E components in blue and the sub points underneath them with a white background.	We have spaced out the wording in the box to try improve readability. We would prefer to keep all the diagnostic criteria information in the one box.
P33 E 'better' or 'more appropriately'?	Wording of 'better attributed' or better explained is common nomenclature when discussing differential diagnosis and thus has been retained here.
P34 associated with 'sleep disorders' or sleep disruption or something else? (Disorder sounds medicalised – when child might be hard to settle which may be normal but with other things might add up etc)	We are wanting to identify concerns here that are not typical but are of a level of concern and requiring support.
- p34, heading 'Co-occuring conditions' – Suggested addition: Where an individual is found to meet criteria for multiple diagnoses (e.g. ADHD and FASD when looking at impairment in attention, executive function and social functioning domains), care should be taken to establish the possible overlap of those symptoms, and consider whether multiple diagnoses provide additional explanatory power to assist in understanding the individual's needs. This will enable interventions to be appropriately targeted and improve understanding of the person.	
As the current diagnostic criteria reads, it seems that infants (and potentially toddlers) will no longer be able to be diagnosed with FASD (old FAS) at birth as they will not be evidence of the B and C criteria, and domain 1 'Brain structure/Neurology' has gone. Is this the intended outcome? While I can see the benefit of children being identified as 'at risk' and then tracked, I wonder about how the potential for them to become to lost in the system. Some clinics have good follow up processes but not all kids remain within the health systems of their birth. They move, they change providers, and their medical information does not always follow them. This may particularly be the case for kids who have been taken into the out of home care system. It also seems the decision to include an 'at risk' designation has in part been informed by access to early intervention services enshrined in current health policy which do not require a FASD diagnosis.	There is a note included as part of criterion B that still allows for diagnosis of infants and young children in these situation. We have also provided additional explanatory notes in the additional information section for assessment of infants and young children.

However policies and the requirements to access a service can change over time. Could this designation require further consideration?	
Given the size of the overall document, could consideration be given to referring by page number for additional information under each criterion? E.g. 'see page 36 Additional Information'. If we take Criteria A, for example, it is not clear *who* is and who is not appropriate to provide 'collateral reports from individuals who directly observed PAE (p. 32). The concern that came to my mind is that reports may be from family members or others who have an acrimonious relationship with the mother. If a clinician were not to refer to the section on Additional Information (p. 35) they may not consider some of the complex issues here. I believe there may be a benefit in being more explicit about these complexities of collateral reports.	We did previously have points throughout the criteria directing to the additional information sections but found this increased the length and wordiness of the criteria section too much. Instead, the layout of the additional information sections were changed to be more clearly linked to each criterion, including specific headings indicating which criterion each section is pertaining too. Further information has been added to the Criterion B additional information section regarding clinicians needing to be careful regarding who is providing collateral reports.
Page 32: "directly observed the PAE" – I think this could be clearer. We get a lot of "I saw her drunk" which we don't count, (lots of things can make a person seem like they're drunk) and we only take observer when they specifically saw the consumption of alcohol.	Changed to 'directly observed the prenatal alcohol use' to make this more specific. Being mindful that we are trying to language of 'prenatal alcohol use' or 'prenatal alcohol exposure' to focus on the exposure, not on the behaviour of the pregnant women/person as per available FASD language use guidelines.
Page 32, last paragraph (box) – 1. "Evidence consistent with a heavy-to-moderate level" – not sure why wording is not 'moderate-to-heavy'.	We had specifically worded it this way based on the available evidence i.e. that based on the evidence we are focused on heavy and above exposure for diagnosis, with the option for clinicians to scale down to include moderate exposure if they believe this is clinically indicated. Further refinement of the wording of Criterion A has been undertaken to improve clarity and implementability.
Aspects that I much prefer: the requirement to substantiate moderate to heavy prenatal alcohol exposure, rather than any, is something that I am much happier with.	

Overall consideration: Is there a reason it's "heavy to moderate" PAE not "moderate to heavy". Completely the same thing, but conventionally we often use smaller to larger when giving a range.	As per above.
p. 33 Infants and young children: I found this confusing, coming as it does, just below Criterion A2, that in the absence of information on PAE, the presence of the three facial features can be taken as indicative of PAE. Why then must 3FF AND confirmed heavy-moderate PAE be required? Later in the text, there is some explanation of why clinically it was thought that this was a recommended cautious approach. I wonder if some additional explanation in the Note on p 33 and/or a link to the fuller consideration would assist in reducing the reader's confusion?	Wording has been adjusted in criterion A2 to "may be considered." The aim of this wording and content included throughout the document is to provide clinicians with flexibility regarding use of 3 facial features in consultation with individuals/families/community regarding the appropriateness of this. As per the point above we removed all the links to the additional information as it was making the criteria too wordy. Have included an extra reference to the additional information section regarding facial features assessment earlier to help direct readers to where to find the information for Criterion A2.
** page 33 first line: "In the absence of PAE…" seems to be saying that it's possible to diagnose FASD/ND-PAE in someone who did not have PAE. Need to change to something like: "In the absence of a confirmed history of PAE…" **	
Assessment of neurodevelopmental impairment in the FASD construct The requirement of 3 neurodevelopmental impairments in FASD is obviously arbitrary. Presumably a minimum of 3 is meant to suffice to indicate that diffuse brain injury has occurred from PAE. I do not necessarily agree with this proposition that 3 neurodevelopmental impairments (of any type) is likely to indicate diffuse brain injury, nevertheless if one accepts this prima facie then it must also follow that probably all neurodevelopmental disorders are also diffuse brain disorders too It stands to reason because the clustering of 3 or more neurodevelopmental impairments is so common as to be the *norm*. And this is regardless of PAE or not. This is backed by decades of research and clinical practice.	Further information has been added to the Criterion B additional information section pertaining to this point. Additional information has also been added to the co-occurring conditions section, as detailed above. We agree that this is arbitrary and not ideal, but currently we need future research to be able to inform changes to the clinical cut off that is being applied. Notably, this is a higher threshold than is currently set in some other diagnostic criteria internationally for FASD.

The point to be made here is obvious - having 3 or even more neurodevelopmental impairments in a child is not exceptional and is in no way discriminatory for PAE itself. I think this point needs to be made explicitly in the guidelines to avoid misunderstandings about the nature of FASD/ ND- PAE. Furthermore, the evidence from observational studies regarding an association between PAE (at different levels) and neurodevelopmental impairments is frequently lacking in precision, reliability and the studies are prone to serious bias (see below for more comments on the evidence). And I, and others, have noted that several of the select neurodevelopmental domains included in the criteria are neuropsychological parameters that are very closely inter-related (eg memory, attention, executive functioning, cognition) and their clinical and functional relevance has not been well elucidated. Further, the neuropsychological domains included do not have discriminatory power or specificity for PAE and this is not explicitly stated.	Importantly, the neurodevelopmental part of the diagnostic criteria is not being considered in isolation, Criterion A is the first and primary criterion and the neurodevelopmental impairments are considered in the context of the PAE evidence. The neurodevelopmental domains are inter-related, and this is discussed in the neurodevelopmental domains evidence section and why extensive additional information is provided regarding assessment practices in the neurodevelopmental table and the best practice statements provided in the assessment section of the document. We have addressed this in multiple places as we agree this is very important part of neurodevelopmental assessment practice. We are encouraging clinicians to take a holistic or 'gestalt' approach in considering all the neurodevelopmental domains in making determinations about where the impairments best fit, based on the available information. The previous FASD diagnostic guide unintentionally over-simplified this process and we have done our best to communicate the complexities of the assessment to try and avoid people taking 'tick box' approaches to meeting the neurodevelopmental criteria.
"Wherever possible adjusted outcomes were used that incorporated consideration of confounding variables. However, the available neurodevelopmental evidence did not often include adjusted outcomes. As such, the available evidence often did not exclude the impact of other factors that may also influence neurodevelopmental outcomes. To provide additional examination of the evidence, a summary of the studies that included regression analyses was also undertaken (results provided in the Technical Report of the Systematic Review of Diagnostic Components). Overall, the pattern of results was consistent, whereby after controlling for confounding variables, results remained significant at higher levels of PAE." (Page 49) My interpretation of the evidence from the association studies that has cited and analysed in this systematic review differs significantly from yours. In my opinion, my	The interpretation you are describing here of the regression studies is the same interpretation we have. Once confounding variables were controlled for, there was no evidence available demonstrating an association at light levels, results only remained significant after controlling for confounding variables at heavy and above levels of PAE. This is also consistent with the majority of meta-analysis findings. Again, your interpretation about the levels of PAE is the same as we have drawn, and we are glad that the way the evidence is presented is making it easy to draw these conclusions. However, we need to also consider the limitations of the evidence. Specifically, that we could not control for timing of the exposure in our analyses. So whilst for diagnostic purposes

analysis of the evidence, including from the regression studies, indicates there is no conclusive evidence of a relationship between light PAE and any of the specified neurodevelopmental domains of impairment; and there is inconclusive, inconsistent and contradictory evidence for moderate PAE - indeed many of the larger studies demonstrate no association between moderate PAE with neurodevelopmental impairments following regression analyses. Thus in my opinion I do not believe a clear conclusion can be reached for moderate PAE and neurodevelopmental impairment from the studies so far. Further, although the studies for heavy PAE do in some cases seem support an association for some neurodevelopmental impairments, there is by no means evidence for all of the neurodevelopmental domains specified in the criteria. Thus, overall, the evidence which underlines this neurodevelopmental construct is weak.	we are encouraging people to focus on heavy and above exposure, we wanted to be careful in how this is applied in practice at an individual level, as we are unsure from the evidence about the conclusions regarding moderate PAE given the limitations of the evidence, thus there could be situations where it has or has not played a role. Thus, clinicians need to be careful about making determinations about impacts of PAE at a moderate level. We have tried to re-word Criterion A to highlight this point and have tried to re-structure the discussion of the limitations of the evidence review to better communicate this information. Regarding the last point, we are including 'confirmed unquantified PAE' as a proxy heavy/very heavy group, consistent with how PAE is reported in these studies. And although we couldn't show all of the neurodevelopmental evidence in the summary figures, due to the wide diversity of measures applied all of evidence in the Appendices was reviewed and considered in this decision.
Page 34: Criterion C – I like the inclusion of functional impairment – i.e., necessitates significant supports across areas of functioning. This is important for any diagnosis we make as Neuropsychologists.	
In terms of criterion D, I think it's important that we make sure that we get previous assessment results and check medical records. It's not unusual for some clients to have had assessments that have been conducted years earlier, prior to coming to our team. I'm making the assumption that if such assessments are not available, then perhaps reports from parents (i.e. in clinical interview) might provide some indication as to whether neurodevelopmental impairments were apparent early on.	A sentence has been added to the additional information section for Criterion D to clarify that previous assessments can be used as support if they are available.
Page 34:	This section has been re-worded as per a suggestion above.

"Clinicians need to assess and diagnose all relevant co-occurring conditions", maybe add "within their scope of practice" here. "All relevant co-occurring conditions" is a lot when you're working with complicated kids.	
P. 34 'Associated with' seems to need a clarifying statement to begin with, i.e. 'FASD can be associated with…' and that statement about why it is important to note these added.	Re-worded to clarify.
Page 34 – Prenatal - how would be determine whether exposure to other drugs would better account for the symptoms? There doesn't seem to be enough research evidence yet to make such determinations?	The Appendix of the summary of the regression studies, includes some studies that have compared different drug exposures. We will aim to pull together a brief summary of some of the other key studies that have been undertaken investigating prenatal drug exposures to make this information more accessible for clinicians.
Page 34 - Post-natal – how would we determine whether ACEs better explain symptoms? This is a complex assessment.	Throughout the document where appropriate we encourage clinicians engage in interprofessional case discussions and access discipline specific supervision to support practice. We have provided information in multiple parts of the document to support diagnostic decision making.
Page 36 – third paragraph "the evidence review indicated that associations between PAE and the relevant diagnostic outcomes examined were *occasionally* found for moderate levels of PAE". This is a relationship but not causal and what does occasional mean – how many children was no relationship found when there was moderate alcohol use?	We are preparing a more detailed visual summary to include in the document, we won't have this ready for the public consultation version, but will be available in the final document and hope that this will support communication of this point.
- p37, 'Criterion B': Presence of neurodevelopmental impairments – The arbitrary selection of a threshold of '3 or more' neurodevelopmental domains without a rationale based on evidence is likely the weakest element of the diagnostic guidelines. As noted, further empirical research is required to establish the validity of this threshold. As such, additional cautions are recommended in this section to strongly encourage clinicians to consider whether impairments in the domains observed (which cover most impairments seen in practically all DSM-5 disorders), are likely to be caused by PAE. In the case of true comorbidity, for example, an individual with both ASD and	Additional information has been added to the co-occurring conditions section as per a previous point and to the additional information section for Criterion B. Although it should be noted that this applies in the application of all diagnostic criteria in cases of co-occurring conditions.

FASD, the functional impact of the FASD cannot be accurately captured and explained simply by referencing which of the 10 domains are considered 'met'. This is because due to the presence of ASD, multiple domains will already be impaired based on ASD alone. The clinician may need to consider a higher threshold for 'pervasive impairments' in the presence of multiple comorbidities.	
Page 37: Continued criterion of three neurodevelopmental domains needed for a diagnosis of FASD. This feels arbitrary as you mentioned, although I agree there needs to be impairment across in more than one area of development and that impairment needs to be significantly low. For example, someone with severe speech and language difficulties and learning difficulties usually has significant functional impairment, which becomes more apparent as they get older, leading to secondary disabilities like low self-esteem, school dropout, unemployment etc. Should FASD be considered for those kids that have two severe domains (say <2nd percentile), which causes significant functional impairment? Like in the case of Intellectual Disability where we diagnose based on intellectual ability and adaptive behaviour (as per DSM-5; i.e., two neurodevelopmental domains). Or even two very severe domains? For example 0.1st or 0.5th percentile across two domains could be just as impairing as <2nd on three domains? Page 39: reference to "GDD could be indicative of clinically significant impairment in three or more neurodevelopmental domains" – according to DSM-5 GDD "pertains to children who are unable to meet developmental targets in a number of areas of intellectual performance but who are not capable or too young to take part in methodical/standardized evaluations of intellectual functioning.	The guideline development group considered a range of possible structures to the domains and cut-offs, we choose to maintain consistency with the previous guidelines given a lack of evidence currently for any particular model. Thus, we are not currently suggesting that diagnosis should be provided for children with 2 domains of clinically significant impairment. As described, the cut off is arbitrary and requires further research but is being retained as 3 domains of impairment. This is the exact type of diagnostic question we would like to be able to explore through the collection of nationally consistent assessment data (i.e., data collection of all individuals attending for assessment, not just data collection on individuals who received a diagnosis. We have developed a draft database template to support this in practice and welcome input and feedback on this. We have described in the intellectual abilities section of the neurodevelopmental domains section how individuals with significant impairments in intellectual abilities may have impairments across multiple domains of functioning.

As per DSM-5, GDD "involves reconsideration following a phase of time". As such, perhaps referral to early intervention under ECEI - NDIS should be the recommendation in the case of GDD given some kids go on to meet future developmental milestones while others continue to show a gap in functioning from same-aged peers. Future assessment after age 5 if / when the child is capable of completing formal assessment to determine if they meet criteria for FASD. I think the diagnostic criteria applied in these guidelines for GDD needs to be referenced due the variability used by different disciplines (e.g., Paeds vs psychologists).	Clinicians can determine what they feel is the most appropriate approach given the available information for infants and young children. We have re-worded to try and clarify this. We have re-worded this section to clarify.
-P37 – last paragraph – Refers to Appendix A however this should be Appendix B.	
Page 38 – Guilmette's table – the "Below Average" range classification seems out of place as this is quite a low result. Other tests we use, such as WPPSI, WISC, ABAS, etc. would use "Very Low" or previously was reported as "Borderline". The range "Below Average" and "Low Average" are used interchangeably in these tests and represents just below average (9^{th}-25^{th} percentile approx.) so I think this terminology should be changed.	This is the consensus recommendation from the Guilmette publication, but we are not directing clinicians to use these test labels. We have just provided this table for information regarding the percentile ranges. A note is provided under the table highlighting this point.
-p39, paragraph 1 – Suggested addition: Singular test scores should not be used to establish impairments in multiple neurodevelopmental domains.	
-p39, paragraph 2 – Suggested addition: Different clinicians in a multi-disciplinary setting should not simply contribute their assessments of aspects of the neurodevelopmental domains without consideration of all of the domains, in consultation with their team.	Added this information p. 40 paragraph 2 where discussing need for a collaborative approach.
p.39: Given these considerations raised by the Advisory Groups and that diagnosis is not required to access early intervention in Australia, the Guidelines Development Group have decided that a cautious approach is currently recommended at this time. –	

It should be “has” not “have” (group is singular) and *currently* and *at this time* have same meaning. Suggest rewording of this sentence.	
Page 40 – I agree that the tick box approach is probably not ideal, and clinicians should determine impairments in each area. However, there is a high likelihood that if a child has an impairment in one area, they will have impairments in multiple areas (e.g., a child with ADHD would likely have difficulties in EF/Attention/Memory/Emotion Regulation) irrespective of PAE.	Additional information has been added to the co-occurring conditions and additional information for Criterion B sections regarding this point.
Page 41 – table – second last point. I agree that discrepancies in IQ tests was an unusual criterion. We have children who now would no longer meet criterion for FASD based on this change. This makes me worried about the type I/Type II error with this diagnosis.	Sensitivity and specificity are a concern in the development and application of all diagnostic criteria. We have done our best to make changes that we thought would improve sensitivity and specificity or alternatively not make changes where we did not have evidence to inform changes. But future research is required to investigate this and to enable continuous quality improvement of the diagnostic criteria. Changing the criteria and therefore who may be eligible for diagnosis is an inherent part of the review process.
-P41 – column ‘Specific assessment considerations’ – suggested addition: Clinicians should also consider the impacts of motor skills on measures that include motor requirements. Moreover, clinicians must consider performance validity including effort measures. The relevance of performance validity is crucial particularly in Justice contexts given the significant presence of feigned deficits for secondary gains.	We feel this is basic clinical practice information and have provided these as examples of clinical practices in the ‘assessing neurodevelopmental domains in practice’ section and encouraged clinicians to access relevant discipline specific information and supervision.
P.42: Communication is how we receive and convey ideas, thoughts, feelings etc. to other people. Please include a full definition of communication here instead of the use of etc. SPA could provide the definition is required.	
Literacy/Memory/Attention – I think it is important to consider the overlapping and co-occurring problems in these diagnoses. I do wonder how we will tease out the impacts of these disorders vs. FASD.	Additional information has been added in a number of sections as per comments above regarding co-occurring conditions we hope this is helpful in supporting clinicians in their decision making.

Table 4 'Other causes of impairment on motor tests such as the vestibular system, executive functioning, musculoskeletal functioning, and peripheral nervous system problems (e.g., balance, co-ordination, ball skills) should be considered.' –do we need to define the neurological challenges more – the PNS includes the sensory nervous system ie sensory processing, integration and modulation and the motor systems which is the voluntary and involuntary operations of our muscles in response to this and the adapting task demands. Being more specific around motor performance ie muscle tone, other neurological consideration such as coordination and should oral-motor challenges be included here as well?	There is already a note included in the communication section of the neurodevelopmental table regarding the lack of evidence and practice suggestions for this.
Visual motor integration is complex and should be considered in the motor domain as it is the person perceiving visual information and adjusting their motor performance to produce the desired response – of course the aetiology of this will lead to suitable interventions – ie deficits in visual spatial, motor skill – or both.	We do have visual motor integration included in the motor skills domain.
Additionally visual scanning – noted in attention could also have an oculomotor origin and is a process of visual processing – wonder if this needs to be clarified?	Added to the Attention domain.
In communications should speech disorders be included?	There is already a note regarding this in the communication section. There was insufficient evidence for these to be included in the diagnostic criteria.
p.42: could the mention of SPA's 'Clinical Guidelines' please be changed to 'Practice Guidelines' (SPA's terminology changed recently)	
Page 42: "verbal learning and memory" is not a domain of communication and should be removed from the communication section.	Verbal learning and memory is noted in the communication section as there may be situations where this is better attributed to that domain rather than the memory domain. We are wanting to encourage clinicians to carefully consider assessment findings holistically rather than at an individual domain level only. We also have wording about this in the memory section that we hope is helpful to clinicians in making these determinations.

Page 44: love the reference to educational exposure in the literacy/numeracy section	
Page 44 memory: in the considerations part, could we add anxiety? E.g. “Consider the interplay between attention, language skills intelligence… and anxiety”. Verbal encoding is particularly susceptible to anxiety.	
p.44: Literacy and /or Numeracy - Consideration must also be given to an individual’s educational placement (e.g., mainstream, educational support class, special school) and opportunities (e.g., remote location, multi-lingual setting, new immigrant) and the type of level of supports that are provided. (should this read type and level of supports that are provided?).	
p.44: Consider the interplay between attention, language skills, intelligence, executive functioning, and memory; and based on test performance what the best explanation is for any impairments. (consider a reword)	Apologies, couldn’t see what the re-word suggestion was here.
Page 45 attention: what evidence is there for including immediate attention span under attention rather than overall intellectual functioning? Focussing on sustained attention is most likely to map to clinically significant impairment.	The intention of the wording in the general intelligence domain regarding individuals with significant intellectual abilities is intended to help account for the general factor of intelligence. There is mixed evidence about the relationship between sustained attention and PAE, focusing solely on this would not be the most helpful approach.
Page 46 EF: we have “EF” as the abbreviation for “executive functioning” but then we use it in a sentence as though it’s the abbreviation for both “executive functioning” and “executive function”. Which is a bit hard to read.	
Page 46: EF in young kids – is it unitary or would we not expect those skills to have developed yet / the range of normal is very big in early childhood?	That is what we mean by unitary concept. Have added additional information to clarify.
Page 46: EF: I like the hot vs cold EF model provided, I think it will be helpful.	
Love the explanation around EF – and what are the best ways to tap into the differentiating functions and context specific capabilities ie a combination of tools to	

inform the assessment – both formal and informal which enables more robust discussion around a persons EF.	
Great to see that EF's and emotional/behavioural regulation are not tied together – makes it clearer to see problematic higher order functioning/regulations as opposed to problematic emotional and behavioural regulation.	
p.46: EF - Consideration should be given to performance of EFs across settings (including but not limited to home, school, work, and social engagement) ..... - consider changing schools to education and care settings or just education settings (this would capture early childhood education and care settings and schools), although we understand these are just examples.	
Page 47 – third and fourth point. I don't know how we will be able to determine if an individual's historical information best explains a child's presentation above and beyond FASD. I do not feel there is enough research behind FASD to make these fine grained distinctions. There needs to be specific FASD factors that do not occur in other diagnoses. A parent's substance use associated with an increase genetic and environmental risk for emotional and behavioural regulation problems is very common, and it will be difficult to tease that apart. Usually, they are all inter-related.	Additional information has been added as per the points below that will hopefully provide further information.
-P47 – Table row 'Emotion and/or behaviour regulation' – column 'specific assessment considerations' – Dot point 5 appears to be a potential area of difficulty/misattribution particularly as many clinicians doing FASD assessments are not specifically/appropriately trained in psychiatric/mental health diagnosis. We would suggest adding here that "Care must be taken to consider whether the observed deficits in psychological functioning are directly related to the impairments associated with the PAE, or to other factors. Where there are significant other factors present that impact on functioning, impairments in this domain may be weak evidence of impairment caused by PAE".	Rather than providing this information at a domain level, we have provided an overall comment on the limitations of the evidence that should be considered across all the neurodevelopmental domains.
Page 47 – last point: "when there is sound evidence to suggest they are due to the direct effects of PAE or secondary effects of the disabilities that have arisen from PAE	We provided additional information in the co-occurring conditions section and the assessing the neurodevelopmental domains in practice section.

and there is reasonable evidence to suggest these impairments are not due to another cause that is not related to PAE". I don't know how we are going to determine other causes – if a child is diagnosed with ASD how do we know that the ASD would not have occurred anyway irrespective of alcohol use?	There are challenging determinations to make, and clinicians are required to use all the available information (e.g., family history, other prenatal exposures/events etc.) to make the best clinical decisions that they can in each individual case.
P47 emotional regulation second column – word missing – taking things that belong to others	
-P48 – Adaptive functioning is influenced by all aspects of an individual's functioning and a range of impairments, potentially unrelated to PAE. Therefore suggestion is to add "Care must be taken to consider whether the observed deficits in adaptive functioning are directly related to the impairments associated with the PAE, or to other factors. Where there are significant other factors present that impact on functioning, impairments in this domain may be weak evidence of impairment caused by PAE."	As per comment above, overall information is included in the assessing neurodevelopment in practice section, instead of at a domain level.
-P49 – paragraph 3 – As noted here, within the 10 domains, some can be considered primary and others secondary (academic, adaptive, social). Given recognition of this, the development group should consider more explicitly recommending that less diagnostic weight (i.e. variance explained) is given to the secondary domains being met, particularly if primary domains aren't met. This would help to reduce the likelihood of misattribution of non-cognitive level factors to direct evidence of PAE impacts. We disagree that this would add "another arbitrary element to the diagnostic criteria", as we have observed the lack of higher order grouping to result in greater misdiagnosis rates.	As per a previous comment the guidelines development group considered a range of possible structures. We would like to be able to move to a different structure for the neurodevelopmental domains, however we need data to inform what this should look like. We are putting forward a consistent clinical database template in the hope we will be able to collect data to inform this type of change in the future.
Pg. 49/50 Criterion C- shifting the criterion from from clinically significant distress to a support perspective in light of the social model of disability is an important change that I strongly agree with.	
-P49 – Criterion C – The described decision to move away from the DSM-5-TR conceptualisation of impairment towards a "social model of disability" is problematic in	We are not moving away from the DSM conceptualisation of impairments; we are moving away from the conceptualisation of the need for 'clinically

the context of accurate diagnosis. While we advocate for considering a social model of disability when looking at an overall formulation and planning for an individual, this is insufficiently specific at the point of diagnosis. The clinician MUST consider whether the neurodevelopmental impairments *caused by PAE,* have resulted in significant functional impairment, and this impairment must be defined in line with other differential diagnoses to ensure equity etc. To demonstrate, if an individual does not have clinically significant impairments on standardised adaptive testing, but has a range of high level needs due to a chaotic family context or a physical disability, this level of functional need cannot simply be attributed to PAE and used to justify a FASD diagnosis.	significant distress.' As per Criterion B clinically significant impairments must be present and Criterion C states that these impairments result in significant support needs (i.e., the support needs are not resulting from other contextual factors they are resulting from the impairments). Further information has been added to the additional information section for Criterion C to clarify that the supports being considered here are not the result of other contextual factors.
P.51: Clinicians are encouraged to use shared decision-making with individuals and families attending for assessment to provide information about the limitations of the current norms and tools available in Australia, so that people can make informed decisions about their assessment process. (Lengthy sentence).	
-P51 – Assessment of facial features for individuals from culturally diverse backgrounds – The guide should make a statement that the current facial norm reference used is likely to be inappropriate, but is only being used as no other alternative currently exists. A lack of critical honesty about this with clients implies a level of systematic racism that appears to be inconsistent with the stated goals of the Guide. The guide should explicitly state that collection of appropriate norms for Aboriginal people from different cultural groups (and other culturally/racially diverse groups), is an urgent research priority and that additional care must be taken when using this source of evidence in the meantime. (not sufficient to just include this point in the Appendix at p97).	Further information has been included in the additional information sections pertaining to assessment of facial features.
Assessment of facial dysmorphic features. The use of facial dysmorphology features as specifiers for PAE is very problematic and fraught in clinical practice mainly because of the limited amount of reliable normative data available to make informed evidence based clinical decisions upon. Further, due to the small number of studies, many of which were decades ago, there is also still lingering uncertainty about the relevance of 1 or 2 out of 3 facial dysmorphology	As per the previous point, further information has added regarding the current limitations of assessment of facial features in the Australian context. Given the discrepancies in international diagnostic criteria regarding inclusion of diagnosis at 2 vs 3 facial features, and current limited evidence to inform such decisions/changes to diagnostic criteria, we are

features as specifiers for PAE at all, *even* in Caucasian populations, where there is relatively more data available. Of note, the lack of facial morphology normative data and studies correlating dysmorphology to PAE is most acute in non-White/ non-Caucasian ethnocultural groups. The particular issue here is that FASD has historically been diagnosed at significantly and disproportionately higher rates in minority groups (indigenous, Black and other minority groups) in European countries, North America and Australia. The Tsang study is often cited in FASD literature (pg 50) as evidence to support the use of existing norms for FASD facial dysmorphology analysis in Aboriginal children in Australia, however this study was simply a "which is a better fit study?" comparing the limited number of existing norms (Scandinavian and American), none of whom included any indigenous normative data. Nor did Tsang's study attempt to establish normative data for Indigenous Australians, even in the small population that it studied. Thus, Tsang's study falls significantly short of providing robust evidence upon which to make evidence informed decisions. In summary, at the current time, there is a lack of normative data to reference for facial dysmorphology assessment, most notably in "minority" groups; as well, there is a lack of consistent and reliable evidence of studies correlating dysmorphology to PAE in minority populations. This makes its application in clinical practice very problematic.	recommending retaining of the more robust cut offs of 3 facial features and communicating the importance of excluding other causes of the facial features. This is consistent how we have worded the description of the Tsang et al study "norms were the best fit from the norms available," noting that the available evidence is very limited. We are using this study in the context of recommendations for norms for the whole population, not in the assessment of facial features for people from different cultural backgrounds. We do transparently state these current research gaps, and as per other points we have updated wording of Criterion A to clarify that there is flexibility regarding the inclusion of facial features as part of the diagnosis. Although, as described in the document it is critical that these decisions are made in consultation with individuals and families.
p. 52 paragraph 4 – add 's' to members & 'the' before Advisory Groups	
Appreciate the move away from arbitrary cut-offs towards clinical judgement and integration of multiple information sources to comment on the severity of impairment.	
Criteria C – like that it is framed in the context of support needs as opposed to functional impairment. This means that parents / carers putting in significant efforts to scaffold and support their children aren't put at a disadvantage diagnostically.	

Positive that other disorders are considered to be co-occurring rather than counting automatically towards a “severe” impairment rating. Places the emphasis back on the clinical integration and assessment of severity.	
General intellectual abilities domain – appreciate the adjusted category name from “cognition” and removing the discrepancy analysis as evidence of “significant impairment” unless this is functionally relevant.	
Communication / language – slightly confused regarding the addition of pragmatic language in the communication section for the purposes of a clinical guideline. Hypothetically, does this mean that a child with co-occurring ASD, corresponding pragmatic challenges and age-appropriate core language skills could class as “severe” and then “language disordered”?	Additional information has been included to clarify this point.
Emotional and / or behavioural regulation: concerned that this category could be used inappropriately, particularly when there is not access to appropriate clinicians / MDT to try to disentangle WHY these impairments are occurring and whether the dysregulation is secondary to other neurodevelopmental factors as opposed to alcohol.	We agree and have thus provided an extensive specific assessment conditions sections for emotional/and or behavioural regulation. Throughout the document where appropriate we are encouraging clinicians to engage in consultative/collaborative approaches and access appropriate clinical supervision to support decision making.
The removal of brain structure/neurology as one of the 10 neurodevelopmental assessment domains, so there are now 9. I think this makes sense as it isn’t really a developmental domain per se.	
Ditching the AUDIT-C and using some quantification based on g/week. The requirement to substantiate moderate-heavy prenatal alcohol exposure is one that many clinicians will be happier with, rather than any prenatal alcohol exposure.	
“Criterion C: The neurodevelopmental impairments necessitate significant supports.” How is this to be determined?	Further information has been added to the additional information section for criterion C to help support clinical decision making.

"Criterion D: Onset of neurodevelopmental impairments in the early developmental period." How is this to be determined?	The additional information section provides information regarding this Criterion. Clinicians are required to use all the available information to understand if the impairments were present earlier in life (i.e., that the impairments are not transitory in nature due to current life circumstances).
Criterion E. The symptoms are not better attributed to another condition or exposure." Also a bit nuanced. We can't know if a neurological disorder such as epilepsy is due to FASD or is independently contributing to the developmental disability. We can't know if prenatal co-existing exposure to other teratogens such as amphetamines better explain the developmental disability unless we know the amount of exposure from each teratogen.	Please note that we have removed seizures of unknown origin from the previous diagnostic criteria, this is now recommended to be recorded as an 'associated features' if present. These are challenging determinations to make. We are encouraging clinicians to take these things into consideration as much as possible given the clinical information available.
It seems the main problem with FASD is that it implies causation – alcohol use causes these impairments, but in reality alcohol use increases the probability. The research appears relational and not causative (will never be causative) and we cannot tease out other factors that may be related or would have occurred anyway. We know alcohol has a part to play in these neurodevelopmental conditions, but we cannot determine exactly how much, when during gestation, or differentiate the effects of alcohol versus other causes. I am not sure why we need to label FASD an overarching diagnosis, perhaps we could just say "confirmed moderate alcohol use" associated with XXX diagnoses. Many if not the majority of children in our team would automatically receive a FASD diagnosis if parents reported alcohol use because of the comorbidity between ASD, LD, ID, ADHD, DLD, memory, etc.	The alternative diagnostic terminology neurodevelopmental disorder associated with PAE has been included based on discussions with the Advisory Groups regarding the available research evidence and the want to be able to reflect the multi-factorial nature of many presentations. However, as described in the document there was no consensus that could be reached at this time regarding diagnostic terminology. We suggest that ultimately, it is the individuals and their families who should have the right to choose the terminology that is most helpful/appropriate for them. We plan to develop a resource to support clinicians in having these discussions with individuals and families and hope to undertake future research to better understand the needs and preferences of individuals attending for assessment.
From what I understand, these guidelines are giving the clinician more flexibility when considering the diagnosis of FASD	
Feedback on the main guidelines document: Assessment process, assessment of PAE & Medical Assessment sections	

The lived experience statements are really helpful.	
The section Assessment process is clear and very useful guide to support cultural factors/considerations when exploring pathways with the family and ensuring informed consent/ascent making it seem a lot more doable and weighing up options with current resources and health care models. V comprehensive GPS Medical Assessment – nice and clear regarding tools determining FAS and Growth etc and loving the GPSs	
The finding your way shared decision making resource is already published. We probably don't need this covered in the FASD diagnostic guidelines at all. It's helpful, but it's also common sense and common practice already.	Other feedback indicates clinicians have found this to be a helpful inclusion. Specific information pertaining to FASD is included with the resource that is not available with the original resource.
The shared decision-making tool is great and I'll be looking to adapt this for all of our developmental assessments where I work in remote Aboriginal and Torres Strait Islander communities.	
The section regarding integrated and shared decision making with the yarning process was really well clear and helpful.	
p.56: Suggested reword: The assessment process aims to encourage all practitioners, no matter what setting or type of practitioner you are to contribute to the assessment. Table 3 provides a brief overview of what and who may be involved in each component/part of the assessment process. (This is language used in the table 3 heading and is more concise)	

P57 last box, could include child protection in the list of settings given it will be relatively common, and similarly child protection workers.	
Table 3 (p. 57) provides a general outline of people who may be involved in the process, but it doesn't clearly articulate which clinicians are mostly likely needed to undertake each part of the assessment process. Whilst it is useful to articulate the flexibility here, I think it may be confusing to people who are new to FASD diagnosis and are trying to work out *who* they need input from in order to undertake an assessment. For example, is not clear in the Developmental section that a Psychologist (Neuro or clinical) will need to undertake the Psychometrics.	We have tried to keep this stage broad and indicate that it may or may not include the use of standardised tools. We have added additional information to the assessing neurodevelopmental domains in practice section to help clarify this point. We are aiming to communicate that ideally specific disciplines would be assessing specific domains, however we want to also provide some flexibility as we don't want this to be a barrier to people accessing assessment in areas where all the disciplines are not available.
P58 multi-disciplinary team – must it be a psychiatrist- could say psychiatrist/psychologist?	We have psychology listed as a potential discipline member of the MD team.
P59 is 'inherent' appropriately used regarding interpreters.	
P60 personally I think the implementation consideration re Indigenous framework regarding informed consent represent best practice in general for all – that approach would appear to be only for Indigenous people – could it be highlighted as best (as well as Indigenous informed)?	We agree, as described in the Foundational section for the Indigenous Framework, that is our belief, implementing these recommendations will be beneficial for all Australians.
P64 if the person being diagnosed has child/children in their care – risk of child removal with FASD diagnosis would need to be mitigated, would be big concern for First Nations people (and these tools are likely to be applied regarding reports for teens in the crim justice system.)	We have kept the shared decision making section broad, but yes if there are specific fears, concerns and risks for any family it is important for these to be discussed and appropriately supported.
-P65 – 'Weigh up the odds' – Suggested additional point: "How will a diagnosis of FASD help me/my child?"	
p. 68 paragraph 5 – can be used 'to' assess alcohol paragraph 6 5th line 'convert' rather than 'covert'	

p. 69 paragraph 1, line 1 self-reporting or self-report	
Pg 69, final paragraph. Suggestion the first paragraph down so the point starts with "Clinicians should be mindful" (pg 70)	Sorry don't follow what the recommended change is here.
-P70 – heading 'Implementation considerations: child protection settings' – in relation to the first dot point, at least in WA, it is standard procedure for child protection staff to record alcohol usage alongside other teratogens and factors impacting child safety/wellbeing in their files. There are however issues with sharing of this data with private or other public sector clinicians, given the sensitivity of the content.	We have revised this in the document. Although we note that not providing routine prenatal history disadvantages children in out of home care and may contribute to further challenges for the family when they need to be asked about this information again in the future.
p.70: To support early identification of prenatal factors that can influence developmental outcomes, critical information that could affect longer term health outcomes for children can be transferred from the pregnancy record to the child's health record. (lengthy sentence –comma added)	
Page 71: The quote from the UNCRC in the justice setting section is wonderful and will now be incorporated into all my reports in the youth justice setting. Thank you!	
-P71 – heading 'Implementation considerations: justice settings' – We are concerned that this section focuses too heavily on diagnoses as the only indicators of an individual's appropriateness for involvement in the justice system, however individuals who have a range of cognitive deficits (but no specific diagnosis) are equally at risk of being inappropriately disadvantaged in this system. We would advocate for routine assessment of any individual considered at risk for cognitive issues relevant in the justice system, irrespective of the presence or absence of diagnosis. We are not aware of high quality research indicating that individuals with FASD are uniquely disadvantaged in the justice system compared with other individuals with similarly impaired cognitive abilities, despite the pressure from legal professionals to suggest this is the case.	There is a range of information included here that doesn't only relate to diagnosis including the UNCRC comment that advocates for assessment of a range of delays and conditions. We also discussed the need to be mindful of scope, these are guidelines focused on FASD.

p.75: pathologize or pathologise ? Australian English	
Potentially requires some more clarification regarding confirmed alcohol with unknown levels, as many screening processes (historically) have had tick and flick confirmation boxes with no details and can often be an only source.	We have included some additional visuals to assist in communicating this information.
Informed consent- great to have this included. A rationale for my this is particularly important with FASD (stigma etc) could be provided here. Overall this section could be smaller with some editing.	Information has been added to provide the rationale for the inclusion of this section – which was based on feedback from Advisory Group members regarding concerns that referrals and assessments were taking place without were being made without appropriate informed consent.
Feedback on the main guidelines document: Holistic assessment and profile, formulation, and feedback sections	
Very comprehensive – it was good to read and see that GPS and caregiver experiences align with what you may already have embedded into good practice – makes the process of engaging in the assessment process less confronting and gives clear guidelines on what to consider when making a plan for the person/and or family. Loved the inclusion of collaborative goal setting and co-design of the journey.	
Excellent nuanced approach.	
I think emphasising the need for a holistic assessment is really important, however I think this section contains too much detail (see final comment below).	We have reviewed the document and tried to reduce unnecessary wording wherever possible. And plan to provide the document online through links for each of the sections to make it more accessible.
Pg. 60, paragraph 3, minor typo- should be a full stop after (Joffe, 2003).	
p.77: Suggested reword: This facilitates an assessment that extends beyond a focus on impairment and diagnosis to include a wide range of meaningful areas for individuals, such as functional, participatory, wellbeing, cultural, and environmental factors.	

-P81 – 'Co-occuring and differential diagnosis' – It should be added here that part of the reason for the difficulty in diagnosis of FASD against so many potential differentials is that there is a lack of cognitive phenotype specific to FASD identified in the literature.	Further information is included in the additional information section for Criterion B regarding this point.
Page 83: the organisation of this information and the use of inconsistently sized letters is making it harder to read. Can this be turned back to plain text?	We will plan to make an updated version of this section; we may not have it ready in time for the public consultation version but will revise for the final version.
-P95 – Dot point 8 – 'High scores or the lack of low scores do not preclude the determination of functional limitations or 'impairment'. This point seems to conflate a few issues and may reflect differences in terminology. 'Functional limitations' are considered quite separately to 'impairments' (such as in body systems, cognition etc) within the disability model used by WHO ICF. For example, high scores or lack of low scores on a standardised test that specifically measure an area of cognitive function (e.g memory) DOES preclude calling this an area of impairment. It may not preclude considering that the person has *functional* memory problems, but we would say that there are other reasons for the functional issues, such as mood, environment etc, not their underlying cognitive ability. This point either needs to be expanded or removed due to the high likelihood of adding confusion and potentially encouraging questionable practice.	Seems like could be differences in terminology – the wording used is as per the reference. The additional information just aims to further highlight information in the document that the scores on a standardised test alone should not be used in isolation to make determinations about impairments and functional impacts i.e., test scores do not equal impairments.
Feedback on the Indigenous Framework document	
This is such a rich and powerful document, with relevance far beyond FASD assessment. I can't wait until this is in the public domain to be used as a resource for supporting all of our child development clinicians for their work with Aboriginal and Torres Strait Islander families and communities. I expect to regularly come back and review this document as part of my own self-reflection and growth. My deep thanks to the Cultural Advisory Group, this document is a gift.	
This is an important component and great to see included.	

Such an important framework that fosters understanding and reflection on our beliefs and approaches so that people can work in respectful and authentic partnerships, and the recognition that it is very compatible with other models of disability – really needs to be included in Australia university medical, health and rehab curriculums across the lifespan.	
Thank you for this document. We believe the Indigenous Framework is essential reading for all Australians, as it provides some really important insights for all of us as humans, and especially as clinicians, regardless of whether or not FASD is relevant to our work. It is a shame that it is likely only to be read by people interested in FASD – I wonder if there could be a way of it being more widely promoted?	
p.53 – half way down, there's a minor typo. It should say "talk to your local Child Development clinic" (the 'r' is missing off 'your')	
I don't really feel I have the skills and knowledge to comment on this document so would defer to others. Maybe on p24 heading could be Yarning rather than The Yarn. I thought that sounded unusual.	Wording of "The Yarn" has been selected purposely to bring specific focus to working on it, 'yarning' dilutes that focus and remove the emphasis and therefore importance of this key practice.
I also thought a review of the use of the word intervention to see if that could be avoided might be a good idea.	
I wondered also in advocacy p41 whether advocacy for connection with mob might be specifically identified given that many in the crim justice system in the cities be in contact as a result of colonisation.	
Phillips, L., Bunda, T. and Quintero, E. (2018). p.8 missing from reference list.	
Feedback on the Administrative and Technical Report	
Page 17 table 4: there is an asterix next to 2016 for the Australian guidelines that doesn't refer to anything	

Page 19, figure 3: the formatting of this means it is hard to read. Can we increase the minimum font size?	
Clear and concise, contributes to the high level of transparency in the development of this guideline.	
Long but easy read 😊. Layout helps to synthesis and relate information across technical areas especially for professional with minimal exposure to research techniques/methodologies and criteria. Nice to see timeline of development and table indicating where things are located related to criteria and mapping NHMRC requirements. Interesting comparing different diagnostic guidelines and justification internationally – obviously more research is required in growth and structural/dysmorphology. Due to pervasive nature of PAE it makes sense that multiple neurodevelopmental domains should be considered when looking at dysfunction and disability – of course life experiences and other factors such as genetics might also come into play.....	
I am wondering if all of those involved should be acknowledged in the main guidelines document (by name only) at the beginning or end, given that the document is likely to be picked up and read by a wide variety of people. It might add weight to demonstrate the sheer number of people and diverse feedback involved in the process?	An acknowledgements section has been added to the start of the document.
Feedback on the Technical Report for the systematic review of the components of the diagnostic criteria	
18 thousand records. An incredibly ambitious project and very helpful to read the synthesis provided. Thank you.	
Thanks for including all this but I found these documents overwhelming, but I know they are important, but I have no specific feedback except – Well done – I appreciate and respect the rigour applied to developing these guidelines, gives me assurance that	

they are useful and based on current evidence with I'm sure new research question evolutions.	
-P57 – Limitations and Future Directions – Given the outcomes of the meta-analyses and statement that "aside from the physical size domain, there was a lack of studies providing high quality evidence across the different levels of PAE and outcomes currently included in the diagnostic criteria for FASD", we believe this necessitates more explicit reference in the main document that there is currently weak peer-reviewed evidence of direct impact of PAE on specific neurodevelopmental domains, and thus the literature supports extreme caution by clinicians when ascribing low test scores to PAE.	We have re-worded this statement as we think it is being mis-interpreted. This statement was referring to the lack of evidence across all exposure levels (i.e., for light and moderate specifically in the neurodevelopmental domain). As per the previous comments, we have significantly expanded on the information included in the main document regarding the limitations of the evidence review.
-The meta-analyses also appear to show very limited association between lower levels of PAE and the cognitive outcomes and so it does not appear to logically or scientifically follow that lower levels of PAE are likely to lead to neurodevelopmental impairments. While technically true to say that any impact of PAE cannot be ruled out at this stage due to limitations of the research, in consideration of the potential downsides to false positives articulated below (and due to current weak scientific evidence), we believe that the Guide should discourage diagnosis of FASD in those cases.	That is the aim of the inclusion of a PAE threshold for Criterion A of the diagnostic criteria, based on the evidence review. Further information has been added based on previous points to try and clarify this further in the additional information section for Criterion A. However, as described in previous points we need to be mindful about applying the evidence in practice at an individual level. Hence, the need for the consideration of the limitations and need for clinicians to use their clinical judgement at the individual case formulation level.
Feedback on the Technical Report for the systematic review of the lived experiences of the assessment and diagnostic process	
Very helpful, thankyou	
The lived experience guideline statements across the assessment journey including giving feedback which can be very challenging, are great in supporting clinicians who are considering providing FASD assessment and diagnosis. It enables clinicians to be more mindful and intentional in their approach to make it a worthwhile and family centred approach – ie to de-medicalise and provide accessible, authentic and realistic	

answers to client and family referral questions. You can clearly see the links in the approaches and guidelines in the main guidelines document.	
Feedback on the Technical Report for the scoping review of holistic assessment	
Very helpful, thankyou	
Great read – gels with OT models and IPP frameworks and so important when supporting clients and families in a strength based and individual approach/ways – very empowering – can see the threads through the guidelines document. Very interesting and relevant	
Feedback on the Technical Report for the scoping review on resources and models of care	
No comments, thank you	
Well written – this is a good read identifying challenges globally but also some models demonstrating success and adaptability in accordance to clientele and location – obviously a need to start collecting more of this data across clinical settings	
Feedback on the dissemination, implementation, and evaluation report	
Love the idea of discipline specific summaries being developed.	
Is there a strong evidence base for updating the guidelines every three years? I would have suggested every 10 years is sufficient. Considering how similar these guidelines are to the previous guidelines, it doesn't feel like a lot changed in the last 4 years.	We have revised this section and provided a more individualised approach for these guidelines.
No direct feedback but very relevant when advocating for services.	
Any other feedback you had at this stage not captured in the sections above	

Aside from the production of the guidelines, these documents provide an extraordinary resource. This is an amazing job everyone has done!	
Main document page 94: I don't think this is needed. These are diagnostic guidelines, definitions of a percentile are outside of the scope of this document. Again on page 95. Providing the reference for the original publication by Guilmette would be sufficient.	We have left this in as based on previous feedback from Clinical Advisory Group members concerns have been raised about practices in these areas, so to make the information more accessible we have retained it as an appendix.
Thank you for the opportunity to contribute. These guidelines far exceed my expectations in thoughtfulness and rigour.	
After our team had a discussion about these new guideline documents, we all agreed that it is good that it is not so much of a 'tick box' diagnosis and that more thought needs to go into it.	
As noted above, I think the team has done a great job and I am in alignment with the decision to include all of the elements that extend beyond the previous version of the guidelines. This said, I have the following global feedback that I wish to share: As someone with a fairly high level of FASD knowledge, the main document was easy for me to understand. However, it was also very lengthy, it took me a few hours to read. I do wonder whether people who may be new to FASD and/or who are very time-poor may find the amount of information overwhelming and that this may prevent them from engaging with the information as intended, or even deter them from undertaking the assessment process. There seemed to be different writing styles throughout, which may reflect the collaborative approach, however this means that some of the information in the document is inconsistently delivered, or that text has be included that is not strictly necessary. Both of these issues may be contributing to the document being so large.	We agree the document is long and needs further proof reading. We will try to reduce where possible and improve readability further through the review process. Another planned strategy is that once the document is available online, we will break down each of the sections (i.e. where the sub-title pages are) so that people can use individual sections of the document as required.

Some examples: on p. 49 paragraph 1: the example 'there was mixed evidence' could be deleted to make it more succinct. On p. 81 the 'Co-occurring and differential diagnosis section' starts with an overview of a systemic review. Paragraph 2 in this section makes a statement about Co-occurring disorders: this might be a better place to start, with the systemic review simply referenced, saving a paragraph of text. P. 83 content might fit better in the technical report. There is quite a lot of repetition throughout, and the reader needs to flip through multiple areas to get relevant information. E.g. there is information on prenatal alcohol exposure on page 32, additional information on PAE on page 35 and a whole section on it from page 67. I think, if time and budget allow, it may be worth considering engaging a professional editor to help resolve some of these issues & identify places where there is information that could be set aside. Even a small reduction of the overall word count might help make the document more accessible.	
In our previous submission to the Development Group we identified several weaknesses in the architecture of the Australian Guide of which many have been addressed or at least acknowledged in the main document. We would like to see more emphasis at the start of the main document, regarding protections for poor operationalisation of the guide by clinicians. As previously stated, we have ample evidence of poor diagnostic practice within WA and so we believe the Guide could do more to ward against these practice errors/pitfalls. We reiterate some of our previous points which we do not feel have been adequately addressed thus far: *Operationalisation of the guide* - The guide should explicitly warn against a "checklist" or mechanistic approach to the clinical diagnosis of FASD. Comorbidity must be carefully considered as it has been observed that clinicians are typically using FASD as an aetiology to explain all comorbid	As stated below regarding misdiagnosis we are not including a specific section on this, as that is the intention of the entire document. Extensive information is included throughout the whole document, across all elements of the assessment process aimed at improving assessment and diagnostic practices.

7 deficits rather than considering whether FASD adds additional explanatory power or diagnostic utility. - Significant psychiatric comorbidities are not given due consideration as potentially accounting for observed impairments. It should be noted that common psychiatric conditions can cause (often transient) impairments in cognitive functions that could be misattributed as caused by PAE, so clinicians must be careful. We would also like to suggest inclusion of a section that more clearly articulates the consequences of misdiagnosis, as this may assist clinicians to take pause and consider both positive and negative consequences, and discourage mechanistic approaches to diagnosis in practice: *Consequences of Misdiagnosis* 1. Systematic misdiagnosis hampers scientific progress – If many cases of FASD are misdiagnosed, then research progress in the future to elucidate a phenotype for example, may be extremely difficult due to the heterogeneity of aetiologies actually captured in the sample. 2. An inaccurate understanding of the individual can lead to poorly specified interventions and supports for individuals – A poorer understanding of an individual also perpetuates inaccurate expectations of individuals placed on them by family, community and broader society. 3. Inaccurate/inappropriate stigmatisation of mothers – the specification of aetiology being from PAE by default shifts responsibility for the child's issues to the mother. Where this is not accurate (wrong aetiology or multifactorial causes) it can have a range of unwarranted negative outcomes such as conflict within families and communities (blame and shame) and raise questions in relation to care and protection of children. 4. Reinforcement of institutional racism and racism in the community – Inaccurate attribution of FASD to individuals in already disadvantaged communities may serve to	It is explicitly noted in the additional information section for the diagnostic criteria that clinicians should avoid taking a checklist approach to diagnosis. Additional information has been added in multiple places regarding co-occurring conditions. As per the information contained in the Introductory chapter of the guidelines. The entire content of the guidelines aims to balance concerns raised by Advisory Group members regarding both over-and under-diagnosis. Given concerns already raised regarding the length of the document we do not want to include an additional section specifically focused on this. Rather the approach we have taken is trying to embed information throughout the document across all stages of the assessment process. (e.g., regarding point 4 we have included an implementation consideration in the PAE assessment section 'bias in assessment'). We hope that the

reinforce existing institutional racism. For example, children may be considered to have disability/severe impairment due to a brain condition, when in reality they function poorly due to alternative and modifiable contextual factors. This serves to disempower them in adulthood, such as regarding their decision-making capacity and autonomy. Inappropriate blame of mothers in a particular community may reinforce or perpetuate existing racial stereotypes.	wide range of information we have included throughout the document will improve assessment and diagnostic practices.
As a general statement though, I think it is very regrettable that this review of the FASD guidelines has only included a very small fraction of the developmental paediatricians, clinical geneticists and other paediatricians in Australia who are actively working with and diagnosing children with neurodevelopmental problems ie front line medical profressionals.	We were unable to control who volunteered to take part in the Advisory Groups. We extended invitations to professional associations to share with their members and the Steering Committee circulated invitations throughout their professional networks. We did our best to involve as many people in the process that we could. You are welcome to share the public consultation versions of the documents with your colleagues to provide further feedback.

Appendix J: Summarised Evidence to Decision Frameworks

Narrative summaries of the strength of the association sections have been provided. For review and discussion versions of these documents the Guidelines Development Group versions previously contained the clinically relevant GRADE summary tables. These have been amended for length and to avoid duplication of information. GRADE summary tables are available in the Supplemental Files for the Technical Report for the components of the diagnostic criteria.

QUESTION

What is available evidence for using physical size as part of the diagnostic criteria for FASD?	
POPULATION:	Individuals with prenatal alcohol exposure (PAE) or fetal alcohol spectrum disorder (FASD)
EXPOSURE:	PAE
COMPARISON:	Control (typically developing and non/minimal PAE exposure)
MAIN OUTCOMES:	Birth weight; birth length; postnatal weight; postnatal height (i.e., postnatal measures refer to any measures taken after birth).
SETTING:	Multidisciplinary specialist clinics; single discipline specialist clinics; primary health care
PERSPECTIVE:	Practitioner population perspective
BACKGROUND:	There are discrepancies between current diagnostic criteria for FASD regarding the inclusion of physical size in diagnostic criteria. Canadian/Australian criteria currently do not include physical size. Some criteria include restrictions in physical size at the 10th percentile (e.g., Hoyme et al., 2016; Landgraf et al., 2013). One diagnostic criteria (Astley 2013) includes both the 3rd and 10th percentile.
CONFLICT OF INTERESTS:	None

BIRTH WEIGHT

Strength of the association How substantial is the association between PAE and the outcome?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	At **very heavy** levels of PAE there was a medium association between PAE and birth weight for the more critical outcomes of small for gestational age (SGA) and low birth weight (LBW). At **heavy** levels of PAE there was a minimal to small association of SGA and small association for LBW. At **light** and **moderate** levels of PAE there was no to minimal associations found. At **very heavy** PAE the mean difference (MD) in birth weight (grams) between PAE and control was clinically significant. At **heavy** PAE the MD between PAE and control was statistically significant, but potentially not clinically significant. For the diagnosed studies: As expected, groups including participants with a clinical diagnosis, which included physical size as a diagnostic criterion had higher mean differences in birth weight compared to controls. *See the systematic review report pages for an overview of findings and Supplemental File C for all available results.*	The overall judgement is based on the more critical outcomes of SGA and LBW at heavy and very heavy levels of exposure. SGA definitions: 12 studies defined SGA as <10th percentile; 1 study (Jaddoe et al 2007) defined SGA as <3rd percentile); 1 study (McDonald et al 1992) defined SGA as <5th percentile; 2 studies (Niclasen et al 2014, Popova et al 2021) did not define SGA. LBW: Preferenced adjusted values for LBW where available. Eight studies adjusted for gestational age. There were other studies that reported adjusted Odds Ratios (aORs) but included other covariates besides gestational age. While the outcome of LBW does not account for gestational age most LBW studies did adjust for gestational age in the analysis Diagnosed studies: Somewhat limited utility of the evidence from the diagnosed studies – as participant allocation to groups is based on presence/absence of physical

		size as a feature. Therefore, these outcomes were not considered as critical in the overall judgements provided.
Certainty of evidence What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ○ No included studies ○ Varies	Generally, higher levels of certainty found for studies assessing SGA and LBW compared to birthweight in grams. Certainty also varied based on the level of exposure within each of the outcomes, with higher certainty found at higher levels of exposure. SGA studies at heavy and Very Heavy exposure level were rated as Moderate certainty. LBW studies Low to Moderate Certainty mostly driven by risk of bias. Birth weight in grams Very Low to Low Certainty driven by risk of bias and inconsistency. *See the relevant systematic review report pages 20-24 for an overview of findings and Supplemental File C for all available results.*	Overall judgement based on more critical outcomes of SGA and LBW. Data collected on raw birthweight were often reported as participant demographics and therefore had higher risk of bias. Most critical exposure levels were the heavy and very heavy levels.
Values Is there important uncertainty about or variability in how much people value the outcome?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**

○ Important uncertainty or variability ○ Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ○ No important uncertainty of variability	No information systematically collected regarding how individuals attending for assessment/their caregivers value birth weight. In terms of different outcome measures SGA and LBW are the more important outcomes than raw birth weight (grams). The Guideline Development Group did not believe that there would be important uncertainty in how much people valued the different birthweight outcomes.	

Resources required. How large are the resource requirements (costs)?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Large costs ○ Moderate costs ○ Negligible costs and saving ○ Moderate savings ○ Large savings ○ Varies ○ Don't know	No information systematically collected regarding resources required for assessing birth weight. In the context of assessments being completed when individuals are older (e.g., preschool age and up) sometimes parents/caregivers have birthweight information available, but for many children in out-of-home care and for adults, this information often needs to be requested from the hospital records. Sometimes there is variability in the ease of accessing hospital records – could require some follow-up time from an administrative staff member. However, this information is likely to already be requested as part of the current	

	assessment process when FASD is being considered, therefore the Guideline Development Group believes there to be negligible costs/savings.	

Certainty of evidence of required resources What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Very low ○ Low ○ Moderate ○ High ○ No included studies	No included studies directly assessing this.	

Equity What would be the impact on health equity?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Reduced ○ Probably reduced ○ Probably no impact ○ Probably increased	No information systematically collected regarding equity. Given there are a range of factors that can influence birth weight that are associated with social determinants of health, use of birth weight without consideration of these factors could lead to overdiagnosis in some groups of people in Australia. Good practice statements are provided to support implementation to reduce impacts on health equity.	

○ Increased ○ Varies ○ Don't know		

Acceptability Is the outcome acceptable to be measured by key stakeholders?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know	No evidence was systematically collected regarding acceptability. Given birth weight is a routine measure the Guideline Development Group believes this is likely to be acceptable.	

Feasibility Is the outcome/criteria feasible to be measured/collected across all relevant settings?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies	Generally, birthweight is already collected as part of routine care across all relevant settings and thus we know it is feasible to collect. Guideline Development Group noted that sometimes there can be challenges with accurately collecting information regarding gestational age and therefore this has been rated as probably yes.	

○ Don't know		

Diagnostic utility Is the yield/uniqueness/value of the outcome/criteria for specifically identifying condition of interest? (including the ease of using other tests based on that factor to rule out other associated conditions with that criteria)		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Very low ○ Low ○ Moderate ○ High	The dose-response relationship found here provides support for the potential diagnostic utility of birth weight in the presence of PAE. However, there are a wide range of other factors (e.g., genetic conditions, other prenatal exposures, prenatal nutrition) that can also be associated with reductions in birthweight. Diagnostic utility varies across the levels of PAE, with very heavy levels of PAE found to have increased risk of low birth weight. Moderate diagnostic utility noted in the presence of very heavy PAE.	Diagnostic utility is assessed here in the presence of PAE. Diagnosis using this feature would not be considered in situations where information regarding PAE is not available.

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
STRENGTH OF ASSOCIATION	Trivial	**Small**	**Moderate**	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	**Low**	**Moderate**	High			No included studies
VALUES	Important uncertainty or variability	Possibly important	**Probably no important**	No important uncertainty or variability			

	JUDGEMENT						
		uncertainty or variability	**uncertainty or variability**				
RESOURCES REQUIRED	Large costs	Moderate costs	**Negligible costs and savings**	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			**No included studies**
EQUITY	Reduced	**Probably reduced**	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
DIAGNOSTIC UTILITY	Very low	Low	**Moderate**	High			

TYPE OF RECOMMENDATION

Strong recommendation against the outcome	Conditional recommendation against the outcome	**Conditional recommendation for the outcome**	Strong recommendation for the outcome
○	○	○	○

CONCLUSIONS

Recommendation

The Australian FASD Guidelines Development Group suggests that birthweight corrected for gestational age according to the appropriate age- and sex-specific charts, be considered in the diagnosis of FASD and to account for individual variability it has been listed as a diagnostic specifier.

Assessment of birthweight needs to be part of a comprehensive medical examination. This medical exam should consider both other causes and conditions that may better explain reductions in birth weight, in conjunction with the available evidence regarding the level of prenatal alcohol exposure. Clinical decision making is required based on the information provided in the 'Subgroup' and 'Implementation' sections below to determine if the level of physical size restriction for an individual is of concern. Good practice statements and implementation considerations are provided in the medical assessment section of the main guidelines document to support implementation.

Justification

This process compared different levels of prenatal alcohol exposure (i.e., light, moderate, heavy, and very heavy) reported in the available studies and quantified and grouped these exposures consistently across all studies. This was done according to the grams per week to enable equivalency in comparing the effects across the different studies. The available evidence demonstrated a small to moderate association between birth weight outcomes at heavy and very heavy levels of prenatal alcohol exposure with a low to moderate level of certainty. The strength of the association and the level of certainty of the evidence increased with the level of prenatal alcohol exposure. The available evidence did not allow for comprehensive comparison regarding the association between prenatal alcohol exposure and birth weight across different percentile ranges.

Subgroup considerations

It should be taken into consideration that birthweights can vary across the population, due to a wide range of demographic, maternal, placental, and fetal medical factors (Fiken et al., 2018). Identifying and differentiating between what is typical birth weight and small for gestational age should be based on a combination of medical assessment and consideration of relevant individual risk factors. Over-reliance on growth charts alone, without consideration of wider contextual information may pathologize typical variation or miss children in need of support (Thompson, 2021). Taking into consideration background physical size modifying factors such as maternal size, ethnicity and parity can allow for more accurate detection of pathological birth weight measures (Clayton et al., 2007).

Implementation considerations

Birth weight charts

Assessment of birth weight for full-term infants should be undertaken using the WHO 2006 growth standards.

In 2012, all Australian states and territories agreed to adopt the WHO 2006 growth standards for children aged 0 to 2 years (see the Royal Children's Hospital Melbourne, Child Growth e-learning module for more information). The WHO growth standards are used in Australian babies' personal health records (e.g., yellow, blue, or red books).

Assessment of birth weight corrected for gestational age for preterm infants (i.e., < 37 weeks) should be undertaken using the Fenton growth charts, which are widely used throughout Australia.

Customised Australian birth weight percentiles have been developed but currently lack validation (Joseph et al., 2020).

Practical considerations in the assessment process

Assessment of birth weight requires accurate knowledge of gestational age, which ideally is based on a first trimester ultrasound. For some pregnant women/people who were unaware of their pregnancy until later in pregnancy or who were unable to access prenatal care, this may need to be estimated (e.g., from date of the last menstrual period [LMP] + 282 days; Nguyen 1999), but it should be noted that LMP based estimations are subject to error (Morin, 2005).

When completing a medical evaluation of an individual later in life (i.e., school aged children, adolescents, and adults) information regarding birth weight is sometimes not available directly from the individual attending for assessment or their parents/caregivers. In instances where individuals are born in Australia, practitioners can submit a request to the hospital to access their birth record. Different hospitals have different processes for accessing and providing this information. Practitioners also need to be aware that there is variability in the timeliness of the completion of record requests across different hospitals and take this into consideration in the assessment process (e.g., could have a process of requesting medical records during the intake or early information gathering processes, which could be supported by administrative staff).

Management

Practitioners need to be aware of their local state/territory clinical guidelines regarding assessment, diagnosis, and management of small for gestational age infants, as local guidelines can contain variations in current practice-based recommendations across clinical settings.

Monitoring and evaluation

Birthweight information should be collected and reported as a percentile for all infants (i.e., not just reported to the 3rd or 10th percentiles) to enable monitoring and future research regarding the consideration and incorporation of different percentile ranges to continue to improve diagnostic practices.

Research priorities

Future research is needed to understand the association between different birth weight outcomes and likelihood of adverse life outcomes to facilitate further understanding of the biological and clinical basis for different percentile thresholds for diagnosis. Most available literature defines small for gestational age (SGA) at the 10th percentile, with a small number of studies using 3rd or 5th percentile cut offs. However, 3rd or 10th percentile cut-offs for SGA are arbitrary. Further research is needed to understand the relationships between different clinical cut-offs and the likelihood of adverse outcomes. For example, Xu, Simonet, Luo et al. (2009) reported that 15th percentile birth weight may be the optimal cut-off, based on more than 2-fold risk of neonatal mortality and the 5th percentile may be more optimal to identify severe SGA, where infants were at 3-fold increased risk of neonatal mortality.

BIRTH LENGTH

Strength of the association

How substantial is the association between PAE and the outcome?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	At **very heavy** and **heavy** levels of PAE there was a moderate association between PAE and birth length (cm). At **very heavy** and **heavy** levels of PAE, the mean difference (MD) between PAE and control was clinically significant. There was no clinically significant association at moderate or light PAE based on the available research.	There was significantly less research available assessing birth length compared to birth weight. Birth length (cm) is raw data and generally did not include control for potential confounding variables. Diagnosed studies:

	There was a significant association and clinically significant difference between FASD diagnosed groups and controls. Birth length was similar between the available diagnostic groups, although there was no available evidence summarising an FAS only group compared to other diagnostic groups. *See the systematic review report for an overview of findings and Supplemental File C for all available results.*	Somewhat limited utility of the evidence from the diagnosed studies – as participant allocation to groups is based on presence/absence of physical size as a feature. Therefore, these outcomes were not considered as critical in the overall judgements provided.
Certainty of evidence What is the overall certainty of the evidence of effects?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Very low ○ Low ○ Moderate ○ High ○ No included studies	Exposure studies had Very Low to Low Certainty, most commonly due to risk of bias and then inconsistency and imprecision. Diagnosed studies had Very Low Certainty due to risk of bias, inconsistency, and indirectness. *See the systematic review report for an overview of findings and Supplemental File C for all available results.*	Birth length assessed in the exposure studies is the more critical outcome compared to birth length assessed in the diagnosed studies.
Values Is there important uncertainty about or variability in how much people value the outcome?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**

○ Important uncertainty or variability ○ Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ○ No important uncertainty of variability	No different measures to compare here (i.e., all studies assessed birth length in cm).	

Resources required How large are the resource requirements (costs)?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Large costs ○ Moderate costs ○ Negligible costs and saving ○ Moderate savings ○ Large savings ○ Varies ○ Don't know	No information systematically collected regarding resources required for assessing birth length. In the context of assessments being completed when individuals are older (e.g., preschool age and up) sometimes parents/caregivers have this information available, but for many children in out-of-home care and adults this information often needs to be requested from the hospital records. Sometimes there is variability in the ease of accessing hospital records – could require some follow-up time from an administrative staff member.	

Certainty of evidence of required resources What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Very low ○ Low ○ Moderate ○ High ○ No included studies	No evidence available directly assessing costs/resources required for assessing birth length.	
Equity What would be the impact on health equity?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Reduced ○ Probably reduced ○ Probably no impact ○ Probably increased ○ Increased ○ Varies ○ Don't know	No information systematically collected regarding equity. Given there are a range of factors that can influence birth length that are associated with social determinants of health, use of birth length without consideration of these factors could lead to overdiagnosis in some groups of people in Australia. Good practice statements are provided to support implementation approaches that reduce impacts on equity.	
Acceptability		

Is the outcome acceptable to be measured by key stakeholders?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know	Given that birth length is a routine measure collected the Guideline Development Group believes this is likely to be acceptable.	
Feasibility Is the outcome/criteria feasible to be measured/collected across all relevant settings?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know	Generally, birth length is already collected as part of routine care across all relevant settings and thus we know it is feasible to collect. Guideline Development Group noted that sometimes there can be challenges with accurately collecting information regarding gestational age and therefore this has been rated as probably yes.	
Diagnostic utility Is the yield/uniqueness/value of the outcome/criteria for specifically identifying condition of interest? (including the ease of using other tests based on that factor to rule out other associated conditions with that criteria)		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**

○ Very low ○ Low ○ Moderate ○ High	The available research indicating a dose-response relationship provides support for the potential diagnostic utility of birth length in the presence of PAE. However, there are a range of other factors that could be associated with reductions in birth length. Diagnostic utility varies across the levels of PAE, with heavy and very heavy levels found to higher risk of impacts on birth length. Judgement of diagnostic utility was assessed at heavy and very heavy levels of PAE. Whilst there was a smaller body of evidence available to assess for birth length, compared to birthweight, the degree of change in birth length required to result in a clinically significant change was smaller compared to birth weight.	Assessed in the presence of PAE. Diagnosis of would not be considered in situations where information regarding PAE is not available.

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
STRENGTH OF ASSOCIATION	Trivial	Small	**Moderate**	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	**Very low**	**Low**	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	**Probably no important uncertainty or variability**	No important uncertainty or variability			
RESOURCES REQUIRED	Large costs	Moderate costs	**Negligible costs and savings**	Moderate savings	Large savings	Varies	Don't know

	JUDGEMENT						
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			**No included studies**
EQUITY	Reduced	**Probably reduced**	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
DIAGNOSTIC UTILITY	Very low	Low	**Moderate**	High			

TYPE OF RECOMMENDATION

Strong recommendation against the outcome	Conditional recommendation against the outcome	**Conditional recommendation for the outcome**	Strong recommendation for the outcome
○	○	○	○

CONCLUSIONS

Recommendation

The Australian FASD Guidelines Development Group suggests that birth length corrected for gestational age according to the appropriate age- and sex-specific charts is considered in the diagnosis of FASD and to account for individual variability it has been listed as a diagnostic specifier.

Assessment of birth length needs to be part of a comprehensive medical examination. This medical exam should consider both other causes and conditions that may better explain reductions in birth length, in conjunction with the available evidence regarding the level of prenatal alcohol exposure. Clinical decision making is required based on the information provided in the Subgroup and Implementation Considerations sections below to determine if the level of physical size restriction for an individual is of concern. Good practice statements are provided in the medical assessment chapter of the main guidelines document to support implementation of this recommendation.

Justification

This process compared the available evidence across different levels of PAE (i.e., moderate, heavy, and very heavy) reported in the available studies and quantified and grouped according to the grams per week of prenatal alcohol exposure to enable equivalency in comparing the effects across the different studies. The available evidence demonstrated a moderate association between birth length at heavy and very high levels of prenatal alcohol exposure with a very low to low certainty of evidence. There was no research available that provided information regarding the association between different percentile ranges and birth length.

Subgroup considerations

It should be taken into consideration that birth lengths can vary across the population, due to a wide range of demographic, maternal, placental, and fetal medical factors (Fiken et al., 2018). Identifying and differentiating between what is typical birth length and small for gestational age should be based on a combination of medical assessment and consideration of relevant individual risk factors. Over-reliance on growth charts alone, without consideration of wider contextual information may pathologize typical variation or miss children in need of support (Thompson, 2021). Taking into consideration background physical size modifying factors such as maternal size, ethnicity and parity can allow for more accurate detection of pathological birth length measures (Clayton et al., 2007).

Implementation considerations

Birth length charts

Assessment of birth length for full-term infants should be undertaken using the WHO 2006 growth standards.

In 2012, all Australian states and territories agreed to adopt the WHO 2006 growth standards for children aged 0 to 2 years (see the Royal Children's Hospital Melbourne, Child Growth e-learning module for more information). The WHO growth standards are used in Australian babies' personal health records (e.g., yellow, blue, or red books).

Assessment of birth length corrected for gestational age for preterm infants (i.e., < 37 weeks) should be undertaken using the Fenton growth charts, which are widely used throughout Australia.

Practical considerations in the assessment process

Assessment of birth length corrected for gestational age requires accurate knowledge of gestational age, which ideally is based on a first trimester ultrasound. For some pregnant women/people who were unaware of their pregnancy until later in pregnancy or who were unable to access prenatal care, this may need to be estimated (e.g., from date of the last menstrual period [LMP] + 282 days; Nguyen 1999), but it should be noted that LMP based estimations are subject to error (Morin, 2005).

When completing a medical evaluation of an individual later in life (i.e., school aged children, adolescents, and adults) information regarding birth length is sometimes not available directly from the individual attending for assessment or their parents/caregivers. In instances where individuals are born in Australia, practitioners can submit a request to the hospital to access their birth record. Different hospitals have different processes for accessing and providing this information (e.g., completing a request form and sending requested information electronically, sending a request form and information via fax). Practitioners also need to be aware that there is variability in the timeliness of the completion of record requests across different hospitals and take this into consideration in the assessment process (e.g., could have a process of requesting medical records during the intake or early information gathering processes, which could be supported by administrative staff).

Management

Practitioners need to be aware of their local state/territory clinical guidelines regarding assessment, diagnosis, and management of reductions in birth length for infants, as local guidelines can contain variations in current practice-based recommendations across

clinical settings.

Monitoring and evaluation

Birth length information should be collected and reported to all percentiles for all infants (i.e., not just reported to the 3rd or 10th percentiles) to enable monitoring and future research regarding the consideration and incorporation of different percentile ranges to continue to improve diagnostic practices.

Research priorities

Future research is needed to investigate the effect on birth length across different levels of prenatal alcohol exposure.

Future research is needed to investigate the association of different birth length percentile ranges and varying levels of prenatal alcohol exposure.

Future research is needed to better understand the association between different birth length percentiles for individuals with prenatal alcohol exposure and the likelihood of adverse life outcomes to facilitate further understanding of the biological and clinical basis for different percentile thresholds for diagnosis.

There was a lack of current evidence available to compare the impact of different percentile cut offs. There is variability in other FASD guidelines internationally and the wider literature regarding definitions of reduced birth length.

POSTNATAL WEIGHT

Strength of the association How substantial is the association between PAE and the outcome?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small	Very large association found for very heavy exposure.	Exposure studies and the outcome of weight < 10th%tile was the more

○ Moderate ○ Large ○ Varies ○ Don't know	Small association found for moderate and heavy exposure. Potentially a clinically significant difference in weight (kg) > 12 months but not for < 12 months. Expected pattern was observed whereby FAS group that included growth restriction as a diagnostic feature had higher mean differences in current weight compared to controls across all age groups and available outcomes. Larger mean differences were found for older children (9-18 years) compared to younger children (6-9 years) for FAS group and the opposite was found for pFAS and ARND groups. More severe reductions in weight (i.e., as part of FAS diagnoses) may be more likely to persist over time. *See the systematic review report for an overview of findings and Supplemental File C for all available results.*	critical outcome used to inform the overall judgements.
Certainty of evidence What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ○ No included studies	Exposure studies (weight < 10th percentile) had Very Low to Low Certainty. Generally due to risk of bias and imprecision. *See the relevant systematic review report for an overview of findings and Supplemental File C for all available results.*	Exposure studies and outcome of weight < 10th percentile was the more critical outcome used here to inform the overall judgement.
Values Is there important uncertainty about or variability in how much people value the outcome?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**

○ Important uncertainty or variability ○ Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ○ No important uncertainty of variability	No information systematically collected regarding patient values. The Guidelines Development Group believes there would be no uncertainty or variability in the importance of the measures.	
Resources required How large are the resource requirements (costs)?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Large costs ○ Moderate costs ○ Negligible costs and saving ○ Moderate savings ○ Large savings ○ Varies ○ Don't know	No information systematically collected regarding resources required for assessing postnatal weight. However, weight is already routinely collected as part of the standard medical examination, across all relevant service settings. Therefore, the Guideline Development Group believes there would be negligible costs/savings.	
Certainty of evidence of required resources What is the certainty of the evidence of resource requirements (costs)?		

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ○ No included studies	No included studies.	
Equity What would be the impact on health equity?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Reduced ○ Probably reduced ○ Probably no impact ○ Probably increased ○ Increased ○ Varies ○ Don't know	No information systematically collected regarding equity. Given there are a range of factors that can influence postnatal weight that are associated with social determinants of health, use of postnatal weight without consideration of these factors could lead to overdiagnosis in some groups of people in Australia. Good practice statements are provided to support implementation approaches to reduce impacts on health equity.	
Acceptability Is the outcome acceptable to be measured by key stakeholders?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ No ○ Probably no ○ Probably yes ○ Yes	Given that weight is a routine measure collected the Guideline Development Group believes this is likely to be acceptable.	

○ Varies ○ Don't know		

Feasibility

Is the outcome/criteria feasible to be measured/collected across all relevant settings?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know	Already collected measure as part of routine care across all relevant settings and thus we know it is feasible to collect.	

Diagnostic utility

Is the yield/uniqueness/value of the outcome/criteria for specifically identifying condition of interest? (including the ease of using other tests based on that factor to rule out other associated conditions with that criteria)

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High	There was a dose response relationship across the available evidence for moderate and very heavy levels of PAE, which provides support for diagnostic utility of postnatal weight in the presence of PAE. However, this was slightly inconsistent across moderate and heavy levels of PAE. There are a range of other factors that could be associated with postnatal weight, this includes both prenatal and postnatal factors. Diagnostic utility varies across the levels of PAE, associations were seen between moderate and very heavy levels for postnatal weight. Odds ratio for very heavy PAE was higher for postnatal weight compared to birthweight. However, there was wider variability in the findings for postnatal weight compared to birthweight.	There was less research available assessing postnatal weight compared to birthweight for exposure studies and wider variability in available data. Assessed in the presence of prenatal alcohol exposure. Diagnosis based on

		this feature would not be considered in situations where information regarding PAE is not available.

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
STRENGTH OF ASSOCIATION	Trivial	Small	**Moderate**	**Large**		Varies	Don't know
CERTAINTY OF EVIDENCE	**Very low**	**Low**	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	**Probably no important uncertainty or variability**	No important uncertainty or variability			
RESOURCES REQUIRED	Large costs	Moderate costs	**Negligible costs and savings**	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			**No included studies**

	JUDGEMENT						
EQUITY	Reduced	**Probably reduced**	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	**Yes**		Varies	Don't know
DIAGNOSTIC UTILITY	Very low	Low	**Moderate**	High			

TYPE OF RECOMMENDATION

Strong recommendation against the outcome	Conditional recommendation against the outcome	**Conditional recommendation for the outcome**	Strong recommendation for the outcome
○	○	○	○

CONCLUSIONS

Recommendation

The Australian FASD Guidelines Development Group suggests that postnatal weight according to the appropriate age and sex specific growth charts should be considered in the diagnosis of FASD and to account for individual variability it has been listed as a diagnostic specifier.

Wherever possible, weight should be assessed over more than one occasion to ascertain that there has been a consistent pattern of weight restriction. Assessment of postnatal weight needs to be part of a comprehensive medical examination that excludes other causes, conditions or illnesses and monitoring of nutrition and exercise that may explain restrictions in postnatal weight. Clinical decision making is required based on the information

provided in the Subgroup and Implementation Considerations sections below to determine if the level of physical size restriction for an individual is of concern. Good practice statements are provided in the medical assessment section of the main guidelines document to support implementation of this recommendation.

Justification

This process compared the available evidence across different levels of PAE (i.e., moderate, heavy, and very heavy), where the PAE level reported in the available studies and was quantified and grouped according to the grams per week of prenatal alcohol exposure to enable equivalency in comparing effects across different studies. The available evidence demonstrated a moderate to large association between postnatal weight < 10th percentile at moderate and very heavy levels of PAE, with a very low to low certainty of evidence.

There was less consistency in the results for postnatal weight compared to birth weight, which may be a consequence of the wide range of postnatal influences on physical size outcomes. However, based on the available evidence, there was a group of individuals with very heavy PAE who may present with significant restrictions in postnatal weight and evidence that even at moderate levels of PAE there could be reductions in postnatal weight for some individuals.

Subgroup considerations

It should be taken into consideration that postnatal weight can vary across the population, due to a wide range of demographic, health behaviour and medical factors. Identifying and differentiating between what is typical postnatal weight or reduced levels of postnatal weight for an individual's age and sex, should be based on a combination of medical assessment and consideration of relevant individual risk factors. Over-reliance on growth charts alone, without consideration of wider contextual information may pathologize typical variation or miss individuals in need of support (Thompson, 2021). Taking into consideration background physical size modifying factors such as ethnicity, nutrition and health status can allow for more accurate detection of pathological postnatal weight measures.

Implementation considerations

Postnatal weight charts

For children up to 2 years of age the WHO 2006 growth standards are used throughout Australia for assessment of postnatal weight. The WHO growth standards are used in Australian babies' personal health records for tracking growth trajectories (i.e., Red or Blue Books)

The United States Centre for Disease Control (CDC) growth charts are used in most jurisdictions for children and adolescents aged 2 to 18 years.

The Northern Territory has adopted the WHO 2006 growth standards for 2 to 18 years olds.

Western Australia has adopted the WHO 2006 growth standards for children up to 5 years of age.

Practitioners are encouraged to check their local health services practice guidelines to ensure they are up to date with the current recommendations in their context.

Corrections for prematurity

It is recommended to correct age for prematurity for children born < 37 weeks until the age of 2 years or until the child 'catches up', whichever occurs sooner. Once an infant reaches their expected birth date, growth can be plotted on the WHO 0 – 2 years charts (Royal Children's Hospital Melbourne, Child Growth e-learning modules).

Assessment of weight for adults

Growth charts are only available until 18 years of age. Where available, physical size measurements for ages < 18 years of age could be requested from medical records and considered to see if an individual has presented with a pattern of restrictions in weight over time.

One-off measures vs serial measures

A one-off measurement plotted on a growth chart describes an individual's current physical size not their growth. To describe an individual's pattern of growth, serial measurements over time are required. Assessment of growth involves reviewing the overall trajectory of weight-for-age, length/height-for-age and weight compared to length/height, or BMI-for-age (> 2-year-olds) to determine how an individual is tracking and whether they are crossing percentiles in an upward or downward fashion. The direction of the measurements on the growth curve is considered to be more important than the actual percentile (Royal Children's Hospital Melbourne, Child Growth e-learning modules).

Management

Practitioners need to be aware of their local state/territory clinical guidelines regarding assessment, diagnosis and management of postnatal weight, as local guidelines can contain variations in current practice-based recommendations across clinical settings.

Monitoring and evaluation

Postnatal weight information should be collected and reported to the percentile range found for all children (i.e., not just to the 3rd or 10th percentiles) to enable monitoring and future research regarding the consideration and incorporation of different percentile ranges to continue to improve diagnostic practices

Research priorities

Future research is needed to investigate postnatal weight outcomes across different levels of prenatal alcohol exposure.

Future research is needed to investigate further the associations between different postnatal weight percentiles ranges and varying levels of prenatal alcohol exposure.

Future research is needed to understand the associations between different postnatal weight percentiles for individuals with prenatal alcohol exposure and likelihood of adverse life outcomes to facilitate further understanding of the biological and clinical basis for different percentile thresholds for diagnosis.

POSTNATAL HEIGHT

Strength of the association How substantial is the association between PAE and the outcome?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	Moderate to large association found for **moderate, heavy, and very heavy** PAE for postnatal height <10th%tile. In the 6-9 years age group, FAS and pFAS groups had similar mean differences in height (cm). In the 9–18-year age group, FAS had a larger mean difference, followed by pFAS/FAS and ARND. Larger mean differences in older groups (9-18 years) compared to children 6-9years for FAS. Larger mean difference in younger group compared to older for pFAS/FAS and ARND/other. *See the relevant systematic review for an overview of findings and Supplemental File C for all available results.*	Most critical outcome available are the exposure studies assessing height < 10th percentile.
Certainty of evidence What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ○ No included studies	Exposure studies had Very Low to Low Certainty due more often to risk of bias and imprecision. *See the relevant systematic review report pages 20-24 for an overview of findings and Supplemental File C for all available results.*	Most critical outcomes exposure studies assessing postnatal heigh < 10th percentile.
Values Is there important uncertainty about or variability in how much people value the outcome?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**

○ Important uncertainty or variability ○ Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ○ No important uncertainty of variability	No information systematically collected regarding patient values. Guidelines Development Group believes there is no uncertainty.	

Resources required How large are the resource requirements (costs)?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Large costs ○ Moderate costs ○ Negligible costs and saving ○ Moderate savings ○ Large savings ○ Varies ○ Don't know	No information systematically collected regarding resources required for assessing postnatal height. Postnatal height is already routinely collected as part of the standard medical evaluation across all relevant contexts. Therefore, the Guideline Development Group believes that there would be negligible costs/savings.	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Very low ○ Low ○ Moderate ○ High ○ No included studies	No included studies.	
Equity What would be the impact on health equity?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Reduced ○ Probably reduced ○ Probably no impact ○ Probably increased ○ Increased ○ Varies ○ Don't know	No information systematically collected regarding equity. Given there are a range of factors that can influence postnatal height that are associated with social determinants of health, use of postnatal height without consideration of these factors could lead to overdiagnosis in some groups of people in Australia. Good practice statements are provided to support implementation approaches to reduce impacts on health equity.	
Acceptability Is the outcome acceptable to be measured by key stakeholders?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**

○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know	Given that is already collected as part of routine medical examinations likely to be acceptable.	
Feasibility Is the outcome/criteria feasible to be measured/collected across all relevant settings?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know	Already collected measure as part of routine care across all relevant settings.	
Diagnostic utility Is the yield/uniqueness/value of the outcome/criteria for specifically identifying condition of interest? (including the ease of using other tests based on that factor to rule out other associated conditions with that criteria)		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**

○ Very low ○ Low ○ Moderate ○ High	Dose response relationship was seen across the available evidence for moderate and very heavy levels of PAE, which provides evidence for diagnostic utility in the presence of PAE. However, there are a range of other factors that could be associated with postnatal height measures, including both prenatal and postnatal factors. Diagnostic utility varies across the levels of PAE, associations seen between moderate and very heavy levels of PAE for current height (<10th percentile). Larger odds ratios for postnatal height < 10th percentile compared to birth measures. However, wider variability in the findings for postnatal height compared to birth length.	Assessed in the presence of prenatal alcohol exposure. Diagnosis of would not be considered in situations where information regarding PAE is not available.

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
STRENGTH OF ASSOCIATION	Trivial	Small	**Moderate**	**Large**		Varies	Don't know
CERTAINTY OF EVIDENCE	**Very low**	**Low**	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	**Probably no important uncertainty or variability**	No important uncertainty or variability			
RESOURCES REQUIRED	Large costs	Moderate costs	**Negligible costs and savings**	Moderate savings	Large savings	Varies	Don't know

	JUDGEMENT						
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			**No included studies**
EQUITY	Reduced	**Probably reduced**	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	**Yes**		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	**Yes**		Varies	Don't know
DIAGNOSTIC UTILITY	Very low	Low	**Moderate**	High			

TYPE OF RECOMMENDATION

Strong recommendation against the outcome	Conditional recommendation against the outcome	**Conditional recommendation for the outcome**	Strong recommendation for the outcome
o	o	o	o

CONCLUSIONS

Recommendation

The Australian FASD Guidelines Development Group suggests that postnatal height according to the appropriate age- and sex- specific growth charts is considered in the diagnosis of FASD and to account for individual variability it has been listed as a diagnostic specifier.

Assessment of postnatal height needs to be part of a comprehensive medical examination that excludes other causes and conditions that may better explain restrictions in postnatal height. Clinical decision making is required based on the information provided in the subgroup and implementation considerations sections below to determine if the level of physical size restriction for an individual is of concern. Good practice statements are provided in the medical assessment section of the main guidelines document to support implementation of this recommendation.

Justification

This process compared the available evidence across different levels of PAE (i.e., moderate, heavy, and very heavy) where the PAE level reported in the available studies and quantified and grouped according to the grams per week of prenatal alcohol exposure to enable equivalency in comparing effects across different studies. The available evidence demonstrated a moderate to large association between postnatal height < 10th percentile at Moderate and Heavy and Very Heavy levels of PAE, with a very low to low certainty of evidence.

There was less consistency in the results for postnatal height compared to birth length, which may be a consequence of the wide range of postnatal influences on physical size outcomes. However, based on the available evidence, there was a group of individuals with heavy and very heavy PAE who may present with significant restrictions in postnatal height and evidence that even at moderate levels of PAE there could be reductions in postnatal height for some individuals.

Subgroup considerations

It should be taken into consideration that postnatal height can vary across the population, due to a wide range of demographic, health behaviour and medical factors. Identifying and differentiating between what is typical postnatal height or reduced levels of postnatal height for an individual's age and sex, should be based on a combination of medical assessment and consideration of relevant individual risk factors. Over-reliance on growth charts alone, without consideration of wider contextual information may pathologize typical variation or miss individuals in need of support (Thompson, 2021). Taking into consideration background physical size modifying factors such as ethnicity, mid-parental height, nutrition, and health status can allow for more accurate detection of pathological postnatal height measures.

Implementation considerations

Postnatal height charts

For children up to 2 years of age the WHO 2006 growth standards are used throughout Australia for assessment of postnatal height. The WHO growth standards are used in Australian babies' personal health records for tracking growth trajectories (i.e., Red or Blue Books)

The United States Centre for Disease Control (CDC) growth charts are used in most jurisdictions for children and adolescents aged 2 to 18 years.

The Northern Territory has adopted the WHO 2006 growth standards for 2 to 18 years olds.

Western Australia has adopted the WHO 2006 growth standards for children up to 5 years of age.

Practitioners are encouraged to check their local health services practice guidelines to ensure they are up to date with the current recommendations in their context.

Corrections for prematurity

It is recommended to correct age for prematurity for children born < 37 weeks until the age of 2 years or until the child 'catches up', whichever occurs sooner. Once an infant reaches their expected birth date, growth can be plotted on the WHO 0 – 2 years charts (Royal Children's Hospital Melbourne, Child Growth e-learning modules).

Calculation of mid-parental height

Where information from an individual's biological parents is available, practitioners can calculate mid-parental height to determine if a child is meeting their genetic potential for their height. This can then be taken into considering in clinical decision making to determine if reductions in height are pathological.

Assessment of postnatal heigh for adults

Growth charts are only available until 18 years of age. Where available, physical size measurements for ages < 18 years of age could be requested from medical records and considered to see if an individual has presented with a pattern of restrictions in height over time.

One-off measures vs serial measures

A one-off measurement plotted on a growth chart describes an individual's current physical size not their growth. To describe an individual's pattern of growth, serial measurements over time are required. Assessment of growth involves reviewing the overall trajectory of weight-for-age, length/height-for-age and weight compared to length/height, or BMI-for-age (> 2-year-olds) to determine how an individual is tracking and whether they are crossing percentiles in an upward or downward fashion. The direction of the measurements on the growth curve is more important than the actual percentile (Royal Children's Hospital Melbourne, Child Growth e-learning modules).

Management

Practitioners need to be aware of their local state/territory clinical guidelines regarding assessment, diagnosis and management of postnatal height, as local guidelines can contain variations in current practice-based recommendations across clinical settings.

This includes being aware of local referral guidelines for Endocrinology services. Referral criteria can include: if there is an immediate downward trajectory of height-for-age percentiles, if more than 2 centiles below mid-parental height or outside of expected family pattern or if present with significantly poor growth/short stature (< 3rd percentile).

Monitoring and evaluation

Postnatal height information should be collected and reported to the percentile range found for all individuals (i.e., not just to the 3rd or 10th percentiles) to enable monitoring and future research regarding the consideration and incorporation of different percentile ranges to continue to improve diagnostic practices.

Research priorities

Future research is needed to investigate postnatal height outcomes across different levels of prenatal alcohol exposure.

Future research is needed to investigate further the associations between different postnatal height percentiles ranges and varying levels of prenatal alcohol exposure.

Future research is needed to understand the associations between different postnatal height percentiles for individuals with prenatal alcohol exposure and likelihood of adverse life outcomes to facilitate further understanding of the biological and clinical basis for different percentile thresholds for diagnosis.

Perumal et al. (2018) argue that there is no biological basis for the current 2 SD definition of 'stunting' and that this is an arbitrary cut point and "in reality, the risk of undesirable outcomes including mortality does not change drastically when cross the magic cut-off point" (p. 2044S).

Olofin et al. (2013) undertook a pooled analysis of prospective studies including children < 5 years of age and found the risk of mortality of all causes increased for every 0.5 SD decrease in height-for-age z-scores below –1SD without evidence of an inflection point.

Sudfeld et al. (2015) found that height-for-age z-scores were correlated with cognitive, communication and motor development among children 18-36 months of age across the height-for-age z-score range, with no threshold effect identified at 2SDs or any other cut-off point.

QUESTION

What is available evidence for using major facial features as part of the diagnostic criteria for FASD?	
POPULATION:	Individuals with PAE/FASD
EXPOSURE:	PAE

COMPARISON:	Control (typically developing and non/minimal PAE exposure)
MAIN OUTCOMES:	Philtrum smoothness, vermilion thinness, palpebral fissure length
SETTING:	Multidisciplinary specialist clinics; single discipline specialist clinics; primary health care
PERSPECTIVE:	Practitioner population perspective
BACKGROUND:	There are discrepancies between current diagnostic criteria for FASD regarding how facial features are considered as part of criteria. This includes: the number of facial features included for diagnosis (i.e., the IOM criteria includes 2 facial features and all other criteria include 3 features); the clinical cut off applied for palpebral fissure length (10th percentile vs 3rd percentile) and how facial features are assessed (i.e., computer analysis vs hand measurements).
CONFLICT OF INTERESTS:	None

MAJOR FACIAL FEATURES

Strength of the association How substantial is the association between PAE the outcome?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ○ Large	Philtrum and lip had data available for moderate, very heavy and confirmed unquantifiable (i.e., quasi heavy to very heavy). Philtrum – large associations for all PAE levels.	Where available information is provided regarding the lip/philtrum guide and

	Lip – no to small association (moderate PAE), borderline medium association (very heavy PAE) to large (confirmed unquantified) associations. Palpebral fissure length had data available for moderate, heavy, very heavy and confirmed unquantifiable. Palpebral fissure length – all large associations, although heavy was highly variable. There were very large associations between diagnostic outcomes that included the presence of facial features as part of the diagnostic criteria and small associations for those diagnostic groups that do not include facial features as part of the diagnostic criteria. *See the relevant systematic review for an overview of findings and Supplemental File E for all available results.*	norms used to assess PFL length. The majority of available evidence applied the UW Lip/Philtrum Guide. The majority of evidence did not report the norms used to assess palpebral fissure lengths. Diagnosed studies: Somewhat limited utility of the evidence from the diagnosed studies – as participant allocation to groups is based on presence/ absence of features. Therefore, these outcomes were not considered as critical in the overall judgements provided.
Certainty of evidence What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ Very low ○ Low ○ Moderate ○ High ○ No included studies ○ Varies	Very Low to Low certainty for the exposure studies. Risk of bias was a concern for all outcomes. *See the systematic review report for an overview of findings and Supplemental File E for all available results.*	

Values

Is there important uncertainty about or variability in how much people value the outcome?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ○ No important uncertainty of variability	Information not systematically collected regarding how much people value the different major facial features outcomes. The Guidelines Development Group believes there is no differences in how people value the different facial features.	

Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o Large costs o Moderate costs o Negligible costs and saving o Moderate savings o Large savings o Varies o Don't know	Information has not systematically been collected regarding resources required for assessing facial features. Facial features assessment could be undertaken by hand or using the University of Washington facial analysis software. Both options require purchase/access to some specific resources (i.e., lip/philtrum guide, small clear plastic ruler and/or facial analysis software). For practitioners/clinics who are already doing assessments costs/savings will be negligible. But for new practitioners/clinics this need to be factored into service design and delivery as the resources will need to be purchased and practitioners will require training in being able to undertake the physical examination.	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o Very low o Low o Moderate o High o No included studies	No included studies directly assessing this.	

Equity

What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

o Reduced o Probably reduced o Probably no impact o Probably increased o Increased o Varies o Don't know	Being able to undertake an assessment of facial features does require additional training for medical professionals. This can mean that this assessment is not always available across all settings/contexts, and this could impact on health equity. Further work could be done to upskill and incorporate a wider range of medical professionals (e.g., GPs, nurse practitioners) in the assessment process, particularly in resource poor locations, which could contribute to reducing impacts on health equity. For example, there are clinic models in the U.S where the medical component of the assessment is undertaken by nurse practitioners. And there have been different models of care developed and provided in Australia where the medical components are undertaken by GPs and nurses. An assessment approach and good practice statements are provided to support implementation approaches to reduce health equity. Additionally, there are no local tools (i.e., lip/philtrum guides, facial analysis software or palpebral fissures norms available for the Australian context). Based on feedback from the Advisory Groups, this is an important consideration in the Australian context. To help reduce health inequities, practitioners can provide this information to individuals attending for assessment and shared decision making could be used to determine if facial features assessment is something that family would like to have included as part of their assessment.	

Acceptability

Is the outcome acceptable to be measured by key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o No o Probably no o Probably yes o Yes	Information not systematically collected regarding acceptability. Facial features are already assessed as part of the assessment process in Australia when considering FASD as one possible outcome. However, based on feedback collected from the Advisory Groups	

○ Varies ○ Don't know	there may be some impacts on acceptability of the assessment of facial features currently due to the lack of locally developed lip/philtrum guides and palpebral fissure norm charts.	

Feasibility

Is the outcome/criteria feasible to be measured/collected across all relevant settings?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know	Information has not been systematically collected regarding feasibility. Assessment of facial features is already undertaken as part of the assessment process when considering FASD as one possible outcome. The Guideline Development Group believes that with some additional training and practice medical professionals who are not currently undertaking assessments of facial features across all relevant settings would be able to complete an assessment of an individual's facial features.	

Diagnostic utility

Is the yield/uniqueness/value of the outcome/criteria for specifically identifying condition of interest? (including the ease of using other tests based on that factor to rule out other associated conditions with that criteria)

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○Very Low ○ Low ○ Moderate ○ High	For those individuals who present with all 3 facial features, once other causes have been considered that could potentially be associated with dysmorphic facial features the diagnostic utility of all three facial features is high.	No studies were identified in the evidence review that compared the diagnostic utility of 2 vs. 3 facial features.

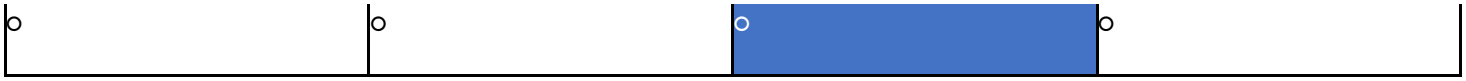
SUMMARY OF JUDGEMENTS

	JUDGEMENT						
STRENGTH OF ASSOCIATION	Trivial	Small	**Moderate**	**Large**		Varies	Don't know
CERTAINTY OF EVIDENCE	**Very low**	**Low**	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	**Probably no important uncertainty or variability**	No important uncertainty or variability			

RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	**Varies**	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			**No included studies**
EQUITY	Reduced	**Probably reduced**	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
DIAGNOSTIC UTILITY	Very Low	Low	Moderate	**High**		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the outcome	Conditional recommendation against the outcome	**Conditional recommendation for the outcome**	Strong recommendation for the outcome



CONCLUSIONS

Recommendation

The Australian FASD Guidelines Development Group suggests philtrum smoothness, vermilion thinness and palpebral fissure length be considered in the diagnosis of FASD and to account for individual variability it has been listed as a diagnostic specifier.

Assessment of facial features needs to be part of a comprehensive medical examination that considers other potential causes of dysmorphic facial features. Good practice statements and implementation considerations tools and tips are provided in the medical assessment section of the main guidelines document to support implementation of this recommendation.

Justification

The available evidence demonstrated a moderate to large association between the three sentinel facial features at moderate and high levels of PAE with a very low to low certainty of evidence.

There was no evidence available that included a control group and investigated the diagnostic utility of 2 compared to 3 facial features, therefore there was no evidence to support a change from 3 to 2 facial features as part of the diagnostic criteria at this time.

Australian practitioners currently use the University of Washington lip/philtrum guides, and this was what the majority of available research evidence had applied.

Across the exposure literature there very few studies available to compare results between the 10th and 3rd percentile cut offs and these studies were often not available at the same level of prenatal alcohol exposure to enable appropriate comparisons.

There was significantly limited information available reporting on the palpebral fissure length norms that were applied in all available research studies.

Another consideration in providing the current recommendation is the impacts on clinical practice in terms of implementability of a recommendation. Currently, the majority of practitioners in Australia use the University of Washington facial analysis software, which applies a 3rd percentile cut off to

palpebral fissure lengths and consequently, changes to a clinical cut-off at this time without the appropriate tools in place to support clinical practice could have impacts on the feasibility of assessment and diagnosis.

Subgroup considerations

There are no locally produced lip/philtrum guides or palpebral fissure norms for individuals from First Nation backgrounds. One study (Tsang et al 2017) compared the two versions of the UW lip/philtrum guide and different PFL norms (i.e., Hall, Stromland, Clarren or Iosub) and found that the African American Lip-Philtrum Guide and the Stromland PFL norms were the best fit for a sample of Aboriginal children from the Kimberley region in WA from the currently available norms and tools.

Given the lack of local tools and norms for assessment of facial features, this information should be provided to individuals accessing assessments from different cultural backgrounds, their families and support networks so they can be involved in shared decision making regarding the assessment process.

Implementation considerations

Lip-Philtrum Guide: The University of Washington Lip/Philtrum Guide is currently used in clinical practice in Australia and is recommended for continued use.

Palpebral fissure length norms: The Stromland norms span the entire age range from birth to adulthood and are recommended for use for all Australians.

There was limited information available that reported on the norms that were applied in the included research studies. The only Australian study comparing the applicability of different palpebral fissure norms (Tsang et al., 2017) was undertaken in an Aboriginal population in WA. The previous Australian Guidelines and revised Canadian guidelines recommend use of the Clarren norm charts from age 6 years and the Stromland norms for < 6 years. Astley et al. (2019) documented that this change in norms resulted in an artificial reduction in the rate of short PFLs in children > 6 years due to the PFL for age in the Clarren charts being approximately 0.5SDs larger than the PFL in the Stromland chart and recommends that the Stromland norms be used across the lifespan.

Photos vs hand measurements of palpebral fissure lengths: In terms of the available information comparing the accuracy of photos compared to hand measurements, a limited number of studies have been undertaken with mixed results reported.

The only Australian study comparing these methods (Tsang et al., 2017) found no statistically significant difference between hand measurements and measurements taken using photos. Practitioners are encouraged to use the University of Washington facial analysis software if possible, or if not possible take measurements by hand using a small clear plastic ruler, depending on what the practitioners are able use in their context and the needs of the individual attending for assessment (e.g., for some individuals it may be culturally inappropriate to take photos as part of the assessment). Furthermore, it is important to consider feedback from Advisory Group members, which indicated that some practitioners are experiencing barriers in implementing the University of Washington facial analysis software as this program is no longer compatible with computer operating systems and is not able to be used in some clinical contexts.

Monitoring and evaluation

Number of facial features should be collected for all individuals (i.e. not just documented as presence or absence of three facial features) to support monitoring and future evaluation.

Palpebral fissure length should be collected and reported to the percentile range found for all individuals (i.e., not just to the 3rd percentile) to enable monitoring and future research regarding the consideration of different percentile ranges to continue to improve diagnostic practices.

Research priorities

Exposure studies that examine sentinel facial features across varying levels of prenatal alcohol exposure.

Research evidence in Australian populations comparing the diagnostic utility of short PFLs being defined at the different cut offs (e.g., 3rd or 10th percentiles) or to inform the development of a diagnostic algorithm that could incorporate both.

Investigate the appropriateness of developing local and culturally appropriate lip/philtrum guides.

Investigate the appropriateness of developing local and culturally appropriate palpebral fissure norm charts.

Develop new 2D facial analysis to support practitioners to overcome the current barriers in using the available facial analysis software due to current computer operating systems and to support the application of different PFL cut-offs research and potentially future clinical purposes.

Further research regarding the clinical and diagnostic utility of 3D facial analysis.

QUESTION

What is available evidence for using minor dysmorphology as part of the diagnostic criteria for FASD?	
POPULATION:	Individuals with PAE/FASD
EXPOSURE:	PAE
COMPARISON:	Control
MAIN OUTCOMES:	All minor dysmorphic features
SETTING:	Multidisciplinary specialist clinics; single discipline specialist clinics; primary health care
PERSPECTIVE:	Practitioner population perspective
BACKGROUND:	Minor dysmorphology features are currently noted during the assessment process but not included in any diagnostic criteria for FASD.
CONFLICT OF INTERESTS:	None

MINOR DYSMORPHOLOGY

Strength of the association How substantial is the association between PAE the outcome?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	Three exposure studies were identified assessing association between minor features and prenatal alcohol exposure. Significant variability in the strength of associations between different minor features at the same levels of PAE. For the diagnosed studies, stronger associations found for diagnostic outcomes of FAS/pFAS compared to ARND/other diagnostic outcomes. *See the systematic review report 20 and 26-27 for an overview of findings and Supplemental File E for all available results.*	
Certainty of evidence What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ○ No included	Very low to low certainty. Very wide confidence intervals noted across most of the minor features.	

studies ○ Varies	*See the systematic review report for an overview of findings and Supplemental File E for all available results.*	

Values

Is there important uncertainty about or variability in how much people value the outcome?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ○ No important uncertainty of variability	Based on information collected from the Advisory Groups there are discrepancies in the value placed on minor dysmorphic features with some people with lived experience placing significant value on the presence of minor features as being key evidence of exposure of prenatal alcohol exposure and other people not.	

Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

o Large costs o Moderate costs o Negligible costs and saving o Moderate savings o Large savings o Varies o Don't know	Information has not been systematically collected regarding resources required for assessing minor dysmorphic features. However, no specific tools are required. Practitioners may require additional training to identify the minor features if this is something they are not already doing.	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o Very low o Low o Moderate o High o No included studies	No included studies directly assessing this.	

Equity

What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o Reduced o Probably reduced o Probably no impact o Probably increased o Increased o Varies o Don't know	Information has not been systematically collected regarding equity. Being able to undertake an assessment of minor dysmorphology features does require additional training for medical professionals. This can mean that this assessment may not always be available across all contexts/settings.	
Acceptability Is the outcome acceptable to be measured by key stakeholders?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
o No o Probably no o Probably yes o Yes o Varies o Don't know	Information has not been systematically collected regarding acceptability. Some medical professionals are already undertaking assessments of minor dysmorphic features however, this may not be a routine assessment for all medical professionals involved in assessments that are considering FASD as one possible outcome. Based on discussions in the Guidelines Development Group there is likely to be differences acceptability between medical professionals.	
Feasibility Is the outcome/criteria feasible to be measured/collected across all relevant settings?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**

o No o Probably no o Probably yes o Yes o Varies o Don't know	Information has not been systematically collected regarding feasibility. The Guideline Development Group believes that with some additional training and practice medical professionals across all relevant settings would be able to complete this assessment.	

Diagnostic utility Is the yield/uniqueness/value of the outcome/criteria for specifically identifying condition of interest? (including the ease of using other tests based on that factor to rule out other associated conditions with that criteria)		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
o Very Low o Low o Moderate o High	There was limited evidence available to examine the association between minor dysmorphic features and prenatal alcohol exposure. Limited ability to examine dose response relationships between minor features and prenatal alcohol exposure. Wide variability in the presence of minor features found in the exposure studies identified. The available diagnostic studies documented a pattern of increasing rates of minor features with diagnostic outcomes that included other physical manifestations (i.e., FAS/pFAS and physical size and facial feature outcomes). However, there was still wide variability in the presentation of features, which would result in low diagnostic utility.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
STRENGTH OF ASSOCIATION	Trivial	Small	Moderate	Large		**Varies**	Don't know
CERTAINTY OF EVIDENCE	**Very low**	**Low**	Moderate	High			No included studies
VALUES	Important uncertainty or variability	**Possibly important uncertainty or variability**	Probably no important uncertainty or variability	No important uncertainty or variability			
RESOURCES REQUIRED	Large costs	Moderate costs	**Negligible costs and savings**	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			**No included studies**
EQUITY	Reduced	**Probably reduced**	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
DIAGNOSTIC UTILITY	Very Low	**Low**	Moderate	High			

TYPE OF RECOMMENDATION

Strong recommendation against the outcome	Conditional recommendation against the outcome	Conditional recommendation for the outcome	Strong recommendation for the outcome
○	○	○	○

CONCLUSIONS

Recommendation

The Australian FASD Guidelines Development Group recommends against including minor dysmorphic features in the diagnostic criteria for FASD.

Practitioners can document dysmorphic features as part of 'associated features' and good practice statements and implementation considerations, tools and tips are provided in the medical assessment section of the main guidelines document to support practitioners.

Justification

There was limited evidence available from exposure studies assessing minor dysmorphic features. The available evidence demonstrated significantly varia associations between the outcomes with a very low to low certainty of evidence.

Subgroup considerations

Implementation considerations

Assessment and collection of minor dysmorphic features can provide clinically useful information and medical professionals can document the presence or absence of these features as part of a physical examination. An 'associated features' section is included that provides information about dysmorphic features that practitioners can document during the assessment.

Monitoring and evaluation

Collection and documentation of all minor dysmorphic features as part of the assessment process would support monitoring and future research regarding the diagnostic utility of these features in the future.

Research priorities

Exposure studies that examine the presence of absence of minor dysmorphic features across different levels of PAE are required to understand the association between PAE and minor dysmorphic outcomes.

There were varying definitions found for minor features across the available research studies. Future research could aim to harmonise definitions to support more accurate comparison of results across studies.

QUESTION

What is available evidence for using head circumference as part of the diagnostic criteria for FASD?

POPULATION:	Individuals with PAE/FASD
EXPOSURE:	PAE
COMPARISON:	Non-exposed control
MAIN OUTCOMES:	Head circumference <10th percentile, head circumference (cm), head circumference <3rd percentile
SETTING:	Multidisciplinary specialist clinics; single discipline specialist clinics; primary health care
PERSPECTIVE:	Practitioner population perspective
BACKGROUND:	There are discrepancies between current diagnostic criteria for FASD how head circumference is considered as part of the diagnostic criteria for FASD. Australian/Canadian and 4-Digit Code criteria includes head circumference **≤** 3rd percentile, Revised IOM Guidelines includes head circumference ≤ 10th percentile and the German Guidelines includes both 10th and 3rd percentiles. The Canadian criteria include head circumference as part of the neurodevelopmental domains, whereas other criteria consider head circumference separately (e.g., revised IOM, 4-Digit Code. There are also differences in whether head circumference is used as a proxy for impairment (4 Digit Code, German Guidelines, Canadian criteria for young children) or whether functional evidence is also required (Revised IOM).
CONFLICT OF INTERESTS:	None

HEAD CIRCUMFERENCE

Strength of the association How substantial is the association between PAE the outcome?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	**Exposure studies** Large association at heavy and very heavy levels of PAE. Minimal to small association at moderate levels of PAE. Generally, no association to minimal at light PAE, one single study with a significant effect at a light exposure level. *See the systematic review report for an overview of findings and Supplemental File G for all available results.*	More critical outcomes considered here for rating were exposure studies and heavy, very heavy or confirmed unquantified exposure. No exposure studies included head circumference < 3rd percentile.
Certainty of evidence What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ○ No included studies ○ Varies	Certainty ranged from very low to low across the most critical outcomes (exposure studies at heavy, very heavy). Majority of studies across the most critical outcomes were rated as Low Certainty commonly due to risk of bias and imprecision. *See the systematic review report for an overview of findings and Supplemental File G for all available results.*	
Values		

Is there important uncertainty about or variability in how much people value the outcome?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ○ No important uncertainty of variability	Information was not systematically collected regarding how individuals attending for assessment/their caregivers value head circumference. Guideline Development Group did not believe that there would be important uncertainty in how much people valued this outcome.	
Resources required How large are the resource requirements (costs)?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Large costs ○ Moderate costs ○ Negligible costs and saving	Information was not systematically collected regarding resources required. However, head circumference is a routine measure collected as part of the assessment process. In the context of assessments being completed when individuals are older (e.g., preschool age and up) sometimes parents/caregivers have birth information available, but for but for many children in out-of-home care and for adults, this information often needs to be requested from the hospital records. Sometimes there is variability in the ease of accessing hospital records – could require some follow-up time from an administrative staff member. However, this information is likely to	

○ Moderate savings ○ Large savings ○ Varies ○ Don't know	already be requested as part of the current assessment process when FASD is being considered, therefore the Guideline Development Group believes there to be negligible costs/savings.	

Certainty of evidence of required resources What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Very low ○ Low ○ Moderate ○ High ○ No included studies	No included studies directly assessing this.	

Equity What would be the impact on health equity?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Reduced ○ Probably reduced ○ Probably no impact ○ Probably increased	Information was not systematically collected regarding equity. However, given that reduced head circumference can be associated with factors that can be influenced by social determinants of health the potential impacts on including this as a diagnostic feature need to be considered. Without taking appropriate consideration of other factors that could influence head circumference, this could lead to over diagnosis is individuals who come from lower socio-economic backgrounds. Good practice statements are provided to support implementation approaches to reduce impacts on health equity.	

○ Increased ○ Varies ○ Don't know		

Acceptability

Is the outcome acceptable to be measured by key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know	Information was not systematically collected regarding acceptability. Given head circumference is a routine measure collected the Guideline Development Group believes this is likely to be acceptable.	

Feasibility

Is the outcome/criteria feasible to be measured/collected across all relevant settings?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies	Information was not systematically collected regarding feasibility. But head circumference is an easily collected measure across all relevant settings. Guideline Development Group noted that sometimes there can be challenges with accurately collecting information regarding gestational age and therefore this has been rated as probably yes.	

○ Don't know		

Diagnostic utility Is the yield/uniqueness/value of the outcome/criteria for specifically identifying condition of interest? (including the ease of using other tests based on that factor to rule out other associated conditions with that criteria)		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○Very Low ○ Low ○ Moderate ○ High	The dose-response relationship found provides support for the potential diagnostic utility of head circumference in the presence of PAE Diagnostic utility varies across the levels of PAE, with increasing associations found with increasing levels of PAE. However, there are a range of other factors that could be associated with reductions in head circumference that need to be considered and excluded.	Assessed in the presence of prenatal alcohol exposure. Diagnosis of would not be considered in situations where information regarding PAE is not available.

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
STRENGTH OF ASSOCIATION	Trivial	Small	Moderate	**Large**		Varies	Don't know
CERTAINTY OF EVIDENCE	**Very low**	**Low**	Moderate	High			No included studies

	JUDGEMENT						
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	**Probably no important uncertainty or variability**	No important uncertainty or variability			
RESOURCES REQUIRED	Large costs	Moderate costs	**Negligible costs and savings**	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			**No included studies**
EQUITY	Reduced	**Probably reduced**	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
DIAGNOSTIC UTILITY	Very Low	Low	**Moderate**	High		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the outcome	Conditional recommendation against the outcome	**Conditional recommendation for the outcome**	Strong recommendation for the outcome

CONCLUSIONS

Recommendation

The Australian FASD Guidelines Development Group suggests that head circumference corrected for gestational age according to the appropriate age- and sex-specific charts is considered in the diagnosis of FASD and to account for individual variability it has been listed as a diagnostic specifier.

Reductions in head circumference are ideally confirmed where repeated head circumference measurements over time remain smaller than expected compared with infants of the same age. Assessment of head circumference needs to be part of a comprehensive medical examination. This medical exam should consider both other causes and conditions that may better explain reductions in head circumference, in conjunction with the available evidence regarding the level of prenatal alcohol exposure. Clinical decision making is required based on the information provided in the 'Subgroup' and 'Implementation' sections below to determine if the level of head circumference restriction for an individual is considered to be of concern. Good practice statements and implementations, considerations, tools and tips are provided in the medical assessment section of the main guidelines document to support implementation of this recommendation.

Justification

This process compared different levels of prenatal alcohol exposure (i.e., light, moderate, heavy, and very heavy) reported in the available studies and quantified and grouped these exposures consistently across all studies. This was done according to the grams per week to enable equivalency in comparing the effects across the different studies. The available evidence demonstrated a strong association between head circumference outcomes at heavy and very heavy levels of prenatal alcohol exposure with a low level of certainty.

The available evidence did not allow for comparison regarding the association between prenatal alcohol exposure and birth weight across different percentile ranges for exposure studies.

Subgroup considerations

It should be taken into consideration that head circumference can vary across the population, due to a wide range of demographic, maternal, placental, and fetal medical factors (Fiken et al., 2018). Identifying and differentiating between what is typical head circumference and small head circumference should be based on a combination of medical assessment and consideration of relevant individual risk factors. Over-reliance on growth charts alone, without consideration of wider contextual information may pathologize typical variation or miss children in need of support (Thompson, 2021).

Implementation considerations

Head circumference growth charts

Assessment of head circumference corrected for gestational age for full-term infants should be undertaken using the WHO 2006 growth standards. The WHO growth standard goes up to 5 years for head circumference. After 5 years the Nellhaus (1968) can be used to assess head circumference up to 18 years of age.

In 2012, all Australian states and territories agreed to adopt the WHO 2006 growth standards for children aged 0 to 2 years (see the Royal Children's Hospital Melbourne, Child Growth e-learning module for more information). The WHO growth standards are used in Australian babies' personal health records (e.g., yellow, blue or red books).

Assessment of head circumference corrected for gestational age for preterm infants (i.e., < 37 weeks) should be undertaken using the Fenton growth charts, which are widely used throughout Australia.

Practical considerations for the assessment process

Assessment of head circumference corrected for gestational age requires accurate knowledge of gestational age, which ideally is based on a first trimester ultrasound. For some pregnant women/people who were unaware of their pregnancy until later in pregnancy or who were unable to access prenatal care, this may need to be estimated (e.g., from date of the last menstrual period [LMP] + 282 days; Nguyen 1999), but it should be noted that LMP based estimations are subject to error (Morin, 2005).

When completing a medical evaluation of an individual later in life (i.e., school aged children, adolescents, and adults) information regarding birth head circumference is sometimes not available directly from the individual attending for assessment or their parents/caregivers. In instances where individuals are born in Australia, practitioners can submit a request to the hospital to access their birth record and early developmental checks.

Different hospitals have different processes for accessing and providing this information. Practitioners also need to be aware that there is variability in the timeliness of the completion of record requests across different hospitals and take this into consideration in the assessment process (e.g., could have a process of requesting medical records during the intake or early information gathering processes, which could be supported by administrative staff).

Relationship between head circumference and neurodevelopmental outcomes.

Whilst there is evidence regarding the potential for reduced head circumference for individuals who have experienced prenatal alcohol exposure. There is inconsistent evidence available regarding the association between reduced head circumference and functional outcomes across the general population and in specific at-risk populations, including FASD (e.g., Treit et al., 2016). Therefore, practitioners should be cautious regarding the use of reductions in head circumference as a proxy for functional impairments.

Diagnosis of young children with three facial features and microcephaly.

There was no research available in the systematic review to examine this. The decision to include this in the Canadian and subsequent Australian Guide was based on the results of one retrospective diagnostic cohort study (Astley 2013). This study indicated that the presence of both 3 sentinel facial features and microcephaly (< 3rd percentile) was associated with significant neurodevelopmental impairment in children older than 8 years. For this reason, it was suggested that infants and young children presenting with 3 sentinel facial features and microcephaly may be provided with a diagnosis of FASD. Given the limited evidence available regarding this, and the concerns raised by the Advisory Group regarding current facial features assessment in Australia (i.e., lack of inter-rater reliability across practitioners and lack of local tools and tools) it is preferred that this diagnosis is made in the presence of confirmed PAE. Future research needs to develop local tools and norms and implementation needs to include a focus on upskilling practitioners to support more accurate facial feature assessment and development of more accessible software to support assessment of facial features.

Monitoring and evaluation

Head circumference should be collected and reported in both centimetres and percentiles for individuals (i.e., not just reported to the 3rd or 10th percentiles) to enable monitoring and future research regarding the consideration of different percentile ranges to continue to improve diagnostic practices.

Research priorities

Future research is needed to understand the association between different head circumference outcomes and likelihood of adverse life outcomes to facilitate further understanding of the biological and clinical basis for different percentile thresholds for diagnosis.

QUESTION

What is available evidence for using structural brain abnormalities as part of the diagnostic criteria for FASD?	
POPULATION:	Individuals with PAE/FASD
EXPOSURE:	PAE
COMPARISON:	Non-exposed control
MAIN OUTCOMES:	Clinically significant incidental findings
SETTING:	Multidisciplinary specialist clinics; single discipline specialist clinics; primary health care
PERSPECTIVE:	Practitioner population perspective

BACKGROUND:	There are discrepancies between current diagnostic criteria for FASD regarding if structural brain abnormalities are included and if they are included how they are considered as part of the diagnostic process. Australian/Canadian considers structural brain abnormalities as part of the brain structure/neurology domain and if present counts as one of the neurodevelopmental domains. Hoyme et al and 4-Digit code consider structural brain abnormalities as a separate component (i.e., not part of the neurobehavioural criteria). German Guidelines excluded structural brain abnormalities (except for head circumference) due to the poor evidence available.
CONFLICT OF INTERESTS:	None

STRUCTURAL BRAIN ABNORMALITIES

Strength of the association How substantial is the association between PAE the outcome?		
JUDGEMENT ○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	RESEARCH EVIDENCE Only one exposure study identified. This one study found a moderate association between increased number of clinically significant MRI findings in individuals with PAE compared to controls. *See the systematic review report for an overview of findings and Supplemental File G for all available results.*	ADDITIONAL CONSIDERATIONS There is a significant body of research documenting the associations between structural brain abnormalities and prenatal alcohol exposure however, nearly all these studies are quantitative research MRI studies. These types of approaches are not available in a clinical context. The research considered here is from the available qualitative clinical MRI studies, for which 3 studies with control groups could be identified. Only one of these was an exposure study.

Certainty of evidence What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ○ No included studies ○ Varies	For the one exposure study available was very low certainty, due to imprecision and risk of bias. *See the relevant systematic review for an overview of findings and Supplemental File G for all available results.*	
Values Is there important uncertainty about or variability in how much people value the outcome?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ○ Probably no important uncertainty or variability	Information was not systematically collected regarding how individuals attending for assessment/their caregivers value this outcome. However, misconceptions currently exist amongst caregivers that the impacts of prenatal alcohol exposure are visible on MRI and that this should be undertaken as part of the assessment process. This may be due to results of quantitative research MRI studies, which people may not be aware are different to what is available in a clinical context.	

○ No important uncertainty of variability		

Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ○ Moderate costs ○ Negligible costs and saving ○ Moderate savings ○ Large savings ○ Varies ○ Don't know	Information was not systematically collected regarding resources required. However, there would be significant costs if MRI was to be included as a requirement of the diagnostic assessment process.	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ○ No included studies	No included studies directly assessing this.	

Equity

What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ○ Probably increased ○ Increased ○ Varies ○ Don't know	Information was not systematically collected regarding equity. However, equity would be reduced if MRI was required as part of a diagnostic assessment process. As many individuals would not have access to this type of specialist service.	

Acceptability

Is the outcome acceptable to be measured by key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know	Information was not systematically collected regarding acceptability. If an MRI was clinically indicated for another reason as part of the assessment process, this would be viewed as acceptable. However, would likely not be acceptable to be required as a specific part of the diagnostic process.	
Feasibility Is the outcome/criteria feasible to be measured/collected across all relevant settings?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know	Information was not systematically collected regarding feasibility.	
Diagnostic utility Is the yield/uniqueness/value of the outcome/criteria for specifically identifying condition of interest? (including the ease of using other tests based on that factor to rule out other associated conditions with that criteria)		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**

○Very Low ○ Low ○ Moderate ○ High	There is limited research available. No relationship found demonstrating a dose-response relationship between structural brain abnormalities on qualitative clinical MRI.	There is a large body of evidence available for quantitative research MRI, but these types of approaches are not currently available in clinical practice.

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
STRENGTH OF ASSOCIATION	Trivial	Small	**Moderate**	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	**Very low**	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	**Possibly important uncertainty or variability**	Probably no important uncertainty or variability	No important uncertainty or variability			
RESOURCES REQUIRED	**Large costs**	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			**No included studies**

	JUDGEMENT						
EQUITY	Reduced	**Probably reduced**	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		**Varies**	Don't know
FEASIBILITY	No	**Probably no**	Probably yes	Yes		Varies	Don't know
DIAGNOSTIC UTILITY	**Very Low**	Low	Moderate	High		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the outcome	Conditional recommendation against the outcome	Conditional recommendation for the outcome	Strong recommendation for the outcome
○	○	○	○

CONCLUSIONS

Recommendation
The Australian FASD Guidelines Development Group recommendations against including structural brain abnormalities as observed on clinical imaging in the diagnostic criteria for FASD.

Justification

There is a significant body of research documenting impacts of prenatal alcohol exposure on brain development via quantitative research MRI. However, these types of scans are not currently available in clinical settings. There is limited research available that includes control groups, which have examined radiologist-identified brain abnormalities. The one exposure study available concluded that routine clinical MRI did not reveal a consistent pattern of brain abnormalities that could be used diagnostically (Treit et al., 2020). Based on the currently available evidence this outcome is not likely to improve diagnosis of FASD, but rather may lead to confusion amongst parents/caregivers and health professionals and potentially the completion of unnecessary tests for individuals attending for assessment.

Subgroup considerations

Implementation considerations

In situations where brain imaging is clinically indicated or was previously completed, and structural brain abnormalities are found on brain imaging these can be recorded as 'associated features.' Good practice statements and implementation considerations, tools and tips are available to support practitioners with implementing this recommendation.

Monitoring and evaluation

Presence of brain abnormalities should be documented as part of the assessment process to enable monitoring and future evaluation of these clinical features.

Research priorities

Practitioners can document any identified structural brain abnormalities under the associated features section when reporting diagnostic outcomes. This will allow monitoring of this and future review.

As technology improves research can re-examine the diagnostic utility of clinical MRI in the FASD diagnostic process.

QUESTION

What is available evidence for using other neurological conditions as part of the diagnostic criteria for FASD?	
POPULATION:	Individuals with PAE/FASD
EXPOSURE:	PAE

COMPARISON:	Non-exposed control
MAIN OUTCOMES:	Presence of seizures, cerebral palsy, hearing, and vision impairments.
SETTING:	Multidisciplinary specialist clinics; single discipline specialist clinics; primary health care
PERSPECTIVE:	Practitioner population perspective
BACKGROUND:	There are discrepancies between current diagnostic criteria for FASD regarding how other neurological conditions are considered as part of the diagnostic process. Australian/Canadian considers these as part of the brain structure/neurology domain and if present counts as one of the neurodevelopmental domains. Hoyme et al, 4-Digit code and German guidelines consider as a separate component (i.e., not part of the neurobehavioural criteria).
CONFLICT OF INTERESTS:	None

OTHER NEUROLOGICAL CONDITIONS

Strength of the association How substantial is the association between PAE the outcome?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	**Seizures:** 1 exposure study included. Light, moderate PAE and binge exposure at any time during pregnancy was not associated with increased risk of seizures. Exposure at 11-16 weeks gestation had an increased risk – moderate association. **Cerebral palsy:** 2 exposure studies – both confirmed unquantifiable: exposure group defined as those with alcohol use disorder (AUD). Non-exposed group defined as those without AUD. Small to moderate associations found. **Visual impairment:** 2 exposure studies and 1 diagnosed study were included. Variable results found across PAE levels. All had confidence intervals crossing the line of no effect. Also, discrepancies in definitions of visual impairment across studies. **Hearing loss:** 2 exposure studies eligible for inclusion from this review. Heavy PAE had a large association. Unclear definition of hearing loss (i.e., available outcome was frequency of abnormal hearing abilities). *See the relevant systematic review report for an overview of findings and Supplemental File G for all available results.*	

Certainty of evidence What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ○ No included	Varied from very low to moderate. 1 study for seizures was rated as moderate, 2 studies for cerebral palsy (1 low and 1 moderate), visual impairment majority very low and hearing loss all very low. *See the systematic review report for an overview of findings and Supplemental File G for all available results.*	

studies ○ Varies		

Values Is there important uncertainty about or variability in how much people value the outcome?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ○ No important uncertainty of variability	We have no systematically collected information regarding how individuals attending for assessment/their caregivers value neurological conditions. Guideline Development Group did not believe that there would be important uncertainty in how much people valued this outcome.	

Resources required How large are the resource requirements (costs)?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**

○ Large costs ○ Moderate costs ○ Negligible costs and saving ○ Moderate savings ○ Large savings ○ Varies ○ Don't know	Information has not been systematically collected regarding resources required. However, given this information tends to already be collected as part of the assessment process likely no negligible costs/savings.	
Certainty of evidence of required resources What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Very low ○ Low ○ Moderate ○ High ○ No included studies	No included studies directly assessing this.	
Equity What would be the impact on health equity?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**

○ Reduced ○ Probably reduced ○ Probably no impact ○ Probably increased ○ Increased ○ Varies ○ Don't know	Information has not been systematically collected regarding equity. However, given that other neurological conditions can be associated with factors that can be influenced by social determinants of health the potential impacts on including this as a diagnostic feature would need to be considered.	

Acceptability

Is the outcome acceptable to be measured by key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know	Information has not been systematically collected regarding acceptability. However, given this information tends to already be collected as part of the assessment process likely to be acceptable.	

Feasibility

Is the outcome/criteria feasible to be measured/collected across all relevant settings?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know	Information has not been systematically collected information regarding feasibility. However, given this information tends to already be collected as part of the assessment process likely to be feasible.	

Diagnostic utility Is the yield/uniqueness/value of the outcome/criteria for specifically identifying condition of interest? (including the ease of using other tests based on that factor to rule out other associated conditions with that criteria)		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○Very Low ○ Low ○ Moderate ○ High	Limited information available regarding association between prenatal alcohol exposure and the outcomes. Limited information providing evidence of a dose-response relationship between prenatal alcohol exposure and these outcomes.	

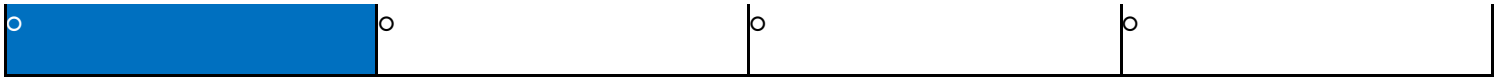
SUMMARY OF JUDGEMENTS

	JUDGEMENT						
STRENGTH OF ASSOCIATION	Trivial	Small	**Moderate**	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	**Very low**	**Low**	Moderate	High			No included studies

	JUDGEMENT						
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	**Probably no important uncertainty or variability**	No important uncertainty or variability			
RESOURCES REQUIRED	Large costs	Moderate costs	**Negligible costs and savings**	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			**No included studies**
EQUITY	Reduced	**Probably reduced**	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
DIAGNOSTIC UTILITY	Very Low	**Low**	Moderate	High		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the outcome	Conditional recommendation against the outcome	Conditional recommendation for the outcome	Strong recommendation for the outcome



CONCLUSIONS

Recommendation

The Australian FASD Guidelines Development Group recommends against including other neurological conditions of hearing and vision impairments, seizures, and cerebral palsy in the diagnostic criteria for FASD.

Justification

Whilst there was some evidence available demonstrating higher prevalence of some of these conditions in individuals with FASD, there was limited information available examining the association between prenatal alcohol exposure and these conditions.

Subgroup considerations

Implementation considerations

Practitioners can document the presence of other neurological conditions as ‘associated features’ as part of the assessment process.’ Good practice statements and implementation considerations, tools and tips are available to support practitioners with implementing this recommendation.

Monitoring and evaluation

Research priorities

Practitioners can document the presence of other neurological conditions under the associated conditions section when reporting diagnostic outcomes. This will allow monitoring of this change to the diagnostic criteria and future review.

Future research at varying levels of prenatal alcohol exposure is needed to examine the association between other neurological conditions.

QUESTION

What is available evidence for using functional neurodevelopmental outcomes as part of the diagnostic criteria for FASD?	
POPULATION:	Individuals with PAE/FASD
EXPOSURE:	PAE
COMPARISON:	Non-exposed control

MAIN OUTCOMES:	General intellectual abilities, language, motor, memory, attention, executive functioning, working memory, behaviour (internalising/externalising), adaptive behaviour, social functioning, sensory regulation.
SETTING:	Multidisciplinary specialist clinics; single discipline specialist clinics; primary health care
PERSPECTIVE:	Practitioner population perspective
BACKGROUND:	All diagnostic criteria include neurodevelopmental/neurobehavioural impairments as a key feature of diagnosis. There are discrepancies in what areas are considered and how the areas included count towards diagnosis.
CONFLICT OF INTERESTS:	None

FUNCTIONAL NEURODEVELOPMENTAL OUTCOMES

Strength of the association How substantial is the association between PAE the outcome?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	**Overall:** Across all areas examined there was potential for adverse neurodevelopmental outcomes following PAE; however, where information was available regarding PAE levels, this was an important influencing factor. The pattern of association tended to be that associations were more commonly observed at heavy and above levels of PAE. With none to small associations at a moderate level and none to minimal at a light PAE level. **Intellectual abilities (i.e., cognition, IQ scores)** <u>Exposure studies</u>	Overall, across the functional neurodevelopmental areas there is a large body of evidence to be considered. The complexity of this area compared to the physical areas means that there is a significantly larger number of areas and outcomes, which made it challenging

	Light: no effect. Moderate: no effect to small positive effect. Heavy: minimal to medium negative effect. Very heavy: minimal to large negative effect. Confirmed unquantified: medium to large negative effect. <u>Diagnosed studies:</u> All FASD diagnoses associated with lower full-scale IQ, verbal and performance sub-scales and non-verbal IQ scores. **Language** <u>Exposure studies</u> Light: Single study with no effect. Moderate: 2 analyses with no to minimal positive effect. Confirmed unquantifiable: minimal to large negative effect. Heavy or very heavy exposure: No studies. <u>Diagnosed studies:</u> Generally, all diagnostic groups demonstrated weaker language skills compared to controls. Small to large associations. **Motor** <u>Exposure studies</u> Light: 2 single outcomes with no to minimal effect. Moderate: no effect to small negative effect. Heavy: 3 single outcomes with minimal to moderate effects.	from a quantitative analysis perspective. Exposure levels that informed the overall rating was the heavy to very heavy PAE levels – including confirmed unquantifiable i.e. consider quasi heavy to very heavy level.

	Very heavy: 2 analyses with large negative effect. Confirmed unquantifiable: 11 outcomes with no to large effects. Diagnosed studies: Generally, diagnostic groups demonstrated poorer motor abilities compared to controls. Minimal to large associations. **Memory** Exposure studies Light: 2 single outcomes with no to minimal positive effect. Moderate: 2 single outcomes with minimal positive effect. Heavy: 1 outcome with moderate negative effect. Very heavy: no studies. Confirmed unquantifiable: 6 outcomes with moderate to large negative effect. Diagnosed studies: Nearly all outcomes across diagnostic were large negative effects. Except for verbal long delay and visual/verbal short delay FASD groups – moderate effect, visual/verbal short delay ARND minimal effect, non-verbal FAS moderate effect, non-verbal short delay FASD no effect, Non-verbal long delay FAS moderate effect & non-verbal long delay FASD no effect. **Attention** Exposure studies Light: 4 single outcomes with no effect. Moderate: 5 single outcomes with no to small effects. Heavy: 7 outcomes with minimal to large effects. Very heavy: 1 caregiver reported outcomes with large effect.	

	Confirmed unquantifiable: large effects on caregiver reported studies. Diagnosed studies: Increased attention problems on both caregiver and teacher report, although there was wide variability found for the pFAS group on caregiver reports. Variability across different direct attention measures found. Overall, minimal to large effects. **Executive Functioning** Exposure studies Light: 6 single outcomes with minimal positive to minimal negative effect. Moderate: six single outcomes with minimal positive to minimal negative effect. Heavy: six single outcomes with minimal to medium negative effect. Very heavy: no outcomes. Confirmed/unquantifiable: small to large negative effect. Diagnosed studies: Majority of diagnostic groups associated with poorer performance on EF measures. Varied from minimal to large effects. **Working Memory** Exposure studiesLight, moderate, heavy, or very heavy: No outcomes. Confirmed unquantifiable: Large negative effect. Diagnosed studies: Nearly all diagnostic outcomes demonstrated large effects across WM measures. **Academic** Exposure studies Light: 1 single outcomes with no effect.	

	Moderate: 5 single outcomes with no effect to minimal positive effect. Heavy: 5 single outcomes with minimal to medium negative effects. Very Heavy: 3 single outcomes with moderate to large negative effects. Confirmed/unquantifiable: moderate negative effects. Diagnosed studies: Generally large effects across diagnostic groups and outcomes. Excluding ARND/Other group for overall academic achievement minimal positive effect, FAS and pFAS overall academics were small to moderate effects. **Adaptive Behaviour** Exposure studies Light, moderate, heavy or very heavy: No studies. Confirmed unquantifiable: 14 studies with all large negative effects. Diagnosed studies: Moderate to large effects across all diagnostic groups. **Behaviour (internalising/externalising)** Exposure studies Light: 18 single studies with no to small negative effect – predominately minimal negative effects. Moderate: 18 single studies with no to moderate effect – predominately minimal negative effects. Heavy: 10 single studies with minimal to moderate effects – more commonly moderate effects. Very Heavy: 5 single studies with small to large effects. Confirmed unquantifiable: 23 studies with small to large negative effect. Diagnosed studies: Predominately moderate to large effects across diagnostic groups.	

	Social Exposure studies Light: 3 single outcomes with no to small effect. Moderate: 5 outcomes with no to minimal effect. Heavy: 1 outcome with small effect. Very Heavy: 1 single outcome with large negative effect. Confirmed unquantifiable: 7 outcomes all large negative effects except 1 study – SDQ self-reported peer problems. No exposure outcomes identified assessing social cognition outcomes. Diagnosed studies: All large effects except FASD social skills teacher report (moderate effect) and Social skills FASD group (small effect), some FASD theory of mind outcomes (moderate effects), **Sensory processing/soft neurological signs** Exposure studies: Light, heavy, very heavy or confirmed unquantifiable: No outcomes. Moderate: 8 outcomes – none to small effects – predominately minimal effects. Diagnosed studies: Moderate to large effects. *See systematic review report for an overview of findings and Supplemental File F for all available results.*	
Certainty of evidence What is the overall certainty of the evidence of effects?		

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ○ No included studies ○ Varies	Certainty ranged from very low to high across the neurodevelopmental outcomes. More often rated very low to low. More commonly due to concerns with risk of bias and imprecision. *See systematic review report pages 29-44 for an overview of findings and Supplemental File F for all available results.*	

Values

Is there important uncertainty about or variability in how much people value the outcome?

JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ○ No important uncertainty of variability	Information was not systematically collected regarding values. However, The Guidelines Development Group believes there is probably no important variability in values of this outcome.	

Resources required How large are the resource requirements (costs)?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Large costs ○ Moderate costs ○ Negligible costs and saving ○ Moderate savings ○ Large savings ○ Varies ○ Don't know	Information collected from the Advisory Groups indicate that this area requires significant resources to provide comprehensive neurodevelopmental assessment. Varies has been selected as availability of practitioners varies across settings, particularly when comparing rural/remote areas to metro settings. Resource requirements would also vary depending on if clinics were already providing neurodevelopmental assessments or not. The Guidelines Development Group discussed a range of strategies that could support resource requirements. Content regarding this has been integrated into the main guidelines document to support practitioners across different settings. In brief this includes: Increasing collaboration across different levels of the health system and different sectors to facilitate different parts of the assessment process to be commenced or provided by a wider range of professionals to reduce the level of care needing to be provided in specialist services, providing more developmentally informed and individualised assessment processes that do not necessarily require assessment all domains but effectively meet the needs of individuals attending for assessment.	

Certainty of evidence of required resources What is the certainty of the evidence of resource requirements (costs)?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Very low ○ Low ○ Moderate ○ High	No included studies directly assessing this.	

○ No included studies		

Equity

What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ○ Probably increased ○ Increased ○ Varies ○ Don't know	Information collected from the Advisory Groups indicates that this is a key area of concern for practitioners as there are limited locally developed or adapted tools for assessment of neurodevelopmental outcomes for First Nations Australians. Application of diagnostic criteria without consideration of these factors could lead to reduced equity. The Guidelines Development Group have incorporated flexibility into the diagnostic criteria regarding the use of standardised assessments and provided a series of assessment principles to help reduce inequities in the assessment and diagnostic process. The Cultural Advisory Group have recommended the use of shared decision making with families regarding the use of standardised neurodevelopmental assessment tools. A range of good practice statements are also provided with the aim of reducing impacts of health equity.	

Acceptability

Is the outcome acceptable to be measured by key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know	We have no systematically collected information regarding acceptability. However, feedback from the Advisory Groups and lived experience systematic review indicate that neurodevelopmental assessment is viewed as beneficial for understanding of the person through the assessment process, supporting understanding of behaviour has been beneficial. The Guidelines Development Group have discussed the inclusion of a range of assessment principles that may increase acceptability of neurodevelopmental assessment.	

Feasibility Is the outcome/criteria feasible to be measured/collected across all relevant settings?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know	Based on information collected from the Advisory Group members, feasibility varies depending on the setting that practitioners are working in. However, in general it is reported that there is a lack of access to allied health professionals who can provide neurodevelopmental assessments, and this is particularly true for adolescents and adults across many states and territories. It will be important for the assessment process to take into consideration differences in feasibility across different clinic contexts.	
Diagnostic utility Is the yield/uniqueness/value of the outcome/criteria for specifically identifying condition of interest? (including the ease of using other tests based on that factor to rule out other associated conditions with that criteria)		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○Very Low ○ Low ○ Moderate ○ High	Available research documented a dose-response effect for prenatal alcohol exposure across all the neurodevelopmental areas. The assessment process aims to identify individuals who present with significant and pervasive neurodevelopmental impairments. Neurodevelopmental impairments are not specific to prenatal alcohol exposure, and consideration needs to be given to the range of other factors that could be better explanations for an individual's presentation and providing diagnoses of co-occurring exposures and conditions as appropriate to provide the best understanding of an individual's functioning.	Assessed in the presence of prenatal alcohol exposure. Diagnosis of ND-PAE/FASD would not be considered in situations where information regarding PAE is not available.

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
STRENGTH OF ASSOCIATION	Trivial	Small	**Moderate**	**Large**		Varies	Don't know
CERTAINTY OF EVIDENCE	**Very low**	**Low**	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	**Probably no important uncertainty or variability**	No important uncertainty or variability			
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	**Varies**	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			**No included studies**
EQUITY	Reduced	**Probably reduced**	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	**Probably yes**	Yes		**Varies**	Don't know

	JUDGEMENT						
DIAGNOSTIC UTILITY	Very Low	Low	**Moderate**	High		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the outcome	Conditional recommendation against the outcome	**Conditional recommendation for the outcome**	Strong recommendation for the outcome
○	○	○	○

CONCLUSIONS

Recommendation

The Australian FASD Guidelines Development Group suggests that neurodevelopmental outcomes of communication, motor skills, general intellectual abilities, attention, memory, executive function, emotional and/or behavioural regulation, literacy and/or numeracy, and adaptive/social functioning be considered in the diagnostic criteria for FASD.

The Australian FASD Guidelines Development Group recommends against including neurodevelopmental outcome of social cognition, social communication/pragmatics, motor speech impairments, speech-sound impairments and sensory processing in the diagnostic criteria for FASD.

Neurodevelopmental assessment needs to be part of a comprehensive assessment process that considers both other causes and conditions that may better explain neurodevelopmental impairments or could be co-occurring with prenatal alcohol exposure and help to explain an individual's presentation. Clinical decision making is required to determine whether the level of neurodevelopmental impairments for an individual is of concern. Additional information, good practice statements and implementation considerations, tools and tips are provided to support practitioners in implementing this recommendation.

Justification

This process compared different levels of prenatal alcohol exposure (i.e., light, moderate, heavy, and very heavy) reported in the available studies and quantified and grouped these exposures consistently across all studies. This was done according to the grams per week to enable equivalency in comparing the effects across the different studies. The available evidence demonstrated a moderate to large association between neurodevelopmental outcomes at heavy and above levels of prenatal alcohol exposure with a very low to low level of certainty. There were limited studies available that examined the association between prenatal alcohol exposure and different percentile ranges on available standardised assessments.

Subgroup considerations

It should be taken into consideration that neurodevelopmental outcomes can vary across the population due to a wide range of factors. Identifying and differentiating what is typical development or impaired development should be based on a combination of assessment approaches. Over-reliance on standardised assessment tools alone, without consideration of wider contextual information may pathologise typical variation or miss children in need of support.

Flexibility is provided in the diagnostic criteria and assessment principles to support practitioners in their clinical decision making regarding the use of standardised assessment tools for individuals from First Nations and culturally and linguistically diverse backgrounds. The Indigenous Framework Practitioner Toolkit also provides information and recommendations for practitioners to discuss the fact that we lack neurodevelopmental assessment tools that have local norms and engage in shared decision making to support families in making informed decisions about the assessment process.

Implementation considerations

An individual case formulation approach should be applied. The Guidelines Development Group have provided a list of assessment principles, additional information and good practice statements that should be taken into consideration in the assessment and diagnostic processes.

Monitoring and evaluation

Research priorities

Future research at varying levels of prenatal alcohol exposure across all the neurodevelopmental outcomes.

Future research investigating the association between different percentile ranges and prenatal alcohol exposure and how this relates to long-term outcomes.

Research is currently behind practice regarding the assessment tools that are in use in clinical practice i.e., updated versions of many of the standardised tools used in clinical practice have not been used in research. Future research is required using updated neurodevelopmental assessment tools.

Appendix K: Public Consultation Feedback and Responses

No.	Submission source	Public Consultation Feedback	Responses
1	Individual Clinician, Patches	1) Additional guidance in relation to prenatal exposure to other drugs (eg. cannabis) and whether this is of any relevance.	In planning the current review other teratogens that may commonly be associated with prenatal alcohol exposure were discussed. It was determined that examining the substantial body of evidence relating to other drug exposures was outside the scope, available funding, and timeframe of the current activity. A summary of some of a small sub-section of the available literature is included in Supplemental File D – Regression Summaries. The Guidelines Development Group considers that an implementation resource summarising the evidence relating to other significant prenatal drug exposures would be highly beneficial in supporting clinicians in understanding the potential role of other prenatal exposures on neurodevelopmental outcomes. Additional funding will be required to develop these types of additional implementation resources.
		2) Changes in relation to head circumference/microcephaly are confusing. Microcephaly is defined as <3rd percentile but the guidelines suggest that head circumference <10th percentile is sufficient to meet neurology domain?? Also, unclear whether weight OR height OR head circumference would be relevant to diagnosis.	Additional information has been added to clarify this point. The available evidence indicated that head circumference <10th percentile was significantly associated with PAE. The proposed diagnostic criteria structure supports documentation of head circumference, physical size, and facial features across a continuum. However, a more stringent definition of small head circumference has been recommended in situations where clinicians are using head circumference as an indicator for neurodevelopmental impairments, where assessment information is not available.
		3) The guideline is very 'full' with context and long explanations - it will be great to have a more succinct version.	There was substantial input collected through the Advisory Groups that informed the development of the content included in the guidelines (summarised in the Administrative and Technical Report and results of the initial priority setting survey Hayes et al., 2022).

			The Guidelines Development Group acknowledges this has resulted in a lengthy document. An abridged version of the main document is now also provided. We also plan to provide each section of the full document as standalone sections once it is published online to make it easier to navigate the full guidelines document.
2	Individual Clinician	"Excellent" or "great" noted for all documents.	Thank you for taking the time to review and provide your feedback on the guidelines.
3	Individual Clinician, Drug and Alcohol Services South Australia	Embedding cultural perspectives and Indigenous framework is excellent in supporting clinicians with guiding principles to approach and patient and culturally centred care.	Thank you for this feedback regarding the Indigenous Framework. The Guidelines Development Group would like to acknowledge the leadership of Ms Nicole Hewlett and the Cultural Advisory Group in the development and embedding of the Indigenous Framework. We agree that this is an excellent addition to the guidelines and are grateful for the generous contributions of Ms Nicole Hewlett and the Cultural Advisory Group.
		The terminology and use of ND-PAE to reduce stigma of alcohol and pregnancy but in addition is more specific regarding ND associated with PAE as the focus of the guidelines is not other possible adverse outcomes of PAE and pregnancy.	The Guidelines Development Group have tried to reflect the diversity of views in Australia regarding diagnostic terminology by providing multiple options, noting that there is no consensus currently.
		The inclusion of PAE evidence review regarding PAE levels and risk of ND impairment ie heavy and very heavy use more consistently associated with adverse diagnostic outcomes but uncertain regarding impacts of moderate PAE although it has its limitations and provides further evidence re PAE threshold and will be an addition to guide us re clinical discussions regarding risks.	The Guidelines Development Group is happy to hear that the evidence provided PAE levels will be helpful to support clinical discussions regarding risks. Wording has been updated to further support these discussions and decision making around level of risk and diagnostic decision making.

		Assessment process section in main document – comprehensive Indigenous Framework document – Excellent and useful addition	Thank you for this feedback.
		Section Prenatal alcohol exposure assessment-excellent addition with GPS and implementation statements specifically systems in transferring pregnancy information that can influence child's longer term health to child's file -this has been an ongoing concern re documentation and gaps in processes. and addition Re Importance of PAE pre and post pregnancy recognition.	This was an important area of concern raised from the feedback from the Advisory Groups, and the suggestions provided from the Advisory Group have been reflected in the relevant Implementation considerations as an immediate and easily actionable outcome for health service providers to implement.
4	Individual Clinician, Danila Dilba	The document is very long - it details the need for understanding the complexity of assessment of children, however may be difficult for clinicians to use. Most will not have time to read the entire document. A summary of the most important aspects is suggested. FASD / ND- PAE is already complex and lengthy to diagnose - a summary of assessments and diagnostic criteria is extremely helpful. Most medical clinicians in my region considering this diagnosis do not operate from within a multi-disciplinary clinic - and will have limited time to arrange/co-ordinate/make assessments. If the clinical information they need to make the assessment is not clear, the diagnosis is not likely to be made (leading to potential underdiagnosis).	There was substantial input collected through the Advisory Groups that informed the development of the content included in the guidelines (summarised in the Administrative and Technical Report and results of the initial priority setting survey Hayes et al., 2022). The Guidelines Development Group acknowledges this has resulted in a lengthy document. An abridged version of the main document is now also provided. We also plan to provide each section of the full document as standalone sections once it is published online to make it easier to navigate the full guidelines document.
5	Health and Social Policy Branch, NSW	*Main document Introduction:* Excellent. Particularly liked the Actionable Statements Format for Recommendations, incorporating Evidence-based	These were all important suggestions from the Advisory Groups that we have tried to incorporate into the document to provide

	Ministry of Health – *submission 1*	(GRADE) recommendations, Lived Experience statements, Good Practice statements and tools and tips. The conceptual frameworks underpinning the guidelines, including the Indigenous, Human Rights and Functional (ICF) framework, is welcome.	evidence-based information, but also critical contextual information to help inform assessment and diagnostic practices.
		Main document assessment principles: Approve of this section. The option to use FASD or ND-PAE is welcome- needs to be informed by the family/community. There is a good balance between providing (GRADE) evidence-based recommendations as well as pushing for multi-informant perspectives. The life course view is also supported.	The Guidelines Development Group has tried hard to balance the diversity of views, use evidence to inform practice where available and advocate for a life course approach. We are glad to hear that you feel this has been well balanced.
		Main document assessment process: Particularly like the integration of Shared Decision-Making into the assessment process. Of concern, for individual clinician assessments, access to the University of Washington (UW) Lip-Philtrum Guide or the Stromland (1999) palpebral fissure norms, is not easily available. Suggest that the Guidelines come with hyperlink access to these guides for clinicians- more prominently displayed and easily accessible	There are two implementation considerations included in the medical assessment section that include the hyperlinks to the UW Lip-Philtrum Guides and software. An additional implementation consideration about how to access the PFL calculator has been included to support access to the Stromland norms for clinicians not using the facial analysis software. We have also included a note to clinicians about these implementation considerations in the additional information section of the diagnostic criteria.
		Main document holistic assessment: Figure 10- Overview of studies comparing outcomes following prenatal alcohol exposure (PAE) and adverse childhood experiences (ACEs)- is very useful. The Feedback and Strengths-based pathways is excellent, especially this point- which should possibly be emphasised more and	The Guidelines Development Group is pleased to hear that the Figure 10 is a useful resource and the importance of including strengths and interests in reports. We considered the feedback regarding re-ordering this list of Lived Experience Statements but have retained the current order as we think the current order

		right up front: When writing reports, emphasise the individual, strengths and interests, while also addressing areas needing support.	reflects the typical order of the feedback process (i.e., verbal feedback first followed by written feedback).
		Indigenous Framework: Good *Technical Report diagnostic components:* Very thorough *Tech report lived experiences:* Good *Tech report costs and models of care:* This section is excellent and the scoping review welcome addition to the literature	Thank you for reviewing and providing your feedback on these documents.
	Health and Social Policy Branch, NSW Ministry of Health – *submission 2*	Figure 2 - suggest keeping text colour consistent	Text colour has been updated.
		Compared to a document like the previous, Australian Guide to diagnosis of FASD, this document seems to have significantly more academic and background information. If the intention of this document is to guide clinical practice, it is likely clinicians would find a summarised and directive version more helpful. Suggest an edited or condensed document may have more utility.	A short version will be provided, with a summary of key information from the main document.
		Pg 9 diagnostic assessment: it would be helpful for the document to clarify what is meant by, frequent alcohol use. This may need to be quantified to avoid risk of confusion with imprecise terms.	This section of the document has been revised.
		Pg 11 the Audit C quoted here is modified as is the scoring - this should be noted.	Thank you for identifying this. The previous version of the FASD Guide did include incorrect scoring in the AUDIT-C, this has been updated.

		Throughout the assessment principles and diagnostic criteria sections, it is somewhat difficult to gauge what is a clear direction and what is guidance. Suggest working on the language to make sure anything that necessitates a stronger direction is clear.	Wording has been revised where appropriate to improve communication of the document.
		Regarding the Indigenous Framework on pages 29- 32 in the main document, it is recommended that the Indigenous Framework be linked within the document and included on the landing page with other resource. Further comments are included below in the Indigenous Framework document section.	Once the documents are available online, the Indigenous Framework can be hyperlinked in the main documents.
		From page 73 onwards the acronym ,GPS, is used for the Good Practice Statements. It would read better if the full words were used to be consistent with the other tables and to prevent confusion.	Thank you. This change has been made.
		On page 74, the 'Finding Your Way' resource should be hyperlinked. This section was also a little difficult to understand - I believe it was lifted from the resource and adapted to be specific to alcohol exposure however this integration isn't clear.	Thank you for your feedback. We have added information to the section to better contextualise this resource.
		Main document holistic assessment: Figure 10 summarises research findings however the graphic contains a lot of content which impacts its readability. Recommend considering its relevant to practitioners for inclusion. It may be better suited as part of the appendix.	Thank you. We have included a summarised version of Figure 10 that has less detail

		It may be useful to compile the implementation considerations throughout the document and add these to a concluding chapter to assist the reader.	Thank you for identifying this. Summary of these statements is provided at in the summary of actionable statements.
		Appendices Appendix A1. It is not clear why the evidence for maternal alcohol use is also 3 months prior to pregnancy? I think this is flagged here for the first time. Is this to cover unplanned pregnancy? Other evidence of exposure Can the language be changed from alcohol to use please. Suggest link to diagnosis of alcohol dependence, what is this, how to diagnose. Why are other substances included? Needs some explanation. Postnatal, history of abuse, what does this mean? Is this for the mother or child?	We were unclear what this was referring to.
		Please note this point of feedback is being maintained as a direct quote from reviewer: It is unfortunate that there was no opportunity for Torres Strait Islanders to contribute to the document; however, as a proud Biripi woman, reviewing the Indigenous framework on page 29 of the document for comment was a great read. It is enlightening to read the historical factors that have contributed to the issues that Aboriginal and Torres Strait Islander people have faced and continue to face.	Thank you for this feedback. This is the first iteration of an Australian Indigenous Framework, and it is hoped to be a starting point to begin an ever-evolving journey. It is hoped that the Indigenous Framework will be able to continue to be refined in the future to continue to improve the framework through the integration of a wider range of perspectives, including Torres Strait Islander perspectives.

		Technical Report of lived experiences: Page 5,Regarding the summary. The 3 subheadings in the form 3 questions make the text easier to engage with and understand, especially for non-researchers. Page 6 - the research question is clearly stated. Page 7, a wide range of search terms were used to capture lived experience. Page 26 , The 11 lived experience action statements for health care providers to consider when providing assessment and diagnosis of FASD are clearly stated and the layout within the document is engaging. The 11 lived experience action statements are also included in the main document on pages 13, 14 and 17.	Thank you for reviewing this document and providing this feedback.
		Whilst the focus of this document is on diagnosis, it would be useful to provide links to other documents that assist in the prevention of alcohol related harm in pregnancy such as the Australian Alcohol Guidelines and the soon to be released NSW Substance Use in Pregnancy Clinical Guidance.	Relevant section in the Introduction has been expanded on to further discuss prevention of PAE.
		Dissemination, implementation and evaluation report: It is difficult to know who the intended audience is for the implementation considerations, in the main document. It is suggested that the implementation considerations are linked to an implementation plan or clear strategy where this is made clearer, perhaps either in the appendix or as a separate document.	Implementation considerations are included in the summary of actionable statements and have been added to the dissemination and implementation report.

6	Individual Clinician	I would like to see more clarity on using the Audit C during antenatal care. At present the initial screen attended at the antenatal booking history asks about CURRENT alcohol use. This does not reflect the weeks before a woman was aware of her pregnancy and not the weeks while she is waiting for the appointment. I would like to see a two-part question- 1. that reflects alcohol use prior to pregnancy confirmation and 2. reflects alcohol use since pregnancy was confirmed.	The Guidelines Development Group agrees this is a critical change in practice that needs to occur regarding assessment of PAE risk. A resource is provided in Appendix D – Practitioner support templates, which provides a template for use of the AUDIT-C pre-recognition and post-recognition of pregnancy. There is also an implementation consideration included regarding this point, we have moved this up to the start of the Implementation Considerations section in the PAE assessment section of the document to make this easier to find. Once the documents are available online, we will also provide each of the practitioner resources as separate documents to further make this resource easier to locate.
7	NOFASD Australia	The Indigenous Framework document is outstanding and represents an important step forward in recognition, support, and management of FASD for Indigenous communities. Thank you for your work coordinating the draft guidelines for the diagnosis of FASD, a challenging and important task. NOFASD is in receipt of the current draft which is open for public consultation. Unfortunately, initial indicators are that concerns about the impact of the proposed changes are significant. Besides time pressures for those with living experience there are concerns around the process of development, the interpretation of evidence, the distribution reach of	Thank you for this feedback regarding the Indigenous Framework. The Guidelines Development Group would like to acknowledge the leadership of Ms Nicole Hewlett and the Cultural Advisory Group in the development and embedding of the Indigenous Framework. We agree that this is an excellent addition to the guidelines. NOFASD Australia was a project consortium partner and provided with opportunities for membership at all governance levels of the guidelines review project, including Steering Committee, Advisory Groups and Guidelines Development Group. To maximise time for individuals and organisations to review and discuss the draft documents and provide formal feedback, the Steering Committee and Advisory Groups were provided with the documents 7 weeks prior to the public consultation. NOFASD Australia was included in this process. However, no formal feedback was provided. A 6-week period was provided for public consultation, with an additional 1-week extension provided to NOFASD. Therefore,

		the public consultation and technical issues related to this. At this stage NOFASD anticipates a formal response from the Organisation being submitted by the 21st of May, 2024. Additional submissions are likely from the Lived Experience Expert Advisory Group. I apologise for the delay, however the Guidelines represent 25 years work in FASD in Australia and do require careful stewardship.	NOFASD had a total of 14 weeks to provide formal feedback on the draft documents. Prior to the formal feedback process described above, there was also a formal Advisory Group process for all members to provide verbal and/or written feedback on the draft diagnostic criteria. NOFASD also had a representative in the Guidelines Development Group and thus were informed of all project timeframes/processes and had access to the draft documents prior to their circulation to the Advisory Groups and the public consultation.
		Additional submission provided from NOFASD Australia during the public consultation period. Alcohol as the causation The cause of FASD – alcohol – has not been addressed in the revised guidelines. This is a significant omission from the current guidelines, without explanation. As openly acknowledged, whilst clinicians are the primary audience of these guidelines, they will not be the only ones to read them. The guidelines are intended for a wider audience, including pregnant women, policy makers, allied health professionals, the public, and the alcohol industry. It should <u>never</u> be assumed that the role of alcohol is understood, even by professionals who, in theory, should be well-versed on the topic.	Additional information is provided in the Introduction section. Specifically, the wording of the Canadian National FASD Database Annual Report has been included "FASD is both an etiological diagnosis (i.e., identifying the cause) and a functional diagnosis (i.e., identifying consequences and needs)." However, as described in this section of the Introduction it is also important to understand that PAE is a risk factor for FASD, not every exposure will result in a diagnosis of FASD. Significant additional information is now provided to better explain this for readers too.
		Task scope There is no doubt that the dense scientific work undertaken is thorough and commendable, however, key issues associated with FASD have not received adequate	The development of these clinical practice guidelines was undertaken according to the NHMRC Procedure and Requirements for Meeting NHMRC Standards for Clinical Practice Guidelines (2022). These standards do require the development of a range of

		recognition. The increased scope of work, in contrast to the original publicised intent, disable genuine capacity for LE to contribute meaningfully. Nearly 1000 pages of scientific work cannot be adequately grappled with, and effectively responded to, by brief visits to large group committee meetings and document circulation with unrealistic turnarounds. Such documents included decisions, made without collaboration, that will monumentally change the course of FASD awareness, acceptance and understanding for decades.	Administrative and Technical Reports and formatting requirements that need to be adhered to. The project consortium did their best to undertake the rigorous evidence-based process required for meeting the NHMRC standards and be as inclusive of as many stakeholders as possible in the development process, given the funding and time that was available. Many meetings were held across all Project Groups (i.e., Guidelines Development Group, Steering Committee, Advisory Groups), for which NOFASD had representatives on all groups, discussing the results of the evidence review, and discussing draft diagnostic criteria. Decisions were made collaboratively in the Guidelines Development Group, based on an extensive amount of information gathered from the Advisory Groups to inform these decisions. The GDG agree and acknowledge the absolute importance of translating research to practice. The government set the funding and time available for this piece of work, not the GDG and we would welcome NOFASD's advocacy for additional funding to support the GDG in translating the 1000s of pages of scientific work into co-designed resources that are more easily accessible by the public and other important stakeholder groups. The point regarding the time provided to NOFASD has been addressed above.
		Terminology The introduction of an additional term to describe FASD, and the clear preference for the "new" term, was not part of the guideline scope. It is a critical decision with profound impact and requires independent focus of	The GDG acknowledges that FASD is the term currently used in public health and awareness campaigns and therefore are *not suggesting this term should be changed*.

		experts – including public health professionals. Over more than a decade, the Australian Government has invested millions of dollars in research and initiatives with the use of one term (FASD) as the notable outcome of prenatal alcohol exposure. The change and duplication of nomenclature is a decision which should be made in a global context, with consideration of Australia's role in this setting. In the English-speaking world, most countries align their diagnostic guides and terminology with FASD. The outlier is the United States, where both terms are used, however, a very clear preference is given for FASD. This has resulted in confusion and a lack of national unity within the US. NOFASD is not aware of any document generated by the Australian Government which has utilised the proposed alternate terminology. The DSM, the source of the alternate term, does not have universal acceptance and endorsement of its work; thus, resulting in many instances of contested professional space amongst definitions. The GDG noted some criticism of the DSM and its processes (Researchers e.g., First, 2017; Kendler & Solomon, 2016 have highlighted that the DSM has not consistently used systematic reviews to inform decision making). At its essence, ND-PAE is an underutilised American term. Its confusing introduction is unwarranted and would disrupt Australia's progress in FASD to date. The gradual understanding and knowledge of the existing term is a positive step forward for many in the FASD-informed space. ND-PAE is not a suitable replacement term for FASD as it is a neurodevelopmental descriptor,	The GDG would also like to note that there is no suggestion more broadly for the term FASD to not be used. The term FASD was always to be retained. However, consideration of diagnostic terminology *is* within the scope of the current project, as evidence-based diagnostic criteria are being developed. The inclusion of an additional diagnostic term is primarily to allow individuals undergoing diagnostic evaluations to have additional choice and control over the diagnostic term they choose to identify with. This is another instance where it may be important to consider different approaches in *public health* contexts compared to *diagnostic clinic* contexts. This is important to provide client-centred care. Based on the consultation undertaken throughout this project, it is indeed clear that there is a wide diversity of views regarding diagnostic terminology. Whilst the perspective of NOFASD is an important one and has been taken into consideration in these guidelines through retaining the diagnostic terminology of FASD, this is not the perspective shared by all people with living experience in Australia. Although some find the term FASD helpful to identify with, there is a diverse range of views on this issue across the community. Additional information has been added to the document regarding this point. The GDG acknowledge there are limitations to the processes followed in the DSM in the development of diagnostic criteria more broadly, but the DSM is commonly used by Australian clinicians. Inclusion of ND-PAE as a condition for further study and as a specified condition under 'other specified neurodevelopmental disorder - neurodevelopmental disorder associated with prenatal alcohol exposure' is a recent and critical development in the FASD

		which excludes the physical symptoms which have high specificity and sensitivity. Thus, its inclusion is a harmful step backwards. To consider a name change, specific and directed focus between the FASD Advisory Group and the Government is required. Consideration to the comfort levels of practitioners should second this. Practice evidence indicates that name changes are often a misguided attempt to avoid stigma and are not a long-term solution. One of the most important pieces on stigma research and FASD was excluded from consideration by the GDG, for reasons which are unclear. Stigma focus requires the best evidence-based research, before decisions like name change are undertaken.	field. This has significant implications for access to services for individuals, as there are a wide range of clinicians who may now consider this as part of their remit in providing services. Therefore, this is an important opportunity that we can capitalise on. Consequently, the alternate terminology being offered is already terminology that clinicians in Australia are using. It is important for the guidelines to be consistent with international practice, particularly those contained in diagnostic manuals that are commonly used in the Australian context. Additional information has been included in the document to better explain the context regarding this. As per the comment above regarding this point, the GDG is not suggesting a name change, we are *providing options for use in clinical practice*.
		Research realities The reality of undertaking research in this area is not acknowledged in the guidelines. Randomised control trials are not possible in this space. Yet the most frequently asked question by the public, media and even those who are direct stakeholders, (whether they realise it or not) is *"what quantity of alcohol consumption in pregnancy is safe*?". The guidelines need to provide transparency to the realities of research on this space, specifically related to definitions of harmful alcohol consumption. Self-report of consumption is notoriously unreliable and worthy of far more consideration if guidelines are to be so radically altered. Definitions of consumption are	The GDG completely agree with this statement regarding research realities in this area and have included this in the summary of key limitations of the evidence review in the main document. This point is also discussed in the relevant Technical Reports. Risk of bias assessment for all studies included in the systematic review of diagnostic criteria components. Within this assessment was a question specifically focused on the risk of bias in the assessment of PAE. Risk of bias assessments also form part of the GRADE ratings of the overall certainty of the evidence at the meta-analysis level. These guidelines are transparently reporting the results of the evidence review. Revisions have been made throughout the document to improve the communication of the findings of the

		subjective and public health research points to consumers typically defining themselves as “low risk drinkers”; when their actual consumption patterns do not align with this statement. The most accurate and transparent response to this requires adequate explanation that in human subjects, precise PAE will never be proved as a matter of scientific fact.	evidence review and to support practitioners when using these results in practice. The GDG completely agree there are challenges in assessing PAE and the guidelines provide a number of Good Practice Statements regarding PAE assessment to help address this. Consistent with this feedback, the guidelines recommend incorporating other sources of evidence (e.g., observer reports, medical and legal records). Importantly, parents are not asked to define their level of risk (e.g., as “low risk”) but to provide descriptions of the prenatal alcohol exposure including the type and amount of alcohol consumed to allow an accurate evaluation of the overall exposure level. The AUDIT-C is recommended as a tool to assist with this process, consistent with the previous guidelines. However, additional information and guidance is now provided for clinicians in use of the AUDIT-C to assess risk separately for pre-recognition of the pregnancy and post-recognition of pregnancy, to provide a more accurate assessment of risk.
		The visceral reaction by Australians (and Canadians), to the recent release of their respective national health guidelines about alcohol consumption and risks, demonstrates the reluctance of consumers to accept health information about alcohol. There is an almost instinctive response to “shoot the messenger”.	The GDG acknowledges that asking about PAE and providing education around this can be challenging and is an area of concern for many clinicians. The guidelines make clear recommendations on how this information is collected and disseminated and provides advice on how clinicians can do this in a sensitive and supportive way to achieve the best outcomes.
		The absence of discussion related to animal model research is concerning. FASD is a disability which can be replicated to a fine degree in this research, unlike other disabilities. In the absence of human subject research, it is not acceptable to discount animal model research. Specifically, as vague definitions of low to moderate	There was extensive clinical (i.e., human) research available that informed the development of the diagnostic criteria. Pre-specified PAE exposure groups were created to enable appropriate comparison of the available research evidence. The light PAE level was defined based on the common clinical situation of where a biological parent reports having no more than 1-2 drinks per week.

		consumption have been included as evidence in the guidelines. The statement “absence of evidence, is not evidence of absence” is particularly true in this discussion and informed inclusion of animal model evidence, in context, is essential.	The Moderate PAE level was developed based on the NHMRC Alcohol Guidelines. The PAE levels were developed for the purpose of the evidence review and are not intended to be used as clinical cut-offs for clinicians, but to be a way to communicate a complex body of research evidence to support diagnostic decision making. The main document has been revised to better communicate this to readers. There was not an absence of evidence available regarding light and moderate exposures. There were actually more analyses completed at a light PAE level compared to a very heavy PAE level. And more analyses at a moderate level, compared to a heavy and very heavy level. The results of the evidence review indicate that while there is the potential for adverse outcomes at a light level, there is a low likelihood of FASD diagnosis at this level of exposure. Revision of the main document has been undertaken to better communicate these findings for the reader.
		Current research found relatively light levels of prenatal alcohol exposure was associated with significantly greater behavioural and psychological problems, and changes in brain structure (Lees et al., 2020), and a recent systematic review into low and moderate PAE reported detrimental effects in six studies, no effect in five studies and weak positive effect in two. This highlights the conflicting results to date and the limited research into low-moderate PAE levels available (Romer et al.,2020). Whilst the results of the review were heterogenous, impacts on early neurological development from low to moderate prenatal alcohol exposure were still evident (Romer et al.,2020). Further	The approach to the guidelines specifically sought to address these issues in applying the research through the use of the GRADE approach, which explicitly considers heterogeneity of the evidence, which informed the certainty ratings. The need for further research at all levels of exposure is discussed in Appendix C: Evidence gaps and in the Technical Report. Assuming this point is referring to Lees et al (2020) ‘Association of prenatal alcohol exposure with psychological, behavioural and neurodevelopmental outcomes...’ as there are multiple Lees et al (2020) papers, this is the result of a single study (albeit a large study), whereas the evidence review for these guidelines has involved bringing all of the available evidence together to look at

		research is needed to understand the effects of PAE exposure at <u>any level</u>, whilst considering confounding extraneous family and social variables across cohort studies. (Romer et al., 2020).	the combined results across studies (i.e., meta-analyses) for equivalent exposure levels. A significant challenge in the PAE research field is that different studies define their exposure levels in different ways. The systematic review and meta-analyses undertaken for these guidelines is an important step forward in being able to better interpret the available evidence. This is because all the studies have been quantified to the grams per week of alcohol consumed and grouped according to the same levels of PAE, instead of using the study-defined PAE levels (i.e., one study would define a certain exposure level as light, while another study would define this as moderate or even heavy). For example, the Lees et al 2020 'light-reducer' group is equivalent to a moderate exposure level (i.e., 32 g/week). This leads to misinterpretation of evidence, and PAE risks and critically, incorrect communication of PAE risks to the public. This is also a key limitation with the Romer et al 2020 review, which has not quantified PAE, so they are not able to draw informative comparisons regarding the PAE levels. Many of the studies with significant effects in the Romer et al paper are studies that we have included moderate levels of PAE. Extensive changes have been made throughout the guidelines document to better communicate the potential adverse outcomes at a low level of PAE. Additional information is also provided to help readers better understand the evidence regarding low levels of exposure in the context of diagnosis of FASD and how this differs from the public health context.

		The findings of the Muggli study are not incorporated for its most relevant outcome. A large cohort study producing evidence of subtle changes to facial dysmorphology detectable under MRI is research practitioners need to be aware of. Low risk drinking which leads to changes in the facial shape of a developing child is not a desirable birth outcome and consumers have the right to be aware of this evidence, in the context of advice that low consumption of drinking may not lead to a FASD outcome.	Unfortunately, 3D facial imaging is not available as a tool in clinical practice and as stated by Muggli et al "the clinical significance of our findings is yet to be determined." Due to lack of 3D facial imaging studies, diversity of available outcomes and lack of availability of this as a current clinical tool for diagnostic purposes, 3D facial imaging was not a key outcome of the evidence review. As per the previous comment, amendments have been made to the guidelines to better describe the potential adverse outcomes of PAE at low exposure levels. However, based on the best available evidence currently available there is a low likelihood of diagnosis of FASD for individuals at a low level of PAE. Clinical practice guidelines need to be evidence-based and as the evidence changes so to can the guidelines.
		PAE The Page 41 statement – *All criteria A-E must be present "Evidence consistent with heavy or very heavy prenatal alcohol exposure (PAE) at any time during gestation, including prior to pregnancy recognition."* conflicts with almost everything we know about good practice and emerging knowledge of alcohol consumption, pregnancy and FASD. Despite multiple and recent epidemiological investigations and systematic reviews, there is no clear dose-response relationship between PAE and the impact on the fetus (Muggli et al.,2024), and the effects produced by alcohol consumption and the mechanisms of toxicity remain unclear (Gonzalez et al., 2024).	Notably, a key part of the previous wording of this criterion has been omitted here, which describes how moderate exposure levels are also recommended to be considered. However, the GDG acknowledges that the previous wording of Criterion A could be misinterpreted and have revised this accordingly. The results of the evidence review for these guidelines provide novel evidence regarding the dose response relationship between PAE and diagnostic outcomes. This is the most comprehensive systematic review and meta-analyses that have been undertaken worldwide to date. As per the previous comments, the reason the guidelines evidence review provides this novel information about dose-response relationships is due to the substantial work that was undertaken by the research team to independently quantify the exposure levels and re-classify them so they would be grouped and compared appropriately.

			Of note, the Muggli et al study cited here found no meaningful association between low-moderate PAE on neurodevelopmental outcomes.
		Women with severe alcohol dependency will be subject to further and increased stigmatisation by the implementation of the Guidelines as they stand. They are the most likely to be identified by the implementation of these standards.	The GDG takes very seriously the concerns raised regarding stigmatisation of pregnant individuals with alcohol use disorders and have revised the document accordingly.
		The definition of alcohol consumption implies patterns which are standardised. The reality is that consumption is a fluid and socially constructed activity, and amounts consumed are difficult to verify. We know that alcohol consumption quantities are typically under-reported, as consumers seek to respond to a perceived desirable or normative pattern. The implication that FASD results from heavy drinking and adverse childhood experiences (ACE) is embedded in the document. Emerging patterns point to an increasing prevalence of undiagnosed FASD in Australia occurring in settings in which there are few, if any ACE's, and low exposure to alcohol.	As described in responses above, the PAE exposure levels were developed and used for the evidence review, this is in the context of detailed data collection throughout pregnancy for research purposes. The PAE exposure levels are not intended to be used as clinical cut offs, but to transparently report the findings of the evidence review to support clinical decision making. Information in the document has been revised to better communicate this point.
		Defining heavy to very heavy use of alcohol as a threshold for FASD will perpetuate the damaging notion that FASD only impacts individuals/families who are 'heavy drinkers". It has taken some time to shift this narrative and these Guidelines will inevitably undermine this and strengthen the most common myth about FASD - that it only affects low-socioeconomic communities and	As per the comment above, The GDG takes very seriously the concerns raised regarding increased stigmatisation and have revised information contained in the document accordingly. It will also be important for public health messages to continue to inform consumers that the best available evidence indicates that no alcohol consumption during pregnancy is the safest option, but also critical to correct misconceptions about the PAE risk levels for FASD. Public health messages need to take into consideration unintended

		women who are defined by the stigmatising term "alcoholic".	consequences, and currently an unintended consequence is that individuals who have consumed very low levels of alcohol (i.e., 1-2 drinks before they knew they were pregnant) are worried their child has FASD. This is not evidence-based and is contributing to distress and inappropriate referrals for assessments. The GDG agree that practitioners and the public should not make assumptions regarding risk of FASD based on a person's sociodemographic background and implementation considerations were already included specifically addressing this point, with wording included from members of the living experience Advisory Group.
		The terminology related to consumption and PAE utilised in the 2016 Guidelines to the Diagnosis of FASD is excellent and should be retained. There is no evidence that low risk consumption is safe. Whereas evidence does indicate the prevalence of recall bias amongst consumers, imprecise quantity reporting and a reduced willingness to disclose accurate consumption.	The aim of the evidence review is not to identify a 'safe level of prenatal alcohol exposure.' The findings of the evidence review highlight that there is the potential for adverse outcomes at a low level of exposure, but the extent of the adverse outcomes did not reach a threshold where diagnosis of FASD would be likely. The document has been revised to better communicate this point.
		The PAE threshold was acknowledged in the draft 2024 Australian FASD guidelines as a point of major debate amongst the Guideline Development Group. The guidelines clearly state that practitioners can consider moderate PAE: '*It is possible that a lower level of PAE at a critical period of gestation could result in adverse outcomes and practitioners need to have flexibility and use clinical judgement to take this into consideration.'* However, this messaging is inconsistent across the guidelines, and diagnostic flowchart figures - which will ultimately become the reference point for time-poor	As per the comment above, the document has been revised to better communicate information regarding the recommended minimum PAE threshold. As per comments above, it is important to consider that different approaches are required in the context of public health messaging compared to diagnosis of FASD. Further information has been added to the Introduction section to better communicate this for readers.

		health professionals – require threshold levels of heavy-very heavy PAE for diagnosis. The misalignment of the diagnostic PAE threshold with current public health messaging and current evidence, creates a confusing message for uninformed health professionals. Most alarmingly, it perpetuates the harmful notion that significant impairment in the fetus is only associated with heavy PAE levels, and low-moderate levels are tolerated in pregnancy. This undoes years of advocacy in this space and disregards the risks and uncertainty of what we know about alcohol and pregnancy.	
		Adults The recognition of FASD as a life span issue is an important step forward. However, adults are the largest cohort of people affected by FASD that are not adequately addressed. This group reach out daily, often with overwhelming needs regarding identification of their condition and access to supports which are FASD-informed and relevant. It was perhaps beyond the scope of the GDG to address these concerns, however, this document highlights the urgent need for adults to receive proper consideration and approaches to diagnosis.	The guidelines aim to take a lifespan approach. It is stated in the document that the guidelines are intended for use for individuals accessing assessment of all ages. There is also specific wording provided in the diagnostic criteria to support adult assessment and diagnosis and a specific assessment principle highlighting this point.
		Test instruments and scores. Practitioners are time poor and stronger recommendations around tests which can be utilised and thresholds to be applied, are an important consideration for best practice. The incorporation of testing expertise across broad disabilities with some similarities to FASD, may have strengthened this aspect of the Guidelines.	As per the next NOFASD comment, thresholds are provided to support diagnostic decision making. Although based on other feedback received through the public consultation, the GDG have restructured the section on defining clinically significant impairments to make this information easier for readers to find. The GDG discussed providing a list of standardised tests. Based on feedback from the Advisory Groups, the previous list of example

			tools led to several unintended adverse consequences. For example, this included inappropriate use of certain tools in certain population groups, including First Nations Australians and clinicians interpreting the guide to mean that if they didn't have access to the particular tools included, they couldn't assess for FASD, negatively impacting on access to services. Further, standardised test versions quickly become out of date, further impacting on applicability and usability of the guidelines. The GDG weighed up the potential risks and benefits and decided against including a list of example tools. Assessment tools vary greatly, their availability also varies across different settings and the ages of individuals attending for assessment, and they change over time (e.g., become outdated). Further, tests are only validated within certain populations, and have limitations when used outside of these populations. It is impossible for the guidelines to cover all the available assessment tools for children of all ages, adolescents, and adults to the appropriate level of detail to support clinicians with making these decisions. It is the responsibility of clinicians to not act outside their area of expertise and seek clinical supervision. Standardised tests are one piece of the information that clinicians can use, where appropriate to inform diagnostic decision making, but tests don't diagnose, clinicians do. There are no standardised tests designed to specifically detect FASD. Clinicians are required to select the tests they use based on a wide variety of factors. The guidelines recommend clinicians seek clinical supervision if they do not feel they have the appropriate knowledge to make these decisions.

			The GDG would also like to draw attention to the fact that not providing a list of standardised tests is aligned with other Australian Clinical Practice guidelines e.g., the Autism Guidelines state: "Practitioners should consider using, but not rely solely on, standardised assessment, to support clinical decision-making in relation to referral, Assessment of Functioning, Medical Evaluation, and Diagnostic Evaluation. Practitioners should know what concepts are being assessed by each tool, and the extent to which they will contribute information that is relevant to the purpose of the assessment. Be aware of the limitations of standardised assessments from a cultural perspective, including where they have not been developed, validated, and/or normed with a population relevant to the client, and therefore may be inaccurate, misleading, invalid, and/or otherwise inappropriate. Practitioners should not use standardised diagnostic tests solely, or as a substitute, for clinical decision making and diagnostic formulation that considers all relevant sources of evidence."
		A welcome addition to the proposed new guidelines is specific reference to the importance of confidence intervals and holistic clinical assessment when determining level of impairment. "*Where confidence intervals are available or can be calculated, practitioners should use confidence intervals together with the suggestions in Appendix B to support interpretation*" pg48. Also welcome is a recognition that "*Test scores in the exceptionally low score range and the below average score range could be considered as being significantly*	The GDG is happy to hear that these changes are a welcome addition to the new guidelines.

		below the normative level". Specifying that scores in these ranges may be reflective of impairment which is significantly below normative level, enables clinicians to be confident in applying their clinical judgement in the broader context of functional impact. "*Test scores or score labels do not equal impairment only a function can be impaired*" (Guilmette et al., 2020, p. 442) Perumal et al (2018) argue that there is no biological basis for the current 2 standard deviation definition of 'stunting' and that this is an 'arbitrary' cut point, and "*in reality the risk of undesirable outcomes including mortality does not change drastically when you cross the magic cut point*" (p. 2044S). This is the case for all clinical cut points currently applied in the diagnostic criteria. Pg 107. Recognition that 2SD below the mean is an arbitrary cut-off of impairment for all criteria and that assessment needs to consider the broader functional impact for the individual is critical. This is an asset to the proposed guidelines.	
		Supporting practitioners in transitioning clients from the diagnostic phase into the intervention/support phase by suggesting Collaborative Goal setting is applauded. By providing suggested tools including PEGS, FGST, AAGST provides a starting point for practitioners and promotes embedding these actions into practice readily. This ultimately allows individuals and their support networks to advocate for the right supports and improve participation in a more efficient manner. These recommendations and guidance for practitioners, however, have not been retained for the actual	See detailed response provided above regarding the decision to not include an example list of standardised tests. Teaching clinicians to diagnose is part of their post-graduate training and subsequent supervision. Clinicians who do not know where to start with respect to assessment tool choice for neurodevelopmental domains must seek supervision, as per our professional ethical guidelines.

		diagnostic process which is puzzling. Whilst clinicians are encouraged to apply their own judgment and use assessments that are appropriate to culture and circumstance, there should be a starting point to assist practitioners in what assessments MAY be considered. Omitting a possible assessment list per domain, as stated in the previous guidelines, is a clear deficit of the review. This creates a barrier for individuals seeking diagnosis and for clinicians who are seeking to deliver efficient and effective services. FASD is not being adequately addressed in our higher education training and as a result, practitioners need ready access to functional and easily accessible guidelines which include proposed assessments. Extract from the proposed Guidelines "*Recommended assessment tools and workforce capability: We had discussions about whether or not to include recommended assessment tools in the document – it was decided that the list of tools was leading to barriers to access (e.g. people not doing assessments as they didn't have the specific tools that were listed) or people thinking they could only assess for FASD using those specific tools and the list of tools was also viewed as impacting on the cultural responsiveness of assessments*." The wording of the assessments for each neurodevelopmental domain in the 2020 FASD guidelines states 'examples of standardised tests', not 'recommended' or 'suggested'. This flags with the reader that whilst the listed tools are relevant and appropriate for use with that domain, they are not prescriptive. Given the prevalence of health	

		professionals in Australia who are unaware of FASD, it is difficult to comprehend that a list of example assessment tools would be considered a 'barrier' to access, particularly as a range of different assessments were listed in the 2016 guidelines, for both direct and indirect assessment.	
		The recommendation is to include an example list of assessments alongside a statement which clearly ensures decision making is not prescriptive, and is at the discretion of the clinicians, their available resources and considering for personal/cultural factors of the client. Such statements are already included in other areas of the draft guidelines, such as the PAE threshold – "*As per the assessment principles section, the PAE criterion A1 should not be rigidly applied in isolation…Rather, the available evidence should be used to inform clinical decision making as part of an individual's case formulation".*	As per the comments above, The GDG weighed up the risks and benefits of providing an example list of tests and decided that the risks of taking this approach again outweighed the benefits.
		Sensory issues Evidence based practice indicates that sensory issues are amongst the most difficult challenges faced across by those living with FASD and their circles of support. Approximately 90% of families who attend support groups are faced with difficulties that are at times insurmountable and span the lifespan of the individual. Examples discussed with NOFASD include extreme light sensitivity - to the point of requiring houses to be shielded from natural light, not wearing clothes due to skin sensitivity and significant disordered eating due	The research team listened to the concerns raised by parents/caregivers and clinicians about sensory processing challenges through the initial priority setting for the guideline review (Hayes et al., 2022) and reviewed the available evidence in this area. The results did not provide evidence for an association between PAE and sensory processing. The guidelines recommend broad assessment to capture any co-occurring conditions or issues, of which sensory processing is listed (see the associated features section). The GDG agrees this can be an important area for treatment and hence the inclusion as an associated condition to support consideration of this in the assessment process.

		textural sensitivity. Sensory disorders are often the direct cause of school exclusion, school disruption and offending behaviours. The diversity, complexity and disabling nature of sensory issues is overwhelming and is consistently a feature of those impacted by FASD. The stark reality of these challenges are often not observed and/or evident in brief appointments and testing situations, and therefore, are not identified as significant and typical symptoms for individuals with FASD.	
		Alignment with public health guidelines Diagnostic guidelines are the exact place to reinforce public health messaging and why public health messaging exists. It is understood that PAE is a risk for neurodevelopmental impairments and is not predetermined. However, current research has failed to establish a 'safe level' of alcohol that a women can consume across the pregnancy: '*…there is no safe period and no safe amount of alcohol that can be consumer during pregnancy without any harm to the unborn child*." (Romer et al., 2020). International health polices recommend abstinence as the safest option (Muggli et al.,2024). This aligns with the current Australian public health messaging from the NHMRC (2020), advising that '*…women who are pregnant or planning pregnancy should not drink alcohol.'*	Information in the Introduction section has been expanded to better communicate the alignment with the NHMRC Alcohol Guidelines and public health messages.

		Document accessibility. A user summary will be an important part of these Guidelines when they are approved and released. Initial feedback from potential users indicates that whilst comprehensive and thorough, the practical application of the Guidelines will prove challenging.	A short version of the document will be provided and pending further funding, the GDG hope to develop a range of associated resources to support implementation of the guidelines.
		To diagnose or not to diagnose? Throughout the proposed guidelines, there is an underlying implication that there is a significant risk attached to diagnosing FASD, and substantial effort must be made to prove there is no other causation for identified symptoms. There is no evidence of over-diagnoses of FASD occurring in Australia, nor is there a pattern of incorrect diagnosis. If anything, this is the opposite - 80% of NOFASD contacts report a previously incorrect or incomplete diagnosis before finally obtaining their FASD diagnosis. International research supports this finding.	The emphasis of the guidelines is to improve accuracy of the diagnostic process. Feedback has been received from Advisory Group members and external organisations noting concerns with poor quality assessments that may lead to inaccurate diagnoses.
		Lifespan, drug and alcohol and judicial studies indicate that individuals with PAE who did not receive timely diagnosis, appropriate interventions, or support, had an increased likelihood of addictions, interpersonal relationship issues, being victims or perpetrators of abuse, employment issues, homelessness, and other adverse secondary outcomes. The FASD diagnosis brings with it clarity, improving paths for management and recognition by Medicare, the NDIS, justice, and education systems.	The GDG agrees and has highlighted this in relevant implementation considerations.

		Evaluation The size and scope of the changes proposed in the guidelines, unquestionably necessitates an evaluation and review prior to public release.	The GDG has discussed the need for evaluation of the guidelines. As per previous comments, The GDG did not set the time and funding available, this is the determined by the government. Future evaluation of the guidelines is contingent on research funding.
		Recommendation 1: The original statement and information about alcohol be retained as key features of the guidelines, as stated in the 2016 guidelines. There should be a strong opening statement that acknowledges the unequivocal role of alcohol as a teratogen, neurotoxin, and Class 1 carcinogen. No safe amount of alcohol consumption for cancers and health can be established, therefore, this must be consistent for the developing fetus. Guidelines can only be considered "low risk" not "no risk" and this messaging must be emphasised throughout the document to underscore the possible risk to the subsequent health of the developing fetus and the mother. If the opening paragraph fails to adequately emphasise the potential adverse impacts of alcohol, it could inadvertently send mixed signals to the community about the safety of its consumption during or planning pregnancy.	Additional information has been added to the Introduction section to better explain the alignment of these guidelines with other relevant Australian guidelines. Clinicians require evidence-based information about the level of PAE risk to inform accurate diagnostic decision making. It is an important advance in clinical practice that this information is now available for clinicians and will hopefully lead to increased uptake of assessment and diagnosis across a wide range of general health settings which is the approach advocated in these guidelines. The model of care put forward in these guidelines aims to enable the assessment and diagnosis of FASD across a range of primary and tertiary health settings.
		Recommendation 2: NOFASD recommends that the terminology ND-PAE and its origin is explained at the beginning of the guidelines. It is then recommended that the existing evidence-based term FASD is utilised throughout the entire document, and in its long form where possible. If necessary, the subject of a terminology review could be referred to the FASD Advisory group for further consideration. This review should further scope	Additional information has been included provide further contextual information regarding diagnostic terminology that can be used in clinical practice. As described above, it is within the scope of this project to be reviewing diagnostic terminology, as evidence-based diagnostic

		other language translations, to achieve further uniformity in terminology.	criteria have been developed. It is not the role of the National Advisory Group to make decisions about diagnostic nomenclature.
		Recommendation 3: Adult Diagnosis is the central focus of a supplementary, but separate Australian Diagnostic Guide. This Guide from the outset should include the Indigenous Framework enabling the product to be inclusive and of benefit to Aboriginal peoples, Torres Strait Islander peoples, non-English speaking peoples and other Australians.	The main guidelines embed content from the Indigenous Framework throughout the document. As described above, these guidelines take a lifespan approach and advocate for assessment and diagnosis of individuals of all ages.
		Recommendation 4: Provide curated, evidence based, best practice guidelines in regard to the selection and application of test instruments and relevant thresholds with particular attention to adaptions which can be applied for effective use amongst diverse groups.	Unfortunately, this evidence-base does not exist. There is no evidence-base available that has examined currently available versions of standardised tests and performance of these tests regarding identification of FASD. There is a highly limited range of tests that are available for diverse populations. This is a complex area, extending well beyond the FASD field and thus the scope of this project to address. A detailed response regarding this point has been provided above.
		Recommendation 5: The final iteration of these Guidelines should include more numbering and sequence formats to increase ease of use, reference, and accessibility. The final iteration should also include a summary user guide which is clear and easy to use.	The final document will include numbering, hyperlinks, and other formatting features to support document navigation. A short version of the guidelines will also be provided.
		Recommendation 6: Sensory issues must be highlighted in a way that ensures practitioners understand the debilitating nature of these disabilities and their consistent presence in FASD. It is not helpful to deny	As per comment above, this was reviewed, and available evidence did not enable inclusion in the diagnostic criteria. Sensory processing challenges are included as an associated condition and can and should be incorporated into supports as clinically indicated.

		diagnosis without consideration of this complex but consistent symptom.	
		Recommendation 7: The diagnostic guidelines should be aligned with and reinforce public health messaging.	As described above, additional information has been added to the Introduction section to better explain the alignment with public health messaging, but also highlighting why diagnosis of FASD needs to be different from public health messaging.
		Recommendation 8: It seems that neurodevelopmental areas chosen for exclusion lack sufficient research-based information to justify their exclusion. Evidence points overwhelmingly to the inclusion of areas which are very disruptive to individuals impacted by PAE.	An extensive review of the evidence was undertaken. To be eligible for inclusion in the diagnostic criteria, evidence needed to be available demonstrating an association between PAE and the particular outcomes of interest. Future reviews of the diagnostic criteria and guidelines will be able to re-examine the evidence and update this as evidence evolves so will the guidelines.
		Recommendation 9: Gaps in research related to public health messaging have a direct impact on the recording and accuracy of alcohol consumption in pregnancy reports. Without consideration of this reality, the proposed assessment process will not cater for a high prevalence of individuals. This will ostracise a large group of individuals who do not meet the criteria for diagnosis, despite displaying all facets and disruptions caused by the disability. These gaps must be addressed. Low to moderate consumption being excluded as a basis for diagnosis is not acceptable.	Whilst it is not the role of these guidelines to improve public health messaging, as described in comments above improvements in public health messaging are needed. However, clinicians should not be applying the sample principles of public health messaging in the diagnosis of FASD. As per responses above, additional information has been added to the document regarding alignment with public health messaging. Based on the feedback provided by NOFASD, it seems the organisation is misinterpreting PAE risks in two ways: What the GDG are recommending for a clinician to consider as a moderate exposure is being interpreted by NOFASD as being low risk.

			A misunderstanding of the risks associated with light exposure in the context of diagnosis of FASD. These are both critical factors in improving public health messaging and improving assessment and diagnosis of FASD. Moderate exposure can be considered for diagnosis of FASD (for example, including one binge episode), wording has been revised to better explain this throughout the document were appropriate. The evidence review informed the minimum threshold for PAE for the diagnostic criteria. Wording of the document has been updated to clarify this point. This aligns with international best practices and increasing evidence in the field. As described in previous responses, the GDG hopes to be able to develop associated resources to assist in better communicating the findings of the evidence review underpinning this decision.
		Recommendation 10: Based on the statement in the Guidelines that alignment with public health messaging is not required, it is inappropriate to release these guidelines over the course of the FASD awareness month of September 2024 and the months leading up to this period. The Australian Government has invested in this increasingly global campaign led largely by Australian initiatives and it will undermine the messaging of these campaigns to release altered information and terminology at the same time. The new content of the Guidelines conflicts with key International FASD Awareness month messaging.	This appears to be a misinterpretation of the information provided in the revised diagnostic guidelines. We are not suggesting that alignment with public health messaging is not required. The guidelines support the view that there is no known safe amount of alcohol during pregnancy. The draft document has been revised as described in the above responses to better clarify this point for readers.

		Recommendation 11: Significant and increased investment in understanding the impact of FASD is essential. Clinicians need to better understand that it is not a disservice to diagnose a patient with FASD. Australia has one of the highest rates of alcohol consumption in the world and where there is alcohol, there is FASD. The false belief that a diagnosis will prevent an individual from being labelled or stigmatised is extremely harmful and is jeopardises the quality of life of thousands of individuals prenatally exposed to alcohol.	These guidelines are not suggesting it is a 'disservice to diagnose.' It is a disservice to individuals and families to provide low quality assessment and diagnostic services for all conditions, and FASD is no exception. All Australians deserve access to high quality care, which provides appropriate consideration of FASD as one possible outcome of neurodevelopmental assessments, alongside all the other possible causes of neurodevelopmental impairments.
		Recommendation 12: Before the finalisation of the Guidelines, a process of review and revision is required to address the concerns raised. Following this, a practice-based pilot evaluation should be undertaken, and the results incorporated into the documents for final release.	The NHMRC procedures and requirements have been followed throughout this project and will continue to be followed. It is unfortunately outside the scope of the funding and time that has been provided for this project to undertake an evaluation of the guidelines prior to release. As per response provided above, funding and time available is not decision of the GDG.
		Recommendation 13: Before the finalisation of the Guidelines, animal model research and the evident harm caused by low level exposure to alcohol should be incorporated.	As per comments above this was not required from a scientific perspective as there was an extensive body of research available from human participants available and included in the meta-analyses.
9	NOFASD Parent, Carer and Expert Advisory Group (PEAG)	*The GDG notes that many of the same points have been raised across the two NOFASD submissions. Both have been responded to, although briefer responses may be provided to this 2nd submission in some places, given these points have been addressed in detail above. The GDG also understands that individual consumers and*	The project tried to be as inclusive as possible of a wide range of different stakeholders throughout the process, within the limitations of the project scope, funding, and time available. NOFASD had a representative in the Guidelines Development Group, which means that NOFASD had advance notice of all the project timeframes and processes and access to the draft

		individual clinicians listed below who requested additional time are members of the PEAG. Insufficient time to address provisional guidelines. For families living with FASD, time is their most precious commodity. The permanency of FASD is felt 24/7 and across the lifetime. The daily challenge and responsibility of managing FASD erodes quality of life and consumes the allocation of daily hours. Families with the most pressing needs are overtaxed and have the least amount of time and capacity to provide valuable input - *"Again, I apologize for not being able to dedicate as much time as I'd like to review these sections. It's disappointing that we weren't given more time to prepare our submissions when there are so many pages, considering how important our input is."* (Participant 3, Appendix D). By contrast, the work undertaken by professional experts sits within the context of, or is affiliated with, their daily employment and is aligned with their career goals and directly linked to their education. For LE individuals, their contribution takes place amidst their own employment sphere: unplanned calls to the school, specialist medical appointments, therapy, and associated logistics - coupled with the demands of maintaining a stable routine in a structured environment. The timeframe for feedback for the provisional FASD guidelines was 12th March – 21st April, approximately 5 weeks. The main document was 126 pages, accompanied by 5 supporting documents. In comparison, the National	documents prior to their circulation to Advisory Groups and the public consultation. To maximise opportunities for feedback there was an initial 7 weeks provided for feedback on the draft documents prior to public consultation, for which NOFASD was included. Then the 7 weeks provided for public consultation (initial 6 weeks + 1 week extension). Resulting in a 14-week period of consultation on the draft documents. The GDG aimed to provide as much time as possible for feedback to be provided on the draft documents. It is outside of the GDG's control when and how organisations sought feedback from their own staff/members. Please also note that when the draft documents were first circulated to Advisory Group members, including NOFASD we suggested that group submissions could be prepared to help reduce burden on individuals in providing individual responses.

		Autism Strategy (52-page document) opened for public review from 2nd April – 31st May, approximately 8 weeks. This is a noticeably longer timeframe for a much shorter document, particularly as ASD has greater consistency in diagnosis and care, in comparison to FASD. Considering the extent of documents to review, the large cohort of individuals (131) within the project groups to consult, and the time-poor life of overburdened LE individuals, the timeframe for public review should have been substantially longer. This would have ensured all readers had the opportunity to provide informed feedback, and thus, be fairly represented – *"It is very disappointing that they won't allow more time for us to prepare our submission, because I think our input is just so significant."* (Participant 6, Appendix A).	
		Complexity and length of documentation To understand and apply the information discussed during the guideline development, and advocate this effectively to an audience of highly skilled professionals, is not a realistic ask for LE individuals without appropriate guidance and timeframes. The document/s are extremely lengthy, and it was not possible nor feasible for all LE individuals to read and understand this in a timely manner. - *"I got lost in the paperwork due to it being too long, I didn't understand it, I tried to read it twice but didn't know what I was meant to read…. the language itself is hard enough. I found that overwhelming, so I didn't respond, but if I can't read and*	As per above regarding the time that was provided for feedback. When the request was put out for feedback it was suggested that group feedback could be a way for people to reduce the burden of time to provide feedback and we welcomed organisations to get together and provide feedback together, rather than having to complete this on an individual basis. A short version of the document, a plain English summary and a frequently asked questions document are now provided. Unfortunately, funding for the project ended last year and the project consortium have done their best to continue to the project without additional funding and have the draft documents ready for the public consultation.

		understand what you're asking me to do, then I don't know what to say to that." (Participant 1, Appendix A). LE individuals <u>want</u> to provide feedback. Minimal LE feedback prior to submissions closing does not represent a lack of disinterest. Many LE individual voice feeling disheartened, guilty and/or shamed that the complexity and length of the guidelines meant that they were unable to contribute. *"I want to give you a response, but the document needs to be broken down into simpler terms. It's hard for me to understand what's being asked of me, especially with complex language." – LE with FASD* (Appendix D). Whilst relevant for clinicians, researchers and other experts, technical jargon is a barrier for the lay person, hindering understanding among any individual who is unfamiliar with the terminology or vocabulary used. *"The documents are hard to read as they are too long, technical, and confusing. Attention needs to be paid to the wording and graphic design".* (Appendix D). The document did not feel relatable to all LE members: *"The document is inaccessible, long, difficult to read, and very hard to relate to my own personal lived experience with my child."* (Participant 3, Appendix A) *Recommendations* A supplement accessible and/or visual document is strongly recommended. The benefit of this document is not isolated to LE individuals and would support a variety of individuals and groups in their understanding of FASD.	It is hoped that further funding will be available to support the co-design of a range of associated documents to support increased accessibility of the information for people with living experience.

		For example, alongside the Draft of the National Autism Strategy, an Easy Read Version was supplied. A shortened document highlighting key points, additions and/or changes would be highly beneficial for the time-poor LE individual (and time-poor health professional or educator). For example, Cochrane Plain language summaries exist to summarise key questions and findings in plain, clearly set out language. They avoid technical jargon and use wording and sentence structure that is easy to understand. The summaries help people understand otherwise complex health evidence. A summary document would assist LE individuals and all researchers, practitioners, educators, and services providers orientating the field.	
		LE as key stakeholders and the true inclusion of LE voice Whilst the inclusion of LE as an advisory group had sincere and genuine intentions at its core, the lack of alignment between the guidelines and LE feedback has generated feelings that their placement was tokenistic. "*The quotes from people with lived experience are included to validate the document. I do not want my name to the document and … ask for my comments to be removed*." (Participant 5, Appendix A). The LE group do not believe their voice was represented accurately across the guidelines, which is extremely disheartening and creates a harmful and untrue narrative for future LE readers. *"I am deeply upset to the point where I will be writing… to take my quotes off the*	As described above, multiple phases of feedback were provided to maximise the opportunities for all members to have input into the draft documents. Also as described above, the funding came to an end and additional funding was sought but not available, which made it very difficult to continue to progress the project across the 2nd half of 2023 and the start of 2024. The inclusion of the quotes were a suggestion from some people with living experience, so that people could speak directly to clinicians reading the document to share their perspectives. There are a wide diversity of views between people with living experience across the different groups. Whilst the perspectives individuals involved with NOFASD are important and have been taken into consideration, these are not reflective of all people with living experience of FASD. Additional information has been included

		document because it doesn't represent my views". (Participant 4, Appendix A) There is a general sense that the responses captured from the LE participants were formally noted, but not accepted. – "*I very clearly expressed my concerns and the things that I didn't like."* – in reference to concerns raised in LE meeting not being reflected in the guidelines (Participant 4, Appendix A). The length of time between LE advisory group meetings was flagged, alongside the changes and decisions made between meetings, without forewarning or further consultation. True collaborative and shared decision making did not seem to be undertaken, and LE advisory members feel somewhat misled by intake wording, as to the purpose of their involvement. *Recommendations* Opportunity was provided to LE to share their voice, however, true partnership was not developed. In line with the shared decision-making process within the guidelines, ample time, discussion, and collaborative decision making and planning is required. The Consumer group felt that an opportunity to speak directly to the other groups to explain concerns, would have been extremely beneficial for all. Particularly regarding a shift in terminology and experiences throughout the diagnostic process.	in the main document to try and better communicate about the diversity of views. Information was provided to all members at the start of the project about what the roles of each of the Project Groups. Individuals with living experience were offered the opportunity to be part of the Advisory Groups and the Guidelines Development Group. Expression of Interest forms with the information about the groups were disseminated through the Steering Committee, which included NOFASD. As described above, as much consultation was undertaken as possible with a wide range of stakeholders, including people with living experience, clinicians, people with cultural expertise and researchers, given the funding and time limitations of the project. Whilst as described above, the views of people involved with NOFASD are important, these views were not always reflective of other people's views, including others with living experience across other project groups. It has been important to the project to be inclusive and respectful of a diverse range of views. Additional information has been added to the document to better communicate this.

		Definition and context of FASD FASD is a medical condition and recognised disability, and the diagnostic guidelines do not give context and definition to the condition being diagnosed. There is a lack of FASD descriptor and context across the entirety of the guidelines document. Excerpt from the Guidelines: "*The Guidelines Development Group did not want terminology to be a barrier to individuals accessing services*." (p 40). The inconsistency with diagnostic terminology remains a barrier in numerous settings, specifically education, and can result in mislabelling of children impacted by PAE. A lack of description for FASD in its diagnostic guidelines will only further exacerbate this issue. *Recommendations* The opening paragraph of any guideline sets the tone for the entire document. In the instance of FASD, the emphasis must be placed on alcohol as the problem, not women. Additionally, it should be highlighted that alcohol use prior to pregnancy recognition is a particularly vulnerable time for women and families. Clear statements are needed on alcohol as a teratogen e.g. alcohol is a teratogen, neurotoxin, and class 1 carcinogen that poses risks to all individuals, including the developing fetus.	Further information is provided in the Introduction section regarding prenatal alcohol exposure and diagnostic terminology. Significant focuses is paid to prenatal alcohol exposure throughout the document. Including a detailed section focused on assessment of PAE that includes good practice statements regarding the importance of assessment of exposure during the pre-recognition period.

		The context of alcohol in Australia, both past and present, and amongst women AND men in current society, must be acknowledged. The extremely adverse secondary outcomes that can develop (if appropriate diagnosis and care is not received) must be flagged, to highlight the importance of accurate and timely diagnosis – or lack of. It is imperative that this context is not limited to the introduction but laced throughout the entirety of the document. As the guidelines will be accessible to a wide audience, including groups such as the media and/or alcohol industry, it is vital the reader can develop a stance that is fully informed.	
		Terminology – FASD/ND-PAE The confliction regarding a consensus of the diagnostic terminology is acknowledged in the provisional guidelines. The guideline group recommended that: *"Future research should seek to understand the preferences of people with living experience of FASD/ND-PAE," (pg.40).* Thus, the comments below provide a response to this, highlighting firsthand the preference of LE individuals – to retain FASD as the predominant terminology.	The terminology of FASD was always being retained. The document has been revised to clarify this. Clinicians and individuals and families do have options to use different diagnostic terminology that is appropriate for each individual attending for assessment.
		Australia's diagnostic criteria was introduced in 2016, and was developed with broad consultation with families, clinicians, and researchers. The Delphi process was used, which ensured unanimous endorsement, to simplify/improve the diagnostic process and the	As described above, there are diverse views across different people with living experience. It is important that we are respectful and inclusive of these different perspectives. As noted in the response to the other NOFASD submission on this point, it is important for NOFASD to consider that individuals connected with this

		outcomes for individuals. It is vital to build on this work, rather than unravelling it, and to use terminology endorsed at a LE level.	organisation represent a specific group of people who have found the term FASD to be helpful to identify with, whereas there is a diverse range of views on this issue across the community. Additional information has been added to the document regarding this point.
		The FASD acronym is beginning to become more identifiable in Australia. "*It's taken many years to explain what FASD is, it's still hard enough to explain to people."* (Participant 2, Appendix A). Since the introduction of the current (2016) guidelines, evidence indicates an increase in diagnosis and albeit slowly, more appropriate support and services for those living with FASD. This is strengthened by increased familiarity with the term FASD and its growing identity in Australia.	FASD is being retained as the predominate terminology. The draft document has been revised to better communicate this for readers.
		It has taken countless years of work by families to have FASD recognised and more widely understood in Australia, supported by health professionals, governments, and researchers. A change in terminology is a change in identity, and jeopardises the 25 years of relentless advocacy, education and progress achieved in Australia to date. LE are the stakeholder group who will be most directly impacted by this disruption and are therefore voicing their disagreement with this change.	FASD is being retained as the predominate terminology. The draft document has been revised to better communicate this for readers.
		A statement of how the new terminology relates to international terminology is omitted, thus, the audience has no context to whether this is common practice internationally. A change in terminology risks putting	Additional information is provided in the Introduction section to provide more of the context regarding different diagnostic terminology.

		Australia out of step with the rest of the global FASD movement, which is not deal for all in this space.	
		The DSM Manual terminology relates only to the neurobehavioral aspect of FASD. FASD is far more than that, it is a disability. ND-PAE is a descriptor and does not do justice to the condition.	There are 2 different terminologies that are used in the DSM, the terminology that is being discussed in the document is the terminology that is already in use by clinicians in Australia, not the neurobehavioural disorder proposed in the DSM under the area for further study. Additional information is provided in the Introduction to better explain this.
		It is alcohol that causes FASD, not women. By removing causation (alcohol) from the forefront of diagnostic terminology, the role it plays is undermined – *"A whole area of education is going to be neglected because the cause is not going to be addressed, and the reason behind it. The strategies will be used the same as they are for other disabilities and don't work"* (Participant 10, Appendix A).	Extensive attention has been paid to the relationship between prenatal alcohol exposure and the potential for a wide range of adverse outcomes.
		To achieve greater levels of FASD prevention, alcohol needs to be included in the conversation - the silence regarding alcohol is what increases stigma. The terminology of ND/PAE downplays the role of alcohol. This could have a detrimental effect on prevention efforts, ultimately leading to an increase in alcohol exposed pregnancies and/or cases of FASD - "*We need to ask the question 'If there are clinicians who are worried about stigma and labelling relating to the terminology FASD are they really going to add the PAE to their diagnosis?"* (Appendix A).	The terminology of neurodevelopmental disorder associated with prenatal alcohol exposure is terminology already in use in Australia, and the predominate reason for discussing this in the guidelines is based on the individuals and families who do not want to use FASD as a diagnostic term. Whilst this is not the experience of individuals associated with NOFASD, we tried to be respectful of a range of different experiences by retaining FASD, but also providing other options for individuals and families, with the ultimate aim of increasing accessibility of services for as many people as possible.

		Children/adults exposed to alcohol in utero have very complex and unique neurodevelopmental profiles, unlike any other neurodevelopmental disability. The phrasing of 'spectrum' in 'FASD' captures this complexity and the array of behaviours and symptoms that may present.	FASD is being retained as the predominate terminology. The draft document has been revised to better communicate this for readers.
		Changing the terminology increases confusion for all to not only LE individuals, but professionals, educators, and the public. It reduces the understanding of FASD altogether and risks FASD staying a 'hidden' disability – restarting the demanding educational process all over again - *"ND-PAE is a whole raft of big words that few will understand. An analogy could be changing the name of Diabetes to glucose overload disorder caused by pancreatic insufficiency"* (Appendix C).	The Guidelines Development Group is not proposing to change the terminology to ND-PAE, as described above, different options are already being used in practice since the publication of the most recent DSM.
		The terminology suggested by CANFASD (and adopted by NOFASD and numerous other organisations), meets the need for a clear and internationally shared definition of the disorder, and is inclusive of the wording 'spectrum'; which is vital for a true understanding of this condition. This updated terminology is used in Canada, Australia, Scotland, all countries considered leaders in addressing FASD at a policy level. 'Suspected ND-PAE' could be included as a third diagnostic term in the Australian guidelines. Suspected ND-PAE has role when assessing children with known prenatal exposure, who are either too young or don't currently meet FASD diagnostic criteria. This would be helpful for families seeking extra support for their child	As per previous comments regarding terminology. The guidelines include a strong focus on a developmental approach to include follow-up for children who may not currently meet the criteria for FASD but may be at risk in the future.

		and may flag with practitioners the need re-assessment, at a later time.	
		PAE Threshold The new diagnostic criteria for PAE infers that FASD occur only in the instance of heavy and prolonged alcohol use across a pregnancy – *"The proposed messaging around PAE moves the likelihood of diagnosis back to people who have been alcohol dependent or had an alcohol misuse disorder and is completely tone deaf to the reality of Australian life and its impact on the prevalence of FASD."* (Participant 4, Appendix D). This will likely reinforce harmful stereotypes and stigma, in addition to perpetuate the still existing misconception that FASD is solely an issue for people stigmatised with the term 'alcoholic'. Regardless of intention, there is a significant risk that societal messaging will change regarding the safety of alcohol in pregnancy. The reality is, we live in a time where well-meaning but uninformed health professionals suggest a small amount of alcohol during pregnancy <u>will not cause harm.</u> Family members and friends of pregnant women suggest that 'they drank during pregnancy, and their children were fine'.	Wording has been revised throughout the draft document where appropriate to better communicate the PAE threshold for diagnosis. As per the responses to the above NOFASD submission. Revision of the documents has been undertaken regarding public health messaging and how these guidelines align with public health messaging, but also describing why a different approach is required in the diagnostic context.
		This could negatively impact the mental health of birth mothers who have already disclosed alcohol consumption during pregnancy as they will now be "labelled" as heavy drinkers. This will likely decrease the number of alcohol dependent women seeking help.	As per previous NOFASD submission response. The GDG takes seriously concerns regarding increased stigmatisation and have revised the draft document accordingly.

		The quantities of alcohol included within the diagnostic threshold of *heavy – very heavy*, are quite substantial. It needs to be flagged whether it is realistic that women are likely to disclose "heavy" alcohol use. "*Admitting to extremely large quantities of alcohol (10-20 drinks per week throughout the entire pregnancy) is a pretty big thing to 'admit' to."* (Appendix C).	It is realistic for people to be reporting these levels of alcohol use when clinicians are providing a supportive, sensitive and non-judgmental space for people to describe their experiences, as recommended in the best practice statements regarding prenatal alcohol exposure assessment.
		There are many confounding variable and factors that need to be further understood between PAE and whether this will result in FASD. Emerging studies conclude that low level alcohol exposure does affect the developing baby on some level, indicating no safe level of alcohol consumption during pregnancy.	Additional information has been added to the document to better explain that there is the potential for adverse outcomes across all levels of prenatal alcohol exposure.
		The proposed threshold disregards the risk of harm caused at any level, and the numerous diagnosis that have occurred to date from much smaller PAE levels "*My alcohol consumption would not have met the essential criteria in these revised Guidelines, and my child who is significantly impacted would not have received a diagnosis under them".* (Participant 4, Appendix D).	Additional information has been added to the document to better explain that there is the potential for adverse outcomes across all levels of prenatal alcohol exposure and better communicate the PAE minimum exposure threshold. Good practice statements and resources are also provided to support clinicians in assessing PAE and determining the level of risk. An important consideration in these assessments of risk is separating out pre-recognition and post-recognition patterns of exposure. As per responses to the previous NOFASD submission, additional information has also been included to better explain why different approaches are required in public health messaging compared to diagnostic contexts.
		Extensive consideration must be given to the reality of Foster and Adoptive parents, and the likelihood of meeting the PAE criteria under the proposed guidelines.	Information about prenatal alcohol exposure is often absent from the child's medical records, which can relate to issues transferring information from the mother's records to the child's records but

		Records of maternal alcohol use are still not routinely transferred to the child's records, and when children enter the out of home care system because of parental substance misuse, prenatal alcohol exposure is usually not documented adequately. Unless the biological mother discloses her alcohol consumption, it is extremely difficult and disconcerting for a foster family to put forward a suggesting she consumed alcohol at such heavy levels.	more frequently relates to a lack of systematic assessment and recording of this information. The guidelines provide multiple implementation considerations to help improve this process. Revised wording and additional information regarding the PAE criterion is also provided to better explain this information for readers.
		Many individuals impacted by PAE are highly likely to remain un-diagnosed or risk misdiagnosis. This will lead to delayed treatment, inadequate/unsuitable supports, and poor adult prospects.	The guidelines advocate for an assessment process that is provided across a wide range of different settings to increase accessibility of assessment and diagnostic services across the community. In order to be able to do this, clinicians need to have access to evidence-based information to support their decision making, if we want to get this assessment out of nearly solely taking place in specialist diagnostic clinics, which have multiple year long wait-lists.
		Alignment with Public Health Messaging Extract from the guidelines: *"It is not the role of these guidelines to provide public health messages regarding PAE. Rather, the aim of the evidence review was to support practitioners in deciding at what level of PAE to consider a potential diagnosis of FASD/ND-PAE."* It is extremely alarming that the diagnostic criteria of a medical condition do not bear resemblance to the preventive health advice for the same condition – *"Medical professionals have an internationally recognised duty of care to provide accurate health information, this certainly includes guidelines that accurately expose risks,*	Additional information is provided in the Introduction section regarding the alignment of these guidelines with public health advice. However, it is also critical that diagnostic criteria do have a different process compared to public health messaging. The same principles do not apply, as not every exposure results in a diagnosis of FASD. Further information has also been added with the aim of better communicating this to readers.

		define clear cut offs and clarify causation." (Participant 4, Appendix D). The proposed threshold undermines the government's efforts to promote prevention, specifically those related to current public health messages and campaigns, and the introduction of pregnancy warning labels on alcohol. *"The message within the wording so clearly goes against the public health message that we've been funded for, and we have worked for, collectively, for decades".* (Participant 7, Appendix A). The shift from a unified public health messaging is extremely harmful and creates a serious risk that alcohol industry advocates will identify this conflict and accuse the public health message advocates of being unnecessarily alarmist. *"This is a public health system issue, and we have a right to understand the full causation of FASD."* (Participant 7 Appendix A). If public health campaigns and diagnostic guidelines have conflicting messaging, this will evidently create confusion for health professionals in the space and spread misinformation. *"Far too much is left to the discretion of the clinician assessing, which can be positive in the case of experienced clinicians who are equipped with an understanding of the living experience, however, for the majority, the 'fear' of stigmatising the mother and child, prevents many from asking the question and exploring the diagnosis."* – (Participant 7, Appendix D).	

		Research on the impact of male alcohol use is an omission in the Guide. It is a common question and warrants inclusion and references.	This is an interesting and emerging area of research, but it is outside the scope of the evidence review of the current guidelines.
		Recommendations Increased messaging is required to raise awareness about the importance of supporting women/families with drug/alcohol usage. with strategies to address the social determinants at a wider level. rather than a shift in terminology away from the emphasis of alcohol.	Wording around the diagnostic terminology has been revised to better explain this.
		Concern for Misdiagnosis and/or Underdiagnosis Whilst the stringency and layers of the proposed diagnostic criteria are intended to ensure thorough and accurate diagnosis, it unknowingly sends a message of apprehension to health professionals that there is a risk of 'over diagnosing' FASD Current evidence clearly indicates the high prevalence of undiagnosed FASD, rather than risks or implications of over diagnosis. An overly stringent diagnostic criteria increases the likelihood of missing diagnosis and/or misdiagnosis. Fewer diagnoses do not equate to less FASD, it equates to an increase in missed and misdiagnosis which could deny individuals impacted by PAE increased access to health services. Health services which will improve their well-being across the lifespan. No adult should be homeless or in our prison system because of factors relating to undiagnosed FASD, that was missed due to barriers in meeting diagnostic criteria; barriers beyond the individual's control. Misdiagnoses	As per the comment above from this submission, diagnostic decision making is 'the discretion of the clinician assessing' and thus it is vital that detailed information is provided to clinicians to support their decision making. To be able to support assessment and diagnostic processes clinicians need to have access to all the information they require to make diagnostic decisions, this is particularly true when we are moving FASD out of predominately specialist only settings to be provided in a wide range of other settings, including primary health care services. The information contained in the guidelines a summary of the complex decision making that clinicians have to go through when they are making these diagnostic decisions and this needs to be transparently reported to support diagnostic practices. The prevalence of a condition is intrinsically linked to diagnostic criteria such as those in the current guidelines. As neurodevelopmental impairments can result from a range of factors/conditions, the guidelines discuss a need to exclude other causes of impairment. The purpose of the guidelines is not to capture all cases of alcohol related harm and we recognise that

		doesn't make FASD go away and doesn't lessen the difficulties that person is experiencing. It deprives the person of targeted services and understanding, and it deprives the family and support group who are responsible for that person's care from receiving guidance and support from others who understand the *Recommendations* The inclusion of a statement emphasising to clinicians the negative impact that a missed/misdiagnosis can have on families and individuals living with FASD voices. Such statements voice real LE concerns and give light to the potential secondary conditions and reality faced by many individuals.	there may be outcomes of prenatal alcohol exposure that do not meet the threshold for diagnosis. There are multiple disorders characterised by the presence of neurodevelopmental impairments (e.g. Intellectual Disability, ADHD, ASD) that may co-occur with FASD and may also apply to individuals who do not meet diagnostic criteria for FASD. The guidelines development group recognises and advocates for the need for all individuals to receive appropriate supports and access to health services irrespective of diagnosis and notes that this is a key principle outlined in the NDIS review. As stated in the guidelines: To reduce barriers experienced by individuals and families, assessment can be provided across a range of settings. This includes, but is not limited to, specialist FASD services, child development services, adolescent and adult private and public health services, primary care, mental health, disability, justice, and child protection services. As described in responses above, the guidelines put forward a model of care for assessment that aims to include a wide range of health professionals working across more settings to support increased access to assessment and diagnostic services.
		Exclusion of Sensory Issues Sensory processing challenges are experienced by most individuals with FASD, albeit different severities. Families are constrained by avoidance of sensory triggers, community expectations and a general lack of understanding from the public. Thus, sensory issues are a crippling component of the FASD profile, for both the individual and caregivers. The exclusion of sensory issues from the diagnostic guideline is highly concerning and dismisses the issues raised by LE. Further, it limits guidance for practitioners managing	Sensory regulation challenges are included as an associated condition. The evidence was reviewed regarding the association between PAE and sensory processing and based on the best available evidence this could not be included in the diagnostic criteria at this time. The concerns raised by people with living experience and clinicians were heard, extensive time was taken to review the available evidence is this area. Information is provided in the document as to

		sensory challenges, and reduces the priority and likelihood of further research in this area. Reasoning as to why sensory processing is not assessed as a neurodevelopmental domain (for diagnostic purposes) is required for both LE and clinician understanding.	why sensory processing was not able to be included as a neurodevelopmental domain at this time, based on the lack of available evidence.
10	Individual Consumer	As a carer of 2 children with FASD And NOFASD Lived experience advisory group member I was so many concerns with this document and it should not be published ! more time for submissions to be allowed. * time frame for public consultation need to be extended this is not user friendly BIG inaccessible and very difficult to reflect especially for lived experience for people actually living with FASD or carer.	An additional week was provided to everyone who provided this piece of feedback on the online form. The NHMRC procedures were developing clinical practice guidelines were followed, which note a minimum of 1 month period for public consultation. To maximise time for individuals and organisations to review and discuss the documents and provide formal feedback, the Steering Committee and Advisory Groups were provided with the documents prior to the public consultation, this included NOFASD. Specifically, a formal Advisory Group feedback process of 7 weeks was undertaken on the draft documents prior to public consultation. A 6-week period was provided for public consultation, with an additional 1-week extension resulting in a total 7-week period provided. A total of 14 weeks of consultation on the draft documents. It is also noted that NOFASD had representatives on the Guidelines Development Group and thus, could have commenced their own consultation process within their organization much earlier than this 14 week period. The Guidelines Development Group have developed a short version of the guidelines and a layperson summary to provide easier and more accessible options for accessing the details of the main guidelines document.

		* A lot of people with Lived experience have being working hard on term FASD and this just confused People with term NDP-AE we need to name it for what it is and practitioners need to have those hard conversations' with their patients. Simce 2015 NDP-EA only citeid x8 and FASD 5000 !	There are diverse views on the issue of diagnostic terminology. There was no consensus on this issue, with some people preferring terminology of FASD and others preferring terminology of ND-PAE, or similar. To reduce confusion, terminology of FASD is used without ND-PAE on the cover of documents and throughout, but the key principles underpinning the guidelines of human rights-based approaches and shared decision making are retained, whereby individuals have choice and control over decisions throughout the assessment process, including the diagnostic terminology applied. Further information has been provided to describe the different diagnostic terminologies included in both the DSM-5-TR and ICD.
		*Risk Factors !!! any amount of Alcohol in pregnancy can have an impact not just heavy and very heavy. According to physician chart mother can 2 drink daily baby has NO RISK we now KNOW this to NOT be the case and physician guideline only advise stage 3 mothers heavy drinker NO Alcohol where we know if pregnant NO ALCOHOL should be advised from day 1 !!!	Additional information has been added to the guidelines document to clarify that these guidelines are aligned with public health messages regarding prenatal alcohol exposure. Additional information has also been added to the guidelines document to try and better explain why public health approaches need to be different from diagnostic approaches for FASD. This is due to the fact that not every exposure will result in a diagnosis of FASD, so clinicians require guidance and support to help them in making these complex diagnostic decisions.
		* history of alcohol hard to determine / remember for bio but for children who care may not have access to record but suspects should still be considered for assessment	All historical records should be requested and reviewed and interviews completed with biological parents wherever possible. Changes have been made to the document to clarify for people that whilst in an ideal world specific information about the level of prenatal alcohol exposure would be available, you do not need to have an exact number of drinks to be able to consider a diagnosis of FASD.

		*missed out middle case white women that may have 1-2 glasses of wine a night.	1-2 drinks every night would be considered as a moderate level of exposure and a diagnosis of FASD would be considered. These guidelines also aim to increase the accessibility of assessment and diagnosis of FASD across a wider range settings, through the model of care presented in the assessment process section, to help make assessment and diagnosis of FASD available across a wide range of general settings, rather than only taking place in specialist clinic settings. The guidelines also emphasise that a diagnosis of FASD should be considered across all classes and cultural groups where PAE occurs.
		* Any unplanned Pregnancy should be considered and Low ALCOHOL must be considered	A template is provided for clinicians to support information gathering for pre-recognition of pre-pregnancy to support accurate assessment of prenatal alcohol exposure risk. While the evidence review shows that from a public health perspective a low level of alcohol exposure (i.e., 1 to 2 drink per week) can result in adverse outcomes, the level of risk for these outcomes being severe enough to warrant a diagnosis of FASD is low.
		* If causations not supported then targeted therapies can not be supported or early intervention (WHich is key)	Prenatal alcohol exposure is the differentiating factor for FASD and all other neurodevelopmental conditions and significant attention has been given to the importance of PAE, including a whole section supporting how to assessment PAE. The GDG agree that an accurate diagnosis of FASD will facilitate access to early intervention and targeted therapies and as such have contributed significant efforts to developing guidelines that are evidence-based to improve the accuracy of diagnosis of FASD.
		* And when know that not all have 3 facial feature so why go back to this diagnostic tool !	There are no major differences in the way facial features are assessed in these guidelines compared to the previous guidelines.

			The only major difference is that these guidelines are recommending for clinicians to engage in shared-decision making with individuals and families to understand if assessment of facial features would be appropriate for them, given the lack of local tools and norms that currently exist.
		* Facial images should be updated to reflect aboriginal face not african American.	Unfortunately, there are currently no locally developed facial assessment images or tools for Australian populations. Funding is required to support the development of these tools and the Guidelines Development Group agrees this is an urgent area for future research. Given that this is not available, these guidelines provide flexibility for facial assessment to not be included if the individual and family do not feel this is appropriate for them.
		* If Lived experience soooo important asa said then why leave out page 10 blank (in preparation) lived experience advisory group .	The Cultural Advisory Group requested to have a letter at the front of the document and the same opportunity was offered for people with living/lived experience. It was communicated to the GDG that this was in the process of being developed, and an offer was made to provide support in the development of this letter. We did not want to place pressure on people with living/lived experience to have this completed for the public consultation, so have left a space for it to be included if it is something people would still like to do. The opportunity is still available if this is something people with living experience would like to have included.
11	Individual Consumer	Not nearly enough time has been given to dissect the enormity of these guidelines, particularly to those with lived experience. I have many issues with this document and subsequent diagnostic criteria and would sincerely request more time be given to disseminate these guidelines for what is an incredibly complex disability. Children have basic human rights to receive an in-depth	An additional week was provided to everyone who provided this piece of feedback on the online form. The NHMRC procedures were developing clinical practice guidelines were followed, which note a minimum of 1 month period for public consultation. These guidelines put forward a holistic approach to assessment and diagnosis of FASD that is grounded in an evidenced-based human

		diagnosis to form subsequent best practice recommendations and I do not believe those guidelines in their entirety provide this. I do not agree to proceeding with these guidelines in their current form.	rights approach to support not just provision of a diagnosis but a comprehensive understanding of functioning, strengths, challenges, and individualised supports. These guidelines advocate for and put forward a model of care to support uptake of assessment and diagnosis of FASD across a much wider range of settings, to increase the accessibility of assessment and diagnosis of FASD to support more individuals in accessing these services.
12	Individual Clinician, Mustard Seed Occupational Therapy	Further timeframe is required for review. *Indigenous Framework document:* Difficult to read, not user friendly. *Administrative and Technical Report:* Difficult to read, not user friendly. *Technical Report diagnostic criteria:* Difficult to read, not user friendly. *Technical Report lived experiences:* Further time is required for consideration *Technical report costs and models of care:* Difficult to read Dissemination, implementation and evaluation report: Further time is required for evaluation. *Technical report holistic review:* Not holistic, difficult to understand	An additional week was provided to everyone who provided this piece of feedback on the online form. The NHMRC procedures were developing clinical practice guidelines were followed, which note a minimum of 1 month period for public consultation. The National Health and Medical Council (NHMRC) Guidelines process has requirements that we need to follow and specific documents that we need to prepare (e.g., the Administrative and Technical Reports). The Guidelines Development Group plans to prepare a number of associated documents, for example, a short version of the guidelines, a layperson summary and an easy-to-read overview of the NHMRC Guidelines requirements and purpose/process in the next few months.

13	Individual Consumer	Extension for the submission of feedback	An additional week was provided to everyone who provided this piece of feedback on the online form. The NHMRC procedures were developing clinical practice guidelines were followed, which note a minimum of 1 month period for public consultation.
14	Individual Consumer	As a carer my ward has multiple co morbidities that make diagnosis complex such as genetic issues that impact facial features presenting.	Thank you for sharing this information. Your comment highlights the complexities that clinicians can face in diagnosis and the importance of a comprehensive assessment process to properly understand everything that an individual is faced with, which then supports individualised recommendations and supports.
		Assessment should be neuropsych as well as functional and as evidenced by research may not present until a child is older. Early intervention is imperative to prevent educational risk and minimise juvenile justice contact	The guidelines are aligned with all these points. The guidelines recommend: Input from multiple professionals, including psychologists Include a specific point in the diagnostic criteria highlighting to clinicians that impairments may not fully manifest until individuals are older A specific implementation consideration is provided highlighting the importance of assessment and diagnosis to prevent and divert individuals away from involvement with the justice system.
		As previously stated diagnostic criteria should reflect current best practice research of which is absent in the proposed review.	The diagnostic criteria were developed from the most comprehensive evidence review undertaken to date in the field of FASD.
		Technical Report lived experiences of assessment: This entire report is not accessible by those it impacts.	The National Health and Medical Council (NHMRC) Guidelines process has requirements that we need to follow and specific documents that we need to prepare (e.g., the Technical Reports). The Guidelines Development Group plans to prepare a number of associated documents, for example, a short version of the guidelines, a layperson summary and an easy-to-read overview of

			the NHMRC Guidelines requirements and purpose/process in the next few months to better communicate a wide range of the evidence and information contained in the guidelines documents.
		The long-term costs of not managing people with this diagnosis will be crippling for society and the individual. People sustaining a traumatic head injury don't have to rationalise their diagnosis and neither should those innocent victims of fasd.	We agree that accurate assessment and diagnosis of FASD is important. All health conditions have associated diagnostic criteria and often clinical practice guidelines to support accurate identification of these conditions.
15	Individual Consumer	I have many concerns and request extra time for submissions.	An additional week was provided to everyone who provided this piece of feedback on the online form. The NHMRC procedures were developing clinical practice guidelines were followed, which note a minimum of 1 month period for public consultation.
16	Individual Consumer	It's unfortunate this document has not had time or transparency to make it to the families that care for children with suspected fasd in a timely manner. I hold concerns around the changes drafted. Fasd is complex and all too often there is minimal feedback sought from the carers that care for the children with fasd. An extension in timeframe to review and respond is requested.	An additional week was provided to everyone who provided this piece of feedback on the online form. The NHMRC procedures were developing clinical practice guidelines were followed, which note a minimum of 1 month period for public consultation. As per responses above, extensive consultation was also undertaken prior to the public consultation period.
17	Individual Consumer	There are many concerns which need further time to examine this very complex situation. More time is needed to enable thorough submissions to be prepared.	An additional week was provided to everyone who provided this piece of feedback on the online form. The NHMRC procedures were developing clinical practice guidelines were followed, which note a minimum of 1 month period for public consultation. As per responses above, extensive consultation was also undertaken prior to the public consultation period.

18	Individual Consumer	There needs to be extended time on submissions and public consultation for this new diagnostic guideline for FASD assessment and diagnosis. This document is not user friendly, it is big, inaccessible and very difficult to interpret for those with lived experiences and people with FASD or carers.	An additional week was provided to everyone who provided this piece of feedback on the online form. The NHMRC procedures for developing clinical practice guidelines were followed, which note a minimum of 1 month period for public consultation. As per responses above, extensive consultation was also undertaken prior to the public consultation period. The Guidelines Development Group have developed a short version of the guidelines and a layperson summary to provide easier and more accessible options for accessing the details of the main guidelines document.
19	Individual Consumer	There are a number of issues with this document and I believe those with lived experience need more time to be able to give appropriate feedback. It is a very important document to that will have great impact moving forward in how FASD is understood and received in Australia. The terminology of NDP-AE is a confusing term. Those of us in the FASD advocacy sphere have worked hard for people to become familiar with and understand the term of FASD. NO ALCOHOL should be advised from DAY ONE. There are many more points to consider but more time is requested from those of us in the Lived Experience group to give feedback.	An additional week was provided to everyone who provided this piece of feedback on the online form. The NHMRC procedures were developing clinical practice guidelines were followed, which note a minimum of 1 month period for public consultation. As per responses above, extensive consultation was also undertaken prior to the public consultation period. There was wide diversity of views regarding diagnostic terminology and no consensus on this issue, with some people preferring terminology of FASD and others preferring terminology of ND-PAE, or similar. To reduce confusion, terminology of FASD is used without ND-PAE on the cover of documents and throughout, but the key principles underpinning the guidelines of human rights-based approaches and shared decision making are retained, whereby individuals have choice and control over decisions throughout the assessment process, including the diagnostic terminology applied. Further information has been provided to describe the different diagnostic terminologies included in both the DSM-5-TR and ICD.

			Additional information is provided in the document to clarify the alignment with public health messaging.
20	Individual Consumer	students miss essential and very specific FASD support. The following points need to be considered... Recognizability and Awareness: FASD has become a well-recognized term both within educational and medical communities and the public. Changing it to ND-PAE could potentially lead to confusion and reduce awareness about the condition. The familiarity of FASD helps in understanding the spectrum of disorders caused by prenatal alcohol exposure. Historical Context: FASD has a long history of research, diagnosis, and advocacy efforts. Changing the name might undermine the progress made in raising awareness, funding research, and developing interventions for individuals affected by prenatal alcohol exposure. Stigmatization Reduction: FASD has already gained some acceptance as a medical condition, and changing the name might reintroduce stigma or misunderstanding. ND-PAE could inadvertently perpetuate negative stereotypes or misconceptions about individuals with the disorder. Clarity of Diagnosis: FASD provides clarity regarding the primary cause of the disorder, which is prenatal alcohol exposure. ND-PAE may be too vague and fail to emphasize the direct link between prenatal alcohol exposure and neurodevelopmental issues.	Terminology has been revised throughout the document and additional information provided regarding different terminologies currently available for use in clinical practice. Ultimately, it is the choice of the individual attending for assessment and their family what terminology is applied. As per detailed responses provided above there is a wide diversity of views on the issue of diagnostic terminology.

		Legal and Educational Considerations: In legal and educational contexts, FASD is recognized as a specific condition requiring specialized support and accommodations. Maintaining the name helps ensure that affected individuals receive appropriate services and accommodations. Global Consistency: FASD is recognized internationally, and changing the name could lead to inconsistencies in terminology across different regions. A consistent terminology helps facilitate communication, research collaboration, and sharing of best practices. Community Preferences: Many individuals and families affected by FASD have become accustomed to the term and may prefer its continued usage. Respect for the preferences of the affected community is important in discussions about terminology changes. Overall, while acknowledging the importance of accurately reflecting the nature of the disorder, retaining the name Fetal Alcohol Spectrum Disorder strikes a balance between clarity, recognizability, and sensitivity to the needs of affected individuals and their families. I do not accept the FASD Guideline document.	
		As a foster parent of a teen with FASD I am very disappointed with many of the guideline recommendations and cannot agree that they are ready to be released to the public. So many areas do not align with the living experience we encounter every day.	There are a wide diversity of views of people with living experience and the GDG has tried to be respectful and inclusive of this wide range of different perspectives. The GDG agrees there is a need for access to modern software that includes the use of AI and local tools and norms for use in Australia.

		My teen presented for a FASD assessment in early 2020 and I was very surprised to watch as her face was compared to an image of an African American, she is an Australian Aboriginal. I question the use of African American images to measure the facial features of an Australian Aboriginal, for a diagnoses. I would like to have seen evidence from a facial recognition expert to confirm this is BEST practice. Surely with modern technology, AI and more, the Australian Guidelines would be suggesting the use of AUSTRALIAN images to support diagnosis.	Research funding is required to support the development of these tools that are designed specifically for the Australian context. Given that these tools are not yet available, we continue to use the best tools we have from an international context. However, due to these limitations we have provided advice for clinicians to use shared decision making with individuals and families to allow for control and choice of families around this part of the assessment.
		I have serious concerns around a number of the conclusions the new guidelines have reached. It is an arduous and complex document to research, and I feel strongly that many clinicians would struggle to fully interpret the full document, simply because it is not at all , and in fact wordy, lengthy, and difficult to comprehend.	The GDG acknowledges that addressing need for additional information to support assessment practices has resulted in a lengthy document. A short version of the guidelines is now also provided to support clinical practice.
		My understanding is that the guidelines suggest to significantly contribute to FASD outcomes, a mother would typically need to consume alcohol at heavy or very heavy levels during pregnancy, which means more than 10 standard drinks per week or more than 20 drinks per week, respectively. As I personally know mothers who did not consume alcohol at a heavy level during pregnancy, making sure they followed the pre-2016 guidelines, of a minimal amount low level, alcohol consumption, and yet have a child diagnosed with FASD.	The wording of the PAE Criterion and relevant sections of the document has been revised to better communicate these points.

		If low level consumption is not going to be considered with the new guidelines, then a significant number of children would not be diagnosed with FASD, despite reaching other criteria. This greatly concerns me, as a foster mother and educator, I know the great importance of gaining a diagnosis so that essential support networks can be engaged. Making it more difficult to gain a diagnosis does not mean that FASD or that a fewer number of children diagnosed means that there is less FASD in the school/community/Australia. It just means there are more children needing but NOT receiving support. A tragic outcome.	
21	Individual Clinician, Tweed Coast Psychology and Educational Programs	I don't understand how there can be Australian guidelines for the diagnosis of ND-PAE when that is a DSM-5-TR diagnosis - presumably the diagnostic criteria are set by the American Psychiatric Association. This is problematic and perhaps ND-PAE should not be included in the Australian guidelines for the diagnosis to FASD.	Additional information has been added to provide further contextual information regarding diagnostic terminology and options for practitioners in clinical practice.
		The changes in the 10 brain domains seem to be quite confusing. Emotional and behavioural regulation is part of executive functioning, so I don't understand why it is now a separate category. But that is just a minor issue.	The emotional and/or behavioural regulation domain is a reconceptualisation of the previous affect regulation domain. Wording of the final point in the EF domain has been updated to try reduce confusion.
		I am very worried about the heavy and very heavy drinking guidelines. The people who need this diagnosis are often in out of home care and/or involved with youth justice. They may be 16 or 18 years old. Their birth mothers (from whom they may have been removed)	Revision of the relevant sections of the document have been undertaken to better communicate the information regarding PAE risk. This includes stating in multiple places that whilst in an ideal world specific information about consumption levels would be available, this is not always the case in clinical practice and as such

		tend to deny all PAE even when their grandmothers or aunts confirm alcohol and drug consumption during the pregnancy. I am afraid that needing to have confirmation of a specific amount such as 10 drinks per week is never going to be possible with this very vulnerable population and that the vast majority of them will be deprived of a diagnosis. They will get no consideration from the courts and no support from the NDIS. Please see the Supreme Court sentencing remarks by Chief Justice Bowskill in Queensland in The King v BXY (2023) QSC 42 for the importance of a diagnosis of FASD. This is freely available online. The problem is even greater if the person is an adult involved with the criminal justice system. Finding evidence of PAE is extremely difficult and to have to quantify the amount will make the task impossible. My reports say "there is no safe amount and no safe time" to consume alcohol during a pregnancy, and if the person has severe neurodevelopmental impairments (usually 5, 6 or 7 - not 3) and there is evidence of any alcohol being consumed, FASD seems the most likely explanation. Under these new guidelines it seems that the diagnosis would not be possible.	clinicians are required to use the available information to make decisions about PAE risk to inform diagnostic decision making. Whilst inconsistent history regarding PAE can be a key frustration for clinicians, the reality is that clinicians are neither trained nor delegated the right to determine the accuracy of one informant over another in these situations. There can be a range of complexities at play, and clinicians need to be careful not to make assumptions in either direction. Good practice statements are provided in the PAE assessment section to guide clinicians in how to consider and manage inconsistencies in PAE history. It is helpful from a public health messaging perspective to think in terms of 'there is no safe amount and no safe time in pregnancy'. However, diagnosis requires a more comprehensive and nuanced consideration of the level of PAE risk alongside the wide range of other risk and protective factors. The number of domains impacted or the level of severity of the neurodevelopmental impairments does not, in isolation, equate to evidence of these impairments being caused by PAE. Individuals can present with severe neurodevelopmental impairments across all domains, which can be due to a wide range of other causes and conditions. Careful consideration of other explanations of neurodevelopmental impairments is therefore necessary and prudent and could lead to alternative diagnoses. These guidelines aim to support clinicians in taking the relevant factors into consideration to facilitate accurate diagnosis of FASD/ND-PAE. The Guidelines Development Group has provided additional information throughout the main document where appropriate to clarify this point.

		My impression is that the proposed new guidelines are much more complicated than the original 2016 guidelines and I am surprised that so much money was spent on perhaps creating more difficulties in diagnosis. The comments I am hearing from colleagues and people with lived experience are generally negative. I have been doing FASD assessments, diagnoses, and writing reports (often for court) for more than 7 years now and I am troubled by the possible consequences of these changes - especially the need to quantify the amount of alcohol that the fetus was exposed to.	The comprehensive content contained in these guidelines is based on input from over 100 key stakeholders and a comprehensive review of the evidence using the most rigorous review framework currently available (See the Technical Reports and associated peer reviewed publications; Hayes et al., 2023; Hewlett et al., 2023; Kent et al., 2023; Reid et al., 2023). Development of these guidelines has followed the National Health and Medical Research Council (NHMRC) procedures and requirements for meeting the NHMRC standard for guidelines. It will be a great achievement for FASD in Australia and internationally if these guidelines achieve NHMRC approval. A notable achievement of this process is also the unprecedented evidence review undertaken for these guidelines, which has potential for significant impacts on research and practice internationally. Clinical practice guidelines typically cost on average 1 million dollars to produce (see the NHMRC Guidelines for Guidelines website for further information: https://www.nhmrc.gov.au/guidelinesforguidelines/plan/project-planning). The fact that the current guidelines have been developed in that framework for $600,000 reflects another significant achievement. The Guidelines Development Group acknowledges that addressing the requests for additional information to support assessment practices has resulted in a lengthy document. A short version of the guidelines is now also provided to support clinical practice. As noted above, the new guidelines do not require specific quantification of PAE. Updates to wording in the document have been made to better communicate this to clinicians.

22	Individual Clinician, HopscotchED	The co-design of the Australian FASD indigenous framework is excellent and a worthwhile inclusion, in addition to the detail around the impact of colonisation and multigenerational trauma. Actionable statements integrated with lived experience is also welcome. The overall document however is lengthy and in some areas poorly written, repetitive or unnecessarily complicated / contradictory. A major change is the reference to diagnostic terms. Whilst we appreciate the DSM references ND-PAE and NOT FASD, the NDIA is opposite and the material within Australia aiming to educate clinicians/ families/ educators and Justice is all FASD. When most in Australia are unaware of the condition, interchangeable terms will dilute impact/ awareness/ advocacy and increase ambiguity for community as a whole.	Thank you for this feedback regarding the Indigenous Framework. The Guidelines Development Group would like to acknowledge the leadership of Ms Nicole Hewlett and the Cultural Advisory Group in the development and embedding of the Indigenous Framework. We agree that this is an excellent addition to the guidelines and are grateful for the generous contributions of Ms Nicole Hewlett and the Cultural Advisory Group. The Guidelines Development Group acknowledges that addressing need for additional information to support assessment practices from a wide range of stakeholders has resulted in a lengthy document. A short version of the guidelines is now also provided. The NDIS review has outlined that current approaches to accessing the scheme are inequitable, including the use of diagnostic lists, and signalled plans to update their approach. Additional information has been added to the document to better explain the context regarding diagnostic terminology internationally and particularly in the context of DSM-5-TR. The name FASD was always being retained. The GDG was not proposing to change the name, but to provide opportunity for different terminology to be used based on the needs of individuals and families attending for assessment. Notably, there are different views between different stakeholders on this issue. To reduce confusion, terminology of FASD is used without ND-PAE on the cover of documents and throughout, but the key principles underpinning the guidelines of human rights-based approaches and shared decision making are retained, whereby individuals have choice and control over decisions throughout the assessment process, including the diagnostic terminology applied. Further information has been

			provided to describe the different diagnostic terminologies included in both the DSM-5-TR and ICD.
		We welcome the statement around reducing barriers to assessment and that assessment by MDT may not always be possible or standardised assessments not always possible. Emphasis that the Ax should prioritise function and environment and should ideally be conducted in 'naturalistic' settings is also worthwhile.	Thank you.
		-Test score guidance around 2 SD below mean should be referenced to assist clinicians ,whilst not set in stone this does provide some framework even though clinicians SHOULD know this, not all do.	The Guidelines Development Group is not recommending a strict 2SD clinical cut off. Detailed information is provided regarding appropriate use of standardised tools for assessment. The guidelines are providing a percentile range to support clinical decision making. This section has been restructured to make this information easier to identify in the defining clinically significant impairments section.
		-Some statements poorly written and difficult to follow and may contribute to confusion or misinterpretation eg pg 17 statement 2.	This section has been reviewed and adjusted to try to reduce confusion and misinterpretation. This may be dependent on a person's discipline, as many allied health training courses do include content on psychometrics and test selection as does the Graduate Certificate in the Assessment and Diagnosis of FASD offered at the University of Western Australia.
		- Not providing a list of possible ax tools will provide confusion and add to lack of action for clinicians. This is not included in any allied health course at undergraduate or Post graduate levels in any detail. Clinicians need to know where to begin.	This may be dependent on a person's discipline, as many allied health training courses do include content on psychometrics and test selection as does the Graduate Certificate in the Assessment and Diagnosis of FASD offered at the University of Western Australia.

			The GDG discussed providing a list of standardised tests. Based on feedback from the Advisory Groups, the previous list of example tools led to several unintended adverse consequences. For example, this included inappropriate use of certain tools in certain population groups, including First Nations Australians and clinicians interpreting the previous guide to mean that if they didn't have access to the particular tools listed, they couldn't assess for FASD, negatively impacting on service access. Further, standardised test versions quickly become out of date, further impacting on applicability and usability of the guidelines. The GDG weighed up the potential risks and benefits and decided against including a list of example tools. Assessment tools vary greatly, their availability also varies across different settings and the ages of individuals attending for assessment, and they change over time (e.g., become outdated). Further, tests are only validated within certain populations, and have limitations when used outside of these populations. It is impossible for the guidelines to cover all the available assessment tools for children of all ages, adolescents, and adults to the appropriate level of detail to support clinicians with making these decisions. It is the responsibility of clinicians to not act outside their area of expertise and seek clinical supervision. Standardised tests are one piece of the information that clinicians can use, where appropriate to inform diagnostic decision making, but tests don't diagnose, clinicians do. There are no standardised tests designed to specifically detect FASD. Clinicians are required to select the tests they use based on a wide variety of factors. The guidelines recommend clinicians seek clinical supervision if they do not feel they have the appropriate knowledge to make these decisions.

			The GDG would also like to draw attention to the fact that not providing a list of standardised tests is aligned with other similar Australian Clinical Practice guidelines e.g., the Autism Guidelines state: “Practitioners should consider using, but not rely solely on, standardised assessment, to support clinical decision-making in relation to referral, Assessment of Functioning, Medical Evaluation, and Diagnostic Evaluation. Practitioners should know what concepts are being assessed by each tool, and the extent to which they will contribute information that is relevant to the purpose of the assessment. Be aware of the limitations of standardised assessments from a cultural perspective, including where they have not been developed, validated, and/or normed with a population relevant to the client, and therefore may be inaccurate, misleading, invalid, and/or otherwise inappropriate. Practitioners should not use standardised diagnostic tests solely, or as a substitute, for clinical decision making and diagnostic formulation that considers all relevant sources of evidence.”
		- Removing social cog/ social pragmatics/communication and not including sensory processing ,Äì re limited evidence is questionable. This can potentially be included as part of functional impact adaptive functioning but should be highlighted as a potential contributing factor to difficulties.	See the Technical Report of the diagnostic criteria for the details of the evidence review. To be considered as part of the diagnostic there needs to be evidence demonstrating an association between PAE and a particular outcome. This evidence is not currently available for sensory processing and social cognition/social communication. The Guidelines Development Group recognises that these factors may contribute to functional impairments and are an important

			component for treatment planning if clinically appropriate. Information is included in the guidelines that describes how these areas can and should be part of assessments to support understanding (e.g., see communication domain that includes pragmatics as an area of the assessment). These areas of challenge can be also included in the associated conditions section, listed under the diagnostic criteria box.
		-Aspects of the Guidelines are confused and this exacerbates confusion for clinicians Eg, ALL must be met, and, Should not rigidly be applied in isolation.	Wording has been reviewed and simplified throughout the document where possible.
		Criteria A1 ,PAE , heavy/ very heavy, VERY alarming language that reinforces stereotypes and preconceived ideas of FASD presentations. This leads to confusion amongst clinicians and broader community around messaging - there is NO safe limit. The small print, does acknowledge that it is possible at lower levels of PAE during critical periods could result in diagnosis However when clinical expertise in this area is SO LOW and confused already, these mixed guidelines are detrimental to campaign that has tried to be more consistent around public health message.	Wording of Criterion A and the associated additional information section of the diagnostic criteria has been revised to better communicate this information for readers. Additional information has been provided to clarify alignment of the guidelines with public health messaging. However, it is important to note that diagnostic approaches do require different approaches to public health messaging, and additional information has been added to further clarify this point.
		Wholeheartedly agree that an holistic assessment is required and beneficial including 'formulation and feedback' however, guidance MUST be given to clinicians around where to begin and what assessments are worth using to generate this. This is SO poorly covered in our university sector our medical/ allied health professionals need greater guidance in this space.	Detailed assessment principles and good practice statements have been provided to support practitioners alongside practitioner templates in the appendix to support clinicians with history taking and diagnostic formulation. University training can never cover all the conditions and areas of practice to the required depth.

			As per feedback received regarding the already lengthy nature of the document, the guidelines document will also never be able to cover all of the required information that clinicians require. The GDG have done their best to meet the requests for more information, but there are limits to what can be covered in this context. It is the responsibility of the clinician to undertake the necessary additional training and supervised experience to be capable of working in specific contexts and with specific conditions. There are a range of professional development opportunities already available in Australia, and no doubt these will be updated to reflect the new guidelines and it will be the responsibility of clinicians to update their practice via these avenues, as is consistent in all other areas of practice.
		Figure 8 demonstrates scope of research yet to be considered. Big decisions have been made in updating these guidelines 'based on research' however there are clearly A LOT of areas that haven't YET been researched widely. This is perhaps where there needs to be a genuine integration of lived experience and what we know about FASD.	Figure 8 demonstrates the scope of the research that was considered in these guidelines. Figure 8 is the results of 1 out of 4 of the systematic reviews completed to inform the development of these guidelines. Figure 8 and the associated technical report and research publication (Reid et al., 2022) provides practitioners with critical information regarding the wide range of factors that they need to consider to support holistic assessments for individuals with FASD. Diagnostic criteria and clinical practice guidelines need to be based on the best available evidence. Whilst there are gaps in the available evidence, we have to do our best to use this evidence to inform clinical practice. The evidence review underpinning these guidelines provides clear directions for how future research can improve diagnostic criteria and clinical practice guidelines.

			Feedback from the Living Experience Advisory Group has been integrated throughout the document, including as implementation tips and informed content written across many sections of the document. Additionally, the lived experience statements integrate the available research evidence regarding experiences of the assessment and diagnostic process throughout the document.
		Indigenous Framework: Great. Would be good to make reference to the use of 'The Tracking Cube' by Griffith University and collaborators.	There is no peer-reviewed citation available for the tracking cube specifically yet, but we have included some other relevant citations regarding development.
		Worthwhile to include the Technical reports although they all demonstrate that there are significant gaps in research. Surely the guidelines should reflect this and not make major changes as a result. Eg exclusion of seizures etc as a diagnostic criteria "Neurodevelopmental outcomes could be more consistent and needs to include up-to-date standardised tools" as stated in Technical report for diagnostic criteria. Also stated, "Also, due to limited data and disparate definitions, the evidence review was unable to examine impacts of exposure. Therefore, this review highlights that there are critical gaps in the evidence underlying the currently available diagnostic criteria for FASD, providing many opportunities for future research."	It is vital that the evidence review transparently reports the current gaps in evidence are, so that future research will be able to address these gaps. As per the previous comment, clinical practice guidelines need to use the best available evidence to inform clinical practice. Even though there have been previous diagnostic criteria and guidelines, this is actually the first time worldwide that this type of evidence review has been undertaken. Seizures are not included in the diagnostic criteria as there was not currently evidence available to support their inclusion. As evidence changes so too will the criteria and guidelines. Having rigorous evidence-based clinical practice guidelines will increase the uptake of assessment and diagnosis with clinicians, as being evidence-based and transparently reporting the evidence gaps is trustworthy. It is also vital that these critical evidence gaps are transparently reported to demonstrate the need for future research and support advocacy for the much-needed research funding to address all of these research gaps.

		Why change the guidelines when there is limited data, and 'critical gaps'???? In doing so we are generating MORE barriers for assessment and recognition of FASD in our community.	
		The time allowed for feedback is unreasonable given the expansive document and the great alterations that have been made to FASD diagnostic guidelines. Time for review has been inadequate.	An additional week was provided to everyone who provided this piece of feedback on the online form. The NHMRC procedures were developing clinical practice guidelines were followed, which note a minimum of 1 month period for public consultation. To maximise time for individuals and organisations to review and discuss the documents and provide formal feedback, the Steering Committee and Advisory Groups were provided with the documents prior to the public consultation. Specifically, a formal Advisory Group feedback process of 7 weeks was undertaken on the draft documents prior to public consultation. A 6-week period was provided for public consultation, with an additional 1-week extension resulting in a total 7-week period provided. A total of 14 weeks of consultation were undertaken on the draft documents.
		Recommendations for Intervention programs/ techniques should be provided IF the document is going to be as detailed as it is. What , supports, are considered ,evidence-based, or worthwhile once assessment complete. This is lacking.	These clinical practice guidelines focus on assessment and diagnosis. Including specific recommendations on interventions is outside the scope of the guidelines. The Guidelines Development Group agrees that guidelines to inform interventions and supports are important and needed, but a formal evidence review process to develop such clinical practice guidelines would be required.
23	Australasian Association of	P15 point 5 (and repeated on P86)	Thank you. Wording has been updated.

	Clinical Geneticists	Consider other syndromes or genetic conditions in which dysmorphic features can also be present. If unsure, refer to a clinical geneticist for review. Replace with: Consider other syndromes, genetic conditions or teratogenic disorders in which dysmorphic features and/or neurodevelopmental impairment can also be present. If unsure, refer to a clinical geneticist for review. Reference: Hoyme HE, Kalberg WO, Elliott AJ, Blankenship J, Buckley D, Marais AS, Manning MA, Robinson LK, Adam MP, Abdul-Rahman O, Jewett T, Coles CD, Chambers C, Jones KL, Adnams CM, Shah PE, Riley EP, Charness ME, Warren KR, May PA. Updated Clinical Guidelines for Diagnosing Fetal Alcohol Spectrum Disorders. Pediatrics. 2016 Aug;138(2):e20154256. doi: 10.1542/peds.2015-4256. Epub 2016 Jul 27. PMID: 27464676; PMCID: PMC4960726. Table 4 is a partial list of genetic and teratogenic conditions which can mimic FASD.	
		P41, section A.2 Point 2 should be DELETED as these features are not specific for FASD. They are present together in a number of chromosomal and single gene disorders. Some are listed in the article referenced above; there are 28 monogenic conditions listed in the Possum dysmorphology database (https://www.possum.net.au/) and 49 chromosomal and monogenic conditions in the Face2Gene database	Whilst these features are not specific to FASD, there is research documenting the relationship between PAE and the sentinel facial features, as summarised in the evidence review. This point has been re-structured, to have the exclusion of other causes first. This is consistent with the previous criteria used in Australia, and some international criteria. Although some international criteria

		(https://www.face2gene.com/) with all three features of FASD. While we recognise that it may be difficult to obtain a documented history of alcohol exposure during pregnancy, the presence of these three facial features should not be used as a substitute. This could lead to misdiagnosis with important socio-cultural and recurrence risk repercussions.	allow diagnosis of FASD without PAE in the presence of two facial features instead of three.
		P42 section E Genetic conditions (e.g., Fragile X, copy number variants including microdeletion or duplication syndromes, or chromosomal anomalies that are known to be associated with neurodevelopmental impairment). Replace with: Genetic conditions (e.g., Fragile X, chromosomal variants including microdeletion or duplication syndromes, or single gene disorders that are known to be associated with neurodevelopmental impairment).	Thank you. Wording has been updated.
		P42 section E Other neurological conditions (e.g., delirium, dementia, seizure disorders [e.g., genetic seizure syndromes, epilepsy encephalopathies], metabolic [e.g., mucopolysaccharidoses] or other neurocognitive conditions).	Thank you. Wording has been updated.

		Replace with: Other neurological conditions (e.g., delirium, dementia, seizure disorders [e.g., genetic epilepsy syndromes, developmental and epileptic encephalopathies], metabolic [e.g., mucopolysaccharidoses] or other neurocognitive conditions).	
		Appendices section: P103 Copy number variants (CNVs): Small genetic deletions or duplications. Many of these variants appear to have no impact on health, but some are associated with diseases or can have clinically relevant effects. Replace with: Copy number variants (CNVs): Genetic deletions or duplications. Many of these variants appear to have no impact on health, but some are associated with diseases or can have clinically relevant effects. P103Epilepsy encephalopathies Replace with: Developmental and epileptic encephalopathies	Thank you. Wording has been updated.
24	Individual Clinician, Speech Educators	Very happy that you are identifying gaps in the research.	Thank you for this feedback.
		Great that you are hoping that this area can be covered across all sectors. Is it possible to think of a possible pathway as to how this could be implemented? Cost would be very high for private practice to implement.	Additional information has been added to the dissemination and implementation report to help aid implementation of the proposed assessment model of care.

		Wait lists are huge already, and chances of people being seen in public system seem to be quite low at this stage.	
		Re Communication. I would like to see a recommendation that some kind of test for Language reasoning is included. I have been doing FASD assessments for some years, particularly for Justice Department, (which have limitations in practice) and find Test of Problem Solving (TOPS)3 very useful. It is picture based, conversational, gives a good overall look at use of language, speech, and insight into how many of the executive function implications affect functionality of communication.	'Language reasoning' assessment tools often do provide useful information in understanding the breadth of communication challenges, but do not fit into models of language development. It is agreed that tools such as the Test of Problem Solving provides a good window into the impacts of executive functioning on communication. Its psychometric properties in terms of assessing and diagnosing disordered language is limited. The focus on the changes in the communication domain was to incorporate the best practice guidelines of the CATALISE studies with some major points re-iterated in the specific considerations. Given there is no well researched model of verbal problem solving and that it draws upon both linguistic and cognitive factors, it holds value as an adjunct assessment to explore the breadth of communication impairments. There was a strong consensus to remain assessment tool agnostic with an emphasis on assessing communication thoroughly. If a clinician feels that an assessment such as the Test of Problem Solving helps describe the difficulties an individual has, then they are encouraged to use their judgement in its appropriateness as part of a broader assessment.

			As stated in the definition of the communication domain '*There is currently limited evidence that other communication disorders (e.g., motor-speech, speech sound, pragmatic/social communication, and voice disorders) are associated with or attributable to PAE. Therefore, such communication disorders will not solely contribute to a FASD/ND-PAE diagnosis but are important to the overall clinical profile and treatment of a client and should be characterised and documented in reports, with recommendations made as appropriate.'* We felt this statement allowed clinicians the freedom to make assessment decisions based on their expertise and clinical judgement.
		Good suggestion that if not all the multidisciplinary team are available then a clinical judgment can be made by those who are available as long as the have the necessary qualifications, training and expertise.	Thank you.
		Interested in how the information can be dispersed eg through Speech Pathology Australia and other representative bodies.	Some initial contact has occurred with Speech Pathology Australia regarding the possibility of a podcast episode. We will also be planning a series of dissemination workshops and are hoping to seek additional funding to support the development of targeted implementation resources and professional development to further support all sectors with implementation of the guidelines recommendations.
25	The Townsville Hospital and Health Service multidisciplinary FASD team	Public health messaging (Pg 23), States that it is not the role of these guidelines to provide public health messages regarding PAE. However, considerations regarding the level of PAE at which clinicians may consider a potential diagnosis of FASD affects the public health message that is indirectly sent.	Additional information has been added to this section to provide further clarification regarding alignment with public health messaging and why public health messaging and diagnosis of FASD requires different approaches.

		Indigenous framework (Pg 29-32, & 75-79) Feedback provided by Indigenous Health Worker , questions about client, knowledge, fears/worries, and hopes are relevant and useful. Other questions such as , what is important to you? are perhaps less helpful and useful in practice. Some of the suggested questions could be considered directed or insensitive and may not be appropriate in practice (e.g., what does culture mean to you?). Non-indigenous clinicians asking some of these questions may be insensitive or inappropriate.	Thank you for your feedback. We have included the question about "what is important to you" to better understand the values and beliefs of a person and their family. This enables clinicians to discuss options in the context of these values and beliefs so people can make informed choices about the things that will impact their lives – including whether they would like a diagnosis or not. That said, this makes those directed and potentially insensitive questions redundant i.e. what does culture mean to you? Do you participate in or have access to cultural activities...." etc because if a person or family feel comfortable enough to share these, these will come up in their answers to "What is important to you." Thank you for picking this up.
		We see many children with IUGR. Physical size initially not included in guidelines due to lack of sensitivity. Increasing diagnosis of genetic conditions, which impact growth, will impact sensitivity to identifying FASD-specific growth restriction. Why has physical growth now been included and what is the evidence to support this?	An extensive review of the evidence was undertaken (See Technical Report for the diagnostic criteria components for all the details). In brief, there was strong evidence regarding the associations between PAE and physical size and based on this evidence review it is recommended that it is included in the diagnostic criteria. Notably, whilst the previous guidelines were based on the Canadian Guidelines, there are discrepancies between international guidelines regarding the inclusion of physical size in diagnostic criteria. Given these international discrepancies, the evidence review aimed to understand what the evidence for physical size was, along with all the other diagnostic features considered across all diagnostic criteria worldwide.
		Consider limitations if you don't have access to early growth charts etc. (particularly for children in out of home care situations).	The structure of the diagnostic criteria allows for this. This is also an important consideration for adults. Clinicians can include assessment of physical size where information is available and if not available it can noted as part of their assessment.

		Diagnosing infants/young children. In infants or young children, 3 facial features, microcephaly and global developmental delay may be considered sufficient for diagnosis of FASD/ND-PAE. Is the criteria for GDD only delays in cognitive functioning (as per DSM-V)? O In practice, we consider GDD as having delays in more than one domain (e.g., speech and motor). Therefore, can we consider GDD as we do clinically, or does it need to be quantified? It would be beneficial to have a clear definition of GDD if this is added to the criteria (i.e., less than 3rd percentile). O GDD is often given when delays are not better explained (e.g., by FASD). O Current criteria for infants is sensitive to FASD, requiring GDD (which generally can, be identified until older) may delay diagnosis and access to appropriate targeted interventions.	Relevant section of the diagnostic criteria and section on assessment of infants and young children has been revised to clarify this.
		Clinical cut off, Moving away from percentiles/standard deviations to meet domains may be challenging for clinics with different models of care and that do not complete all assessment in-house. Information is often coming from many sources such as schools, private therapists, other teams etc. (often not the person who has completed the assessment). Therefore, challenging for Case Conference teams to understand the depth of assessment results (e.g., how do we know if they are meeting the criteria with moderate delays?).	The guidelines are still providing a percentile range to support clinical decision making. This section has been restructured to make this information easier to identify in the defining clinically significant impairments section. Additional information has also been provided to try clarify this point for readers.

		Prenatal alcohol exposure - The evidence review indicated that associations between PAE and diagnostic outcomes were more consistently observed across multiple ND domains at heavy and very heavy PAE levels. Significant effects were less often observed at a moderate and light levels. This sounds like significant effects were still found at light levels of PAE and therefore this should not preclude a diagnosis. o Consideration regarding the wording used in this section as currently, there is risk of sending the message that there is a safe amount of alcohol to drink during pregnancy. o Clinically, we have seen children meeting diagnostic criteria and presenting with severe neurodevelopmental delays despite low level PAE and not better explained by other factors/conditions. o Currently, genetic factors are not well enough understood to suggest low levels of PAE are safe for everyone. o Page 45 Flow Chart, suggests that it needs to be higher end of moderate to heavy PAE to see neurodevelopmental domains severely impaired however clinically we see otherwise (important not to exclude the lower level PAE). o Asking for specifics regarding alcohol content/number of standard drinks likely to increase risk of stigma and shame and risk for underreporting. Also consider issues regarding accuracy of reporting (e.g., historical accuracy).	Wording of the PAE Criterion has been updated as well as relevant sections throughout the document to better communicate the information pertaining to PAE risk assessment. Additional wording and an updated visual is provided to better explain the risks of low risk drinking and how the guidelines are aligned with other national alcohol guidelines and to better explain that the guidelines are not recommending that low exposure is safe. Children with low levels of PAE may demonstrate neurodevelopmental delays/impairments, but these may be the results of a range of other unknown factors. It is likely that other causes of neurodevelopmental impairment will frequently co-occur with light PAE given the high prevalence of PAE in Australia. Careful assessment of PAE is also important to provide the most accurate assessment of the risk, as it may be that what is being interpreted as a low-risk exposure is actually a medium or even high-risk exposure before pregnancy recognition. It is important to gather specific information regarding the number of standard drinks where possible. This is part of the recommended assessment process in the current Guide, collecting this level of detail where possible is not a change in practice. Wording of Criterion A and relevant parts of the document has occurred to better communicate the risks associated with different PAE levels to inform clinical decision-making regarding risk and diagnostic outcomes.

		We have worked hard to change the narrative around PAE and FASD. o We acknowledge the working party understand this, perhaps it is just the wording that is misleading. The way it reads is that the take-home message is, low levels of PAE are generally safe.	Wording throughout the document has been revised to clarify the messaging around low exposure.
		GPS's in this section (holistic formulation and strength-based pathways) is vital and clinically important and outlined well.	Thank you.
26	Individual Clinician, Australian Childhood Foundation	Increase of the threshold for exposure to alcohol in pregnancy and use of the terms heavy and very heavy alcohol use: 1) These terms may sound judgmental to those who consume alcohol in pregnancy. 2) Mothers often minimise their alcohol intake in terms of quantity, timing, and duration due to stigma, shame, racism etc. Narrowing the criteria is likely to impact diagnosis and treatment for these families. 3) This may also influence those assessing for PAE who may dismiss alcohol use that is reported as 'light' or 'moderate'. 4)These terms were removed from literature surrounding alcohol treatment several years ago, with preferred terms being low risk, moderate risk, high risk etc. 5) There remains an abundance of research that highlights the effects of low and moderate risk alcohol consumption during pregnancy on children. 6) There is also the potential that removing low-moderate risk drinking from the diagnostic criteria may influence people to believe that this amount of alcohol is safe and healthy during pregnancy.	Thank you for this feedback. Wording has been updated in the criteria and throughout the document as appropriate to address this point, as per previous responses above. Additional wording has also been included in the Introduction section to better explain the alignment with other relevant Australian alcohol guidelines.

		Communication Domain: It is unclear whether severe impairment in this domain can still be applied when there is a significant discrepancy between receptive and expressive language skills. Is the criteria for severe impairment in this domain based on meeting DSM diagnostic criteria for a language disorder? (which may be due to either receptive or expressive language deficits). In which case, it is important to highlight when there are significant discrepancies between receptive and expressive language abilities, particularly when young people with FASD may present as having better language skills than they actually do, which may relate to better developed expressive language skills compared to lesser developed receptive language skills. I would like to see more consideration for use of interpreters or alternative models of assessment for young people who present with English as an additional language which is extremely common in the NT.	Discrepancy based on expressive vs receptive language is a metric unique to the Clinical Evaluation of Language Fundamentals and not a well-accepted metric (see the CATALISE studies), nor is it a stable metric over time (see the work of Conti-Ramsden and others). There was an emphasis on moving towards the best practice points outlined in the CATALISE papers and it is recommended that this be reviewed to better understand how the domain has been formulated and the approach used to assess. Language skills have not been shown to develop along 'receptive' and 'expressive' pathways as the comment suggests. The assessment of this domain has focused on the assessment and diagnostic model agreed upon by the CATALISE consortium, which we agree does not fully align with the DSM-5-TR although is in keeping with current diagnostic terminologies and assessment approaches. We agree that speech pathology assessment is important to better understand an individual's communication profile. However, the review of the literature does not support the statement that individuals with FASD have better expressive language abilities. We agree the use of interpreters is important, and consequently we have addressed this point in the Good Practice statements. Using interpreters is not unique to the communication domain and should be considered by all clinicians working with the health care consumers, as per their recommended clinical guidelines (e.g. APS practice guide on Working with Interpreters). Additionally, the Specific Assessment Considerations highlights '*For assessment with Aboriginal and Torres Strait Islander peoples and other culturally*

			and linguistically diverse individuals, relevant Practice Guidelines produced by Speech Pathology Australia can be used to guide practice.' These outline the use of interpreters, cultural consideration, use of interpreters, dynamic assessment approaches etc., all of which a clinician who has met the standards to practice as a speech pathologist should be familiar. Dictating each aspect of a speech pathology assessment is beyond the scope of these guidelines and if clinicians are unsure, they should seek appropriate professional development and supervision.
		The Indigenous Framework is a welcome addition, and a good step towards embedding more culturally appropriate and culturally safe engagement, assessment, and feedback with families. I would like to see more input/support regarding culturally appropriate assessment of children/young people, particularly when they may not have had exposure to the tasks in formal assessments due to living remotely.	This is discussed in the Indigenous Framework and a key approach recommended by the Cultural Advisory Group is shared decision making, which is discussed in the Indigenous Framework and throughout the main document where relevant.
27	Department of Health and Aged Care – *submission 1*	The Department does not have feedback to provide on any of the specific sections at this time, and notes that that a Summary of Changes from 2016 Guide to FASD Diagnosis is provided in the main guidelines document (pp 19-20). While the Department notes that the primary target users of these guidelines are Australian practitioners undertaking assessments of infants, children,	The Guidelines Development Group has provided detailed responses to all the public consultation feedback and made a wide range of changes throughout the draft documents as indicated. Although it is also noted that there are a wide range of stakeholders involved in the guidelines project (i.e., > 100 people) who have differing opinions on how changes may impact stigmatisation and the GDG have attempted to balance these diverse review, with particular consideration of how this will effect a wide range of people with living experience who may or may not be represented to differing extents through the public consultation process.

		adolescents, and adults, that may result in a diagnosis, we have an ongoing interest in: ensuring that any concerns from stakeholders may be appropriately responded to as part of the consultation feedback process, and; that due consideration is given with regards to any potential for increased stigmatisation.	Given some of the points raised through the public consultation it will be important for a range of targeted implementation resources and approaches to support professional development for health practitioners and enable effective communication of information in different formats for individuals with living experience, to ensure successful uptake of the guidelines into clinical practice.
		The Department notes: the changes summarised will improve the guidelines by making them more contemporary that the UQ has been working with the AGREE-II international tool to assess the quality and reporting of clinical practice guidelines, and the NHMRC requirements for meeting the standard for clinical practice guidelines (admin-and-technical-report pp6). The Department also notes interest in providing additional information imminently from *[name and position of person providing additional feedback redacted].*	Thank you for this review.
	Department of Health and Aged Care – *submission 2*	Noting that the guidelines (p19) references 'embedded lived and living experience perspectives' the department is invested in invested in ensuring key stakeholders are listened to and adequately responded to. In particular, concern that the changes to the guideline in 2024 will result in increased stigma for persons with lived experience and their families and will result in families not presenting for assessment, diagnosis and care.	There are a diverse range of living experience perspectives, and the project has aimed and will continue to aim to be respectful and inclusive of a wide range of perspectives.

		The guideline needs to retain the FASD name. It could refer to ND-PAE within the document but the disorder is widely referred to as FASD internationally and this suggested name change was not within the remit of the guideline developers and is not welcomed by various stakeholders.	Additional information has been added to the document to better explain the context regarding diagnostic terminology internationally and particularly in the context of DSM-5-TR. The name FASD was always being retained. The GDG was not proposing to change the name, but to provide opportunity for different terminology to be used based on the needs of individuals and families attending for assessment. Notably, there are different views between different stakeholders on this issue. For background, the question about considering different terminologies originated out of discussions from the Cultural Advisory Group and then was subsequently discussed across all consultative groups. There was no consensus on this issue, with some people preferring terminology of FASD and others preferring terminology of ND-PAE, or similar. To reduce confusion, terminology of FASD is used without ND-PAE on the cover of documents and throughout, but the key principles underpinning the guidelines of human rights-based approaches and shared decision making are retained, whereby individuals have choice and control over decisions throughout the assessment process, including the diagnostic terminology applied. Further information has been provided to describe the different diagnostic terminologies included in both the DSM-5-TR and ICD. Terminology of neurodevelopmental disorder associated with prenatal alcohol exposure is already in use in Australia through DSM-5-TR.
		The section on prenatal alcohol exposure (PAE) required to meet the criteria needs amending. It is inappropriately specific on the quantity of alcohol consumption needed to meet the criteria for PAE. It says such levels (heavy and very heavy) are 'more consistently found to be associated with adverse diagnostic outcomes'. It says the available evidence is uncertain regarding the impact	These sections have been revised to better communicate the key findings from the evidence review, approaches applied in the evidence review and differences in clinical practice that can occur compared to when PAE information is collected in research settings. Notably, including that the specific levels applied in the evidence review are not intended for use as cut-offs in clinical practice, these were applied to allow appropriate synthesis of the evidence and are

		of ‘moderate PAE’. Noting the uncertainty of the evidence base and other caveats in the guideline on this and the high risk of stigma associated with the resultant labelling and other adverse flow-ons, this specificity is misguided, misleading and potentially damaging. Recommend taking figure 6 out and simplifying this section to indicate our uncertainty here on exactly how much PAE can result in FASD	only meant to guide clinical decision making. It is critical to have this level of specificity in the evidence review, as this information is available in a research context when examining results of pregnancy cohort studies. Whilst in clinical practice specific details around exact levels of exposure are not always available, clinicians are required to make complex decisions assessing risk and protective based on the best available information and require access to transparent information from the best available evidence to inform their clinical decision making. These guidelines aim to transparently report the evidence review findings. Additional information has also been added to the document to better explain that the inclusion of a minimum PAE threshold is aligned with a growing number of international guidelines, including the 2016 Canadian Guidelines, which the previous Australian Guide was based on. There have also been a number of recent international publications that are consistent with the findings of our evidence review (e.g., Bandoli et al, 2023; Jacobson et al., 2024). We also note the feedback provided from the NHMRC Clinical Review and feedback we have received through the peer review process in publication of the evidence review noting the important contribution to the field of this research. The findings the evidence review underpinning the GRADE-based recommendations have now also been published in BMC Medicine (Akison, Hayes et al., 2024). Additional information has also been added to the document to further explain the alignment of the findings with public health messaging, but also why different approaches are required in the context of FASD diagnosis.

		Feedback from neuropsychologists and speech pathologists is that they are concerned about the tests being deployed as they are not thorough enough.	The GDG discussed providing a list of standardised tests. Based on feedback from the Advisory Groups, the previous list of example tools led to several unintended adverse consequences. For example, this included inappropriate use of certain tools in certain population groups, including First Nations Australians and clinicians interpreting the previous guide to mean that if they didn't have access to the particular tools listed, they couldn't assess for FASD, negatively impacting on service access. Further, standardised test versions quickly become out of date, further impacting on applicability and usability of the guidelines. The GDG weighed up the potential risks and benefits and decided against including a list of example tools. Assessment tools vary greatly, their availability also varies across different settings and the ages of individuals attending for assessment, and they change over time (e.g., become outdated). Further, tests are only validated within certain populations, and have limitations when used outside of these populations. It is impossible for the guidelines to cover all the available assessment tools for children of all ages, adolescents, and adults to the appropriate level of detail to support clinicians with making these decisions. It is the responsibility of clinicians to not act outside their area of expertise and seek clinical supervision. Standardised tests are one piece of the information that clinicians can use, where appropriate to inform diagnostic decision making, but tests don't diagnose, clinicians do. There are no standardised tests designed to specifically detect FASD. Clinicians are required to select the tests they use based on a wide variety of factors. The guidelines recommend clinicians seek clinical supervision if they do not feel they have the appropriate knowledge to make these decisions.

			The GDG would also like to draw attention to the fact that not providing a list of standardised tests is aligned with other similar Australian Clinical Practice guidelines e.g., the Autism Guidelines state: "Practitioners should consider using, but not rely solely on, standardised assessment, to support clinical decision-making in relation to referral, Assessment of Functioning, Medical Evaluation, and Diagnostic Evaluation. Practitioners should know what concepts are being assessed by each tool, and the extent to which they will contribute information that is relevant to the purpose of the assessment. Be aware of the limitations of standardised assessments from a cultural perspective, including where they have not been developed, validated, and/or normed with a population relevant to the client, and therefore may be inaccurate, misleading, invalid, and/or otherwise inappropriate. Practitioners should not use standardised diagnostic tests solely, or as a substitute, for clinical decision making and diagnostic formulation that considers all relevant sources of evidence."
		The diagnostic algorithm has been removed from this update. This will make implementation of the Guideline very difficult in clinical practice. This includes specifications for cut-points for impairment have been removed and left to clinical judgement. This is also unhelpful for clinicians using the guideline.	Not yet developing a diagnostic algorithm in the draft guidelines is an issue of available resources and time, not desire to have an algorithm. It is planned for the final version of the guidelines to include this. The project team have done their best to prepare a set of draft documents for public consultation but note that funding for this project ended mid 2023. This has limited the capacity of the team to undertake further consultation and development of the required implementation tools and resources.

			Regarding the cut-points for impairment, the document does already provide a percentile range to inform diagnostic decision making. Although this section of the document has been re-structured to make this information easier for readers to locate. The 'determining the clinical significance of neurodevelopmental impairments' – subsection entitled 'cut scores' also provides detailed information regarding this complex issue to support clinicians in their practice.
25	Individual clinician, University of Western Australia	After reading the guide, I'm concerned about the mixed messages we will be sending out to the public in relation to alcohol use in pregnancy. For instance, the fact that FASD can only be diagnosed with moderate to heavy/very heavy exposure in utero under the new guidelines can lead to misinterpretation by community members about how low levels of alcohol consumption are safe in pregnancy. While the impact of low PAE on development has only been demonstrated in animal models/studies, this does not mean that low PAE does not result in severe neurodevelopmental difficulties in humans. While research in this area is lacking, as part of my clinical work, I have seen young children with low PAE who exhibit severe impairments across several neurodevelopmental domains and require substantial support.	Additional information has been added to better explain how these guidelines are aligned with public health messages. Changes have been made to the wording of the diagnostic criteria to better communicate regarding the risk levels of PAE. The evidence review identified a large amount of research that has been undertaken at low levels of PAE. Whilst more research is always needed to better understand these relationships, lack of research at low levels was not the key limitation of this evidence. Based on the best available evidence, there is a low likelihood of diagnosis when there is a low-risk exposure.
		Secondly, the removal of the strict clinical cut-off is also an area of concern. While I understand the reasoning behind this, this may lead to inconsistencies in how clinicians go about diagnosing FASD. A child might not receive an FASD diagnosis when they see a clinician who	A percentile range is provided to support clinicians with their diagnostic decision making. The defining clinically significant impairments section of the document has been restructured to make this information easier to locate.

		adopts a stricter cut-off for impairments (e.g., 3rd percentile). On the other hand, the child might meet the FASD diagnostic criteria for impairment in 3 neurodevelopmental domains if seen by a clinician with a more lenient approach (e.g., 10th percentile). From a researcher's point of view, this would make comparing findings across studies very challenging as there is no standardisation in how severe impairments are defined.	A database template is in development to support collection of test scores across any clinic settings who would like to participate in this type of data collection.
		Under the current guidelines, the AUDIT-C is the recommended tool for the assessment of PAE. However, it is unclear how the AUDIT-C is supposed to map onto the new evaluation of PAE under the new guidelines. Under the new guidelines, a mother who consumes 4 standard drinks every week throughout the pregnancy would fall under the moderate range if I understand this correctly. Additionally, even if the child demonstrates moderate impairments across numerous domains, they would not meet the diagnostic criteria for FASD. Under the revised guidelines, these children may fall through the cracks and miss the opportunity for funded support even with evidence of impairments in at least 3 domains, given the lack of a diagnosis. This is also likely to give off the impression that a moderate level of drinking during pregnancy is ok as this is not enough to meet the diagnostic criteria for FASD. While the additional information section indicates that PAE criterion A1 should not be applied rigidly, I suspect clinicians who are new to the FASD assessment process and who are unfamiliar with the FASD literature are likely to adhere to	Additional information is provided to support practitioners in the assessment of PAE risks, including use of the AUDIT-C. With the revised guidelines moderate exposure (for example, one binge episode) can be considered for diagnosis. Revision of the wording has been undertaken to clarify this point. Children with moderate impairments are not currently diagnosed under the current Guide. However, the revised guidelines do not require a strict <3rd percentile threshold as evidence for severe impairment. Instead, there is a focus included on understanding the functional impairment and use of clinical judgement, consistent with diagnosis of other neurodevelopmental conditions, which will hopefully mean less individuals with FASD will 'fall through the cracks'. Additional information has been provided to support alignment of the guidelines with other relevant clinical practice guidelines. Revision of Criterion A wording and supportive information has been undertaken to better communicate this information to clinicians.

		these guidelines strictly, resulting in missed opportunities for diagnosis and support.	
26	Australian Psychological Society	The Australian Psychological Society (APS) is pleased to be part of the public consultation regarding the development of the Australian clinical practice guidelines for the assessment and diagnosis of FASD/ND-PAE. As an evidence-based organisation, we commend the comprehensive and rigorous approach to the development of the guidelines. Although there are many components of the guidelines which are outside the scope of the APS, we would like to draw a few matters regarding psychological aspects of FASD/ND-PAE to the attention of the Guideline Development Group.	Thank you for taking the time to review the documents.
		The APS is the peak professional body for psychologists in Australia. We advocate on behalf of our members and the community for the implementation of evidence-informed prevention, intervention and systemic reform approaches that deliver health and wellbeing for all Australians. The APS embeds social impact and sustainability in our operations, advocacy, and initiatives guided by the United Nations global Sustainable Development Goals (SDG)1 . We consider the reduction of and mitigation of the impacts of FASD/ND-PAE to be an important healthcare challenge in Australia, which can affect all sectors of society. Given this, the development of the Guideline goes some way toward SDG 3: Ensure healthy lives and promote well-being for all at all ages2 .	No response required.

		Firstly, we would like to commend the inclusion of a Cultural Advisory Group and FASD Indigenous Framework (The Framework) which represents a significant change from the 2016 guide. It is essential that the implementation and evaluation of the guidelines is also genuinely co-developed with First Nations Peoples3 to ensure that all Australians can access appropriate care and support post-diagnosis. As acknowledged in The Framework, this is particularly important for a number of reasons including: • The unique impact of colonisation means that there must be deep recognition of the intergenerational trauma and ongoing disenfranchisement that has been created in Australian society. • Acknowledging that many of the social determinants of high alcohol use are not uniform across communities. Interaction with the criminal justice system,4 racism and discrimination,5 service inequalities, disconnection from country, education outcomes, health outcomes, and substance use are some of the many factors that may contribute to alcohol misuse in Indigenous communities as well as poor mental health. These inequalities must be addressed appropriately in order to see tangible progress. • Recognising that access to mainstream services is not equitable. When dedicated services are not available, some initiatives need to be adapted to become more	Thank you for this feedback regarding the Indigenous Framework. The Guidelines Development Group would like to acknowledge the leadership of Ms Nicole Hewlett and the Cultural Advisory Group in the development and embedding of the Indigenous Framework. We agree that this is an excellent addition to the guidelines and are grateful for the generous contributions of Ms Nicole Hewlett and the Cultural Advisory Group.

		responsive to the particular needs of Aboriginal and Torres Strait Islander peoples.	
		Similarly, we also commend the inclusion of lived experience voices throughout the different components of the development, including the 'Actionable Statements'. Incorporating lived experience voices into the development and implementation of guidelines enhances empathy, tailors services to patient needs, and fosters inclusive, culturally competent care. It brings valuable insights, improves decision-making, reduces stigma, and ultimately leads to better health outcomes and patient satisfaction.	Thank you for this feedback. The authors believe this is the first time that specific lived experience actionable statements have been provided.
		In consideration of the Main Guidelines Document, in particular the Actionable Statements, the APS notes: 1. A holistic approach – The APS commends the inclusion of a holistic approach which considers a diversity of social determinants of health. As discussed in the Main Guidelines Document, it is vitally important to consider that FASD/ND-PAE occurs as a result of multifactorial and interacting circumstances and often intersectional disadvantage. We commend the thorough holistic approach to assessment undertaken by the Guidelines team.	Thank you for this feedback.
		2. Shared decision-making, including yarning – an approach which should be central to all healthcare, the APS commends the inclusion of shared decision making as an underlying principle to the guidelines.	Thank you for this feedback.

		3. Gender inclusive language – the APS commends the use of gender-inclusive language (for example, use of parent/caregiver) however, recommends that more inclusive language could be extended to the forms in the appendices (for example, page 109) as not all birthing parents identify as mothers.	Thank you for identifying this omission in the Appendix, this has been corrected.
		4. Greater focus on prevention and early intervention – first and foremost, given the lifelong impacts of FASD/NDPAE e.g. 6 it is essential that the guidelines are embedded within a context of prevention and early intervention see also 7,8. Although the Main Guidelines Document is clear, that public messaging regarding FASD/ND-PAE is outside the scope of the document, not focussing on prevention represents a lost opportunity to: (a) reduce future incidence, (b) increase awareness and potentially early intervention, and/or (c) reduce stigma (see below).	Additional information has been included to support public health messaging and prevention of prenatal alcohol exposure.
		5. Taking a lifespan approach – consideration of the impact of early experiences and challenges throughout the entire lifespan is a central tenant to psychologists, in particular Educational and Developmental Psychologists. We commend the Guidelines not limiting the focus to purely be on children but also incorporating downstream impacts and repeating assessments as necessary, however, this should also include a greater recognition of the increased risk of suicide and related behaviours and cognitions in people who have PAE9 .	The GDG agrees regarding the importance of suicide. Suicide-related behaviours are included as part of the emotional and/behavioural regulation neurodevelopmental domain.
		6. Elevation of the role of psychologists – Given the psychosocial influences on alcohol use and the	The GDG recognises that psychologists have a role in treating mental health conditions, however these clinical practice guidelines

		developmental, neuropsychological, and mental health impacts of FASD/ND-PAE6 , psychologists can play an important role in the holistic approach to healthcare. Psychologists are able to provide any behavioural and/or developmental support and mental health care to individuals affected, as well as interventions to reduce problematic drinking in parents see also 10 to prevent further incidence of FASD/ND-PAE. For example, there are opportunities to elevate the importance and role of psychologists when discussing referral pathways.	focus on assessment and diagnosis. Including specific recommendations on interventions is therefore outside the scope of the guidelines. But we would welcome future collaborations with the APS to develop further specific resources for psychologists to highlight the key roles psychologists can play.
		7. Importance of stigma reduction - We commend the inclusion of providing 'non-stigmatising support' in the Lived Experience Actional Statements (page 14) and suggest that psychologists may be able to assist in the reduction of perceived (or self) stigma for individuals and contribute to related public health stigma-reducing initiatives.	The GDG have tried to take an interprofessional approach to encourage all clinicians to contribute to these areas. But as per the previous comment, we would welcome future collaborations with the APS to develop further specific resources for psychologists to highlight the key roles psychologists can play.
		8. Greater consideration of support for Australians in regional and remote communities – Although FASD/ND-PAE occurs in every sector of society, it is important that adequate support is given to Australians outside of metropolitan regions. We commend the flexibility in the guidelines regarding reusing previous assessments and clinical judgement, however, this is no replacement for well-funded health services in rural and remote Australia. In keeping with our ongoing advocacy, we advocate for greater funding and support to ensure that every Australian with FASD/ND-PAE has the best possible care, regardless of their geographical location.	Additional information has been added to the dissemination, implementation and evaluation report regarding this point.

		9. Importance of interdisciplinary teams – the APS commends the transtheoretical ethos underlying the Guidelines which includes multiple inter-professional approaches (page 28).	Thank you for this feedback.
		10. Expectations of the use of the document – it is important to acknowledge that many health practitioners are timepoor and have to balance many competing demands and priorities see 14,15. Introduction of the guidelines will not be the "magic bullet16(p. 530)" for every patient and practice and should not replace appropriate training and a strong interdisciplinary approach. Given the lengthy and detailed nature of the guidelines, it is likely that some practitioners will only refer to the summary on an ongoing basis. It is essential, therefore, that the holistic, biopsychosocial and interdisciplinary approaches be integrated into an Executive Summary or abridged version in an easy to digest, accessible format.	Thank you for this suggestion. We have now provided a short version of the guidelines, which still highlights the importance of holistic interprofessional approaches.
27	Joint feedback from 2 Clinicians: Occupational Therapist Australian Catholic University, Canberra Development	The cultural component is well considered and respectful.	Thank you for this feedback regarding the Indigenous Framework. The Guidelines Development Group would like to acknowledge the leadership of Ms Nicole Hewlett and the Cultural Advisory Group in the development and embedding of the Indigenous Framework. We agree that this is an excellent addition to the guidelines and are grateful for the generous contributions of Ms Nicole Hewlett and the Cultural Advisory Group.
		A statement about current Australian prevalence could be helpful ie rural/remote vs metropolitan, indigenous vs non-indigenous (or a link to AIHW data).	Due to concerns regarding document length this hasn't been included.

	Clinic, Sunshine Coast Health and Hospital Service, CICADA. Physiotherapist Royal North Shore and The John Walsh Centre for Rehabilitation University of Sydney	The evidence based approach pages 12 – 17 is very helpful. A traffic light system could be adopted to distinguish level of evidence (green = yes, orange = some, red = none/low level) as has been done elsewhere eg CP guidelines	Thank you for this suggestion. It is planned to develop further associated resources to support communication of the evidence review, although this will be dependent on availability of funding.
		"Summary of Changes from 2016 Guide to FASD Diagnosis" page 19 helpful for understanding the context of proposed changes.	Thank you.
		A statement about how these guidelines fit/correspond with other well respected international guidelines is missing. For example the International clinical practice recommendations on the definition, diagnosis, assessment, intervention and psychosocial aspects of Developmental Coordination Disorder (Blank et al., 2019).	Additional information has been added regarding some of the other relevant guidelines.
		A statement about how the new terminology (FASD vs ND-PAE) fits/corresponds with international terminology is missing. A shift from FASD to ND-PAE could be confusing for public health campaigns and recognition of FASD in Australia amongst the wider community.	Additional information has been added to the document to better explain the context regarding diagnostic terminology internationally and particularly in the context of DSM-5-TR. The GDG was not proposing to change the name, but to provide opportunity for different terminology to be used based on the needs of individuals and families attending for assessment. Notably, there are different views between different stakeholders on this issue. There was no consensus on this issue, with some people preferring terminology of FASD and others preferring terminology of ND-PAE, or similar. To reduce confusion, terminology of FASD is used without ND-PAE on the cover of documents and throughout, but the key principles underpinning the guidelines of human rights-based approaches and

			shared decision making are retained, whereby individuals have choice and control over decisions throughout the assessment process, including the diagnostic terminology applied. Further information has been provided to describe the different diagnostic terminologies included in both the DSM-5-TR and ICD.
		Could there be a “2-stream” diagnostic framework developed – one (i) linked to the medical model of standardised assessments and cut-offs to define impairment and the other more (ii) holistic and suited to specific populations.	The Guidelines are encouraging practitioners to use standardised tests where appropriate, but to not be making decisions about level of impairment based on test scores alone. This is relevant for all individuals attending for assessment. We encourage practitioners to also review wording of this in the Autism guidelines, some of which is included in responses above, which is also aligned with this approach.
		“Clinically significant impairment” is not defined and relies on clinical judgement; however no guideline is provided to support clinical judgement.	Section titled ‘determining the clinical significance of neurodevelopmental impairments in practice’ provides this information. This section has also been restructured to help make this information easier to locate.
		This is a very long document, and some sections are a little repetitive particularly in the introduction section. Similar to Cochrane reviews, could there be a shortened version, along with a comprehensive version	The Guidelines Development Group have developed a short version of the guidelines and a layperson summary to provide easier and more accessible options for accessing the details of the main guidelines document.
		Could there be a visual illustration / diagram developed (1 page) and included to explain diagnosis to Indigenous populations (including diagnosis for infant vs child or adolescent age groups)?	Thank you for this suggestion. We plan to develop a layperson summary document and a visual of this nature will be good to include in that document.

		How do these new guidelines affect NDIS approvals, particularly if the wording of the FASD diagnosis is changed to NDD-PAE?	The NDIS review has outlined that current approaches to accessing the scheme are inequitable, including the use of diagnostic lists, and signalled plans to update their approach. Therefore, it is a broader issue of what the eligibility process of NDIS will be.
		We felt that experienced clinicians with FASD knowledge could navigate these guidelines but a shortened version would be helpful to those orientating to the field	As per comment above, short version will be provided.
		The new holistic diagnostic guidelines could overly depend on the caregivers/families' narrative to identify domains of function affected. If a parent/caregiver was not obliging/supportive this could risk a vulnerable child's opportunity for assistance / therapy input.	The diagnostic criteria include the need for both information from informants and direct evidence of impairments. A template is also provided to support clinicians with collecting a wide range of pertinent background information.
		Members of the cultural steering group are not acknowledged.	We greatly value input from the Cultural Advisory Group and all members are listed as part of the acknowledgments of Advisory Group Members.
		There needs to be further specification about who can implement these guidelines including what level of clinical competence they require. There is mention of clinicians seeking clinical supervision from their own discipline. Having a list or reference point of who is able to provide clinical supervision would be helpful. Consideration of credentialing or specific training for implementation of the guidelines is recommended. For example, this occurs with autism diagnostic training and use of the ADOS and/or MIGDAS tools.	It is outside the scope of the guidelines to provide this information, as to be applicable these types of lists would need to be maintained and there is no ongoing funding to support updating of such implementation resources. There are a range of training options available in Australia, including The University of Western Australia Graduate Certificate in the Assessment and Diagnosis of FASD. These professional development opportunities will no doubt be updated with the update of the guidelines.

		Motor domain: The changes are well considered, specifically assessing both fine and gross motor skills and not relying on one single assessment.	Thank you for this feedback.
		Noted that recommended standardised assessment tools are missing from this section (and have been presented else where eg for the assessment of facial features).	As per detailed responses provided above, The GDG weighed up the risks and benefits of providing an example standardised tool list and it was decided that based on the feedback received across the Clinical Advisory Groups regarding previous unintended adverse consequences of this list, the risks outweighed the benefits. An additional Good Practice Statement is also now provided regarding this point.
		Noted that no cut-offs have been provided to define a domain being PAE affected (and have been suggested elsewhere eg 4 digit diagnostic code - University of Washington facial analysis software).	As per comment above, Section titled 'determining the clinical significance of neurodevelopmental impairments in practice' provides this information. It has been restructured to make this information easier to locate.
		Some examples of how clinical judgment could be used to define impairment could be helpful or the use of frameworks to identify.	Thank you for this suggestion. However, as you can see from the feedback provided there have been concerns raised already regarding the current length of the document. This would make an excellent implementation resource to support clinicians in applying the guidelines and the GDG hopes that further funding will be available to support the development of these types of resources.
		We absolutely acknowledge that some children have significant functional impairments that do not meet 1 or 2 SD cut-offs.	The GDG hopes that the approach taken in the diagnostic criteria will support practitioners in taking this into consideration in diagnostic decision making. As per comments above, a percentile range is provided to support clinicians in their diagnostic decision making.

		It would be helpful to know what evidence-based suitable options of tools for FASD are available to guide clinical practice. For example, recent literature has indicated that the BOT2 short form is not sensitive to detect motor impairment in FASD compared to the MABC2 (Johnston et al., 2019). By contrast, the BOT2 comprehensive form has not been compared to the MABC2 (or even MABC3 which is now available). No research has been done on the MABC3 for a FASD specific population, yet the manual indicates that it is suitable for assessment with a FASD population.	The evidence review demonstrated there is very limited evidence available that has actually applied the currently available versions of standardised tools. This is noted as a limitation of the evidence. It is unfortunately outside the scope of the guidelines to provide a comprehensive examination of all of the available tools across all of the domains and required ages (i.e., infants – adults). The GDG have discussed that if additional funding and time was available, this is the type of implementation resource that could be developed.
		There continues to be emerging evidence of the impact of sensory processing differences in FASD and the recent development of a neuro-affirming sensory preferences tool (MYSET https://autismqld.com.au/myset-announcement/) that is not norm referenced and used to indicate therapeutic supports. People with FASD often do experience sensory processing differences and require therapeutic supports.	As stated above, the research team listened to the concerns raised by parents/caregivers and clinicians about sensory processing challenges through the initial priority setting for the guideline review (Hayes et al., 2022) and reviewed the available evidence in this area. The results did not provide any current evidence for an association between PAE and sensory processing. It is noted in the document that whilst this is not included in the criteria it can still be included as part of the assessment and can be noted under the 'associated features' - see this section under the diagnostic criteria box supporting provision of recommendations and supports.
		Could a note about why sensory processing is not assessed as a neurodevelopmental domain for diagnostic purposes be included?	This is included in the section 'neurodevelopmental domains: evidence for inclusion.' Evidence was not available at this time to support inclusion in the criteria – see the Technical Report of the diagnostic criteria components for the specific details of the results of studies that included sensory processing outcomes and had control groups.

28	National Aboriginal Community Controlled Health Organisation (NACCHO)	It is important to note that while FASD is more commonly reported in Aboriginal and Torres Strait Islander children, this may be due to higher rates of diagnosis which may not accurately reflect disparities in actual prevalence with non-Aboriginal children. This can be related to several factors, including poor data, incorrect differential diagnosis, social stigma and systemic racism in the healthcare sector. Despite this, the review process and updated FASD guidelines are welcome contributions to the primary healthcare sector and represent strong articulation of the National Agreement on Closing the Gap.	Thank you for taking the time to provide this review.
		Priority Reform Area 1 – Formal partnerships and shared decision-making This Priority Reform commits to building and strengthening structures that empower Aboriginal and Torres Strait Islander people to share decision-making authority with governments to accelerate policy and place-based progress against Closing the Gap. Priority Reform Area 2 – Building the community-controlled sector This Priority Reform commits to building Aboriginal and Torres Strait Islander community-controlled sectors to deliver services to support Closing the Gap. In recognition that Aboriginal and Torres Strait Islander community-controlled services are better for Aboriginal and Torres Strait Islander people, achieve better results, employ more Aboriginal and Torres Strait Islander people and are often preferred over mainstream services.	The Guideline Development Group would like to acknowledge the strong leadership of the Cultural Advisory Group in recommending a shared decision making approach to assessment and diagnosis of FASD and the alignment of this with the National Agreement on Closing the Gap.

		Priority Reform Area 3 – Transformation of mainstream institutions This Priority Reform commits to systemic and structural transformation of mainstream government organisations to improve to identify and eliminate racism, embed and practice cultural safety, deliver services in partnership with Aboriginal and Torres Strait Islander people, support truth telling about agencies' history with Aboriginal and Torres Strait Islander people, and engage fully and transparently with Aboriginal and Torres Strait Islander people when programs are being changed. Priority Reform 4 – Sharing data and information to support decision making This Priority Reform commits to shared access to, and capability to use, location-specific data and information (data sovereignty) to inform local-decision making and support Aboriginal and Torres Strait Islander communities and organisations to support the achievement of the first three Priority Reforms. NACCHO recommends that implementation of the revised guidelines align with the National Agreement and its four Priority Reform Areas.	
		Policy context Children and youth with fetal alcohol spectrum disorder (FASD) have limited access to assessment, diagnostic, and treatment resources - a distinct disadvantage in meeting their care needs in Australia. Notably, the lack of support for children with FASD increases the risk of adverse outcomes, including	The GDG would like to thank NACCHO for their ongoing advocacy in this space, and the supportive and collaborative approach they have taken to the development of these guidelines.

		incarceration, homelessness, mental health problems, and early mortality. In Australia, the child protection and justice systems are key sources of referral for FASD screening and diagnosis[1] . Children with FASD are often cared for in the child protection system by kinship carers, many without a diagnosis or the benefits of FASD informed care[.2]. As such, there is an urgent need to prioritise diagnosis and referral pathways for people with suspected FASD, particularly Aboriginal and Torres Strait Islander people across their lifespan as part of Government's commitments to the National Agreement and the *National Aboriginal and Torres Strait Islander Health Plan 2021-2031*. This has become increasingly urgent noting: The Productivity Commission's 2023 Review of the National Agreement on Closing the Gap report, which made clear that the Priority Reforms have not been prioritised by Government. The worsening rate of over-representation of Aboriginal and Torres Strait Islander children in out-of-home care and in youth detention[3]. FASD has significant health and social impacts from birth to death. The Department of Health's *National Fetal Alcohol Spectrum Disorder (FASD) Strategic Action Plan 2018-2028* is an important strategic document to guide coordinated efforts and investment to address FASD in Australia. It strongly aligns with the vision of the *National*	

		Aboriginal and Torres Strait Islander Early Childhood Strategy - that Aboriginal and Torres Strait Islander children (0-5 years) are born healthy and remain strong, nurtured by strong families and thrive in their early years. Underpinning the delivery of these strategic plans and goals is the need to access culturally safe screening, diagnostic and referral pathways. The proposed changes to the FASD guidelines support these outcomes, however further work is required to improve Aboriginal and Torres Strait Islander people's access to the NDIS. NACCHO recommends the Australian FASD/ND-PAE Guidelines Development Group (GDG) and Government accept the proposed changes to the FASD Guidelines in full noting their strong alignment with the *National Fetal Alcohol Spectrum Disorder (FASD) Strategic Action Plan 2018- 2028*, *National Aboriginal and Torres Strait Islander Early Childhood Strategy* and the National Agreement on Closing the Gap.	
		Evidence-based, culturally appropriate guidelines The FASD Strategic Action Plan identified the need to review the FASD Guidelines to ensure alignment with international best practice diagnostic tools and adoption of emerging evidence- based practices and appropriate referral pathways. NACCHO acknowledges the Government's and the University of Queensland's contribution to this objective through this review and public consultation process.	The Guidelines Development Group is happy to hear that NACCHO supports the evidence-based process, the rights-based model of care and the Indigenous Framework put forward in these guidelines and the model of care to improve accessibility of services, including in ACCHO settings.

		NACCHO supports this review and the draft guidelines and appreciates this has followed a rigorous evidence-based process. This is essential for providing clinicians with trustworthy guidelines that have the potential to increase uptake and access to assessment and FASD diagnostic services. This evidence-based approach is also a significant advancement in the guidelines to support improved assessment and diagnosis of FASD in Australia. The revised draft FASD guidelines provide critical information for health care providers on diagnosis, referral, and management of FASD. This facilitates early and successful interventions that support both the individual with FASD and family/carers through a human-rights based approach. The right-based model of care put forward in these guidelines is a significant step forward in assessment and diagnosis of FASD in Australia. The emphasis on shared decision-making in the 'Finding your way' approach focuses on respectful, culturally safe, client-centred care which aligns with NACCHO Core Services and Outcomes Framework. This approach will be important to improve the accessibility of culturally appropriate services to advance the health and wellbeing of Aboriginal and Torres Strait Islander peoples who are assessed and diagnosed with FASD, as well as the wellbeing of their carers and families.	

		NACCHO recommends the GDG adopt the proposed guidelines and Government support these updates following GDG's inclusive and evidence-based review process that has effectively integrated Aboriginal and Torres Strait Islander cultural considerations.	
		Access to paediatricians for FASD diagnoses is problematic in regional, rural and remote locations but can be overcome through the revised FASD guidelines. Research has highlighted the need for more practitioners to be able to identify Australian children living with FASD[4]. While multidisciplinary team assessments are the recommended approach to FASD diagnosis, specialist multidisciplinary clinics are not available in all areas of Australia and have extensive waiting lists. There is recognition that FASD diagnosis needs to be accommodated in routine assessment practices of child development units and other allied health practitioners across all locations to meet demand[8]. It is therefore critical that FASD diagnosis can be made by practitioners from various disciplines who hold specialist FASD knowledge. The updated guidelines significantly reduce FASD diagnostic barriers through empowering other highly qualified health professional – such as GPs and clinical psychologists – while maintaining the integrity of the assessment and diagnostic process. NACCHO recommends the GDG incorporate information in their implementation report on the benefit of	Thank you for highlighting this. Additional information has been added to the dissemination, implementation and evaluation report to communicate the need for capacity building amongst a wide range of health practitioners to support the proposed model of care for providing assessment and diagnostic services, including across rural and remote locations.

		additional health practitioners providing a child and adult diagnosis of FASD with consultation from specialists as required (e.g. Paediatrician, or Psychiatrist that are FASD informed) as one strategy to overcome barriers to diagnosis by paediatricians and maintain this significant change to the FASD Guidelines.	
		Prioritise implementation of these updated guidelines as an important next step. The FASD Strategic Action Plan acknowledges the need to prioritise implementation of the Australian Guidelines for Assessment and Diagnosis of FASD. This includes building on efforts to disseminate and train medical and health professionals in the FASD Guidelines, and prioritising translational and implementation of research to drive adoption of the guidelines, diagnostic activity and therapy support models. Doctors are often not trained in making a FASD diagnosis, and there may be concerns among clinicians that a label of FASD will stigmatise the mother and affected individual[9]. The Australian institute of Family Studies 2022 update on FASD policy and practice in Australia[10] noted that the ability to diagnose children with FASD may be improved through: -encouraging practitioners to identify and refer for FASD assessment; -increasing the workforce capacity to offer diagnostic services; and -encouraging the accurate documentation of alcohol use during pregnancy.	Thank you for this suggestion. Additional information has been added to the dissemination and implementation report to highlight the need for targeted implementation resources and supports for ACCHOs and the design of professional development programs that have CDP accreditations to support successful implementation of the guidelines.

		While this public consultation process is welcome, effective dissemination and implementation of the revised FASD guidelines is necessary. NACCHO recommends the GDG include in in their implementation report the need to develop targeted implementation of the FASD Guidelines in ACCHOs and embed this in CPD accredited training for clinicians.	
		NACCHO recommends: Government prioritise and fund implementation of the updated guidelines as an important next step through: The Australian Government Department of Health support NACCHO's proposal to work with the University of Queensland to develop targeted implementation approaches to effectively embed the new FASD Guidelines in ACCHOs. The Australian Government Department of Health support NACCHO's proposal to build online CPD accredited FASD training for clinicians in ACCHOs. The National Disability Insurance Agency support NACCHO's proposed NDIS alternative commissioning model to enable more effective referral pathways following diagnosis. Australian Universities and Medical colleges mandate the integration of these guidelines into clinical training. HumanAbility Jobs and Skills Council consider the development of a FASD Unit of Competency in the VET	Thank you for these practical suggestions, additional information has been added to the dissemination and implementation report to highlight these opportunities. The GDG looks forward to the opportunity in further collaborating with NACCHO to undertake this important work to improve accessibility of FASD-related services.

		Health training package to upskill health workers, practitioners and enrolled nurses in FASD.	
30	Royal Australian College of General Practitioners (RACGP)	Aboriginal and Torres Strait Islander health The RACGP welcomes the addition of the *FASD Indigenous Framework*, which takes a human rights based approach and centres cultural safety, shared decision making and a strengths based approach. Cultural safety is paramount in supporting patients with FASD and their families and the FASD Indigenous Framework provides guidance for clinicians to build their culturally safe practice. The RACGP acknowledges the recommendation from the *FASD Indigenous Framework*	Thank you. We appreciate your review of the documents and support and advocacy in building local referral pathways and supports.

		to build community led clinical support and local referral pathways and the important role of Aboriginal Community Controlled Health Organisations in that, including their primary healthcare team. General practitioners as a part of the healthcare team have an important role to play in supporting culturally safe care, including patient advocacy, care coordination and reducing stigma associated with FASD.	
		Implementation of guidelines and overcoming barriers to early diagnosis and management Early diagnosis is crucial and successful outcomes are most likely when interventions supporting both the individual with FASD and family/carers are strengths based as well as child and family centred with management decisions made with input from families and educators. With significant and growing barriers to accessing paediatricians in regional, rural and remote areas the RACGP supports the guideline development group's inclusive approach to be relevant to a variety of practitioners including general practitioners. This aligns with the Department of Health's *National Fetal Alcohol Spectrum Disorder (FASD) Strategic Action Plan 2018-2028:* *where access to specialist teams is limited, it is important that other health and community service professionals are equipped to detect the possibility of FASD and contribute to the diagnostic process.*	Thank you for highlighting this point. Additional information has been added to the dissemination, implementation and evaluation report regarding this point. The GDG looks forward to the opportunity in further collaborating with RACGP to undertake this work.

		Given workforce and service limitations, primary health care providers in remote locations can play a key role in the coordination of screening services. *A key objective under the Plan is to consider how access to appropriate and evidence-based diagnosis and support services can be improved. Existing programs and screening tools (including those being used internationally) should be examined and combined with strategies to ensure appropriate communication and training is delivered to professionals engaged in these programs.* The RACGP recommends expansion of the implementation plan for the guidelines, specifically in relation to the role of general practitioners as part of a multidisciplinary team to support individuals, families and communities in prevention, diagnosis and management of FASD across the life course. Doctors are often not trained in making an FASD diagnosis, and there may be concerns that a label of FASD will stigmatise the mother and affected individual.[i] In the prevention space, a reluctance to ask about prenatal alcohol exposure may also stem from a belief that there is little that can be done to alleviate the effects of FASD.[ii] These barriers can limit people with FASD to access diagnostic and support services. Some literature suggests local community-based behavioural and developmental assessment services could, with appropriate supports and training, be	

		embedded in primary health[iii,iv]. These would need to be well funded and supported as part of any implementation plan and the RACGP would like to see more detail (or contribute to further discussion) on proposed training, upskilling and targeted implementation approaches. Support for people with FASD is crucial to prevent adverse outcomes such as incarceration, homelessness, mental health problems, and early mortality. Children with FASD are often present in the child protection system, many without a diagnosis or the benefits of FASD informed care. Having said this, the child protection and justice systems are key sources of referral for FASD screening and diagnosis and the role of the healthcare team in this, including general practitioners, is an important consideration. The RACGP would welcome the opportunity to be involved in further discussions about how general practitioners as part of a multidisciplinary team can be involved in prevention, diagnosis and management of FASD in a range of settings.	

Appendix L: NHMRC Methodological and Expert Review

Methodological Review Comments				
		Reviewer Comment	NHMRC Comment	Developer Response
		Mandatory Requirements – changes required		*Note:* we sought feedback from NHMRC Guidelines regarding feedback regarding the location of information across the different documents. We were informed that it was ultimately the decision of the GDG where to include information. We have tried to balance the methodological review suggestions with feedback from Advisory Groups and public consultation regarding the length of the main guidelines document in determining location of information and any repetition of any information across documents.
1	C.1	The research questions selected to guide the evidence review are not stated in a format in the guideline that clearly defines the boundaries of the topic (e.g. population, exposure, comparator, outcome).	Please define PICO questions.	The PECO tables are provided in the Technical Reports. Placeholders for hyperlinks are now included linking to these reports and once available online, hyperlinks will be added to make this information easier to access. Based on the feedback we have received concerning the length of the document we have not repeated these tables in the main document.
2	C.4	The publication period covered by the searches is stated; however, the latest date is not within 12 months of the first day of public consultation (assuming public consultation commenced in March 2024 – exact date not clear from documentation available).	Please confirm publication search period dates.	Additional information has been added to the Administrative and Technical Report providing the dates of the public consultation. Details of dates of each of the searches are provided in the relevant Technical Reports and have now also been added to the main document (Chapter 11). Feedback was sought from NHMRC regarding possible flexibility of the 12-month period. It was discussed that whilst our timeframe is outside of the 12-month period we

				had search alerts set up, there has been limited new research published and that none of recently published research would influence the findings of the evidence review.
3	C.8	Evidence summaries meeting C.8 requirements are not provided in the **guideline** document for the GRADE-based recommendations (or Lived Experience Statements). There is no clear discussion in the guideline on the body of evidence underpinning each GRADE-based recommendation (or Lived Experience Statement) and no references are provided for relevant studies.	Please include evidence summaries in the guideline document. Please add general statement about the body of evidence.	Additional information has now been included at that start of Chapter 2 – Summary of Actionable Statements and an additional chapter (Chapter 11) has now been added to the main guidelines document to provide an overview of the body of available evidence and clear links to the evidence summaries and all references included systematic review technical reports are now also included in the main document. As per the comment above regarding the concerns about document length, we have tried to keep this brief and link to the other technical documents and evidence summaries. The Supplemental Files with the evidence summaries are too large to be included within the main document.
4	C.9	A recommended date for future update of the guideline needs to appear in the **guideline** document.	Please add future update comment to the guideline document.	This information is provided in the dissemination, implementation and evaluation report. A brief comment regarding this has been added to Introduction (p. 20) of the main document with a placeholder to insert a link to the dissemination, implementation, and evaluation report.
5	D.3	The supporting references are not listed in the guideline for GRADE-based recommendations (or Lived Experience Statements) and should appear in the **Guideline** document.	Please add references to the guideline document.	All references from each of the Technical Reports are now also included in the main guidelines document.
6	D.6	The method used to achieve consensus (e.g. voting, Delphi) for the actionable statements where consensus was used (e.g. Good	Please add text to describe the process for developing consensus statements.	Consensus was achieved through discussion, revision and approval of the statements. Further information describing this process has been added

		Practice Statements) is not stated. This information must appear in the Administrative and Technical Report.		to the Administrative and Technical Report (section 5 – developing actionable statements; p. 33 -35).
7	D.8	Strengths and limitations of the body of evidence underpinning the Lived Experience Statements is not addressed in the guideline.	Please add commentary on the evidence quality for the lived experience statements.	Additional information regarding the strengths and limitations of the body of evidence is provided in the new chapter that is included in the main document (Chapter 11; p. 123- 130).
8	D.14	The potential impact of each recommendation on clinical practice or outcomes is not addressed in the guideline text.	Please add a general statement on impacts of the recommendations.	A general statement of the impacts of the GRADE-based recommendations has been added (p. 82).
9	G.2	Key recommendations most likely to lead to improvements in health outcomes have not been highlighted for consideration in implementation. This information must be included in the Dissemination, implementation and evaluation report.	Please highlight key recommendations and add to the dissemination report.	In the context of these guidelines, given the GRADE-based recommendations pertain to the diagnostic criteria, a summary of key good practice statements have been provided in the dissemination report.
10	General comment	The following formatting/administrative issues were noted and should be addressed: • Appendix J does not appear in the table of contents for the Administrative and Technical Report. • The introduction to Appendix J mentions that GRADE summary tables are available in the appendices for the Technical Report though they are actually provided as Supplemental Files (not appendices). • The various Technical Reports are referred to as Technical Reports in the file names and in the guideline, but not on the document title pages. Document titles should be consistent for clarity, and references to these documents in the guideline should be consistent with the document titles. • No reference to the resources and models of care Technical Report was located in the guideline. The developer should ensure that in all final documents, cross-references are correct, table of contents are up to date and complete, and documents are named and referenced consistently	Please rectify the formatting issues.	All formatting has been updated across all documents as appropriate.

		throughout all documents. This will assist with navigation and clarity.		
11	General comment	Some required information is contained in Supplemental Files. The developer should confirm that these files will be made available alongside the Guideline and Technical Reports.	Please confirm this information will be included in the guideline and reports.	These files will be made available and placeholders are now included for where these will be hyperlinked.
12	D.10, D.11, D.8.1, D.11.1, D.12.1, D.16, D.17, D.18.	These items were assessed as 'not applicable' and have been included in this table in line with the introductory paragraph to this (Introduction) section.	Please add information to main guideline document to rectify this.	D.10 was N/A D.11 and 11.1 was not marked as N/A and is described throughout where relevant. D.12.1 was N/A D.16 and 17 was N/A D18 was N/A
13	A.1	The organisations responsible for developing and publishing the guideline is not clearly stated in the **guideline** document. Suggest incorporating this in the table on p.2 of the guideline; if the organisations are the same as those who received funding, clarify this.	Please add all organisations responsible for developing and publishing the guideline.	Added statement to clarify (p. 2).
14	A.3	To meet this requirement, the processes and criteria for selecting members of the Advisory Groups and GDG must be included in the **guideline** document.	Please add information to main guideline document to rectify this.	This information is included in the Administrative and Technical Report. Placeholders for hyperlinks are now provided (p.3 & 19-20), but this information has not been repeated in the main document due to feedback received during the public consultation regarding the document being too lengthy.
15	A.5	The information listed in requirement A.5 must appear in the **guideline** document. This information is currently included in the Administrative and Technical Report (Table 1, Table 2 and Table 3)	Please add information to main guideline document to rectify this.	As per above, this information is included in the Administrative and Technical Report and has not been repeated in the main document.

		with the exception of profession or discipline for the Steering Committee members (Table 1).		Disciplines for the Steering Committee Members has also been added to the Table 1 of the Administrative and Technical Report.
16	A.7	A list of organisations formally endorsing the guideline must appear in the **guideline** and can also appear in administrative report (currently pending).	Please add information to main guideline document to rectify this.	Pending. This will be included once available.
17	C.1	The **Technical report – resources and models of care** needs to include the (relevant) research question, as had been done in the other technical reports**.**	Please consider whether the reviewer has valid points and if so consider whether editing is required.	Amended to include the research question (p.6).
18	C.4	The date of submission of the final draft guideline to the NHMRC for approval is unknown, therefore, the timeframe requirement relative to the search dates could not be assessed.	Please include the search dates.	Dates of the searches were included in the Technical Reports and are now also included in the main guidelines document (Chapter 11).
19	C.7	The 'Strength of the association' and 'Certainty of evidence' sections of the summarised versions of the Evidence to Decision tables (Administrative and Technical Report, Appendix J) do not always refer to the correct Supplemental Files or the correct section of the Technical Report. The developer should review all cross-references and correct any discrepancies.	If the reviewer has interpreted this correctly, please check inconsistencies between recommendations and ETDs.	These references to supplemental materials and Technical Reports have been checked and updated as required.
20	C.8	Discrepancies in the wording of the GRADE-based recommendations between the guideline and the Evidence to Decision tables were identified. For example: • The second sentence in the recommendation relating to major facial features (p.164 of the Administrative and Technical Report) is not included in the corresponding recommendation in the Guideline (p.13, p.63).	If the reviewer has interpreted this correctly, please check inconsistencies between recommendations and ETDs.	Wording has been cross-checked and updated between all the GRADE-based recommendations and associated evidence to decision framework tables.

		• The recommendations relating to 'other neurological conditions' and 'functional neurodevelopmental outcomes' (p.199 and p.211, respectively, of the Administrative and Technical Report) are worded differently to the recommendations in the Guideline (p.13, p.64). • The certainty of the evidence and strength of the recommendation relating to 'other neurological conditions' is different between the Evidence to Decision table and the Guideline. The developers should cross-check all GRADE-based recommendations against the Evidence to Decision tables and address or justify any inconsistencies.		
21	D.1	Justification should be provided for assigning 'Strong Recommendations against' for including minor dysmorphic features, structural brain abnormalities and other neurological conditions in the diagnostic criteria, given the body of evidence for each was Very Low certainty or Very Low to Low certainty. In particular, justification should be provided for the 'Strong Recommendation against' other neurological conditions in the Guideline, when the Evidence to Decision table (Administrative and Technical Report, p.199) landed on a 'Conditional Recommendation against'.	If the reviewer has interpreted this correctly, please check inconsistencies between recommendations and ETDs.	For this project we applied a number of novel applications of GRADE. One of these approaches was that we used slightly different methods to determine strength of then recommendations for each of the candidate diagnostic features. Where evidence was lacking regarding the association between prenatal alcohol exposure and a candidate diagnostic feature, this resulted in a strong recommendation against the inclusion of this features in the diagnostic criteria. This would traditionally be considered a discordant recommendation, but our goal was to find superior candidate diagnostic features. We are currently preparing a GRADE Notes paper to publish details regarding the novel application of GRADE for the development of diagnostic criteria for FASD.

				Additional information regarding strong recommendation against has been added to the main guidelines document (Chapter 2; p. 23-25) and the Administrative and Technical Report (section 5; p. 33) to clarify this point.
22	D.2	Some inconsistencies in the actionable statements in the Guideline were noted. For example: • the last GRADE-based recommendation on p.13 is worded slightly differently to the same recommendation on p.64 • the last Lived Experience Statement on p.13 is worded slightly differently to the same recommendation on p.68 • the first GPS on p.16 is more abridged than the same GPS on p.89. Suggest including the supportive text on p.89 as a footnote or in different font to differentiate it as supportive information. The developer should cross-check all recommendations to ensure they are worded consistently throughout the guideline and associated documents. On p.16, the last GPS under the heading 'Holistic developmental, functional, and wellbeing assessment' appears to be missing a word (e.g. services) after 'multi-disciplinary'. Any corrections should be carried through to the same recommendation on p.90. The developer may wish to consider adding the term 'gestalt' to Appendix A or using an alternative word in the relevant GPS.	Please check wording of recommendations for consistency.	All actionable statements have been cross-checked throughout the document and corrected as required.

				The term gestalt has been added to the Appendix.
23	D.3	The developers may wish to consider defining 'strong' and 'conditional' in the context of GRADE-based recommendations in the guideline (see examples in GRADE Handbook). The GRADE-CERQual confidence in the evidence for the Lived Experience Statements is not reported alongside the statements. The developers may wish to consider whether it would be appropriate to include this.	If the reviewer has interpreted this correctly, please consider whether editing is required.	Additional information has been added to define meaning of strong and conditional recommendations (Chapter 2; p. 23-25). Thank you for this suggestion. The text has been amended to including the GRADE-CERQual confidence in the evidence for the Lived Experience Statements.
24	D.4	No recommendations were identified as being developed by consensus in the absence of quality evidence from a systematic evidence review. Where the certainty of the evidence was Low or Very Low, the recommendation was graded as either Conditional or Strong, rather than assigning a Consensus-based recommendation. The developer should provide justification for categorising such recommendations as GRADE-based (Strong or Conditional) rather than consensus-based (or similar) – as per comments relating to D.1.	Please consider whether the reviewer has valid points and if so consider whether editing is required.	According to GRADE, recommendations can still be made (and should be made) when the certainty in the evidence is low or very low. All recommendations went through a consensus process.
25	D.7	No areas of major debate were identified for the Lived Experience Statements or Good Practice Statements. These should be addressed in the guideline if there were any, and the various significant viewpoints outlined.	Please include comments on areas of major debate.	There were no areas of major debate for the lived experience statements or the good practice statements. The areas of major debate are included in Chapter 4 (p. 83-84) and pertain to the diagnostic criteria (i.e., GRADE-based recommendations).

26	D.8	The guideline includes limited discussion of the body of evidence reviewed to inform the GRADE-based recommendations, particularly strengths of the body of evidence. The developer should expand the discussion of the body of evidence.	Please consider adding information about the available body of evidence.	An additional chapter (Chapter 11) is now provided discussing the available body of evidence, including further details of the strengths and limitations of the available evidence.
27	D.15	AGREE II assessment of the guideline and recommendations by at least two independent reviewers was pending at the time of methodological review. This requirement must be addressed in the Administrative and Technical Report once completed.	Please add this information once completed.	Relevant information has been added to the Administrative and Technical Report (section 7; p. 36- 37).
28	E.1	The publisher, copyright information (including the copyright holder), and the ISBN number need to appear on the guideline title page. The address to contact to request permission to reproduce material in the text needs to be clear on the guideline title page. If one/both of the email addresses provided for the corresponding author can be used for this purpose, clarify this.	Please add this information once completed.	Discussed with NHMRC and ISBN is not required as online publication only. Information has been added regarding requesting permission to reproduce material (p. 2).
29	E.2	Navigation of the guideline is currently limited due to the absence of bookmarks, some hyperlinks and cross-references not working, and some incorrect page numbers in the table of contents. This should be addressed in the final document, including checking the functionality of all hyperlinks and cross-references. Bookmarks would greatly assist navigation.	Please consider adding hyperlinks to assist with document navigation.	All formatting and document navigation has been updated.
30	E.3	A plain English summary is currently not included in the guideline, and must be included to meet this mandatory requirement (currently pending).	Please add this information once completed.	Plain English summary document is now available.

31	E.5	Some acronyms/abbreviations are missing from Guideline Appendix A (e.g. EF, NDIS, CRPD, SD). The developer should ensure that all relevant technical terms, acronyms and abbreviations are included in Appendix A in the final document.	Please check all acronyms and abbreviations are defined in the appendix.	All added and defined in the Appendix.
32	E.6	Epilim is mentioned on p.104 of the guideline. The generic name should be used rather than the brand name.	Please use generic medicine name rather than brand name for this medication.	This has been updated.
33	E.7	The developer may wish to consider: • assigning unique numbers to each actionable statement to assist navigation and usability • using additional visual clues to differentiate between Strong and Conditional recommendations • ensuring that colours assigned to the actionable statement types are not used in other guideline images (except where intentional), to avoid confusion. These suggestions are for consideration (i.e. not mandatory) but may assist with identification of recommendations within the text.	Please consider these comments and make edits if appropriate.	Thank you for this suggestion. We have restructured the Summary of Actionable Statements section of the main document and re-organised these by statement type and assigned unique numbers to assist navigation and usability.
34	E.8	The date of access is not stated for electronic references. This needs to be added for all electronic references. Some references do not provide sufficient information for the reader to locate them (e.g. 'Astley S. (2004). Diagnostic guide for fetal alcohol spectrum disorders: The 4-digit diagnostic code.'). Sufficient information should be included to enable the reader to locate all references. Formatting of references is inconsistent in some instances (e.g. author names). Consistent formatting of references would improve clarity.	Please add date accessed to all electronic references, ensure full publication information is available and formatting is consistent.	Formatting of references has been updated and additional information added.

35	E.9	The Table of Contents (TOC) refers to 'Chapters' 1-10, however, this terminology is not reflected throughout the guideline. Adding 'Chapter […]' to the relevant section headings would assist navigation. Numbering the guideline headings and sub-headings would also assist navigation. In some chapters, the first heading in the chapter is the same as the chapter heading (e.g. Chapter 6 Assessment Process). It would assist navigation if the heading was not duplicated. Sub-headings are inconsistently displayed in the TOC. (e.g. Chapter 5 'Additional Information' is missing the first sub-heading 'Structure of the diagnostic criteria and "associated with" section'). The TOC should be updated for consistency.	Please review TOC and chapter headings and sub headings for consistency.	Formatting of TOC and headings has been updated.
36	E.11	Assuming the technical reports will remain as separate documents to the guideline, they must be provided in a readily accessible location, such as a website, which is indicated in the guideline (e.g. placeholder link in Guideline, p.2 – to be updated in final document).	Please update link.	All documents will be made available online following final approvals. Hyperlinks will be included throughout all documents. Placeholders for these links have been added to the main document.
37	E.12	Assuming the Administrative and Technical Report remains as a separate document to the guideline, it must be provided in a readily accessible location, such as a website, which is indicated in the guideline (e.g. placeholder link in Guideline, p.2 – to be updated in final document).	Please update link.	All documents will be made available online following final approvals. Hyperlinks will be included throughout all documents. Links will be updated throughout the main document once the documents are available online.
38	F.1, F.2, F.3, F.4	Public consultation remained open at the time of commencing the methodological review. Compliance with mandatory requirements F.1, F.2, F.3 and F.4 could not be assessed based on the information provided for review.	Please complete post public consultation changes to meet these requirements.	Information has been added to the Administrative and Technical Report regarding the public consultation period (section 6; p. 35 – 36).

		Desirable Requirements – changes are optional.		
39	A.2.1	The developer may wish to consider adding the amount and percentage of total funding received from each funding source to the **Administrative and Technical Report** (table p.2)	Please consider adding percentage of funding received to the funders section.	This information was included in the main document and has now been added to the Administrative and Technical Report (p. 2).
40	A.4.1	For clarity, the developer may wish to consider describing the Cultural Advisory Group membership in the **Administrative and Technical Report** similar to the summary provided in the Guideline (i.e. 'Aboriginal and Māori peoples working in community, clinical or research positions in the FASD/ND-PAE field or in relevant professional associations'). Participation in the guideline development process by representatives of other culturally and linguistically diverse communities is not explicitly addressed and should be included in the **Administrative and Technical Report** if relevant.	Please add information regarding the members of the Cultural Advisory Group for consistency across the advisory group reporting.	All members of the Advisory Group are listed together in the Advisory Group table, none of these groups have been separated.
41	D.2.1	Recommendations/actionable statements are mostly formulated using consistent grammar, syntax and wordings, however minor inconsistencies across the guideline were noted (see actions required for D.2).	Please note this comment.	Wording of the actionable statements has been reviewed and updated where necessary.
42	D.9.1	While a top-level summary of changes from the 2016 Australian Guide to the diagnosis of FASD is provided (p.19-20), in general this does not identify specific recommendations that deviate from current practice. The developer may wish to consider identifying recommendations/actionable statements in the updated guideline that deviate from current practice (if relevant).	Please consider this comment.	Overall, it is challenging for us to do this as currently practice varies greatly – as evidenced by some of the responses received from the public consultation. There is currently no explicit advice provided to practitioners regarding many of the actionable statements provided in these guidelines. Some additional information has been included in the Dissemination, Implementation and Evaluation

				Report (section 3.1), highlighting some of the new actionable statements, which for some practitioners will differ from current practice. Future research and evaluation is needed be able to monitor and assess this.
43	D.9.2	The developer may wish to consider addressing the resource implications and cost effectiveness of the proposed assessment process compared with the current assessment process. If included this information should appear in the guideline text.	Please consider this comment.	We have added information regarding this point in section 5.2 (p. 87) of the main document, although this is an empirical question that needs to be examined.
44	E.2.1	The developer may wish to consider adding an index to the guideline.	Please consider this comment.	An index has been added to the main document.
45	E.2.2	The developer has indicated that bookmarks will be included in the final PDF version of the guideline. This will significantly improve navigation.	Please add this information once completed.	This has been completed.
46	E.2.3	It is not clear if a web version of the guideline will be published in addition to the online PDF. If a web version is published, the developer may wish to consider including hyperlinks to facilitate navigation.	Please consider this comment.	Yes, a web version will also be available, and hyperlinks will be added once documents are available online.
47	E.4.1	The developer has indicated that the summary of actionable statements/ recommendations (p.13 – 17) will be made available as a separate document. To meet this desirable requirement the guideline will need to include text indicating where to obtain the separate summary document. The placeholder hyperlink for document access on p.2 of the guideline may address this.	Please add this information once completed.	Placeholder hyperlinks have been included in the document.
48	E.7.1	The developer may wish to consider ensuring that the design of the guideline is suitable for people with visual impairment. It is noted that colour is used throughout the guideline and colour contrast may be a consideration for accessibility.	Please consider this comment.	Microsoft Word Accessibility Toolbar suggestions have been implemented including adjusting colour contrast to improve readability and including Alt text for all visuals.

49	F.2.1	The developer may wish to consider making a version of the public consultation submissions summary publicly available, with submissions de-identified.	Please consider this comment.	All public consultation submissions have been included as an Appendix to the Administrative and Technical Report and a high level summary of these is also included in the body of the report (section 6; p. 35-36).
50	G.3	The developer may wish to consider including a practical implementation plan in the Dissemination, implementation and evaluation report.	Please consider this comment.	Additional information has been added the dissemination, implementation and evaluation report based on feedback from the public consultation. We are currently awaiting the outcome of a funding request and based on the outcome of this a more detailed practical implementation plan will be developed, aligned with available funding to support this.
51	G.5	The developer may wish to consider including accompanying consumer information in the guideline.	Please consider this comment.	A plain English Summary and Frequently Asked Questions documents have been developed. The GDG also has plans to develop a range of other accompanying consumer information, pending further funding to support this.
52	G.6	The developer may wish to consider providing versions of the plain English summary and consumer information in different languages.	Please consider this comment.	To be considered pending additional funding.
53	G.7	The developer may wish to consider including suggestions for local adaptation and adoption of the guideline. If included, this should be in the guideline document.	Please consider this comment.	Considered outside scope of current capacity of the GDG due to available project funding and time. Pending further funding, this could be considered in the future implementation project.
54	G.8	To meet this desirable requirement, information regarding the measures for determining the extent to which key guideline recommendations are implemented need to be addressed in the **guideline** document. Information regarding the Clinician Guideline Determinants Questionnaire and how it has been and will be used	Please add this information to the guideline document once completed.	As per the comment is included in the dissemination, implementation and evaluation report and due to concerns regarding document length we have decided not to repeat this

		to measure implementation is currently included in the Dissemination, implementation and evaluation report.		information in the main document. We have included a placeholder hyperlink to this document.
55	G.9	To meet this desirable requirement, information regarding the evaluation strategy to assess the extent to which guideline recommendations are adopted into routine practice would need to be addressed in the **guideline** document. The Dissemination, implementation and evaluation report currently describes monitoring and evaluation plans.	Please add this information to the guideline document once completed.	As per point 54.
Expert Review Comments				
		Reviewer One (UK)	**NHMRC Comment**	Developer Response
56		I commend the research team's efforts to systematically identify, synthesise, and appraise the complex information on the diagnostic components of FASD in the available literature, including recommendations of areas for further research.	Please note this comment, no action required.	
57		The use of a specific threshold for PAE within the FASD diagnostic criteria is also an area of debate (as noted in the consultation document). I note that the review team have considered published evidence to support the proposal of a threshold of (predominantly) 'heavy' – 'very heavy' PAE in formulating FASD diagnoses. The evidence remains mixed on the impact of low-moderate PAE with some studies suggesting that this low level of exposure can impact outcomes relevant to FASD diagnosis, including low birth weight, for example, while other studies show no effect of low-moderate PAE, and others show some benefit (e.g. on educational outcomes, likely due to residual confounding by socioeconomic status).	Please consider this suggestion Also see comments 57, 58, 59, 67, 68, 69, 75, 102, 103	Based on feedback received from the Advisory Groups and Public consultation, revisions have been undertaken to refine wording of Criterion A and the associated information to provide clinicians with a practical framework to support PAE risk assessment and evidence-based diagnostic decision making.
58		Furthermore, as described above, PAE is likely to be underreported, or undocumented for various reasons, and the impact of different levels of PAE are likely to vary at the individual due to a range of physical, social, environmental (e.g. co-occurring exposures) and genetic factors.[1] For this reason, I suggest that setting a threshold	Please consider this suggestion	As per comment above. Wording of Criterion A and additional information provided has been refined.

		for PAE when considering a diagnosis of FASD at the individual level is problematic, particularly if, for example sentinel facial features are present.	Also see comments 57, 58, 59, 67, 68, 69, 75, 102, 103	As stated in the document, we do not intend for the evidence review levels to be applied as clinical cut-offs for diagnosis. We have developed a new Figure and range of associated information to better describe this. Whilst PAE may be under-reported, there is some evidence also indicates that retrospective reporting can be more accurate than prospective reporting of PAE. We also provide a range of Good Practice Statements to support assessment of PAE in a sensitive and non-judgemental manner, which increases chances of accurate reporting of PAE. The diagnostic criteria allow for consideration of sentinel facial features in the absence of PAE (see Criterion A2).
59		Good Practice Statement: If there is information suggesting heavy or very heavy (or potentially a moderate) level of PAE, including before pregnancy recognition, discuss assessment options and after obtaining informed consent provide assessment or support access to further assessment (p. 14). Suggest quantifying the amount of alcohol that 'moderate, heavy/very heavy PAE' is supposed to refer to since this can have very different interpretations. E.g. a subsequent Good Practice Statement states: Explain what a standard drink of alcohol is (i.e., 10g of ethanol).	Please consider this suggestion Also see comments 57, 58, 59, 67, 68, 69, 75, 102, 103	This Good practice statement has been re-worded based on changes in the points above.

60		Good Practice Statement. Sometimes there may be inconsistencies about PAE in available information. In instances when information was collected directly from the pregnant woman/person during an assessment, this information should be prioritised over other sources. Practitioners can document any inconsistencies and indicate that re-assessment could be considered should additional information arise (p. 14). While I agree with the other points in this section around the importance of encouraging sensitive and respectful conversations around PAE, and of reducing blame and stigma, unfortunately evidence shows that self-report methods are likely to underestimate true PAE for reasons including social desirability bias, fear of persecution, and an inability to accurately recall and quantify drinking behaviour.[2-6] Therefore, giving precedence to pregnant women/people's reports of PAE, over other sources, could have the consequence of missing opportunities for follow up to help support them to reduce/stop alcohol intake during pregnancy, and to appropriately follow up children at risk of PAE. Furthermore, what would happen if a child/person presents with sentinel facial features of FASD (which have been shown to be highly specific to FASD to the extent that if these features are available confirmation of PAE is not required), but their mother has not reported PAE? **To overcome this issue, an alternative to this good practice statement could be something more along the lines of that suggested by the UK National Health and Care Excellence Quality Standard for FASD (in italics below):** *"Probable prenatal alcohol exposure: This can be based on information suggesting it is likely there has been alcohol exposure during pregnancy, such as: • reliable clinical observation • self-*	Please consider whether the reviewer has a valid point and if so consider whether rewording is required.	Criterion A of the diagnostic criteria already provides information about the different sources that can also be used in the assessment process. The Good Practice Statements are provided to support practitioners with implementation of the diagnostic criteria, including in situations where there is conflicting information. Giving precedence to other reporters over the pregnant individual where they have reported no alcohol use can also have adverse consequences that need to be considered, including in situations where individuals have the facial features.

		report or report by a reliable source • medical records documenting positive blood alcohol concentrations • treatment for alcohol-related problems. The presence of all 3 facial sentinel features (short palpebral fissures, smooth philtrum and thin upper lip) has high specificity for prenatal alcohol exposure and FASD which means that confirmation of alcohol exposure is not needed when all 3 are present. [Adapted from Scottish Intercollegiate Guidelines Network guideline on children and young people exposed prenatally to alcohol, recommendations 2.1.1 (page 11) and 3.1.1 (page 15)]" [7(p.17)]		
61		Yes – international guidelines vary in terms of the specific diagnostic criteria and thresholds used to diagnose FASD. This leads to significant variability in diagnostic outcomes according to which guideline is used (e.g. examples of comparisons of guidelines reported in the literature here: [8-11]) Guidelines also vary in diagnostic nomenclature (reflected in the current consultation document which did not reach consensus on FASD vs ND-PAE).	Please note this comment, no action required.	Additional information has been included in the Introduction section (p. 15-16) to provide more contextual information regarding the diagnostic terminology currently in use nationally and internationally.
62		A recent study (led by a member of the current Australian Guidance development team – Dr Reid) indicated that 90% of clinicians included in an international survey of diagnostic approaches and view on unification of diagnostic criteria for FASD were in favour of unified criteria.[12] Therefore, it is not clear that introduction of another guideline with varying thresholds/ terminology would be beneficial in this respect. That said, there is no current consensus on what diagnostic approach is 'best', and it is likely that considerations will need to be given to the characteristics of specific populations when formulating FASD diagnoses. Therefore, I appreciate that this is a challenging area and one that has not yet been reconciled.	Please note this comment, no action required.	As noted by the reviewer this is a challenging area given the current state of affairs in our field. We grappled with what the best approach would be given the current challenges and aimed to take an evidence-based approach to determining the approach to diagnosis in Australia. We hope that the evidence review of the diagnostic components undertaken in the current project will contribute to improving alignment and unification of diagnostic criteria in the future.
		Reviewer Two (Scotland)	**NHMRC Comment**	Developer Response

63		The creation of a steering group, guideline development group and four advisory groups is thorough and the use of a priority setting survey by the four advisory groups is to be commended. The inclusion, on an equal footing, of an advisory group comprising those with cultural experience and expertise in addition to a group with lived experience and expertise alongside those with clinical and research expertise is appropriate.	Please note this comment, no action required.	
64		Best practice has been adopted during systematic reviews of the evidence including the use of the GRADE approach to determining the certainty of compiled findings. The choice to conduct a separate review of every component of the diagnostic guidance is to be highly commended and will be a significant benefit to the international community working in this field.	Please note this comment, no action required.	
65		The guideline has reviewed all international guidelines of which I am aware.	No action required.	
66		The authors have, of necessity, made difficult decisions in order to make firm recommendations. While the authors have made every effort to be guided by the research evidence, they acknowledge that the absence or lack of evidence has made this task difficult. In the absence of sufficient evidence however, some decisions may open the door to potential risks.	No action required.	
67		The focus on 'heavy and very heavy PAE', while reflecting the limited research evidence, may increase the risk of under-diagnosis amongst those with a history of low or moderate PAE. The authors have endeavoured to offset this risk by highlighting that practitioners are encouraged to use their clinical judgement in such circumstances. Practitioners, particularly those who are less experienced, are however likely to be deterred by the emphasis on heavier PAE which is further reinforced by the flowchart on page 66 which makes no mention of low or moderate PAE.	Please consider this suggestion Also see comments 57, 58, 59, 67, 68, 69, 75, 102, 103	Revision of Criterion A wording and associated content has been undertaken to better communicate the assessment of PAE and support clinicians in applying the best available research evidence in practice at an individual level.

68		In Figure 6 the use of the term 'drinks' rather than units may be misleading (a self-poured drink may be many units). In the same figure, the alignment of greater impairment under heavier PAE may accurately reflect the dose response relationship that can be observed in PAE but may mislead the reader to consider, for example, that very heavy drinking can not lead to 'no impairment'.	Please consider this suggestion Also see comments 57, 58, 59, 67, 68, 69, 75, 102, 103	Wording in this figure has been updated to 'standard drinks' to clarify this point. This Figure (now Figure 9) has also been re-worded to better communicate associated risk levels, and we believe these changes will also address the point that heavy drinking may not lead to impairment.
69		Table 2 appears to assume a consistent weekly pattern throughout pregnancy removing the ability to record infrequent but very high PAE or differing patterns before and after pregnancy recognition.	Please consider this suggestion Also see comments 57, 58, 59, 67, 68, 69, 75, 102, 103	This table has been removed to reduce confusion and relevant information included in Figure 9 instead.
70		On page 53 the use of index scores in measures of intelligence appears to suggest that a single index score would be sufficient stating 'or one or more major subdomains. This is highlighted to ensure that it is intentional.	Please confirm that the reviewer's interpretation is correct.	Wording has been refined to better communicate this point (p. 68).
71		On page 60, the definition of Criterion C 'the neurodevelopmental impairments necessitate significant supports' appears difficult to operationalise being framed in terms of whether a person's difficulties can be ameliorated by the provision of support rather than the extent of difficulties requiring support.	Please consider and accept or rebut the reviewer's assumption.	Discussion was undertaken regarding this Criterion and it was decided to move away from traditional DSM wording of the impairments causing "clinically significant distress" to be more aligned with a social model of disability (i.e., disability is the result of the interaction between people living with impairments and the environment). The social model of disability is the internationally recognised e.g. part of the UNCPRD and ICF, which more broadly underpin these guidelines.

				Criterion C does not require a person's difficulties to be ameliorated. Criterion C requires that the impairments and functional impacts necessitate significant supports.
72		On page 105 arguments are provided against the use of percentiles to determine whether significant difficulties are experienced within a particular cognitive or functional domain. While all of the points are accurate, there is a concern that, without the clarity provided by defined percentile or score ranges, practitioners will be deterred from attempting assessments in the context of the additional complexity. The guidelines do make the excellent point elsewhere that confidence intervals should be considered to take into account measurement error and adopting this approach may in part offset this concern. Another approach may be to provide clear criteria for, or name, assessments that are sufficiently robust that, when used with a population for which normative data are available, could be interpreted with regard to their percentiles.	Please consider whether the reviewer has a valid point and if so consider whether rewording or additional text is required.	We have provided a percentile range to support interpretation of clinically significant impairments. We have restructured this section to make this information easier for readers to locate (section 4.3.3.2; p. 61-65).
73		On page 73 with regard to informed consent it would be helpful to **consider whether such consent should include the specific mention of FASD.** There is an argument to seek informed consent for a broad neurodevelopmental assessment so as to avoid any unnecessary anxiety or distress were FASD to be discussed initially but be determined not to be the correct diagnosis. This possibility could be raised at a later date if indicated and further consent sought.	Please consider whether the reviewer has a valid point and if so consider whether additional text is required.	There is Implementation Consideration, Tool and Tip included that specifically addresses this point (number 7; p. 93). There will be differences in approach to consent across different settings based on models of care, so we did not want to be too prescriptive about these processes, but we have provided information for practitioners to take into consideration in their clinical context.
74		On page 86 there is reference to a microarray 'may' be requested. **Given the potential harm that may result from the misattribution of a genetic disorder to harm resulting from PAE consideration should be given to incorporating this test into all assessments.** I	If you agree with this comment please consider including genetic testing for all assessments.	Wording has been revised to remove 'may' (Good Practice Statement 19).

		note there is a discussion of this on page 94 which highlights the importance of genetic testing.		
75		The Canadian and Scottish guidelines consider lower levels of PAE potentially relevant than the 'heavy or very heavy' PAE incorporated into these guidelines.	Please consider this suggestion Also see comments 57, 58, 59, 67, 68, 69, 75, 102, 103	These guidelines do allow consideration of moderate levels of PAE, however based on the available evidence practitioners need to be careful in assessing risk at this level as findings from the evidence review regarding associations between PAE and diagnostic outcomes at this PAE level are mixed. Wording has been revised throughout the main guidelines document where appropriate to better communicate this for practitioners.
		Reviewer Three (USA)	**NHMRC Comment**	Developer Response
		General comments		
76		The report was extremely comprehensive and transparent. I did not see anything missing. I also thought the scope was appropriate and very clear and questions very clinically relevant.	Please note this comment, no action required.	
77		The use of clear guidelines and frameworks helps lay out everything in a matter of fact way and illustrate how important considerations were weighed.	Please note this comment, no action required.	
		Comments on the Administrative and Technical Report		
78		Page 6, 1.3 Guidelines procedures, standards and reporting I really appreciate use of formal guidelines and table in appendix showing how these two sources align and implemented	Please note this comment, no action required.	

79		Page 8, Advisory Groups major strength of this approach!	Please note this comment, no action required.	
80		Page 19, Figure 3 some orienting text or more detailed figure title/caption would help guide reader in what is going on here. After looking at it for a few minutes I understood that the central blue circles are highest priority themes from survey, which each encompass a number of 2nd level themes (green) - a couple of which have additional 3rd level subthemes. But there is a lot going on and so something to orient to start in center and track outwards.	Please consider whether the reviewer has a valid point and if so consider whether additional text is required.	Additional information has been included as a footnote for this Figure.
81		Page 25, 3.3.1 Clinical questions these are great and comprehensive. I've also seen journal publications about some of these already, which is excellent that this work is also contributing to scientific literature base. So impressed with the rigorous process this revision has undertaken!!	Please note this comment, no action required.	
82		Page 25, 3.3.3 Selection of the evidence what an incredible amount of work!	Please note this comment, no action required.	
83		Page 123 high level of transparency and rigor throughout this process.	Please note this comment, no action required.	
84		Page 129, Summary of judgements I love this way of visualizing and summarizing this information	Please note this comment, no action required.	
		Comments on dissemination, implementation and evaluation report		

85		Page 4, 3.1 Framework of guideline implementability love this section!	Please note this comment, no action required.	
86		Page 6, 4.1 Monitoring and evaluation Is there an incentive / reminder system / workflow tool that will help facilitate this? I see description of REDCap database, which I anticipate will likely work well for FASD specialty diagnostic clinics, but I wonder if additional resources might help clinicians outside specialty FASD clinics. How comparable will this be with Canadian database? Might be some great opportunities to harmonize or compare some common elements in the future!	Please consider the reviewers comment and consider whether additional text is required.	Thank you for these questions/suggestions. There are currently no incentives, workflow tools or additional resources available to support implementation of the clinic database. This will be contingent on future funding to support implementation of the required monitoring and evaluation of the guidelines. We are definitely interested to explore opportunities for harmonisation and comparison of databases across different countries.
87		Page 6, 4.2 Clinician guideline determinants questionnaire I wonder if there are additional incentives or facilitators that could engage more providers not already engaged in FASD work to complete this survey.	Please consider the reviewers comment and consider whether additional text is required.	Unfortunately, we have no further funding available at this point in time to continue recruitment for this survey.
88		Page 11, Table 6 I am wondering if it might be useful to add a column how some of the planned implementability strategies might address some of these specific barriers identified?	Please consider whether the reviewer has a valid point and if so consider whether additional text is required.	Thank you for this suggestion. We have added an additional section and table that provides a summary of the strategies that have been employed to overcome the identified barriers practitioners reported in the survey.
		Reviewer Four (USA)	**NHMRC Comment**	Developer Response
89		The team charged with aggregating the data on evidence regarding the symptoms of prenatal alcohol exposure has done an excellent job of synthesizing and communicating the results and the limitations of their survey of the extant literature.	Please note this comment, no action required.	

90		The recommendations for clinical practice were weighed thoughtfully and input from key stakeholders was thoughtfully incorporated.	Please note this comment, no action required.	
91		There are various FASD-related diagnostic systems that are conflicting. Some are quite out of date and are not functionally being used anymore (i.e., CDC has a booklet on Guidelines for Referral and Diagnosis published in 2004). This schema differs from the 4 digit code, which has a large group who utilize this schema but many are not happy with it for various reasons. The Hoyme method, probably the second largest, uses criteria based on professional consensus and is conflict with this diagnostic formulation. The WHO has outline two potential diagnostic codes for ICD11 -LD2F.00-Fetal Alcohol Syndrome and 6AOY- Neurodevelopmental Syndrome due to Prenatal Alcohol Exposure so it may be useful to cross map to these codes for future monitoring.	Please note this comment on diagnostic tools, no action required.	Thank you for this suggestion. Additional information has been added following the diagnostic criteria section regarding the available codes in the ICD and DSM (section 5; p. 55).
92		The introduction tends to focus a bit too much on the Aboriginal population in Australia. I realize that there is a disproportionate amount of individuals with Aboriginal heritage that are being identified in Australia and the team is congratulated for their thoughtful integration of information from this community into the development of their recommendations. My concern is that it tends to lose focus on those who are not of Aboriginal heritage but who are most certainly impacted by heavy prenatal alcohol exposure. You want to present the information for all of your citizens impacted. **I think it is just a matter of tweaking the focus of the presentation of information, particularly at the beginning**, so that people understand the criteria apply to all subpopulations within Australia.	Please consider emphasizing all populations affected by FASD in Australia.	We have intentionally embedded Indigenous perspectives throughout the Guidelines, including the beginning to support best practice in Australia – for all Australians. This precedent acknowledges the negative legacies of colonialism while elevating the deep wisdom of Aboriginal peoples for our collective hope and healing. As with all precedents, we appreciate there is caution yet diligence about embedding Indigenous perspectives throughout a guideline that focuses on FASD. However, privileging and prioritising Aboriginal voices does not result in an exclusion of non-Aboriginal, in fact a plethora of research highlights the opposite is indeed true. Aboriginal worldview is inherently strengths-based, healing-informed and culture-centred, which offers immeasurable benefits to Indigenous and non-Indigenous knowledges and practices. You will note

				that much of the advice and understanding cultivated by the Aboriginal information provided in the guideline can be applied to non-Aboriginal peoples and make assessment and diagnosis of FASD more accessible to all cultures living in Australia. By decolonising practices and making services and supports more accessible to Aboriginal peoples, the most marginalised communities in this country, we make the services equitable for all Australians. We embed Aboriginal wisdom in in these guidelines not because PAE or FASD are "Aboriginal issues" (narratives and beliefs borne of colonialism and racism) but rather because this ancient wisdom benefits all those impacted in Australia. We are proud to lead the way in creating an unprecedented, decolonised Guideline.
93		FASD or ND with PAE is different. Historically ND-PAE has been seen as within the FASD spectrum-not as its super-ordinate category.	Please review the definition as this comment was made by many reviewers.	Thank you for highlighting this point. Wording around the diagnostic terminology has been revised.
94		Medical Assessment -page 86 and Holistic information-page 89 I think the information included is sufficient for diagnosis but **recent evidence on the adverse health consequences suggest closer monitoring of cardiovascular health symptoms and diabetes is necessary.**	If you agree with this comment, please consider adding cardiovascular and diabetes monitoring.	Wording of one of the good practice statements in the medical assessment section has been revised to capture this point. This reads: "Medical professionals should complete and request additional tests as clinically indicated to identify and monitor current physical health concerns (e.g., cardiovascular-kidney-metabolic health) exclude other potential impacts on functioning, such as thyroid tests, vitamin B12, iron studies and imaging."

95		Some colors for graphics and text can reduce the readability of the documents-there are screening software (accessibility software) within word that can be used to improve this.	Please consider changing the colours to meet accessibility standards.	Microsoft Word Accessibility Toolbar suggestions have been implemented including adjusting colour contrast to improve readability and including Alt text for all visuals.
		Reviewer Five (USA)	**NHMRC Comment**	Developer Response
96		As a diagnostician with 25 years of experience in the assessment of children with prenatal alcohol exposure, the language of FASD/ND-PAE is especially confusing. If, as is stated on **page 22, "a key consideration in the development of the current guidelines was… that there is no unified diagnostic criteria for FASD/ND-PAE"** then, appreciating the challenges of naming, settling on two names is not clearer. There is no citation of NDPAE during this discussion and as such, I think there is conflict in the use of ND-PAE as this is identified in the DSM-5. Alternatively, if the term is being used more generally how would a diagnostician distinguish between ND-PAE and NB-PAE (Astley)?	If you agree with this comment, please consider modifying diagnosis language for consistency.	Additional information has been included in the Introduction section (Chapter 1; p.) and the Assessment Principles and Diagnostic criteria section (Chapter 4; p. 55) to clarify this point. To simplify the document terminology of FASD is used throughout. Aligned with DSM-5-TR alternative terminology of neurodevelopmental disorder associated with prenatal alcohol exposure is included at the start of the diagnostic criteria section. This terminology of neurodevelopmental disorder associated with prenatal alcohol exposure is already in use in some clinics in Australia.
97		Clinically speaking, the inclusion of birth length and post-natal weight is weak but relevant – reflected in the lower GRADE based recommendation of Very Low to Low Certainty	Please note this comment, no action required.	
98		P.62 use of 10th percentile does not make sense as definitions outside normative growth mean </= ~3rd percentile ie. -2 standard deviations. This makes thresholds potentially inconsistently defined eg. **do the authors mean to also include 10th percentile scores for cognition which would be low normative? What is the evidence for that**?	If you agree with this comment please review the 10th percentile scores for cognition.	Consideration for physical size at the 10th percentile is based on the best available evidence regarding the associations between PAE and physical size. We are not proposing to include use of the 10th percentile for neurodevelopmental assessment as there was not evidence available to indicate this. Although we are proposing a percentile range to support interpretation of standardised assessments of neurodevelopment. As there is currently no

				evidence for a clinical cut off of the 3rd percentile for diagnosis of FASD. This is discussed in detail (section 4.3.3.2; p. 61-65).
99		Recommendations regarding dysmorphology reflect current knowledge and are appropriate	Please note this comment, no action required.	
100		While I understand the clinical challenges of recommendation to not include structural brain conditions, it is no more or less challenging that postnatal growth or dysmorphology considered individually. For that **reason *I would NOT agree with this recommendation and would recommend inclusion with at least LOW certainty***. However I would AGREE with the recommendations against including neurological conditions of hearing and vision impairments, seizures, and cerebral palsy in the diagnostic criteria for FASD/ND/PAE (Strong Recommendation, Very Low Certainty).	If you agree with this comment please review the certainty rating.	Based on the findings of the evidence review, there is not currently evidence available to support the inclusion of brain abnormalities available through clinical imaging. As evidence and technology evolves in the future, so can the recommendations and diagnostic criteria. Brain abnormalities and neurological symptoms are included as 'associated features' (p. 54, 79-80) provide information regarding this.
101		Language disorder – p.51 should be FASD with Language Disorder, not Language Disorder associated with FASD	If you agree with this comment, please change to FASD with language disorder.	We respectfully disagree with this comment This does not fit with the CATALISE (PHASE 2) framework in how language disorders are assessed and diagnosed. The suggestion conflates two separate ideas, 1) how should language be measured and meet criteria for the domain of language in the FASD guidelines, 2) how should language disorders be diagnosed and reported upon.

				I think the reviewer may be thinking the diagnosis would only appear once in this format, however most places would probably present it as.... e.g. "Meets X number of domains (memory, attention, language etc.)....meets FASD criteria.... Additionally meets criteria for a language disorder.....in the context of x y and z....prognostic indicators....best described as Language Disorder associated with FASD."
102		I would re-iterate concerns that having two named diagnoses could be especially confusing in a legal setting for youth and adults where a system could require one representing the individual to "decide" between the two names or determine which is "more severe". Furthermore, relating these terms to past terminology could be further confusing.	Please consider this suggestion Also see comments 57, 58, 59, 67, 68, 69, 75, 102, 103	As per above wording regarding diagnostic terminology has been revised. Terminology is interchangeable and does not indicate a more 'severe' presentation.
103		As noted above, I have concern about confusion between American DSM-5 language of ND-PAE and FASD ie. are they the same? Is ND-PAE "less than" FASD in some way – the way that "Partial FAS" used to be seen as a "lesser" form of FAS. This is overall a valuable re-thinking of diagnostic guidelines. I would not like to see the potential confusion arising from comments above hinder the refining of the guidelines. These guidelines offer new thinking in approaching FASD assessment and diagnosis and with tightening up would demonstrate leading practices.	Please consider this suggestion Also see comments 57, 58, 59, 67, 68, 69, 7langu5, 102, 103	Thank you for this feedback. Wording regarding the diagnostic terminology has been revised and as per comments above additional information included in relevant sections of the document discussing this point.
		Reviewer Six (USA)	**NHMRC Comment**	Developer Response

104		Yes, it is very evident that the committee utilized an extremely thorough process in developing the guidelines - including reviews of the literature, meta-analyses, extensive consensus processes, and consultation with various stakeholders including representatives from Australia's native groups. I found the meta-analyses and detailed reviews of the evidence in the literature to be very comprehensive and highly relevant to the development / refinement of the guidelines.	Please note this comment, no action required.	Thank you for taking the time to review our draft guidelines it is much appreciated.
105		It appears that there has been extensive effort paid to inclusivity in the process of developing / refining the guidelines. Potential risks and harms have definitely been considered and many caveats / contextual considerations have been described and are discussed in the documents. I am not aware of any medico-legal implications that would result from the revised guidelines that would be any different from the already existing common medico-legal issues.	Please note this comment, no action required.	
106		As you know, there are many existing guidelines / systems that cover the diagnosis of FASDs / ND/PAE and there are differences among these systems including the categories of assessment, criteria, thresholds / cutoffs for criteria, etc. In reviewing the revised Australian guidelines, it is apparent that the committee has considered each of the other existing diagnostic systems / guidelines. There is ample reference to these and to the associated literature around diagnosis. The rationale for each of the committee's decisions is explicitly described and it is very easy for the reader to see the committee's process and follow the train of logic that resulted in the decisions made.	Please note this comment, no action required.	