Medical Journal of Australia

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GUIDELINE SUMMARY

Australian Guidelines for Assessment and Diagnosis of Fetal Alcohol Spectrum Disorder: Overview of the Development Process and Revised Diagnostic Criteria

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Received: 2 June 2025 | **Revised:** 6 November 2025 | **Accepted:** 25 November 2025

Keywords: diagnosis | fetal alcohol spectrum disorders | neurodevelopmental disorders

ABSTRACT

Introduction: The *Australian Guidelines for the Assessment and Diagnosis of Fetal Alcohol Spectrum Disorder* were released in May 2025. These guidelines, updated from the 2016 Australian Guide, were developed through extensive stakeholder consultation, a comprehensive review of empirical evidence and the application of a novel Grading of Recommendations, Development and Evaluation (GRADE)-based approach for developing evidence-based diagnostic criteria.

Recommendations: The guidelines include 11 GRADE-based recommendations, forming the core of the diagnostic criteria, and 11 lived experience statements, supporting client-centred assessment approaches. The guidelines also feature 40 good practice statements and 18 implementation considerations, tools and tips as practical resources and supports for practitioners.

Changes in Management as a Result of the Guidelines: Key changes in the new guidelines include: A minimum prenatal alcohol exposure threshold for diagnosis to support more precise identification of fetal alcohol spectrum disorder (FASD); The assessment of neurodevelopmental impairments and functioning has been refined, including detailed advice for practitioners seeking to identify clinically significant impairments; Inclusion/exclusion of neurodevelopmental domains

as part of the assessment; and Revisions to some of the content of the included neurodevelopmental domains. Changes have also been made with attention to the needs of First Nations Australians and people from other culturally and linguistically diverse backgrounds. The guidelines advocate for the use of shared decision-making approaches, promoting collaboration between practitioners, individuals attending for assessment and their support network. Importantly, the guidelines will enable an accessible, holistic and flexible assessment process, supporting timely and accurate assessment and diagnosis of FASD in Australia. The rigorous development process also provides practitioners with confidence in the guidelines, promoting increased uptake of assessment and diagnostic practices, and informing international diagnostic criteria and guidelines.

JEL Classification: Pediatric medicine, General medicine, Mental disorders

1 | Introduction

Prenatal alcohol exposure (PAE) is prevalent in Australia, with close to half of pregnancies affected (estimated 48%; 95% confidence interval, 38%–57%) [1], with high rates of alcohol consumption early in pregnancy, often before pregnancy awareness [2, 3]. PAE is associated with a wide range of potential adverse obstetric and birth outcomes, including miscarriage, haemorrhage in late pregnancy, placental abruption, preterm birth, stillbirth and being born small for gestational age [4]. In addition, PAE can lead to a diagnosis of fetal alcohol spectrum disorder (FASD) or neurodevelopmental disorder associated with PAE [5]. Based on global prevalence estimates of FASD (7.7 per 1000 population), it is estimated that one in 13 pregnancies exposed to alcohol results in a child having FASD [6].

Research indicates that early diagnosis of FASD (i.e., before 6 years of age) leads to fewer behavioural challenges, co-occurring conditions and better quality of life compared with later diagnosis [7, 8]. Access to assessment and diagnosis can also support increased understanding for individuals and families and access to funding, services and targeted interventions. To establish a consistent approach to diagnosis in Australia, the *Australian Guide to the Diagnosis of FASD* was created in 2016 [9]. Following an individual consultation with stakeholders and review of existing international guidelines [10], the 2016 guide was adapted from the *Canadian FASD Guidelines* [11] and incorporates elements of the University of Washington 4-Digit Diagnostic Code [12].

1.1 | Rationale for Revising the 2016 FASD Guide

In 2020, the Australian Department of Health and Aged Care commissioned a national consortium to review and update the existing *Australian Guide to the Diagnosis of FASD* [9]. The primary aim of the review was to ensure that the guidelines aligned with the latest evidence and international best practice and met the National Health and Medical Research Council (NHMRC) standards for clinical practice guidelines [13]. Research on the uptake of, or clinicians' experiences with, using the 2016 guide has been limited. One study [14] examined the outcomes and needs of 52 health and education professionals following FASD-specific training. The clear presentation and content, associated training and the establishment of a national consensus on diagnosis were highlighted by practitioners as facilitating the use of the 2016 guide. However, lack of time and resources to conduct assessments as recommended, concerns about the quality of the evidence supporting some of the neurodevelopmental domains included for assessment, insufficient consideration of individuals with moderate levels of impairments and the 2016 guide's limited applicability to Aboriginal and Torres Strait Islander peoples and people from culturally and linguistically diverse backgrounds contributed to reported barriers in using the 2016 guide. More recently, another study [15] surveyed 106 Australian psychologists to understand their knowledge and practices in assessing and diagnosing FASD, including their familiarity with the 2016 guide. Although 60.4% of psychologists were familiar with the 2016 guide, most (58%) were not confident in assessing PAE, with only 31% reporting feeling confident in assessing for an FASD diagnosis.

1.2 | Diagnostic Challenges

The distinctive feature of FASD, compared with other neurodevelopmental conditions, is the presence of a specific exposure (i.e., PAE). However, there are differing perspectives in the field—for example, around the minimum threshold for PAE diagnosis—and, as a result, there is no agreed set of diagnostic criteria, with over 10 different diagnostic systems currently in use internationally [16]. Key differences among these diagnostic systems include whether a PAE threshold is required for diagnosis, variability in diagnostic features (e.g., physical size, number of facial features), and discrepancies in the level of neurodevelopmental impairment considered necessary for diagnosis. In addition, there is considerable variation in the diagnostic terminology used worldwide, including terms such as FASD with (or with less than) three facial features, fetal alcohol syndrome, partial fetal alcohol syndrome, alcohol-related neurodevelopmental disorder, static encephalopathy and neurobehavioural disorder [9, 11, 12, 17]. Developing robust, evidence-based clinical practice guidelines for FASD is therefore a substantial challenge. In this guideline summary, we describe the process of developing the 2025 *Australian Guidelines for the Assessment and Diagnosis of Fetal Alcohol Spectrum Disorder* and the resulting revised diagnostic criteria. We note that the information presented here is a summary of the guideline development process, and we recommend interested readers to refer to the full guidelines for more detailed information on the rationale for these methods and the specific methods applied in the development of the new guidelines (https://child-health-research.centre.uq.edu.au/australian-guidelines-assessment-and-diagnosis-fetal-alcohol-spectrum-disorder and https://www.fasdhub.org.au/fasd-information/australian-guidelines-for-assessment-and-diagnosis-of-fasd/).

2 | Methods

2.1 | Overview of the Guidelines Revision and Development Process

The review and development of the guidelines followed the NHMRC-recommended processes [13], which align closely with the Appraisal of Guidelines for Research and Evaluation (AGREE) II criteria [18], and Grading of Recommendations, Development and Evaluation (GRADE) guidance [19]. The guidelines were also reported according to the RIGHT statement [20].

Key steps in the process included:

- Establishing expert Advisory Groups, including practitioners from multiple disciplines, researchers, cultural advisors and people with living/lived experience. Input and feedback were collected from Advisory Group members through various formats, including a priority setting survey to collect initial individual input [21], Advisory Group meetings and presentations and formal written feedback submissions.
- Establishing a Guidelines Development Group, comprising 26 members with expertise in guidelines methodology, First Nations health, living/lived experience, research and representation from disciplines involved in the assessment and diagnostic process. The group was chaired independently by Professor Philippa Middleton.
- Undertaking a series of comprehensive evidence reviews of the literature (systematic, meta-analytic and/or scoping reviews) based on best practice guidelines (e.g., Cochrane systematic review guidelines).
- Applying GRADE [22] processes to rate the certainty of the evidence.
- Using a GRADE-informed approach—a novel multi-stage Evidence to Decision Framework process was developed to provide a transparent and evidence-based process for developing the assessment and diagnostic criteria [23].
- Undertaking public consultation with stakeholders to understand areas of concern and responding to feedback to improve the final guidelines.
- Involvement of the NHMRC in providing independent expert methodological and clinical reviews of the guidelines and refining the final guidelines.
- Obtaining endorsement of the guidelines by the NHMRC, whose members include state, territory and Commonwealth Chief Health/Medical Officers in Australia.

These steps were undertaken to ensure the guidelines were methodologically rigorous and inclusive of stakeholder perspectives.

2.2 | The Evidence Base for the Guidelines

Multiple sources of evidence were included in the review and development of the guidelines (Figure 1). These included:

- The 2016 *Australian Guide to the Diagnosis of FASD* [9].
- Review of international diagnostic criteria and guidelines.
- Findings from the comprehensive evidence review.
- Input from the Clinical, Research, Cultural and Living Experience Advisory Groups.

2.3 | The Evidence Review

Four research questions were developed to guide the evidence review:

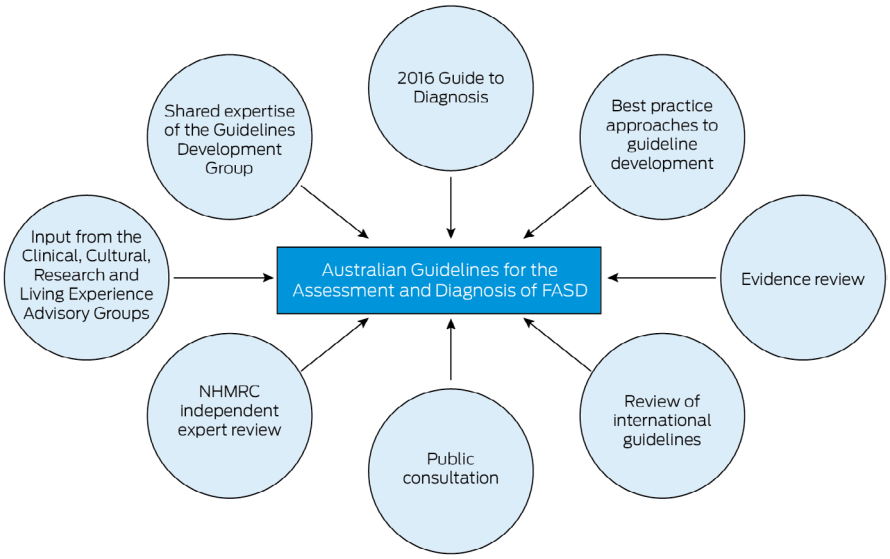

FIGURE 1 | Sources of evidence informing the review and development of the guidelines. FASD, fetal alcohol spectrum disorder; NHMRC, National Health and Medical Research Council.

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

Research protocols were developed and registered (CRD 42021230542; CRD42021230522; osf.io/7rcfs; osf.io/58gnh), outlining the scope of the reviews, including search strategies and synthesis plans. Information on the rationale and approach to the evidence reviews is also detailed in the main guidelines document and in the published reviews [24–27]. Risk of bias in the quantitative studies was assessed in duplicate using an amended version of the Research Triangle Institute (RTI) Item bank for assessing risk of bias and confounding for observational studies of interventions or exposures [28]. Certainty of the evidence was evaluated using the GRADE approach for prognostic factors [29]. The quality of qualitative studies was assessed in duplicate using the Critical Appraisal Skills Programme (CASP) Checklist for Qualitative Studies [30]. The certainty of the qualitative evidence was established using the GRADE–CerQual approach [31, 32]. Results of the evidence review were presented and discussed with the Advisory Groups, and technical reports and peer-reviewed publications were prepared for each of the four reviews [24–27].

2.4 | Evidence to Decision Process for the Development of the Diagnostic Criteria

Before the development of these guidelines, there was a lack of structured and transparent evidence-based processes for developing diagnostic criteria for a condition without a biomarker, test or unique symptom profile. To address this limitation, we adapted the GRADE approach to ensure appropriate and rigorous assessment of the evidence by developing a novel multi-stage evidence-to-decision process. This approach considered each of the candidate diagnostic features identified through systematic reviews and meta-analyses, as well as the overall diagnostic criteria. This enabled the findings from the systematic reviews and meta-analyses of the diagnostic components to be summarised using appropriate evidence-to-decision frameworks. These frameworks informed the development of GRADE-based recommendations for each component of the diagnostic criteria. The development process of this method has been described in detail elsewhere [23].

2.5 | Developing Actionable Statements

The Guidelines Development Group reviewed and discussed different approaches to presenting the actionable statements (i.e., recommendations). The framework proposed by Lotfi and colleagues [33] was used to inform the development and presentation of these statements, with some adaptations made for these specific guidelines (Figure 2). For example, based on the systematic review of qualitative evidence examining the lived experiences of the assessment and diagnostic process [27], a novel type of actionable statement, the lived experience statement, was developed to reflect the perspectives of people with lived experience. To differentiate these statements from the diagnostic criteria statements, the terminology GRADE-based recommendations was used for statements relating to the diagnostic criteria, instead of the term 'formal recommendations', used by Lotfi and colleagues [33]. As no 'research only' recommendations were identified during the review, this type of actionable statement was not included. The wording and definitions of good practice statements and implementation considerations, tools and tips were retained as per Lofti and colleagues [33]. These adaptations ensured that the final actionable statements were both evidence-based and suitable for the specific context of these guidelines.

2.6 | Development of an Australian FASD Indigenous Framework

Advisory Group input, including the initial priority setting survey [21] and the evidence review [24], highlighted a current gap in available information supporting culturally responsive assessment

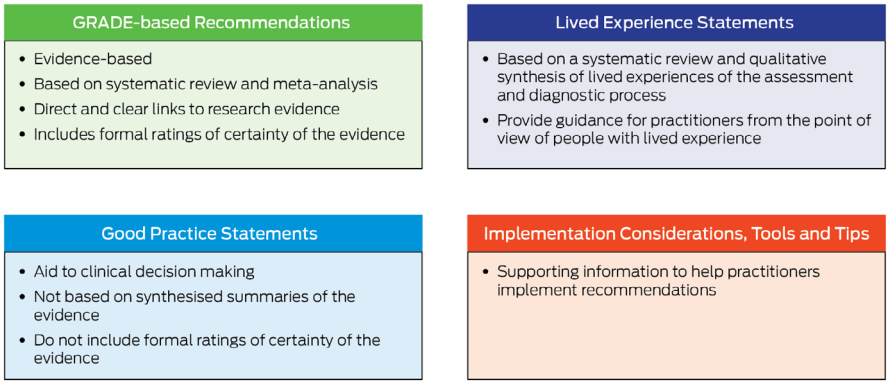

FIGURE 2 | Overview of the actionable statement types included in the guidelines. *Source:* Australian Guidelines Development Group (2025). *Australian Guidelines for the Assessment and Diagnosis of Fetal Alcohol Spectrum Disorder.* Child Health Research Centre, University of Queensland (https://child-health-research.centre.uq.edu.au/fasd-guidelines).

and diagnostic practices, which led to the Cultural Advisory Group developing the Australian FASD Indigenous Framework [34]. The framework is dedicated to facilitating access to healing-informed, strengths-based and culturally responsive knowledge, assessments, diagnosis and supports. With deep respect and appreciation for the benefits of Aboriginal and Torres Strait Islander strengths-based, holistic and well-being–focussed approaches for all Australians, perspectives and strategies from this framework have been incorporated throughout the main guidelines document.

The FASD Indigenous Framework document accompanies the guidelines, with the aim of supporting culturally responsive approaches to practice in practitioners and the broader community. A culturally significant component of the framework was the creation of artwork that incorporates a community-informed design. The artwork embodies the strength, interconnectedness and timelessness of culture, and draws upon the healing and knowledge qualities of water, and the nourishing and flourishing qualities of fresh vegetation. The colours are included throughout the guidelines document to reflect these culturally significant themes.

2.7 | Public Consultation and Independent Expert Review

Public consultation is a key feature of the NHMRC guidelines development process [13]. Consistent with the NHMRC recommendations, the draft guidelines were released for a 6-week period (11 March–22 April 2024), with an additional week provided on the request of stakeholders. The public consultation was advertised on the NHMRC website, in the NHMRC newsletter and the FASD Hub Australia website, and shared on social media. Invitations were also directly sent to numerous stakeholders, including Director Generals, Chief Executives or Secretaries of each state, territory and Commonwealth health departments, and other relevant government departments (e.g., education, child protection and justice), spanning a range of relevant professional organisations. In total, 30 public consultation submissions were received, representing a diverse range of stakeholders, including diagnostic clinics, health services, consumer groups, and individual practitioners and consumers. All submissions were considered and responded to formally in writing.

After revisions were undertaken in response to the public consultation, the guidelines underwent independent expert review by one methodological expert and six clinical experts in the field of FASD. Following feedback from the expert review, the guidelines were further refined. The guideline recommendations were subsequently approved by the NHMRC Chief Executive Officer on 24 March 2025 and were released on 13 May 2025.

3 | Recommendations

3.1 | Overview of Included Recommendations

After reviewing the empirical evidence, the Guidelines Development Group established 11 GRADE-based recommendations, which form the basis of the diagnostic criteria. In addition, 11 lived experience statements were developed to provide practitioners with guidance in supporting client-centred assessment approaches. Forty good practice statements are included to support implementation of the diagnostic criteria, covering all aspects of assessment, including PAE assessment; medical assessment; holistic developmental, functional and well-being assessment; and the development of case formulations and application of strengths-based perspectives. Finally, 18 implementation considerations, tools and tips were developed to provide practical resources and support for practitioners in implementing the actionable statements. Table S1 provides a summary of the actionable statements included in the guidelines.

3.2 | Overview of the Diagnostic Criteria

Based on the multi-stage evidence-to-decision framework process, evidence-based diagnostic criteria for FASD were developed and are presented in Box 1. To further aid readers in applying the diagnostic criteria, we have also included an algorithm in Figure 3. Criteria A–E all need to be met to receive a diagnosis of FASD, with the relevant specifiers documented for reference in both the diagnostic process, and to inform future research. The new guidelines emphasise that standardised tests are only one component of the diagnostic process and that clinicians should use their professional judgement to integrate test results with a comprehensive understanding of the individual's context. The guidelines also provide assessment principles, with detailed information to support practitioners in applying the diagnostic criteria available in the main guideline documents published online.

3.3 | Limitations and Future Research Recommendations

Despite the rigorous process applied in developing the 2025 guidelines, a range of limitations are evident in the research literature. As such, we have provided recommendations on future research directions, detailed in the main guidelines, with the view that new evidence will inform future advancements of the guidelines. Recommended areas for future research included the need for high-quality studies of quantified levels of PAE on development outcomes; local tools and norms to support assessment of facial features; tests, normative data and culturally safe practice in neurodevelopment assessment; understanding the interplay between genetics and environmental factors on influencing neurodevelopmental outcomes; and monitoring and evaluation of the diagnostic criteria in clinical practice.

4 | Accessing the Guidelines

The full guidelines are available online at https://child-health-research.centre.uq.edu.au/australian-guidelines-assessment-and-diagnosis-fetal-alcohol-spectrum-disorder and https://www.fasdhub.org.au/fasd-information/australian-guidelines-for-assessment-and-diagnosis-of-fasd/. A project is currently underway to disseminate the guidelines, funded by the Australian Government Department of Health, Disability and Ageing, and will include the development of training workshops and

BOX 1 | Diagnostic Criteria for Fetal Alcohol Spectrum Disorder—Also Termed Neurodevelopmental Disorder Associated With Prenatal Alcohol Exposure (PAE).

All criteria (A–E) must be considered, and all relevant specifiers applied for diagnosis.

A. Evidence of PAE (confirmed by point 1 or 2).
   1. PAE above a low-risk level at any time during gestation, including prior to pregnancy recognition. Confirmation of PAE may be obtained from any of the following sources: self-report of alcohol use in pregnancy, and/or collateral reports from individuals who directly observed the prenatal alcohol use, and/or information obtained from medical or other records.
   2. In the absence of a confirmed history of PAE, following the exclusion of other causes, the presence of the three sentinel facial features (i.e., short palpebral fissures, thin upper lip, and smooth philtrum) may be considered sufficient to meet criterion A.

B. Presence of pervasive neurodevelopmental impairments.

This is evidenced by clinically significant impairments in three or more neurodevelopmental domains (intellectual abilities, communication, motor skills, literacy and/or numeracy skills, memory, attention, executive functioning, emotional and/or behavioural regulation, adaptive/social functioning).

Clinically significant impairment is defined by points 1 and 2:

1. Reports indicative of clinically significant developmental and/or behavioural problems as described by the individual undergoing assessment and/or multiple informants across different settings and
2. Direct evidence of clinically significant impairments. Practitioners should use standardised tests where appropriate but not rely solely on these tests in assessing the significance of impairments and functional impacts. See further information below on defining clinically significant impairments.

Note: In infants and young children, in the absence of direct evidence of clinically significant impairments and following exclusion of other causes, microcephaly (≤ 3rd percentile) may be used as an indicator of neurodevelopmental impairment, meeting criterion B.

C. The neurodevelopmental impairments result in functional impacts that necessitate significant supports across multiple areas of functioning, relative to an individual's developmental stage and cultural context.

D. The onset of neurodevelopmental impairments is evident during the developmental period.

Note:

- Intellectual, behavioural and functional capabilities emerge variably as individuals grow and mature, and some delays in development may represent age or developmentally appropriate diversity, rather than impairments.
- Neurodevelopmental impairments may not become apparent or fully manifest until the demands of life and context exceed developmental capabilities. Repeat assessments may therefore be required.

E. An individual's presentation is not better attributed to another condition or exposure.

Diagnosis requires consideration of other conditions or exposures, which could better explain the person's presentation. However, some conditions and exposures can co-exist with fetal alcohol spectrum disorder (FASD). This includes consideration of other neurodevelopmental risk factors such as, but not limited to

- *Predisposing/familial* (e.g., family history of learning disorders, cognitive impairments, mental ill-health, intergenerational trauma).
- *Genetic conditions* (e.g., fragile X syndrome, chromosomal variants including microdeletion or duplication syndromes, or single gene disorders that are known to be associated with neurodevelopmental impairment).
- *Prenatal* (e.g., exposure to other teratogens, including prescription medications [e.g., sodium valproate] and/or other drugs (e.g., nicotine, cannabis, amphetamines, opioids, pregnancy complications, congenital infections, premature birth, other environmental factors [e.g., nutritional deficiencies during pregnancy]).
- *Postnatal* (e.g., hypoxic ischaemic encephalopathy; adverse childhood, adolescent or adult experiences; acquired or traumatic brain injury; central nervous system infections; or cranial malformation).
- *Other neurological conditions* (e.g., delirium, dementia, seizure disorders [e.g., genetic seizure syndromes such as genetic epilepsy syndromes, developmental and epileptic encephalopathies], metabolic [e.g., mucopolysaccharidoses] or other neurocognitive conditions).
- *Current medications or substances* (i.e., the direct physiological effects associated with the use of medications or substances by the individual being assessed).

Specify the following physical features:

- 1, 2 or 3 or no sentinel facial features (include the specific measurements for palpebral fissure length (e.g., 10th [SD, 1.28], 5th [SD, 1.65], ≤ 3rd percentile [SD, ≤ 2]));
- Head circumference restriction at birth and/or postnatally (e.g., at the 10th [SD, 1.28], 5th [SD, 1.65], ≤ 3rd percentile [SD, ≤ 2]; include the specific measurements for head circumference at birth and postnatally);
- Physical size restriction at birth and/or postnatally (weight and/or length/height at the 10th [SD, 1.28], 5th [SD, 1.65], ≤ 3rd percentile [SD, ≤ 2]; include specific measurements at birth and postnatally).

BOX 1 | (Continued)

Note: These physical features provide clinically meaningful information and are an important part of the assessment. These features are not provided as specifiers to diminish their importance but because not all individuals will present with these physical features. This approach encourages practitioners to document these physical features along a continuum, informing both current and future clinical care and research.

Associated features: Record all associated features including structural brain abnormalities, neurological conditions (e.g., seizures of unknown origin, cerebral palsy, hearing, or vision impairments), congenital anomalies (e.g., cardiac, renal, or other organ defects, ptosis, strabismus), musculoskeletal conditions, (e.g., flexion contractures), other health problems (e.g., sleep disorders, eating/feeding or toileting concerns), sensory processing challenges, social cognition impairments, social communication/pragmatics, motor speech or speech-sound impairments.

Co-occurring conditions: FASD can co-occur with a wide range of conditions. This includes but is not limited to other neurodevelopmental conditions (e.g., ADHD, ASD, language disorders, specific learning disorders) and mental health conditions (e.g., anxiety, depression, trauma and other stressor-related conditions, substance use conditions). Assessment should include consideration of relevant co-occurring conditions to enable appropriate conceptualisation of an individual's treatment and support needs. When an individual is found to meet the criteria for multiple diagnoses, care should be taken to consider the possible overlap of symptoms and whether multiple diagnoses assist in understanding the individual's needs.

ADHD, attention deficit hyperactivity disorder; ASD, autism spectrum disorder; SD, standard deviation.

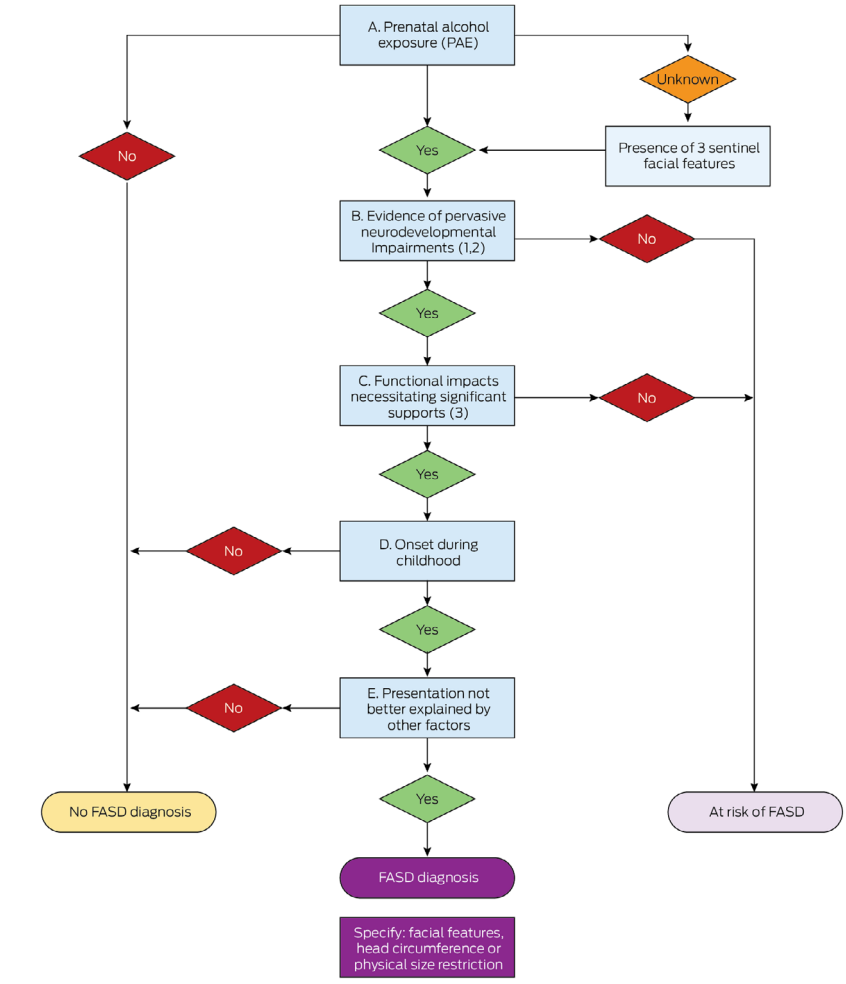

FIGURE 3 | Fetal alcohol spectrum disorder (FASD) diagnostic algorithm. *Source:* Australian Guidelines Development Group (2025). Australian clinical practice guidelines for the assessment and diagnosis of fetal alcohol spectrum disorder. Child Health Research Centre, University of Queensland (https://child-health-research.centre.uq.edu.au/fasd-guidelines).

resources for practitioners, along with additional resources to support individuals with living experience.

Author Contributions

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Acknowledgements

We thank the members of the guidelines Steering Committee: Kerryn Bagley (La Trobe University), Alison Crichton (VicFAS, Monash Children's Hospital), Elizabeth Elliott (University of Sydney), Amy Finlay-Jones (Telethon Kids Institute), Rowena Friend (Patches Paediatrics, Charles Darwin University), Sophie Harrington (NOFASD Australia), Nicole Hewlett (University of Queensland), Karen Moritz (University of Queensland), Raewyn C. Mutch (Te Kāhu Taurikura, University of Western Australia, Perth Children's Hospital, Telethon Kids Institute), Dianne Shanley (Griffith University), Haydn Till (Child Development Service, Gold Coast Hospital and Health Service, Queensland Health), Andrew Webster (West Moreton Health) and Alan White (West Moreton Health). We also thank all members of the Australian FASD Guidelines Advisory Groups for their input and feedback throughout the guideline development process.

Funding

This study was funded by the Australian Commonwealth Department of Health and Aged Care (GO2647). Zachary Munn is supported by a National Health and Medical Research Council (NHMRC) Investigator grant APP1195676. Philippa Middleton is supported by an NHMRC Investigator grant APP1172870. Elizabeth J. Elliott is supported by an NHMRC Investigator Grant APP2026176 and NHMRC Centre of Research Excellence APP2044613.

Disclosure

The authors have nothing to report.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

This article includes no original data.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Data S1:** Supplementary table with recommendations.