

National Institute for Health and Care Excellence

Fetal alcohol spectrum disorder

Consultation on draft quality standard – deadline for comments 5pm on 18/09/20

Please email your completed form to: QSconsultations@nice.org.uk

Note that this is an extension to the consultation exercise which was held from 6 March to 3 April 2020. The content of the quality standard remains unchanged. If your organisation commented previously, you do not need to resubmit your comments. However, if you have additional comments that you would like to submit, you are welcome to.

Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly.

We would like to hear your views on these questions and any other comments you have on the quality standard.

1. Does this draft quality standard accurately reflect the key areas for quality improvement?
2. Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be for these to be put in place?
3. Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.
4. Do you have an example from practice of implementing the guideline that underpins this quality standard? If so, please provide details.

Organisation details

Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank)	BPAS
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Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	N/A
Name of person completing form	
Supporting the quality standard Would your organisation like to express an interest in formally supporting this quality standard? More information.	
Type	[Office use only]

Comments on the draft quality standard

Comment number	Section	Statement number	Comments Insert each comment in a new row. Do not paste other tables into this table because your comments could get lost – type directly into this table.
<i>Example 1</i>	<i>Statement 1 (measure)</i>	<i>1</i>	<i>This statement may be hard to measure because...</i>
1	Statement 2 (Quality Statement, Rationale); Equality Impact Assessment	2, EIA	<p>“Pregnant women have information on their alcohol consumption recorded throughout their pregnancy...and then transferred to a child’s health records after birth”</p> <p>The above proposal is made without any reference to informed consent, or whether pregnant women would even agree to having this information routinely recorded throughout their pregnancy, and subsequently transferred on to a child’s record. While questions of legality and proportionality have been extensively raised within our first submission of comments (during consultation period 6 March- 3 April 2020), we have since commissioned polling to assess the acceptability of these proposals, as such insight had not been attempted within your Equality Impact Assessment.</p>

In a survey conducted by Censuswide, we asked:

“Unplanned pregnancy is common in the UK. Women therefore may have drunk before confirming a pregnancy, but the Chief Medical Officer says the risk of harm to the pregnancy from this is likely to be low.

With this in mind, to what extent do you agree or disagree with the following statement?

“Healthcare professionals should not be able to share information about any alcohol women drink in pregnancy, including before they knew they were pregnant, on their child’s health record unless they have given them permission to do so.”

The question was run separately for validity with both a) mothers (with no reference to whether they drank alcohol, whether during or outside of pregnancy) and b) those who have or do use alcohol either during or outside of pregnancy. The results were nevertheless similar, with 60% of mothers in (a) agreeing with the statement that alcohol information should not be recorded on to their child’s health record without their consent, and 65% of mothers in (b) agreeing the information should not be shared. Fewer than one in seven (14%) mothers expressed support for the proposals outlined in the Quality Standards by disagreeing that healthcare professionals should not be able to share data without consent. This shows women who have been pregnant and who would have experienced the implementation of the Quality Standards had they been in operation reject the proposals outlined, regardless of their alcohol use. More than 700 women expressed their view.

We further asked more than 1,000 women aged 18-45 the following question:

“To what extent do you agree or disagree with the following statement? I believe that woman should avoid alcohol in pregnancy.”

The vast majority (86%) of those asked agreed that they thought women should avoid alcohol in pregnancy, **with less than 2.5% of those polled disagreeing**. The results were the same regardless of whether women were mothers. This indicates that public health messaging efforts surrounding the risks associated with alcohol consumption during pregnancy have been successful and there is widespread awareness of the possible harms associated with alcohol in

pregnancy, including among those who have not already had a child. This therefore raises questions about the need for repeated “advice” during antenatal appointments about the harms of consumption, alongside mandatory screening. Antenatal appointments are short and women already find that alcohol and smoking are issues they receive significant information on, to the detriments of other issues which they would like covering – in particular managing stress and mental health.

While these results indicate women recognise the harms associated with alcohol in pregnancy, and believe it should be avoided, crucially this does not translate into support for the transfer of information about alcohol consumption in pregnancy.

The opinions of and impact on women – which is undeniable based on the scope of Statement 2 in redefining ‘routine antenatal care’ – need to be further researched and accounted for before these Quality Standards can progress further.

BPAS have been contacted by a number of women who want to voice their concerns over the proposals. This comment, by way of example, was sent to us by **Jessica Cohen- Murray**:

“I was horrified to read the NICE QS for alcohol in pregnancy.

One of the most discouraging development in maternity care both in this country & in others – especially the US – is the transformation of maternity care from mother-centred to foetus-centred. Foetus-centred care is unsafe care; when women are considered as merely the vessels of their children, rather than autonomous human being with full rights over their own bodies, their health suffers. In the US, women are routinely criminalised for drinking, smoking or even having miscarriages.

This adversarial environment has led to the US having some of the worst outcomes for mothers and babies in the developed world.

These QCs cement the mother as a second class citizen in her own care, subordinate to the needs of the foetus, her privacy invaded and her choices scrutinised. It will destroy trust between midwives and the women they care for, and the most vulnerable women will lose out the most.

			<p>I hope NICE will rethink this alarming change in direction in maternity care, and reaffirm their commitment to autonomous mother-centred maternity care.”</p>
<p>2</p>	<p>Statement 2 (Quality Statement, Rationale)</p>	<p>2</p>	<p>“Pregnant women have information on their alcohol consumption recorded throughout their pregnancy...and then transferred to a child’s health records after birth”</p> <p>Comment provided by Dr Pam Lowe, Senior Lecturer in Sociology and policy, Aston University: I am deeply concerned about the proposals in the NICE Draft Quality Standards on Foetal Alcohol Spectrum Disorder (FASD) which include mandating the routine sharing of confidential medical information from maternity care to children’s health records. As the briefing by bpas¹ has made clear, there remains no compelling evidence that low levels of alcohol consumption during pregnancy causes harm to the developing foetus, and most women already limit their consumption of alcohol during pregnancy. Thus, in the overwhelming majority of pregnancies, this breach of confidentiality will be completely medically unnecessary. Even amongst cases where there is a legitimate concern about the level of alcohol consumption, the data about drinking is only really unavailable when children have been removed from their parents. In 2019, there were 640,370 births in the UK². There were 4,330 children who had an adoption decision made³. This is less than 1% of the live birth rate. FASD cases will be a feature of a fraction of these removals. Clearly these numbers will vary from year to year, and there may be other reasons for not been able to simply ask a mother about her behaviour during pregnancy. The numbers are very unlikely to rise significantly though. It is hard to see how mandated disclosure of confidential health information by thousands of women can be justified given the tiny numbers of child removals where this information is lacking.</p> <p>The General Medical Council guidance on confidentiality recognises that there are issues for disclosure when genetic or other information can affect people other than the patient. They suggest that there can be incidences where the sharing of information might be justified without informed consent if failure to disclose places others ‘at risk of death or serious harm’⁴. This position was recently upheld in law, where the withholding of a diagnosis of Huntingdon’s Disease from other family members was seen as justified⁵. Although FASD can have serious</p>

			<p>neurodevelopmental effects, <u>the shared information makes no difference to the level of harm.</u> Consequently, alcohol consumption during pregnancy does not meet the public interest threshold of harm. It also remains the case that even with information about prenatal exposure to alcohol, FASD <i>remains an uncertain diagnosis</i> in the absence of classic features, as the impairments overlap with other conditions⁶. Thus, care pathways and treatments will always need to depend on the impairment presentation, not any certainty of diagnosis.</p> <p>Overall, it appears that these draft standards have been written without considering that pregnancy does not, and should not, override normal standards such as informed consent and medical confidentiality. I hope that the outcome of the consultation will be to preserve these standards, rather than risk undermining trust and confidence in maternity services.</p> <p>¹https://www.bpas.org/media/3373/bpas-briefing-fasd.pdf ²https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/livebirths ³https://corambaaf.org.uk/fostering-adoption/looked-after-children-adoption-fostering-statistics/statistics-england ⁴https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/confidentiality/disclosures-for-the-protection-of-patients-and-others#paragraph-73 ⁵ABC v St George's Healthcare NHS Trust & Ors [2020] EWHC 455 (QB) (28 February 2020) ⁶Hoyme, H. E., Kalberg, W. O., Elliott, A. J., Blankenship, J., Buckley, D., Marais, A. S., ... & Jewett, T. (2016). Updated clinical guidelines for diagnosing fetal alcohol spectrum disorders. <i>Pediatrics</i>, 138(2).</p>
3	Statement 2 (Quality Statement)	2	<p><i>“Pregnant women have information on their alcohol consumption recorded throughout their pregnancy...and then transferred to a child’s health records after birth”</i></p> <p>Comment provided by Dr Marianna Iliadou, Durham Law School, Durham University: <u>Recording of alcohol consumption:</u> There seems to be no discussion of informed consent for recording alcohol consumption. This goes against the standards set by the Supreme Court in <i>Montgomery (Appellant) v Lanarkshire Health Board (Respondent) (Scotland)</i> in terms of the patient's autonomy and the spirit of cooperation between healthcare professionals and the pregnant woman. Shared Decision Making, a crucial concept in modern medical treatment recognised by NICE, seems to be absent, which is very problematic. The absence of a provision on informed consent does not encourage or support a shared decision-making approach to the pregnant woman’s treatment.</p>

4	Statement 2 (Quality Statement, Rationale)	2	<p><i>“Pregnant women have information on their alcohol consumption recorded throughout their pregnancy...and then transferred to a child’s health records after birth”</i></p> <p>Comment provided by Professor Ellie Lee, Director, Centre for Parenting Culture Studies, University of Kent: The proposition in this Quality Standard is to establish a system of ongoing monitoring and recording of the detail of any and all alcohol consumption on the part of all pregnant women through the Health Service, which is then carried forward into a child’s health record once born.</p> <p>The basis on which this system of surveillance of the entire population of pregnant women will bring the significant advantages to children and families who may be impacted by FASD remains currently unclear. It is readily apparent from evidence submitted to NICE, and in the wider discussion and literature on the subject, that the main group seeking greater support for the impact of childhood disability are parents, carers and children involved with adoption. The inadequacies of present support including in educational provision are very serious and must be addressed, and full and due consideration should be given to much more specific and targeted approach. This is not what the QS proposes.</p> <p>Unfortunately, in what is proposed instead, the potentially detrimental effects for pregnant women are ignored. The problematic implications of using resources to establish a system directed at the general population of pregnant women need to be subjected to proper examination.</p> <p>Precautionary advice to avoid alcohol should not be translated into the message to women, backed up by a recording system set out in the QS, that low levels of alcohol consumption is the cause of a wide variety of childhood disabilities. To do so is to:</p> <p style="padding-left: 40px;">a) depart radically from the necessity of communicating the basis for precautionary advice as what it is, which is <i>an absence</i> of evidence of a causal relation between childhood disability and all consumption of alcohol before and during pregnancy;</p>
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			<p>b) deny to women their autonomy in assessing this risk and making judgements regarding pregnancy on the basis of accurate information provided to them;</p> <p>c) cause unnecessary anxiety, worry and self-blame during pregnancy and after birth about child health and development, which is already recognised to be a significant burden to women;</p> <p>d) generate specific anxiety regarding the policing character of interactions with health care professionals who women look to, to help them; and</p> <p>d) waste valuable time in appointments where woman have many other concerns they would prefer to seek help for and spend time discussing.</p>
5	Statement 2 (Quality Statement, Rationale)	2	<p><i>“Pregnant women have information on their alcohol consumption recorded throughout their pregnancy...and then transferred to a child’s health records after birth”</i></p> <p>Comment provided by Dr Emma Milne, Assistant Professor in Criminal Law and Criminal Justice, Durham University: There is no discussion of informed consent of pregnant women, nor that they are being informed how the data collected about them is being used and will be used in the future. There is also no discussion of a woman’s ability to opt-out of such intrusive questioning of her lifestyle and behaviour. If there is no intention to provide women with a reasonable level of information to allow them to make an informed decision as to whether or not they wish to opt-out of this data collection, then this intervention will be coercive in nature.</p> <p>There is potential for this initiative to reignite attempts to hold women liable (criminally or civilly) for their actions while pregnant that are deemed to have a negative impact upon the health and welfare of the foetus post-birth. While this is not the intent of the quality standards, it must be remembered that by recording such information and transferring it to the health records of a child born alive then a record of behaviour will be created, which may be drawn upon as ‘evidence’. Therefore, this policy has the potential for opening up the door to women facing legal consequences. Holding women legally liable for their actions (including inactions) while pregnant has significant implications for women’s rights, resulting in a sex-based discrimination for all</p>

			women due to the 'risk' of becoming pregnant (Brazier, 1999; see Milne, 2020 for a summary of the debate about foetal protection and women's rights).
6	Statement 2 (Quality Statement, Rationale)	2	<p><i>“Pregnant women have information on their alcohol consumption recorded throughout their pregnancy...and then transferred to a child’s health records after birth”</i></p> <p>Comment provided by Dr Alexandra Mullock, Senior Lecturer in Health Care Law, University of Manchester</p> <p>The NICE draft standards are extremely problematic for a number of important reasons. In my opinion they will achieve the reverse of what is intended with respect to pregnant women who do abuse alcohol, while women who might consume (but not abuse) a small amount of alcohol during pregnancy will be made to feel anxious, guilty and unnecessarily concerned for the welfare of their unborn child. These standards might encourage women most in need of the support of maternity services to avoid professional help.</p> <p>While it is proven that consuming a very excessive or significant amount of alcohol during pregnancy can have adverse consequences for both the pregnant woman and the foetus, including causing FASD, the evidence does not support the conclusion that <i>any</i> small amount of alcohol during pregnancy is harmful. Therefore, there is insufficient evidence to support the policy.¹</p> <p>Since the mid-1970s, it has been known that excessive alcohol consumption during pregnancy can have adverse consequences, and the gradual reduction in safe levels (from 1 to 2 units per week) to the advice (in 2016) that no alcohol is safe means that alcohol consumption in pregnancy is widely known to be against medical advice. Advice and guidance is provided to all individuals seeking maternity services and so those who do abuse or consume excessive alcohol will either do so because they do not (yet) know they are pregnant, or because they have a problematic relationship with alcohol. The first group should not be blamed and made to feel anxious and guilty because there is no possible advantage in recording such consumption. The second group require specialist support and very sensitive care. They might be vulnerable and the NICE standards will discourage, rather than encourage people with alcohol problems to seek</p>

			<p>advice. Those with problematic alcohol consumption are likely to either avoid services or be dishonest about their drinking. This will hamper the attempts of care-providers both during pregnancy and after birth, with the risk of long-term disengagement from services. These likely adverse consequences have not been properly examined or assessed.</p> <p>As Arkell states in her recent blog,² this approach risks failing to adhere to the requirement for informed consent. This a problem that already afflicts maternity services in other areas of screening (e.g. HIV, Downs) with women being processed through the system without being fully informed about their treatment and/or the reasons for screening measures/recording information.</p> <p>Recording every small amount of alcohol consumed represents an infringement on pregnant women, which encourages narratives of maternal-foetal conflict and tension between patients and health care professionals. Pregnancy is a life-changing and, for some, very challenging event, during which the autonomy, bodily integrity and wellbeing of women is often adversely affected.³ Any policy that has the potential to negatively impact on the care and experiences of pregnant individuals should be fully justified and proportionate.⁴</p> <p>¹ B Thom, R Herring and E Milne, 'Drinking in Pregnancy: Shifting Towards the "Precautionary Principle,"' in Susanne MacGregor and Betsy Thom (eds), <i>Alcohol, Drugs and Risk: Framing Dangerous Classes and Dangerous Spaces: Historical and Cross-Cultural Perspectives</i>, (Routledge 2020).</p> <p>² R Arkell, 'NICE Draft Quality Standards: A misplaced focus?' August 2020 Blog available at: https://blogs.bmj.com/medical-ethics/2020/08/20/nice-draft-quality-standards-on-fasd-a-misplaced-focus/?utm_campaign=shareaholic&utm_medium=twitter&utm_source=socialnetwork</p> <p>³ EC Romanis, D Begović, M Brazier and A Mullock, 'Reviewing the Womb,' (2020) <i>Journal of Medical Ethics</i> 10.1136/medethics-2020-106160.</p> <p>⁴ C Bowden, 'Are We Justified in Introducing Carbon Monoxide Testing to Encourage Smoking Cessation in Pregnant Women?' (2019) 27 <i>Health Care Analysis</i> 128.</p>
7	Statement 2 (Quality Statement, Rationale)	2	<p><i>“Pregnant women have information on their alcohol consumption recorded throughout their pregnancy...and then transferred to a child’s health records after birth”</i></p> <p>Comment provided by Catherine Bowden, PhD Candidate in Bioethics and Medical Jurisprudence, Centre for Social Ethics and Policy (CSEP), University of Manchester</p>

Although the draft quality standard refers to ‘identifying children at risk of FASD’ the aim of this policy appears to be facilitating the diagnosis of children with FASD, rather than preventing FASD. I wish to highlight three concerns in relation to this: this policy will not achieve its stated aim, it is likely to do more harm than good, and it is not likely to pass the public interest test required to justify the breach of confidence it represents.

1. There is little evidence to show that low-level alcohol consumption during pregnancy is linked to FASD. Therefore, what could be of use in diagnosing children with FASD is a record of when their mothers drank heavily during pregnancy. Women who drink heavily during pregnancy commonly suffer from addiction and other mental health and social difficulties and are likely to already feel judged and condemned for their behaviour making them understandably reluctant and sometimes unable to be open about their alcohol intake. There is a risk that being repeatedly asked by healthcare professionals about their alcohol intake, knowing that this will be recorded not only on their health records but also on their children’s will only add to these women’s fears that this information will be used against them, potentially even leading to their children being removed from their care. As we have already seen in cases such as *D (a minor) v. Berkshire County Council and others* [1987] 1 All E.R. 20, a woman’s behaviour during pregnancy can be used against her in care proceedings concerning her children. These feelings of judgment and fear are likely to cause women who drink heavily during pregnancy to either conceal their alcohol consumption from their healthcare professionals or to disengage from antenatal care altogether. Neither of these outcomes will achieve the stated aim of making it easier to diagnose FASD in children.
2. Although a record of when mothers drank heavily during pregnancy may be of some assistance in diagnosing children with FASD, this must be viewed in the context of the wider aim to reduce the number of children suffering FASD. Focusing on gathering information to assist with diagnosing children with FASD has the potential to negatively impact on this wider aim. As it is likely that the policy of recording women’s alcohol intake during pregnancy will alienate the women who need the support of their healthcare professionals the most, there is a real risk that this will increase the incidence of FASD and other negative outcomes for children. It would be perverse if a policy aimed at helping

			<p>children suffering with FASD led to more children suffering from FASD. The interests of women and their children would be better served by addressing the factors causing women to drink heavily during pregnancy and supporting them to make the best choices for themselves and their future children rather than prioritising diagnosing harm after the event.</p> <p>3. The rationale of recording women’s alcohol intake throughout pregnancy to facilitate the diagnosis of FASD in her child in the future raises serious concerns regarding the legality of medical professionals breaching their duty of confidence to the pregnant woman by sharing her medical information in someone else’s medical records. This could potentially be justified only if the public interest in sharing the information outweighed the public interest in maintaining that confidence (<i>X v Y</i> [1988] 2 All ER 648 and <i>W v Edgell</i> [1990] 1 All ER 835). Given that recording women’s alcohol intake on their children’s records is unlikely to assist with diagnosing FASD (for the reasons explained above) and could increase the incidence of FASD and other negative outcomes by alienating women from their healthcare professionals, it seems unlikely that this could be seen to be in the public interest.</p> <p>Engagement with good quality antenatal care is vitally important for producing positive outcomes for women and children and any policy that puts this at risk must be justified by compelling evidence as to its benefit. My concern is that in focussing solely on diagnostic capability, the wider cost-benefit analysis is being missed.</p>
8	Statement 2 (Quality Statement, Rationale)	2	<p><i>“Pregnant women have information on their alcohol consumption recorded throughout their pregnancy...and then transferred to a child’s health records after birth”</i></p> <p>Comment provided by Dr Alexis Paton, Lecturer in Social Epidemiology and the Sociology of Health, Aston University</p>

Surveillance of pregnancy bodies to the extent suggested by Quality Statement 2, i.e. mandatory and routine collection of data on alcohol consumption, is currently unprecedented in antenatal care. Pregnant women are currently not required to disclose the use of illegal drugs (<https://www.nhs.uk/conditions/pregnancy-and-baby/illegal-drugs-in-pregnancy/>), nor to disclose their consumption of other substances of concern in pregnancy such as high levels of caffeine, mercury or vitamin A. This significant breach of privacy and autonomy requires a substantial benefit in order to be considered proportionate to the harm it may cause to patients. While the briefing paper makes a single reference to the bioethical principles developed by Beauchamp and Childress, the quality standards do not account for, nor address the significant ethical concerns with regards to patient autonomy, specifically with regards to the difficulties pregnant mothers report when they try to make autonomous decisions about their pregnancy care (<https://www.birthrights.org.uk/wp-content/uploads/2019/07/Birthrights-Dignity-in-Childbirth-Press-Release-13.10.13.pdf>).

Quality Statement 2 has been proposed as a way to aid in the screening and diagnosis of FASD, however pregnant women and their partners routinely report difficulties exerting any autonomy or choice when undergoing routine antenatal screening. Additionally, while non-directive counselling is considered the gold standard of practice for both antenatal screening and behavioural change for substance misuse, previous work in maternity care has shown that antenatal counselling can be at best directive and at worst paternalistic, with patients reporting that they feel coerced or pushed into making decisions they are not comfortable making (Paton et al., In Press; Lotto et al. 2018). Additionally, it is well recognised that a persistent power dynamic exists between patients and their healthcare staff, making it difficult for patients to act against the recommendations or counsel of their doctors, nurses and midwives (Paton, 2017).

If NICE wishes to include Quality Standard 2 in standard practice without violating the NHS' commitment to patient autonomy, it is strongly recommended that:

1. Patients are made fully aware that they do not need to disclose alcohol consumption to any of their healthcare staff.
2. Recording of alcohol consumption during pregnancy is voluntary, and only recorded after informed consent is given in writing.
3. Only alcohol consumption that is indicative of substance misuse be considered for inclusion in children's red books—and only with express written permission of the mother.

			<p>Lotto RR, Smith LK, Armstrong NA. 2018. Diagnosis of a severe congenital anomaly: a qualitative analysis of parental decision-making and the implications for healthcare encounters. <i>Health Expectations</i>, 21 :678-684</p> <p>Paton A, Armstrong NA, Smith LK, Lotto RR. In Press. Parents' decision-making following diagnosis of a severe congenital anomaly in pregnancy: practical, theoretical and ethical tensions. <i>Social Science and Medicine</i>. https://doi.org/10.1016/j.socscimed.2020.113362</p> <p>Paton, A. 2017. No Longer Handmaiden: The role of social and sociological theory in bioethics. <i>IJFAB</i>, 10(1): 30-49.</p>
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Insert more rows as needed

Checklist for submitting comments

- Use this form and submit it as a Word document (not a PDF).
- Complete the disclosure about links with, or funding from, the tobacco industry.
- Combine all comments from your organisation into 1 response. We cannot accept more than 1 response from each organisation.
- Do not paste other tables into this table – type directly into the table.
- Underline and highlight any confidential information or other material that you do not wish to be made public.
- Do not include medical information about yourself or another person from which you or the person could be identified.
- Spell out any abbreviations you use
- Please provide concise supporting information for each key area. Provide reference to examples from the published or grey literature such as national, regional or local reports of variation in care, audits, surveys, confidential enquiries, uptake reports and evaluations such as impact of NICE guidance recommendations
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