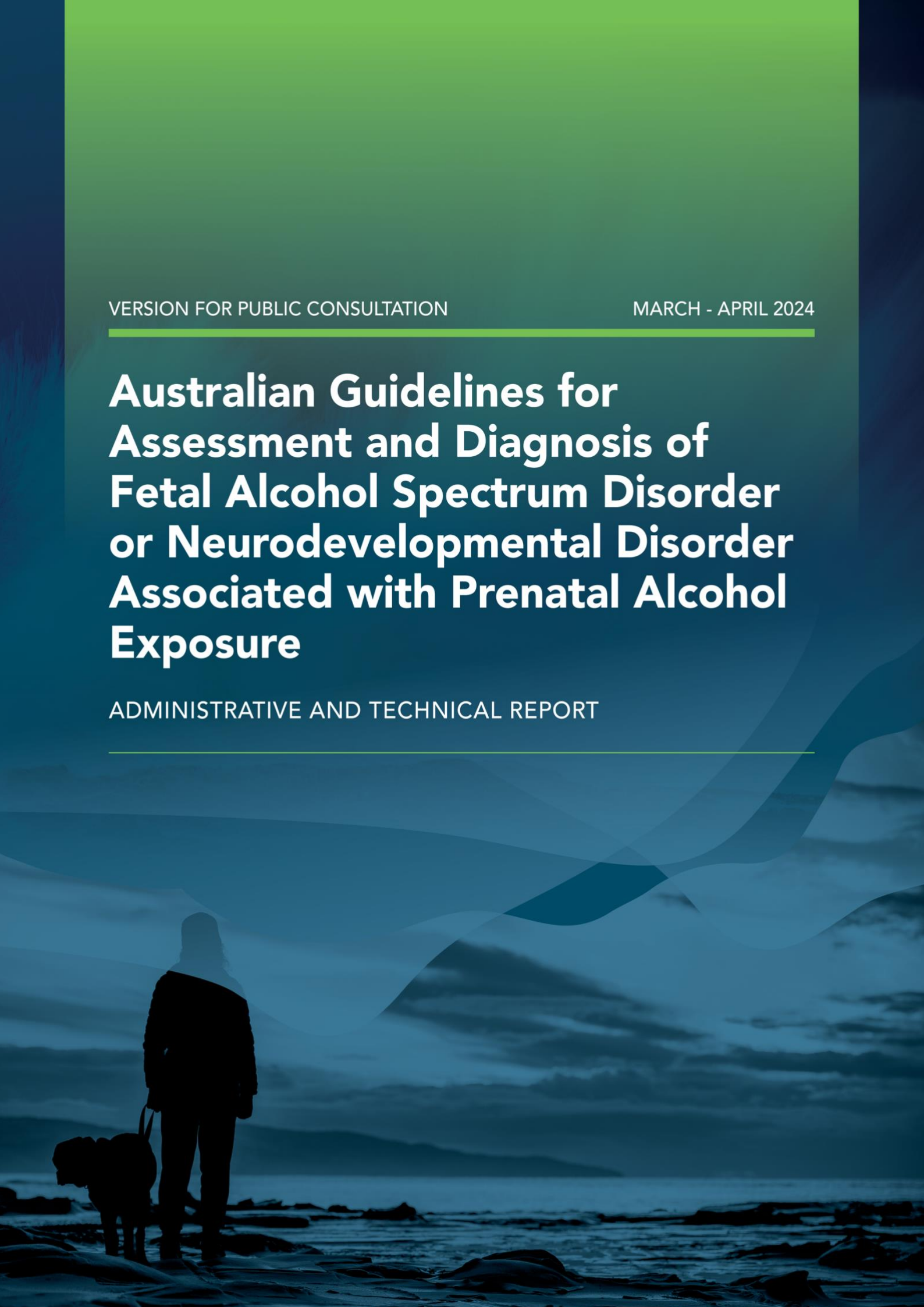
VERSION FOR PUBLIC CONSULTATION MARCH - APRIL 2024

Australian Guidelines for Assessment and Diagnosis of Fetal Alcohol Spectrum Disorder or Neurodevelopmental Disorder Associated with Prenatal Alcohol Exposure

ADMINISTRATIVE AND TECHNICAL REPORT



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Documentation access:	These guidelines and related documents can be found online at: website link TBA.

Contents

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
ND-PAE	Neurobehavioral disorder associated with prenatal alcohol exposure
NHMRC	National Health and Medical Research Council
OFC	Orbitofrontal cortex
PAE	Pre-natal 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

Consistent with the importance for improved assessment and diagnosis of fetal alcohol spectrum disorder (FASD) or neurodevelopmental disorder associated with prenatal alcohol exposure (ND-PAE), in 2016 the Australian Government funded the development and distribution of The Australian Guide to the Diagnosis of FASD in 2016 (Bower & Elliott, 2016). The Guide aimed to offer clinicians a standardised means of diagnosis, as well as tools to support or refer individuals and their families. The Guide was an adaptation of the Canadian National Guidelines (Cook et al., 2016) with updates centred on a literature review, consultation of stakeholders, and inclusion of elements from the University of Washington's 4-Digit Diagnostic Code (Astley, 2004). Significant improvements in the uptake and consistency of diagnostic practices in Australia have been made since the Guide was first released (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. This was to ensure that the Guide continues to reflect best international practice, reflective of 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/ND-PAE.

Objective: Bring together the best available evidence, lived experience voices, cultural and clinical wisdom to develop Australian clinical practice guidelines for the assessment and diagnosis of FASD/ND-PAE.

1.3 Guidelines procedures, standards, and reporting

The AGREE-II (Brouwers et al., 2010) is an international tool to assess the quality and reporting of clinical practice guidelines. There are also specific procedures and requirements according to the Australian Government National Health and Medical Council (NHMRC) Procedures and requirements for meeting the standard for clinical practice guidelines (NHMRC, 2020), which mostly align with the AGREE-II tool, but there are some slight differences. See Appendix A for an overview of the AGREE-II and NHMRC standards applied to the current project.

2. Guidelines Governance Structure

Genuinely including and collaborating with stakeholders has been critical to the development process of these guidelines. Extensive time was committed to the process of stakeholder inclusion to incorporate a wide range of views in a meaningful way that will strengthen the guidelines. This is supported by research that demonstrates that stakeholder involvement leads to increased uptake and implementation of clinical practice guidelines (NHMRC, 2018). Stakeholders are considered to be any person 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 included representatives from each of the organisations who were members of the consortium for the Commonwealth Department of Health funding for the review of the guidelines. The role of the Steering Committee was to provide strategic direction to support the success of the project and ensure project completion aligned with the funding objectives. See Table 1 for an overview of the primary and proxy representatives of the Project Steering Committee.

Table 1. Membership of the Guidelines Steering Committee

Organisation	Primary representative	Proxy representative
The University of Queensland	Dr Natasha Reid	Professor Karen Moritz
University of Sydney	Professor Elizabeth Elliott	Dr Melissa Cheung
Telethon Kids Institute	Dr Amy Finlay-Jones	Dr Rochelle Watkins
La Trobe University	Dr Kerryn Bagley	Dr Jo Spong
Griffith University	Professor Dianne Shanley	Dr Erinn Hawkins
Gold Coast Hospital and Health Service – Child Development Service	Dr Haydn Till	Dr Francoise Butel
NOFASD	Ms Sophie Harrington	Ms Nicole Hewlett
Patches Paediatrics	Ms Rowena Friend	Ms Serena Cribb
Monash – VicFAS	Dr Alison Crichton	Dr Katrina Harris
West Moreton Health	Mr Andy Webster	Mr Alan White
FASD CARE	Dr Raewyn Mutch	Dr Robyn Williams

2.2 Advisory Groups

Four types of Advisory Groups were established: (1) clinicians; (2) researchers; (3) cultural; and (4) lived experience. The purpose of these groups was to enable broad consultation with key stakeholders regarding the revision, updating and dissemination of the guidelines. Depending on the topic for presentation or discussion, meetings were held as separate groups or in one session. Separate group meetings were utilised to allow all members to have a safe space to discuss their specific values, needs and preferences, which enabled comprehensive input and feedback across all the different types of key stakeholders. For the combined group meetings, sessions were recorded, and slides and recordings disseminated following the meetings and 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 form were developed in consultation with the Steering Committee (Appendix B). Steering Committee members were requested to circulate copies of the terms of reference and expression of interest form to all key stakeholders in their networks whom they believed would have the relevant expertise to be involved. The terms of reference and expression of interest form (Appendix B) were also emailed to all the relevant professional associations who were offered the opportunity to nominate members of their organisations or circulate the EOI form to their members so they could self-nominate.

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 Ross-Clunies	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 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	NAACHO	NAACHO	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	Royal Australasian College of Physicians	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	-	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 purpose of the Guidelines Development Group was 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 the guidelines documents.

2.3.1 Membership Selection Process

Terms of reference and an expression of interest form was developed in consultation with the Steering Committee (Appendix C). Steering Committee and Advisory Group members were offered the opportunity to self-nominate and were requested to circulate copies of the terms of reference and expression of interest form (Appendix C) to all key stakeholders in their networks whom they believed would have the relevant expertise to be involved.

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 sought from the Steering Committee members and discussed at the Steering Committee meetings. Professor Phillipa Middleton was recruited to act as an independent Chair of the Guidelines Development Group.

The Steering Committee sought advice and recommendations from a range of different sources, including the Australian Government National Health and Medical Research Council team. All potential experts were discussed, and Professor Zachary Munn was selected as the preferred candidate to act as the methodologist for this guideline.

2.3.3 Membership

Table 3 provides an overview of 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 Guidelines Development Group members reviewed the policy and completed the declarations of interest form. All members were provided with multiple opportunities to ask questions and discuss any potential interests that they were unsure about declaring, both in meetings and individually as required. Appendix E provides a summary of all members' declarations of interest.

3. Guidelines review and development components

There were three key components that informed the guidelines review and development process summarised in Figure 2. An overview of each of these components is provided here, and further expanded on in the relevant Appendices and associated reports for each of the systematic and scoping reviews.

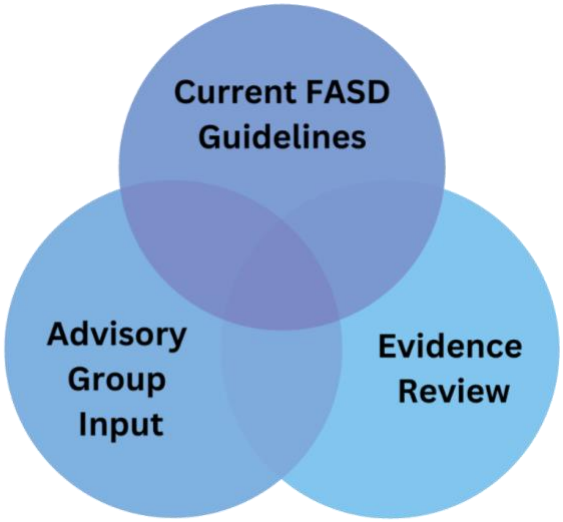

Figure 2. Key components of the review and development process

3.1 Current FASD Guidelines

A review of all published international FASD guidelines was undertaken. Tables 4 provides an overview of the current FASD guidelines that were reviewed, and Table 5 provides the diagnostic outcomes provided in each of these. Appendix F provides an overview of the content, reasoning and evidence cited to support the decisions made in these guidelines. Further detailed data extraction of the evidence that has been cited across the relevant guidelines documents was also undertaken and has been used as required in the evidence review process, but for the purpose of brevity is not presented here.

3.2 Advisory Group Input

A number of different strategies were undertaken to collect input and feedback from Advisory Group members. This has included Advisory Group meetings, a priority setting survey (Figure 3; Table 6; Appendix G; Hayes et al., 2022), evidence to decision framework survey for the diagnostic criteria (Appendix H), and the opportunity to individual feedback on the final draft documents. A summary of the feedback received on the final draft documents and how this was considered is provided in Appendix I. High quality and comprehensive input and feedback was received through each of these mechanisms.

Table 4. 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 5. 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.

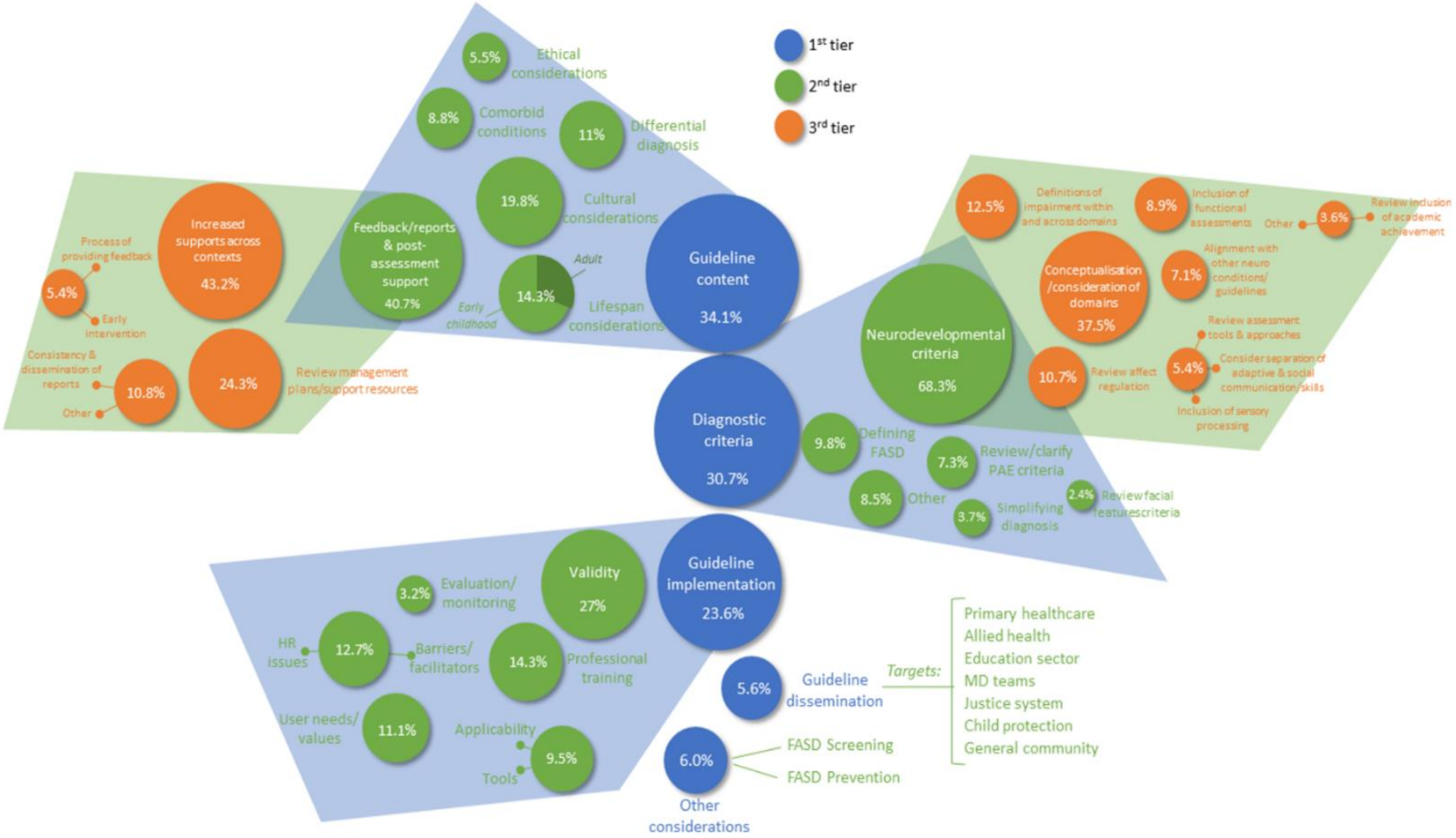

Figure 3. Overview of Advisory Group priority setting survey results

Table 6. 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/ND-PAE 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/ND-PAE 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/ND-PAE 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

3.3.4a 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 of each

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

If the study was found not to have assessed and controlled for confounding, then it was rated as having a critical risk of bias and was excluded from the meta-analysis. If a study had a major methodological flaw or multiple minor flaws, the overall risk of bias was scored as serious. If there were minor methodological flaws the overall risk of bias in the study as moderate. If the study did not contain methodological flaws, then the overall risk of bias as was rated as low. Risk of bias was assessed independently by two reviewers and checked and summarised by a third reviewer. See the Technical Report for the systematic review of diagnostic criteria components and associated Supplemental Files for all results.

3.3.4b 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.

3.3.5 Assessment of the available evidence

3.3.5a 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 make an assessment of the certainty of evidence. Assessment was based on a number of factors including methodological limitations (risk of bias), imprecision, inconsistency, indirectness) and publication bias. With consideration of these factors, overall certainty in evidence was categorised as high, moderate, low, or very low. A prognostic factors approach (Foroutan et al., 2020) was taken, whereby bodies of evidence started as high and were rated down based on the domain assessments. Completion of assessments as well as generation of overall GRADE ratings were completed using GRADEpro (McMaster University & Evidence Prime, 2022). See the Technical Report for the systematic review of diagnostic criteria components and associated Supplemental Files for all results.

3.3.5b GRADE – CERQual (Confidence in the Evidence from Reviews of Qualitative Research) for qualitative studies

GRADE CERQual was used to assess confidence in qualitative evidence (Lewin et al., 2018; Noyes et al., 2018). Similarly, 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 (degree to which there are concerns about study conduct or design), coherence (how clear and convincing or well supported the fit is between data from the primary studies and review syntheses) adequacy of data (overall determination of the extent of richness and quantity of data illustrating a finding), relevance (extent to which the primary studies support a review finding is appropriate to the setting detailed in the review question).

Concerns regarding each of the above components were rated as either no/very minor, minor, moderate, or serious. With consideration of these factors, overall confidence in evidence was categorised as high, moderate, low, or very low. See the Technical Report of the systematic review of lived experiences of the assessment process for the full results.

3.3.6 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 is an example results summary figure for the systematic review of the components of the diagnostic criteria. Figure 6 is an overview of the theme areas of the systematic review of the lived experiences of the assessment process (Hayes et al., 2023). Figure 7 is a summary of the content analysis results of the scoping review of the broader factors that could be considered as part of a holistic assessment when considering FASD/ND-PAE (Reid et al., 2023). Figure 8 is 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).

3.3.6 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 in a transparent manner and support development of GRADE-based recommendations evidence to decision frameworks (EtDFs) were generated for each of the components of the diagnostic criteria. To suit the specific purpose of these guidelines, an adapted EtDF structure was developed. Summarised versions of the EtDFs are provided in Appendix J. The process of populating the EtDFs involved (1) the research team inputting the review findings and draft content of the EtDF domains; (2) review and discussion of the draft EtDFs by the Guidelines Development Group; (3) discussion and agreement on EtDF domain ratings; and (4) discussion and agreement on resulting recommendations. Notably, given the number and variability of outcomes assessed in each of the components of the diagnostic criteria, the decision was made to provide a certainty range for each of the EtDFs to provide 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) identified the importance of undertaking 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 the framework have been incorporated throughout the main Guidelines document and in an additional more detailed Framework document. Figure 9 provides a visual overview of the Framework. See the associated Framework document and publication (Hewlett et al., 2023) for further details regarding the development and practical application of the framework. There is also a letter from the Cultural Advisory Group included at the start of the Main Guidelines document that provides critical contextual information and considerations for clinicians.

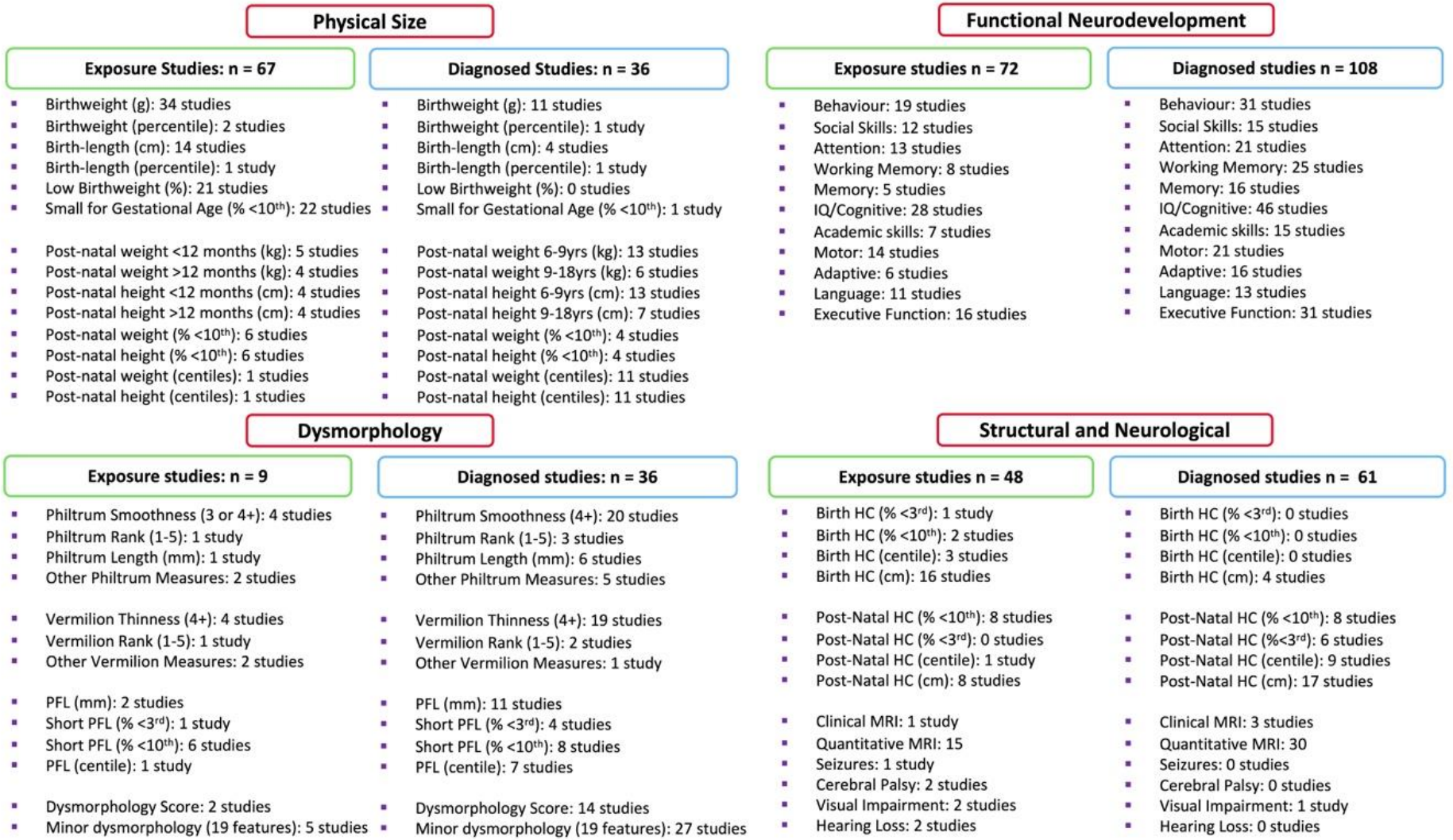

Figure 4. Overview of outcomes included in the systematic review examining the components of the diagnostic criteria. *Note.* g = grams, cm = centimetres, mm = millimetres, PFL = palpebral fissure length, IQ = intelligence quotient, HC = head circumference, MRI = magnetic resonance imaging.

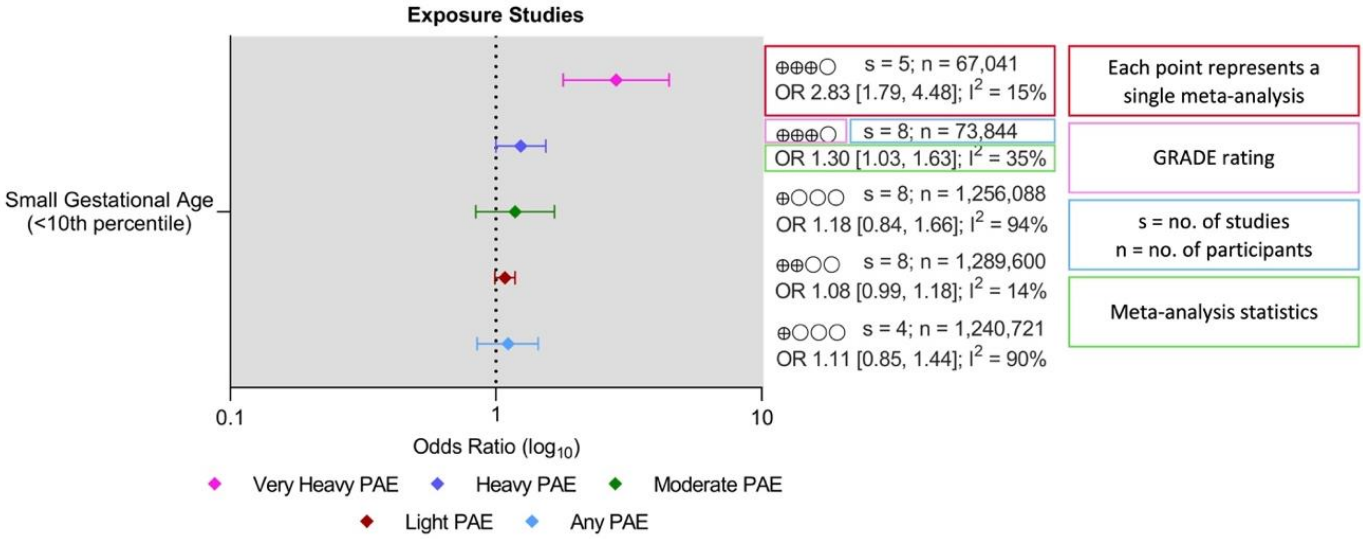

Figure 5. Example and explanation of a results summary Figure for the systematic review examining the components of the diagnostic criteria. *Note.* PAE = prenatal alcohol exposure; Light PAE = 1-20 g of alcohol per week or up to 2 standard drinks per week; Moderate PAE = 21-100 g per week or up to 10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

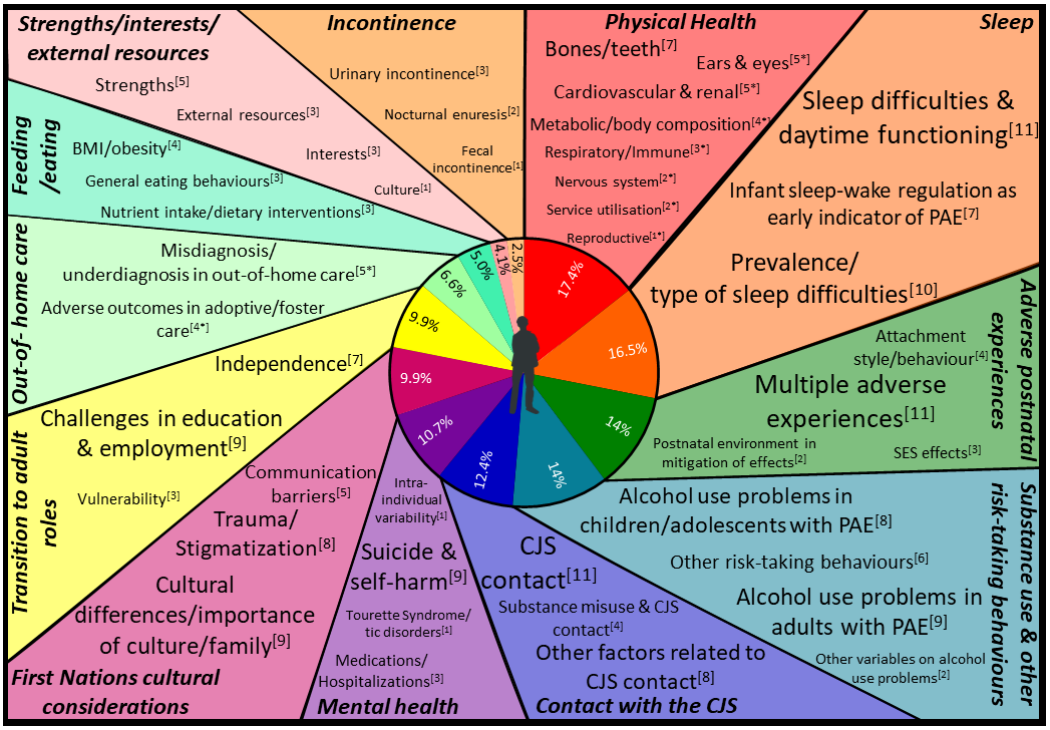

Figure 7. Results of the content analysis for the scoping review of broader factors that could be considered as part of a holistic assessment (Reid et al., 2023). *Note.* The size of the font and number in superscript brackets depict the number of studies that addressed each sub-area. *=sub-areas that 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%.

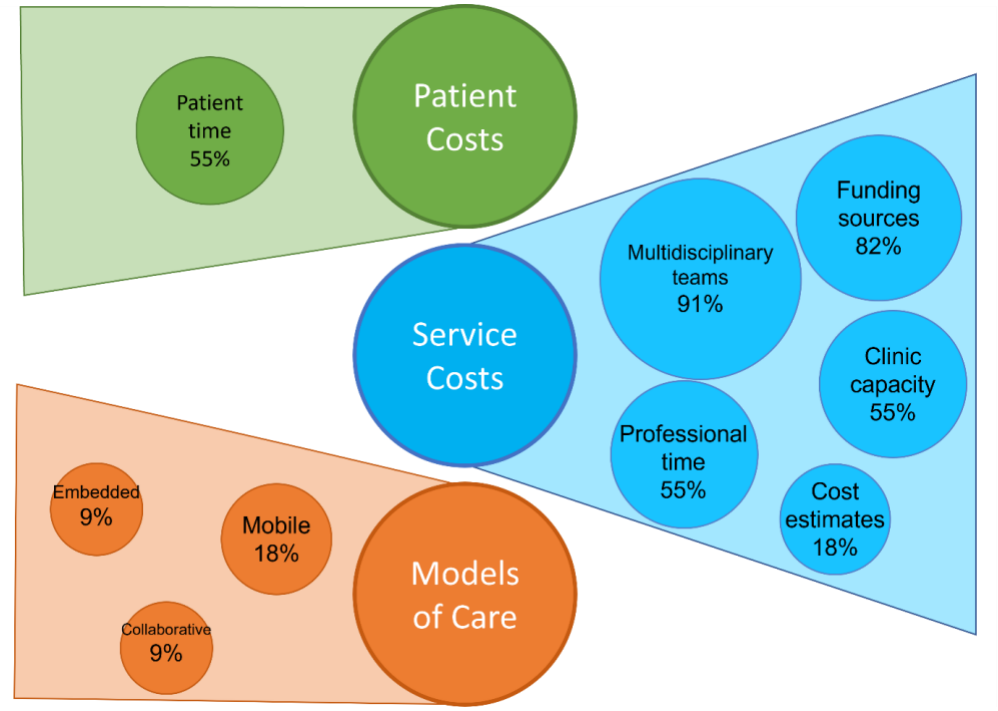

Figure 8. Results of the content analysis for the scoping review of the costs, other resource implications and models of care (Kent et al., 2023). *Note.* The size of the bubble represents the percentage of papers that addressed each sub-topic relative to the total number of papers included in the scoping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

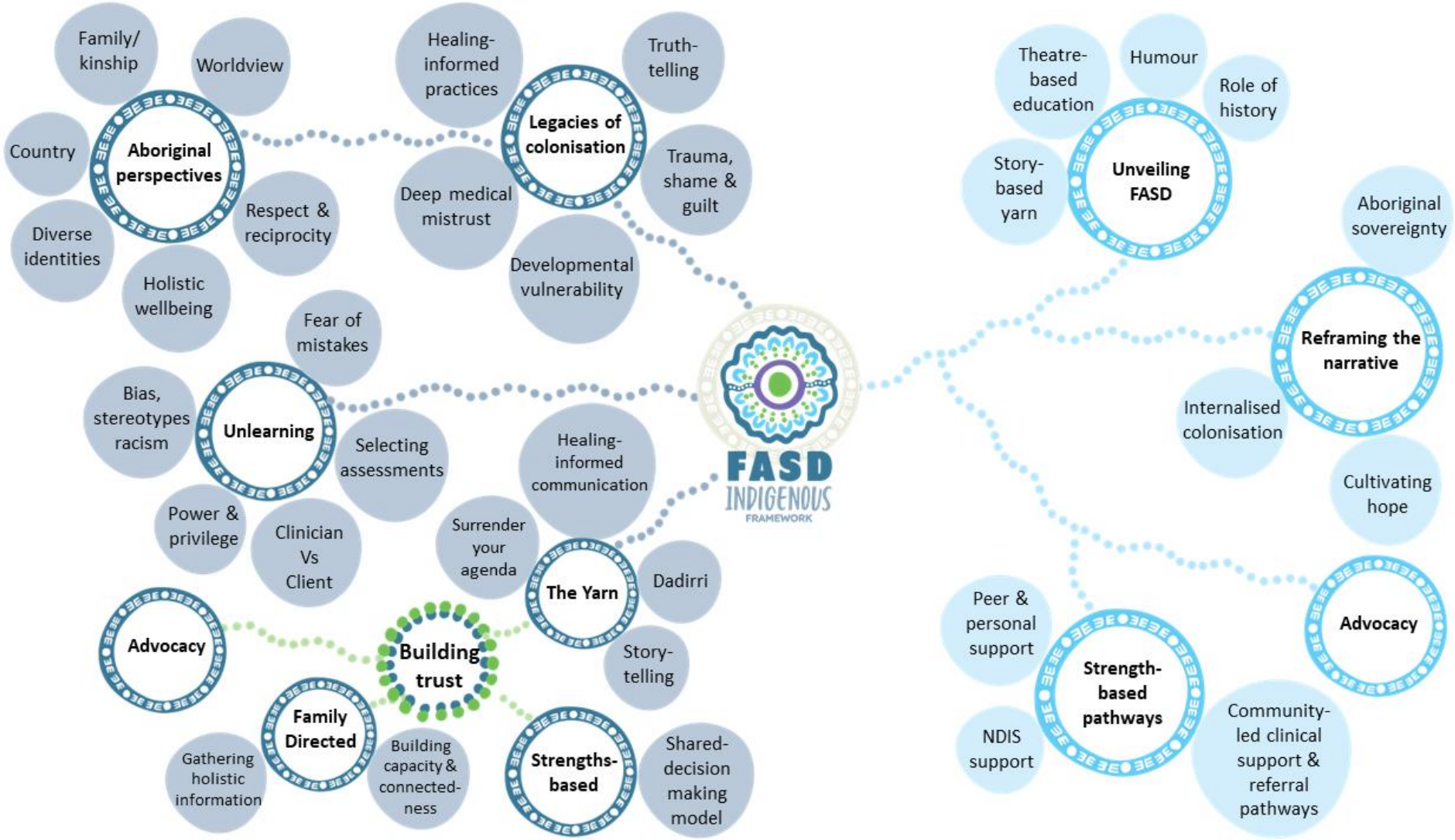

Figure 9. Overview of the Indigenous FASD Framework (Hewlett et al., 2023).

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 1 provides an overview of the different types of actionable statements. The type of statement is identified and colour-coded in the Main Guidelines document, this colour coding aligns with the artwork from the Indigenous Framework.

Briefly, regarding the development process of each type of statement. *GRADE-based recommendations* resulted from the systematic review of the diagnostic criteria components and were developed using EtDFs, which were reviewed, discussed, and amended with the Guidelines Development Group. An overarching evidence to decision framework of the diagnostic criteria as a whole was also created to examine the potential implications of the criteria. This was developed based on a survey completed by Advisory Group members (Appendix J).

Lived experience statements were based on the results of the systematic review of lived experiences of the assessment process (Hayes et al., 2023). Wording of the statements were reviewed and edited by the Guidelines Development Group. Results of the systematic review were also presented and discussed with the Lived Experience Advisory Group, to ensure that the results were consistent with experiences of individuals and families in the Australian context.

Good practice statements were firstly developed from the content of the current Guide for Diagnosis of FASD, as if there were current clinical practices that should be maintained, the Guidelines Development Group did not want to be suggesting unnecessary changes to practice. Subsequently, 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 used to improve 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.

Implementation considerations, tools and tips were developed from the priority setting survey, Advisory Groups and Guidelines Development Group meetings and the Indigenous Framework. There were a wide range of additional implementation tools suggested by Advisory Groups, which the Guidelines Development Group would have liked to be able to develop, but this will require access to additional funding to support the development of these resources.

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

Table 1. 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.

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7. Appendices

Appendix A: AGREE-II and NHMRC 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.	Advocating for shared decision-making process throughout & inclusion of Lived Experience Statements.
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 for interventions but highlighted in context of these guidelines

AGREE-II criteria	Mapping NHMRC requirements	Location
	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 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.	To be completed
	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.	To be completed
	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.	To be completed
	F.2.1 A version of the public consultation submissions summary is publicly available, with submissions de-identified.	To be completed

AGREE-II criteria	Mapping NHMRC requirements	Location
	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.	To be completed
	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 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.
	E.4 The guideline includes an executive summary that lists all the recommendations and their grade using an NHMRC-approved method.	Summary of statements

AGREE-II criteria	Mapping NHMRC requirements	Location
IDENTIFIABLE KEY RECOMMENDATIONS Present the key recommendations so that they are easy to identify.		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. **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.	All complete in main document.
	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.

AGREE-II criteria	Mapping NHMRC requirements	Location
	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.
	E.3 The guideline includes a brief (e.g., 1 page) plain English summary.	To be completed
	G.2 Key recommendations that are most likely to lead to improvements in health outcomes are highlighted for consideration in implementation.	To be completed
	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.	To be completed
	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.

AGREE-II criteria	Mapping NHMRC requirements	Location
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.
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:

1. Provide input regarding the guideline scope and areas to consider for each clinical question to be addressed in the guideline
2. Provide feedback regarding the feasibility and acceptability of the recommendations
3. Provide input and feedback on the content of the draft guideline and supporting documentation
4. 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:

1. Clinician Advisory Group
    a. Members will include: paediatricians, psychologists, occupational therapists, physiotherapists, speech pathologists, and social workers. This will include invitations to all relevant health professional associations.
2. Research Advisory Group
    a. Members will include: national and international researchers.
3. Cultural Advisory Group
    a. Members will include representatives from a variety of cultural groups and representatives from relevant associations.
4. Consumer Advisory Group
    a. Members will include: carers of individuals with FASD, young people and/or adults with FASD and consumer group representatives.
5. Other Key Stakeholder Group
    a. 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:

1. Refining the guideline scope and identifying the key clinical questions to be addressed in the guideline
2. Reviewing the research evidence using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) methodology
3. Reviewing input and feedback gathered from the key stakeholder advisory groups
4. Developing appropriate evidence-based and consensus-based recommendations
5. Reviewing the acceptability, feasibility, potential risks and benefits of recommendations
6. Developing the content and reviewing a draft of the guideline (including additional resources)
7. Developing and reviewing a draft of the implementation plan
8. Considering and deliberating on public consultation submissions
9. Finalising the draft guideline and implementation plan for NHMRC approval
10. 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:

1. Content experts that have clinical experience in the assessment, treatment and management of FASD in children, adolescents and/or adults;
2. Content experts that have knowledge and expertise in pre-clinical and/or clinical research on prenatal alcohol exposure and/or FASD;
3. Consumers representatives of individuals with FASD and their carers;
4. Cultural representatives
5. 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 –	Changed wording to 'language impairments'

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).	
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 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.)	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 your 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	Wording has been updated to "individuals attending for assessment." Please note we have tried to avoid using wording of "assessment for

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".	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	Have included the word 'recommendations' in brackets for many of the first uses of this terminology throughout the Introductory section of the document.

'recommendations for practice'? If so, perhaps more plain language could be used for this section, which comes right at the start?	
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 situations.

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. We have re-worded to clarify this point further and provide more consistent links to the evidence review. Further information has also been added to the additional information section for criterion A to clarify this point.
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. We won't be able to have this summary of other studies prepared in time for the public consultation version of the document but will prepare an appendix to be able to include in the final document.
Page 34 - Post-natal – how would we determine whether ACEs better explain symptoms? This is a complex assessment.	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.
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.
- 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	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.

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 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 general 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. Have included reference to the DSM.
-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)	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.
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 condition' 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 ND-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 with FASD/ND-PAE 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/ND-PAE.

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. We would love to have access to a professional proof-reader, but unfortunately our funding has been exhausted.

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 pre-natal 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 Appendices 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 analy 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 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.	

○ 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	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**
o Reduced o Probably reduced o Probably no impact o Probably increased o Increased o Varies o Don't know	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.	
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	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**
o No o Probably no o Probably yes o Yes o 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	

○ Don't know	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 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 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 Guidelines Development Group suggests that birthweight corrected for gestational age according to the appropriate age- and sex-specific charts is included in the diagnostic criteria for FASD/ND-PAE.

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.

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 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.*	• 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: • 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	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.	

○ Varies ○ Don't know		
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
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 Guidelines Development Group suggests that birth length corrected for gestational age according to the appropriate age- and sex-specific charts is included in the diagnostic criteria for FASD/ND-PAE.

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.

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 ○ Moderate ○ Large ○ Varies ○ Don't know	• Very large association found for very heavy exposure. • 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.	Exposure studies and the outcome of weight < 10th%tile was the more critical outcome used to inform the overall judgements.

	• 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.*	

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 information systematically collected regarding patient values. The Guidelines Development Group believes there would be no uncertainty or variability in the importance of the measures.	

○ 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	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 ○ Varies ○ Don't know	Given that weight 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	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

	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 Guidelines Development Group suggests that postnatal weight according to the appropriate age and sex specific growth charts should be included in the diagnostic criteria for FASD/ND-PAE.

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.

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
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 Guidelines Development Group suggests that postnatal height according to the appropriate age- and sex- specific growth charts is included in the diagnostic criteria for FASD/ND-PAE.

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.

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. • 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 D for all available results.*	Where available information is provided regarding the lip/philtrum guide and 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 D for all available results.*	

Values Is there important uncertainty about or variability in how much people value the outcome?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
o Important uncertainty or variability o Possibly important uncertainty or variability o Probably no important uncertainty or variability o 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**
○ 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**

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 o Varies o Don't know	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 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 Guidelines Development Group suggests philtrum smoothness, vermilion thinness and palpebral fissure length are included in the diagnostic criteria for FASD/ND-PAE. Assessment of facial features needs to be part of a comprehensive medical examination that considers other potential causes of dysmorphic facial features.

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 D 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	Very low to low certainty. Very wide confidence intervals noted across most of the minor features. *See the systematic review report for an overview of findings and Supplemental File D 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**
○ Large costs ○ Moderate costs ○ Negligible costs and saving ○ Moderate savings ○ Large savings	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.	

o Varies o Don't know		
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	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.	

o Increased o Varies o Don't know		
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 Guidelines Development Group recommends against including minor dysmorphic features in the diagnostic criteria for FASD/ND-PAE.

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 adapted checklist has been created that provides a summary of the most prevalent to the least prevalent features based on the available research evidence.

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.	More critical outcomes considered here for rating were exposure studies and heavy, very heavy or confirmed unquantified exposure.

	See the systematic review report for an overview of findings and Supplemental File F for all available results.	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 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	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.	

variability ○ 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, 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 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 ○ Increased ○ Varies ○ Don't know	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.	

Acceptability

Is the outcome acceptable to be measured by key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes	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.	

○ 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	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.	
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
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 Guidelines Development Group suggests that head circumference corrected for gestational age according to the appropriate age- and sex-specific charts is included in the diagnostic criteria for FASD/ND-PAE.

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.

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 F 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	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 F 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	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.	
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**

o Reduced o Probably reduced o Probably no impact o Probably increased o Increased o Varies o 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
o No o Probably no o Probably yes o Yes o Varies o 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
o No o Probably no o Probably yes o Yes o Varies	Information was not systematically collected regarding feasibility.	

○ 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	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 Guidelines Development Group recommendations against including structural brain abnormalities as observed on clinical imaging in the diagnostic criteria for FASD/ND-PAE.

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 an associated condition.

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 conditions 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 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	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 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	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.	

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 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	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.	

○ Yes ○ Varies ○ 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	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
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		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 Guidelines Development Group recommends against including other neurological conditions in the diagnostic criteria for FASD/ND-PAE.

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 an associated condition as part of the assessment process.

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	**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	Overall, across the functional neurodevelopmental areas there is a

○ Moderate ○ Large ○ Varies ○ Don't know	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)** Exposure studies 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. Diagnosed studies: All FASD diagnoses associated with lower full-scale IQ, verbal and performance sub-scales and non-verbal IQ scores. **Language** Exposure studies 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. Diagnosed studies: Generally, all diagnostic groups demonstrated weaker language skills compared to controls. Small to large associations. **Motor**	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 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.

	Exposure studies 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. 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 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 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 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	Information was not systematically collected regarding values. However, The Guidelines Development Group believes there is probably no important variability in values of this outcome.	

uncertainty of variability		

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 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**
o Very low o Low o Moderate o High	No included studies directly assessing this.	

o No included studies		

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 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
o No o Probably no o Probably yes o Yes o Varies o 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			

	JUDGEMENT						
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 Guidelines Development Group suggests that neurodevelopmental outcomes are included in the diagnostic criteria for FASD/ND-PAE.

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.

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 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.