

# NICE Draft Quality Standards on Foetal Alcohol Spectrum Disorder

## British Pregnancy Advisory Service Briefing – August 2020

The British Pregnancy Advisory Service (bpas) is a reproductive healthcare charity that offers pregnancy counselling, abortion care, miscarriage management, contraception and STI testing to around 100,000 women each year via our clinics in England, Wales, and Scotland.

We counsel and care for many women who are concerned about the impact their lifestyles (including alcohol or substance use), prescription medication or medical condition may have had on their pregnancy, and provide abortions for women whose doctors have advised them that continuing with their pregnancy poses a serious risk to their life or health.

We also advocate for women's reproductive choice and the right to make their own choices about their own bodies and treatments, with access to impartial, evidence-based information and services to support their decision making.

### Overview

In early March 2020, NICE published draft Quality Standards on FASD. Due to the ongoing COVID-19 pandemic the consultation period was formally postponed. The consultation now runs for comment **August 20<sup>th</sup> – September 18<sup>th</sup>, 2020**.

Key elements of these standards, and the source guidance they draw upon, include:

- 1) A pregnant woman will be asked about her alcohol consumption throughout her antenatal appointments and the information recorded,
- 2) Once her child is born the information about her alcohol consumption will be recorded into every child's health record, including maternity birth notifications, the "Red Book" and the child's electronic care summary record,
- 3) There will be no threshold below which consumption will not be recorded, as under these standards *any* alcohol is deemed to put a child at risk of neurological impairment, and
- 4) A child with 3 areas of neurodevelopmental delay/impairment (for example, problems with attention, memory, poor social skills) and confirmed prenatal alcohol exposure can be diagnosed with FASD.

We believe that any Quality Standards on FASD should be based on the highest quality evidence in order to best inform women, families and caregivers in making decisions, and they should seek to achieve the best possible outcomes for women and their families. We believe these standards, as they stand, fail dramatically to meet these requirements, and represent an unprecedented and unjustifiable intrusion in the lives of women and their

families, involving data transfer which may well be unlawful. In particular, we raise the following concerns:

- **There is an insufficient evidence base on harm caused by alcohol in pregnancy to warrant this significant intrusion in family life** - there is little evidence of harm at lower levels of alcohol consumption in pregnancy yet under these standards hundreds of thousands of children would be deemed “at risk” of neurodevelopmental impairment as a result of their mother’s behaviours.
- **Lack of confidentiality and erosion of trust** - routine sharing of private information on a child’s health records fundamentally comprises a woman’s own right to medical confidentiality and thwarts the opportunity to develop trusting, personal relationships between a woman and her care provider. This does not benefit the woman or the child she goes on to have and indeed may place them at considerable risk.
- **This represents a significant expansion of diagnostic criteria** - Nearly half of pregnancies are not formally planned, and many women will have drunk before they confirm pregnancy. Under this standard any child with areas of neurodevelopmental impairment whose mother drank at any stage and at any level in pregnancy could receive a diagnosis of FASD. The implications for women and their families of this approach may be profound but have not been considered by any of the stakeholders developing these standards.

bpas wholly supports the development of appropriate care pathways for children with neurological impairments, and the provision of intervention and support for all children and their families, regardless of cause. We do not believe these Quality Standards are the way to achieve this.

### **Insufficient evidence base on harm caused by alcohol to warrant this significant intrusion in women’s lives**

There remains no compelling evidence of harm at low levels of alcohol consumption in pregnancy, yet these Quality Standards propose treating any alcohol consumption as potentially having a causal relationship with any subsequent neurodevelopmental impairments a child develops. In 2016, the Chief Medical Officer released new guidance advising an abstinence-only approach in pregnancy, when previous guidelines – including evidence-based ones issued by NICE – had advised that there was no evidence of harm at low levels of consumption, recommending that women did not exceed a total of 4 units per week. There was no new evidence to underpin this change in guidance, but the revision was made on the basis, both that the risks of low harm could not be categorically ruled out, and that some women may misunderstand the existing guidance as a “recommendation” to drink at lower levels in pregnancy. Studies have sought consistently to find evidence of harm at low to moderate levels of consumption, but have overwhelmingly failed to do, with contradictory findings and an inability to adequately control for confounders. The draft Quality Standards refers, at length, to a 2017 study from McQuire et al, which concluded that as many as one in 6 children in the UK are born with symptoms of FASD. However the research, based on a cohort from 30 years ago and with a lack of case controls, was widely

criticised, with the authors acknowledging their data was unable to prove that alcohol was the cause of any impairment documented.

Although the CMO guidance did not produce nor claim to produce new evidence of harm, the shift to an abstinence-only approach is treated by the source guidance for these standards as evidence that *any* level of alcohol consumption can be the causal factor of *any* neurodevelopmental disorder identified in the child. This approach cannot be supported by the evidence.

### Lack of confidentiality and erosion of trust

NICE have not included any information as to how the screening for alcohol consumption they propose will meet current standards of informed consent, whether women will be told about the way in which this data will be recorded, or whether they will be able to decline the transfer of their personal medical information into their child's health record. We believe this unprecedented inclusion of sensitive, personal information on a child's health record is a breach of a woman's right to confidentiality - particularly in the absence of evidence of harm that may overrule that right, and it compromises her ability to develop a trusting relationship with her midwife. Far from securing better outcomes for children, this Quality Standard puts those children at greater risk by thwarting a woman's ability to confide in her care provider and seek the advice and support she needs – particularly if she is struggling with alcohol dependency.

We are also concerned that the inclusion of a confirmation of prenatal alcohol exposure on a child's health record could impact upon a woman's relationships with a range of services, including health visitors, GPs and potentially safeguarding teams, who will all have access to this information. We are of the view that the automatic inclusion of such information is irresponsible and unjustified, due to the potential increase in stigma, surveillance and mistrust that could occur if maternal consumption is brought to the forefront of such future interactions in this way. The Equality Impact Assessment has absolutely failed to consider the specific gendered consequences for women as a result of this policy.

### Expansion of diagnostic criteria

This Draft Quality Standard further embeds a drastic expansion of diagnostic criteria into UK policy with no international equivalent. The principle source guidance for these standards is SIGN 156: Children and Young People Exposed Prenatally to Alcohol (2019), which draws heavily on Canadian diagnostic guidelines, first published in 2005 and updated in 2016. The Canadian guidelines allow for a diagnosis of FASD in the absence of sentinel facial features (e.g. thin upper lip, smooth or flattened area between nose and upper lip) when there are three or more areas of neurodevelopmental impairment (memory, attention, executive function, poor academic achievement) and confirmed alcohol consumption in pregnancy “*at a level known to be associated with neurodevelopmental effects*”. However, the SIGN guideline removed this reference to a threshold in order “*to make consistent [sic] with the UK CMO advice for no safe level of alcohol consumption during pregnancy*”. As previously noted, the guidance from the CMO is not based on evidence of harm, but the precautionary principle.

Nearly half of pregnancies are not formally planned, and alcohol consumption before confirmation of pregnancy is common. There are very few studies looking at alcohol consumption by gestational band, but those that do find higher levels in the first trimester, when pregnancy may not be known, dropping dramatically by the second. The NICE source material suggests around 40% of women drink during pregnancy: however by the booking appointment less than 3% of women are drinking more than a unit per week, with the remainder drinking either nothing or negligible quantities. A recent survey by bpas of 250 women who had been pregnant since the guideline changed found 80% said they did not drink at all in pregnancy, 11% stopped drinking as soon as they found out they were pregnant, and the remaining 7.5% drank at very low levels (the majority of these, 6%, less than once a month or less, the remainder, 1.5%, 2 units or less per week). There will be women who do not disclose the extent of their alcohol consumption for fear of judgement, even within an anonymous survey, but these women are even less likely to confide in a midwife if they know this data is to be collected and shared. Nevertheless, even with this high level of abstinence, 128,000 children each year based on the current birth rate for England and Wales will have a record of prenatal alcohol exposure on their child health record, and as many as 256,000 if NICE source guidance calculations of alcohol consumption in pregnancy are used.

Even with more conservative estimates, these Quality Standards will result in a major expansion of those deemed “*at risk*” of neurodevelopmental impairment, pathologizing many thousands of children and placing huge burdens on GPs, paediatricians, and health visitors. The proposal to treat any amount of consumption as a potential cause of any neurodevelopmental divergence will mean women are increasingly held responsible, if not accountable, for any challenges their child may face.

## Conclusion

It is adequate care pathways and treatment options for children recognised as having areas of neurodevelopmental delay or impairment which will lead to better outcomes, not confirmed exposure to alcohol in utero, and the proposed expansion of the numbers of children “*at risk*” is highly unlikely to deliver the support and assistance that those genuinely in need require. The confidential relationship between a woman and her midwife is an essential component of securing the best outcomes for a mother and her baby. These Quality Standards erode that trust and in doing so compromise those outcomes.

**We urge stakeholders to consider the impact on both women and the children they go on to have and raise their concerns during this consultation on the draft Quality Standards.**

## Contact

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