National Institute for Health and Care Excellence
Fetal alcohol spectrum disorder

Consultation on draft quality standard – deadline for comments 5pm on 03/04/20

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

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)	**British Pregnancy Advisory Service**
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	**Clare Murphy**
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.
Example 1	*Statement 1 (measure)*	*1*	*This statement may be hard to measure because…*
1	Statement 1 (**Quality Statement**)	1	***'Pregnant women are given advice not to drink alcohol during pregnancy at their first contact appointment':*** *We agree that this phrasing is appropriate and measured. We believe that the current advice given by the CMO is guidance and advice, not a mandate- and this needs to be made clear within this quality standard.* *Half of pregnancies are not formally planned, and many women will have drunk before confirming a pregnancy. Pregnant women should be reassured that the risk of harm if they have drunk before they have confirmed a pregnancy is likely to be low, as stated in the CMO low-risk drinking guidelines 2016. Current guidance adopts the precautionary principle not because of evidence of harm of low levels of drinking in pregnancy but because harm cannot categorically be ruled out. Inflating the risks of inadvertent alcohol consumption can cause extreme anxiety and lead to the termination of wanted pregnancy.* *Healthcare professionals must be free to tailor their advice and support according to women's needs and preferences – a woman suffering severe pregnancy sickness or concerned about the impact of her antidepressants on her pregnancy will not want a lengthy conversation about*

			alcohol, she will want a conversation that meets her needs. This prescriptive standard compromises women's access to care that meets their own individual requirements.
2	Statement 1 (**Rationale**)	1	***'There is no known safe level of alcohol consumption during pregnancy.':*** *We maintain that this phrasing is misleading when taking the paucity of evidence regarding the relationship between consumption (especially low-level consumption) and harm. Rather, quality standards must be firm in articulating that due to current evidence, harm cannot be ruled out in low level drinking.*
3	Statement 1 (**Quality Measures: Structure**)	1	***'Evidence of local arrangements to ensure that midwives and doctors carrying out antenatal appointments are <u>aware of advice</u> in the UK CMO's low- risk drinking consumption in pregnancy':*** *We agree with the phrasing that the UKCMO guidelines solely amount to advice, and this is advice that HCPs should be aware of. However, we implore that HCPs should also be aware of the inconclusive evidence base, and this evidence should inform HCPs when providing advice and guidance (<u>not</u> mandates) to their patients. Such an approach is reflecting in the BMA 2016 report: Alcohol and Pregnancy: Preventing and Managing Fetal Alcohol Spectrum Disorders.* *Healthcare professionals must be free to tailor their advice and support according to women's needs and preferences – a woman suffering severe pregnancy sickness or concerned about the impact of her antidepressants on her pregnancy will not want a lengthy conversation about alcohol, she will want a conversation that meets her needs. This prescriptive standard compromises women's access to care that meets their own individual requirements, and presents an undue burden on HCPs by mandating the recording of a conversation that may not be necessary.*
4	Statement 1 (**Quality Measures: Structure**)	1	***'Evidence of local arrangements to ensure that midwives and doctors carrying out antenatal appointments are <u>aware of the risks</u> of drinking alcohol in pregnancy, including the risks of FASD':*** *This statement should be rephrased to include that HCPs are 'aware of the evidence and associated risks' and additionally should be aware of their duty to reassure women (especially in relation to low level drinking) following the BMA 2016 report: Alcohol and pregnancy: preventing and managing fetal alcohol spectrum disorders' (5.1.3:*

			'Healthcare professionals have an important role in ensuring those patients that have consumed alcohol do not feel stigmatised, and to reassure patients that- while there is no definitive evidence- the risks associated with drinking small quantities of alcohol are likely to be small. To support this, healthcare professionals should be aware of the uncertainty around the risks of consuming alcohol at low-to-moderate levels during pregnancy and be comfortable explaining this uncertainty to patients.') *Healthcare professionals must be free to tailor their advice and support according to women's needs and preferences – a woman suffering severe pregnancy sickness or concerned about the impact of her antidepressants on her pregnancy will not want a lengthy conversation about alcohol, she will want a conversation that meets her needs. This prescriptive standard compromises women's access to care that meets their own individual requirements, and presents an undue burden on HCPs by mandating the recording of a conversation that may not be necessary.*
5	Statement 1 (**Quality Measures: Structure**)	1	***'Evidence of local arrangements to ensure that first contact appointments include discussion of drinking alcohol in pregnancy and the advice in the UK Chief Medical Officers' low-risk drinking guidelines':*** *This statement should be rephrased to make clear that the full extent of the discussion should depend on the individual needs of the patient, and that the extent of the conversation will only be permissible with the consent of the patient. Healthcare professionals must be free to tailor their advice and support according to women's needs and preferences – a woman suffering severe pregnancy sickness or concerned about the impact of her antidepressants on her pregnancy will not want a lengthy conversation about alcohol, she will want a conversation that meets her needs. This prescriptive standard compromises women's access to care that meets their own individual requirements, and presents an undue burden on HCPs by mandating the recording of a conversation that may not be necessary.* *This state should further be rephrased to include acknowledgement of the uncertainty around evidence concerning drinking in pregnancy, and that the CMO advice takes a precautionary approach. In line with the BMA 2016 report: Alcohol and pregnancy: preventing and managing fetal alcohol spectrum disorders'- any discussions should make reference to the uncertainty,*

			particularly around low to mid level consumption, and HCPs should feel comfortable explaining this uncertainty of evidence (5.1.3, BMA 2016).
6	Statement 1 (**What the quality statement means for different audiences**)	1	***'Service providers':*** *The direction to service providers should be rephrased to reflect that HCPs should be aware of the evidence base surrounding alcohol and pregnancy in addition to the associated risks. This phrasing is of utmost importance to ensure that information is given as advice and guidance, as opposed to a prescriptive mandate.* *Details of what 'verbal and written advice not to consume alcohol in pregnancy based on the UK CMO's low-risk drinking guidelines' entails needs to be provided to ensure that it makes clear that: 1) it is advice, not a mandate; 2) it is reflective of the paucity of evidence relating to alcohol consumption in pregnancy; and 3) the UK CMO guidance adopts a precautionary approach.*
7	Statement 1 (**What the quality statement means for different audiences**)	1	***'Healthcare professionals':*** *The direction to Healthcare Professionals should be rephrased to reflect that HCPs should be aware of the evidence base surrounding alcohol and pregnancy in addition to the associated risks. This phrasing is of utmost importance to ensure that information is given as advice and guidance, as opposed to a prescriptive mandate.* *Details of what 'verbal and written advice not to consume alcohol in pregnancy based on the UK CMO's low-risk drinking guidelines' entails needs to be provided to ensure that it makes clear that: 1) it is advice, not a mandate; 2) it is reflective of the paucity of evidence relating to alcohol consumption in pregnancy; and 3) the UK CMO guidance adopts a precautionary approach.* *We support the necessity of using a 'non-judgemental approach' and the need to 'discuss any concerns and ensure supportive follow-up care if needed'. In order to adhere to this approach, as detailed in the BMA 2016 report: Alcohol and pregnancy: preventing and managing fetal alcohol spectrum disorders', HCPs must both be able to explain the uncertainty around alcohol consumption in pregnancy, and be able to reassure patients that- 'while there is no definitive evidence- the risks associated with drinking small quantities of alcohol are likely to be small.' (5.1.3. BMA, 2016). This is of utmost importance recognising that half of pregnancies are not formally planned, and many women will have drunk before confirming a pregnancy.*

			This statement needs to further clarify how HCPs will determine whether 'follow-up care' is deemed necessary, how this information will exist on antenatal records, and provide information as to how informed consent will be obtained for any subsequent care.
8	Statement 1 (**What the quality statement means for different audiences**)	1	***'Pregnant Women':*** *This prescriptive standard works to undermine institutional trust in women to understand relevant evidence concerning the relationship between alcohol in pregnancy and harm. The result, in combination with standard 2, is to transform 'guidance' into 'mandate', thereby creating unprecedented obligations for behaviour during pregnancy.* *This prescriptive standard further presupposes every woman's relationship with alcohol, without due consideration to individual situations (e.g. medical needs or religious views). This treatment of women could have a severe impact on a women's medical autonomy, affecting her ability to raise additional concerns which are more pressing to her within her time-constrained antenatal appointments.*
9	Statement 1 (**Source Guidance**)	1	***SIGN 156 (2019) Recommendation 2.1 (page 11):*** *We are concerned at how this recommendation will be used alongside Statement 1, in particular:* *"All pregnant and postpartum women should be screened for alcohol use with validated measurement tools by service providers who have received appropriate training in their use. All women should be advised not to consume alcohol in pregnancy; additionally those women drinking above the low-risk guidelines for the general population should be offered early, brief interventions (i.e. counselling and/or other services)."* *We are concerned with the inclusion of such screening methods without robust, ethical scrutiny, nor additional information for how such screening would take place in line with current standards of informed consent.* *We are further concerned that due to the revision SIGN has made (replacing the phrase 'risk of heavy alcohol use' with 'above the low-risk guideline for the general population') in order quantify a level of consumption which actions interventions, any woman who has answered*

			more than 'never' in relation to alcohol consumption will be offered interventions when this may not be necessary. This phrasing has universalized the risk of adversely affected pregnancies, increasing this risk of stigmatisation of women. *If service providers are to use validated screening tools (as referenced in SIGN 156) any answer over 'never' will amount to confirmed pre-natal alcohol exposure for diagnostic purposes, without any attempt to quantify a lower threshold for harm. As detailed in quality statements 3 and 4, this confirmation would see placing a child 'at risk' of neurodevelopmental impairment without due regard to the quantity of alcohol consumed. This is a stark departure from available evidence and would result in a major expansion of those deemed 'at risk' of neurodevelopmental delay, potentially placing a significant burden on GPs, paediatricians and health visitors.* *This source guidance makes no reference to any robust ethical assessment of the impact these changes could potentially have on women's medical decision making and on-going relationships with HCPs.*
10	Statement 2 (**Quality Statement**)	2	***'Pregnant women have information on their alcohol consumption recorded throughout their pregnancy':*** *This quality statement transforms the offer of guidance and advice concerning alcohol consumption into a measurable mandate for individual behaviour during pregnancy. Despite efforts to distance Statement 2 from any rhetoric of screening practices, the proposed measures, as incorporated through SIGN 2019 Recommendation 2.1 amount to practices which have been repeatedly dismissed by the UK National Screening Committee.* *This marks an unprecedented method of operationalising a precautionary approach, without a concrete evidential basis of doing so. This lack of a firm basis calls into the question the legality of data collection and subsequent processing. With reference to current data protection requirements (GDPR), there must be a legal basis for processing of personal data before it is considered lawful.* *Article 6(1) of the GDPR sets out 6 legal bases. To process personal data about health, a controller (e.g. service providers) must have both a lawful basis under Article 6 and fall under*

			an exemption in article 9. The purpose for recording information on alcohol consumption throughout pregnancy, as included in the quality statements, fails to meet a sufficient legal basis under Article 6 due to the following reasons: • *The collection of information cannot be considered necessary to protect the vital interests of the data subject (i.e. the woman) or another natural person (current legal precedent – CP v CICA 2014 – unborn children do not reach this threshold) (6(d) GDPR).* • *This processing cannot be considered necessary in the performance of a task carried out in the public interest (the interest of an early diagnosis must be considered in light of: an uncertain evidence base concerning prenatal alcohol consumption and harm, the use of widely criticised prevalence estimates, and a lack of evidence regarding care pathways post diagnosis) (6(e) GDPR);* • *Finally, this type of processing cannot be considered necessary for the purposes contained in the draft quality standard, thereby overruling the interests and fundamental rights and freedoms of the data subject (i.e. the woman). On balance (the impact this collection of information could have on subsequent medical decision making and relationships v. an uncertain evidence base on consumption), it is clear that the fundamental rights and freedoms of women should be prioritised.* *This proposal thwarts the ability of women to develop trusting, personal relationships with their healthcare providers. If a woman is unable to have a discussion with her midwife without the findings being transferred to her child's medical records, those most in need of support may be dissuaded from engaging with medical services. Essentially this proposal deprives women of access to a service (confidential discussion about alcohol use) other members of the population are entitled to as it makes access to that service contingent on her data being shared on her child's medical record. The needs of these women have not been considered in the Equality Impact Assessment. This means the standard may well have the opposite effect of what it seeks to achieve: women struggling with alcohol consumption need access to confidential support and advice. Restricting that may harm both mother and baby.*
11	Statement 2 (**Rationale**)	2	***'Identifying children <u>at risk</u> of fetal alcohol spectrum disorder (FASD) depends on accurate recording of a mother's alcohol consumption during pregnancy.':*** *To date- no*

			conclusive evidence of the causal relationship between low to mid-level alcohol consumption during pregnancy and harm. In order to gloss over this gap in the evidence base, the quality standards (drawing on SIGN 156) have used to term 'at risk' without an adequate explanation of what this designation means – a definition has not been included within this statement. *If the quality standards are to use the definition included in SIGN 156 (Recommendation 2.5, page 23), any confirmed exposure (i.e. an answer of <u>any</u> alcohol consumption during pregnancy, regardless of quantity) will warrant a designation of "at risk" of FASD.* *Based on current birth rates, this data would mean 280,000 children each year would have confirmed pre-natal alcohol exposure within their health record, without any attempt at meaningful quantification of alcohol consumption. This means these standards would result in a major expansion of those deemed "at risk" of neurodevelopmental delay, potentially placing a significant burden on GPS, paediatricians and health visitors.*
12	Statement 2 (**Rationale**)	2	***'Antenatal appointments allow questions on alcohol consumption to be asked as part of <u>routine healthcare</u> throughout pregnancy...':*** *In the absence of any proposals to obtain informed consent for this process, the draft quality standards attempt to frame screening as discussions as part of routine antenatal care, when this is not the case. The inclusion of mandatory recording as a condition of open discussion is unprecedented in routine antenatal care. Any screening of this kind would necessarily have to be offered on a voluntary basis, with accompanying risks and benefits of such screens (in relation to the patient: the woman). This has not been adequately accounted for in the quality standards. Such benefits would have to be presented in light of the paucity of evidence on FASD, including a lack of conclusive evidence regarding the relationship between low-level alcohol consumption and harm.* *This proposal thwarts the ability of women to develop trusting, personal relationships with their healthcare providers. If a woman is unable to have a discussion with her midwife without the findings being transferred to her child's medical records, those most in need of support may be dissuaded from engaging with medical services. Essentially this proposal deprives women of access to a service (confidential discussion about alcohol use) other members of the population are entitled to as it makes access to that service contingent on her data being*

			shared on her child's medical record. The needs of these women have not been considered in the Equality Impact Assessment. This means the standard may well have the opposite effect of what it seeks to achieve: women struggling with alcohol consumption need access to confidential support and advice. Restricting that may harm both mother and baby.
13	Statement 2 (**Rationale**)	2	***'…The timing, quantity and frequency of alcohol use should be recorded in maternity records and then <u>transferred to the child's health records after birth</u>.':*** *This aspect of the quality standard goes far beyond the information gleaned by any validated screening tools (as included in SIGN 156) which are used to identify problem drinkers. The use of such tools would involve a robust informed consent process, therefore any process which involves the collection of <u>more</u> data, and the subsequent transferral of said data onto another's health records must also involve a robust informed consent process – which has not been included in these quality standards.* *In the absence of information on informed consent, the legal basis of this form of data processing (including the subsequent transfer of data post collection) has not been proven.* *With reference to current data protection requirements (GDPR), there must be a legal basis for processing of personal data before it is considered lawful. Article 6(1) of the GDPR sets out 6 legal bases. To process personal data about health, a controller (e.g. service providers) must have both a lawful basis under Article 6 <u>and</u> fall under an exemption in article 9. The purpose for recording information on alcohol consumption throughout pregnancy and subsequent transferral to a child's health record, as included in the quality statements, fails to meet a sufficient legal basis under Article 6 due to the following reasons:* • *The collection and subsequent transferral of information cannot be considered necessary to protect the vital interests of the data subject (i.e. the woman) or another natural person (current legal precedent – CP v CICA 2014 – unborn children do not reach this threshold) (6(d) GDPR).* • *This processing cannot be considered necessary in the performance of a task carried out in the public interest (the interest of an early diagnosis must be considered in light of: an uncertain evidence base concerning prenatal alcohol consumption and harm, the*

			use of widely criticised prevalence estimates, and a lack of evidence regarding care pathways post diagnosis) (6(e) GDPR); • *Finally, this type of processing cannot be considered necessary for the purposes contained in the draft quality standard, thereby overruling the interests and fundamental rights and freedoms of the data subject (i.e. the woman). On balance (the impact this collection of information could have on subsequent medical decision making and relationships v. an uncertain evidence base on consumption), it is clear that the fundamental rights and freedoms of women should be prioritised.*
14	Statement 2 (**Quality Measures: Structure**)	2	***'Evidence of local proformas or templates for maternity records which include sections to document information on alcohol consumption during pregnancy':*** *This measure could be burdensome documentation that may not be applicable to every patient. It must be acknowledged that HCPs have extremely limited time with each patient, and such a requirement may take time away from the needs of the individual patient. HCPs are best placed to make assessments concerning what information to document during antenatal appointments, and this may not concern alcohol consumption at all.* *Furthermore if such templates for maternity records reflect the model assessment forms issued alongside SIGN 156 (e.g. 'Sample FASD Assessment Form: Maternal Alcohol Use': includes the type of information on alcohol consumption, which this Quality Standard seeks to record), a duty to assess the reliability of women, with regard to their self-reporting, is placed on HCPs. This form of documentation would further embed an approach to scrutiny, rather than trust, within the patient/HCP relationship. Such an approach could be counterintuitive, leading to patients disengaging with healthcare services, rather than seeking support. Assessing the reliability of information could pave the way for further invasive measures, which is why an ethical assessment for this form of documentation is of utmost important. These quality standards, and SIGN 156 both fail to adequately engage with these ethical considerations and adverse impacts on the ongoing relationships between patient and HCP.*
15	Statement 2 (**Quality Measures: Structure**)	2	***'Evidence of local arrangements to ensure that maternity services transfer information on a mother's alcohol consumption in pregnancy to her child's health record after the birth':*** *In the absence of information on informed consent, the legal basis of this form of data processing (including the subsequent transfer of data post collection) has not been proven.*

			With reference to current data protection requirements (GDPR), there must be a legal basis for processing of personal data before it is considered lawful. Article 6(1) of the GDPR sets out 6 legal bases. To process personal data about health, a controller (e.g. service providers) must have both a lawful basis under Article 6 and fall under an exemption in article 9. The purpose for recording information on alcohol consumption throughout pregnancy and subsequent transferral to a child's health record, as included in the quality statements, fails to meet a sufficient legal basis under Article 6 due to the following reasons: • *The collection and subsequent transferral of information cannot be considered necessary to protect the vital interests of the data subject (i.e. the woman) or another natural person (current legal precedent – CP v CICA 2014 – unborn children do not reach this threshold) (6(d) GDPR).* • *This processing cannot be considered necessary in the performance of a task carried out in the public interest (the interest of an early diagnosis must be considered in light of: an uncertain evidence base concerning prenatal alcohol consumption and harm, the use of widely criticised prevalence estimates, and a lack of evidence regarding care pathways post diagnosis) (6(e) GDPR);* • *Finally, this type of processing cannot be considered necessary for the purposes contained in the draft quality standard, thereby overruling the interests and fundamental rights and freedoms of the data subject (i.e. the woman). On balance (the impact this collection of information could have on subsequent medical decision making and relationships v. an uncertain evidence base on consumption), it is clear that the fundamental rights and freedoms of women should be prioritised.*
16	Statement 2 (**What the quality statement means for different audiences**)	2	***'Service Providers':*** *This measure could be burdensome documentation (Maternity services: 'ensure that antenatal appointments include discussion and recording of alcohol consumption in pregnancy) that may not be applicable to every patient. It must be acknowledged that HCPs have extremely limited time with each patient, and such a requirement may take time away from the needs of the individual patient. HCPs are best placed to make assessments concerning what information to document during antenatal appointments, and this may not concern alcohol consumption at all.*

			Furthermore if such templates for maternity records reflect the model assessment forms issued alongside SIGN 156 (e.g. 'Sample FASD Assessment Form: Maternal Alcohol Use': includes the type of information on alcohol consumption, which this Quality Standard seeks to record), a duty to assess the reliability of women, with regard to their self-reporting, is placed on HCPs. This form of documentation would further embed an approach to scrutiny, rather than trust, within the patient/HCP relationship. Such an approach could be counterintuitive, leading to patients disengaging with healthcare services, rather than seeking support. Assessing the reliability of information could pave the way for further invasive measures, which is why an ethical assessment for this form of documentation is of utmost important. These quality standards, and SIGN 156 both fail to adequately engage with these ethical considerations and adverse impacts on the ongoing relationships between patient and HCP. *In the absence of information on informed consent, the legal basis of this form of data processing (the aforementioned recording information and ensuring 'systems are in place to transfer this information after the birth to GPs and health visitors for inclusion in the child's health records') has not been proven.* *With reference to current data protection requirements (GDPR), there must be a legal basis for processing of personal data before it is considered lawful. Article 6(1) of the GDPR sets out 6 legal bases. To process personal data about health, a controller (e.g. service providers) must have both a lawful basis under Article 6 and fall under an exemption in article 9. The purpose for recording information on alcohol consumption throughout pregnancy and subsequent transferral to a child's health record, as included in the quality statements, fails to meet a sufficient legal basis under Article 6 due to the following reasons:* • *The collection and subsequent transferral of information cannot be considered necessary to protect the vital interests of the data subject (i.e. the woman) or another natural person (current legal precedent – CP v CICA 2014 – unborn children do not reach this threshold) (6(d) GDPR).* • *This processing cannot be considered necessary in the performance of a task carried out in the public interest (the interest of an early diagnosis must be considered in light of: an uncertain evidence base concerning prenatal alcohol consumption and harm, the*

			use of widely criticised prevalence estimates, and a lack of evidence regarding care pathways post diagnosis) (6(e) GDPR); • *Finally, this type of processing cannot be considered necessary for the purposes contained in the draft quality standard, thereby overruling the interests and fundamental rights and freedoms of the data subject (i.e. the woman). On balance (the impact this collection of information could have on subsequent medical decision making and relationships v. an uncertain evidence base on consumption), it is clear that the fundamental rights and freedoms of women should be prioritised.*
17	Statement 2 (**What the quality statement means for different audiences**)	2	***'Healthcare professionals':*** *This measure could be burdensome documentation ('Midwives and GPs record information on a woman's alcohol consumption during pregnancy in her maternity records at antenatal appointments. They document the number and types of alcohol drinks consumed, as well at the pattern and frequency of drinking') that may not be applicable to every patient. It must be acknowledged that HCPs have extremely limited time with each patient, and such a requirement may take time away from more the needs of the individual patient. HCPs are best placed to make assessments concerning what information to document during antenatal appointments, and this may not concern alcohol consumption at all.* *Furthermore if such templates for maternity records reflect the model assessment forms issued alongside SIGN 156 (e.g. 'Sample FASD Assessment Form: Maternal Alcohol Use': includes the type of information on alcohol consumption, which this Quality Standard seeks to record), a duty to assess the reliability of women, with regard to their self-reporting, is placed on HCPs. This form of documentation would further embed an approach to scrutiny, rather than trust, within the patient/HCP relationship. Such an approach could be counterintuitive, leading to patients disengaging with healthcare services, rather than seeking support. Assessing the reliability of information could pave the way for further invasive measures, which is why an ethical assessment for this form of documentation is of utmost important. These quality standards, and SIGN 156 both fail to adequately engage with these ethical considerations and adverse impacts on the ongoing relationships between patient and HCP.* *In the absence of information on informed consent, the legal basis of this form of data processing (aforementioned recording of information and 'after birth, they pass this information*

			to the GP and health visitor in transfer of care documentation so that it is recorded in the child's health record.') has not been proven. *With reference to current data protection requirements (GDPR), there must be a legal basis for processing of personal data before it is considered lawful. Article 6(1) of the GDPR sets out 6 legal bases. To process personal data about health, a controller (e.g. service providers) must have both a lawful basis under Article 6 and fall under an exemption in article 9. The purpose for recording information on alcohol consumption throughout pregnancy and subsequent transferral to a child's health record, as included in the quality statements, fails to meet a sufficient legal basis under Article 6 due to the following reasons:* • *The collection and subsequent transferral of information cannot be considered necessary to protect the vital interests of the data subject (i.e. the woman) or another natural person (current legal precedent – CP v CICA 2014 – unborn children do not reach this threshold) (6(d) GDPR).* • *This processing cannot be considered necessary in the performance of a task carried out in the public interest (the interest of an early diagnosis must be considered in light of: an uncertain evidence base concerning prenatal alcohol consumption and harm, the use of widely criticised prevalence estimates, and a lack of evidence regarding care pathways post diagnosis) (6(e) GDPR);* • *Finally, this type of processing cannot be considered necessary for the purposes contained in the draft quality standard, thereby overruling the interests and fundamental rights and freedoms of the data subject (i.e. the woman). On balance (the impact this collection of information could have on subsequent medical decision making and relationships v. an uncertain evidence base on consumption), it is clear that the fundamental rights and freedoms of women should be prioritised.*
18	Statement 2 (**What the quality statement means for different audiences**)	2	***'Pregnant women':*** *These quality standards impose a normalisation of invasive screening, without due concern for the potential adverse impacts it could have. Rather than this form of routinisation, women should be told that this is a separate screening process, and not part of routine healthcare. Women should be informed of the benefits of such a screening, the potential impact it could have on their ongoing care, and how the information collected will be subsequently used. Women need to be informed of a robust and continuous informed consent*

			process before the screening, including information regarding the refusal of consent and the process for those who refuse to be screened. *This proposal thwarts the ability of women to develop trusting, personal relationships with their healthcare providers. If a woman is unable to have a discussion with her midwife without the findings being transferred to her child's medical records, those most in need of support may be dissuaded from engaging with medical services. Essentially this proposal deprives women of access to a service (confidential discussion about alcohol use) other members of the population are entitled to as it makes access to that service contingent on her data being shared on her child's medical record. The needs of these women have not been considered in the Equality Impact Assessment. This means the standard may well have the opposite effect of what it seeks to achieve: women struggling with alcohol consumption need access to confidential support and advice. Restricting that may harm both mother and baby.*
19	Statement 2 (**Source Guidance**)	2	***SIGN 156 (2019) Recommendation 2.1 (page 11):*** *We are concerned at how this recommendation will be used alongside Statement 2, in particular:* *"All pregnant and postpartum women should be screened for alcohol use with validated measurement tools by service providers who have received appropriate training in their use. All women should be advised not to consume alcohol in pregnancy; additionally those women drinking above the low-risk guidelines for the general population should be offered early, brief interventions (i.e. counselling and/or other services)."* *We are concerned with the inclusion of such screening methods without robust, ethical scrutiny, nor additional information for how such screening would take place in line with current standards of informed consent.* *We are further concerned that due to the revision SIGN has made (replacing the phrase 'risk of heavy alcohol use' with 'above the low-risk guideline for the general population') in order quantify a level of consumption which actions interventions, any woman who has answered more than 'never' in relation to alcohol consumption will be offered interventions when this may not be necessary. This phrasing has universalized the risk of adversely affected pregnancies,*

			increasing this risk of stigmatisation of women. *If service providers are to use validated screening tools (as referenced in SIGN 156) any answer over 'never' will amount to confirmed pre-natal alcohol exposure for diagnostic purposes, without any attempt to quantify a lower threshold for harm. As detailed in quality statements 3 and 4, this confirmation would see placing a child 'at risk' of neurodevelopmental impairment without due regard to the quantity of alcohol consumed. This is a stark departure from available evidence and would result in a major expansion of those deemed 'at risk' of neurodevelopmental delay, potentially placing a significant burden on GPs, paediatricians and health visitors.* *This source guidance makes no reference to any robust ethical assessment of the impact these changes could potentially have on women's medical decision making and on-going relationships with HCPs.*
20	Statement 2 (**Source Guidance**)	2	***SIGN 156 (2019) Recommendation 2.1.2 (page 12):*** *We are concerned at how this recommendation will be used alongside Statement 2, in particular:* *"The number of type(s) of alcohol beverages consumed (dose), the pattern of drinking and the frequency of drinking in pregnancy should all be documented. This information should be routinely recorded by the midwife in antenatal notes and communicated to the GP and health visitor in Transfer of Care documentation. This will ensure that PAE information (confirmed/confirmed absent/unknown) will be more easily accessed and remain within the child's records.'* *We are concerned with the inclusion of this mandate, which goes far beyond the information gained by validated screening tools, without robust, ethical scrutiny, nor additional information for how such screening would take place in line with current standards of informed consent.* *If service providers are to use validated screening tools (as referenced in SIGN 156, Recommendation 2.1) with this mandate for additional data collection, any answer over 'never' will amount to confirmed pre-natal alcohol exposure for diagnostic purposes, without any attempt to quantify a lower threshold for harm. As detailed in quality statements 3 and 4, this*

			confirmation would see placing a child 'at risk' of neurodevelopmental impairment without due regard to the quantity of alcohol consumed. This is a stark departure from available evidence and would result in a major expansion of those deemed 'at risk' of neurodevelopmental delay, potentially placing a significant burden on GPs, paediatricians and health visitors. *With reference to current data protection requirements (GDPR), there must be a legal basis for processing of personal data before it is considered lawful. Article 6(1) of the GDPR sets out 6 legal bases. To process personal data about health, a controller (e.g. service providers) must have both a lawful basis under Article 6 and fall under an exemption in article 9. The purpose for recording information on alcohol consumption throughout pregnancy and subsequent transferral to a child's health record, as included in the quality statements, fails to meet a sufficient legal basis under Article 6 due to the following reasons:* • *The collection and subsequent transferral of information cannot be considered necessary to protect the vital interests of the data subject (i.e. the woman) or another natural person (current legal precedent – CP v CICA 2014 – unborn children do not reach this threshold) (6(d) GDPR).* • *This processing cannot be considered necessary in the performance of a task carried out in the public interest (the interest of an early diagnosis must be considered in light of: an uncertain evidence base concerning prenatal alcohol consumption and harm, the use of widely criticised prevalence estimates, and a lack of evidence regarding care pathways post diagnosis) (6(e) GDPR);* • *Finally, this type of processing cannot be considered necessary for the purposes contained in the draft quality standard, thereby overruling the interests and fundamental rights and freedoms of the data subject (i.e. the woman). On balance (the impact this collection of information could have on subsequent medical decision making and relationships v. an uncertain evidence base on consumption), it is clear that the fundamental rights and freedoms of women should be prioritised.* *This source guidance makes no reference to any robust ethical assessment of the impact these changes could potentially have on women's medical decision making and on-going relationships with HCPs.*

21	Statement 2 (**Source Guidance**)	2	***'Alcohol-use disorders: prevention NICE guideline PH24: Recommendation 9':*** *This recommendation focuses on 'screening adults'. While it references screening during for alcohol use during antenatal appointments, it makes no reference to the mandatory recording and sharing of information – without quantification of consumption. These quality standards would mark a drastic expansion of the current guidance, when there is no consensus on evidence necessitating it.* *This source guidance makes no reference to any robust ethical assessment of the impact these changes could potentially have on women's medical decision making and on-going relationships with HCPs.*
22	Statement 2 (**Definitions of terms used in this quality statement**)	2	***'Pregnant women have information on their alcohol consumption recorded':*** *This definition with particular reference to defining the recording of information as 'routine antenatal care', marks an unprecedented and unjustified expansion of healthcare. This form of screening sits separate from routine healthcare and should be framed as such. The mandatory recording and transfer of information fundamentally changes the nature of private discussions between women and their trusted HCPs.* *This proposal thwarts the ability of women to develop trusting, personal relationships with their healthcare providers. If a woman is unable to have a discussion with her midwife without the findings being transferred to her child's medical records, those most in need of support may be dissuaded from engaging with medical services. Essentially this proposal deprives women of access to a service (confidential discussion about alcohol use) other members of the population are entitled to as it makes access to that service contingent on her data being shared on her child's medical record. The needs of these women have not been considered in the Equality Impact Assessment. This means the standard may well have the opposite effect of what it seeks to achieve: women struggling with alcohol consumption need access to confidential support and advice. Restricting that may harm both mother and baby.*
23	Statement 3 (**Quality Statement**)	3	***'Children and young people with physical, developmental or behaviour difficulties and probable prenatal alcohol exposure are referred for assessment.':*** *While ensuring referral for assessment is an undisputed, we hold concerns that this quality statement sees and*

			expansion of the diagnostic criteria. This would see a stark increase of those considered 'at risk', despite the lack of evidence of harm at lower levels of consumption. *As articulated in statements 1 and 2, there is no lower threshold below which recording is not required and any alcohol consumption in pregnancy will be evidence of confirmed pre-natal alcohol exposure under this proposal, placing a child "at risk" of neurodevelopmental impairment. As classic sentinel facial features of Fetal Alcohol Syndrome (FAS) are not required for a diagnosis of FASD under these standards, a child with neurodevelopmental impairments in 3 or more areas (eg problems with learning, attention, memory or language, poor problem-solving and confused social skills) with confirmed pre-natal alcohol exposure is a candidate for an FASD diagnosis.* *Nearly half of pregnancies are unplanned and alcohol use is common before pregnancy confirmation. It is suggested in the briefing paper around 40% of women have drunk some alcohol in pregnancy, however studies suggest this is overwhelmingly in the first trimester, with the proportion of women drinking into the second trimester falling dramatically. Based on current birth rates, this data would mean 280,000 children each year would have confirmed pre-natal alcohol exposure within their health record, without any attempt at meaningful quantification of alcohol consumption. This means these standards would result in a major expansion of those deemed "at risk" of neurodevelopmental delay, potentially placing a significant burden on GPS, paediatricians and health visitors.*
24	Statement 3 (**Rationale**)	3	***'Early diagnosis of FASD allows for early treatment and a better overall outcome.':*** *The framing of the rationale behind statement 3 is misleading and provides a prima facie justification for the unprecedented recording and sharing of private information.* *The quality and care which those diagnosed with FASD bears no relevance to the routine screening of women. We maintain that efforts should be made towards establishing adequate specialist treatment and care pathways, as opposed to fundamentally changing standards of antenatal care.*

25	Statement 3 (**What the quality statement means for different audiences**)	3	***'Service Providers':*** *The development of both training programmes for HCPs, and multidisciplinary teams with expertise in FASD are of the utmost importance. However, such developments, including the pathways for referral, must ensure that they are based on the best available evidence – acknowledging the uncertainty surrounding the relationship between alcohol consumption and harm – as opposed to a precautionary approach. Such an approach would work to reduce the potentially increased burden these quality statements impose on HCPs.*
26	Statement 3 (**What the quality statement means for different audiences**)	3	***'Healthcare professionals':*** *We are concerned that the quality standards, as drafted, will result in an increased burden on HCPs in making referrals. This is mainly due to the drastic expansion of diagnostic criteria. Despite the lack of evidence of harm at lower levels of consumption, there is no lower threshold below which recording is not required and any alcohol consumption in pregnancy will be evidence of confirmed pre-natal alcohol exposure under this proposal, placing a child "at risk" of neurodevelopmental impairment.*
27	Statement 3 (**What the quality statement means for different audiences**)	3	***'Children and young people with physical, developmental or behavioural difficulties who may have had exposure to alcohol before birth':*** *We agree that explicit consent is necessary for any referral for an assessment by an expert in FASD. Informed consent is paramount and should be extended to every aspect of these quality standards - including maternal alcohol screening.*
28	Statement 3 (**Definitions of terms used in this quality standard**)	3	***'Probable prenatal alcohol exposure':*** *The quality standard defines probable PAE on 'documentation that the biological mother consumed alcohol during the index pregnancy based on: reliable clinical observation, self-report or reports by a reliable source.'* *These draft standards fail to provide any additional definitions as to what amounts to a 'reliable clinical observation' (e.g. observation by who? Amount of time? Where this would take place and under what circumstances? How is reliable defined?) nor 'reports by a reliable source' (e.g. who amounts to a reliable source? How does this impact on a woman's relationships of trust with friends and family members? How is reliable defined?). Such a vague and potentially damaging definition is wholly inappropriate for inclusion in these quality standards.*

			Additionally, such a definition fails to account for the informed consent processes in which this information is acquired, and further embeds issues of 'reliability' into the documentation. This forces HCPs into a position of scrutiny, as opposed to trust, when treating their patients. *This proposal thwarts the ability of women to develop trusting, personal relationships with their healthcare providers. If a woman is unable to have a discussion with her midwife without the findings being transferred to her child's medical records, those most in need of support may be dissuaded from engaging with medical services. Essentially this proposal deprives women of access to a service (confidential discussion about alcohol use) other members of the population are entitled to as it makes access to that service contingent on her data being shared on her child's medical record. The needs of these women have not been considered in the Equality Impact Assessment. This means the standard may well have the opposite effect of what it seeks to achieve: women struggling with alcohol consumption need access to confidential support and advice. Restricting that may harm both mother and baby.*
29	Statement 4 (**Quality statement**)	4	***'Children and young people with <u>confirmed prenatal exposure</u> <u>or</u> <u>all 3 facial features associated with prenatal alcohol exposure have a neurodevelopmental assessment if there are clinical concerns':*** *Despite the lack of evidence of harm at lower levels of consumption, there is no lower threshold below which recording is not required and any alcohol consumption in pregnancy will be evidence of confirmed pre-natal alcohol exposure under this proposal, placing a child "at risk" of neurodevelopmental impairment. As classic sentinel facial features of Fetal Alcohol Syndrome (FAS) are not required for a diagnosis of FASD under these standards, a child with neurodevelopmental impairments in 3 or more areas (eg problems with learning, attention, memory or language, poor problem-solving and confused social skills) with confirmed pre-natal alcohol exposure is a candidate for an FASD diagnosis.* *Nearly half of pregnancies are unplanned and alcohol use is common before pregnancy confirmation. It is suggested in the briefing paper around 40% of women have drunk some alcohol in pregnancy, however studies suggest this is overwhelmingly in the first trimester, with the proportion of women drinking into the second trimester falling dramatically. Based on current birth rates, this data would mean 280,000 children each year would have confirmed pre-natal alcohol exposure within their health record, without any attempt at meaningful*

			quantification of alcohol consumption. This means these standards would result in a major expansion of those deemed "at risk" of neurodevelopmental delay, potentially placing a significant burden on GPS, paediatricians and health visitors. *While the development team at SIGN 156 have incorporated the phrase 'significant amounts of alcohol' within their recommendations on referral, to safeguard against "unmanageable increases in inappropriate referrals" (Recommendation 2.1.4, page 14), such an approach has not been included within these quality standards.* *The causes of neurodevelopmental impairment are complex and still not well understood. There is no good evidence to show lower levels of alcohol consumption in pregnancy cause neurodevelopmental impairment, yet these standards treat any alcohol consumption as having a causal role in the development of these difficulties. This will mean women are increasingly held responsible, if not accountable, for any neurodevelopmental challenges their child may face. The negative impact on both the woman and her relationship with her child should not be under-estimated.*
30	Statement 4 (**Rationale**)	4	***'A neurodevelopmental assessment is needed for a diagnosis of FASD… Confirmation of a diagnosis of FASD (or being at risk of FASD) ensures the right treatment, care and support while plans for longer-term management are being made.':*** *We are concerned with the inclusion of 'at risk' within this quality statement, without any explanation concerning what this designation means. As defined in SIGN 156 (recommendation 3.1.2. page 16), the 'at risk' designation is given when:* • *"There is confirmation of PAE,* • *The CNS diagnostic/descriptive criteria for FASD are <u>not</u> met, and* • *There is some indication of neurodevelopmental disorder in combination with a plausible explanation as to why the neurodevelopmental assessment results failed to meet the criteria for significant impairment (for example patient was too young; assessment was incomplete etc.)"*

			As the SIGN development team explains, the phrase from Canadian recommendation 5.2.1 "the estimated dose at a level known to be associated with neurodevelopmental effects", which was used to describe a threshold for PAE has been removed to make consistent with the UK CMO advice for no safe level of alcohol consumption during pregnancy. *This choice was taken in adherence to a precautionary approach, as opposed to being based on the best available evidence regarding alcohol consumption and harm. The result will be to see a vast expansion for those deemed being at risk.* *It is not clear whether these quality standards will use the same definition, but if so, this could have serious ramifications for services. Nearly half of pregnancies are unplanned and alcohol use is common before pregnancy confirmation. It is suggested in the briefing paper around 40% of women have drunk some alcohol in pregnancy, however studies suggest this is overwhelmingly in the first trimester, with the proportion of women drinking into the second trimester falling dramatically. Based on current birth rates, this data would mean 280,000 children each year would have confirmed pre-natal alcohol exposure within their health record without any attempt at meaningful quantification of alcohol consumption. This means these standards would result in a major expansion of those deemed "at risk" of neurodevelopmental delay, potentially placing a significant burden on GPS, paediatricians and health visitors.*
31	Statement 4 (**What the quality statement means for different audiences**)	4	***'When diagnosing FASD, healthcare professionals should create an environment that supports all those affected, and avoid blaming, stigmatising and inducing feelings of guilt in the parents':*** *Such an approach is of utmost importance when dealing with incidence of diagnosing FASD, yet these quality standards fail to make clear how this approach can be reconciled with mandatory screening and the wider institutionalised mistrust of self-reporting as included within the quality statements. Arguably stigmatisation is likely to increase if 'confirmed PAE' – with or without any attempt of meaningful quantification – is the first piece of information a Health Visitor sees when visiting a family. It is likely that already marginalized groups, such as those women who need additional support with alcohol consumption, will feel this increased stigmatisation more acutely.*

			The causes of neurodevelopmental impairment are complex and still not well understood. There is no good evidence to show lower levels of alcohol consumption in pregnancy cause neurodevelopmental impairment, yet these standards treat any alcohol consumption as having a causal role in the development of these difficulties. This will mean women are increasingly held responsible, if not accountable, for any neurodevelopmental challenges their child may face. The negative impact on both the woman and her relationship with her child should not be under-estimated.
32	Statement 4 (**Source Guidance**)	4	***SIGN 156 (2019) Recommendation 3.5 (page 23):*** *This recommendation makes clear:* *"Assessment of all children with a history of PAE was not thought to be practical. With the current universal developmental surveillance checks in place, health visitors should be aware of the potential increased risk and be proactive with early referral of children where there is cause for concern."* *However- there is no information as to how PAE will be recorded, other than 'confirmed/confirmed absent/unknown' (as included in SIGN recommendation 2.1.2 – listed alongside quality statement 2 within these standards). This could potentially see scrutiny of both the parents and child in unwarranted situations. This would undoubtedly place a huge burden on those HCPs, particularly GPs and health visitors, and jeopardize on-going relationships of trust.*
33	Statement 4 (**Definitions of terms used in this quality standard**)	4	***'Clinical concerns':*** *As articulated within these standards- neurodevelopmental assessment would take place if there confirmed PAE (not quantified) and cause for clinical concern. The definition for the phrase "cause for clinical concern" is extremely wide and vague:* *It is defined as: "Significant behavioural issues causing disruption to family and school, developmental delays that are affecting the child or young person's life, and failure to thrive physically and emotionally." This definition has been cited as 'expert opinion' with no reference to a source.*

			The causes of neurodevelopmental impairment are complex and still not well understood. There is no good evidence to show lower levels of alcohol consumption in pregnancy cause neurodevelopmental impairment, yet these standards treat any alcohol consumption as having a causal role in the development of these difficulties. This will mean women are increasingly held responsible, if not accountable, for any neurodevelopmental challenges their child may face. The negative impact on both the woman and her relationship with her child should not be under-estimated.
34	Statement 5 (**Quality Statement**)	5	***'Children and young people with a diagnosis of fetal alcohol spectrum disorder (FASD) have a management plan to address their needs':*** *Ultimately the focus of these Quality Standards should be ensuring the best management plan for treatment of those diagnosed with FASD to meet their individual needs. Ensuring this should be the first priority of emerging policy concerning FASD.*
35	**EIA**	N/A	***Equality Impact Assessment:*** *By their very nature, Equality impact assessment must be concerned with the individuals who are likely to be impacted at the time the Quality Standards apply. For Statements 1 and 2, this is indisputably women, yet this key group has been completely omitted from this assessment.* *The Equality Impact Assessment has failed to engage with the individual lives of women, and how such prescriptive standards could adversely impact their lives. For example, these standards presume that all women have the same relationship with alcohol – it fails to recognise individual circumstances of women (including their medical needs or religious views). It fails to account for their legal, ethical and medical rights in accessing treatment and care, and fails to consider any additional safeguards that may need to apply to ensure these are protected.*

Insert more rows as needed

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- Combine all comments from your organisation into 1 response. We cannot accept more than 1 response from each organisation.
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- Spell out any abbreviations you use
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