
Downloaded from
https://kar.kent.ac.uk/96050/ The University of Kent's Academic Repository KAR

The version of record is available from
https://doi.org/10.1136/jme-2022-108170

This document version
Author’s Accepted Manuscript

DOI for this version

Licence for this version
CC BY-NC (Attribution-NonCommercial)

Additional information

Versions of research works

Versions of Record
If this version is the version of record, it is the same as the published version available on the publisher’s web site. Cite as the published version.

Author Accepted Manuscripts
If this document is identified as the Author Accepted Manuscript it is the version after peer review but before type setting, copy editing or publisher branding. Cite as Surname, Initial. (Year) ‘Title of article’. To be published in Title of Journal, Volume and issue numbers [peer-reviewed accepted version]. Available at: DOI or URL (Accessed: date).

Enquiries
If you have questions about this document contact ResearchSupport@kent.ac.uk. Please include the URL of the record in KAR. If you believe that your, or a third party’s rights have been compromised through this document please see our Take Down policy (available from https://www.kent.ac.uk/guides/kar-the-kent-academic-repository#policies).
Using Meconium to Establish Prenatal Alcohol Exposure in the UK: 
*Ethical, Legal and Social Considerations*

**Abstract**

An expanding policy framework aimed at monitoring alcohol consumption during pregnancy has emerged. The primary justification is prevention of harm from what is termed ‘Prenatal Alcohol Exposure’ (PAE), by enabling more extensive diagnosis of the disability labelled Foetal Alcohol Spectrum Disorder (FASD). Here we focus on proposals to include biomarkers as a PAE ‘screening tool’, specifically those found in meconium (the first new-born excrement), which are discussed as an ‘objective’ measure of PAE.

We ask the overarching question, ‘Can routine screening of meconium to establish PAE be ethically or legally justified’, and we answer, ‘No’. To reach this conclusion, we discuss three areas. First, we consider the reasons why meconium screening should not be deemed ‘typical’ within the scope of accepted screening tools. We argue that given the aim and necessary timing of the screen, it cannot achieve what it promises. Second, we outline why patient autonomy and consent are not properly accounted for and cannot be reconciled with the ‘routinization’ of the proposed ‘screening’. Last, we outline why the benefit of such a screen is not clear, focussing on the significance of trust in Healthcare Practitioners (HCP) for the best interests of the future child and pregnant woman.

While recognising the adverse effects of heavy alcohol consumption during pregnancy, we emphasise the case for robust ethical, legal, and social considerations and the central need for trust between HCP and patients in maternity care. We conclude the permissibility of meconium screening has not been proven and it is not justified.
Using Meconium to Establish Prenatal Alcohol Exposure in the UK: Ethical, Legal and Social Considerations

Introduction

In recent years, use of neonatal biomarkers (‘objective indications of medical state observed outside the patient’)[1] for confirming alcohol consumption during pregnancy has been increasingly considered. Justifications refer to both prevention and detection of the form of disability labelled Foetal Alcohol Spectrum Disorder (FASD). FASD is described as a hidden epidemic and national emergency in the UK,[2] with claims made that 1 in 6 children are affected.[3] These figures underpin collective responses in policy. A framework comprised of guidelines, quality standards and policy documents has emerged and is expanding. It includes: ‘Guideline 156: Children and Young People Exposed Prenatally to Alcohol’ (Scottish Intercollegiate Guidelines Network (SIGN, 2019); one of a series of ‘Maternity High Impact Area’ policy documents from Public Health England (PHE) highlighting ‘Reducing the incidence of harms caused by alcohol in pregnancy’ (December 2020); guidance from the Department of Health and Social Care (DHSC) providing a health needs assessment for those living with FASD (2021) and most recently a Quality Standard on FASD published by the National Institute of Health and Care Excellence (March 2022), based in part on SIGN 156.

This framework claims alignment with the UK Chief Medical Officers’ ‘Low Risk Drinking Guidelines’ (2016). These endorse a precautionary approach to alcohol consumption during pregnancy. They advocate alcohol abstinence when planning and during pregnancy, justifying this approach to risk on the basis that research has not proven the safety of low to mid-level consumption. This guidance is clear the advice is not based on new evidence of harm, but rather absence of evidence of safety, and a case for the ‘simplicity’ of guidance. However, the policy framework about PAE goes further than endorsing alcohol abstinence; it operationalises the ‘precautionary principle’ in novel ways.[4] Each document referred to above endorses as mandatory what is termed ‘screening’ of pregnant women and the recording of all alcohol information. Further, SIGN 156 and a previous draft of the NICE Quality Standard both call for this information to be subsequently transferred to her child’s health record. The primary justification is the necessity of such information to make an FASD diagnosis, which assumes women cannot be relied upon to accurately and honestly report their alcohol consumption. SIGN 156 removes a lower threshold of alcohol information for this purpose, arguing that consistency with the 2016 CMO Guidance means any maternal alcohol consumption places a child ‘at risk’ of FASD.

This approach may explain the recommendations for further research into meconium ‘screening’ as a tool for establishing PAE, with the case made that examination of meconium can reliably assess a pregnant woman’s alcohol consumption. Meconium, a neonate’s first faeces, can be examined to measure the levels of fatty acid ethyl esters (FAEEs), which result from the interaction between alcohol and fatty acids. Meconium begins to form from around 12 weeks’ gestation, it is argued giving it a clear advantage over maternal hair or blood samples as a ‘long-term marker’ of alcohol intake.[5] The collection of samples is also deemed less invasive than with other options due to its status as a waste product. Discussion of meconium screening appears in international literature from the late 1980s but was not trialled in the UK context until 2006.[6] The emerging policy framework discussing its use positively signals an explicit declaration to encourage further research in the UK. The calls for further research focus on the efficacy and advantages of such screening for detection of
PAE. With some notable exceptions, [7-10] attention to ethical, legal, and social permissibility is less extensive, especially in the UK context.

The perceived advantages of objectivity and reliability are linked to the growing authority associated with biomedical technologies, and the pre-existing depletion of institutional trust in women to accurately self-report substance use during pregnancy. Routine carbon monoxide screening at every antenatal appointment was first introduced into NICE guidance in 2010, with the aim of providing an ‘objective’ measure of maternal smoking status throughout pregnancy[11] Throughout the associated consultations the majority of comments made were in support. In the 2013 consultation, only one stakeholder raised the notion that this use of technology could be considered ‘inappropriate’, functioning as a ‘lie detector’ with the ‘potential to damage the midwife-woman relationship’. [12] There is a distinct lack of scholarship which engages with the presumed ethical permissibility of enforcing routine carbon monoxide monitoring on an opt-out basis. An exception is Bowden who argues that the reliance on biomedical technology implies that pregnant women cannot be trusted to tell the truth about their lives, questioning their ability ‘to make decisions in the best interests of themselves and their future children in the way that non-pregnant individuals are.’ [13] Direct parallels can be drawn with the assumptions behind advocacy of routine screening for alcohol consumption.

This background to meconium screening highlights its core justification: the benefit of the future child in having an accurate and reliable record of their mother’s alcohol consumption to facilitate a diagnosis of FASD. This point has been reiterated many times within the policy framework, including within the well-publicised public consultation for the NICE Quality Standard on FASD. [14-17] It is widely thought that an earlier diagnosis of FASD can be considered beneficial for those adversely impacted by prenatal alcohol exposure, as it can lead to the prevention of secondary harms, and consequently, better outcomes. Indeed, SIGN 156 states earlier diagnosis can make ‘significant differences to the developmental progress of the affected child’ and help prevent the onset of secondary disabilities.[17]

Such claims of a benefit for the future child through the prevention of harm are weighty. In line with the case made by Bennett and Bowden[10], we argue however they must be balanced against currently under discussed concerns about the effects of this definition of ‘routine’ screening for maternal and child health and maternal autonomy. We argue a meconium screen cannot be considered ‘typical’ when viewed within the scope of accepted screening tools in preventative medicine; we contend the routinisation of such screening is conflict with vital attention to autonomy and consent in the antenatal setting; and last, we argue for the priority of trust between midwives and women, which is jeopardised by this version of screening.

**A Meconium Screen cannot achieve what it promises.**

The purpose of screening is to identify those who can be deemed ‘at risk’ of a particular disease, condition or health issue.[18] For meconium screening, the ‘health issue’ would be risk of FASD based on a positive screen of PAE. As noted, in policy documents the drive for collecting maternal information is linked to making a diagnosis of FASD with this information regarded as pivotal for access to support and care Thus, the drive for finding an ‘objective’ measure of exposure comes from efforts to establish the most effective way to elicit ‘reliable’ information to aid earlier diagnoses.
However, assessing meconium can only be considered an ‘atypical’ ‘screening tool’ at best. Identifying PAE is not the same as diagnosing FASD. PAE is elevated to appear as the core causal factor in the presence of impairment, rather than a possible risk factor. The cause of any disease can encompass multiple factors and screening needs to be based on a high threshold of certainty about markers for disease. The current treatment of PAE can be thought of as based on a reverse causal proposition.[19] As Miller notes, policy surrounding PAE shifts the primary question away from ‘can PAE lead to disorders under the umbrella term FASD’ to ‘PAE did lead to disorders under the umbrella term FASD’, wrongly treating PAE as a marker as though a high degree of certainty is accepted.[19]

Policy documents calling for further research into meconium screening further embed this purported causal association between any alcohol consumption and FASD. SIGN 156 adapts Canadian Guidelines for FASD. The latter use a threshold of alcohol dosage and a measure below this cannot be used diagnostic purposes, but this is removed from SIGN 156. In providing a rationale for this revision, the Guideline’s authors state, ‘the estimated dose at a level known to be associated with neurodevelopmental effects’ used in the Canadian Guidance to describe a threshold for PAE ‘has been removed to make consistent with the UK Chief Medical Officers’ advice for no safe level of alcohol consumption during pregnancy.’[17] By embedding the ‘precautionary principle’ this way the authors effectively attribute the causation of harm to any alcohol, despite the lack of evidence or consensus.

In the text of SIGN 156, it is left unclear as to how this diagnostic threshold would be incorporated into any use of meconium screening, raising the question of the aims of this intervention. The immediate aim is to provide an assessment of PAE paving the way to achieving long-term aims: using this assessment for either diagnostic purposes or prevalence studies. Of antenatal care, SIGN 156 states, the ‘associated use of particular biomarkers…alongside brief screening questionnaires should be considered’, and it also recommends further ‘feasibility studies’ on the use of meconium and placental biomarkers.[17]

However, neither aim accords with the recognised objective of screening. Meconium ‘screening’ can only be viewed as an intervention aimed at preventing the development of secondary harms through providing information which might assist with a diagnosis of FASD. It cannot assist diagnosis of disease in either mother or child and cannot be seen as a public health intervention aimed at ‘avoiding harm’ as the ‘risky’ exposure has already taken place by the time the infant is born. Furthermore, as Bennett and Bowden note in their recent article on routine alcohol screening, the use of meconium has a clear disadvantage in relation to harm reduction in comparison to self-reporting, as the retrospective nature of the screen means it cannot be used to identify those pregnant women who may benefit from specialist services to reduce their consumption[10]. Lastly, a positive screen of PAE from meconium screening is not a necessary requirement for a diagnosis, since this information can be provided through way less invasive means, namely self-reporting.

Given this critique, we now discuss question of consent

Consent cannot be accounted for.

Meconium is classified as a waste product, and so an argument has been made that consent need not apply to this form of screening. Legal scholar Bernard Dickens makes this case with reference to the laws of evidence, arguing that if the product is to be routinely discarded or ‘abandoned’, it could, by analogy, be deemed admissible for testing if recovered by HCPs.[7] He acknowledges this notion is borne from criminal law not the healthcare context but maintains the possibility. In essence, he raises the question of ownership: does the meconium belong to the birth mother or the neonate? By
maintaining parental consent is unnecessary, Dickens has prioritised the information that can be gleaned from such a screen, as opposed to any implications for the mother and therefore the responsibilities she may be owed.

However, meconium is being assessed as a direct reflection of maternal consumption, thus producing information about private life and health. Within diagnostic or research contexts, a meconium screen would be used to bypass the disclosure of information through other possible screening tools, such as verbal questionnaires or self-reporting, both of which should require robust models of informed consent. Due to the privacy and medical confidentiality implications involved, it is unfathomable that a model of consent would neither be ethically nor legally required. This should not just extend to ensuring birth mothers are adequately informed about the screening process itself, but to how this information will be stored and subsequently used.

There is a difference between the collection of data for clinical practice and the collection of data for research purposes. If a meconium screen were to be implemented for research purposes, such as prevalence studies, anonymity could be ensured. While this does not preclude the requirement of a consenting process, ensuring anonymity could give due respect to the birth mother’s privacy interests. Recommendations in relevant policy documents discuss future clinical practice for diagnostic purposes yet have nothing to say on ensuring anonymity. What consenting considerations would need to be accounted for, if such a screen were to be introduced?

In legal and professional standards consent is widely considered an ongoing process, rather than a single occurrence. It must be sought at various stages of medical interventions, including the initial actions itself and any subsequent measures suggested or recommended. Reflecting the principle of autonomy, the consenting process must encompass robust information provision, ensuring that valid decision-making can occur. It must provide adequate information pertaining to the risks and benefits of any given intervention and any reasonable alternatives – including the option of no intervention at all. [20-22] In the case of meconium screening, this must detail both the intervention itself and how the information gathered is to be stored and subsequently used. Consent must be voluntarily given, free from coercion, and the right to refusal must be respected. There is no consideration of such informed consent in the emerging UK policy framework; rather, as we now discuss, the emphasis is on ‘routinization’ and expanding efforts to incorporate screening practices into the remit of ‘routine’ antenatal care.

Some Clinical Commissioning Groups (CCGs) have been enforcing mandatory screening and collection of maternal alcohol information from as early as 2016;[23] but this practice is not commonplace. Through ‘routinization’, the aim is to screen all pregnant women, not just those who may be deemed at risk of having an alcohol exposed pregnancy. The inclusion of screening practices so far has been limited to considering the use of validated tools, which primarily take the form of alcohol use questionnaires (for example, T-ACE, TWEAK and AUDIT-C). The intention to develop the use of biomarkers falls within this same trajectory,[17] with no consideration given to differences between research and a clinical intervention, and the question of consent in either scenario.

Consideration of how existing interventions are presented within antenatal care (the questionnaires in use) could shed light on current issues. This is not anywhere available yet and could help to ensure valid consent can be achieved if meconium screening were to be introduced. Further, commentary on other versions of ‘routine screening’ highlights questions that must be addressed. Bennett raises the fundamental tensions between achieving public health goals and respecting individual autonomy in routine antenatal HIV testing.[24] In providing ‘routine’ screening on an ‘opt-out’ basis, Bennett maintains that while this may increase uptake, questions remain whether consent can truly be
accounted for. Such a system is designed to ‘secure’ the testing of those who many not have voluntarily chosen it, concealing “levels of coercion that are not deemed acceptable in many other areas of medical testing or treatment.”[24] In making something ‘routine’ the message that acceptance is recommended becomes implicit. As Bennett notes, this could result in midwives feeling it’s ‘their duty’ to persuade women to accept the HIV screen, especially if they are to reach a target of, for example, 90% uptake.[24]

For routine carbon monoxide screening, Bowden reaches similar conclusions. She acknowledges that while it is possible for pregnant women to refuse the screen,

This fact that it is to be offered routinely at all antenatal appointments and given the emotive language used; presenting it as a test to see if someone is taking hold of the umbilical cord and squeezing it tightly, it seems inevitable that pregnant women will feel pressurised to take it.[13]

In HIV screening and carbon monoxide monitoring in the UK, routinisation means pregnant women are treated differently from the general population. Not only is such screening atypically routinely offered to all pregnant women, but further is presented as not requiring active, voluntary consent, on the basis that protecting the health of the foetus overrides this otherwise normal requirement. Proposals for meconium screening raise exactly these problems.

Not in anyone’s best interests.

DHSC Guidance, providing a health needs assessment for those living with FASD, their carers and families, and those at risk of alcohol-exposed pregnancies in England was published in 2021. This is the first document considering PAE that includes consideration of ‘Law and Ethics’, noting:

There is a strong social ethical imperative to ensure the well-being of future children, and this needs to be carefully managed in view of the importance of ensuring that we protect women’s rights and freedom from interference by the state.[25]

The imperative noted by the DHSC to ‘ensure the well-being of future children’ appears laudable, but the phrasing above pits the well-being of children against the rights of their mothers. It suggests there is great clarity about how best to protect child well-being, and the need to ‘manage’ the opposing rights of women to do so (conceding these may matter). This account of the ethical and legal stakes fails to fully capture how best to protect the best interests of mothers and children.

First, in regard to the interests of the child, we have noted meconium screening, while often hailed due to its perceived objectivity, fails to prevent any ‘primary’ harms since exposure has taken place by the time of the screen. It can only provide information in aid of a diagnosis, to prevent ‘secondary’ harms. This rationale can only provide a guise of benefit at best. Evidence of exposure does not always lead to a diagnosis of FASD; nor does a diagnosis lead to adequate support and care. More attention is given to prevention (and how to best ‘manage’ women’s rights) than to ensuring a suitable and effective care pathway. It would be of more benefit to the child to diagnose their care needs rather than diagnosing the behaviour of their mother during pregnancy.

Second, the notion of mandatory screening for the ‘benefit’ of future diagnosis is false, particularly if meconium is to be considered a potential replacement for self-reporting, as it does not work to prevent future incidences of exposure. It also further embeds a questionable understanding of causality since the emphasis on screening works to ‘promise’ a diagnosis. SIGN 156 itself recognised that ‘no evidence was identified which directly links a maternal history that has involved alcohol use
to improved rates of diagnosis and better outcomes for a woman or her children.’[17] Similarly, the DHSC note that the ‘development of biomarker testing for alcohol use may be of more harm than benefit’.[25]

In relation to patients and antenatal care, we have discussed rights as part of consent. Beyond this, we contend it is not correct to pose the ethical problem as limited to one of the management of women’s rights. Rather, in line with Bennett and Bowden, we suggest priority in regard to ethics needs to be given to the question of trust. They raise crucial concerns regarding the implications of routine screening for the possibility of trusting relationships between midwives and patients, with clear implications for both mothers and babies. Trust is a known, key component of the patient-HCP relationship.[26-28] In instances of ‘risky behaviour’ during pregnancy, including alcohol use, many view a ‘trusting relationship’ as vital to ensure pregnant women receive appropriate advice, support, and care.

The best available evidence highlights the need to centre the discussion of the ethics of screening on trust. Schölin and colleagues, exploring midwives’ views on ‘barriers and facilitators’ to implementing alcohol guidelines in the UK, highlighted the perceived importance of communication. ‘Communication with women’ was highlighted as a prominent theme which focused ‘on the need to establish a trusted relationship with women’; this, they found, enabled discussion surrounding alcohol. They further noted that building such a relationship of trust, which promotes open discussion, takes time, and that the ‘perception that women do not disclose if they are drinking’ is a barrier to such open conversations.[29] Given the social norms of ‘good’ motherhood and ‘healthy pregnancy’ now extended to the preconception period,[30] behaviour choices during pregnancy are increasingly perceived as ‘signal moments’, in which women’s ‘mothering abilities’ are judged and scrutinized.[31] HCPs need to be able to address this context; the danger is that mandatory screening makes this harder.

This risk of stigmatisation (and self-stigmatisation) has been raised by HCPs. Commenting on the NICE Draft Quality Standard, the Royal College of Midwives (RCM) noted that the proposals could prove to be ‘self-defeating’, maintaining that, in addition to potentially disrupting relationships of trust, many women may ‘feel the need to conceal the consumption of alcohol from their midwife.’[32]

Recent research by the WRISK project found that many of these concerns have come to fruition. For carbon monoxide monitoring, women reported the use of ‘objective’ measures undermined their relationship with midwives. One interviewee felt the screening ‘strengthens the power imbalance between clinician and patient’ when any questions concerning smoking are routinely followed by an objective screen.[33] The rights of privacy, confidentiality and trust are central to the fiduciary relationship between the patient and her midwife, and if threatened, could have a wider impact on the medical profession more widely.

In her work, Armstrong has explored the notion of a ‘dual responsibility’[34] as felt by HCPs in caring for pregnant women. Care and concern for the unborn baby is a central part of obstetrics and gynaecology,[35] resulting in the common thought that there are two patients involved in pregnancy. While often unproblematic, this line of thought can encourage the notion of conflicting interests in pregnancy, and the effects for the obligations owed by the fiduciary relationship between a pregnant woman and her HCP need far greater consideration. This concern has not been explored anywhere within the current policy framework but there is a public interest in protecting this relationship.
Conclusion

As noted, the current consensus is that meconium screening has not reached the accepted levels of specificity and sensitivity to be useful in the clinical context.[36] However, as we have noted, policymakers and researchers alike are calling for further research on the basis that routine meconium screening could be a necessary and important addition to maternity care, providing ‘objective’ measures to compliment ‘routine screening’ (verbal questionnaires) in the antenatal setting. Situating these calls within their wider policy context, we have argued routine screening of meconium to established PAE cannot be justified.

We have made the case that this form of screening is atypical, meaning it cannot provide justifiable health benefits, with its current framing in policy discussion inflating the case for potential benefits. The problem of informed consent, as part of ‘routine’ antenatal screening has already been noted for carbon monoxide and HIV screening, and proposals for meconium screening face the same ethical and legal issues. Finally, in the absence of any firm evidence that meconium screening would lead to harm prevention, it is difficult to see how this form of screening could be in anyone’s best interest. Rather, it is likely to prove counterproductive, for the best interests for babies, mothers and HCPs because of its undermining of trust relations between pregnant women and HCPs.

The current policy framework merely assumes ethical and legal permissibility of meconium screening by calling for ‘feasibility studies’. Before any questions concerning feasibility should be asked, this form of intervention has to be justified, and as we have argued, it currently is not.

References:


13. Bowden C. Are we justified in introducing carbon monoxide testing to encourage smoking cessation in pregnant women? *Health Care Analysis* 2019;27(2):128-45


---

¹ This guideline has been updated and replaced by the NICE guideline on tobacco: preventing uptake, promoting quitting and treating dependence (NG209)


22. Montgomery v Lanarkshire Health Board [2015] UKSC 11


35. Wise J. Life as a physician in obstetrics and gynaecology. *BMJ*. 2020 Jan 24;368