NATIONAL INSTITUTE FOR HEALTH AND   
CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1. Quality standard title

Fetal alcohol spectrum disorder

Date of quality standards advisory committee post-consultation meeting: 11 May 2021

1. Introduction

The draft quality standard for fetal alcohol spectrum disorder (FASD) was made available on the NICE website for a 4-week public consultation period between 6 March 2020 and 3 April 2020. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. During this period, a national lockdown began in response to the COVID-19 pandemic and development of the FASD quality standard was paused.

As the ability of some stakeholders to comment had been affected by the lockdown, a second consultation took place between 20th August and 18th September 2020.

Comments were received from 45 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the quality standards advisory committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the committee as part of the second meeting where the committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the committee.

Consultation comments that may result in changes to the quality standard have been included within this report. Comments suggesting changes that are outside of the process have generally not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the committee should read this summary alongside the full set of consultation comments. Appendix 1 of this report contains comments from registered stakeholders only.

1. General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

* Quality standard must be the beginning, not the end, of change.
* Would have transformative impact and significantly improve services.
* The scope of the quality standard does not address adults.
* Education, social services, fostering, adoption justice and prison services are not addressed or need more emphasis.
* Need to promote awareness of the risks of alcohol in pregnancy.
* No mention of genetics, genomics or clinical genetics.
* No mention of the need to ask about foetal alcohol exposure when seeing children with developmental difficulties and/or poor growth.
* Quality standard is closely related to ADHD and Autistic Spectrum Disorder, but this is not covered.
* Guidance is needed on how to determine probable and confirmed prenatal alcohol exposure given the limited evidence for thresholds of alcohol consumption.
* There are risks of being judgmental and blame that need consideration.
* Statements impact on privacy, patient confidentiality, data protection and consent.
* Statements assume that any alcohol consumed in pregnancy will be harmful to the fetus.
* Quality standard does not involve women in discussions to make informed decisions about their care.

Stakeholders were invited to respond to 4 general questions at consultation.

#### Consultation question 1: Does this draft quality standard accurately reflect the key areas for quality improvement?

Stakeholders made the following comments:

* Accurately reflects key areas for improvement.
* Statements 1 and 2 are key priorities, but statements 3 and 4 are ‘woolly’.

#### Consultation question 2: Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be to be for these to be put in place?

Stakeholders made the following comments:

* Systems are not in place but feasible to implement with partnerships and information sharing agreements.
* Systems are in place to collect data.
* Systems are in place, but not the processes to collect information.

#### Consultation question 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?

Stakeholders made the following comments:

* Statements are achievable with partnerships and information sharing agreements.
* Resources will need to assigned to FASD services, but this will result in a more effective and efficient use of resources. Currently the target population is using resources, often in an endless circle of incorrect / partial diagnoses, inappropriate referrals and treatment.
* There is a lack of professionals with FASD skills and knowledge; few places have dedicated multidisciplinary team diagnostic services.
* Resources for community paediatrics are extremely stretched; services would need extra doctors, speech and language therapists, psychologists (clinical and educational) and administrative support.
* All that is needed is a standard paediatrics / CAMHS-based pathway assessment of symptom presentation(s); a diagnosis of FASD makes no material difference to the care package that child requires.
* There are inadequate services available to assess all children awaiting ordinary neurodevelopmental assessment at present.

#### Consultation question 4: Do you have an example from practice of implementing the guideline that underpins this quality standard?

Stakeholders made the following comments:

* Local trust has 2 specialist midwife posts based in a substance use team. All women are asked about alcohol use in pregnancy; and a fast-track referral pathway is in place for women who are alcohol dependant.

### Consultation comments on Equalities Impact Assessment

* There are no references to the impacts on women, a group that would be significantly affected.
* EIA should consider impacts of asking about / recording alcohol consumption on consent, on relationships with healthcare professionals and on access to antenatal care. These impacts would affect different population groups and could introduce inequities.

1. Summary of consultation feedback by draft statement
   1. Draft statement 1

Pregnant women are given advice not to drink alcohol during pregnancy at their first contact appointment.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

#### Statement

* Statement wording is appropriate, measured, and reflects the UK Chief Medical Officers (CMO) guidelines that there is no known safe level of alcohol consumption.
* The public is still largely unaware of CMO guidelines from 2016 regarding alcohol in pregnancy.
* Statement would help reduce other risks to a pregnancy from alcohol consumption such as miscarriage, preterm birth, low birthweight etc.
* Statement should promote “No alcohol; No risk” as a straightforward interpretation of the CMO guidelines.
* Message should be ‘no alcohol’ not the ‘safest approach’ as this implies some alcohol is safe.

#### Concerns and potential adverse impacts

* Statement prevents healthcare professionals from being free to tailor their advice and support according to women’s needs and preferences.
* Inflating the risks of inadvertent alcohol consumption can cause extreme anxiety and lead to the termination of wanted pregnancy.
* There is no information on how women can be advised and supported to stop drinking.

#### Advice

* Important to give CMO advice at first contact as there is still confusion over risks of drinking when pregnant.
* Is the statement referring to the first booking appointment or the first time a healthcare professional sees a pregnant woman, for example when providing pregnancy test results?
* Advice should be given at ‘midwife booking appointment’ (8-12 weeks gestation) as the first contact appointment may be an emergency or unscheduled appointment.
* Advice should be ongoing throughout pregnancy not just at first contact.
* GPs no longer perform antenatal care and people can book to see their midwife without seeing a GP.
* 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 guidelines).
* Discussing the risks to the fetus of drinking in pregnancy may cause anxiety.
* Discussions should be non-judgmental and women offered support; training and awareness raising is needed to achieve this.
* Information needed on what verbal and written advice entails.
* Training for professionals giving the advice should draw on best practice from the Greater Manchester Health and Social Care Partnership and other areas.

#### Measures

* Appropriate data sets can be set up to capture the data without undue expense.
* May need audits to collect information.

### Issues for consideration

* Is the 'safest approach' message correct or should it be ‘no alcohol; no risk’?
* When should advice be given? Can it actually be given at 'first contact'?
* NICE recently consulted on a draft antenatal guideline: It says ‘provide early pregnancy information’ at point of referral but what about self-referral? It also says ‘discuss and give information’ at booking appointment and only here is alcohol consumption explicitly referenced.
* How can the statement be changed to improve what it says about providing support?
* How can anxiety be reduced? Would adding the CMO text ‘The risk of harm to the baby is likely to be low if you have drunk only small amounts of alcohol before you knew you were pregnant or during pregnancy’ help?
  1. Draft statement 2

Pregnant women have information on their alcohol consumption recorded throughout their pregnancy.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

#### Potential benefits of statement

* Information on alcohol consumption in pregnancy allows the correct diagnosis to be made for children with developmental delay and this allows for appropriate support.
* Lack of this information is a common barrier to the diagnosis of FASD in children and young people.
* Such information is often not available for children when adoption or social care is needed.
* Current recording of alcohol consumption is inconsistent between areas.
* Collecting information on alcohol consumption is important for wider maternity care as it is associated with increased risks of miscarriage and low birthweight.

#### Concerns and potential adverse impacts

* What is the benefit of a diagnosis of FASD over a diagnosis of developmental disorder for a child or young person?
* It is not proportionate to collect and transfer information for all women.
* Recording information on alcohol consumption could deter pregnant women from engaging in a confidential conversation with a healthcare professional especially if the person does not want it to be shared.
* Statement deprives women of a confidential discussion about alcohol use other members of the population are entitled to.
* Recording information would undermine trust between a healthcare professional and a pregnant woman; those who most need support would be alienated.
* Women who decline to give information on alcohol consumption may be concerned their fitness to parent would be questioned, including a risk of referral to social care.
* Statement does not cover tailored support for those with complex social factors as set out in CG110 [Pregnancy and complex social factors](https://www.nice.org.uk/guidance/cg110).
* Recording information could cause women to experience stigma, feel anxious or guilty and lead to self-blame during pregnancy and after birth about child health and development.

#### Recording information

* Women should be asked sensitively, in a non-judgmental and supportive manner using best practices.
* Who records the information and decides whether it is shared when there are different professionals involved in providing care?
* More emphasis needed on support and what it comprises, including support to help reduce ongoing alcohol use during pregnancy, for problem drinking or alcohol dependency.
* Recording of alcohol consumption across pregnancy needs to be accompanied with reiteration of the CMOs’ advice.
* The role that partners and other close family members have in supporting an alcohol-free pregnancy should be recognised.
* There is not enough time at antenatal appointments to discuss / record alcohol consumption; midwives and health visitors are already overworked.
* The pattern and frequency of alcohol consumption should be recorded at every antenatal appointment.
* Should questions be asked at every antenatal appointment for all women, or should a more tailored approach be used based on discussions at the first antenatal appointment?
* Midwives are best placed to decide what information to document during antenatal appointments and should have autonomy to tailor their advice and support according to women’s needs.

#### Transfer of information to the child record

* Statement wording should make clear it includes transfer of information to child records.
* Information on mother’s alcohol consumption should be transferred to the child’s record in all cases.
* It is not proportionate to transfer information to the child’s record in all cases.
* Information should only be transferred to the child’s medical record if it is directly about the child, such as how they were born. Transfer of any other information should only take place where a woman has given her explicit and informed consent.
* A system where significant alcohol issues are shared with paediatricians and discussed with the woman would be preferable to transferring all information on alcohol consumption to the child’s record.
* Transfer is important for children in care or who are adopted as this information is often not known and prevents diagnosis.
* What information needs to be transferred to the child’s record?
* Smoking and other information that has clinical need is already put onto the child discharge summary record.

#### Widen what is recorded and the sharing of information

* Helpful to measure meconium biomarkers as a continuing measure of alcohol consumption during pregnancy.
* Social workers may have information from pregnancy pre-proceedings/case conferences which need to be captured in the child’s record and not just the mothers.
* Information about prenatal alcohol use should also be recorded in social care documents.

#### Consent

* There is no discussion with the woman on informed consent, purpose of collecting data, how the data will be shared or used in the future.
* Consent should be sought to ask about alcohol consumption, to record the information and transfer it to the child record.
* Disclosure of alcohol use is important to allow support to limit alcohol use during pregnancy but should be confidential to the woman’s health record.
* Explicit consent is required for information to be transferred to the child’s record. It should not rely on implied consent. There are circumstances where transfer can take place without consent, but this would depend on individual circumstances.
* It would introduce mandatory screening for all women and would not be part of routine antenatal care.

#### Measures

* Self-reporting of alcohol consumption may not be reliable and underrepresent drinking habits.
* Process measure could pressure healthcare professionals to persuade women to agree to recording of information.
* Maternity co-operation notes do not include alcohol consumption as a routine question; data will need to come from midwife records in primary and secondary care.
* Maternity Data Set does not currently collect information in proposed measures.
* Annual audit of maternity records would help ensure statement is implemented.
* The way in which women are asked about alcohol consumption and whether the person asking has been trained should be measured.

#### Other (including legal issues)

* No ethical consideration has been given.
* Transferring information about a woman’s alcohol consumption onto her child’s health records may represent a breach of the Human Rights Act 1998 and European Convention on Human Rights (which protect private and confidential information).
* Statement is unlawful as it does not / may not comply with the General Data Protection Regulations.
* Proposal does not / may not meet the basic legal requirements regarding informed consent.
* Potential to open the door to women facing legal consequences for their actions while pregnant.
* The competing interests between maternal privacy rights and future children’s rights to information are not considered.
* Does not / may not comply with General Medical Council (GMC) guidance on confidentiality or the Nursing & Midwifery Council code.
* Strongly recommend further engagement with stakeholders and the public.

### Issues for consideration

* Should this statement be merged with statement 1 (so that giving advice is combined with capturing information)?
* What needs changing to ensure the statement does not undermine trust in the healthcare professional and deter women from speaking openly and seeking support?
* How can information on alcohol consumption be asked for / recorded without creating blame / anxiety / stigma?
* Should the statement say more about what support could be provided? If so, what can be said?
* How does recording information on alcohol consumption improve maternity care?
* Can / should information be recorded for everyone / at every appointment?
* What information on alcohol consumption should be recorded and what information should be transferred?
  1. Draft statement 3

Children and young people with physical, developmental or behavioural difficulties and probable prenatal alcohol exposure are referred for assessment.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

#### Potential benefits

* Early identification and intervention leads to a better outcome.
* Prenatal alcohol exposure is often not considered and children with FASD are incorrectly diagnosed with other behavioural disorders.
* Lack of FASD diagnosis means the criteria to access other services for support (such as services for learning disability or autism) are not met.

#### Concerns and potential adverse impacts

* Would greatly increase the number of children considered ‘at risk’ and referred resulting in a significant burden on healthcare services. This is due to having no threshold for the level of prenatal alcohol exposure.
* Women could be held responsible for any neurodevelopmental challenges their child may face; this would have a negative impact the woman and her relationship with her child.
* Explicit consent is needed before referral.
* Reference to probable prenatal alcohol exposure is not needed. Children and young people with ‘physical, developmental or behavioural difficulties’ should be getting reviewed by their schools/GPs and referred as necessary.
* Statement omits the role of the health visiting service.
* It is unclear how the statement would be delivered.

#### Target population

* Care experienced children should be added to list of children who should be referred for an assessment given the prevalence of FASD among this cohort.
* Statement does not address diagnosis for adults.
* All children with significant physical, developmental, cognitive or behavioural concerns should be referred for specialist assessment/input. Probable prenatal alcohol exposure’ may be relevant to consider as an aetiology.
* ADHD and ASD pathways and assessments should consider FASD.
* Should include those with confirmed prenatal alcohol exposure as well as probable.
* Statement may benefit from a qualifier such as ‘significant’ in relation to any physical, developmental or behavioural difficulties to prevent unmanageable demand. Around 40% of pregnancies are likely to be alcohol exposed and as many children have some sort of behavioural difficulty.
* Distinctive features of other genetic conditions need to be excluded.

#### How can it work based on current services?

* Audience descriptor actions are extracontractual for GP contract holders and can only be enforced if within the GP contract. This is a resource issue as well as a commissioning and contractual issue for NHS England, NHS Improvement and CCGs who commission GP services and integrated pathways.
* There are not enough professionals with expertise / experience or clinics to carry out the assessments.
* Some referrals to trusts with FASD experts do not happen as CCGs do not commission the service or because they require approval through exceptional funding panels.
* Services that do diagnose often discharge in the same appointment preventing access to support.
* Many children will be already known to services such as Child and Adolescent Mental Health Services (CAMHS) or be in other pathways / services (e.g. ADHD, ASD).

#### Training

* Lack of training means FASD is not being considered and referrals are not happening.
* Awareness / training is needed for healthcare professionals (including paediatricians, psychiatrists, GPs midwives, psychologists and health visitors), teachers, commissioners, social care staff and those working with adopted and looked after children.
* Reference to ‘experts in FASD’ should be replaced with “professionals with additional training in FASD” so that is achievable. ‘Expertise’ should be replaced with ‘training or experience in assessing for FASD’.

#### Referral

* GPs will not have direct access to specialists with expertise in FASD. All children with neurodevelopmental disorders are sent to community paediatrics who then assess the child appropriately.
* Most / some referrals come from schools rather than primary care.
* Birth parents, carers, education and social care professionals should also be able to refer.
* Assessment of multi-source referral information should not be the duty of the referring GP but of the service providing FASD assessments.
* Referral would be to a multidisciplinary team rather than to a health professional trained in FASD.
* The team is likely to be headed by a paediatrician or CAMHS specialist and include input from psychologists, speech and language specialists, occupational therapists and physiotherapists.
* Discussion with GP needs to be done in a very sensitive way to avoid stigma. It will not be appropriate to name alcohol as the origin of a child’s difficulties prior to assessment.
* Would the statement work by creating a regional specialist FASD clinic as a one stop shop or by embedding FASD into existing commissioned services?

#### Definitions

* Definitions need greater detail, e.g. what is a reliable clinical observation?
* Physical, developmental or behavioural difficulties:
* Characteristic facial features should be removed as this will encourage services to dismiss the case if facial features are not present.
* There will often need to be input from clinical genetics to ensure that any other contributing genetic conditions are excluded prior to concluding they are due to prenatal alcohol exposure.
* Emotional regulation and executive function should be included.
* Probable prenatal alcohol exposure:
* Inclusion of self-reporting suggests that it may not be reliable. The value of it being recorded in Statement 2 is therefore questionable.
* It is not clear how probable prenatal alcohol exposure differs from confirmed prenatal alcohol exposure in Statement 4.

### Issues for consideration

* Is statement 3 sufficiently distinct from statement 4?
* Does statement 3 correctly reflect the SIGN recommendation which is for a referral that considers PAE as a possible cause of a neurodevelopmental disorder?
* Would the statement overburden services? The SIGN guideline uses the term ‘significant’ to reduce referral numbers.
* Few services exist, actions are extracontractual for GPs and referrals require agreement by exceptional funding pattern. Is it realistic to have a statement in these circumstances?
* Does the language need changing from ‘professionals with expertise in FASD’ to ‘professionals with additional training in FASD’?
* Who should refer, and who would they refer to?
* Definition of physical, developmental or behavioural difficulties needs improving.
  1. Draft statement 4

Children and young people with confirmed prenatal alcohol exposure or all 3 facial features associated with prenatal alcohol exposure have a neurodevelopmental assessment if there are clinical concerns.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

#### Statement

* Statement wording provides balance between providing access and preventing excess unnecessary referrals in a stretched system.
* The lack of a threshold for the level of prenatal alcohol exposure would greatly expand the number of children referred (compared to the Canadian guideline) and result in a significant burden on healthcare services.
* Children and young people with symptoms/behaviours sufficient to warrant neurodevelopmental assessment should be referred anyway as part of standard neurodevelopmental referral pathways. If this is happening, there should be no increase in referral rates.
* Statement should include those with probable prenatal alcohol exposure as well as those with confirmed prenatal exposure.
* Clinical concerns may only arise as a child gets older and some aspects of neurodevelopmental assessment are age dependent.
* There are not sufficient resources to implement it; and not enough health professionals with the required expertise.

#### Potential adverse impacts

* Women could be held responsible for any neurodevelopmental challenges their child may face.
* Diagnosis can affect the mental health of mother and child, their relationship, and the functioning of the family unit, so need to be carefully considered.

#### Neurodevelopmental assessment

* Neurodevelopmental assessment should include mental health comorbidities, anxiety or depression.
* All children where there are concerns should have a comprehensive bio-psycho-social assessment.
* Whilst FASD needs to be recognised as an individual disorder, assessment, care and support should be framed within a comprehensive and holistic neurodevelopmental assessment.
* Assessment should consist of putting the child at the centre of a process; determining the child’s primary and secondary areas of cognitive/social /emotional /sensory- motor/behavioural difficulties and the interactions between them.
* FASD may co-exist with other conditions. It is not clear how a child with neurodevelopmental symptoms secondary to other causal factors, who has confirmed PAE, will avoid being categorised as FASD.
* Where FASD is a possible diagnosis, differential diagnoses (such as an underlying genetic disorder) should be fully considered, especially in cases where prenatal alcohol exposure is unconfirmed or low.
* Developmental trauma or traumatic childhood experiences is not referred to as part of the assessment yet there are high levels of comorbidity with FASD.
* No role for a clinical geneticist or genetics service is identified.
* A pilot study of FASD assessment in NHS Ayrshire and Arran compared specialist versus mainstream models (utilising CAMHS & Community Paediatric Services) and found FASD pathways and assessment processes to be less favourable compared with mainstream neurodevelopmental pathways.
* Those providing neurodevelopmental services will need training on FASD.
* Statement needs to be clear that neurodevelopmental assessment is multidisciplinary and should include education psychologists, physiotherapists, clinical psychologists, paediatric neuropsychologists.

#### Measures

* Structure measure should refer to healthcare professionals with expertise in ‘neurodevelopmental assessment and FASD’ or ‘neurodevelopmental assessment and training or experience in assessing for FASD’.
* Outcome: Could educational engagement be measured instead of educational attainment?
* Measure the number of joint multidisciplinary clinics available in localities. This would evidence the ability of neurodevelopmental paediatricians, AHPs and CAMHS colleagues to work together in making the diagnosis.

#### Definition of clinical concerns

* Definition is wide, vague, not based on source guidance and could lead to unnecessary referrals blocking neurodevelopmental pathways.
* Use of the word ‘delays’ could be potentially misleading to those not trained in FASD.
* Fails to take into account that children may present with cognitive, emotional or academic problems.

#### Definition of neurodevelopmental assessment

* An assessment does not simply determine if a set number of cognitive “domains” are impaired; this risks a diagnosis by numbers and children with difficulties that are better explained by an alternative diagnosis being labelled as FASD.
* Domains are overlapping and not consistent with what is known about how the brain functions. The appropriate approach is a neuropsychological evaluation in conjunction with an expert medical assessment.
* The domain “affect regulation” is not clear by definition. Brain structures like the cerebral cortex include functions of sensory and motor control.
* Abilities assessed in one domain may influence how the child fares on others, so the overlap in domains could lead to “double counting”.

#### Suggestion for additional definition

* Confirmed prenatal alcohol exposure is not defined.

### Issues for consideration

* Is the focus on one aspect of the assessment process (the neurodevelopmental assessment) correct?
* Is there significant overlap between statement 3 and statement 4?
* If the statement is retained, how can the definition of clinical concerns be improved?
* Are amendments needed to improve the definitions and descriptions of neurodevelopmental assessment?
* Is the statement about setting up FASD specific services, or about ensuring existing services that do neurodevelopmental assessments consider FASD and have staff that are trained to do this?
  1. Draft statement 5

Children and young people with a diagnosis of fetal alcohol spectrum disorder (FASD) have a management plan to address their needs.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

#### Statement

* Management plans can be life-changing if they are implemented in cooperation with the families and reviewed as a person ages.
* This statement should be the main focus of the quality standard.
* Many diagnosed with FASD are left to find support externally to the NHS, and to construct their own management pathway.
* Use “support plan” rather than “management plan”.

#### Target population

* Statement should apply to children with a diagnosis of FASD or at risk of FASD.
* Management and support plans must continue into early adulthood.
* Statement needs to address / reference transition into adulthood.

#### Management plans

* Management plan must be co-produced with family, caregivers and the person with FASD in appropriate developmental or transitional stages.
* Plan must have multidisciplinary input.
* Health visitors and school nurses should be included in the plan.
* Who would take responsibility for managing the plan?
* Primary care is central to assisting and monitoring any care plans.
* An FASD lead should be included so there is a point of contact for families.
* Audience descriptors should include training programmes for social care and educational professionals on managing FASD.
* Plan needs to cover social care and educational needs, not just health needs.
* How does the management plan link to an Education, Health and Care Plan?

#### Resource impact

* There may not be sufficient resources to implement the plans.
* Services identified in plans must be provided.
* The majority of commissioned support services have eligibility criteria of LD/ASD so are not available to people with FASD.

#### Measures

* Process measure data source is unrealistic, the denominator (the number of children and young people diagnosed with FASD) is not measurable.
* Measurement possible with a clear audit strategy, but may need guidance as to what this entails and how to delineate the impact of a good compared to simple plan.

### Issues for consideration

* Does the description of the management plan in the statement rationale reflect guideline? SIGN has produced a sample management plan which is a brief 2-page document which lists the areas assessed, issues identified, recommendations, responsibility and timeframe.
* Is transition to adulthood adequately covered? The statement rationale says the plan should cover immediate and long-term needs and may need to be staged / reviewed at intervals.
* Are education and social care adequately covered?

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# Appendix 1: Quality standard consultation comments table – registered stakeholders

Notes: [ ] Text in square brackets at the start of a comment has been inserted by NICE

Consultation column indicates whether the comments were received during the 1st or 2nd consultation.

Table is ordered by section of the quality standard the comments relate to.

| **ID** | **Stakeholder** | **Consultation** | **Section of quality standard** | **Comments[[1]](#footnote-1)**  Please insert each new comment in a new row |
| --- | --- | --- | --- | --- |
| 1 | Adoption UK | 1 | General | Overall, the quality statements go a long way to reflecting the key areas for quality improvement. Adoption UK is particularly pleased to see draft quality standard recognise the need for management plans to address the needs of those living with FASD in Statement 5. |
| 215 | Balance | 2 | General | The health and social impacts of FASD in the UK are significant. FASD is a public health issue, which urgently requires further attention. There is a clear lack of evidence and prioritisation of FASD, leading to gaps in support services as well as a lack of acknowledgement of the condition within policy documents, professional education programmes, clinical practice and many uninformed professionals.  Estimates indicate that FASD is more common than autism spectrum disorders (ASD), yet in contrast to services for ASD there is no coordinated investment in diagnosis or support. Only a few places in the UK have dedicated multidisciplinary team diagnostic services that provide the important information families need in order to put appropriate support in place.  Most of the evidence currently available for the UK is based on estimates from international work, plus a small number of UK-based research studies. We propose that in order to address this important public health issue, FASD needs to be appropriately recognised in health and social policy, prioritised through research and service provision, and adequately addressed in education of professionals likely to come into contact with pregnant women, as well as individuals with FASD.  Specifically, we recommend that there is investment in: accurate data collection of alcohol exposure pre conception and during pregnancy; sustained follow-up of women and children; active case ascertainment studies in the general population, and specific populations, e.g. care-experienced children and young people; service design and professional education to ensure coordinated diagnosis and support can be provided to affected individuals and their families. This will provide accurate prevalence figures and allow robust estimates of the significant cost of this condition in the UK. |
| 7 | Birthrights | 1 | General | We have grave concerns about the timing of this consultation, as set out in the letter sent to NICE jointly from us and bpas on 27 March 2020. Whilst this may not have been fully foreseen when the consultation was opened, we and all maternity organisations are under significant pressure as a result of the Covid-19 pandemic. We believe that the proposed Quality Standards infringe unlawfully upon a woman’s privacy and jeopardise her access to a full and confidential discussion with her midwife about her care needs and any matters of concern (see detailed points below). They therefore require thorough consultation and evaluation. Given the pressure organisations supporting pregnant women are currently under due to the Covid-19 crisis, it is not feasible for these standards to be given the appropriate scrutiny at this time. It is our view that the failure to take measures to ensure appropriate consultation before publication of these standards may leave NICE open to legal challenge. We call on the consultation to be reopened at a time when maternity, and other interested organisations, are better able to engage and provide the appropriate scrutiny. |
| 216 | Birthrights | 2 | General | TO NOTE THAT THESE COMMENTS HAVE BEEN UPDATED & EXPANDED SINCE THE FIRST ROUND OF CONSULTATION IN SPRING 2020. |
| 217 | Birthrights | 2 | General | These proposals represent a significant interference with a woman’s right to a private and family life under Article 8 of the European Convention on Human Rights. As currently set out, they fail to respect legal requirements for informed consent and data privacy in healthcare (see detailed comments below).  The evidence base does not support these proposals. They appear to be based on an assumption that any alcohol consumed in pregnancy will be harmful to the foetus. There is no compelling evidence that this is the case. Whilst the current (2016) policy position is to promote abstinence in relation to drinking in pregnancy, this was explicitly based on the precautionary approach. Studies have sought consistently to find evidence of harm at low to moderate levels of alcohol consumption and have failed to do so.  We are very concerned that these proposals risk woman-blaming for a complex, multi-faceted outcome, will compromise relationships between birthing people and their healthcare providers, and will prove a disincentive for engaging with care for those who may most benefit from (non-judgemental) support. |
| 30 | Blackburn with Darwen Borough Council Public Health and Wellbeing Team | 1 | General | This is much awaited guidance in an area that has been explored thoroughly but is not always looked at as a whole. We need a system and if this can be made to work, partnerships formed, information shared, assessments and referrals made, the children who suffer this preventable condition can be helped and treated in accordance with their individual needs. |
| 252 | British Psychological Society | 2 | General | Other comments on this quality standard.  The diagnosis of the facial features associated with FASD is an expert opinion and attention needs to be drawn to the possible overlap with other syndromes (see appendix D Appendix D: Syndromes with constellations of features which overlap with FASD from Australian Guide to the diagnosis of FASD Updated February 2020; <https://www.fasdhub.org.au/contentassets/32961d4a5cf94de48ebcf985c34d5456/australian-guide-to-the-diagnosis-of-fasd_all-appendices_feb2020.docx.pdf>)  Although this guideline presents an algorithm it needs to be made very explicit that there are no definitive diagnostic tests for FASD. Where FASD is a possible diagnosis, differential diagnoses (such as an underlying genetic disorder) should be fully considered, especially in cases where prenatal alcohol exposure is unconfirmed or low. Referral to a clinical geneticist is recommended. |
| 82 | East Herts and Area FASD Support Network | 1 | General | The East Hertfordshire and Area FASD Support Network would like to express its support for the draft NICE Quality Standard on FASD. Taken as a whole the draft Quality Standard would, if implemented by local NHS CCGs and Trusts, significantly improve services for those with FASD in Hertfordshire. |
| 86 | East Herts and Area FASD Support Network | 1 | General | If we have a criticism of the Quality Standard it is that the needs of adults with FASD are not met. We urge NICE to rectify this unfortunate situation as soon as possible, although we understand that it isn’t possible at this particular time.  We urge NICE to adopt the Quality Standard as drafted. |
| 285 | Healthwatch UK | 2 | General | HealthWatch-UK is concerned that this Quality Standard seems to be at odds with pre-existing NICE antenatal guidance CG62. We believe NICE needs to be much clearer about what help should be offered to women who have difficulty in stopping drinking. There is a danger of unintended consequences if there is a double standard with respect to the content and confidentiality of pregnant women’s medical records, and if they are treated merely ‘as a means to an end’ rather than ‘as an end in themselves’. Details of our concerns are given below. |
| 300 | medConfidential | 2 | General | The issues we raise in the consultation response are in the response and interactions between statements and practice, rather than finding the statement objectionable in of itself: providing care to newborns with FASD is a good thing; incentivising behaviour which hides it, is not. Unfortunately, in attempting to do the former, it does the latter. |
| 301 | medConfidential | 2 | General | Many of the issues we raise below are not covered in the formal Statements of policy, but in the wider text of how to implement it.  The guidance being consulted upon proposes that, if a woman tells her doctor she has drunk just one unit of alcohol at any time during pregnancy, her child’s medical record will automatically be flagged as at risk of FASD. This will potentially have significant adverse consequences for mother and child in interactions with other services.  This consequence seems both disproportionate and beyond the medical advice cited by NICE. The clinical advice is outside the scope of medConfidential’s remit, but we focus on that if NICE are to achieve this goal, that NICE may wish to approach it fundamentally differently.  We note that the Equality Impact statement fails to comment on the impact on women or mothers in any meaningful sense, which suggests consequences have been missed, and the data flows are unlikely to be lawful due to a deeply flawed impact assessment (NICE would not be held liable as a data controller, since it is not one in this context, but it would be the care providers against whom an ICO complaint would need to be lodged). Most notably, the equality impact assessment omits whether there is any divergence by protected characteristics on who has alcohol values recorded within their record, and to what extent the values given are true and accurate for different categories – the guidance notes that the majority of people have “under one” unit recorded, which we presume is actually zero, and the guidance authors simply do not believe that figure for those people, but do believe the figure for others. This seems somewhat inconsistent.  If NICE wishes to place all new born children somewhere on the FASD spectrum, which appears to be the clinical aim, rather than asking all parents questions and deriving risk scores from the parent, there would be none of the data driven concerns if this was to be an informed process conducted for every newborn, normally with the informed consent of their parent.  Deriving this from data alone is prima facie sheer lunacy, of the kind that the UK hasn’t seen in the three weeks since the 2020 A’Level results came out.  Most notably, this automated score from the parent would appear to be an automated decision about the child within the meaning of GDPR, and no consideration seems to have been given about the automated nature of this data processing. It appears to be assumed by NICE that because it could be done this way, it should be.  We would suggest that NICE conduct a meaningful and substantive impact assessment on how, in practice, for example, race and class would impact how answers are treated by clinicians and respondents, and whether this therefore is a fully evidence-informed clinical intervention.  We support the comments of others about the rigour (or lack thereof) of the Equality Impact Assessment for this consultation which seems to lack any sense of acknowledgement of the need for trust in the relationship between a pregnant woman and her care team, and the potential knock on effects for other aspects of care. We do not suggest that such issues can’t be mitigated, we simply raise severe concerns that this guidance has failed to even try. As such, any updated draft of the guidance should go back through the full process after a reset and wider solicitation of input at earlier stages.  When NICE responds to this consultation, we ask that NICE justify any remaining data and automated aspects of this guidance against each of the Caldicott Principles issued by the National Data Guardian. |
| 302 | NHS England and NHS Improvement | 2 | General | Managing FASD is a multidisciplinary task and services may not be commissioned locally to support this. |
| 309 | NHS England and NHS Improvement | 2 | General | This an opportunity to work closely with primary care, so we could reiterate the importance of a joined up approach from primary and secondary care on this, particularly related to pre-conceptual care and communication regarding those who are known to have existing issues. |
| 310 | NHS England and NHS Improvement | 2 | General | Information governance: We share the concerns of birthrights and others that potentially every drop of alcohol consumed could make its way to the child records. We would favour a system whereby significant alcohol issues are shared with paediatricians (as with other relevant concerns) and that this would be discussed with the woman. |
| 112 | NOFAS-UK | 1 | General | NOFAS-UK welcomes the draft NICE Quality Standard on FASD. Standing with our sister organisations in the FASD UK Alliance, we are pleased to convey the overwhelmingly positive feedback this draft Quality Standard has received from stakeholders across England who responded to an online questionnaire. |
| 120 | NOFAS-UK | 1 | General | A comment on accessibility NOFAS-UK has tried to make information about this NICE Quality Standard process accessible to adults with FASD. See for example: http://www.nofas-uk.org/WP/wp-content/uploads/2020/03/20200307-Policy-Matters-Draft-NICE-QS.pdf. We humbly suggest that NICE with its access to leading experts throughout the NHS, commit to providing easy-read and visual materials when seeking consultation on areas that affects those with neurodevelopmental conditions. We regret that it was not possible to get input more broadly from adults with FASD on the actual draft Quality Standard because the material was not presented in an accessible way. |
| 121 | NOFAS-UK | 1 | General | Overall feedback  NOFAS-UK has been advocating for increased attention to prevention, diagnosis and support for those with FASD since 2003. As an organisation we greatly appreciate this transformative impact this NICE Quality Standard on FASD will represent. We stand ready as an organisation, as members of the FASD UK Alliance, and as stakeholders to work to ensure that this leads to actual change in the lives of those with FASD. We appreciate there are pressures on the system in these unusual days. However, bringing the challenges posed by FASD to the surface should not be viewed as a burden to the structures. Rather, it will over the long-term ease pressures by ensuring some of this country’s most vulnerable individuals and families receive the appropriate, individualized and targeted support they need and deserve thereby avoiding the current squandering of precious NHS resources that are being misused because the underlying cause of the challenges is being so widely and tragically misunderstood. While we of course understand the reasons for the relaxation of the deadline for this Quality Standard on FASD and we salute and share our deep respect and appreciation for all those who are working on the frontline of the coronavirus crisis, we look forward to the prompt finalization of this Quality Standard as an urgent priority as soon as this crisis passes.  Over the longer-term it will take resolve to ensure this Quality Standard on FASD leads to meaningful change. We understand that it can often take a couple of years for Quality Standards to begin to show impact on local levels. But we do not consider this a static process. We look forward to working together with relevant entities, organisation and agencies to maximise the impact this Quality Standard can have in creating brighter futures.  We urge NICE to plan now to fill in the gaps by starting the process for NICE guidance on FASD, addressing those areas that are England-specific and not covered by the Scottish SIGN guidance and especially urgently addressing the rest of lifespan for those with FASD. Children and young people with FASD grow into adults with FASD. And to our collective shame, too many adults with FASD are struggling today, undiagnosed and unsupported. |
| 122 | Peterborough family FASD support Group & Field of Enterprise Training & Consultancy | 1 | General | I would like the standard to include education as the impact of FASD has far reaching implications as well as direct links into EHCP planning |
| 123 | Peterborough family FASD support Group & Field of Enterprise Training & Consultancy | 1 | General | I also feel that there needs to be coverage to support individuals (and families) post 18. Speaking as someone with a 20-year-old who has just been diagnosed and also a nearly 18-year-old struggling to get adult support for her FASD. However, I do welcome this for children and young people because it will make getting a diagnosis easier than it has been for three of our children with previous care experience. |
| 129 | Peterborough family FASD support Group & Field of Enterprise Training & Consultancy | 1 | General | My wife and I provide community family support for all those in a wide geographical region who are affected by FASD. Families and affected children and young people. There needs to be a recognition that there is informal support in the tertiary sector, both physical and virtual and we need to develop a pathway to refer into this network and support it.  There also needs to be a mechanism to develop further community support groups in the tertiary sector. |
| 130 | Peterborough family FASD support Group & Field of Enterprise Training & Consultancy | 1 | General | In supporting adults with FASD who have their own child(ren) I suspect that there is a need for the services surrounding that family to offer support to the ‘disabled’ parent that gives them a fair opportunity, where appropriate, to care for their own child who may not be affected in the same way as their parent. Believing that FASD means that an adult cannot parent is still too common a starting point for assessments and becomes a self-fulfilling prophecy. |
| 149 | Royal College of Paediatrics and Child Health | 1 | General | There is no mention of the need to ask about foetal alcohol exposure when seeing children with developmental difficulties and/or poor growth. |
| 150 | Royal College of Paediatrics and Child Health | 1 | General | This document should include, when necessary and with consent, seeking information from the antenatal service and other informants, such as partners etc. |
| 151 | Royal College of Paediatrics and Child Health | 1 | General | It is also important to specifically ask about the time before a woman knew she was pregnant and also ask about a history of binge drinking pre-pregnancy as this is a strong predictor of fetal alcohol spectrum disorder. |
| 152 | Royal College of Paediatrics and Child Health | 1 | General | The reviewer was happy with this quality standard. |
| 342 | Royal College of Paediatrics and Child Health | 2 | General | [Other quality standards to be considered]  In the FASD population reference to ADHD and Autistic Spectrum Disorder guidance would be useful. |
| 153 | Royal College of Physicians | 1 | General | The RCP is grateful for the opportunity to respond to the above consultation.  We would like to endorse the response submitted by Royal College of Paediatrics and Child Health (RCPCH). |
| 162 | Tees Valley Durham and North Yorkshire Neurological Alliance | 1 | General | There will be considerable difficulty delivering the standards in a post Covid-19 environment. The skill is not in local settings and scant regard is paid to the services delivered by the voluntary sector. CCG’s and GP’s should be encouraged to collate an FASD register because lack of data is a barrier to quantifying the need for training and skill in FASD. The guidelines are just the beginning of an essential process because intel and action are in short supply. |
| 166 | Tees Valley Durham and North Yorkshire Neurological Alliance | 1 | General | **Improving Outcomes**  There should be mention of improving access to social care because social workers cause a great deal of distress and failed relationships through lack of understanding about FASD. Families are blamed and sometimes social workers resort to removing adopted or fostered children or young people through Family Tribunal/legal process which is costly, time consuming, detrimental to the mental health of all concerned and unnecessary. Social workers should be involved in all the multidisciplinary discussions and reporting and provide a degree of advocacy and signposting to support services and welfare benefits. Again, parents reported that fragmented working relationships between services were a significant stumbling block to resolving difficulties or accessing other avenues of support.   Time to diagnosis for people with FASD   Experience of NHS services for people with FASD   Skilled advocacy in social care   Health-related quality of life for people with FASD and their carers   Educational attainment of people with FASD |
| 311 | The National Organisation for FASD (formerly NOFAS-UK) | 2 | General | [The National Organisation for FASD (formerly NOFAS-UK) submitted information during to the second consultation as an addition to what had previously been supplied].  Addendum to Submission to NICE Quality Standard on FASD Consultation  The National Organisation for FASD (formerly NOFAS-UK) commissioned a nationally representative poll of 2000 adults on 16-17 September 2020.  Conducted by OnePoll, the results show that 91% of women and 85% of men believe that children should have access to information about harm done to them in utero to help them get diagnosis and support (only 1% of women disagreed or strongly disagreed and 2% of men).  85% of women and 74% of men believe drinking alcohol in pregnancy should be noted as part of routine antenatal care (only 5% of women and 6% of men disagreed or strongly disagreed).  These finding show massive public support exists for the intent of the draft Quality Standard on Fetal Alcohol Spectrum Disorder (FASD) being produced by the National Institute for Health and Care Excellence. They stand in direct counterpoint to recent hyped media stories regarding inclusion of information of alcohol-exposed pregnancies in records.  Information about exposure to alcohol in pregnancy is the first step toward diagnosis and is needed for the more than 90% on the FASD spectrum without the distinctive facial features. Every child with a disability has the right to the correct diagnosis. Having the right diagnosis can be the key to understanding and support. It can be life changing. It is critical that this information is not only included in the mother’s notes but also transferred to the child’s records. Their lives are forever determined by exposure to a teratogen in the womb. Correct diagnosis is also critical to ensuring limited resources are not wasted at great cost to society, let alone the cost to those who may be misdiagnosed or undiagnosed.  Using the tone of the recent public debate, to deny those with who have been prenatally exposed to this teratogen access to this critical piece of information is far from being a ‘nanny state’ and more like Big Brother controlling what they can and cannot see of their own health information. How these discussions with the public are framed is important, both in the public sphere and also in the consultations with pregnant women. With further training for midwives and practitioners, these conversations can be had in an open-ended and supportive way. “No shame, no blame,” is the mantra of those seeking broader awareness of FASD, including birth mothers.  Any current or forthcoming studies that are focused on current experiences of pregnant women reflect a status quo National FASD does not accept as best practice. They do not address what would be possible in future once proper training and awareness is more widespread. There is evidence internationally and increasingly so domestically that training matters. National FASD has helped provide information to more than 16,000 midwives over the past several years and will continue to focus on this in the coming year.  While we understand the limits of this sort of poll, these results reflect what we’ve been hearing from members of the public and experts for years. It also backs what we hear from experts about the urgent need for access to information about alcohol exposed pregnancies in making diagnosis of FASD. It will help ensure that women who need help, if they are unable to stop drinking, will receive that support.  Dr Cassie Jackson, Director of the Centre for FASD in Suffolk said, “Lacking this key information when children come for assessment can mean the difference between receiving a diagnosis that will facilitate appropriate support from services moving forward; and continuing undiagnosed, leaving children and young people potentially misunderstood for a lifetime. Accurate documenting of alcohol use during pregnancy is absolutely necessary for timely and accurate diagnosis.”  Jan Griffin said, “Smoking is recorded in pregnancy, so too should alcohol consumption. I’m a birth mother to a child with FASD and I wish I had been advised better. The right of the young child to an early diagnosis would be any mother’s wish. As a birth mum, I am astounded that some women are thinking only of misplaced privacy. The purpose of noting alcohol consumption is not to nanny state nor cast shame or guilt. As in smoking, genetic disorders, hereditary disabilities the purpose is to access early diagnosis of a condition, be it Down syndrome, cystic fibrosis, low birth weight and FASD. We have an opportunity to help mothers like myself avoid unnecessary outcomes.”  Joanna Buckard said, “For 16 years as a trainer in this field I have repeatedly heard adoptive parents and carers’ frustration at not being able to access diagnosis. Especially heartbreaking are cases of looked after children moving toward independence with no diagnosis and no support. National FASD welcomes the coming NICE Quality Standard on FASD and believes it will be a game changer.”  Sharon Jackson said, “As mum to five young adults with FASD, having a diagnosis and understanding what their problems are is key to their well-being. Why would anyone want to deny access to key information for diagnosis?”  Dr Carolyn Blackburn, Birmingham City University who has authored books on FASD and education said, “We made a commitment to valuing the first 1001 days from conception to 24 months, why then do argue against asking questions that honour this commitment and protect children?”  About the poll  OnePoll conducted the poll on 16-17 September 2020. 2000 adults were polled in a nationally representative sample. They were first informed the questions addressed substance use in pregnancy and were given the opportunity to opt out. They were asked the following questions.  Question 1: To what extent do you agree or disagree with the following statement? 'A child should have access to the right diagnosis and support if their brain was harmed by a substance in the womb before they were born'  • 91% women strongly agree/agree  • 85% men strongly agree/agree  • 88% overall agree, strongly agree  • Only 1% women and 2% of men disagreed or strongly disagreed  Question 2: Smoking during pregnancy is noted as a routine part of antenatal care. Drinking alcohol while pregnant can be more harmful to the unborn child, however this is currently not routinely noted during antenatal care. To what extent do you agree or disagree with the following statement? 'Drinking alcohol during pregnancy should be noted as part of routine antenatal care'  • 85% women strongly agree/agree  • 74% men strongly agree/agree  • 80% overall strongly agree/agree  • Only 5% of women and 6% of men disagreed or strongly disagreed  Loose Women - twitter poll, 17 September 2020  A popular daytime tv show raised these issues in their show in 17 September and conducted an informal twitter poll. Despite having had some serious misinformation about the prevalence and presentation of FASD on their show (which focused only on currently reported cases of Foetal Alcohol Syndrome), nevertheless their poll of 1767 people still showed the majority of people support inclusion of this information in the child’s records too. The British Pregnancy Advisory Service does not speak for all women.  Poll of young people’s understanding of the CMO guidance and risks of alcohol in pregnancy  In April-May 2020 the National Organisation for FASD commissioned OnePoll to survey the gap in understanding that young people have about the risks of alcohol in pregnancy and FASD. OnePoll polled 2000 18-25 year olds across the UK in a nationally representative survey. The results showed that:  • 26% could not identify the current Chief Medical Officers’ guidance that the safest approach is not to drink alcohol at all if pregnant or if you could become pregnant.  • 80% said if they or a loved one (e.g. a sister or friend) were pregnant, that having the occasional drink of alcohol would not be ok. However, their understanding of WHY this is important is limited.  • Only 17% understood that alcohol can cause the most long-term harm to the baby when compared with other substances such as heroin, crack cocaine and smoking.  • Only 22% knew that the acronym FASD stands for Fetal  Alcohol Spectrum Disorder.  • 49% are getting information about these issues from social media, while only 40% are getting if from a teacher and only 36% from a doctor, midwife or nurse.  April-May 2020 poll of 2000 adults regarding the CMO guidance  In addition, OnePoll conducted a one-question survey for us of 2000 nationally representative adults to see if they could recognise the CMO guidance. The good news is that awareness has improved over the same question asked last year.  • 82% of adults (all ages) identified the CMO guidance in April 2020. When broken down by age, this poll supported the above finding with 75% of 18-24 year olds who identified the CMO guidance.  • 76% of adults (all ages) identified the CMO guidance in April 2019. 67% of 18-24 year olds identified the CMO guidance in this poll, so there has been some improvement in the past year. One significant change in the year since is that there has been a push in social media by Greater Manchester Health and Social Care Partnership’s #Drymester campaign which might explain this, although that is supposition and wasn’t tested in our polling.  However, there is no room for complacency as this means a significant proportion of the population still has not taken on board the message that it’s safest to avoid alcohol during pregnancy despite this being the official guidance of the UK’s chief medical officers since 2016. These polls prove the need to ensure all women who are pregnant or who could become pregnant understand the nature of the risks of alcohol in pregnancy and are made aware of the CMO guidance. They demonstrate the absolute importance of ensuring these discussions are held during antenatal visits. To get beyond the facile claims of a ‘nanny state’ people need to understand why it’s important to avoid alcohol and better understand what FASD is.  These findings directly support the NICE Quality Standard’s intention to ensure women are provided the facts in antenatal visits and have the opportunity to discuss alcohol this throughout their pregnancies, with the goal of unlocking support for the women if needed and brighter futures for all. This means the entire health and social care workforce needs to be trained up on these issues as highlighted in the draft Quality Standard.  For more information about these polls (including the data), please see:  <https://nationalfasd.org.uk/learn-more/resources/research/> |
| 31 | British Medical Association | 1 | General / Statement 2 | [The previous submission referred to in these comments is a submission made during topic engagement].  Given the evidence we submitted previously will be carried over, the BMA is not planning to submit a further formal response. However, having discussed with colleagues in our ethics department there was one specific concern I wanted to raise with you. This relates to the impact on patient confidentiality of the transfer of alcohol consumption information from the mother’s record to that of the child. The principle of implied consent for information sharing amongst the healthcare team applies to providing direct care to an individual patient. The draft standard proposes the transfer of information (which is potentially highly sensitive) about the mother to the record of the child – we feel it would therefore be important for NICE to clarify the lawful and ethical basis for the transfer of this information. |
| 19 | Birthrights | 1 | General EIA | Despite the clear impact these draft Quality Standards pose to the equal treatment of healthcare to women there are no references to the impact on women in the Equality Impact Assessment. - Whilst we recognise the need for appropriate care and support for children affected by FASD, including those who are not in the care of their biological mothers, the impact these standards would have on women must be taken into account.  The Equality Impact Assessment needs to recognise the impact on women, including their right to decline medical screening and testing, the impact on relationships with healthcare professionals in both the antenatal and postnatal periods and the risk that the proposed Quality Standards will jeopardise access to antenatal care. As stated above, Birthrights’ and Birth Companions’ research on the experiences of women facing multiple disadvantage ([Holding It All Together 2019](https://www.birthrights.org.uk/wp-content/uploads/2019/09/Holding-it-all-together-Full-report-FINAL-Action-Plan.pdf)) found that women often had fragile relationships of trust with caregivers and were afraid of disclosing information or making choices that they feared might result in judgment or social care scrutiny – this was particularly true for women with mental health needs and younger women. Asking repetitively for women to disclose levels of drinking is likely to damage these relationships further, or potential destroy them and result in women avoiding care altogether. This needs to be accounted for in the EIA. |
| 20 | Birthrights | 1 | General EIA | It is highly concerning that 2.3 states “draft standard 2 aims to ensure that more groups have confirmation of prenatal alcohol exposure”. Whilst it is clearly important that all individuals with neurodevelopmental needs are able to access appropriate assessment and support, this presupposes that maternal drinking is the cause of (a very broad spectrum of) neurodevelopmental needs in the absence of evidence to support this. It also unlawfully places the theoretical ‘interests’ of an unborn foetus – which lacks legal personhood – above those of the woman by introducing seemingly mandatory screening and collecting data on ‘proportion of antenatal appointments attended where alcohol consumption is recorded’ as a primary data source. |
| 230 | Birthrights | 2 | General EIA | Despite the clear impact these draft Quality Standards pose to the equal treatment of healthcare to women there are no references to the impact on women in the Equality Impact Assessment. - Whilst we recognise the need for appropriate care and support for children affected by FASD, including those who are not in the care of their biological mothers, the impact these standards would have on women must be taken into account.  The Equality Impact Assessment needs to recognise the impact on women, including their right to decline medical screening and testing, the impact on relationships with healthcare professionals in both the antenatal and postnatal periods and the risk that the proposed Quality Standards will jeopardise access to antenatal care. As stated above, Birthrights’ and Birth Companions’ research on the experiences of women facing multiple disadvantage ([Holding It All Together 2019](https://www.birthrights.org.uk/wp-content/uploads/2019/09/Holding-it-all-together-Full-report-FINAL-Action-Plan.pdf)) found that women often had fragile relationships of trust with caregivers and were afraid of disclosing information or making choices that they feared might result in judgment or social care scrutiny – this was particularly true for women with mental health needs and younger women. Asking repetitively for women to disclose levels of drinking is likely to damage these relationships further, or potential destroy them and result in women avoiding care altogether. This needs to be accounted for in the EIA. |
| 231 | Birthrights | 2 | General EIA | It is highly concerning that 2.3 states “draft standard 2 aims to ensure that more groups have confirmation of prenatal alcohol exposure”. Whilst it is clearly important that all individuals with neurodevelopmental needs are able to access appropriate assessment and support, this presupposes that maternal drinking is the cause of (a very broad spectrum of) neurodevelopmental needs in the absence of evidence to support this. It also unlawfully places the theoretical ‘interests’ of an unborn foetus – which lacks legal personhood – above those of the woman by introducing seemingly mandatory screening and collecting data on ‘proportion of antenatal appointments attended where alcohol consumption is recorded’ as a process measure. |
| 66 | British Pregnancy Advisory Service | 1 | General EIA | 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. |
| 331 | Royal College of Midwives | 2 | General EIA | Equality Impact Assessment:  The RCM is concerned that women, as a group who will be significantly impacted by the proposals in this quality statement (particularly statements 1 and 2) have not been considered in the Equality Impact Assessment. The Committee should not move forward with the proposals in this quality statement before conducting and Equality Impact Assessment which considers women as a group. |
| 335 | Royal College of Obstetricians and Gynaecologists | 2 | General EIA | We are concerned that women have not been considered in the Equality Impact Assessment, despite being a group who will be significantly impacted by the proposals in this quality statement. It is imperative that an Equality Impact Assessment be conducted which considers women as a group affected by these proposals. |
| 174 | University of Southampton | 1 | General EIA | The Equality Impact Assessment states that no equality issues have been identified. The ways in which these guidelines would restrict the behaviour of, and the potential to adversely affect the care of women is a clear equality issue. This should have been assessed. |
| 21 | Blackburn with Darwen Borough Council Public Health and Wellbeing Team | 1 | Question 1 | Yes this draft accurately reflects key areas for improvement |
| 113 | NOFAS-UK | 1 | Question 1 | NICE through its public consultation process asked: “Does this draft quality standard accurately reflect the key areas for quality improvement?”  The feedback received by the FASD UK Alliance is a resounding “yes!”  The draft Quality Standard focuses on five statements that cover most aspects of FASD.  Quality statement 1: Advice on alcohol consumption in pregnancy  Quality statement 2: Maternal alcohol use in pregnancy  Quality statement 3: Referral for assessment  Quality statement 4: Neurodevelopmental assessment  Quality statement 5: Management plan  These five areas are definitely key to improving quality of care related to FASD. We asked people, “What would be the biggest change in your life if your local CCG or NHS Trust implemented these Quality Standards? As one respondent said, “FASD families would feel believed and validated, and able to better advocate for their children. It would hopefully prevent more incidences of babies born with FASD. Thank you!” Another person replied, “I as a mother would know that my reports of concerns were understood by doctors, nurses and teachers, that it was not our poor parenting. My adult son may have a diagnosis and an understanding of why he found his time in education so, so difficult. He could request support for assessment of his skills to find the most suitable employment. Most of all he would be able to make informed decisions and choices to manage these aspects of his life.”  That said, when finalized, the NICE Quality Standard on FASD must be the beginning, not the end, of change needed in the NHS and across England more broadly.  • Interdepartmental governmental change also is needed.  • More should be done earlier to promote awareness of the risks of alcohol in pregnancy – through schools and public awareness raising generally.  • Women should receive information about the risks of alcohol in pregnancy when they first consult with their GP surgeries for contraceptive advice.  • There also is a strong sense that more needs to be done to address the diagnosis and support of adults with FASD.  • NICE should urgently take on the task of establishing guidance for adults with FASD.  • Intensive attention to FASD is needed in education, social services (including fostering and adoption services), justice and prison services, and other departments that support those who are vulnerable. |
| 371 | Royal College of Psychiatrists | 2 | Question 1 | Public health advice and monitoring of alcohol use in pregnancy – yes  Statements 3 and 4 are very woolly and could mean anything. Routinely screening all children exposed to alcohol in-utero, let alone stating that they all need full assessment for FASD in its own right - no |
| 382 | Scottish Health Action on Alcohol Problems (SHAAP) | 2 | Question 1 | All five statements are important areas for quality improvement for the prevention, diagnosis and management of FASD. |
| 336 | Royal College of Paediatrics and Child Health | 2 | Question 1&Question 2 | The reviewer believes that this quality standard accurately reflects the key areas for quality improvement, this is supported by local systems and structures that are in place to collect data for the proposed quality measures.  However, the reviewer noted that the statements in this draft quality standard may not be achievable by local services. (Please see references). |
| 22 | Blackburn with Darwen Borough Council Public Health and Wellbeing Team | 1 | Question 2 | Systems not in place but feasible to implement with partnerships and information sharing agreements |
| 337 | Royal College of Paediatrics and Child Health | 2 | Question 2 | Collecting this information may be extremely tricky and the reviewer believes that processes are not currently in place. This would take significant time. |
| 371 | Royal College of Psychiatrists | 2 | Question 2 | There are inadequate services available even to assess all children awaiting ordinary neurodevelopmental assessment at present, so if another pseudo-diagnostic group (ie FASD) is added in this just adds demand to overburdened services. If a child with in-utero alcohol exposure presents with symptoms suggestive of ADHD or ASD, they should be getting referred to ND CAMHS or paeds teams anyway. |
| 23 | Blackburn with Darwen Borough Council Public Health and Wellbeing Team | 1 | Question 3 | Statements achievable with partnerships and information sharing agreements. Resource need possibly balanced by potential savings overall for each LA? |
| 114 | NOFAS-UK | 1 | Question 3 | Effective use of resources  With this public consultation NICE seeks input regarding net resources available to implement these draft Quality Standard. Undoubtedly this will be a concern for CCGs and Trusts that are strained already due to budget cuts and the recent coronavirus crisis. NOFAS-UK understands that looking head-on at the challenges of addressing FASD requires the NHS and CCGs and the intercollegiate system to think in a new way. But this isn’t ‘adding on’ a new population into services. It is merely viewing a wide segment of the population that is already using NHS services through a different lens.  • The reality is that those affected by FASD are already in the system at a great cost. Steps outlined in this Quality Standard will allow a more efficient and effective use of limited resources, rather than sending families on an endless circle of misdiagnoses or incomplete diagnoses and inappropriate referrals. This ineffective waste of resources then pressures other parts of the system when those interventions fail because they are not FASD-informed and the individuals spiral as a result.  • To deny individuals with FASD access to diagnosis and appropriate support on funding grounds is simply unacceptable and hypocritical. The UK received some £11.6 billion in alcohol duties in 2018-2019.3 We simply do not accept any argument that says the funding is not available, it’s about priorities. Surely preventing FASD and providing diagnosis and support for those completely innocent beings who were affected for life by alcohol before they drew their first breath should be the first in line for the use of those funds.  • We encourage the National Audit Office to explore the savings that might come across intergovernmental departments by having individuals with FASD appropriately diagnosed and supported, as well as the savings that would come from investing in public awareness and prevention of future cases.  • We also encourage Government to initiate a Green Paper to explore a more comprehensive response across Government to challenges posed by FASD. |
| 338 | Royal College of Paediatrics and Child Health | 2 | Question 3 | The resources for community paediatrics are already extremely stretched, even before the current pandemic, most places haven’t managed to absorb the suggestions for ex premature babies to be assessed at five years yet.  Services would need extra doctors, speech and language therapists, psychologists (clinical and educational) and the associated admin support. |
| 371 | Royal College of Psychiatrists | 2 | Question 3 | It is more likely that children exposed in-utero will come from complex social situations, with possible looked-after status and social care involvement. Making pseudo-diagnoses runs the risk of distracting from central issues of neglect and abuse. Paying professionals to produce lengthy reports on a condition that currently has no official status is also a waste of public resources, when the ‘diagnosis’ makes no material difference to the care package that child requires ie if ADHD symptoms, needs ADHD evidence-based treatment, if conduct disordered in presentation, needs CD evidence-based treatment as per other NICE guidance. Just need standard paeds/ CAMHS-based pathway assessment of their symptom presentation/s |
| 24 | Blackburn with Darwen Borough Council Public Health and Wellbeing Team | 1 | Question 4 | The local substance misuse midwife has submitted case studies/examples of concepts underpinning this guidance in practice currently |
| 106 | Blackburn with Darwen Borough Council Substance misuse service | 1 | Question 4 | Example of current local practice:  The local Trust has 2 specialist midwife post based within the substance use team providing continuity during the antenatal and postnatal period, individualised care planning and close multiagency approach with the family at the centre of all care provision.  All women are asked about alcohol use in pregnancy. For women who are alcohol dependant a fast track referral pathway is in place to enable pregnant women to be fast tracked for inpatient alcohol detox and close follow up and support upon discharge.  Close liaison with health and social care colleagues, hospital maternity and neonatal services to share information in relation to maternal alcohol use so that baby is followed up appropriately.  Case Study / Client story.  We were just a normal happy family until one day, a road traffic accident took my 3 year old daughter`s life.  After that I turned to drink every day, and my mental health was all over the place. For 10 years I didn’t live, I just existed, I pushed all my friends and family away until it was just me and the drink. I was always being sectioned, but I never engaged with any workers as I didn’t believe they could ever help me.  I was always trying to kill myself; I had hit rock bottom and I just didn’t see any way up. That was until I found out I was pregnant. My head was all over the place. I really didn’t know what to do. I went to the doctors who referred me to Inspire to see the midwife there (I was in a very bad place at the time). Anyway, something told me I could believe and trust the midwife, so I opened and told her everything. I felt like she never judged me (and after ten years of not trusting anyone). I felt like she believed in me and not just that, I felt like she really cared and wanted to help (like it was not just a job/case to her). She referred me to all the right agencies and before I knew it, I was getting the right help and feeling better in myself.  Since being under the care of the midwife, my key worker, my mental health worker and psychiatrist, I have not had a drink in 9 months.  Eleven weeks ago, I gave birth to a beautiful little boy. The support before and after from all the team has been amazing, I could not have done it without them. Not just that, it has even helped my family because they have got their daughter back.  We are so glad of the support we have had because like my family say, the way I was going before Christmas, I would not be here now.  I am so thankful of the help and support available to me because I could not have done it otherwise, and my child would not have come home with me. |
| 200 | AIMS - the Association for Improvements in the Maternity Services | 2 | Statement 1 | We are concerned about the lack of evidence-base for this statement.  It is controversial to suggest that maternity services should be advising all women to abstain from alcohol during pregnancy, and we cannot support this approach. The need for this recommendation is not supported by the current evidence base, and we are concerned that NICE is unable to support the quality statement via its usual careful consideration of available evidence, to include, for example, evidence about whether there are susceptibilities within some families. Also relevant is the discussion in our further comment below (comment 2) about the need to build trust in the relationship between service users and health care professionals, which depends vitally on honest information sharing.  The evidence-base, on which women can base their decisions, is weak. We need better evidence to inform women about the risks of alcohol during pregnancy so that they can make their own informed decisions: the blanket abstinence recommendation is unhelpful and risks undermining honest conversations between the pregnant woman and health care professionals. |
| 201 | AIMS - the Association for Improvements in the Maternity Services | 2 | Statement 1 | If the maternity services wish to support pregnant women to reduce alcohol consumption, this is more likely - evidence of the recommendation permitting (see comment 1) -  to be effective within a continuity of carer relationship and following the provision of easily accessible pre-conception guidance (to enable some women to address the issue of alcohol consumption before they become pregnant). It is also possible that women who want to address issues of alcohol consumption, who are provided with sources of support to help them to do so, are more likely to engage in this if they are not expected to disclose details of their current levels of consumption to the doctor or midwife: this suggests that there may be a contradiction between quality statements 1 and 2 which needs to be further examined.  Thus we are not sure that these quality standards will lead to the positive impact intended. To reduce the incidence of FASD, we suggest that a broader programme of change is necessary encompassing (a) action at the societal level (in the UK, we have a widespread acceptance of alcohol, with drinking cultures - including amongst young people - that need to be addressed for FASD to be significantly reduced; this is because no pregnant woman lives in a vacuum, but acts within their context); and (b) a wider focus on family alcohol consumption, including mothers and fathers, pre-conception and during pregnancy. In this way, a shift away from a maternal-centric paradigm presented in these Quality Standards is likely to improve the effectiveness of any programme. Discussion suggests that father’s preconception alcohol consumption, for example, may be a significant factor in FASD development. |
| 210 | Balance | 2 | Statement 1 | It is estimated that 41.3% of women in the UK consume alcohol during pregnancy; the fourth highest in the world. Popova, S., et al., Estimation of national, regional, and global prevalence of alcohol use during pregnancy and foetal alcohol syndrome: a systematic review and meta-analysis. Lancet Glob Health, 2017. 5(3): p. e290-e299.  Prevalence rates of FASD in children in the UK are unknown, but FASD symptoms have been identified in 6-17% of a large scale, longitudinal cohort study. McQuire, C., et al., Screening prevalence of foetal alcohol spectrum disorders in a region of the United Kingdom: A population-based birth-cohort study. Prev Med, 2019. 118: p. 344-351.  The public is still largely unaware of the CMO guidelines from 2016 regarding alcohol in pregnancy, which advise women who are pregnant or planning pregnancy to abstain completely from alcohol, to remove risk of PAE and FASD. This was a significant change from previous guidance, which advised pregnant women to avoid consuming alcohol but to limit their intake if they chose to drink. Balance carried out a Public Perceptions survey in 2019, which showed that 62% of 18-44 year olds did not know the 2016 guidelines around drinking in pregnancy. Taking all of this into account, we believe it is hugely important to educate women and their families and prevent future harm to unborn children, thereby reducing the prevalence rate of children with FASD.  A key part of this should be giving pregnant women, their families and couples who are trying to conceive, advice not to drink alcohol during pregnancy – both at their first contact appointment and at any subsequent contacts throughout the pregnancy. |
| 8 | Birthrights | 1 | Statement 1 | Pregnant women are given advice not to drink in pregnancy:  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. |
| 10 | Birthrights | 1 | Statement 1 | Evidence of local arrangements to ensure that midwives and doctors carrying out antenatal appointments are aware of the risks of drinking alcohol in pregnancy including the risks of FASD:  In order for midwives to be able to appropriately support women, any training under this measure would need to cover both the CMO guidelines AND the state of evidence on risk of harm from drinking alcohol at different levels. Without this, midwives will not be able to provide personalised and tailored support to women. |
| 218 | Birthrights | 2 | Statement 1 | Pregnant women are given advice not to drink in pregnancy  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, with concerns about perinatal mental health or multifacted factors of disadvantage 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. It should be noted that perinatal mental health and multiple disadvantage have been associated with maternal deaths in successive MBRRACE reports. It is highly concerning that women’s ability to receive tailored care as and when she needs it during pregnancy will be compromised by this standard. |
| 219 | Birthrights | 2 | Statement 1 | The background paper to the Quality Standard notes that, in a review of booking data from the Maternity Services Dataset, more than 97% of women whose drinking status was known reported drinking less than one unit of alcohol a week. The paper goes on to state that this figure may be unreliable as it is self-reported. If this figure is in any way reliable it would suggest there is little evidence of potentially harmful levels of alcohol consumption during pregnancy by the vast majority of women – all of whom would be affected by the proposed Quality Standard. If the figure is not considered accurate because it is self-reported, it is unclear why a Quality Standard based on maternal self-reporting should be deemed to be reliable unless predicated on an assumption that ‘any drinking’ equates to ‘lying about more drinking’. This is unlikely to support the stated desire that women should be given “non-judgemental” and “supportive” care. |
| 220 | Birthrights | 2 | Statement 1 | Evidence of local arrangements to ensure that midwives and doctors carrying out antenatal appointments are aware of the risks of drinking alcohol in pregnancy including the risks of FASD  In order for healthcare professionals to be able to appropriately support women, any training under this measure would need to cover both the CMO guidelines AND the state of evidence on risk of harm from drinking alcohol at different levels. Without this, midwives will not be able to provide personalised and tailored support to women. They risk losing the trust of women who ask about the evidence behind CMO advice, including those who have read the CMO advice and noted the statement “The risk of harm to the baby is likely to be low if you have drunk only small amounts of alcohol before you knew you were pregnant or during pregnancy.”  HCPs will also need to be aware of the 2016 BMA report on ‘Alcohol and pregnancy: preventing and managing fetal alcohol spectrum disorders’, which states at 5.1.3 that “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.” |
| 25 | Blackburn with Darwen Borough Council Public Health and Wellbeing Team | 1 | Statement 1 | Feedback suggests that many women are just not aware of the guidance on alcohol use during pregnancy. Our local SM service makes service users aware of the CMO’s recommendations but how does the message get out to the wider population who seem to be unaware of the risks to their unborn child? |
| 100 | Blackburn with Darwen Borough Council Substance misuse service | 1 | Statement 1 | [Statement] Accurately reflects key areas for improvement. |
| 101 | Blackburn with Darwen Borough Council Substance misuse service | 1 | Statement 1 | [Measures] Some of these measures are already integrated in practice locally, but this Guideline will encourage managers to allow more training and support for staff updates and training re maternal alcohol use and to raise awareness. |
| 102 | Blackburn with Darwen Borough Council Substance misuse service | 1 | Statement 1 | Further resources may be required in terms of time to allow for training/updates, plus admin time for data collection. |
| 32 | British Pregnancy Advisory Service | 1 | 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. |
| 33 | British Pregnancy Advisory Service | 1 | Statement 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. |
| 34 | British Pregnancy Advisory Service | 1 | Statement 1 | [Structure measure] ‘Evidence of local arrangements to ensure that midwives and doctors carrying out antenatal appointments are aware of advice 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 (not 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. |
| 35 | British Pregnancy Advisory Service | 1 | Statement 1 | [Structure measure] ‘Evidence of local arrangements to ensure that midwives and doctors carrying out antenatal appointments are aware of the risks 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. |
| 36 | British Pregnancy Advisory Service | 1 | Statement 1 | [Structure measure] ‘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). |
| 37 | British Pregnancy Advisory Service | 1 | Statement 1 | [Audience descriptors] ‘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. |
| 38 | British Pregnancy Advisory Service | 1 | Statement 1 | [Audience descriptors] ‘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. |
| 39 | British Pregnancy Advisory Service | 1 | Statement 1 | [Audience descriptors] ‘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. |
| 40 | British Pregnancy Advisory Service | 1 | Statement 1 | [Source guidance] 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. |
| 243 | British Psychological Society | 2 | Statement 1 | Pregnant women are given advice not to drink alcohol during pregnancy at their first contact appointment.  As the aim is to reduce maternal drinking, potential mothers should be given this information at Assisted Conception Units and when undergoing pre-conception genetic consultations. |
| 68 | Changing Minds UK | 1 | Statement 1 | The guidance states that the first opportunity to let pregnant women know about the impact of alcohol use during pregnancy is during their first antenatal appointment. We would suggest that perhaps another, more effective, means might be to focus upon the public awareness of the impact of drinking alcohol during pregnancy. The information out there on key websites is varied, and some appears to accept that ‘a small amount of alcohol’ is normal (many people assume that you can ‘have one’ and this clearly is not the case). Therefore, we would suggest that it is important to target public awareness more generally. This would also reduce the likelihood of pregnant women being offered alcohol, or encouraged to drink alcohol, from others. |
| 459 | Cwm Taf University Health Board | 1 | Statement 1 | To reduce maternal drinking, potential mothers should be given this information at Assisted Conception Units, when undergoing pre-conception genetic consultations and when they have first discovered a positive pregnancy test. |
| 276 | FASD NETWORK UK | 2 | Statement 1 | There is no mention of this source - NICE PH28 recommendation 21 p40  Ensure social workers obtain permission to access the child or young person's neonatal and early health information.  Ensure social workers obtain permission to access information on parental health, including obstetric health.  Many of our families have had a block on getting data about pregnancy as social workers have mistakenly said that information about the parent’s pregnancy or health is not permitted when they were seeking data to see if there was any reference to alcohol related behaviour in the maternal notes. So not only should the questions of alcohol be answered and recorded as suggested in QS1 but information about that parent’s health and pregnancy should be sought and accessible for the child’s diagnostic needs too. |
| 286 | Healthwatch UK | 2 | Statement 1 | The statement on page 5 that HCPs should ensure supportive follow-up care if needed, such [as] counselling or help to stop drinking is too vague. There exists an evidence-based process whereby people can be helped to stop drinking or reduce their alcohol consumption; this is known as SBIRT (see Rehm J, Anderson P, Manthey J et al.,Alcohol and Alcoholism, Volume 51, Issue 4, July/August 2016, Pages 422–427) and the standard should promote the use of this approach. Following on from the above, page 6 should require commissioners to commission SBIRT services for those drinkers whose need for abstinence advice is particularly important, such as women who are pregnant or planning a pregnancy. Since the amount that a woman drinks is often a reflection of how much her friends and family drink, commissioners should also build the risks of alcohol consumption in pregnancy into their general strategy for reducing the harmful effects of alcohol in their communities.  It is worth looking at the whole issue of how women's consumption of alcohol in pregnancy is meant to be managed, according to NICE guidance on antenatal care (CG62).   What is recommended? In CG62 section 1.1 “Woman-centred care and informed decision-making” it is recommended that antenatal information should be given to pregnant women according to schedule 1.1.1.1 that states this about giving women information at booking: (lifestyle advice, including smoking cessation, and the implications of recreational drug use and alcohol consumption in pregnancy). Much is made of respecting women and their decisions.   What is that advice about alcohol? Since publication, the NICE evidence-based guidance CG62 “1.3.9 Alcohol consumption in pregnancy” was withdrawn in favour of Chief Medical Officer’s guidance about low risk drinking <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/545937/UK_CMOs__report.pdf>. In the introduction the four country CMOs refer to the August 2016 guidelines having “been developed to enable people to make informed choices about their alcohol intake”. However, the expert group did not follow NICE processes of best available evidence. In addition, there were no obstetricians or midwives included on the expert group (see Annex B https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_data/file/545739/GDG\_report-Jan2016.pdf).   Nevertheless, they took a precautionary approach with a simple, clear message. They advise women that the safe level of drinking in pregnancy is nothing. The expert group (now formal CG62 NICE guidance) “felt that current evidence supports a ‘precautionary’ approach and that the guidance should be clear that it is safest to avoid drinking alcohol in pregnancy”. This, but no advice whatsoever about how to achieve teetotalism. They advise women that “If you find out you are pregnant after you have drunk alcohol during early pregnancy, you should avoid further drinking. You should be aware that it is unlikely in most cases that your baby has been affected. If you are worried about alcohol use during pregnancy do talk to your doctor or midwife.”   So what does CG62 advise doctors and midwives to do next after a woman says she has drunk during early pregnancy or is continuing to drink, or has a problem with heavy drinking? Sadly, NICE is silent and offers precisely nothing which makes a considerable contrast with the following section “1.3.10 Smoking in pregnancy” which offers healthcare professions several means of supporting pregnant women and help with smoking cessation.   The RCOG too has no advice. Its 2018 patient information advises women not to drink but to tell their healthcare professional if they do, <https://www.rcog.org.uk/en/patients/patient-leaflets/alcohol-and-pregnancy/>. It then abrogates responsibility to the midwife. They tell women that “Your midwife will offer you information and support on how to cut down or stop drinking alcohol.”   So what will midwives offer? The RCM agrees with advice that the safest level is not to drink, but has no evidence-based guidance for midwives as how to help women achieve this. We note that the RCM is worried about the damage this QS will have on their trusting relationship with women <https://www.rcm.org.uk/media-releases/2020/september/midwives-fear-women-could-feel-stigmatised-if-mandatory-alcohol-screening-introduced-at-every-antenatal-appointment/>. We agree that ‘top-down’ diktats, promising more than they can deliver, are likely to cause cognitive dissonance, and loss of trust, and unlikely to help prevent FAS.  Secondly, the purpose of the Quality Standard is insufficiently justified   Patently, it is unkind to leave the group of women who do not (or more likely cannot) reduce their alcohol intake during pregnancy ‘high and dry’. Pregnant women, as a whole, take lifestyle advice very seriously and do make the healthy changes advised. But they live in a society with a poor public health architecture that we know drives smoking, alcohol and other dependence-inducing behaviours. Government recognises the ‘obesogenic’ environment for example, but it is not successfully addressing the drivers for increased alcohol use by the whole population, which will always include women of childbearing age. Alcohol, for the heavier users, is not a simple ‘lifestyle’ choice, and those pregnant women who are in difficulty need trusting, understanding relationships and extra help. Largely, they will be bringing up the children with FAS (not always).   We cannot find any evidence that the CMO's advice did change people’s behaviour (maybe partly because the ONS data has not been reported beyond 2017 because the government decided not to report it any more. <https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/drugusealcoholandsmoking/bulletins/opinionsandlifestylesurveyadultdrinkinghabitsingreatbritain/latest>). Figure 14 shows 40-50% of women of childbearing age drinking in the past week (relevant to unplanned pregnancy). The little longitudinal data published in Health-Related-Behaviours replacement is also worrying with Figure 15 showing no fall in all age women’s heavy drinking 2014- 2018, and high levels the <https://files.digital.nhs.uk/B5/771AC5/HSE18-Adult-Health-Related-Behaviours-rep-v3.pdf>   Thus this QS appears to be introducing a retrospective ‘screening by stealth’ in the absence of evidence of efficacy for the child or the mother.   If there were a genuine desire to reduce alcohol related damage (rather than just making an accurate diagnosis later), surely there ought to be a Quality Standard checking that women are indeed getting referrals to evidence-based, effective help?. Such evidence-based measures do exist (see above).  Having a quality standard that merely exists to retrospectively ‘clinch a diagnosis’ may make no difference to the mother's or child’s life. There may still be some children where there is no record (or the woman denies alcohol) and thus “?FAS” will have to remain on the differential diagnosis list and be managed “as if” it were FAS. Having a quality standard that contemporaneously improves the health of the mother or the child would be better. |
| 447 | Institute of Health Visiting | 2 | Statement 1 | An important standard but related to, general practice, midwifery and obstetric services so no comment follows. |
| 436 | National Data Guardian (NDG) | 2 | Statement 1 | We note that the Chief Medical Officer’s alcohol in pregnancy advice is one of abstinence based on the precautionary principle. However, this does not override the pregnant person’s right to confidentiality. |
| 306 | NHS England and NHS Improvement | 2 | Statement 1 | How will alcohol consumption rates in pregnancy be measured? Will this be dependent on the question being asked at future antenatal appointments (see below).  How will these measures fit in with the Maternity services data set, which is stated as a source, but does not include this at present? |
| 115 | NOFAS-UK | 1 | Statement 1 | It’s extremely important that attention is given to the training for those professionals engaging in these discussions, drawing on best practices from the Greater Manchester Health and Social Care Partnership and other areas that have been trailblazing on these issues. As one person responded, “medical practitioners in whatever capacity need training in HOW to discuss this with women to avoid any kind of feeling of being judged.”  • NOFAS-UK encourages widespread posting of the Chief Medical Officers’ guidance on the risks of alcohol in pregnancy where ever pregnant women and those of child-bearing years might be present. There are ways to raise these issues in a non-judgmental, non-shaming way.  • We also note that women who themselves have FASD and who become pregnant should receive this advice in an accessible and supportive manner, with visual aids, reminders and appropriate scaffolding. |
| 312 | Northumbria Healthcare Foundation NHS Trust | 2 | Statement 1 | [Comment submitted in format used for comments at topic engagement]  To facilitate early detection of at risk mothers and babies to target referrals and support regardless of location.  To educate women and their families and prevent future harm to unborn children and reduce prevalence rate of children with FASD Disability.  The public is still largely unaware of the new CMO guidelines from 2016 regarding alcohol in pregnancy.  ‘Alcohol guidelines for pregnant women: Barriers and enablers for midwives to deliver advice’.2019  It is estimated that 41.3% of women in the UK consume alcohol during pregnancy; the fourth highest in the world. Popova, S., et al., Estimation of national, regional, and global prevalence of alcohol use during pregnancy and fetal alcohol syndrome: a systematic review and meta-analysis. Lancet Glob Health, 2017. 5(3): p. e290-e299.  Prevalence rates of FASD in children in the UK are unknown, but FASD symptoms have been identified in 6-17% of a large scale, longitudinal cohort study. McQuire, C., et al., Screening prevalence of fetal alcohol spectrum disorders in a region of the United Kingdom: A population-based birth-cohort study. Prev Med, 2019. 118: p. 344-351.  Aligns to Better Births. ‘Where every woman has access to information to enable her to make decisions about her care; and where she and her baby can access support that is centred around their individual needs and circumstances.’  Full recommendations can be accessed in Howlett H, (2020) An antenatal alcohol service evaluation of the north-east of England and north Cumbria, Journal of Public Health, fdaa020, <https://doi.org/10.1093/pubmed/fdaa020>  N.B. A bespoke antenatal alcohol pathway has been developed and implemented in the North East of England. |
| 317 | Northumbria Healthcare Foundation NHS Trust | 2 | Statement 1 | [Comment submitted in format used for comments at topic engagement]  Maternity health professionals to engage with local multi agency alcohol partnership groups to raise the issue of reducing alcohol in pregnancy, and to set and measure meaningful objectives to provide a seamless service that meets the needs of pregnant women and their families. To utilise existing initiatives which address alcohol in pregnancy to facilitate a greater awareness and facilitate prevention.  Prevention of FASD and raising awareness of PAE should be included in all relevant primary care services and gynaecology clinics.  Standardised, mandatory FASD and PAE training for maternity staff should be delivered annually in protected time and preferably face to face. Consistent information and practices should be shared and regularly updated with latest evidence and guidelines.  Training is required for all professionals working with children and substance misuse services to raise awareness of the link between PAE and the risk of FASD.  The risks of alcohol in pregnancy and FASD should be core curriculum for all pre-registration health professionals, teachers and social workers.  To ensure that commissioning prioritises alcohol screening in pregnancy.  Specialist services need to be flexible, immediately accessible and conveniently located to meet the needs of women in urban and rural locations. A clear communication arrangement is required so that women receive a seamless service and maternity staff are kept informed of each woman’s engagement with the service to monitor her progress and provide the relevant additional support.  Training should address some potentially challenging issues including health professional’s attitudes towards alcohol; and how to support women who have already consumed alcohol in pregnancy.  Specific maternity alcohol support would be the gold standard.  Recommendations taken from research submitted for publication.  ‘Working across boundaries to provide and commission maternity services to support personalisation, safety and choice, with access to specialist care whenever needed.’ Better births.  Addresses health inequalities. Guidance for NHS commissioners on equality and health inequalities legal duties <https://www.england.nhs.uk/wp.../hlth-inqual-guid-comms-dec15.pdf>  N.B. A bespoke antenatal alcohol training package has been developed and implemented in the North East of England. |
| 124 | Peterborough family FASD support Group & Field of Enterprise Training & Consultancy | 1 | Statement 1 | I believe that leaving education and advice until a woman knows that she is pregnant is too late. In many cases the impact of alcohol on the foetus may well have happened before a woman seeks medical advice and before she knows that she is pregnant. Therefore, I believe that a more detailed public education drive needs to be in place starting in schools but expanding to a wider public education programme.  I also believe that the chief medical officers’ advice should be strengthened to state that women who are pregnant or thinking of getting pregnant should not drink at all. The current wording leaves too much to interpretation. ‘safest approach … to avoid alcohol’ too woolly. If we learn anything from Covid-19 its don’t sweeten the message or leave it open to personal interpretation.  Change the sheets for first contact when pregnant to say more than just does the woman drink to something that records how much (I understand that this is problematic) and whether advice has been given (even if the woman claims not to drink) and maybe goes as far in the first instance to state there what the CMO advice is. |
| 131 | Public Health England | 2 | Statement 1 | The focus on ensuring that midwives and doctors are aware of the CMOs' guidance and the risks of drinking in pregnancy is welcome, as evidence from a recent survey of midwives suggests that there continues to be some confusion about what the advice is.  Providing advice on not drinking during pregnancy at first contact is also welcome, but we would like there to be clarity as to what this means in practice. Are you referring to first booking or first time a healthcare professional sees a pregnant woman, e.g. when providing pregnancy test results? It could be made clearer in the guidance that conversations on drinking should happen as soon as the opportunity presents itself. |
| 132 | Public Health England | 2 | Statement 1 | [Audience descriptor: Healthcare professionals]  It will be important to be proactive in providing reassurance for those who drank small amounts before they knew they were pregnant and encouraging those who may struggle to stop drinking to seek support. We are conscious that discussing the risks to the foetus of drinking in pregnancy may raise anxiety - particularly where the pregnant woman is dependent on alcohol. It would be helpful if the guidance made clear the link to CG110 for these women and reiterated the need for careful planning when having these conversations. |
| 141 | Royal College of General Practitioners | 1 | Statement 1 | Can we change ‘first contact appointment’ to ‘midwife booking appointment’? This is estimated to be at 8-12 weeks gestation. “First contact” appointment may be an emergency or unscheduled appointment, e.g. threatened miscarriage. It may not be with the patient’s own practice, e.g. out of hours service or a hospital emergency department. The focus at that appointment is on the presenting issue or symptoms, and it is less likely that there will be an enquiry into alcohol consumption. It is important to note that GPs no longer perform antenatal care and people can book to see their midwife without seeing a GP. Can we remove GP from the healthcare professionals list? |
| 142 | Royal College of General Practitioners | 1 | Statement 1 | Can consideration be paid to altering the maternity data set to enable easier data collection of this standard? Currently, the Maternity Services Data Set (MSDS) Data Model v2.0 <https://digital.nhs.uk/binaries/content/assets/website-assets/data-and-information/data-sets/maternity-services/maternity-services-data-set-data-model-v2.0.pdf> appears not mention alcohol, alcohol advice or indeed any other co-existing lifestyle factors such as smoking and substance abuse. |
| 144 | Royal College of General Practitioners | 1 | Statement 1 | Rather than local examples of increasing knowledge on FAS why not review the national professional curricula for health care staff to ensure those in contact with pregnant women are aware of the importance of FAS?   Medical professional including paediatricians, psychiatrists and general practitioners   Other clinicians including midwives, paediatric nurses, mental health practitioners, psychologists and health visitors   Educational including teachers, Special Educational Needs Coordinators (SENCOs), teaching assistants and Educational Psychologists   Others including social workers  The MRCGP Curriculum includes a reference to FAS but no clear guidance, this may require amendment to highlight the significance of FAS more prominently rather than looking at local education. |
| 326 | Royal College of Midwives | 2 | Statement 1 | ‘Pregnant women are given advice not to drink alcohol during pregnancy at their first contact appointment’  As there is no known safe level of alcohol consumption during pregnancy, the Royal College of Midwives (RCM) believes it is appropriate and important to advise women that the safest approach is not to drink alcohol during pregnancy. |
| 148 | Royal College of Paediatrics and Child Health | 1 | Statement 1 | Children are often referred to Clinical Genetics, as a specialty, for the assessment of fetal alcohol syndrome. This is because of the element of Dysmorphology and also that the differential diagnosis of fetal alcohol syndrome includes genetic conditions (please see references below). This issue was raised during the topic engagement exercise earlier in this consultation process, but unfortunately there remains not even a mention of genetics, genomics or Clinical Genetics in this document. This is a significant omission.  References:  Douzgou S, Breen C, Crow YJ, et al. Diagnosing fetal alcohol syndrome: new insights from newer genetic technologies. Archives of Disease in Childhood 2012;97:812-817.  Parker MJ, Teasdale K, Parker MJ. The genetic assessment of looked after children: common reasons for referral and recent advances. Archives of Disease in Childhood 2016;101:581-584. |
| 382 | Scottish Health Action on Alcohol Problems (SHAAP) | 2 | Statement 1 | Under the rationale for quality statement 1, the CMO’s “low risk drinking guidelines” are cited, however a more useful formulation of this message would be a straightforward “No Alcohol, No Risk”. This message also needs to be articulated and promoted prior to pregnancy, not just once pregnancy is confirmed, and antenatal appointments are ongoing.  Many pregnancies are unexpected or unplanned, meaning many women will have continued to drink alcohol unaware that they are pregnant, exposing the fetus to potential harm at this early stage. There is the potential for sensitive messaging around such issues. The “Drymester” initiative in Greater Manchester is one good example: <https://www.drymester.org.uk>. Pre-launch evaluation of this campaign demonstrated that people thought the information shared around pregnancy and alcohol harm was important and provided in an acceptable format.  Another consideration not included in this statement relates to the prevention of FASD by promoting birth control measures for people who regularly consume alcohol. Evidence from North America shows that the “CHOICES” approach to prevention, which combines alcohol counselling with appropriate birth control information is both acceptable to people and reduces subsequent pregnancy alcohol exposure: <https://www.cdc.gov/ncbddd/fasd/choices-program-prevent-alcohol-exposed-pregnancies.html>. It is important that more progress is made on prevention of FASD, alongside diagnosis and management. |
| 393 | Scottish Intercollegiate Guidelines Network | 2 | Statement 1 | Although it is not a standard for diagnosis, it is unfortunate that there is no link currently in the document to emphasise the prevention message that if you wish to avoid having a baby affected by FASD then you need to use effective contraception if you are continuing to drink alcohol. This message needs to go more clearly to all women of child bearing age. |
| 394 | Scottish Intercollegiate Guidelines Network | 2 | Statement 1 | Give a specific ‘No Alcohol No Risk’ message rather than reference to ‘low risk drinking guidelines’. |
| 411 | Surrey and Borders Partnership NHS Foundation Trust and National FASD Behaviour management clinic. | 2 | Statement 1 | This is an important statement to make and is clear and in keeping with guidance and will allow measurement of effectiveness and also develop strategies to improve information that is reliable and balanced to be given to people. |
| 412 | Surrey and Borders Partnership NHS Foundation Trust and National FASD Behaviour management clinic. | 2 | Statement 1 | This depends how it implemented locally/ A PH audit of 5 hospitals in Surrey several years ago unpublished ask this question and showed 5 very different result bused on the approaches being used. It can be audited but this will be a driver to help change |
| 154 | TACT - The Adolescent & Children’s Trust | 1 | Statement 1 | We fully support this statement but feel that, if possible, the advice should be widened to include women trying to get pregnant. We understand this may not be possible for health care professionals to do this but any publicity/advertising should include this group. |
| 163 | Tees Valley Durham and North Yorkshire Neurological Alliance | 1 | Statement 1 | **Rationale**  Local systems do not exist in Tees Valley. There is no onus on the birth mother to tell the truth about alcohol consumption. If services purely rely on the first contact appointment, this is too late and this standard is set to fail.  There must be an infrastructure model disseminated nationally plus a robust national campaign to train frontline public workers, including social workers/Mental Health services and the Police, where the potential mother is already known. |
| 388 | University of Bristol (Law School) | 2 | Statement 1 | There is some level of confusion throughout between whether what is being proposed is a a Quality Standard on FASD or a research protocol for recording and gathering information on alcohol consumption during pregnancy. Throughout the document there is circularity with regard to the justifications used and evidence drawn from on the risks of PAE and the justifications used and evidence for why a departure from standard rules on informed consent with regard to medical record keeping. While it is widely acknowledged that maternal alcohol consumption can have negative consequences for outcomes in children the extent of understanding in this area is hindered by a lack of evidence base. However, in places the consultation document presents uncertain evidence as absolute in order to justify infringements on informed consent. This approach to the evidence, or lack thereof, risks provoking anxiety in pregnant people and decisions such as termination of wanted pregnancies being taken. It also risks undermining confidence in healthcare practitioners (HCPs) where more detailed evidence supporting the proposed advice is requested by the pregnant person.  Generally it is accepted and expected that NICE Quality Standards should be rigorously evidence based – it is not clear that this standard meets this expectations. This is particularly concerning given that this guideline proposes an important shift in how information about maternal behaviors is recorded in the medical record of the future child.  The confidentiality and GDPR implications of this proposal are not fully considered nor the competing interests between maternal privacy rights and future children’s rights to information appropriately weighed up – c.f. Odièvre v. France (application no. 42326/98) for importance of balancing on this latter point.  Finally the practical consequences and fallout of the guidance provided is not fully considered nor is there any evidence assessed on the extent to which mandatory recording and disclosure re alcohol consumption in pregnancy could have on doctor / patient relationship and veracity in doctor patient communications. This is surprising when in other areas of medical practice compulsory disclosure is treated cautiously because of potential negative consequences on trust and veracity in the doctor patient relationship. E.g. Hunter v Mann (1974) QB 767 even where this involves the sharing of information between family members ABC v St George's Healthcare NHS Trust & Ors [2020] EWHC 455 (QB).  The discretion of HCPs to tailor their advice to the particular situation of the individual patient is also constrained by the guidance in its current form, given the variable relevance of conversations about alcohol consumption and FASD. A universal obligation on HCPs to repeatedly engage in such discussions also risks using time which could be spent on topics specifically relevant to the pregnant person’s individual circumstances and, as such, risks overburdening HCPs and providing inadequate medical consultations to pregnant individuals. This approach is also counter the approach outlined in Montgomery v Lanarkshire Health Board [2015] UKSC 11 which emphasises the importance of assessing the needs and interests of the particular patient with regard to information disclosure. |
| 422 | University of Bristol (Medical school / Philosophy dept) | 2 | Statement 1 | Statement 1 states: “Pregnant women need clear and consistent advice on alcohol. The first contact appointment with a midwife or doctor in pregnancy is the earliest opportunity for a healthcare professional to give this.”  i. Earliest time point of intervention. We agree that for many women, the antenatal booking appointment is the first opportunity to give advice and discuss drinking in pregnancy. However, this contact normally occurs around 8-10 weeks into pregnancy and thus there is a risk that significant harm can be caused to the developing fetus by consumption of alcohol prior to this contact.  Therefore, we suggest that earlier intervention is recommended where possible. For example, if a woman approaches her GP to discuss pregnancy planning or stopping contraception then this would provide a valuable early opportunity to give the recommended advice around drinking in pregnancy.  ii. More general awareness of guidelines for healthcare professionals and the public.  Broader initiatives to increase public awareness of guidelines around drinking in pregnancy are also strongly recommended, and are currently lacking. Our recommendations include public health information campaigns, awareness raising initiatives among health care professionals and more targeted initiatives; for example we recommend that alcohol advice ideally would be given to 18-24 year old as part of routine check-ups or coupled with another screening for this age group (e.g. sexual health clinics). This is due to the much higher proportion of unplanned pregnancies in this age group.  In addition, physicians working for children and families’ social care, and who prepare the medical reports of children in care, and examine children while they are in care, should also have an awareness of FASD so they are better able to report/ refer children at a young an age as possible for assessment, treatment and support.  Evidence of what local arrangements are in place to ensure that midwives and doctors carrying out antenatal appointments are aware of advice should be collected to monitor implementation and compliance with this quality standard.  (contributors: CM, LZ, HC, SO) |
| 423 | University of Bristol (Medical school / Philosophy dept) | 2 | Statement 1 | Broader risks to pregnancy  In terms of the statements about discussing the risks of FASD with the mother, we’d add that there are also risks to the pregnancy itself such as miscarriage, preterm birth and early manifestation of risk to the baby such as low birthweight, both of which bear long lasting risks of neurodevelopmental and physical consequences.1,2  (CM, LZ, HC, SO) |
| 424 | University of Bristol (Medical school / Philosophy dept) | 2 | Statement 1 | Transparency and signposting information  We ask NICE to clearly signpost the evidence on which the advice is based (e.g. on NHS Choices) via a ‘Frequently Asked Questions’ (FAQ) type document. This would enable women who are given the advice to access the information themselves. This will help them to understand the degree of (un)certainty underpinning the guidelines, if they so wished, thus building trust, potentially improving compliance and assisting informed decision making. Mention of this further FAQ resource should be made by their midwives/doctors during the consultation, and would help with answering many of the questions the women could have as well as increasing efficiency during the limited time of the consultation.  As researchers with significant expertise in prenatal alcohol exposure and fetal alcohol spectrum disorders, we offer to construct an evidence-based FAQ document in collaboration with NICE to fulfil this suggestion. |
| 425 | University of Bristol (Medical school / Philosophy dept) | 2 | Statement 1 | Avoiding stigma/providing support  Women should not be feeling stigmatised for disclosing their alcohol use in pregnancy. To reduce feelings of stigmatisation, when asked to provide this information they should be offered support and help ‘in return’. Every effort should be made to ensure that non-judgemental conversations take place, and women are offered support when disclosing their alcohol use, especially if this is seen as problematic or they disclose a desire to receive help to stop or reduce their drinking.  (CM, LZ, HC, SO) |
| 172 | University of Southampton | 1 | Statement 1 | Quality Statement 1 requires all pregnant women to be given advice not to drink alcohol during pregnancy at their first contact appointment.  The rationale given is that there is no known safe level of alcohol consumption during pregnancy. It appeals to the UK Chief Medical Officer’s low risk guidelines that state that the safest approach is to avoid alcohol altogether during pregnancy to minimise risks to the baby. However, it should also be noted that the same guidelines state: “Research on the effects on a baby of low levels of drinking in pregnancy can be difficult to interpret. The risks are probably low, but we cannot be sure that this is completely safe” and “[t]he risk of harm to the baby is likely to be low if you have drunk only small amounts of alcohol before you knew you were pregnant or during pregnancy.” (UK Chief Medical Officer’s low risk drinking guidelines, p. 8).  The conclusion that pregnant women should be advised not to drink in pregnancy, given the described state of the evidence, depends on a hidden premise. To get to this conclusion from the described evidence, the following argument is needed:  Premise 1: We cannot be sure that drinking small amounts of alcohol in pregnancy is completely safe.  Premise 2: Pregnant women should be advised to avoid any unnecessary activity unless we can be sure it is completely safe.  Conclusion: Pregnant women should be advised not to drink any alcohol in pregnancy.  The argument depends on the hidden Premise 2. But there are two problems with Premise 2:   1. First, it amounts to an utterly unreasonable demand on pregnant women. There are almost no activities that we can be sure completely safe in pregnancy. So it would require pregnant women to be advised to give up all ‘unnecessary’ activities. Such a standard would undermine maternal well-being, autonomy and self-ownership. (See Woollard, “Motherhood and Mistakes about Defeasible Duties to Benefit”, Philosophy and Phenomenological Research, Published Online First: 16th December 2016. doi : 10.1111/phpr.12355.) 2. Second, the judgment about whether an activity is ‘unnecessary’ is not a purely medical one. It involves a judgment about the role that different activities, and different pleasures, play in one’s life. Alcohol may play a role in religious, cultural or personal practices which are important to an individual. The midwife or doctor is not in a position to judge whether these practices have sufficient importance in the life of an individual to outweigh the ‘probably low’ risks involved.   This relates to the final part of the rationale: “pregnant women need clear and consistent advice on alcohol.” What pregnant women really need is clear, consistent and accurate guidance about the current evidence, which allows them to make an informed decision about what to do, given the importance of the activity under discussion in their lives. Indeed, focusing too much on the advice to give up drinking altogether may be counterproductive: in making decisions about their drinking practices, women may need to know that drinking larger amounts of alcohol presents a greater risk. |
| 2 | Adoption UK | 1 | Statement 2 | Adoption UK welcomes the clear instruction around recording alcohol history in this statement. Alcohol history is first step in the three-stage diagnosis pathway developed and trialled in Scotland (FASD Care Pathway). It is important because children are frequently referred for developmental delay without a clear alcohol history, which can blur the diagnosis. |
| 202 | AIMS - the Association for Improvements in the Maternity Services | 2 | Statement 2 | We are concerned about the effectiveness of measures focussed on the pregnant woman and how this will impact on the quality of maternity care.  In developing these quality standards, it is important to respect the principles of informed decision-making, consent and confidentiality. Informed decision-making on the part of the pregnant woman is key. Before making a decision about disclosing personal information, women need to be informed about how this information will be used and have time to consider the possible implications of their disclosure, e.g. if the information might be used in a future safeguarding issue. Consent: It is unclear what the process is for women to understand how their data will be used and what they are consenting to (including about how the information will be used and who will have access to it). Confidentiality: There is a suggestion that information provision on the part of the pregnant woman would be mandatory, which is an unusual demand to make of healthcare service users.  This seems to be contrary to the principle of building a relationship of trust and confidentiality between the woman and her health care provider. |
| 203 | AIMS - the Association for Improvements in the Maternity Services | 2 | Statement 2 | In developing these quality standards, it is important to take into account the likely practicality, effectiveness and proportionality of the proposed  information collection. We understand that the quality standards have an objective to accurately record the alcohol consumption of pregnant women, for the purposes of diagnosing FASD in the child. We would suggest that this objective requires mutual trust between service users and health care providers in order to be effective. We question whether the approach suggested in the quality standards achieves this objective, and indeed we are concerned that the approach suggested will work to destabilise a trusted relation. |
| 204 | AIMS - the Association for Improvements in the Maternity Services | 2 | Statement 2 | Practicality of data collection: Maternity service antenatal appointments are, following the first appointment, very short appointments during which there are many tasks to be completed.  We query how additional conversations related to alcohol consumption will be facilitated in this short appointment. |
| 205 | AIMS - the Association for Improvements in the Maternity Services | 2 | Statement 2 | Effectiveness of data collection: We query how accurate the record of alcohol consumption will be. There has been much debate about the inaccuracy of self-reporting related to alcohol, whether due to misunderstandings of intake quantities or the stigma around revealing alcohol use (including within certain cultural and religious contexts). See also comment 2. |
| 206 | AIMS - the Association for Improvements in the Maternity Services | 2 | Statement 2 | Proportionality of data: The proposal here is that information is collected during pregnancy for all women. We do not think that this represents a proportionate approach because this data collection may not be necessary at this stage for many families, and its collection risks doing harm to the relationship of trust needed between the mother and her doctor and midwife, as well as to the emotional and mental well-being of the pregnant woman. We would therefore question whether the universal approach suggested, with that timing, is likely to be effective and lead to data that is accurate or indeed always necessary. We feel that there is a further debate to be had around the best point to collect alcohol consumption records of pregnant women, and would suggest that information is better collected at the point of FASD diagnosis (where the birth mother is present) or at the point of ‘handing over’ a child if the child in question is transferred to the care system/is looked after. This would meet the objectives related to gathering information to support a diagnosis. |
| 211 | Balance | 2 | Statement 2 | Experience from the North East indicates that recorded information about alcohol consumption during pregnancy tends to be patchy and inconsistent, depending on practices within individual NHS Trusts. Documented evidence is generally a requirement of FASD diagnosis for children without the classic FAS facial dysmorphia- without this, it is hugely challenging to accurately identify – and provide support – for children with FASD and they can be at risk of alternative and inappropriate diagnoses.  We believe it is hugely important to record information on alcohol consumption throughout pregnancy, to support the mother and unborn child. This could be done by utilising resources already available to practitioners, such as the (red) baby book, which follows the infant throughout childhood. It may be an effective resource to share information with the health visitor, GP, school nurse, teacher or even social worker if required. A special Prenatal Alcohol Exposure (PAE) question in the book could be added and completed in the antenatal period as a simple way to document alcohol use. Any PAE could also be documented in a Regional Perinatal Data Management system such, as BadgerNet UK. Training would also be important, to ensure that all practitioners working with pregnant women and their families, understood the relevance and implications of recording maternal alcohol use. |
| 9 | Birthrights | 1 | Statement 2 | The background paper to the Quality Standard notes that, in a review of booking data from the Maternity Services Dataset, more than 97% of women whose drinking status was known reported drinking less than one unit of alcohol a week. The paper goes on to state that this figure may be unreliable as it is self-reported. If this figure is in any way reliable it would suggest there is little evidence of potentially harmful levels of alcohol consumption during pregnancy by the vast majority of women – all of whom would be affected by the proposed Quality Standard. If the figure is not considered accurate because it is self-reported, it is unclear why a Quality Standard based on maternal self-reporting should be deemed to be reliable unless predicated on an assumption that ‘any drinking’ equates to ‘lying about more drinking’. This is unlikely to support the stated desire that women should be given “non-judgemental” and “supportive” care. |
| 11 | Birthrights | 1 | Statement 2 | Screening: This quality standard would in effect introduce apparently mandatory (see point 6) screening for all women. It is unclear why NICE considers that this would be considered “routine antenatal care and not part of a national screening programme such as those recommended by the UK National Screening Committee”. The proposals would introduce screening for all, with no lower limit/level of consumption considered to designate or indicate prenatal alcohol exposure, implying that any level of alcohol consumption in pregnancy may be associated with neurodevelopmental effects. This would further embed an abstinence only approach into policy, marking a substantial departure from the evidence base. |
| 12 | Birthrights | 1 | Statement 2 | Recording of alcohol consumption: In the absence of any proposals to obtain informed consent for this process, the draft quality standards attempt to frame screening as routine antenatal care, when this is not the case. Any screening would necessarily have to be offered on a voluntary basis, in the absence of any coercion or undue influence, with accompanying risks and benefits of such screens explained (in relation to the patient: the woman). This has not been adequately accounted for in the draft Quality Standards. Such benefits would also have to be presented in light of the paucity of evidence on FASD, including a lack of conclusive evidence re: the relationship between low-level alcohol consumption and harm.  Consent would have to be sought on each occasion when screening was offered. Using the ‘proportion of antenatal appointments attended where alcohol consumption is recorded’ as a data source is likely to increase pressure on healthcare professionals to persuade women to agree to screening/present it as mandatory and pressure on women to give unlawful ‘consent’ in the face of undue influence.  There is also a risk that repeated conversations about alcohol and screening for drinking will take precedent over providing personalised care that meets the woman’s needs, as noted under (2) above. This is also likely to be exacerbated by the proposed data source ‘proportion of antenatal appointments attended where alcohol consumption is recorded’.  Many women are likely to be concerned about the impact of reporting any alcohol consumption, or declining screening, under these proposals, including the risk of referral to social care. Through our advice service, we have supported a number of women who have been told they will be referred to social care for declining ‘routine’ screening tests during pregnancy and believe this is likely to be perceived by women as a significant risk if these proposals are adopted. Referrals should only be made if the woman’s choices indicate there is a threat of significant harm to the baby once it is born. Declining alcohol screening, or reporting low levels of alcohol consumption is highly unlikely to meet this threshold and this must be made clear if the Quality Standards are adopted. |
| 13 | Birthrights | 1 | Statement 2 | Data source: The use of the ‘proportion of antenatal appointments attended where alcohol consumption is recorded’ as a data source is likely to increase pressure on healthcare professionals to persuade women to agree to screening which could constitute undue influence which could invalidate any consent given. |
| 14 | Birthrights | 1 | Statement 2 | Lawful basis of data processing: Under current Data Protection requirements (General Data Protection Regulations 2016), there must be a legal basis for the processing of personal data before it is considered lawful. 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. We do not believe that there is a sufficient legal basis under Article 6 to allow processing of this personal data and therefore the mandatory collection of a woman’s health information of this kind for the purpose proposed in the Quality Standards would be unlawful. This is because:   The collection/transfer 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 – an unborn child would 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 (issues with compelling evidence base, prevalence figures, implications for women’s behaviour during pregnancy etc.) (6(e) GDPR).   This type of processing cannot be considered necessary for the purposes contained in the draft Quality Standard, thereby overriding the interests and fundamental rights and freedoms of the data subject, in this instance: the woman. In balancing the purposes (in light of issues with evidence base, prevalence figures, legal precedent etc.) it is clear that the fundamental rights and freedoms of women, especially bearing in mind the impact of medical decision making in antenatal care should not be overridden. |
| 15 | Birthrights | 1 | Statement 2 | Privacy: In the absence of any proposals to obtain informed consent for this process, the proposal to transfer information about a woman’s alcohol consumption onto her child’s health records represents a significant intrusion into her family life and may represent a breach of Article 8 of the Human Rights Act 1998 and European Convention on Human Rights, which protect private and confidential information. Given the lack of evidence of harm at lower levels of consumption (see above) the recording and inclusion of this data cannot be deemed to be a necessary and proportionate action. |
| 16 | Birthrights | 1 | Statement 2 | Erosion of trust: 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, it is likely many women will not seek the help they need. 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.  The introduction of ongoing scrutiny and impact on trust is likely to be greater for women who are already concerned about feeling scrutinised for their choices in pregnancy and birth. Birthrights’ and Birth Companions’ research on the experiences of women facing multiple disadvantage (Birthrights and Birth Companions (2019)\*) found that women often had fragile relationships of trust with caregivers and were afraid of disclosing information or making choices that they feared might result in judgment or social care scrutiny – this was particularly true for women with mental health needs and younger women. Asking repetitively for women to disclose levels of drinking is likely to damage these relationships further, or potential destroy them and result in women avoiding care altogether. We have concerns that similar erosion of trust may be seen if women know that health visitors and social workers can see that they have drunk some alcohol – however little – on their child’s health record / in their red book. This may compromise both trust and access to services designed to support women at an important transitional time in their lives.  The recommendations in this Quality Standard run counter to the principles espoused in the specialist NICE Guideline for care of the few women who do drink heavily during pregnancy. NICE Guidance on the care for pregnant women with complex social factors (CG110) describes the care that should be provided to women who misuse substances, including alcohol. The Guidance states that women should not be dissuaded from using services, and that care should be taken to address women’s fears about involvement of children’s services and potential removal of their child, and that women should be supported with “feelings of guilt about their misuse of substances and the potential effects on their baby”. It is clear that the small minority of women who drink significantly during pregnancy require tailored support including “what to expect when the baby is born” – however CG110 already provides for this specialist care and support in a far more appropriate way.  \* Holding it all together: Understanding how far the human rights of woman facing disadvantage are respected during pregnancy, birth and postnatal care. London [online]: <https://www.birthrights.org.uk/wp-content/uploads/2019/09/Holding-it-all-together-Full-report-FINAL-Action-Plan.pdf> |
| 221 | Birthrights | 2 | Statement 2 | Pregnant women have information on their alcohol consumption recorded throughout their pregnancy: screening  This quality standard would in effect introduce apparently mandatory (see point 7) screening for all women. It is unclear why NICE considers that this would be considered “routine antenatal care and not part of a national screening programme such as those recommended by the UK National Screening Committee”. The proposals would introduce screening for all, with no lower limit/level of consumption considered to designate or indicate prenatal alcohol exposure, implying that any level of alcohol consumption in pregnancy may be associated with neurodevelopmental effects. This would further embed an abstinence only approach into policy, marking a substantial departure from the evidence base. It is concerning that this has not been justified, given NICE’s commitment to evidence-based guideline development.  This standard also represents a narrative of woman-blaming, holding the birthing person responsible for all outcomes of a pregnancy and risks institutionalising a view of the pregnant individual as a source of risk to the foetus ([Shankar 2016](https://cjds.uwaterloo.ca/index.php/cjds/article/view/276)), whilst failing to recognise the broader socioeconomic and environmental situation she is in. |
| 222 | Birthrights | 2 | Statement 2 | The timing, quantity and frequency of alcohol use should be recorded in maternity records and then transferred to the child’s health records after birth: informed consent  This proposal fails to meet the basic legal requirements regarding informed consent set out in Montgomery v Lanarkshire [2015] UKSC 15. For consent to count in the law, it must be freely given (without any coercion or undue influence) and based on accurate information which includes information on the material risks of the proposed procedure and the risk of doing nothing (i.e. not carrying out screening). The risks/benefits of the intervention need to be given with regard to the patient in question – that is, the woman or pregnant person. As drafted, the standards fail to engage with the legal requirement for informed consent in any way. Indeed the proposals appear to be advocating ‘mandatory’ screening, with no recognition that informed consent is required at all.  In order to support informed consent, women and pregnant people would need to be provided with accurate information on the aims and objectives of the screening and transfer of information. They would need to be provided with accurate evidence on the link between alcohol intake and FASD (as opposed to advice based on a precautionary approach). This would need to cover the lack evidence on the risks of harm associated with low levels of alcohol consumption. Evidence would need to be presented in a non-biased way, to support women in making the decision that is right for them. There would need to be a clear, acceptable, option to decline screening.  Consent would have to be sought on each occasion when screening was offered. Using the ‘proportion of antenatal appointments attended where alcohol consumption is recorded’ as a process measure is likely to increase pressure on healthcare professionals to persuade women to agree to screening or to present it as mandatory. Coercing or otherwise placing a person under undue influence to ‘consent’ is not lawful. The use of ‘proportion of antenatal appointments attended where alcohol consumption is recorded’ is a concern, as it indicated HCPs will be placed under pressure to persuade women to consent to the screening.  Even if women are offered the choice to consent or decline screening, we are concerned that opting to decline will be perceived as unacceptably ‘risky’ or will call into question the woman’s fitness to parent. Through our advice service, we have supported a number of women who have been told they will be referred to social care for declining ‘routine’ screening tests during pregnancy. We believe this is likely to be perceived by women as a significant risk if these proposals are adopted. Referrals should only be made if the woman’s choices indicate there is a threat of significant harm to the baby once it is born. Declining alcohol screening, or reporting low levels of alcohol consumption is highly unlikely to meet this threshold and this must be made clear if the quality standards are adopted. |
| 223 | Birthrights | 2 | Statement 2 | The timing, quantity and frequency of alcohol use should be recorded in maternity records and then transferred to the child’s health records after birth: women’s views  As noted below, the Equality Impact Assessment fails to assess the impact on women and pregnant people in any way. The standard presents no data to suggest that this screening would be acceptable to those receiving maternity care.  Bpas have carried out polling via Censuswide, asking:  “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 majority of respondents to this question (55%) believed healthcare professional should not share data on alcohol consumption in pregnancy on a child’s health record without permission, including 60% of those who were mothers. Only 19% - fewer than one in five women overall- expressed support for sharing this information without consent, and just 14% of mothers.  We consider that this indicates that many women will have significant concerns about the proposals. It is highly concerning that no evidence on the impact on women has been assessed as part of the development and evaluation of these proposals. |
| 224 | Birthrights | 2 | Statement 2 | Proportion of antenatal appointments attended where alcohol consumption is recorded  The use of the ‘proportion of antenatal appointments attended where alcohol consumption is recorded’ as a process measure is likely to increase pressure on healthcare professionals to persuade women to agree to screening which could constitute undue influence which could invalidate any consent given. |
| 225 | Birthrights | 2 | Statement 2 | Proportion of births with information on the mother’s alcohol consumption in pregnancy documented in the child’s health records: lawful basis of data processing  Under current Data Protection requirements (General Data Protection Regulations 2016), there must be a legal basis for the processing of personal data before it is considered lawful. 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. We do not believe that there is a sufficient legal basis under Article 6 to allow processing of this personal data and therefore the mandatory collection of a woman’s health information of this kind for the purpose proposed in the quality standards would be unlawful. This is because:   The collection/transfer 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 – an unborn child would 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 the uncertain evidence base concerning antenatal alcohol consumption and harm, the use of widely criticised prevalence estimates, and a lack of evidence regarding care pathways post-diagnosis) (6(e) GDPR).   This type of processing cannot be considered necessary for the purposes contained in the draft quality standard, thereby overriding the interests and fundamental rights and freedoms of the data subject, in this instance: the woman. In balancing the purposes (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. |
| 226 | Birthrights | 2 | Statement 2 | Proportion of births with information on the mother’s alcohol consumption in pregnancy documented in the child’s health records: Privacy  In the absence of any proposals to obtain informed consent for this process, the proposal to transfer information about a woman’s alcohol consumption onto her child’s health records represents a significant intrusion into her family life and may represent a breach of Article 8 of the Human Rights Act 1998 and European Convention on Human Rights, which protect private and confidential information. Given the lack of evidence of harm at lower levels of alcohol consumption (see above) the recording and inclusion of this data cannot be deemed to be a necessary and proportionate action. |
| 227 | Birthrights | 2 | Statement 2 | Antenatal appointments allow questions on alcohol consumption to be asked as part of routine healthcare throughout pregnancy. The timing, quantity and frequency of alcohol use should be recorded in maternity records and then transferred to the child’s health records after birth: erosion of trust & access to personalised maternity care  This proposal thwarts the ability of women to develop trusting, personal relationships with their healthcare providers. It is unlikely that women who may benefit from support with alcohol consumption will request this help, or feel safe to be open about her need, if she is unable to have a discussion with her midwife without the findings/information being transferred to her child’s medical records. 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 access to this care – or indeed care targeted at any other need that a pregnant person may have - may harm both mother and baby.    For those who have other concerns, an overriding focus on alcohol consumption is likely to erode any trust in her midwife’s ability to provide personalised antenatal care tailored to her needs (and indeed her midwife may in fact be less able to provide such personalised care within time-limited antenatal appointments). Personalised maternity care is a founding principle of the Maternity Transformation Programme, yet this proposal threatens to overrule it with an excessive focus on alcohol consumption.  It is likely that women will be concerned that reporting any alcohol consumption will be a source of stigma, will result in them being placed under additional scrutiny, or risk a referral being made to social care. The Royal College of Midwives has [expressed the same concerns](https://www.rcm.org.uk/media-releases/2020/september/midwives-fear-women-could-feel-stigmatised-if-mandatory-alcohol-screening-introduced-at-every-antenatal-appointment/), saying “this proposed approach could cause women to be stigmatised, or cause self-stigmatisation, and may disrupt or prevent the development of a trusting relationship between a woman and her midwife. We are also concerned that the proposal may be self-defeating, as women who are in most need of help will feel the need to conceal the consumption of alcohol from their midwife”.  There is substantial evidence that when women are heavily policed in pregnancy by medical professionals they disengage from antenatal care. Lack of antenatal care is known to have a substantial impact on the health of both the pregnant woman and her foetus, far greater than the impact of alcohol, cigarette, and legal or illegal substance use. There is substantial evidence on the negative consequences of policing from the US context of criminalisation of maternal behaviour (see e.g. [Boudreaux & Thompson, 2015](http://jaapl.org/content/43/2/137); [Ondersma et al., 2000](https://journals.sagepub.com/doi/10.1177/1077559500005002002)). Whilst these proposals do not introduce punitive measures we anticipate that they will be perceived as policing measures, and act to dissuade women – particularly those who already feel under additional scrutiny or may be particularly benefit from additional support – from engaging with care.  The introduction of ongoing scrutiny and impact on trust is likely to be greater for women who are already concerned about feeling scrutinised for their choices in pregnancy and birth. Birthrights’ and Birth Companions’ [research](https://www.birthrights.org.uk/wp-content/uploads/2019/09/Holding-it-all-together-Full-report-FINAL-Action-Plan.pdf) on the experiences of women facing multiple disadvantage (Birthrights and Birth Companions (2019)\*ref at end of para) found that women often had fragile relationships of trust with caregivers and were afraid of disclosing information or making choices that they feared might result in judgment or social care scrutiny – this was particularly true for women with mental health needs and younger women. Asking repetitively for women to disclose levels of drinking is likely to damage these relationships further, or potential destroy them and result in women avoiding care altogether. We are concerned that similar erosion of trust may be seen in the postnatal period if women know that health visitors, mental health workers, GPs and social workers can see that they have drunk some alcohol – however little – on their child’s health record / in their ‘red book’. This may compromise both trust and access to services designed to support women at an important transitional time in their lives.  The recommendations in this Quality Standard run counter to the principles espoused in the specialist NICE Guideline for care of the few women who do drink heavily during pregnancy. NICE Guidance on the care for pregnant women with complex social factors (CG110) describes the care that should be provided to women who misuse substances, including alcohol. The Guidance states that women should not be dissuaded from using services, and that care should be taken to address women’s fears about involvement of children’s services and potential removal of their child, and that women should be supported with “feelings of guilt about their misuse of substances and the potential effects on their baby”. It is clear that the small minority of women who drink significantly during pregnancy require tailored support including “what to expect when the baby is born” – however CG110 already provides for this specialist care and support in a far more appropriate way.  \* Holding it all together: Understanding how far the human rights of woman facing disadvantage are respected during pregnancy, birth and postnatal care. London [online]: <https://www.birthrights.org.uk/wp-content/uploads/2019/09/Holding-it-all-together-Full-report-FINAL-Action-Plan.pdf> |
| 26 | Blackburn with Darwen Borough Council Public Health and Wellbeing Team | 1 | Statement 2 | Accurate recording of alcohol use in pregnancy is vital, questions must be asked and verified if required in a safe environment. Drinkers are well-known for minimising their alcohol consumption to the medical professions. |
| 103 | Blackburn with Darwen Borough Council Substance misuse service | 1 | Statement 2 | [Statement] Accurately reflects key areas for improvement |
| 41 | British Pregnancy Advisory Service | 1 | 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. |
| 42 | British Pregnancy Advisory Service | 1 | Statement 2 | ‘Identifying children at risk 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 any 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. |
| 43 | British Pregnancy Advisory Service | 1 | Statement 2 | ‘Antenatal appointments allow questions on alcohol consumption to be asked as part of routine healthcare 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. |
| 44 | British Pregnancy Advisory Service | 1 | Statement 2 | ‘…The timing, quantity and frequency of alcohol use should be recorded in maternity records and then transferred to the child’s health records after birth.’: 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 more 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 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. |
| 45 | British Pregnancy Advisory Service | 1 | Statement 2 | [Structure measure] ‘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. |
| 46 | British Pregnancy Advisory Service | 1 | Statement 2 | [Structure measure] ‘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. |
| 47 | British Pregnancy Advisory Service | 1 | Statement 2 | [Audience descriptors] ‘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. |
| 48 | British Pregnancy Advisory Service | 1 | Statement 2 | [Audience descriptors] ‘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. |
| 49 | British Pregnancy Advisory Service | 1 | Statement 2 | [Audience descriptors] ‘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. |
| 50 | British Pregnancy Advisory Service | 1 | Statement 2 | [Source guidance] 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. |
| 51 | British Pregnancy Advisory Service | 1 | Statement 2 | [Source guidance] 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. |
| 52 | British Pregnancy Advisory Service | 1 | Statement 2 | [Source guidance] ‘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. |
| 53 | British Pregnancy Advisory Service | 1 | Statement 2 | [Definitions] ‘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. |
| 232 | British Pregnancy Advisory Service | 2 | Statement 2 | “Pregnant women have information on their alcohol consumption recorded throughout their pregnancy…and then transferred to a child’s health records after birth”  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.  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.  I hope NICE will rethink this alarming change in direction in maternity care, and reaffirm their commitment to autonomous mother-centred maternity care.” |
| 233 | British Pregnancy Advisory Service | 2 | Statement 2 | “Pregnant women have information on their alcohol consumption recorded throughout their pregnancy…and then transferred to a child’s health records after birth”  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.  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 neurodevelopmental effects, the shared information makes no difference to the level of harm. 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 remains an uncertain diagnosis 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.  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.  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)  6 Hoyme, 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. Pediatrics, 138(2). |
| 234 | British Pregnancy Advisory Service | 2 | Statement 2 | “Pregnant women have information on their alcohol consumption recorded throughout their pregnancy…and then transferred to a child’s health records after birth”  Comment provided by Dr Marianna Iliadou, Durham Law School, Durham University: Recording of alcohol consumption: There seems to be no discussion of informed consent for recording alcohol consumption. This goes against the standards set by the Supreme Court in Montgomery (Appellant) v Lanarkshire Health Board (Respondent) (Scotland) 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. |
| 235 | British Pregnancy Advisory Service | 2 | Statement 2 | “Pregnant women have information on their alcohol consumption recorded throughout their pregnancy…and then transferred to a child’s health records after birth”  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.  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.  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. 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:  a) depart radically from the necessity of communicating the basis for precautionary advice as what it is, which is an absence of evidence of a causal relation between childhood disability and all consumption of alcohol before and during pregnancy;  b) deny to women their autonomy in assessing this risk and making judgements regarding pregnancy on the basis of accurate information provided to them;  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;  d) generate specific anxiety regarding the policing character of interactions with health care professionals who women look to, to help them; and  d) waste valuable time in appointments where woman have many other concerns they would prefer to seek help for and spend time discussing. |
| 236 | British Pregnancy Advisory Service | 2 | Statement 2 | “Pregnant women have information on their alcohol consumption recorded throughout their pregnancy…and then transferred to a child’s health records after birth”  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.  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 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). |
| 237 | British Pregnancy Advisory Service | 2 | Statement 2 | “Pregnant women have information on their alcohol consumption recorded throughout their pregnancy…and then transferred to a child’s health records after birth”  Comment provided by Dr Alexandra Mullock, Senior Lecturer in Health Care Law, University of Manchester  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.  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 any small amount of alcohol during pregnancy is harmful. Therefore, there is insufficient evidence to support the policy.1  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 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.  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.    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  B Thom, R Herring and E Milne, ‘Drinking in Pregnancy: Shifting Towards the “Precautionary Principle,”’ in Susanne MacGregor and Betsy Thom (eds), Alcohol, Drugs and Risk: Framing Dangerous Classes and Dangerous Spaces: Historical and Cross-Cultural Perspectives, (Routledge 2020).  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>  3 EC Romanis, D Begović, M Brazier and A Mullock, ‘Reviewing the Womb,’ (2020) Journal of Medical Ethics 10.1136/medethics-2020-106160.  4 C Bowden, ‘Are We Justified in Introducing Carbon Monoxide Testing to Encourage Smoking Cessation in Pregnant Women?’ (2019) 27 Health Care Analysis 128. |
| 238 | British Pregnancy Advisory Service | 2 | Statement 2 | “Pregnant women have information on their alcohol consumption recorded throughout their pregnancy…and then transferred to a child’s health records after birth”  Comment provided by Catherine Bowden, PhD Candidate in Bioethics and Medical Jurisprudence, Centre for Social Ethics and Policy (CSEP), University of Manchester  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 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.  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 (X v Y [1988] 2 All ER 648 and W v Edgell [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.  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. |
| 239 | British Pregnancy Advisory Service | 2 | Statement 2 | “Pregnant women have information on their alcohol consumption recorded throughout their pregnancy…and then transferred to a child’s health records after birth”  Comment provided by Dr Alexis Paton, Lecturer in Social Epidemiology and the Sociology of Health, Aston University  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.  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. Health Expectations, 21 :678-684  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. Social Science and Medicine. <https://doi.org/10.1016/j.socscimed.2020.113362>  Paton, A. 2017. No Longer Handmaiden: The role of social and sociological theory in bioethics. IJFAB, 10(1): 30-49. |
| 244 | British Psychological Society | 2 | Statement 2 | Pregnant women have information on their alcohol consumption recorded throughout their pregnancy.  In order to ensure all relevant medical information is available at the time of possible diagnosis, where feasible, prescription medication and smoking should also be recorded and any evidence of recreational drug use. This is included in the Canadian guidelines and mentioned in SIGN 156 page 12. |
| 69 | Changing Minds UK | 1 | Statement 2 | It will be important that the asking and recording of alcohol consumption to be done sensitively and non-judgementally. |
| 74 | CoramBAAF | 1 | Statement 2 | Needs to state clearly in the statement that this includes child records – only find that out by detailed reading |
| 75 | CoramBAAF | 1 | Statement 2 | Information from social work records may be crucial and important . Health care professionals may need to transfer appropriately information into childs records re maternal alcohol consumption so that this information remains with the child |
| 76 | CoramBAAF | 1 | Statement 2 | Women may not admit – social workers may have evidential information from pregnancy pre proceedings / case conferences which need to be captured in the child’s record not just the mother’s  Lots of delivery maternal information in a child’s record has “ no problems” under mother’s medical information when a child is being seen for an Initial LAC Health Assessment and the SW is clearly reporting drug misuse in pregnancy – how does this standard prevent that also happening for alcohol? |
| 83 | East Herts and Area FASD Support Network | 1 | Statement 2 | It is extremely important for the process of diagnosis that Quality Statement 2 is retained in full. This will enable evidence of alcohol exposure in utero to be entered into the child’s medical record, and facilitate an early diagnosis. |
| 445 | General Medical Council | 2 | Statement 2 | Confidentiality is an important ethical principle of medical practice and we provide [guidance to doctors on this issue](https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/confidentiality).  In this guidance we are clear that doctors need to ask for explicit consent to disclose identifiable information about patients for purposes other than their care, unless disclosure is of overall benefit to a patient who lacks capacity, it is required by law or can be justified in the public interest (see paragraph 8h in our confidentiality guidance). At paragraph 9 we explain the circumstances under which doctors may share information about a patient:   * Where the patient consents, whether implicitly or explicitly for the sake of their own care or for local clinical audit * Where the patient explicitly consents for other purposes * Where disclosure is of overall benefit to a patient who lacks the capacity to consent * Where the disclose is required by law or it is permitted or has been approved under a statutory process that sets aside the common law duty of confidentiality * The disclosure can be justified in the public interest   We go on to detail the further relevant requirements doctors must meet for disclosing information at paragraph 10.  In our guidance, the term ‘direct care’ refers to activities that directly contribute to the diagnosis, care and treatment of an individual, in the present circumstances the mother. Transferring this information to the record of a child once they are born would fall outside of disclosures for the purpose of the direct care of the mother. We would therefore expect doctors to seek explicit consent to do so. Asking for a patient’s consent to disclose information shows respect, and is part of good communication between doctors and patients (see paragraph 13).  There are circumstances in which a doctor may disclose information without consent, but they must be satisfied that there is another legal basis for doing so. If a patient refuses to consent to information being disclosed that would benefit others, disclosure might still be justified in the public interest if failure to disclose the information leaves others at risk of death or serious harm. If a patient refuses consent to disclosure, a doctor needs to balance their duty to make the care of their patient their first concern against their duty to help protect the other person from serious harm. They would need to make this decision based on the individual circumstances of the case and we would usually expect them to discuss this with the patient unless there was a particular reason not to do so (paragraphs 63-70 give more information about disclosures in the public interest).  While we appreciate the intention to prevent or reduce harm to children with foetal alcohol syndrome by improving the likelihood of early diagnosis and intervention, information must be shared within the framework provided by law and ethics. It is not clear to us how this quality standard as currently proposed fits with this framework.  In addition, there may be practical challenges and unintended consequences of this approach if it feels overly intrusive to pregnant women. Women who need support may be less likely to openly share information about their alcohol consumption, meaning that data is inaccurate and engagement with healthcare services may deteriorate. |
| 287 | Healthwatch UK | 2 | Statement 2 | The quality standard refers to the importance of recording a woman's alcohol intake in her maternity notes at every visit and then transferring this information to the child's care records after birth. This Quality Standard about recording alcohol intake is inconsistent with NICE guidance: reviewing the whole antenatal guideline including updates: <https://www.nice.org.uk/guidance/cg62/evidence/full-guideline-pdf-196748323> we cannot find any recommendation that alcohol intake should be asked about at every visit, nor that it should be recorded. In addition, the question of confidentiality, trusting relationships and recording of information in the notes was not explicitly addressed   Despite the fact that the recording of a woman’s alcohol intake and transferring this to the child’s records is referred to twice in the Quality Standard (pages 7 and 9), no mention is made of the issue of gaining the mother's consent for the information to be recorded or the fact that recording such information may seem stigmatising or threatening to the mother.   We feel that HCPs who provide antenatal care must be trained to obtain and record this information sensitively and should expressly record that the mother has consented to such recording, even if only verbally. HCPs should also make it clear to women that they are not obliged to provide information about their intake. |
| 448 | Institute of Health Visiting | 2 | Statement 2 | This is an important issue but raises the question as to who records the information, and when there are different professionals involved if this information is shared between them.  An antenatal visit is one of 5 universal reviews mandated for the health visiting service1. The antenatal health promoting visit for the assessment and review of health and wellbeing is usually carried out by the health visitor between 28-32 weeks of pregnancy, as outlined in the Healthy Child Programme 0-5 years. However, there is widespread variation in the level of uptake of the antenatal contact, which is not offered universally in all areas now, despite mandation.  Health visitors will already be in contact with those families with other children and may make contact earlier, particularly if the family is vulnerable, or seen as being in the ‘universal plus’ or ‘universal partnership plus’1 groups. In other words with additional needs.  1.NHS Healthy Child Programme. 2020. <http://www.healthychildprogramme.com/> Accessed 3.10.20 |
| 449 | Institute of Health Visiting | 2 | Statement 2 | Whilst undertaking a holistic assessment, health visitors (HVs) the mother may disclose their alcohol consumption during pregnancy, but this relies on a level of trust between the mother and the practitioner, enhanced by continuity of health visitor. There may be a need to add this to local record frameworks to prompt practitioners. |
| 450 | Institute of Health Visiting | 2 | Statement 2 | Systems need to in be in place to share information about the risk of fetal alcohol spectrum disorder (FASD) in the antenatal period as maternity records and general practice records are rarely interoperable with those used by health visitors. HVs and midwives don’t tend to interact as much as they once did when this information might have been conveyed informally.  After the birth of the child, the passing of information about alcohol consumption to the health visitor in transfer of care documentation such as maternity birth notifications, personal child health record (the ‘red book’). The child’s electronic care summary record, is to be commended but will need changes in systems, communicating between maternity and health visitor services as well as sensitive management and information governance of 3rd party information about the mother in the child’s record (as the child will have access to these records once they reach the age of consent/ Fraser competence). |
| 451 | Institute of Health Visiting | 2 | Statement 2 | NHS Digital figures indicate that 30% of health visitors were lost between 2015 and 2020. Before Covid 19, health visitor caseloads were therefore far larger than recommended and when under time pressure it is often the antenatal contacts that are omitted. The situation is even worse now. |
| 452 | Institute of Health Visiting | 2 | Statement 2 | As noted above there would need to be changes to IT systems  To promote a quality and universal health visiting service to all children and their parents, as well as those at risk of FASD there needs to a renewed investment in health visiting to increase capacity and restore workforce numbers to the level seen in 2015. |
| 294 | Liberty | 2 | Statement 2 | We write from the human rights NGO Liberty in regard to the NICE Quality Standard on Fetal Alcohol Spectrum Disorder (FASD) which is currently being consulted on.  Liberty is an independent membership organisation. We challenge injustice, defend freedom and campaign to make sure everyone in the UK is treated fairly. Liberty provides policy responses to Government consultations on issues which have implications for human rights and civil liberties.  We note the importance of intervention and support for children with neurological impairments but are concerned that the current draft policy may not achieve its desired outcome. The current proposals as set forward would see alcohol consumption during pregnancy recorded and transferred to a child’s medical records once born, regardless of quantity consumed, and without the woman’s consent. This raises concern on the impact these proposals would have on the woman’s right to privacy.  Liberty has seen the British Pregnancy Advisory Services (BPAS)’s reply to this consultation. Liberty endorses those concerns. We highlight the following concerns in particular.  Quality statement 2 currently states that:  ‘Healthcare professionals (midwives and GPs) would record information on a woman’s alcohol consumption during pregnancy in her maternity records at antenatal appointments. They document the number and types of alcoholic drinks consumed, as well as the pattern and frequency of drinking. 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 records, such as maternity birth notifications, personal child health record (the ‘red book’) and the child’s electronic care summary record.’  BPAS estimate that this policy could involve the data transfer of over 250,000 cases every year while also noting that there is a lack of a firm evidential basis for the need to do so. The lack of evidential basis behind this section of the policy raises questions as to whether the data sharing under it can ever be in the public interest. It also raises questions over the legality of such a policy.  It is unclear whether this policy has given regard to Article 6(1) of the General Data Processing Regulation (GDPR) which sets out the legal basis for personal data about health to be processed and whether the collection of this information can be considered necessary to protect the vital interests of the data subjects. It is also unclear whether informed consent would be obtained from each and every woman whose data it is proposed to be shared.  It is further unclear whether there has been any consideration of Article 8 of the European Convention on Human Rights. Information about a person's health and treatment for ill-health is both private and confidential (Campbell v MGN Ltd [2004] UKHL 22; [2004] 2 AC 457; at [145] and [147] per Lady Hale). As Lord Hoffman observed in Campbell (at [53]) “human autonomy and dignity” dictate that whether health-related information should be communicated to other people is plainly something which an individual is entitled to decide for herself. The communication of the personal data to third parties constitutes an interference with the right to respect for private life.  Interferences with the right to privacy are only lawful if they are in pursuit of a legitimate aim, in accordance with the law, and necessary in a democratic society, which requires an assessment of the proportionality of the measure in question.  Considering the high level of potential data transfer and lack of evidential basis highlighted by the BPAS reply and above, it is therefore very concerning that the current ‘Equality Impact Assessment’ for this policy fails to consider the impact on a women’s right to privacy, particularly of her medical data. Indeed, the equality impact assessment is 1 ½ pages long and simply states that “No equality issues have been identified at this stage”.  A relationship of confidentiality and trust  The General Medical Council’s Guidance entitled Confidentiality: good practice in handling patient information (January 2017) (“the GMC Guidance”) which applies to all doctors, states at paragraph 1:  “Trust is an essential part of the doctor-patient relationship and confidentiality is central to this. Patients may avoid seeking medical help, or may under-report symptoms, if they think their personal information will be disclosed by doctors without consent, or without the chance to have some control over the timing or amount of information shared.” […]” (paragraph 1).  The balancing act required between considering disclosure without the patient’s consent is highlighted at para 64:  “[…] The benefits to an individual or to society of the disclosure must outweigh both the patient’s and the public interest in keeping the information confidential…”  Liberty echoes BPAS concerns that there is potential for this policy to inhibit the ability of healthcare professionals to build relationships of trust with their patients. 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. This is likely to lead to women being deprived of access to an important service, the opposite result of what the policy intended to achieve.  In light of the lack of firm evidential basis and the apparent lack of any human rights or equality impact considerations Liberty considers that this potentially high-level data transfer would be disproportionate and not in the public interest.  Conclusion  Liberty considers that the starting point when considering any policy should be that medical information and information provided/generated in connection with access to medical services is highly sensitive private information and personal data. We consider that the failure to weigh up privacy and equality implications for pregnant women described above and in BPAS reply to the consultation is an oversight that must be addressed.  We would urge the consultation to re-examine the potential negative impact of this quality standard. |
| 299 | medConfidential | 2 | Statement 2 | The guidance being consulted upon proposes, that in practice, if a woman tells her doctor she has drunk just one unit of alcohol at any time during pregnancy (even before she was aware of her pregnancy), her child’s medical record will automatically be flagged as at risk of FASD. This will potentially have significant adverse consequences for mother and child in interactions with other services over time.  This consequence seems both disproportionate and beyond the medical advice cited by NICE. The clinical advice is outside the scope of medConfidential’s remit, but we focus on that if NICE are to achieve this goal, that NICE may wish to approach it fundamentally differently.  If NICE wishes to place all new born children somewhere on the FASD spectrum, which appears to be the clinical aim, rather than asking all parents questions and deriving risk scores from the parent, there would be none of the data driven concerns if this was to be an informed process conducted for every newborn, normally with the informed consent of their parent. We note a variety of GDPR related issues have been raised by others, and we support those comments, especially around removing discretion from clinicians and handing it to an algorithm, mutant or otherwise. |
| 437 | National Data Guardian (NDG) | 2 | Statement 2 | Our understanding is that the draft quality standard anticipates that implied consent would be used as the basis for disclosure of recorded alcohol consumption from the pregnant person’s record to the child’s medical record. |
| 438 | National Data Guardian (NDG) | 2 | Statement 2 | If all alcohol consumption during a pregnancy is to be recorded and transferred to the child’s medical records once he / she is born, this should be part of a transparent process of clearly informing the pregnant person, and seeking their explicit consent for this information to be placed on the child’s record. |
| 439 | National Data Guardian (NDG) | 2 | Statement 2 | The practice of recording all alcohol consumption could deter pregnant people from engaging in a confidential conversation with a mid-wife or health and care professional about alcohol consumption, particularly if the pregnant person does not wish the information to be shared beyond their own medical record. Relationships of trust are critical to support the delivery of high-quality maternity care. |
| 440 | National Data Guardian (NDG) | 2 | Statement 2 | The draft quality standard presents the recording of alcohol consumption as being for routine pregnancy care. However, the intended purpose for recording this information seems to clearly be for FSAD screening for the child. |
| 441 | National Data Guardian (NDG) | 2 | Statement 2 | The question of whether this proposal would have sufficient specificity and sensitivity to be an effective screening tool falls outside the NDG’s remit. However, we would advise that even in the case that it is considered to be an effective screening tool, the likely benefits of the screening should be weighed against the legal, ethical, and potentially negative aspects of recording third party confidential information in the child's records. We believe that this needs further consideration to assess whether this would be a necessary and proportionate use of a person’s confidential information. |
| 442 | National Data Guardian (NDG) | 2 | Statement 2 | If the standard were adopted, we assume that as part of the first contact appointment there would have to be an informed conversation with a health professional regarding the disclosure of the alcohol consumption information for the purpose described. Our experience is that concerns about confidentiality may lead to an underrepresentation of drinking habits in the recorded information and/or a deterrent effect on healthcare seeking. For instance, there is some evidence that mandatory recording and reporting of, for example, female genital mutilation (FGM) has caused some individuals not to seek healthcare, due to the possibility of disclosure. |
| 443 | National Data Guardian (NDG) | 2 | Statement 2 | Whilst the aims are undoubtedly laudable, the draft quality standard proposals fail to address pertinent questions about confidentiality and proportionality. The draft quality standard seeks to embed alcohol screening practices and disclosures for all pregnant persons, regardless of perceived risk, into policy and routine practice, |
| 444 | National Data Guardian (NDG) | 2 | Statement 2 | We strongly recommend further engagement with stakeholders and the public to ensure appropriate consideration is given to the complex ethical and privacy issues that have impact on both the pregnant person and the child. |
| 307 | NHS England and NHS Improvement | 2 | Statement 2 | What is the rationale for recording alcohol consumption at every antenatal appointment? Will the answers be valid given that this is a question that women may perceive has judgement associated it? We suggest a targeted approach, e.g. for women identified with significant alcohol issues at booking, is more appropriate  There needs to be an emphasis on support for those for whom alcohol is a problem, otherwise this appears to be a punitive exercise, particularly if the question is repeatedly asked. How can the need for support be assessed. Are supportive interventions available? What is the evidence for VBA related to alcohol consumption in pregnancy?  How would this fit in with the maternity services data set, which is stated as a source, but does not include this at present? |
| 116 | NOFAS-UK | 1 | Statement 2 | Ensuring that alcohol use in pregnancy is noted in both the pregnant woman’s records and also transferred to the child’s is extremely important and potentially life-changing as this will provide key information needed for later diagnosis. It also hopefully will open the door for support for pregnant women who need help quitting alcohol. This is extremely important for those children who are later in care or who are adopted. As one person commented, “As an ex-nurse and currently a foster carer I see a lot of red books and lots of babies who are withdrawing from prenatal [alcohol] misuse by mom. But I’ve never ever seen it recorded in a red book.” It is also important that pregnant women are educated about FASD so that they can understand what signs to look for later, should problems arise after an alcohol-exposed pregnancy.  • Training is key so that this is done in a non-judgmental and supportive manner throughout the pregnancy, using best practices for open-ended interviews and those screening tools that exist. Any alcohol exposure should be noted. Women should be referred for additional support if needed.  • Social services should be appropriately trained on the reasons why women drink during pregnancy and how to support those women, to ensure this does not lead to shaming and blaming birth mothers and prematurely separating families. There are many best practices out there which should be shared and built upon.  • Women who have FASD and who become pregnant should receive targeted support and care throughout the pregnancy (including visual aids and materials) and appropriate assessments, scaffolding and support after the birth. |
| 313 | Northumbria Healthcare Foundation NHS Trust | 2 | Statement 2 | [Comment submitted in format used for comments at topic engagement]  An antenatal specific screening tool should be considered to maximise the detection of women consuming alcohol in pregnancy, which incorporates all significant information. A universally agreed referral threshold is required.  To ensure that every woman receives equitable support across the country.  A combined role of smoking cessation/alcohol/public health advisor in maternity clinics may be a cost effective option to support midwives.  Currently service provision varies dramatically from one NHS Trust to another.  A stepped approach using Brief Interventions have proved effective and is recommended.  N.B. A bespoke antenatal alcohol screening tool has been developed and implemented in the North East of England. |
| 314 | Northumbria Healthcare Foundation NHS Trust | 2 | Statement 2 | [Comment submitted in format used for comments at topic engagement]  Any maternal disclosure of alcohol consumption in pregnancy must be documented in the antenatal notes.  To facilitate diagnosis. Documented evidence is generally a requirement of diagnosis for children without the classic FAS facial dysmorphia.  To utilise resources already available to us such as the (red) baby book as this follows the infant throughout childhood. It may be an effective resource to share information with the health visitor, GP, school nurse, teacher or even social worker if required. A special Prenatal Alcohol Exposure (PAE) question in the book could be added and completed in the antenatal period as a simple way to communicate. Any PAE could also be documented in a Regional Perinatal Data Management system such as BadgerNet UK, and all baby notes and electronic records should routinely be shared with the multidisciplinary team. |
| 315 | Northumbria Healthcare Foundation NHS Trust | 2 | Statement 2 | [Comment submitted in format used for comments at topic engagement]  A single format of accurate data collection is required across the NHS.  Consistent and clear data should be collected and documented in designated maternal and neonatal medial notes to facilitate this.  We need to unify and utilise existing datasets such as the Maternity Dashboard and Trust Performance Reports to provide invaluable health informatics that can be reliably compared and monitored within each Trust and across the country. |
| 316 | Northumbria Healthcare Foundation NHS Trust | 2 | Statement 2 | [Comment submitted in format used for comments at topic engagement]  An annual audit of local maternity notes would ensure compliance and measure data across the country. Data to be published in NMPI reports to collect national alcohol consumption prevalence and referral rates.  This will provide national data intelligence to inform the planning of FASD service provision and identify training needs in maternity and paediatric staff.  Audit could be part of the role of the maternity alcohol champion or specialist midwife.  Alcohol in pregnancy data should be incorporated into NHS quality targets such as the CQC and Maternity Data Set to ensure that the issue is regarded as a priority nationally. |
| 125 | Peterborough family FASD support Group & Field of Enterprise Training & Consultancy | 1 | Statement 2 | I agree that it is vital that information about maternal alcohol consumption is transferred to child’s medical record. This also needs to be the softer measures, not just what a woman admits to. All of our children (SGO and fostered) did not have anything on their record. In all three cases birth Mums told me about their drinking 2 with ARND identification and the oldest with an identification of FASD with no salient features IF ALCOHOL CONSUMPTION CAN BE PROVED. This took longest to engage services. We started when she was a child, but she was an adult before we had an assessment and in her case my reporting of a conversation wasn’t good enough whereas it was in the other two cases, one of whom is her younger sibling.  In collecting new-born babies from the maternity unit as a foster carer we have found that the only mention of Mum being an alcoholic / using alcohol has been a single line buried in the mother’s hospital notes of her time in the maternity unit. Nothing being transferred to the social care notes. Therefore, there needs to be joined up communication and if alcohol use is only identified in the maternity unit there must be mechanisms to transfer this late information to the child’s medical file.  There needs to be something in the standard that a) requires social care, especially when an adoption or connected care is proposed, that strives to identify whether FASD may be a factor and b) communicates this information transparently to those who in the future may be caring for that individual. Neither is applied in all cases at the moment. |
| 133 | Public Health England | 2 | Statement 2 | [Rationale]  “*A lack of this information is a barrier to a diagnosis of* ***FASD and, in the absence of 3 sentinel facial features, prevents a diagnosis being made***.”  The presence of three sentinel facial features is now considered a diagnosis of foetal alcohol syndrome specifically, rather than FASD. It is possible for FASD cases to have fewer than 3 sentinel features and the Scottish (1) and recently published Australian (2) (published Feb 2020) guidelines both recognise this. We would recommend removing the text highlighted in bold above.  (1) <https://www.sign.ac.uk/assets/sign156.pdf>  (2) <https://www.fasdhub.org.au/contentassets/32961d4a5cf94de48ebcf985c34d5456/australian-guide-to-the-diagnosis-of-fasd_all-appendices_feb2020.docx.pdf> |
| 134 | Public Health England | 2 | Statement 2 | The continued recording of alcohol consumption across pregnancy is welcome, however, it needs to be accompanied (where alcohol is being consumed) with reiteration of the CMO’s advice, and assertive support for the woman - this could / should include support around long acting reversible contraception (LARC) following the birth of a child who has had an alcohol exposed pregnancy. Again clear linkage to CG100 would be helpful. |
| 135 | Public Health England | 2 | Statement 2 | Where problem drinking/ dependency is an issue, pregnant women should be referred to local specialist treatment and social care services and be supported to engage with services post partum where necessary.  As poly drug use is common among people with a dependency, healthcare professionals should find out whether pregnant women who are drinking problematically whether they are misusing other psychoactive substances as well. Similarly, women presenting with opioid and other drug use should be asked about their drinking and receive relevant advice. |
| 136 | Public Health England | 2 | Statement 2 | We would want to recognise the important role that partners and other close family members have in supporting an alcohol free pregnancy. The level of support can be beneficial but, in some cases, can provide additional challenges to mothers and healthcare professionals which can put foetuses at risk. Heavy drinking fathers, for example, are associated with producing low birth-weight neonates with increased risk of cardiovascular abnormalities, while spontaneous abortions and neonatal deaths are also linked to heavy drinking by either parent (Cleaver, Unell, & Aldgate, 2011). |
| 137 | Public Health England | 2 | Statement 2 | [Definitions]  The definitions of terms used in this quality statement on page 9 should be reworded to clarify the distinction between screening and discussion. We suggest the following rewording:  **The provision of advice, and discussion, about alcohol consumption is recorded**  *At antenatal appointments, all women should be advised not to consume alcohol in pregnancy. As part of this health promotion activity the number and types of alcoholic drinks consumed, as well as the pattern and frequency of drinking should be discussed where relevant to the woman. The discussion should be recorded in maternity records.* |
| 143 | Royal College of General Practitioners | 1 | Statement 2 | Can consideration be paid to altering the maternity data set to enable easier data collection of this standard? Currently, the Maternity Services Data Set (MSDS) Data Model v2.0 <https://digital.nhs.uk/binaries/content/assets/website-assets/data-and-information/data-sets/maternity-services/maternity-services-data-set-data-model-v2.0.pdf> appears not mention alcohol, alcohol advice or indeed any other co-existing lifestyle factors such as smoking and substance abuse. |
| 146 | Royal College of General Practitioners | 1 | Statement 2 | Documentation of evidence. Current maternity co-operation notes do not include alcohol consumption as a routine question for each antenatal consultation (for example enquiry about foetal movements). Should this be considered? Collecting the data from these notes will be difficult as they are handheld by patients, but it would be a good aid memoir for all staff reviewing pregnant women. Data will need to come from midwife records in primary and secondary care |
| 327 | Royal College of Midwives | 2 | Statement 2 | ‘Pregnant women have information on their alcohol consumption recorded throughout their pregnancy’  As there is no known safe level of alcohol consumption during pregnancy, the Royal College of Midwives (RCM) believes it is appropriate and important to advise women that the safest approach is not to drink alcohol during pregnancy. However, the RCM has some concerns about the proposal to record information on alcohol consumption throughout pregnancy.  The quality standard proposes to include mandatory screening at every antenatal appointment, despite such measures being repeatedly rejected by the UK Screening Committee. While there remains no conclusive evidence of any causal relationship between low to mid-level alcohol consumption and harm, including FASD, the approach to recording low to mid-level alcohol consumption and transferring this information to the child’s record should be cautious.    This is because, where the proposed approach causes women to be stigmatised or causes self-stigmatisation, recording of alcohol consumption may disrupt, or prevent the development of a trusting relationship between a woman and her midwife. This approach may also be self-defeating, in that the women who are in most need of help, will feel the need to conceal the consumption of alcohol from their midwife.  As such, routine inquiry about alcohol consumption should be approached in a non-judgemental fashion, and recording should occur where women have continued to consume alcohol against advice throughout the pregnancy. Midwives are best placed to make assessments concerning what information to document during antenatal appointments. Given the demands on their time, midwives should maintain the autonomy to tailor their advice and support according to women’s needs.  Careful consideration should be given as to the process by which women’s consent is obtained for any transference of confidential medical information onto the child’s medical record. Where informed consent cannot be obtained, the Committee should consider whether the recording of this information complies with the General Data Protection Regulations.  In addition, the proposals appear to expand the definition of prenatal alcohol exposure (PAE) by removing a lower threshold for alcohol consumption. This would have the effect of flagging children as ‘at risk’ where a woman has recorded any alcohol consumption at all. This approach is poorly evidenced and would cause the number of women and children impacted by the proposals to be very large. This makes it all the more concerning that women have not been considered in the Equality Impact Assessment. |
| 328 | Royal College of Midwives | 2 | Statement 2 | ‘Evidence of local proformas or templates for maternity records which include sections to document information on alcohol consumption during pregnancy’  The Committee should be aware that this measure will create a significant additional burden for already overburdened midwives. Midwives have limited time with each woman during appointments. Any requirement to complete proformas will place additional demands on this time and could take time away from the needs of the individual patient. The RCM believes Midwives are best placed to make assessments concerning what information to document during antenatal appointments and given the demands on their time, midwives should maintain the autonomy to tailor their advice and support according to women’s needs.  In addition, the RCM would caution against the use of a proforma template which establishes a duty to assess the reliability of women with regard to their self-reporting. This manner of recording would embed an approach to scrutiny, rather than trust and could be counterintuitive, leading to patients disengaging with healthcare services, rather than seeking support. Assessing the reliability of the information provided by women could also pave the way for further invasive measures. For this reason, it is also essential that an ethical assessment of these measures is undertaken. |
| 329 | Royal College of Midwives | 2 | Statement 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’  Careful consideration should be given as to the process by which women’s consent is obtained for any transference of confidential medical information onto the child’s medical record. Where informed consent cannot be obtained, the Committee should consider whether the recording of this information complies with the General Data Protection Regulations. |
| 330 | Royal College of Midwives | 2 | Statement 2 | ‘Healthcare professionals’  The Committee should be aware that this measure will create an additional burden for already overburdened midwives. Midwives have limited time with each woman during appointments. Any requirement to complete proformas will place additional demands on this time and could take time away from the needs of the individual patient. The RCM believes Midwives are best placed to make assessments concerning what information to document during antenatal appointments and given the demands on their time, midwives should maintain the autonomy to tailor their advice, including referalls to specialist services, according thier needs. |
| 332 | Royal College of Obstetricians and Gynaecologists | 2 | Statement 2 | Pregnant women have information on their alcohol consumption recorded throughout their pregnancy.  The quality standard proposes to include mandatory screening at every antenatal appointment, despite such measures being repeatedly rejected by the UK Screening Committee. If women are to be given information about alcohol consumption at their booking visit, we do not believe they need a reminder every time they see a midwife.  This level of data collection feels like a box ticking exercise to collect statistics that will likely be burdensome for healthcare professionals and have little impact on patient or childhood outcomes. In our view, it is much more important to make sure proper support is available for those women who need it following their first visit.  The suggested approach risks harming the development of a trusting relationship between a woman and her midwife if the woman feels that she is being continually questioned and her answers recorded. It may also detract from other more pressing issues relating to the pregnancy.  In addition, the proposals appear to expand the definition of prenatal alcohol exposure by removing a lower threshold for alcohol consumption. This would have the effect of flagging children as ‘at risk’ where a woman has indicated any alcohol consumption at all – the only women not flagged will be those who answer that they ‘never’ consume alcohol. This approach is poorly evidenced and would cause the number of women and children impacted by the proposals to be very large. It could result in large numbers of women being offered interventions they do not need, potentially reducing the level of support available for those women who do need it. |
| 333 | Royal College of Obstetricians and Gynaecologists | 2 | Statement 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’  We have concerns at the proposal to transfer information from a woman’s medical record to that of her child. Disclosure of alcohol use is important to allow support to limit alcohol use during pregnancy. However, this information should be confidential to the woman’s health record. A woman may well decide to conceal her alcohol use from her healthcare professional, which is already common, when she realises that the information will automatically be transferred to her child’s records. Rather than helping with diagnosis of, and support for, FASD, this proposal risks creating another barrier to preventing FASD.  Information should only be transferred to the child’s medical record if it is directly about the child, for example, how they were born. The transfer of any other information should only take place where a woman has given her explicit and informed consent. If this cannot be guaranteed, recording such information raises serous information governance concerns. |
| 343 | Royal College of Paediatrics and Child Health | 2 | Statement 2 | It needs to be clearly stated that this includes child records as you can only find that out by detailed reading. |
| 344 | Royal College of Paediatrics and Child Health | 2 | Statement 2 | Women may not admit to having drunk during pregnancy. Social workers may have evidential information from pregnancy pre-proceedings/case conferences which need to be captured in the child’s record and not just the mothers.  Lots of delivery maternal information in a child’s record has “ no problems” under mother’s medical information when a child is being seen for an Initial Health Assessment and the SW is clearly reporting drug misuse in pregnancy, how does this standard prevent that also happening for alcohol? |
| 383 | Scottish Health Action on Alcohol Problems (SHAAP) | 2 | Statement 2 | Under ‘rationale’: “the timing, quantity and frequency of alcohol use” must [not should] “be recorded in maternity records and then transferred to the child’s health records after birth”.  In terms of the advice received at the first antenatal appointment: counselling to avoid alcohol is straightforward, and would be easily achievable within the context of an antenatal appointment. Information about performance on this can be readily captured and audited through midwifery records, and represents basic good practice.  It is worth noting that the first antenatal appointment is already several weeks into a confirmed pregnancy, and significant fetal harm can occur during the initial stages of pregnancy. Given this, it is important that alcohol avoidance advice is given in primary care settings to people trying to conceive, or who may be at risk of conceiving while consuming alcohol. Appropriate data sets relating to the dispensing of this advice can be set up within NHS settings without undue expense, and can feed into the Maternity Services Data Set. It should be recorded that written, as well as verbal advice was offered in these cases. Such records would add important information in circumstances where midwives feel there has been a sceptical response to information and advice about avoiding alcohol during pregnancy, or where there are concerns that advice may not be heeded.  An example of good midwifery practice in the Scottish context comes for the Lanarkshire Additional Midwifery Service, LAMS, which offers a dedicated midwifery service for women with drug and alcohol problems. The team there were awarded the “Presidents Award for Reducing Inequalities” by the Royal College of Midwives in 2017 (<https://www.rcmawards.com/2017-winners>) Experienced midwives in this setting provide an example of excellent practice and basic good working methods ‘on show’ as part of their day to day work. |
| 384 | Scottish Health Action on Alcohol Problems (SHAAP) | 2 | Statement 2 | Under “Definitions of terms used in this quality statement” – “Pregnant women have information on their alcohol consumption recorded”: it should be specified that the pattern and frequency of drinking should be recorded at every antenatal appointment.  Recording the pattern and frequency of drinking at every antenatal appointment is desirable, easily achievable, and measurable within current NHS resources. The information could be captured and fed to a central data set. The outcome following advice offered should ideally also be recorded including any action taken. The importance of ensuring that this information is transferred to the Child Health Record cannot be overstated. This is essential since the physical and growth criteria of FA Syndrome are only observed in around 10% of cases, - the remainder, on the FA Spectrum lack such features and will only feasibly be diagnosed when older and subject to a neurodevelopmental assessment. Maintaining this information in the Child Health Record is of pivotal importance, and easy to set up, monitor and audit. Present practice is very deficient in this area. Lack of satisfactory documentation of maternal alcohol intake in pregnancy is in practice a frequent impediment to the diagnosis of FASD in children and young people. |
| 395 | Scottish Intercollegiate Guidelines Network | 2 | Statement 2 | The way in which women are asked about alcohol consumption and whether the person asking had been trained should be measured. |
| 396 | Scottish Intercollegiate Guidelines Network | 2 | Statement 2 | Training and confidence of practitioners in asking about alcohol should be measured. |
| 397 | Scottish Intercollegiate Guidelines Network | 2 | Statement 2 | It would be helpful as a continuing measure of alcohol consumption during pregnancy to measure meconium biomarkers (Abernethy C, McCall KE, Cooper G, et al Determining the pattern and prevalence of alcohol consumption in pregnancy by measuring biomarkers in meconium. Archives of Disease in Childhood - Fetal and Neonatal Edition 2018;103:F216-F220.) |
| 413 | Surrey and Borders Partnership NHS Foundation Trust and National FASD Behaviour management clinic. | 2 | Statement 2 | This is vital. Whilst some think this screening, it is not. Smoking and other information that has clinical need is already put onto the child discharge summary record. This is about having some insight later on in life if there was exposure or not that is accessible to the child or adult as the maternal records in many cases can be unavailable and without this a diagnosis cannot be made. IT is all about accurate information and diagnosis and whilst we understand concerns about doing something for the sake of it being wrong, in this case there is an absolute clinical need that drives the recommendation and I feel strongly it should stay as it is.If good information and balanced information has been given as part of statement 1 the stigma here should be reduced as well. |
| 414 | Surrey and Borders Partnership NHS Foundation Trust and National FASD Behaviour management clinic. | 2 | Statement 2 | By having a standard approach such as being in a discharge record will allow audits if needed but here care would need to be taken to prevent it being used as a survey of all and some protection to meet the concerns that those who do not see this as a clinical rationale. The balance between the child and the maternal need may need to be considered without undermining the clinical importance |
| 155 | TACT - The Adolescent & Children’s Trust | 1 | Statement 2 | We feel that to avoid possible arguments about this information being confidential to the mother that the Standard should specifically say that alcohol consumption is recorded on both the mother’s and child’s records. |
| 156 | TACT - The Adolescent & Children’s Trust | 1 | Statement 2 | This information should also include alcohol consumption prior to discovering that they were pregnant but in all likelihood were actually pregnant. |
| 389 | University of Bristol (Law School) | 2 | Statement 2 | A key problem with the current consultation is the absence of a full consideration of the privacy and confidentiality issues that may arise as a result of mandatory recording of maternal behaviours on future children’s health records.  When considering a privacy / data protection approach to the collection of this type of data, one might expect a detailed privacy/data protection Impact Assessment (DPIA) to be carried out to:   describe the nature, scope, context and purposes of the processing;   assess necessity, proportionality and compliance measures;   identify and assess risks to individuals; and   identify any additional measures to mitigate those risks. ([ICO DPIA](https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/accountability-and-governance/data-protection-impact-assessments/))  The purpose of the collection of the data on maternal alcohol use and its appending to both the mother and the child’s health and social care record is arguably to aid with the diagnostic process of FASD, particularly in cases where the child is no longer in the care of the birth parents (e.g. in LA care, adopted or in the care of others, including special guardians).  The data to be collected would be as complete as possible a record of the maternal alcohol history. However, this is being undertaken without the usual and expected checks and balances of legal and ethical governance.  The creation of cohorts of children deemed to be ‘at risk’ of FASD based on a flawed interpretation of the existing evidence also risks overburdening an already resource-stretched maternity and early years system.  There is no opportunity for women to opt out of their personal information being used and recorded in this way. Standard accounts of the doctor patient relationship define it as a relationship of trust and confidence. The current proposal does not attempt to consider the extent to which this will be undermined by mandatory recording of information about alcohol maternal alcohol consumption on future child’s record. In addition to the potential to undermine the principles of trust and confidence there is potential to practically lead women to be less likely to disclose important information. |
| 426 | University of Bristol (Medical school / Philosophy dept) | 2 | Statement 2 | Measurement, informed consent and confidentiality  To ensure that recorded information on prenatal alcohol consumption is as accurate as possible, there needs to be an effort to properly ensure confidentiality and promote trust, especially in the vital relationship between women and midwives. For this reason, we believe informed consent should be sought from the mothers, and the purpose of collecting this information appropriately disclosed (some women might worry already about potential harm to the fetus from their drinking, especially in very early stages of pregnancy before they were aware of it, and might even worry that disclosing their alcohol use might jeopardise their parental rights).  (CM, LZ, HC, SO) |
| 427 | University of Bristol (Medical school / Philosophy dept) | 2 | Statement 2 | Measurement – capitalising on new developments  The recent introduction of new maternity information standards, electronic maternity records and Maternity Services Data Set offer a valuable opportunity to improve data collection around whether women are asked about their alcohol use in pregnancy and also to document levels of consumption among pregnant women in the population throughout pregnancy.3,4 These resources should be included in the measurement of Statements 1 and 2 and would be a valuable resource to assess longitudinal outcomes among individuals with prenatal alcohol exposure, for example through linkage to digital red books postnatally and other social and health data sources across the life course. We would be open to discussions about how we could support implementation of this. |
| 428 | University of Bristol (Medical school / Philosophy dept) | 2 | Statement 2 | Social care  Information about prenatal alcohol use should also be recorded in social care documents, in particular the ‘child permanence record’ (CPR) that is then used to document the legal and factual reasons for being placed in care and/ or for adoption.  Many children in the care system do not have full and systematic maternal health and pregnancy records. Lack of recording of drinking in pregnancy of their birth mother means that this information cannot be collected or accessed later, as contact with birth parents is often severed (for child protection reasons) once children are taken into care. Since children in the care system have a high prevalence of FASD, this is particularly important. Many of them would have qualified for an assessment if this information had been collected.  There should be a way to ensure that physicians examining children in care, and writing medical reports on looked after children have access to this information, coupled with an awareness of FASD and assessment and treatment option, so they can refer at the earliest opportunity, where appropriate (there is strong evidence that the younger the age of diagnosis and intervention, the better the outcomes for children affected by FASD). |
| 173 | University of Southampton | 1 | Statement 2 | Statement 2 proposes that all pregnant women should have their alcohol consumption recorded throughout their pregnancy and that this information should be transferred to the child’s health records. There is no discussion in Statement 2 about the need to ensure that pregnant women give informed consent for their data to be recorded and then transferred or of possibly privacy issues arising from the transfer of the data. Will pregnant women be explicitly given a choice whether to provide this data? Will they feel coerced into providing it? It should be remembered here that the guidance advising women to abstain completely from alcohol is not based on evidence of harm, but on a precautionary principle (which I raise concerns about above) and the assumption that women require clear, simple messaging. Requirements to give information, combined with overly simplistic abstinence advice, gives a message of institutional distrust of women. Women may begin to feel that they are the targets of surveillance during their health care appointments. This may have a negative impact on the relationship between women and their health care providers, adversely affecting the quality of the care that women receive. |
| 3 | Adoption UK | 1 | Statement 3 | Care experienced children should be added to list of children who should be referred for an assessment given the prevalence of FASD among this cohort. According to conservative estimates, 1/3 of looked after and adopted children have FASD and so there should be a presumption that these children have been exposed to alcohol in the womb and may have FASD.  Early identification and intervention lead to a better overall outcome for an individual with FASD, as is stated in the briefing paper accompanying this consultation (page 4). Furthermore, adoptive parents and foster carers have a right to understand the needs of the child they are parenting/caring for from the point of placement and will be better placed to meet their needs if that is the case. |
| 4 | Adoption UK | 1 | Statement 3 | Please follow the link below and go to pages 8-9 for more information regarding the FASD Care Pathway and the diagnostic pathway pilot study in Ayrhsire. <https://www.adoptionuk.org/Handlers/Download.ashx?IDMF=91c9c083-a3a3-41a1-887b-b3c089c6f7ff> |
| 212 | Balance | 2 | Statement 3 | As noted above, recorded information about maternal alcohol use tends to be patchy and dependent upon the mother’s willingness to disclose. We believe that it is hugely important to ask questions and document maternal alcohol use throughout pregnancy, to ensure that children and young people with physical, developmental or behavioural difficulties are appropriately signposted for FASD assessment. Historically, a significant proportion of children with FASD will have been diagnosed with other behavioural disorders (such as ADHD) and there are still relatively few FAS diagnostic facilities within the UK. We believe it is important to build capacity in this respect and to adequately document maternal alcohol use, to ensure that children with suspected FASD are referred for appropriate assessments. |
| 27 | Blackburn with Darwen Borough Council Public Health and Wellbeing Team | 1 | Statement 3 | Referral pathway for children at possible risk of FASD needs to include many sources of information from schools, social care, safeguarding. Alcohol Treatment data contains vital information and should be linked in to other sources to identify those at risk |
| 104 | Blackburn with Darwen Borough Council Substance misuse service | 1 | Statement 3 | Systems are in place to ask women about alcohol use during pregnancy. Additional training and updates for healthcare staff would be required. Achievable but may require additional staff hours to update staff. |
| 105 | Blackburn with Darwen Borough Council Substance misuse service | 1 | Statement 3 | Accurately reflects key areas for improvement. |
| 54 | British Pregnancy Advisory Service | 1 | 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. |
| 55 | British Pregnancy Advisory Service | 1 | Statement 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. |
| 56 | British Pregnancy Advisory Service | 1 | Statement 3 | [Audience descriptors] ‘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. |
| 57 | British Pregnancy Advisory Service | 1 | Statement 3 | [Audience descriptors] ‘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. |
| 58 | British Pregnancy Advisory Service | 1 | Statement 3 | [Audience descriptors] ‘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. |
| 59 | British Pregnancy Advisory Service | 1 | Statement 3 | [Definitions] ‘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. |
| 245 | British Psychological Society | 2 | Statement 3 | Children and young people with physical, developmental or behavioural difficulties and probable prenatal alcohol exposure are referred for assessment  Children with a concerning neurodevelopmental presentation should be referred to appropriate services for assessment and support. ‘Probable prenatal alcohol exposure’ in and of itself, may be relevant to consider as an aetiology, but all children with significant physical, developmental, cognitive or behavioural concerns should be referred for specialist assessment/input. However, if this is only viewed through an FASD lens (i.e. by ‘FASD experts/ team’) there is a danger of alternative, more appropriate diagnoses being missed. |
| 246 | British Psychological Society | 2 | Statement 3 | It is important to acknowledge that a proportion of these children will be known to services such as Child and Adolescent Mental Health Services (CAMHS) for a variety of initial problems, not necessarily highlighted as neurodevelopmental in the first instance. They may present as children with behavioural problems, anxiety, anger management, peer relationship issues etc. They may be in services arranged by pathway (e.g. ADHD, ASD) and coded variably between localities depending on service function and structure, which will need to be taken into account to ensure accurate FASD data collection. |
| 247 | British Psychological Society | 2 | Statement 3 | “Denominator – the number of children and young people with physical, developmental or behavioural difficulties and probable prenatal alcohol exposure”.  Should this be the number of children identified by services as fitting into this category? The absolute number will never be known. |
| 70 | Changing Minds UK | 1 | Statement 3 | [Audience descriptors] It is important to also include improved awareness for social care staff and those working with adopted and looked after children (awareness of the impact of prenatal alcohol exposure, how to spot the signs, and how to refer on for an assessment), as often the needs of this population remain undiagnosed and seen as due to the trauma/attachment disruption that they have experienced. |
| 460 | Cwm Taf University Health Board | 1 | Statement 3 | Many of these children will be already known to services such as Child and Adolescent Mental Health Services (CAMHS) for a variety of initial concerns and not necessarily highlighted as neurodevelopmental in the first instance. They may present as children with anxiety, anger management, peer relationship issues and behavioural concerns, etc. They may be in services arranged by ND pathway (e.g. ADHD, ASD) therefore this will be needed to be taken into account if data will be collected for FASD. |
| 84 | East Herts and Area FASD Support Network | 1 | Statement 3 | Although we have a consultant expert in FASD in the East and North Herts Trust, it is currently impossible to be referred to them to obtain a diagnosis of FASD, as the Trust says it is not commissioned by the CCG to provide this service. Implementation of Quality Statement 3 would rectify this situation. |
| 87 | Elucidate Training | 1 | Statement 3 | This statement makes no mention of how adults can be referred for an assessment if they have concerns that they may have FASD it only talks about children and young people. Due to the lack of awareness of FASD a person could suffer from the symptoms and yet not find out until much later that this may be due to exposure to alcohol in utero. Diagnosis is extremely important at any age, indeed you only have to go on YouTube to find a video by Reinier de Smit who did not get diagnosed until he was 56 to understand the importance. |
| 277 | FASD NETWORK UK | 2 | Statement 3 | Referral for Assessment  This statement is welcomed but the challenge we have is the lack of clarity on how it is anticipated to work. Is it considered that there will be a regional specialist FASD clinic as a one stop shop or an adjusting and embedding of FASD into existing locality commissioned systems? CCGs have so many competing/confusing pathways which blur the lines of who is regarded as an ‘expert’ and which pathway to take.  The majority of locality based services are commissioned for people with a ‘learning disability and/or autism’ and the existing commissioned pathways (usually via CAHMS) are not open to a young person with FASD. Is it going to be considered with the new NICE FASD guidance that services will be encourage to be more broadly commissioned ie for ‘people with a learning disability and or neuro-developmental condition’ so that FASD can be included or will the original definition continue and FASD sits outside of the standard commissioning? |
| 453 | Institute of Health Visiting | 2 | Statement 3 | This draft quality standard reflects a key area for quality improvement, but omits the role of the health visiting service. All children are offered a development review at 6-8 weeks old, 10-12 months old and when the child is 2-2.5 years. At 10-12 month and 2-2.5 years developmental review parents are sent out a set of questionnaires about their child’s development, the Ages and Stages questionnaire, (ASQ3 2), as an assessment process in preparation for a face to face contact. Health visitors who are aware of particular issues, or whom have been made aware of the potential increased risk of increased alcohol consumption in pregnancy, can assess for any resulting physical, developmental or behavioural difficulties in the child when they meet with the parent and child.  2. ASQ3. undated. <https://agesandstages.com/products-pricing/asq3/> Accessed 3.10.20 |
| 454 | Institute of Health Visiting | 2 | Statement 3 | The search for health needs, in this case physical, developmental or behavioural difficulties or FASD is a core element of health visiting practice. Like the GPs they may need training to raise awareness in the profession of alcohol exposure before birth as a possible cause of neurodevelopmental disorders. |
| 303 | NHS England and NHS Improvement | 2 | Statement 3 | I would perhaps suggest that the language around onward referral is changed to discussion with local community paediatric/adolescent services about referral options rather than looking for evidence of a locally commissioned service which may not exist. Relevant sentence is: “Evidence of local pathways that allow children and young people with probable prenatal alcohol exposure to be referred to a healthcare professional with expertise in FASD”. |
| 305 | NHS England and NHS Improvement | 2 | Statement 3 | Relevant section: “Service providers (primary care services) have training for GPs to raise awareness of alcohol exposure before birth as a possible cause of neurodevelopmental disorders. Community paediatric services, child development centres and child and adolescent mental health services have training programmes for healthcare professionals on assessing and diagnosing FASD. They establish multidisciplinary teams with expertise in FASD and have pathways for GPs to refer children and young people for assessment.”  This is extracontractual for GP contract holders and can only be enforced if it was within the GP contract.  This is a resource issue as well as a commissioning and contractual issue for NHS England, NHS Improvement and CCGs who commission GP services and integrated pathways. |
| 308 | NHS England and NHS Improvement | 2 | Statement 3 | There is limited evidence for thresholds for alcohol consumption in pregnancy. If any alcohol consumption in pregnancy is being transferred to the child health record, what guidance will be given to determine ‘probable alcohol exposure’ and therefore referral (as per quality standard 3) when physical, developmental or behavioural difficulties (which are not uncommon) arise. Is a more targeted approach more appropriate? |
| 117 | NOFAS-UK | 1 | Statement 3 | The importance of this assessment cannot be underestimated. As one person said, “Assessment and early diagnosis are paramount in supporting the child and meeting their global needs.” NOFAS-UK hopes this is done in a timely manner, and notes for example that the NICE Quality Standard for Autism states that “People with possible autism who are referred to an autism team for a diagnostic assessment have the diagnostic assessment started within 3 months of their referral.” While there will be a lag time as appropriate training on FASD diagnosis spreads across England, there is no reason why there should be any less of an aspiration for those with FASD to receive diagnoses in a timely manner. Indeed, there are crossovers – co-morbidities and sometimes misdiagnoses.  • Autism and neurodeveleopmental teams should be trained to recognise FASD.  • There also is a need for joined up thinking on the best way to tap into the expertise that exists in areas and centres that have been leading the way. For example, the National FASD Clinic has been supporting development of expertise via a hub and spoke model as a temporary measure to help train up other areas quickly. They should receive more resources to be able to operate on more than a part-time basis. |
| 126 | Peterborough family FASD support Group & Field of Enterprise Training & Consultancy | 1 | Statement 3 | The key will be communicating the pathways to access an assessment as well as who can initiate such a step. Currently we faced exceptional funding panels with massive delay and drift and therefore it needs to be part and parcel of the normal referral mechanism from the GP / Community medical services.  At the present time I am concerned about the capacity of the system in England to make the assessments that are needed and if in a clinic outside a CCG area the responsibility of the ‘home’ CCG to accept and identification and provide services to meet the needs assessed elsewhere. In supporting families, currently it is common that ‘diagnoses’ are rejected as a test not used in the ‘home CCG has been applied. This is insulting and represents a huge waste of NHS (and Social care) resources. Therefore, there needs to be a national agreement on the assessment process and the implications of a positive assessment. |
| 138 | Public Health England | 2 | Statement 3 | [Quality statement]  *“Children and young people with physical, developmental or behavioural difficulties and probable prenatal alcohol exposure are referred for assessment.”*  We think 'neurological' should be added (or separated from 'physical') as so much of the diagnostic criteria for FASD fall under neurological domains. |
| 139 | Public Health England | 2 | Statement 3 | [Definition: Probable prenatal alcohol exposure]  “*The presence of all 3 facial sentinel features (short palpebral fissures, smooth philtrum and thin upper lip) has such a high specificity for prenatal alcohol exposure and FASD that confirmation of alcohol exposure is not needed when all 3 are present*.”  According to latest research (Australian guidance), this is true only if severe neurodevelopmental impairment is also present - p.4. <https://www.fasdhub.org.au/contentassets/32961d4a5cf94de48ebcf985c34d5456/australian-guide-to-the-diagnosis-of-fasd_all-appendices_feb2020.docx.pdf>. |
| 140 | Public Health England | 2 | Statement 3 | There is an opportunity for primary care to reinforce the support available around LARC in families where a referral for assessment for FASD is made |
| 145 | Royal College of General Practitioners | 1 | Statement 3 | Rather than local examples of increasing knowledge on FAS why not review the national professional curricula for health care staff to ensure those in contact with pregnant women are aware of the importance of FAS?   Medical professional including paediatricians, psychiatrists and general practitioners   Other clinicians including midwives, paediatric nurses, mental health practitioners, psychologists and health visitors   Educational including teachers, Special Educational Needs Coordinators (SENCOs), teaching assistants and Educational Psychologists   Others including social workers  The MRCGP Curriculum includes a reference to FAS but no clear guidance, this may require amendment to highlight the significance of FAS more prominently rather than looking at local education. |
| 147 | Royal College of General Practitioners | 1 | Statement 3 | This section may need a significant rewrite. GPs will not have direct access to specialists with expertise in FASD. All children with neurodevelopment disorders are sent to community paediatrics who then assess the child appropriately. Most referrals of this type actually come from schools rather than primary care and increasing training for GPs is unlikely to make a difference at a local level. The RCGP would recommend GPs were removed from this aspect of the QS. Once the child is at community paediatrics, they then complete the full assessment and collation of multiple types of evidence. It is impractical and inappropriate to suggest that GPs perform this information gathering exercise. |
| 334 | Royal College of Obstetricians and Gynaecologists | 2 | Statement 3 | Children and young people with physical, developmental or behavioural difficulties and probable prenatal alcohol exposure are referred for assessment.  This statement would be better worded as “Children and young people with physical, developmental or behavioural difficulties with probable prenatal alcohol exposure….” |
| 345 | Royal College of Paediatrics and Child Health | 2 | Statement 3 | The statement should also include confirmed prenatal alcohol exposure. |
| 346 | Royal College of Paediatrics and Child Health | 2 | Statement 3 | If there are distinctive features of other genetic conditions, they will need to be excluded. |
| 347 | Royal College of Paediatrics and Child Health | 2 | Statement 3 | Also include confirmed prenatal alcohol exposure. |
| 348 | Royal College of Paediatrics and Child Health | 2 | Statement 3 | [Structure measures]  Services should also have knowledge in neurodevelopmental assessment (this is so far only referenced in Statement 4). |
| 349 | Royal College of Paediatrics and Child Health | 2 | Statement 3 | [Process Measures]  Include cases of confirmed alcohol exposure (two sentences affected). |
| 350 | Royal College of Paediatrics and Child Health | 2 | Statement 3 | [Outcome Measures]  If this relates to probable prenatal alcohol exposure it will not be justified to give a diagnosis of FASD, if there are no facial features. Would it be better to say time to assessment rather than diagnosis of FASD? |
| 351 | Royal College of Paediatrics and Child Health | 2 | Statement 3 | [Outcome Measures]  Diagnosis rates of FASD: all probable and confirmed cases should be reviewed here. |
| 352 | Royal College of Paediatrics and Child Health | 2 | Statement 3 | In some areas, referrals are submitted via schools as teachers will provide supporting information. Therefore, this should not only state GPs. |
| 353 | Royal College of Paediatrics and Child Health | 2 | Statement 3 | Assessment of multi-source referral information should not be the duty of the referring GP but of the service providing FASD assessments as this is not an effective way of working. As above in many areas, referrals are not through the GP only. |
| 354 | Royal College of Paediatrics and Child Health | 2 | Statement 3 | In many areas, referrals come through schools (as teachers will provide supporting information) and not only the GP – Commissioners should work with colleagues from the Local Authority commissioning. |
| 355 | Royal College of Paediatrics and Child Health | 2 | Statement 3 | This needs to be done in a very sensitive way to avoid stigma. In the reviewer’s opinion, it will not be appropriate to name alcohol as the origin of a child’s difficulties prior to a comprehensive assessment by a multi-disciplinary team with knowledge in FASD as the origin of children’s difficulties are in many cases multi-factorial. Especially, if alcohol use in pregnancy has not been confirmed. |
| 356 | Royal College of Paediatrics and Child Health | 2 | Statement 3 | FASD confirmation of alcohol exposure is not needed when all three are present; in these cases, it is very important to exclude other chromosomal abnormalities (e.g. genetic blood tests) before deciding on FASD. FASD should be a diagnosis of exclusion. |
| 372 | Royal College of Psychiatrists | 2 | Statement 3 | The inclusion of ‘probable prenatal alcohol exposure’ in this statement is redundant. CYP with ‘physical, developmental or behavioural difficulties’ should be getting reviewed by their schools/GPs and referred on as necessary to EPs/paeds/CAMHS whether or not there is a history of alcohol exposure  This is not in any way different from standard practice for al CYP with obvious difficulties. |
| 385 | Scottish Health Action on Alcohol Problems (SHAAP) | 2 | Statement 3 | Quality statement: “Children and young people with physical, developmental or behavioural difficulties and probable prenatal alcohol exposure are referred for assessment”.  It is important to emphasise that there are very few “experts” in FASD in the UK, and even those with extensive experience would agree that assessment and diagnosis demands a team approach, and input from a group of practitioners (likely headed by a Paediatrician or CAMHS Specialist). This group should include psychologists, speech and language specialists, and occupational and physiotherapists. All participants would need training for the assessment of potential FASD children and young people, which can sometimes be challenging. More needs to be done to enhance knowledge and skills for people operating in all these areas of specialisation, including investment of time and resource to ensure diagnostic confidence and competence.  In Scotland, the Scottish Government has committed large sums to provide the necessary support for this training over the last decade. Examples of this include: formal outreach training in FASD assessment from The University of Manitoba Winnipeg; lectures and seminars; a clinicians’ peer-to-peer support forum; funding of neonatal meconium biomarker research; the setting up of a national FASD diagnostic pathway, and of an e-learning FASD training resource. This investment is justified when considering the lifetime cost of diagnosis management and long-term support for an individual with FASD. A conservative estimate of FASD prevalence in the UK (cited by SIGN 156) is at least 3.0%, which means there is still much to do in terms of prevention, diagnosis and management. For a more detailed resume of the measures supported and introduced in Scotland since 2010 please contact Dr Christopher Steer at: [email address removed by NICE].  A national audit of time to diagnosis and rates of diagnosis of FASD (in Scotland as well as the rest of the UK) is long overdue and much needed. This is feasible, though it would require financial backing. The results are likely to reveal the huge shortfall in provision for diagnosis as reported by so many, e.g. when feeding back to support organisations such as the FASD Support Hub Scotland (cf. <https://www.adoptionuk.org/Pages/Site/scotland/Category/fasd-hub-scotland>).  Under “What the quality statement means for different audiences”: It is worth noting that it can be unrealistic to expect that children and young people have a discussion with their GP and their parents about their problems. It therefore would be better to reframe this expectation as, “Caregivers, as well as children and young people with physical, developmental or behavioural difficulties who may have had exposure to alcohol before birth, have a discussion with a GP about their problems”.  Under “Definitions of terms used in this quality statement” and “Physical, developmental or behavioural difficulties”: include Increased risk of autoimmune inflammatory conditions such as Rheumatoid arthritis in addition to the two bullet points already listed. |
| 398 | Scottish Intercollegiate Guidelines Network | 2 | Statement 3 | This statement may benefit from a qualifier such as ‘significant’ in relation to any physical, developmental or behavioural difficulties. As ~40% of pregnancies are likely to be alcohol exposed and as many children have some sort of behavioural difficulty, for example, this may lead to an untenable demand in assessment (which cannot be logistically provided). |
| 399 | Scottish Intercollegiate Guidelines Network | 2 | Statement 3 | As the measurement is diagnostic rates and time to outcome, the referral will likely require a multidisciplinary team approach, rather than to A health professional trained in FASD. The latter in isolation rarely equates to the ability to assess and diagnose FASD (e.g. just a consultant paediatrician). |
| 400 | Scottish Intercollegiate Guidelines Network | 2 | Statement 3 | This section, and in other paragraphs of Quality Statement 3 there is reference to ‘experts in FASD’. This is unlikely to be achievable and should be considered in relation to “professionals with additional training in FASD”. The evidence suggests that without a great deal of experiential contact with FASD cases, confidence despite training will remain low and so professionals will rarely consider themselves ‘expert’ as specified in this standard. The word ‘expertise’ is also used and I would suggest considering ‘training or experience in assessing for FASD’. |
| 401 | Scottish Intercollegiate Guidelines Network | 2 | Statement 3 | After the comment about specificity in relation to the 3 typical facial features, it is necessary to add that there will often need to be input from clinical genetics to ensure that any other contributing genetic conditions are excluded prior to concluding they are due to prenatal alcohol exposure. Exposures to other substances e.g. sodium valproate to be excluded also. This may also influence some wording of Quality Statement 4. |
| 415 | Surrey and Borders Partnership NHS Foundation Trust and National FASD Behaviour management clinic. | 2 | Statement 3 | This is a vital and well worded statement. IT will allow families to try and get a diagnosis that in so many cases is not possible. There are more areas developing pathways and this will expedite that if found not to be in place as was seen in recent reviews and that has not changed over a decade when looking at published literature. This will help families and services push for better pathways. It does not say how it should be delivered therefore still leaves it open to local areas to interpret and may help to keep costs to a minimum by building on their established services and then modifying pathways. |
| 416 | Surrey and Borders Partnership NHS Foundation Trust and National FASD Behaviour management clinic. | 2 | Statement 3 | This will allow trusts and CCG to measure their clinical pathways and begin to fill the lack of service identified in CCG reports. There may need some external support how with examples of how this may look to ensure some consistency but as a start to begin to measure service this is important. This has been done in areas I have worked with to improve standards |
| 157 | TACT - The Adolescent & Children’s Trust | 1 | Statement 3 | In the section on what this means for commissioners the guidance refers to the need to develop referral pathways. We feel that these should include referral pathways for birth parents, carers as well as education and social care professionals rather than, as implied, just for healthcare professionals. |
| 158 | TACT - The Adolescent & Children’s Trust | 1 | Statement 3 | We do have anxiety around the resource implications for this QS. Given the numbers of children who would fit this definition (and it is a definition we would 100% agree with) it is likely that existing provision will not be able to cope in any meaningful way at present |
| 159 | TACT - The Adolescent & Children’s Trust | 1 | Statement 3 | Whilst appreciating that training was not a factor that could be included within a QS, this is a factor that should be included within the guidance notes, especially for commissioners, as without awareness and training many children will still go through undetected |
| 164 | Tees Valley Durham and North Yorkshire Neurological Alliance | 1 | Statement 3 | **Rationale**  The statement - FASD is a lifelong condition; anticipating difficulties can help to avoid poor educational attainment and mental health problems - should be amended because this is too arbitrary and does not offer a commissioner a basic understanding of what to consider. This statement is more of a get-out clause.  Please consider; FASD is an organic brain injury caused by excessive alcohol use before and/or after conception causing cognitive impairments, developmental delays, poor educational attainment and mental health comorbidities which require long term interventions and care.  Although we have contributed to the consultation, a review of adoptive parents’ feedback shows a tenable lack of knowledge and understanding from frontline services about FASD which inhibits a realistic care pathway. Services often diagnose and discharge in the same appointment and thus, gate-keep access to Health visitor, CAMHS or SEN services. There is a high level of blame, against parents for poor parenting, against the young people for obsessive behaviours or poor choices. Current therapeutic delivery concentrates on the historic view that obsessive behaviours can be ‘cured’, such as poor money management or drug abuse.  However, young people cannot be re-trained to accept ‘correct’ behaviours or apply filters that people without an acquired injury can apply, because of the alcohol-induced brain damage. When service-users are deemed to be non-compliant with an intervention they are rejected by the service. The resulting difficulties become a self-fulfilling prophecy. This builds up a level of anger and anxiety at feeling failed, anger when their parents are blamed leading to other behaviours and notably, the high proportion of FASD in the Youth Forensic service.  It must be recognised that there is a dearth of expertise in FASD. There is no post-diagnosis support in education, social work or mental health services. Lack of in-service training makes services inaccessible and transient. Lack of skill leads to lack of continuity of care which is destabilising for the whole family. |
| 167 | The Neurological Alliance | 1 | Statement 3 | P12 - Physical, developmental or behavioural difficulties  Neuro Key (Tees Valley, Durham and North Yorkshire Neurological Alliance) noted in their report Foetal Alcohol Spectrum Disorder: Unlocking minds and opening doors (p.3) that there are not always characteristic facial features.  The word characteristic should be taken out as this will encourage services to dismiss the case if facial features are not present.  This is a current, continuing issue in some regions where parents are waiting many years for support due to being denied initial assessment.  See <https://www.na-tvdny.org.uk/wp-content/uploads/2019/09/FASD_Brochure-web.pdf> |
| 168 | The Neurological Alliance | 1 | Statement 3 | P13 – ‘The presence of all 3 facial sentinel features …… has such a high specificity for prenatal alcohol exposure and FASD that confirmation of alcohol exposure is not needed when all 3 are present.’  This is not universally true and in all cases there should be confirmation of alcohol exposure to establish the need for service support. |
| 390 | University of Bristol (Law School) | 2 | Statement 3 | Informed consent: there is no consideration of this point in the document, including no opportunity for women to opt out of a process of mandatory disclosure.  The suggestion that this information might be ‘enhanced’ by the use of Meconium testing (p.115) - even though this suggestion was not followed - provides an interesting insight into the  thinking that underpins at least some of the Draft Quality Standards on FASD.  It appears to be highly child-centred, with the position of the mother being viewed very much as secondary.  This type of data collection and use does not appear to raise similar concerns as found with HIV+ testing of infants, where the mother’s privacy and the issue of informed consent are also in play. Nor are there the checks and balances one would normally expect for a research trial or a screening programme evident.  There is no explanation given for why mandatory recording of alcohol consumption be exceptionalised other than better information is needed. However, it is clear that this proposal may practically not lead to expected benefits in this regard. It is important to note the comments of the National Screening Committee with regard to their expectations of universal screening during pregnancy including appropriate methods for information gathering.  It is widely acknowledged, including in this document, that those who are particularly vulnerable during the pregnancy period will need extra supports but it isn’t clear that this will be available. There is a real danger that this Guideline/ Standard could lead to further marginalisation of already vulnerable groups and in fact lead to poorer outcomes overall, e.g. disengagement from maternity and broader healthcare services based on concerns about (LA) authority involvement where identification/diagnosis of FASD occurs.  It is vitally important to improve knowledge and understanding of alcohol consumption during pregnancy and impacts on future children including diagnosis of FASD. This should be done in a considered fashion with appropriate legal and ethical safeguards. This Guideline does not fully consider these safeguards. |
| 429 | University of Bristol (Medical school / Philosophy dept) | 2 | Statement 3 | Addressing underdiagnosis  There are at least four causes for underdiagnosis built into the current referral system and all need to be addressed, in order to achieve statement 3.  1. There is a stark lack of expertise and confidence amongst GPs, community paediatricians and CAMHS to even refer children for assessment. Most are not aware of FASD and do not know where to refer to.  2. There is a strong tendency by health professionals named above to reach for better known diagnoses, such as ADHD or ASD, even when these do not fully capture the child’s presentation (or their actual prevalence could be lower than FASD in the UK population).  3. In cases where children are in, or have come through, the care system, the go-to explanation for their difficulties is assumed to be attachment difficulties and psychological trauma. This masks the true nature of the need and means that children who are or were in care do not get referred. This culture of reliance on psychological (rather than organic/ somatic) explanations for these children’s difficulties is a significant barrier for these children to reach assessment.  4. There is no local expertise to carry out full assessments. At the moment only the national FASD Centre in Surrey is able to offer this service, and the waiting list is substantial. This single centre will not be able to cope with a much higher volume of requests for assessments. So this is a significant bottleneck for effective and rapid assessment of children.  Cumulatively, these cause children to be misdiagnosed, not diagnosed at all, given the wrong interventions, or have significant delays in being diagnosed. |
| 430 | University of Bristol (Medical school / Philosophy dept) | 2 | Statement 3 | Building health professional expertise for FASD diagnosis  There are very limited numbers of health professionals with the expertise to diagnose FASD. There is often no regional expertise at all, so it is not clear who these health professionals are. What happens if there is no expertise other than in the national FASD clinic in Surrey? Anecdotal experience of the South West region: parents were unable to find any health professional (either paediatrician, psychiatrist, or neurologist) able to assess or diagnose a suspected case.  (HC, SO) |
| 431 | University of Bristol (Medical school / Philosophy dept) | 2 | Statement 3 | Definition of FASD  The definition of FASD related difficulties is missing the most important features of the condition, namely, emotional regulation and executive function. These cause, by far, the greatest difficulties for FASD affected individuals and are the source of severe problems e.g. high levels of involvement in the criminal justice system. Therefore, these aspects should be included in the definition of FASD. Also, we suggest replacing ‘confused social skills’ with ‘impaired social skills’.  (HC, SO) |
| 17 | Birthrights | 1 | Statement 3&Statement 4 | Referral and assessment for FASD  Expansion of diagnostic criteria: numbers of children now at risk  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.  bpas state that 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. 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. |
| 18 | Birthrights | 1 | Statement 3&Statement 4 | Referral and assessment for FASD  Expansion of diagnostic criteria: maternal responsibility for neurodevelopmental impairment  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.  This is also likely to impact on the relationship of trust between a woman and her caregivers during pregnancy, and the mother and her child’s caregivers following birth. Birthrights have supported women who had been inappropriately referred to social services during their pregnancy, who report feeling under scrutiny from their child’s paediatric team even after cases are closed/apologies made. The recording of alcohol consumption in a child’s red book is likely to exacerbate this sense of scrutiny and distrust throughout the antenatal and postnatal periods and into the early childhood years (and in cases beyond), and may induce women to disengage from services which are intended to support them.  The Quality Standard is not consistent in all places: QS3 includes self-reported consumption as one possible factor indicating “probable prenatal alcohol exposure”, implying that self-reporting is considered unreliable and therefore the screening results are not to be trusted despite the widespread potential negative impacts. It also refers to “reports [of alcohol consumption] by a reliable source” with no further information about what this means and whether others (who?) may be asked about a woman’s drinking (it is distinct, for example, from “reliable clinical observation”). It is then unclear how assessments move from “probable prenatal alcohol exposure” to “confirmed prenatal alcohol exposure” in QS4 – again, if maternal reports are not considered reliable then it is unclear why the significant burden of these proposals is being placed on women and healthcare professionals, and what is envisaged to ‘confirm’ alcohol consumption. Again any further tests or screening on/of the woman would require fully informed consent to be legal. |
| 228 | Birthrights | 2 | Statement 3&Statement 4 | Referral and assessment for FASD  Expansion of diagnostic criteria: numbers of children now at risk  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.  bpas state that nearly half of pregnancies are unplanned and alcohol use is common before pregnancy confirmation. It is suggested in the briefing paper attached to this consultation that 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. 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. |
| 229 | Birthrights | 2 | Statement 3&Statement 4 | Referral and assessment for FASD  Expansion of diagnostic criteria: maternal responsibility for neurodevelopmental impairment  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.  This is also likely to impact on the relationship of trust between a woman and her caregivers during pregnancy, and the mother and her child’s caregivers following birth. Birthrights have supported women who had been inappropriately referred to social services during their pregnancy, who report feeling under scrutiny from their child’s paediatric team even after cases are closed/apologies made. The recording of alcohol consumption in a child’s red book is likely to exacerbate this sense of scrutiny and distrust throughout the antenatal and postnatal periods and into the early childhood years (and in cases beyond), and may induce women to disengage from services which are intended to support them. Indeed, it is arguable that scrutiny and stigmatisation are likely to increase if ‘confirmed prenatal alcohol exposure’ – with or without any attempt of meaningful quantification – is the first piece of information a health visitor sees when visiting a family  The quality standard is not consistent in all places: QS3 includes self-reported consumption as one possible factor indicating “probable prenatal alcohol exposure”, implying that self-reporting is considered unreliable and therefore the screening results are not to be trusted despite the widespread potential negative impacts. It also refers to “reports [of alcohol consumption] by a reliable source” with no further information about what this means and whether others (who?) may be asked about a woman’s drinking (it is distinct, for example, from “reliable clinical observation”). It is then unclear how assessments move from “probable prenatal alcohol exposure” to “confirmed prenatal alcohol exposure” in QS4 – again, if maternal reports are not considered reliable then it is unclear why the significant burden of these proposals is being placed on women and healthcare professionals, and what is envisaged to ‘confirm’ alcohol consumption. Again any further tests or screening on/of the woman would require fully informed consent to be legal. |
| 280 | FASD NETWORK UK | 2 | Statement 3&Statement 4 | A key discussion point is that a lot of people requiring assessment are looked after young people. The NICE Guidance - Looked After Children and Young People – PH28 highlights alcohol as a key reason for entry to care but throughout that document there is no mention of tracking those children with a known alcohol exposure and gaining early access to a specialist FASD assessment. The same guidance signposts to the standard CAHMS pathway and the majority of families have ended up with an attachment focus of a parenting course. The fact that a child may have been removed from home due to issues with alcohol has not red flagged that child to be actively reviewed for FASD.  This guide about the Health of Looked after Children states on point 44 page 17 <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/413368/Promoting_the_health_and_well-being_of_looked-after_children.pdf>  ‘ pay particular attention to health conditions that may be more prevalent in looked after children (such as foetal alcohol syndrome or attachment difficulties) and which may otherwise have been misdiagnosed’.  Despite this document, LAC paediatricians who have responsibility for the medicals have rarely acknowledged or actively investigated FASD (often stating that if a child is labelled an adopter won’t want them). If a child is LAC and have regulation issues then they are automatically considered to have an attachment issue and attachment therapists do not actively consider FASD as all the behaviours tick the attachment boxes. Despite the new NICE guidelines, attachment will still be the primary pathway that our LAC young people will be put on unless LAC medicals include explicit instructions to actively screen for FASD in children coming into the care of the local authority. Is any consideration going to be made in the NICE guidance about the expectation that FASD will be actively screened as there is the potential that they will be put on the attachment pathway instead and they will still be a hidden population of children with FASD. |
| 6 | Association of Paediatric Chartered Physiotherapists | 1 | Statement 4 | Physiotherapists are also key in assessing these children’s motor skills. Therefore suggest physiotherapists are included in this section. |
| 213 | Balance | 2 | Statement 4 | The first cases of Foetal Alcohol Syndrome (FAS) were described over 40 years ago, yet the first UK diagnostic guidelines for individuals exposed prenatally to alcohol were only published in 2019. As the UK evidence base on FASD is limited, this guideline was largely based on best practice from international sources.  A recent pilot study of FASD assessment in NHS Ayrshire and Arran, Scotland, compared specialist versus mainstream models, the latter utilising Child & Adolescent Mental Health & Community Paediatric Services. Importantly, the study found FASD pathways and assessment processes to be less favourable compared with mainstream neurodevelopmental pathways.  The latter facilitates assessment of other conditions, such as Attention Deficit Hyperactivity Disorder (ADHD), Developmental Coordination Disorder (DCD) and Autism, alongside FASD. We believe that optimum pathways should include input from a multidisciplinary team, ideally with access to clinical psychologists, paediatricians, psychiatrists, speech and language therapists, occupational therapists, alongside carers and education professionals. Individuals with FASD will require mental health and/or risk assessment as part of their assessment. |
| 28 | Blackburn with Darwen Borough Council Public Health and Wellbeing Team | 1 | Statement 4 | Neurodevelopmental assessment is an expensive process but in cases where all the elements suggest exposure to alcohol whilst in the womb it should be undertaken to establish baselines for what the expected educational and cognitive impacts might be for the individual concerned |
| 60 | British Pregnancy Advisory Service | 1 | Statement 4 | ‘Children and young people with confirmed prenatal exposure or 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. |
| 61 | British Pregnancy Advisory Service | 1 | Statement 4 | [Rationale] ‘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 not 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. |
| 62 | British Pregnancy Advisory Service | 1 | Statement 4 | [Audience descriptors] ‘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. |
| 63 | British Pregnancy Advisory Service | 1 | Statement 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. |
| 64 | British Pregnancy Advisory Service | 1 | Statement 4 | [Definition] ‘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. |
| 248 | British Psychological Society | 2 | Statement 4 | Children and young people with confirmed prenatal alcohol exposure or all 3 facial features associated with prenatal alcohol exposure have a neurodevelopmental assessment if there are clinical concerns  We do not believe this draft quality standard accurately reflects the key areas for quality improvement for the following reasons (1/3)  1) Use of the term “clinical concerns” where it has been defined in the document 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” fails to take into account that children may present with cognitive, emotional or academic problems.  . |
| 249 | British Psychological Society | 2 | Statement 4 | 2) The term “confirmed prenatal alcohol exposure“ is not clearly defined in this document. On looking at the SIGN guidelines, it appears that use of AUDIT-C is advised as this forms part of the sample assessment. According to this criteria a mother who had one alcohol drink of <3 unit and never exceeded 5 units will get an AUDIT-C score of 1 which falls in the category of “1–4= Confirmed exposure”. This has the potential to lead to inappropriate referrals which would overwhelm clinics (see Statement 4 Question3) and potentially lead to inappropriate diagnoses with considerable repercussions.  We would recommend that clear definitions (e.g. those suggested by Hoyme et al 2016) are employed and that they are based on large epidemiologic studies that demonstrate adverse foetal effects at the suggested levels of consumption.  We highlight it is essential to avoid the risk of false positives by children being inappropriately diagnosed with FASD further to low levels of alcohol exposure which have not been evidenced to cause FASD. It is currently not clear how a child with neurodevelopmental symptoms secondary to other causal factors, who has confirmed PAE, will avoid being categorised as FASD.  The significant detrimental impact of inappropriate diagnoses upon the mental health of mother and child, their relationship, and the functioning of the family unit, needs to be carefully considered.  It is important not to imply that diagnosis of FASD will lead to condition specific interventions. There are no evidence based specialist interventions for cognitive, emotional and behavioural difficulties associated with FASD. Children should be managed in generic services by professionals with skills and knowledge of a broad range of conditions (including FASD) and comorbidities. |
| 250 | British Psychological Society | 2 | Statement 4 | The definition of the term “Neurodevelopmental Assessment” in this document and related documents is problematic.  A Neurodevelopmental assessment should consist of putting the child at the centre of a process that attempts to :   Weigh up and take into account all possible aetiologies of problems and their interactions   Determine the child’s primary and secondary areas of cognitive/social /emotional/behavioural difficulties and the interactions between them, taking into account possible sensory impairments, communication barriers and effort or engagement.   Consider to what extent the profile does (or does not) meet criteria for recognised neurodevelopmental diagnoses   Help to generate interventions to assist the child, family and wider system  Hoyme et al 2016 recommended that “children should have expert psychological/  neuropsychological assessment”. A gold standard neurodevelopmental assessment does not simply determine if a set number of cognitive “domains” are impaired. By making the referral criteria ‘confirmed alcohol exposure’ this biases the assessment and could lead to other significant aetiologies and alternative diagnoses being missed. As stated in the Australian guidelines (2020) FASD may co-exist with other conditions. The suggested domain checklist approach risks a “diagnosis by numbers” and children with difficulties that would be better explained by an alternative diagnosis being labelled as FASD. It would be more accurate to describe these children and young people as having “Neurodevelopmental difficulties with a history of prenatal alcohol exposure” as the aetiology cannot be determined from the available evidence and there is no recognised profile (Lange 2017).  In addition, the “domains” as laid out in the document are overlapping and not consistent with what is known about how the brain functions, in particular the use of the term “cognition” as a distinct domain is confusing and misleading. Cognition is an umbrella term for a range of information processing activities and therefore includes language, attention, memory etc. Although this term has been used in FASD guidelines in other countries it would be clearest to re label this “Intellectual functioning” particularly as the tests recommended for this domain are IQ tests.  It should also be noted that abilities assessed in one domain will influence how the child fares on others. The overlap in domains can lead to “double counting”. For example, poor language and motor skills will lead to lower scores on other tests such as IQ, so the same “deficit” is counted twice. Executive function will correlate with IQ. It is also known that children with language problems can have difficulties developing literacy skills due to the same underlying deficits leading to the same cognitive deficit being counted twice in “Language” and “Academic functioning”.  Further lack of clarity is caused by the fact the SIGN guidelines recommend the same battery of tests (DKEFS) for two different domains attention and executive functioning, and notes that these domains overlap.  We would agree with Hoyme et al 2016 that the appropriate approach is a neuropsychological evaluation in conjunction with an expert medical assessment. The assessment process specified in the NICE guidelines should be designed/informed by a qualified paediatric neuropsychologist. |
| 251 | British Psychological Society | 2 | Statement 4 | 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.  If all children with behaviour concerns whose mother had at least one alcohol drink during pregnancy were referred for a neurodevelopmental service for an assessment this would lead to inappropriate referrals (best managed by CAMHS) and overwhelm clinics, to the detriment of children with very significant problems. Low alcohol consumption has not been found to be predictive of these types of problems (Mamluk 2017), see also UK Teratology Information service (<http://www.uktis.org/>) “Use of Alcohol in Pregnancy”” in July 2019  If, however, all children with neurodevelopmental concerns are referred (regardless of maternal alcohol consumption) then this should be activity as normal and not lead to an increase in referral rates. |
| 71 | Changing Minds UK | 1 | Statement 4 | [Audience descriptors] Healthcare providers will also need training in the assessment of FASD, considering the different presentations and subtleties of FASD and how they may differ from other neurodevelopment presentations. |
| 73 | CoramBAAF | 1 | Statement 4 | Neuro developmental assessment needs to be clear it is multi disciplinary (not just a paediatrician) and how a diagnosis is reached – what the standards are / ICD 10/ Washington guidelines etc being used to diagnose. |
| 77 | CoramBAAF | 1 | Statement 4 | The commissioning of a specialist service / experts / MDT is so unlikely – we still don’t have a properly commissioned MDT for ASD  MDT needs to include education psychology- most support is likely to be in education setting  Some of our members feel that whilst FASD needs to be recognised as an individual disorder, that assessment, care and support should be framed within a comprehensive and holistic neurodevelopmental assessment. We should be able to focus more on identifying an individual childrens specific needs and use a formulation approach to appropriately meeting that childs needs. |
| 78 | CoramBAAF | 1 | Statement 4 | Is there no role for genetics services – not mentioned at all |
| 461 | Cwm Taf University Health Board | 1 | Statement 4 | Neurodevelopmental Assessment  The assessment has been commented to cover: motor skills, neuroanatomy/neurophysiology, cognition, language, academic achievement, memory, attention, executive function, including impulse control and hyperactivity, affect regulation, and adaptive behaviour, social skills or social communication.  The assessment should consist of putting the child at the centre of a process. This includes determining the child’s primary and secondary areas of cognitive/social /emotional /sensory- motor/behavioural difficulties and the interactions between them.  The domains checklist approach may risk a “diagnosis by numbers” and children with difficulties that would be better explained by an alternative diagnosis being labelled as FASD instead. It may be better to describe these children/young persons as having Neurodevelopmental difficulties with a history of prenatal alcohol exposure perhaps as a suggestion as aetiology cannot be determined from the available evidence and there is no recognised profile (Lange 2017).  One of the domains “affect regulation” is not clear by definition. We know from the neuroscience that brain structures like the cerebral cortex includes functions of sensory and motor control. However, most reactive behaviours noted in FASD are due to sensory dysregulation and that it happens in more than one area of brain function. Emerging evidence around sensory processing and integration difficulties are also very commonly reported with children with FASD or have been exposed to alcohol prenatally. Sensory-processing impairments have also been reported by parents and that sensory-processing deficits co-occur with problem behaviours at a high rate in this population (TL Jirikowic, JC Thorne, SA McLaughlin, 2020).  Deficits in sensory processing affect the ability of children with FASD to respond adaptively to their environments (Franklin et al, 2008). Research has revealed that 54%-80% of children who have a diagnosis of FASD, show clinical symptoms of sensory processing and integration difficulties (Abele-Webster et al, 2012). Additionally, Dr Ana Hanlon-Dearman (Developmental Paediatrician & MB FASD network in Canada) has recently conducted a study 10 year study of pre-schoolers with prenatal alcohol exposure. Her findings revealed one of many deficits including significant sensory processing differences particularly evident in preschools and are important in understanding behaviour and in intervention planning. Together, standardized assessment of motor and sensory processing skills, with a comprehensive assessment of language are significant predictors of FASD diagnosis for pre-schoolers with PAE.  It should also be highlighted that abilities assessed in one domain may influence how s the child fares on others. Thus the overlap in domains could lead to “double counting”. For example, if a child presents with poor language and motor skills then this will lead to lower scores on other tests such as IQ, so the same “deficit” is counted twice. Executive function will correlate with IQ. We also, know that children with language problems can have difficulties developing literacy skills due to same underlying deficits leading to the same cognitive deficit being counted twice “Language” and “academic functioning”.  Throughout the document developmental trauma or traumatic childhood experiences does not appear to have been commented on or considered during assessment. It is clear from studies that there are high levels of comorbidity with FASD and developmental trauma, ACES or traumatic childhood experiences and attachment which contribute to increased cognitive and behavioural presentations. (Price et al, 2017)  Australian guidelines (2020) have outlined that FASD may co-exist with other conditions, this should be taken into consideration during the assessment process which is vital to prevent misdiagnosis.  References  Lange, S., Rovet, J., Rehm, J. et al. (2017) Neurodevelopmental profile of Fetal Alcohol Spectrum Disorder: A systematic review. BMC Psychol 5, 22 (2017).  Australian guidelines (2020) FASD. fasdhub.org.au  Sensory Processing in Young Children with Fetal Alcohol Spectrum Disorder, Brenda Fjeldsted and Lin Xue, April 2019.  Parenting stress and sensory processing and FASD T Jirikowic, HC Olson, S Astley (2012)  Sensory processing and ADHD in children with FASD. Lynne A Abele-Webster and Joyce E Magill-Evans. Canadian Journal of Occupational therapy 79 (1), 60-63, 2012.  Anticipatory Guidance for children and adolescents with FASD: Practice points for primary care providers. Hanlon-Dearman, et al. J Population Ther Clini Phamacol. 2015  Prevalence and patterns of sensory processing behaviours in a large clinical sample of children with prenatal alcohol exposure, TL Jirikowic, JC Thorne, SA McLaughlin 2020.  Ten years of evidence for diagnostic assessment of pre-schoolers with prenatal alcohol exposure. Dr A Hanlon-Dearman. Journal of population Therapeutics and clinical pharmacology. Vol.27 No. 3 No. 3 (2020).  Sensory processing and adaptive behaviour deficits of children across the fetal alcohol spectrum disorder continuum. Agnihotri, S., Keightley, M. (2010). Alcohol clin Exp Res.  Children with fetal alcohol spectrum disorders: a descriptive profile of adaptive function. Jirikowic, T., Olson, H., Kartin, D. (2008). Can J Occup Ther.  Including Sensory Dysregulation in diagnosis of FASD. Pilot study across 3 Ontario diagnostic clinics and findings of significance of sensory deficits within FASD. Dr L. A. Scott & L. Elliott 2017.  Prenatal alcohol exposure and traumatic childhood experiences: a systematic review. Price et al, 2017. Vol 80 P89-98.Neuroscience and biobehavioural reviews.  National Child Traumatic Stress Network, Is it ADHD or child traumatic stress? A guide for clinicians, NCTSN, Los Angeles, 2016  C Bower & EJ Elliott, Australian guide to the diagnosis of fetal alcohol spectrum disorder (FASD), Department of Health, Canberra, 2016, apsu.org.au/assets/Uploads/20160505-repaustralian-guide-to-diagnosis-of-fasd.pdf |
| 278 | FASD NETWORK UK | 2 | Statement 4 | Neurodevelopmental Assessment  If prenatal alcohol exposure is not considered, the most prevailing traits are examined first. If they have the typical ADHD/ASD traits then they are put on the existing ADHD or ASD pathways for diagnosis first which can take 1-2 years to journey through. Their health needs related to FASD are not looked at because the only focus is on the singular pathway condition being assessed. This leaves FASD unaddressed for years. Why is FASD not mentioned as part of the ASD or ADHD NICE guidelines as a possible comorbidity that should be considered as part of their assessments? Will this be added to those guidelines?  Alternatively, if prenatal alcohol is considered and a paediatrician suspects FASD, the child can wait years on existing commissioned pathways via CAHMS for a cognitive assessment so in all that time a young person doesn’t qualify for services and support because they have no formal diagnosis and haven’t hit the criteria of being a person with a learning disability or autism for existing services. The designation ‘at risk of FASD’ or ‘suspected FASD’ does not qualify anyone for any services and schools won’t make any adjustments based on that designation as it is not a confirmed diagnosis. |
| 279 | FASD NETWORK UK | 2 | Statement 4 | Some areas have just introduced the St Helens model – a ‘neuro-developmental pathway’ and FASD is not integrated into it. If FASD stands alone then we still have the lack of integration to local commissioned services. |
| 455 | Institute of Health Visiting | 2 | Statement 4 | This draft quality standard reflects a key area for quality improvement related to a multidisciplinary approach from specialists in neurodevelopmental conditions and FASD. |
| 456 | Institute of Health Visiting | 2 | Statement 4 | As noted before [comment on statement 2] a system to make health visitors aware of the maternal increased consumption of alcohol by the mother is needed if the health visitor is to link the child’s physical, developmental or behaviour difficulties with possible FASD. This could be achieved through the uniform use of SNOMED codes to alert practitioners to alcohol consumption in pregnancy or FASD in clinical records, with interoperability of records between different parts of the healthcare system to improve information sharing. |
| 118 | NOFAS-UK | 1 | Statement 4 | A neurodevelopmental assessment was called a ‘unicorn’ by one parent who has been battling for years for this insight into the cognitive challenges their child might be experiencing. Ensuring a neurodevelopmental assessment is conducted is a very welcome step. Another person said, “With better diagnosis and earlier interventions services can start to develop programmes of support and inform research to find even more efficient and evidence- based protocols - seeing long term improvements in the life outcomes for those with FASD should be a primary focus of all services. Working in an integrative, joined up way, we can make life better for all those affected by FASD.”  • NOFAS-UK encourages the training and materials provided to those assessing ‘clinical concerns’ to emphasise that for many the full impact might not become apparent until a young person ages. Even if a child might have done reasonably well in primary school, some of their challenges might become most apparent as they age into secondary school and a neurodevelopmental assessment might be needed then or before they age into adult services.  • This neurodevelopmental assessment should be an essential element of an Education Health and Care Plan assessment, along with other related assessments (Occupational Therapy, Speech and Language Therapy, etc). |
| 127 | Peterborough family FASD support Group & Field of Enterprise Training & Consultancy | 1 | Statement 4 | As notation of maternal alcohol use in records is rolled out this standard will come into its own, but in the meantime (maybe for 18 years) we may not have confirmed prenatal alcohol use or all three of the physical features and therefore what is going to be put in place in the interim to address children and young people (and adults) who probably have been affected, but records aren’t complete?  As above I do not believe that there are enough professionals to make the assessment at the moment |
| 462 | Public Health England | 2 | Statement 4 | See comment number 3 above. [This appears as comment ID 133 in this table] |
| 340 | Royal College of Paediatrics and Child Health | 2 | Statement 4 | Neuro developmental assessment needs to be clear it is multi-disciplinary (not just a paediatrician) and also how a diagnosis is reached, and what the standards are e.g. ICD 10/Washington guidelines etc., that are being used to diagnose the children. |
| 357 | Royal College of Paediatrics and Child Health | 2 | Statement 4 | This standard should say that children/young people with probable or confirmed prenatal alcohol exposure should have a neurodevelopmental assessment as children who have facial features without confirmed exposure might still receive a diagnosis of FASD. In the reviewer’s opinion the Quality statement 3 above should not only be for probable exposure but cover referral for all children who will need assessment. |
| 358 | Royal College of Paediatrics and Child Health | 2 | Statement 4 | Expertise in neurodevelopmental assessment and FASD. |
| 359 | Royal College of Paediatrics and Child Health | 2 | Statement 4 | As above this should also include probable cases of alcohol exposure. |
| 360 | Royal College of Paediatrics and Child Health | 2 | Statement 4 | Confirmed and probable cases of alcohol exposure. |
| 361 | Royal College of Paediatrics and Child Health | 2 | Statement 4 | Re-word this ‘assessment for prenatal alcohol exposure’ as not all children will receive a diagnosis. |
| 362 | Royal College of Paediatrics and Child Health | 2 | Statement 4 | All children where there are concerns should have a comprehensive bio-psycho-social assessment. |
| 363 | Royal College of Paediatrics and Child Health | 2 | Statement 4 | The commissioning of a specialist service/experts/MDT is so unlikely, services still don’t have a properly commissioned MDT for ASD.  MDT needs to include educational psychology as most support is likely to be in education setting.  Some of our members feel that whilst FASD needs to be recognised as an individual disorder, that assessment, care and support should be framed within a comprehensive and holistic neurodevelopmental assessment. Clinicians should be able to focus more on identifying an individual child’s specific needs and use a formulation approach to appropriately meet that child’s needs. |
| 364 | Royal College of Paediatrics and Child Health | 2 | Statement 4 | Is there no role for genetics services, this is not mentioned at all. |
| 373 | Royal College of Psychiatrists | 2 | Statement 4 | This is too vague. CYP with clinical concerns i.e. symptoms/behaviours sufficient to warrant ND assessment should be referred anyway as part of standard ND referral pathways. This statement implies that CYP without symptoms would get referred for ND assessment because an adult in the child’s system was ‘concerned’ that their pre-natal exposure or facial features meant they might have ND disorder. This implication is worrying and could lead to CYP blocking up ND assessment pathways in paeds/CAMHs unnecessarily. |
| 386 | Scottish Health Action on Alcohol Problems (SHAAP) | 2 | Statement 4 | Quality statement 4: Neurodevelopmental assessment  A team approach to neurodevelopmental assessment is essential. Furthermore, such a team would require multidisciplinary membership, rather than assessment being conducted by a single clinician or expert.    In Scotland such a neurodevelopmental assessment is envisaged as an important component of future planning underway within The Children and Young Peoples Mental Health Taskforce. Planning for neurodevelopmental assessment needs to acknowledge that paediatricians will continue to have a central role in assessment and diagnosis of FASD. This is because they are likely to encounter children under diagnostic consideration when they reach school age in a community setting.  There should be no particular barriers to the necessary data collection and audit, as noted in statement 4. |
| 402 | Scottish Intercollegiate Guidelines Network | 2 | Statement 4 | Evidence of local services with health care professionals with expertise in neurodevelopmental assessment will likely not be sufficient to enable FASD ax and dx. Additional training in FASD will be required. Again, consider use of ‘expertise’ versus ‘training’ at this point. |
| 403 | Scottish Intercollegiate Guidelines Network | 2 | Statement 4 | It may be useful to detail “clinical psychologists’ in the healthcare professionals list, as they have the desired skill set for undertaking the neuropsychological assessment elements e.g. executive function, memory, attention etc. It may also be beneficial to detail paediatric neuropsychologists on the list as in practice they are often required for consultation in regards to unusual cognitive profiles and complex differential diagnostic aspects. |
| 404 | Scottish Intercollegiate Guidelines Network | 2 | Statement 4 | Consider use of ‘delays’ in the terminology here, as could be potentially misleading to those not trained in FASD. |
| 406 | Scottish Intercollegiate Guidelines Network | 2 | Statement 4 | It would be helpful to include a measurement/evidence of the ability of neurodevelopmental paediatricians, AHPs and CAMHS colleagues to work together in making the diagnosis. Could be measured by recording joint multidisciplinary clinics available in localities. |
| 407 | Scottish Intercollegiate Guidelines Network | 2 | Statement 4 | It would be helpful if a uniform national coding system using ICD10/11 and/or DSM5 could be used to allow amalgamation of locally gathered data for evidencing national improvement in diagnosis and assisting in research. |
| 417 | Surrey and Borders Partnership NHS Foundation Trust and National FASD Behaviour management clinic. | 2 | Statement 4 | It is important that it is worded like this. There may be concerns that 80% of the population will be referred as 80% of women drink. Even if taking the lower figures of those who drink alcohol in pregnancy alone without the facial features ( less than 5% of those exposed in the UK) the crucial word is those with clinical concerns. Most people with exposure alone will not develop clinical concerns but some will. IT is not possible to predict who that will be and therefore that part of the wording is both important to allow those in need to access support but also to prevent excessive utilisation of service and excess unnecessary referrals in what is already a stretched system. This wording is a good initial balance and will also help support the development of clinical pathways where they do not already exist. The figure that will be referred here will be far lower. IF in the future it is possible to help identify better those are more increased risk this can be modified but for now that is not possible hence this being a good balance between access and preventing overwhelming of service. |
| 418 | Surrey and Borders Partnership NHS Foundation Trust and National FASD Behaviour management clinic. | 2 | Statement 4 | This will be important to help support the arguments about how is and is not referred but may well need to go with wider guidance to support local areas how to do this in a practical way. This has been done in areas I have worked with to improve standards and develop a needs based analysis |
| 160 | TACT - The Adolescent & Children’s Trust | 1 | Statement 4 | We again feel the potential resource requirements to address this Standard may be far greater than envisaged and, whilst 100% supporting the Standard, are concerned that it might be unrealistic……certainly in the short to medium term. |
| 169 | The Neurological Alliance | 1 | Statement 4 | The wording of the Quality Statement: ’confirmed prenatal alcohol exposure or all 3 facial features’ should be amended, for the same reasons as above. Neurodevelopmental assessment should not be restricted where there are concerns but these features are not present. Without a neurodevelopmental assessment, families are spending years locked in a cycle of denial by services and unable to get the educational support that young people need until the young people develop behavioural difficulties as a result of feeling failed or the parents are blamed for poor parenting skills. |
| 170 | The Neurological Alliance | 1 | Statement 4 | P16 - Mental health comorbidities, anxiety or depression should be added to the list of what ought to be covered in an assessment |
| 391 | University of Bristol (Law School) | 2 | Statement 4 | While the provision of neurodevelopmental assessments where FASD and its sequalae are suspected is to be welcomed, it is difficult to reconcile the ethical and legal deficiencies in the guideline, as currently proposed, with the implementation of an evidence-based system of referral and assessment. |
| 432 | University of Bristol (Medical school / Philosophy dept) | 2 | Statement 4 | Building health professional expertise for FASD diagnosis  Same problem here as in statement 3. Who will do the neurodevelopmental assessments? There are not enough health professionals with the required expertise and this needs to be addressed.  (HC, SO) |
| 341 | Royal College of Paediatrics and Child Health | 2 | Statement 4 | Children are often referred to Clinical Genetics, as a specialty, for the assessment of FAS. This is because of the element of Dysmorphology and also that the differential diagnosis of FAS includes genetic conditions (please see references). This was raised during the topic engagement exercise, but unfortunately there remains not even a mention of genetics, genomics or Clinical Genetics in this document. This is a significant omission. |
| 5 | Adoption UK | 1 | Statement 5 | While Adoption UK welcomes Statement 5 but would, however, prefer the phrase “support plan” to “management plan”. It is imperative that management and support plans continue into early adulthood. This requires mechanisms to ensure well-managed transition from statutory services for children and young people to adult services.  An FASD Alliance survey in response to first consultation round last year asked respondents to identify the five priority areas which require improvement for those with FASD or suspected FASD. Nearly two-thirds selected ‘FASD recognised as lifelong disability’ while more than a third selected ‘ensuring continuity of care for young people with FASD entering adult services’. |
| 214 | Balance | 2 | Statement 5 | Internationally, the quality of research into interventions for people affected by FASD remains limited. Reviews of the literature over the last decade have shown development of ideas related to this field, but there has been limited progress towards gold standard randomised controlled trials (RCTs). More research must be done to develop appropriate, tailored interventions for individuals with FASD, to ensure that they have management plans, which address their needs. |
| 29 | Blackburn with Darwen Borough Council Public Health and Wellbeing Team | 1 | Statement 5 | A management plan, overseen by a virtual group may be the most economical way with this? As ever we have to ask “who manages the management plan”? |
| 65 | British Pregnancy Advisory Service | 1 | 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. |
| 72 | Changing Minds UK | 1 | Statement 5 | The rationale states “The plan signposts the child or young person with FASD and their family to resources and services”. In order for the management plan to signpost to services, it is essential that local commissioning groups provide services that can meet the needs suggested in the management plan. While this may be suggested by the use of the word “support” in the statement, the word “support” may need to be explained further to ensure that commissioning groups provide adequate services that can follow through with the suggestions on the management plan. |
| 79 | CoramBAAF | 1 | Statement 5 | A management plan is only of any use if there is any services / support available. Needs to be clearer what this might look like across health and education / third sector |
| 80 | CoramBAAF | 1 | Statement 5 | Needs to mention EHCP and ensure the management plan links to this and isn’t a duplication |
| 81 | CoramBAAF | 1 | Statement 5 | Process data source is unrealistic – denominator is not measurable. |
| 85 | East Herts and Area FASD Support Network | 1 | Statement 5 | Quality Statement 5 is also extremely important. All our families that have managed to get diagnosis for their children have essentially then been left to find support externally to the NHS, and to construct their own management pathway. This is extraordinarily difficult, and families need more support from the NHS. |
| 281 | FASD NETWORK UK | 2 | Statement 5 | Management Plan  The majority of commissioned support services (therapy, short breaks etc) have the eligibility criteria of LD/ASD so support provision is not available to people with FASD. If we are to open the door to comprehensive management and support plans following a diagnosis the commissioned language needs to be changed to those with a ‘learning disability and/or neuro-developmental condition’ to make it less discriminatory and to stop the lack of support and management plans being developed. |
| 457 | Institute of Health Visiting | 2 | Statement 5 | An important quality standard that should be applied to any child or young person that is identified as universal partnership plus or with special needs. The health visitor plays a key role in working in partnership with the family to ensure that the child receives support tailored to their individual needs. It will be important that the health visitor and school nurse are included in the plan as the child is primarily a child living in his or her family and as part of his/ her local and community whether that is a nursery or school. The health visitor and school nurse are therefore ideally placed to work with the child and family in the context in which they live. |
| 304 | NHS England and NHS Improvement | 2 | Statement 5 | I would also suggest that primary care are central to assisting and monitoring any care plans and would make this explicit in terms of shared care. Relevant sentence is:  “… develop a management plan with the team who carried out the assessments before their diagnosis. They discuss what the plan should cover, their priorities and goals, and who the plan should be shared with.” |
| 119 | NOFAS-UK | 1 | Statement 5 | Having an interdisciplinary management plan in place would be a critical step forward. One family responded, “It must be an holistic approach if we are to support these children into adulthood and independence.”  • These management plans can be life-changing if they are implemented in cooperation with input from the families and – importantly – reviewed as a person ages into adult services to avoid this transition becoming a cliff-edge.  • NOFAS-UK encourages each CCG and NHS trusts to identify an FASD lead or ombudsperson so that there is a point of contact families could engage with as they seek to navigate local services. This should be embedded within the NHS. |
| 128 | Peterborough family FASD support Group & Field of Enterprise Training & Consultancy | 1 | Statement 5 | As mentioned above this standard includes a plan to not only guide medical professionals, but also social care and education staff. Therefore, there needs to be a commitment that includes training of staff in all areas so that the plans can be applied, and the necessary flexibility can be built in to any plan to meet the very variable needs of affected individuals.  I believe that in the service providers section it should also state that training programmes for social care and educational professionals on managing FASD must be provided rather than the current suggestion that health care professionals work across disciplines in order to provide information on the effects. There is a huge difference between communicating what might happen to actually having lived professional experience of supporting in the classroom and in social care.  The plan needs to transition into adulthood and be accepted by adult services given that our children often have a developmental age considerably lower than their chronological age, but this may not be as self-evident when adult social care assess their needs. Therefore, the transition of a plan into adulthood is important.  I suspect that in social care a no blame approach to causing FASD in a child may be difficult. There needs to be an increased emphasis on the parent(s) ability to parent in the moment rather than the things that led up to the condition. |
| 339 | Royal College of Paediatrics and Child Health | 2 | Statement 5 | There are very few comments about education, these children are often managed reasonably well in the home but as soon as they enter school where there is less support the children emotionally decompensate and can be very challenging. They often end up in specialist behaviour settings where they are kept out of trouble rather than educated and given a purpose.  Due to the lack of diagnostic services, the majority of these children fail in school and end up in mental health centres, prison or on the streets.  The children the reviewer has dealt with who have received a diagnosis and have had it explained to them, have been helped to understand why they struggle, and this helps them learn what they can do. |
| 365 | Royal College of Paediatrics and Child Health | 2 | Statement 5 | Always state FASD or ‘at risk of FASD’. |
| 366 | Royal College of Paediatrics and Child Health | 2 | Statement 5 | Ensure communication with Local Authority commissioning to include Education and Social Services. |
| 367 | Royal College of Paediatrics and Child Health | 2 | Statement 5 | If describing people with FASD include ‘or at risk of’. |
| 368 | Royal College of Paediatrics and Child Health | 2 | Statement 5 | A management plan is only of any use if there is any services/support available. Needs to be clearer what this might look like across health and education/third sector. |
| 369 | Royal College of Paediatrics and Child Health | 2 | Statement 5 | Needs to mention EHCP and ensure the management plan links to this and isn’t a duplication. |
| 370 | Royal College of Paediatrics and Child Health | 2 | Statement 5 | Process data source is unrealistic, the denominator is not measurable. |
| 387 | Scottish Health Action on Alcohol Problems (SHAAP) | 2 | Statement 5 | Quality statement 5: Management plan.  A clear, written management plan is essential once a diagnostic formulation is in place. This written plan should be clear about a child’s areas of strength as well as the particular challenges that they face, and ensure that appropriate support is in place. This is particularly important in the context of education settings. Here, planning must keep in mind any equivalent of Scotland’s “Getting it Right for Every Child” (GIRFEC) (<https://www.gov.scot/policies/girfec/>) framework or SHANARRI “Wellbeing indicators” (Safe, Healthy, Achieving, Nurtured, Active, Respected, Responsible, Included) ([https://www.gov.scot/binaries/content/documents/govscot/publications/factsheet/2017/08/shanarri/documents/wellbeing-wheel/1d61e4a3-19ad-4959-a7be-97d7b757b0ab/1d61e4a3-19ad-4959-a7be-97d7b757b0ab/govscot%3Adocument/SHANARRI%2B-%2BWellbeing%2Bwheel%2B-%2Bfull%2Btext.pdf](https://www.gov.scot/binaries/content/documents/govscot/publications/factsheet/2017/08/shanarri/documents/wellbeing-wheel/1d61e4a3-19ad-4959-a7be-97d7b757b0ab/1d61e4a3-19ad-4959-a7be-97d7b757b0ab/govscot%3Adocument/SHANARRI%2B-%2BWellbeing%2Bwheel%2B-%2Bfu)). Though these are Scottish measures, we would anticipate some kind of equivalent in the rest of the UK.  During follow-up it is essential that potential psychological and mental health issues be taken into account. Further, follow-up should not be overly dependent on school ‘observational assessments’, as these may eschew and underestimate the importance of information re strengths and weaknesses revealed and shared following diagnostic assessment. Close liaison with colleagues in Education is essential.  With this in mind, a review and audit of supports in place in school settings and an audit of outcomes is important to include in planning. This will be particularly important for sensitive periods of transition, e.g. from Primary to Secondary School settings, and at school leaving age. |
| 405 | Scottish Intercollegiate Guidelines Network | 2 | Statement 5 | Query about use of educational attainment as a measure, as these children by virtue of their difficulties may not be able to access typical measure of this. Could educational engagement be an alternative? Perhaps those involved here will not all be health professionals for these outcomes e.g. educational psychologists and social workers? |
| 408 | Scottish Intercollegiate Guidelines Network | 2 | Statement 5 | There should be a statement in this section about the importance of Transition plans, and appropriate transfer of follow up, as recommended for all children and young people with long term conditions.  Transition from children’s to adults’ services Ref: NICE Quality standard (QS 140)2016 |
| 419 | Surrey and Borders Partnership NHS Foundation Trust and National FASD Behaviour management clinic. | 2 | Statement 5 | This is vital. For so many families the diagnosis is not enough in itself. Having a plan of how to help manage them is also vital. Families want to know what to do not just a diagnosis and this statement moves towards that. Prevention of secondary disabilities comes not from just a diagnosis but the linked management plan and changing the trajectory of the individual. This statement support that |
| 161 | TACT - The Adolescent & Children’s Trust | 1 | Statement 5 | As above, we are 100% in support of this QS, but would stress that we have misgivings about whether this can be met within existing resources. |
| 165 | Tees Valley Durham and North Yorkshire Neurological Alliance | 1 | Statement 5 | **Structure**  Is it possible that ‘co-produced’ could be inserted, ‘…diagnosed with FASD have a co-produced management plan. This would ensure a multi-disciplinary approach, avoid ad hoc blaming and include the input of adoptive/fostering parents. The audit trail for future reference could be a useful learning tool in the absence of other training. |
| 171 | The Neurological Alliance | 1 | Statement 5 | P17 – The management plan must be co-produced with family, caregivers and the person with FASD in appropriate developmental or transitional stages in order to standardise expectation.  This critical stage forms the basis of a range of coping skills for both young person and parents. |
| 392 | University of Bristol (Law School) | 2 | Statement 5 | Many services to manage/ support children with a diagnosis of FASD and their carers with have to be provided by LA Children’s Services for Children in Need or under and Education and Health Care Plan. Local Authority Children’s Services are severely under-funded; Education, Health and Care Plans (EHCPs) and services provided under them are not equitably provided through national government but dependent on LA resources. Simply instructing Commissioners to consider these matters is an inadequate way of securing new services in an area where there has been under diagnosis and a lack of services. |
| 433 | University of Bristol (Medical school / Philosophy dept) | 2 | Statement 5 | Management plan  How will the management plan interact with educational, health and care plans (EHCPs) where these are present?  (HC, SO) |
| 67 | British Society of Gastroenterology | 1 | X | The BSG Adolescent & Young Persons (AYP) section has considered this and from their perspective BSG has no comments. |
| 458 | Department of Health and Social Care | 2 | X | No comments. |

#### Registered stakeholders who submitted comments at consultation

* Adoption UK
* AIMS - the Association for Improvements in the Maternity Services
* Association of Paediatric Chartered Physiotherapists
* Balance
* Birthrights
* Blackburn with Darwen Borough Council Public Health and Wellbeing Team
* Blackburn with Darwen Borough Council Substance misuse service
* BPAS
* British Medical Association
* British Pregnancy Advisory Service
* British Psychological Society
* British Society of Gastroenterology
* Changing Minds UK
* CoramBAAF
* Cwm Taf University Health Board
* Department of Health and Social Care
* East Herts and Area FASD Support Network
* Elucidate Training
* FASD NETWORK UK
* General Medical Council
* Healthwatch UK
* Institute of Health Visiting
* Liberty
* medConfidential
* National Data Guardian (NDG)
* NHS England and NHS Improvement
* NOFAS-UK
* Northumbria Healthcare Foundation NHS Trust
* Peterborough family FASD support Group & Field of Enterprise Training & Consultancy
* Public Health England (submission represents the view of the Alcohol, Drugs, Tobacco and Justice Division; the Chief Nurse, Maternity and Early Years Directorate and the UK National Screening Committee)
* Surrey and Borders Partnership NHS Foundation Trust and National FASD Behaviour management clinic
* Royal College of General Practitioners
* Royal College of Midwives
* Royal College of Obstetricians and Gynaecologists
* Royal College of Paediatrics and Child Health
* Royal College of Physicians
* Royal College of Psychiatrists
* Scottish Health Action on Alcohol Problems (SHAAP)
* Scottish Intercollegiate Guidelines Network
* TACT - The Adolescent & Children's Trust
* Tees Valley Durham and North Yorkshire Neurological Alliance
* The National Organisation for FASD (formerly NOFAS-UK)
* The Neurological Alliance
* University of Bristol (Law school)
* University of Bristol (Medical school / Philosophy dept)
* University of Southampton

1. PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees. [↑](#footnote-ref-1)