NICE National Institute for Health and Care Excellence

Appendix A: Stakeholder consultation comments table

2018 surveillance of Pregnancy and complex social factors: a model for service provision for pregnant women with complex social factors (2010)

Consultation dates: 29 June to 12 July 2018

Do you agree with the proposal to not to update the guideline?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
Royal College of Paediatrics and Child Health	No response provided	Thank you for inviting the Royal College of Paediatrics and Child Health to comment on the NICE guideline on Pregnancy and complex social factors: a model for service provision for pregnant women with complex social factors, call for a surveillance consultation. We have not received any responses for this consultation.	Thank you.
Department of Health and Social Care	No response provided	Confirmed they have no comments to make.	Thank you.
National Organisation for Foetal Alcohol	No response provided	As an organisation we are most willing to participate further on these issues, should that prove useful. We have been involved with helping to provide	Thank you.

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 recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Syndrome-UK (NOFAS-UK)		information to more than 16,000 midwives and we are beginning outreach to GPs and CCGs on issues related to alcohol, pregnancy and FASD as well.	
Royal College of Nursing	No response provided	Nurses caring for people with Pregnancy and complex social factors have reviewed the proposal and have no comments to submit at this stage.	Thank you.
The Survivors Trust	No	The guideline needs to be updated to reflect current understanding and focus on women and girls affected by childhood sexual abuse of any form whether in a family, institutional or exploitation setting. Since the guidance was produced in 2010 there has been a major shift in society in relation to the disclosure of and response to childhood sexual abuse. The Children's Commissioner's Inquiry into Child Sexual Abuse in the Family Environment highlighted that statutory services are only aware of 1 in 8 children that are being sexually abused, with estimates that 1 in 4 women have experienced child sexual abuse. The Independent Inquiry into Child Sexual Abuse has also highlighted the prevalence of sexual abuse and the failure of statutory services to respond appropriately. Research conducted by University of Suffolk, Survivors in Transition and The Survivors Trust also highlighted the failure of statutory services, including health services, to respond effectively to the needs of adult survivors of child sexual abuse.	Thank you for your comments. The population included within the scope of CG110 is pregnant women who do not access or maintain regular contact with antenatal maternity services. CG110 includes a recommendation for supporting women who experience domestic abuse in accessing maternity services. Note that the definition for domestic abuse that has been included in the full version of the guideline is derived from the Home Office definition: 'an incident of threatening behaviour, violence or abuse (psychological, physical, sexual, financial or emotional) between adults who are or have been intimate partners or family members, regardless of gender or sexuality'. NICE has published a guideline on Domestic violence and abuse (PH50) which aims to help identify, prevent and reduce domestic violence and abuse among women and men in heterosexual or same-sex relationships, and among young people. We will add a cross-reference from CG110 to PH50 which includes recommendations noting an increased risk of abuse among women who are pregnant. Uptake of services and providing information and support for all pregnant women will be addressed by the NICE guideline on Antenatal care for uncomplicated pregnancies (CG62). The

		NHS England has now taken over commissioning responsibility for Sexual Assault and Abuse Services and has issued a 5 Year Strategy aimed at improving service provision for victims and survivors. It is therefore timely that this guidance is updated to reflect these developments.	guideline specifies that care should allow women to discuss sensitive issues including sexual abuse. The guideline is currently being updated and after it is published, we will undertake another surveillance review of CG110. In the interim, we will ensure that there are links between CG110 and CG62 and between the relevant pathways for the two guidelines. Thank you for highlighting NHS England's 5 year strategy aimed at improving service provision for victims and survivors. The focus of this strategy is linked to NICE's guideline Harmful sexual behaviour among children and young people (NG55) so we will track the progress of this strategy and consider the impact of outputs and consider if there are implications for CG110.
NICE Quality and Leadership team	Yes	No comment provided	Thank you for your response.
Cardiff and Vale University Health Board	No	New and important evidence of the effectiveness of the Family Nurse Partnership programme in England has been published since the previous guideline. Given the high level of investment in this programme in England for pregnant women under the age of 20, it is considered important this is reviewed by the guideline development group, and the chapter on care of women under 20, be amended. The previous guideline incorporated US generated evidence by Olds et al and cautioned against assuming the evidence could be translated to the UK. This new evidence addresses this issue.	Thank you for highlighting this study which aimed to assess the effectiveness of a Family Nurse Partnership (FNP) programme in addition to usual care on infant and maternal outcomes up to 24 months after birth and included teenage first-time mothers aged 19 years or younger who were recruited at less than 25 weeks gestation. The guideline recommendation states that ccommissioners should consider commissioning a specialist antenatal service for young women aged under 20, using a flexible model of care tailored to the needs of the local population. However, the results of this study indicated that adding FNP to usual health and social care provided no additional short-term benefit to primary outcomes and does not suggest that a change to the recommendation is needed.

		The trial represents a large investment of public money and it is important that the results now inform national recommendations. Robling M, Bekkers MJ, Butler CC, Cannings-John R, Channon S, Hood K, Gregory JW, Kemp A, Kenkre J, Martin BC *et al*: **Effectiveness of a nurse-led intensive home-visitation programme for first-time teenage mothers (Building Blocks): a pragmatic randomised controlled trial**. *The Lancet* 2016, **387**(10014):146–155.	
Birth Companions	No	Birth Companions is a charity that works to improve the lives of perinatal women and babies facing severe, multiple disadvantage through practical frontline work in prisons and the community, and through research and policy development. We would like to suggest an updated guideline considers 1) The evidence base in relation to the needs of women facing severe multiple disadvantage with complex social factors, and how best to address them. Pregnant women with multiple, complex needs are less likely to access maternity care, or will receive less of it, have poorer maternal and infant outcomes, and are more likely to experience perinatal mental health problems (Thomson, G and Balaam, M (2016) Birth Companions Research Project: Experiences and Birth Outcomes of Vulnerable Women, University of Central Lancashire).	Thank you for highlighting the Birth Companions' Impact Report 2017-18 which includes women with a variety of complex social issues. As you note, women can experience a varied range of individual factors in pregnancy and the focus of CG110 is about improving access to antenatal care and improving service organisation for pregnant women with complex social factor. We have considered the references highlighted in your comments: • Birth Companions Research Project: Experiences and Birth Outcomes of Vulnerable Women • Evaluation of birth companion's community link service • Supporting vulnerable pregnant women and new mothers in the community – These reports do not specifically focus on approaches to improving access to antenatal services among pregnant women with complex social factors but they indicate the extent of the

		At Birth Companions we use the term severe, multiple disadvantage to refer to women who face at least three or more 'complex social factors'; many women we support experienced many more. Please refer to Birth Companions' Impact Report 2017-18 for more information about the factors *we* map and how they co-occur for the women that we support. This approach acknowledges the extremely varied individual factors women can experience, which can include those currently referred to in the guidance; further categories suggested by the topic experts in the surveillance proposal consultation document; and others not yet included, such as (but not limited to) safeguarding issues and/or social services involvement (including women who are separated from their babies), vulnerably housed women, women involved in sex work, women affected by the criminal justice system, women who have spent time in care and women who have experienced sexual abuse as children and/or adults. We know that factors not currently identified in the guideline may have recently contributed to maternal deaths. For example, London maternal deaths 2015 review identifies women with social risk factors (including drug and alcohol misuse and mental health) as a high-risk group that requires greater attention, particularly in relation to joint working and information sharing. The report states that 27% of the 26 women who died in 2015 had mental health risk factors and that "five women were identified at booking as high risk due to social factors (already known to social services; previous child on the Child	issue. Importantly, they acknowledge that there is little or no evidence about what works for women with complex needs in the perinatal period 'and particularly for women who are asylum-seekers and refugees, homeless women or those experiencing domestic violence' This matches the findings of the surveillance review and indicates that at the moment, there is insufficient evidence inform updating this guideline in this area. Thank you for highlighting the ongoing research work in this area. We will add the details of these projects to our event tracker and consider the impact of the results on the guideline when available. However, other NICE guidelines provide guidance for supporting women with the social factors you have noted and we will ensure links between the guidelines are added: • NICE's guideline on Antenatal and postnatal mental health (CG192) includes recommendations on identification and management of mental health problems and alcohol misuse in pregnancy. CG192 is listed as a related guideline to CG110. Pregnant women in the criminal justice system are within the scope of NICE's guideline on the Physical health of people in prison (NG57) which includes guidance on referring a woman to a GP and midwife if they think they are pregnant or have a confirmed pregnancy. • CG110 already includes a recommendation for supporting women who experience domestic abuse in accessing maternity services. Note that the definition for domestic abuse that has been included in the full version of the guideline is

		Safeguarding register; domestic violence; temporary housing; homelessness; reluctance to access services as no recourse to funding for care from the woman's perspective; misuse of drugs and alcohol; social isolation)." (London Maternal Deaths A 2015 Review, NHS London Clinical Networks, September 2016). Framing the complex social factors experienced by many women within the paradigm of severe, multiple disadvantage also allows examination of how these factors co-occur and how co-occurrence can amplify the experience of health inequalities and worsen outcomes for women and children. Research done by the LankellyChase Foundation and Agenda identifies how women who experience some factors are more likely to experience others: for example women with experience of severe physical and sexual violence are far more likely to experience physical ill health, and are eight times more likely to be drug dependent than women with little experience of violence and abuse (McNeish, et al (2016) Women and Girls Facing Severe and Multiple Disadvantage, An Interim Report, LlankellyChase Foundation/ DMSS Research/ Heriot-Watt University) and (Scott, S and McManus, S (2016) Hidden Hurt, Violence, Abuse and Disadvantage in the Lives of Women, DMSS Research for Agenda Alliance for Women and Girls at Risk). Furthermore, developing a framework to understand the experiences of women facing severe, multiple disadvantage would also acknowledge intersectionality; that is to say how factors such as race and class may contribute to the	derived from the Home Office definition: 'an incident of threatening behaviour, violence or abuse (psychological, physical, sexual, financial or emotional) between adults who are or have been intimate partners or family members, regardless of gender or sexuality'. In addition, NICE has published a guideline on Domestic violence and abuse (PH50) which aims to help identify, prevent and reduce domestic violence and abuse among women and men in heterosexual or same-sex relationships, and among young people. We are proposing to add a cross-reference from CG110 to PH50 which includes recommendations noting an increased risk of abuse among women who are pregnant.

		inequalities experienced by and poorer perinatal outcomes for this group of mothers and babies. Existing evidence explores the experiences of perinatal women facing severe multiple disadvantage, and how best to address their needs. Two pieces of work examining the impact of specialist, targeted perinatal support models – the Vulnerable Adults and Babies Midwifery Team at the Whittington Hospital in London (Thomson, G and Balaam, M (2016) Birth Companions Research Project: Experiences and Birth Outcomes of Vulnerable Women, University of Central Lancashire) and the work of charity Birth Companions (Clewett, N and Pinfold, V (2015) Evaluation of Birth Companions' Community Link Service, McPin Foundation) – can be accessed here and here. A literature review of evidence on supporting vulnerable mothers and babies in the community, some of which may not yet have been reviewed by the panel, can be accessed here. (Samele, C, Clewett, N, Pinfold, V (2015) Supporting Vulnerable Pregnant Women and New Mothers in the Community, McPin Foundation). More research is currently being undertaken and will be available for review within the next year. Birth Companions is working with charity Revolving Doors on a peer research project in East London Local Maternity System, employing trained researchers with lived experience to understand the experiences of perinatal women facing severe multiple disadvantage and to co-produce practical recommendations mapped against Better Births. This report will be available in September 2018, and a	

		sister project has recently started in North Central Local Maternity System, the outcomes of which will be available in late 2018. Birth Companions is also partnering with Birthrights charity on research looking at the human rights challenges experienced by women facing severe, multiple disadvantage with complex social needs in London.	
Maternity Action	No	The guidance on pregnancy and complex social factors is extremely valuable guidance but is now out of date and poorly used. It requires refreshing to increase take-up. In our experience, there is a low level of awareness about the guidance. The research recommendations in the guidance made in 2010 seem not to have been acted upon –. This has led to the current circumstance in which the review of research reported in the *Surveillance proposal consultation* document found no new evidence of relevant studies and only one relevant piece of ongoing research. Victims of trafficking are not considered in the guidance but experience very complex social factors. As a result of the rise of 'hostile environment' policies, many migrant women face increased barriers to accessing maternity care. Clinicians caring for women affected by 'hostile environment' policies would benefit from up to date guidance.	Thank you for your comments. We are proposing to refresh the guideline to make the links between CG110 and related guidelines in the area much clearer and promote greater awareness of the recommendations. These are detailed in full in the surveillance report. Please note that NICE has also produced an interactive flowchart on pregnancy and complex social factors and any refreshes made to the guideline will also be reflected in the flowchart. We will also amend the flowchart so that it links directly with the antenatal care for uncomplicated pregnancies interactive flowchart. Although we have not identified evidence to address the guideline research recommendations to date, we are aware of an ongoing National Institute for Health Research (NIHR) funded piece of work on Improving maternity care for immigrant women in England. We are tracking the progress of this study and will assess the impact of results on CG110 when available. Thank you for highlighting victims of trafficking as potentially being an omission from the guideline. The groups of women were identified for the scope of CG110 using national maternal and perinatal mortality reports indicating those at

		The guidance was produced in 2010 prior to the new format. Thus it is not incorporated into the interactive flow charts, notably Antenatal and Postnatal Mental Health. This is very important in enabling clinicians and women to find this guidance. In our view there is both enough clinical need and new evidence to warrant a single new review question. A PICO review question might take the form of: would pregnant women with complex social factors benefit from extra mental health care? We think that this is suitable for a single question rapid update process. In CG110 recent migrant mental health is discussed only in relation to social isolation under the head of "Discrimination" but broader issues of anxiety and stress stemming from traumatic personal histories as well as from destitution in the UK are not discussed. These are distinctive mental health issues facing the migrant groups considered in the guidance as well as undocumented migrant women and trafficked women. Amongst other work, studies show that dedicated interventions can help enhance resilience and mental wellbeing in pregnancy of vulnerable migrant women Bick D, Howard LM, Oram S, Zimmerman C (2017) Maternity care for trafficked women: Survivor experiences and clinicians' perspectives in the United Kingdom's National Health Service. PLoS ONE 12(11): e0187856. https://doi.org/10.1371/journal.pone.0187856	increased risk of poor pregnancy outcomes. The most recent Clinical report from 2017 (and the MBRRACE-UK Perinatal Mortality Surveillance Report 2016. do not suggest a significant change in complex social factors that could have an influence on poor birth outcomes for mothers and babies since the guideline was developed. However, the populations described in CG110 are exemplar populations of pregnant women and principles of care can be extrapolated to all women experiencing complex social factors. NICE has produced a guideline on recognising, assessing and treating mental health problems in women who are planning to have a baby, are pregnant, or have had a baby or been pregnant in the past year, Antenatal and postnatal mental health (CG192). Clinical management for pregnant women with complex social factors including mental health issues will be covered by the recommendations in CG192and the studies you have highlighted will be logged and considered when CG192 undergoes surveillance review. We will ensure that cross-references and links are added between CG110 and other relevant NICE guidelines and also links between relevant pathways

		Gagnon AJ, Carnevale F, Mehta P, Rousseau H, Stewart DE (2013) Developing population interventions with migrant women for maternal-child health: a focused ethnography. BMC Public Health. 2013 May 14;13:471. doi: 10.1186/1471-2458-13-471. Neale A, Wand A. (2013) Issues in the evaluation and treatment of anxiety and depression in migrant women in the perinatal period. Australas Psychiatry. 2013 Aug;21(4):379-82. doi: 10.1177/1039856213486215	
National Organisation for Foetal Alcohol Syndrome-UK (NOFAS-UK)	No	Your interactive flow chart and points 1.2.2 on your guidance should specifically note that pregnant women drinking alcohol should be provided with information about the 2016 CMO guidance and also about Foetal Alcohol Spectrum Disorders including links to relevant peer support groups. Your flow chart indicates providing "information about the potential effects of substance misuse on her unborn baby, and what to expect when the baby is born." However, this is not enough – with FASD the full cognitive effects might not be apparent for years, so it is important a woman who drank during pregnancy is given information on what to watch out for as the child ages – emphasising the positive role of early diagnosis and intervention, that people with FASD can lead positive lives with support. Your guidance (1.2.3) and flow charts should make specific reference to the importance of noting in the pregnant woman's file ANY use of alcohol as this	Thank you for highlighting the latest UK Chief Medical Officers' Low Risk Drinking Guidelines published in 2016. As the CMO guidelines adrdess low risk drinking as opposed to alcohol misuse as adressed in CG110, we feel a cross-referral to CMO recommendations is not appropriate. However, the information around drinking in pregnancy will be considered as part of the ongoing update to Antenatal care for uncomplicated pregnancies (CG62). In addition, NICE's guideline on Antenatal and postnatal mental health (CG192) includes recommendations on identification and management of alcohol misuse in pregnancy, Both CG62 and CG192 are noted as related guidelines in CG110.

		could be integral to a later possible diagnosis of a Foetal Alcohol Spectrum Disorder. Guidance (1.2.3) should also indicate that any exposure to alcohol in utero should also be noted in the baby's file to aid a possible diagnosis of a Foetal Alcohol Spectrum Disorder, should concerns arise later as the child ages. 1.2.5 - Training for healthcare staff should include training about FASD to ensure a consistent level of expertise and awareness. Too many are unaware of the full spectrum and give out incorrect information about the presentation of the condition – for example emphasising facial features, which in reality only affect some 10-15% of those on the FASD spectrum and the cognitive impact of the related organic brain damage can be present even if no facial features are present. Commissioners should be urged to make this a priority and Foetal Alcohol Spectrum Disorders should be specifically named. If a woman is drinking in pregnancy, it is important also to review family history. FASD is often present in multiple generations – since it is quite often undiagnosed it is possible that this woman may need extra scaffolding and support and possible diagnosis herself to access support to ensure a healthy pregnancy and may need parenting support.	
Royal College of Obstetricians and Gynaecologists	No	While the RCOG appreciates the evidence base may not have substantively changed, it believes awareness and use of this guidance is low.	Thank you for your feedback. We are proposing to refresh the guideline to make the links between CG110 and related guidelines in the area much clearer and promote awareness. These are detailed in full in

		The guidance was produced in 2010 prior to the new format, and as such it is not incorporated into the interactive flow charts, notably Antenatal and Postnatal Mental Health. This is very important in enabling clinicians and women to find this guidance.	the surveillance report and includes a link to Antenatal and Postnatal Mental Health (CG192). Please note that NICE has also produced an interactive flowchart on pregnancy and complex social factors and any refreshes made to the guideline will also be reflected in the flowchart. We will also amend the flowchart so that it links directly with the flowcharts for antenatal care for uncomplicated pregnancies and for Antenatal and postnatal mental health.
British Pregnancy Advisory Service	No	Complex social factors listed in the guidance are incomplete with several notable exceptions – for instance women in the justice system Separating complex social factors into discrete areas fails to recognise the impact of mixed and multiple disadvantage	Thank you for your comment. The focus of CG110 is about improving access to antenatal care and improving service organisation. The populations listed in CG110 are exemplar populations and principles could be extrapolated to wider populations of women experiencing complex social factors. And as some of these populations are covered by other NICE guidelines, we will refresh and improve cross-references and linkages between CG110 and these other guidelines. Pregnant women in the criminal justice system are within the scope of NICE's guideline on the Physical health of people in prison (NG57) which includes guidance on referring a woman to a GP and midwife if they think they are pregnant or have a confirmed pregnancy.
National Childbirth Trust	No	It is unclear whether the decision not to update the guideline based on 'inadequate quantity and quality of evidence' was taken following a review of the evidence relating to the additional complex social factors identified by the topic experts, or whether only the evidence relating to the existing recommendations was covered. It appears to be the latter, which is why the additional factors are	The surveillance review of this guideline on pregnancy with complex social factors followed standard surveillance processes including feedback from topic experts and other organisations, searching for Cochrane reviews and ongoing research and consulting on the decision with stakeholders. During this process we identified little published evidence suggesting that the recommendations around access to

		mentioned, with signposting to other guidelines. What about the evidence relating to these other areas? As noted by the topic experts, a number of key complex social factors are not covered in guideline CG110. The surveillance review proposal notes that some of these factors are covered in other NICE guidelines. However, these factors impact on pregnant women (and babies) in specific ways, usually with heightened risks, which are unlikely to be covered in sufficient depth within the other guidelines, and should therefore be explicitly addressed within this guideline. For example: - FGM is 'covered' in guideline 76 (Child Abuse & Neglect) – but there is no mention of the consequences of FGM during a woman's pregnancy in this guideline. - With domestic violence, perpetrator's abuse often increases during pregnancy, and it is an opportune moment to intervene. - The impact of long-term mental health problems, in particular a history of severe mental illness, especially trauma, on a pregnant woman, must be clearly separated from 'mild-to-moderate' or first time perinatal mental illness.	maternity services for women with complex social factors need updating. The groups of women were identified for the scope of CG110 using national maternal and perinatal mortality reports indicating those at increased risk of poor pregnancy outcomes. The most recent clinical report from 2017 (and the MBRRACE-UK Perinatal Mortality Surveillance Report 2016. do not suggest a significant change in complex social factors that could have an influence on poor birth outcomes for mothers and babies since the guideline was published. The populations listed in CG110 are exemplar populations and principles could be extrapolated to wider populations of women experiencing complex social factors. And as some of these populations are covered by other NICE guidelines, we will refresh and improve cross-references and linkages between CG110 and these other guidelines. In terms of mental health care in this population, NICE has produced a guideline on recognising, assessing and treating mental health problems in women who are planning to have a baby, are pregnant, or have had a baby or been pregnant in the past year, Antenatal and postnatal mental health (CG192). Clinical management for the population of pregnant women with complex social factors would be covered by the recommendations provided in CG192. We will ensure that there are links between CG110 and CG192 and between the two pathways for the two guidelines. CG110 already includes a recommendation for supporting women who experience domestic abuse in accessing maternity services. Note that the definition for domestic abuse that has been included in the full version of the guideline is derived from the Home Office definition: 'an

			incident of threatening behaviour, violence or abuse (psychological, physical, sexual, financial or emotional) between adults who are or have been intimate partners or family members, regardless of gender or sexuality'. In addition, NICE has published a guideline on Domestic violence and abuse (PH50) which aims to help identify, prevent and reduce domestic violence and abuse among women and men in heterosexual or same-sex relationships, and among young people. We are proposing to add a cross-reference from CG110 to NICE guideline PH50 which includes recommendations noting an increased risk of abuse among women who are pregnant. The full version of the guideline already makes specific reference to forced marriage, female genital mutilation and "honour-based" violence. We don't feel additional content on female genital mutilation is warranted at this time.
Action on Smoking and Health	No	See below	Thank you, please see our response below.
Birthrights	No	1. Birthrights agrees with the topic experts who commented that Guideline CG110 should be expanded to include wider groups of women with social factors in pregnancy. CG110 states that it aims to address the needs of women with 'complex social factors' using the 4 exemplar population groups (under 20s, women experiencing domestic abuse, recent migrants etc, women who have substance abuse issues) but the Guideline makes little reference to women outside those four exemplar groups, and fails to recognise that women may not present with	Thank you for your comment. The groups of women were identified for the scope of CG110 using national maternal and perinatal mortality reports indicating those at increased risk of poor pregnancy outcomes. The most recent clinical report from 2017 (and the MBRRACE-UK Perinatal Mortality Surveillance Report 2016. do not suggest a significant change in complex social factors that could have an influence on poor birth outcomes for mothers and babies since the guideline was developed. As you note, the populations listed in CG110 are intended to be exemplar populations and principles can be extrapolated to wider populations of women experiencing complex social

		simple siloed needs. doesn't actually address much beyond the needs of CG110 explicitly states *"Having undertaken the systematic reviewing that underpins the guideline using the four exemplar populations (substance misusers; recent migrants, refugees, asylum seekers or women with little or no English; young women aged under 20; and women experiencing domestic abuse) the GDG looked for general common themes that could be applied to all vulnerable women with complex social problems in pregnancy. It is acknowledged that there are limitations to this approach. For example, some women would fall into more than one of the categories chosen whilst other socially disadvantaged women would not be represented specifically. It was hoped that by focussing on four different groups and then identifying general themes, generic guidance would be produced that would inform care provision for vulnerable women who face a range of complex social issues in pregnancy." (s3.1, p39).* This is a laudable aim, and we note that the General Recommendations on service organisation (data collection), staff training, care information and support do include some basic guidelines focussed on delivering personalised and respectful care. However, the majority of the recommendations are focussed tightly on women who fall into the four exemplar populations. This is made particularly explicit within the interactive flowchart, which shows that these groups of women are addressed as having separate, siloed needs, based on the exemplar social factors. The Guidance then fails to address specific care needs for women with other complex social	factors. And as some of these populations are covered by other NICE guidelines, we will refresh and improve cross-references and linkages between CG110 and these other guidelines. Uptake of services and providing information and support for all pregnant women will be addressed by the NICE guideline on Antenatal care for uncomplicated pregnancies (CG62). The guideline is currently being updated and after it is published, we will undertake another surveillance review of CG110. We will ensure that there are links between CG110 and CG62 and between the two pathways for the two guidelines. We have considered the individual gaps in population that you highlight in your comment: • Pregnant women in the criminal justice system are within the scope of NICE's guideline on the Physical health of people in prison (NG57) which includes guidance on referring a woman to a GP and midwife if they think they are pregnant or have a confirmed pregnancy. • CG110 already includes a recommendation for supporting women who experience domestic abuse in accessing maternity services. Note that the definition for domestic abuse that has been included in the full version of the guideline is derived from the Home Office definition: 'an incident of threatening behaviour, violence or abuse (psychological, physical, sexual, financial or emotional) between adults who are or have been intimate partners or family members, regardless of gender or sexuality'. In addition, the NICE guideline on Domestic violence and abuse (PH50) aims to help identify, prevent and reduce

		factors who do not fall into those four exemplar populations. This is also evident in the evidence tables (annex E) of the guideline and the 2012 evidence update, as well as in some of the research recommendations in the guideline. For example, on models of service provision the recommendation is to investigate *"what models of service provision exist in the UK for the four populations addressed in this guideline who experience socially complex pregnancies (women who misuse substances, women who are recent migrants, asylum seekers or refugees or who have difficulty reading or speaking English, young women aged under 20, and women who experience domestic abuse)? How do these models compare, both with each other and with standard care, in terms of outcomes?"* (p46). There is no broader view of models of service provision for women with needs outside those exemplar populations. Thus the use of these populations acts as limitations on the usefulness of the Guideline for care of women facing other or multiple complex needs. Birthrights calls for the Guideline to be reviewed with a specific focus on the needs of women who fall outside the four exemplar populations, including women who face multiple complex needs. Research shows that women with multiple complex needs are less likely to access maternity care/receive less of it, have poorer maternal and infant outcomes, and are more likely to experience perinatal mental health problems (Thomson, G. and Balaam, M.-C. (2016) *Birth Companions Research Project: Experiences and Birth Outcomes of Vulnerable Women*.). Poor quality	domestic violence and abuse among women and men in heterosexual or same-sex relationships, and among young people. We are proposing to add a cross-reference from CG110 to NICE guideline PH50 which includes recommendations noting an increased risk of abuse among women who are pregnant. • NICE's guideline on Antenatal and postnatal mental health (CG192) includes recommendations on iderntification and management of mental health problems and alcohol misuse in pregnancy. CG192 is already listed as a related guideline in CG110. • In terms of learning disabilities, NICE has developed a guideline on Learning disabilities and behaviour that challenges (NG93) that covers services for children, young people and adults with a learning disability. We will add your comments to the issues logs for all these related guidelines so they can be considered further in the context of the relevant areas. Thank you for highlighting references related to the guideline, we have considered these in turn: • Thomson, G. and Balaam, M.-C. (2016) *Birth Companions Research Project: Experiences and Birth Outcomes of Vulnerable Women*. • Samele, C., Clewett, N. and Pinfold, V. 2015. *Birth companions commissioned literature review: Supporting vulnerable pregnant women and new mothers in the community*. – Although these reports draw attention to vulnerable women's experiences of maternity care

		or disrespectful care is associated with trauma and post-traumatic stress disorder (REED, R., SHARMAN, R. & INGLIS, C. 2017. Women's descriptions of childbirth trauma relating to care provider actions and interactions. *BMC Pregnancy and Childbirth*, 17, 21.; HARRIS, R. & AYERS, S. 2012. What makes labour and birth traumatic? A survey of intrapartum 'hotspots'. *Psychology & Health*, 27, 1166-1177.); this is particularly acute for women with a history of maltreatment (Seng, J. (2015) 'How does traumatic stress affect pregnancy and birth?', in Seng, J. and Taylor, J. (eds.) *Trauma informed care in the Perinatal period*. United Kingdom: Dunedin Academic Press, pp. 57–73.). The 2015 London Review of Maternal Deaths found that women with complex social needs were over-represented in maternal deaths and "present a real challenge for professionals". It also noted that physical and psychological needs often co-present, requiring a "co-ordinated and robust care management approach" (NHS London Clinical Networks. 2016. London maternal deaths A 2015 review). A revision of the Guideline should consider a PICO review taking into account recent evidence reviewing models of service provision, and maternity care needs, of women facing multiple complex needs and/or severe disadvantage. The category of complex social needs should be broadened to include women with a history of safeguarding issues (for themselves e.g. care leavers or within their family), women with learning disabilities; women with current or historic experience of sexual violence, women with current or historic involvement in sex work, women	they don't provide evidence of effective mechanisms for increasing access to antenatal. • REED, R., SHARMAN, R. & INGLIS, C. 2017. Women's descriptions of childbirth trauma relating to care provider actions and interactions. *BMC Pregnancy and Childbirth*, 17, 21.; • HARRIS, R. & AYERS, S. 2012. What makes labour and birth traumatic? A survey of intrapartum 'hotspots'. *Psychology & Health*, 27, 1166-1177 – These reports focus on intrapartum care which is outside the scope of the guideline. • NHS London Clinical Networks. 2016. London maternal deaths A 2015 review. – Thank you for highlighting this report as it supports the importance of NICE guideline CG110 to improve access to antenatal services among women with complex social factors. • Bick D et al. 2017 Maternity care for trafficked women: Survivor experiences and clinicians' perspectives in the United Kingdom's National Health Service. PLoS ONE 12(11): e0187856. – The results of this qualitative study indicate that one in four women become pregnant while trafficked. However, the study does not suggest any additional influence of trafficking on poor birth outcomes for mothers and babies. Neither does it focus on factors that might improve access to antenatal services among this group.

		with current or historic involvement with the criminal justice system (including imprisonment). Within the category of asylum seekers and refugees, there should be recognition of women with current or historic experience of detention, and women who have been trafficked and/or are victims of modern slavery. In the period since the last evidence review, a number of new studies have been published which have explicitly reviewed models of service provision and the needs of women facing severe and multiple disadvantage. These include evidence on specific interventions which increase the likelihood of women receiving dignified and respectful care, and facilitating choice, as well as addressing issues included in the current CG110 such as access to care, information provision, tailored advice and ongoing referral to other services. For example, MALOUF, R., MCLEISH, J., RYAN, S., GRAY, R. & REDSHAW, M. 2017. 'We both just wanted to be normal parents': a qualitative study of the experience of maternity care for women with learning disability. *BMJ Open*, 7; MCLEISH, J. & REDSHAW, M. Maternity experiences of mothers with multiple disadvantages in England: A qualitative study. *Women and Birth*. [in press]; Thomson, G. and Balaam, M.-C. (2016) *Birth Companions Research Project: Experiences and Birth Outcomes of Vulnerable Women*.; research on inclusion health (see LUCHENSKI, S., et al. 2018. What works in inclusion health: overview of effective interventions for marginalised and excluded populations. *The Lancet* for overview). Further	• MALOUF, R., MCLEISH, J., RYAN, S., GRAY, R. & REDSHAW, M. 2017. 'We both just wanted to be normal parents': a qualitative study of the experience of maternity care for women with learning disability. *BMJ Open*, 7; MCLEISH, J. & REDSHAW, M. Maternity experiences of mothers with multiple disadvantages in England: A qualitative study. *Women and Birth*. [in press]; – This study explored the lived experiences of pregnancy, childbirth, prenatal and postnatal care and services received by women with learning disabilities in the UK. However, we feel this population is covered within the scope of the NICE guideline Learning disabilities and behaviour that challenges: service design and delivery (NG93). We will add this study to the issues log for NG93 so it can be considered fully when this guideline undergoes surveillance. Finally, we note that you are carrying out research on the issues experienced by women face in accessing maternity care. We would be interested in tracking the progress of this work and considering the impact of the results on the guideline when available. Please send any details of this research to surveillance@nice.org.uk.

		references can be found in Samele, C., Clewett, N. and Pinfold, V. 2015. *Birth companions commissioned literature review: Supporting vulnerable pregnant women and new mothers in the community.* The review needs to explicitly consider the cross-cutting support needs of women facing severe and multiple disadvantage and the role of continuity of carer and specialist services in ensuring that women's holistic needs are met (Thomson, G. and Balaam, M.-C. (2016) *Birth Companions Research Project: Experiences and Birth Outcomes of Vulnerable Women.*; Hestia 2018. Underground Lives Pregnancy and Modern Slavery, London.). Birthrights and Birth Companions are currently carrying out research on the rights-issues experienced by women facing severe and multiple disadvantage accessing maternity care, recognising the ongoing evidence needs in this area. This research is due to complete by the end of the year and we would be happy to share the findings with NICE and the Guideline Committee. 2. The needs of women with no recourse to public funds need to be better addressed within the Guideline, in line with recent policy changes on charging and eligibility for NHS care. Whilst the Guideline reflects that women may not make full use of antenatal services because of unfamiliarity with the health service or communication issues, it fails to mention that women may also have legitimate concerns about NHS charging. This may be the case whether or not they are themselves chargeable, given immigration status is often not static, women (whether or not they are chargeable) may not have	

		suitable proof of their status, lack of knowledge that maternity care is considered immediately necessary (and thus not eligible for upfront charging) and fears about impacts of receiving high bills on future immigration decisions. See, for more detail, the work of Maternity Action. Whilst the Guideline sets out the need for training of healthcare staff on up-to-date access and entitlement policy, there is no recognition of the need to ensure that HCPs and overseas officers are fully ready and able to engage sensitively and appropriately with pregnant women, ensuring that they are aware that their care cannot be withheld because of a lack of ability to pay, likely charges and that chargeable care is charged at 150% tariff, and that they are entitled to agree a realistic repayment plan based on their income and expenditure. Meeting this need requires action in relation to training (1.3.6), but also uptake of antenatal care (1.3.1), service organisation (1.3.5) and information provision (1.3.7). Evidence on some of the practical and knowledge issues faced by clinicians (as well as needs and access barriers for women) can be found in Bick D et al. 2017 Maternity care for trafficked women: Survivor experiences and clinicians' perspectives in the United Kingdom's National Health Service. PLoS ONE 12(11): e0187856. 3. Birthrights notes the urgent need for further evidence on the needs and optimum models of care for women with multiple complex needs – not limited to the four exemplar groups currently highlighted – and calls for the NICE research	

		recommendations to be reviewed and further promoted within funding streams. For example, the research recommendation on models of service provision is important and, if taken forward, offers a very positive opportunity to build on best practice and ensure that services are appropriately resourced, and reach the women that they are aimed at / evaluate any issues around equality of (appropriate) access. Birthrights notes that the REACH programme has been highlighted as having potential impact on recommendations, but there are likely to be other evaluations of practice models. For example, Thomson, G. and Balaam, M.-C. (2016) *Birth Companions Research Project: Experiences and Birth Outcomes of Vulnerable Women* (previously referenced) work for Birth Companions included an assessment of the impact of the specialist team at the Whittington hospital which provides care for a subset of the local women with multiple and complex needs including both women's experience of maternity care itself, outcomes and engagement with other services.	
The Birmingham City University	Yes	Though several of the elements are pretty vague in the guidance probably due to lack of evidence.	Thank you for your response.

Do you have any comments on areas excluded from the scope of the guideline?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
The Survivors Trust	Yes	In excluding consideration of women and girls affected by childhood sexual abuse of any form, the	Thank you for your comments. The population included within the scope of CG110 is pregnant women who do not access or maintain regular

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 recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

		Guideline fails to address the needs of both the patient and also staff training and support needs. The Independent Inquiry into Child Sexual Abuse published a research paper drawing together current research on the lifelong impact that sexual abuse can have on the victim/survivor's health and wellbeing The impact of child sexual abuse: A rapid evidence assessment The Report highlighted the impact of sexual abuse on health, including sexual health and access to services. It was noted that "pregnancy and perinatal period is a particularly vulnerable time for female childhood sexual abuse victims and survivors, with the risk of having traumatic experiences triggered and experiencing post-natal depression and other mental health problems." Medical examinations and childbirth itself are highlighted as trigger points with potential to trigger dissociation and 'shutting down' as a means of coping. The Report also notes that some victims/survivors choose to remain childless as a result of their experiences. It is most concerning that the failure to include childhood sexual abuse as a specific area in the guidance means that specific staff training and supervision are also not highlighted in the guidance. Staff training in responding to victims/survivors is essential. It is well recognised that any worker who is exposed to traumatic material can be at risk of	contact with antenatal maternity services. CG110 includes a recommendation for supporting women who experience domestic abuse in accessing maternity services. Note that the definition for domestic abuse that has been included in the full version of the guideline is derived from the Home Office definition: 'an incident of threatening behaviour, violence or abuse (psychological, physical, sexual, financial or emotional) between adults who are or have been intimate partners or family members, regardless of gender or sexuality'. In addition, NICE has published a guideline on Domestic violence and abuse (PH50) which aims to help identify, prevent and reduce domestic violence and abuse among women and men in heterosexual or same-sex relationships, and among young people. We are proposing to add a cross-reference from CG110 to NICE guideline PH50 which includes recommendations noting an increased risk of abuse among women who are pregnant. In addition, we will ensure linkages between the relevant NICE pathways. Uptake of services and providing information and support for all pregnant women will be addressed by the NICE guideline Antenatal care for uncomplicated pregnancies (CG62), The guideline specifies that care should allow women to discuss sensitive issues including sexual abuse. The guideline is currently being updated and after it is published, we will undertake another surveillance review of CG110. In the interim, we will ensure that there are links between CG110 and CG62 and between the relevant pathways for the two guidelines. Additionally, the NICE guideline on Child abuse and neglect (NG76) covers recognising and responding to abuse (including sexual abuse) and neglect in children and young

		developing vicarious trauma, with an impact on their own mental and physical health. The Wales Government recently issued guidance through its Live Fear Free Programme: Live Fear Free Wales Government Guidance Vicarious Trauma Whilst sensitive practice will be at the heart of service provision for pregnant women, it cannot be assumed that staff will have the knowledge and understanding of working with trauma to manage both their patient's responses and their own reactions. In a context where more and more women are feeling empowered to disclose they have experienced childhood sexual abuse, and this may be prompted by examinations and discussions around pregnancy, it is a failure of the guidance to ensure that staff are trained and supported to work in a trauma-informed way.	people aged under 18. We will add your comments to the issues log for this guideline so they can be considered fully in the surveillance review of NG76.
NICE Quality & Leadership team	No	There are no placeholder statements to suggest that additional areas should be included in the scope of the guideline.	Thank you for your response.
Cardiff and Vale University Health Board	No	The scope is considered to be appropriate.	Thank you for your response.
Birth Companions	Yes	As well as acknowledging the issues described above that fall outside the scope of the current guideline we would like to suggest	Thank you for your comment. Trauma occurring in the perinatal period is more relevant to NICE's guideline on Post-traumatic stress disorder (CG26,

		2.1) An examination of how women's experiences of trauma impact on their experiences of care during the perinatal period, and of how a trauma-informed approach to maternity care could address these issues The perinatal period provides a golden opportunity to triage, engage and work with vulnerable women to improve their lives and outcomes for their children. Maternal health services are unique in that many vulnerable women who present might not engage with, or may mistrust other services. However, pregnancy is often a point at which women with complex needs most want to make changes and accept offers of help. If care is developed with vulnerability and trauma in mind, the knock-on effect will be that the pathway experience will be greatly improved for all services users. It is also important to acknowledge that women can be considered vulnerable for reasons beyond those highlighted above and that pregnancy and childbirth in themselves are recognised as having the potential to trigger trauma in those who would normally be excluded from conventional vulnerability criteria. For example, the 11% of women who are survivors of childhood sexual abuse (not all of whom would fall into the multiple/complex needs cohort), those experiencing perinatal mental ill-health and those who have experienced previous miscarriage, stillbirth, traumatic births or birth related complications. Reshaping service pathways that take into account the need of the most vulnerable will also result in	currently being updated) which considers traumatic events to be wide ranging (for example, assaults, rape, road traffic accidents and childhood sexual abuse and traumatic childbirth). We will add CG26 to the list of related guidelines in CG110. We will also add the details of your comment to the issues log for CG26. In relation to abuse, CG110 already includes a recommendation for supporting women who experience domestic abuse in accessing maternity services. Note that the definition for domestic abuse that has been included in the full version of the guideline is derived from the Home Office definition: 'an incident of threatening behaviour, violence or abuse (psychological, physical, sexual, financial or emotional) between adults who are or have been intimate partners or family members, regardless of gender or sexuality'. In addition, the NICE guideline on Domestic violence and abuse (PH50) aims to help identify, prevent and reduce domestic violence and abuse among women and men in heterosexual or same-sex relationships, and among young people. We are proposing to add a cross-reference from CG110 to NICE guideline PH50 which includes recommendations noting an increased risk of abuse among women who are pregnant. The NICE guideline on Child abuse and neglect (NG76) covers recognising and responding to abuse (including sexual abuse) and neglect in children and young people aged under 18. We will add your comments to the issues log for this guideline so they can be considered fully in the surveillance review of NG76. Pregnant women in the criminal justice system are within the scope of NICE's guideline on the Physical health of people in prison (NG57) which includes guidance on referring a woman

		services that are safer and more accessible to all pregnant women. Agenda Alliance for Women and Girls at Risk recommends that all services coming into contact with women who have experienced abuse should be able to manage and respond to their needs. They state that services should "understand the impacts of violence and abuse on women's lives and be offering support around these issues. 'Routine enquiry' (asking women and girls whether they have experienced violence and abuse) should become standard practice across a range of health and support services and be accompanied by proper support for those who disclose past or present experiences of abuse". (McManus, S, Scott, S and Sosenko, F (2016) Joining the dots: The combined burden of violence, abuse and poverty in the lives of women, Agenda Alliance for Women and Girls at Risk). 'Trauma-informed care' is an approach to understanding and meeting the needs of people who have experienced trauma that now informs many UK statutory and voluntary sector services including mental healthcare, drug and alcohol services and the prison system for women, but has yet to gain traction in maternity services. We would advocate an exploration of how trauma-informed maternity services could meet both the needs of perinatal women who have disclosed experiences of trauma through trauma-specific services and the needs of those who do not disclose through a universal trauma-informed approach.	to a GP and midwife if they think they are pregnant or have a confirmed pregnancy. We will add the reference you highlight to the issues log for this guideline. The main focus of CG110 is on improving access to antenatal care and improving service organisation, therefore separation of children from mothers is outside the scope and more relevant to NICE's guideline on Looked after children (PH28). An update of this guideline is planned so we will pass your feedback to the developers for consideration in the scoping of this update, particularly around social services involvement during the perinatal period with a focus on reducing repeated separations of babies from mothers. Finally, thank you for highlighting the Pause project. It aims to reduce the number of children being removed into care which is not directly related to recommendations in CG110 which focuses on improving access to antenatal care and improving service organisation. Therefore, no impact on CG110 is expected.

		Trauma-informed care in the perinatal period is a study that looks at the evidence base in relation to the impact of trauma in experiences and outcomes of mothers and babies, and at both aspects of care in the UK and overseas. One Small Thing is a charity that has led a training programme to roll out trauma-informed care across the women's prison estate. Emerging findings from Birth Companions/Revolving Doors' peer research project in the East London Local Maternity System suggests that trauma is a major theme and this research will be available in September 2018. Birth Companions has worked with perinatal women affected by the criminal justice system in England and Wales for the last 22 years, providing frontline services in prisons and the community, and on improving the care women experience across the country. We suggest that this guideline provide 2.2) A specific section on women affected by the criminal justice sector (women in custody and the community) There is a wealth of recently and soon to be published research on the experiences of perinatal women in the prison system that advocate for improvements in the care this group receives from a range of stakeholders including healthcare professionals. These include (Kennedy, A et al (2016) Birth Charter for Women in Prison in England and Wales, Birth Companions), (Public Health England (2018) Gender Specific Standards to Improve Health and Well-being for Women in Prison in England) and	

		(Cuthbert, C et al (2015) All Babies Count – Spotlight on the Criminal Justice System – An Unfair Sentence, NSPCC/ Barnardo's). The Royal College of Midwives and Birth Companions recently made a submission to the Parliamentary Health and Social Care Committee's review of healthcare in prison. Soon to be published is Laura Abbott's 2018 doctoral thesis 'The Incarcerated Pregnancy: An Ethnographic Study of Perinatal Women in English Prisons' which will be licensed to the University of Hertfordshire Research Archive. We believe that a section on women affected by the criminal justice sector should sit within guideline CG110 on pregnant women with complex social factors because the needs of this group of women, particularly in the community, are best seen in the wider context of severe, multiple disadvantage. However, because of the distinct and singular nature of some of women's experiences within the criminal justice sector we believe this warrants recommendations on improving access to care for this specific group. We would like to suggest the guidance contains 2.3) A specific section on women referred to maternity services because of safeguarding or child protection concerns/ with social services involvement during the perinatal period/ experiencing separation from their babies/ who have experienced repeated separations from their babies	

		The number of women coming into contact with maternity services who fulfil the criteria above is unknown. To give some sense of the scale however, in one 2016 study of women giving birth over a year one London hospital there were 315 referrals of women for safeguarding/child protection concerns out of a total population of women giving birth of 3,511 – this amounts to 8.9% of the population (Thomson, G and Balaam, M (2016) Birth Companions Research Project: Experiences and Birth Outcomes of Vulnerable Women, University of Central Lancashire). There are strong arguments that early intervention with some vulnerable mothers during pregnancy can be helpful in addressing problems before they develop further, and thus improving outcomes for families. The study above identified positive outcomes for the small number of women from this group who were able to access targeted support (either from specialist midwives or a charity or both) but this was a small proportion (7.6% of the vulnerable women). Some women do go on to experience separation from their children, and an increasing number experience repeated removals. A recent influential study found that between 2007 and 2014 over 11,000 mothers had more than one child removed (Broadhurst, K et al (2017), Vulnerable Birth Mothers and Recurrent Care Proceedings, Lancashire University /Centre for Child and Family Justice Research). This study makes the case that services, including maternity services, have their part to play in understanding the complex reasons that contribute	

		to repeated removals, supporting women through these experiences and ultimately to breaking the negative cycle. For example, it reports that women "consistently described an acute phase of grief following child removal, which greatly exacerbated their difficulties. Descriptions of mental health difficulties indicated concerning and enduring levels of mental distress for many women. Complicated and persistent grief responses need to be understood as difficult to resolve and require skilled and well-resourced professional help". Emerging findings from Birth Companions/Revolving Doors peer research project in East London Local Maternity System (to be published in September 2018) suggest that fear of social services involvement is a major barrier to engagement with maternity services. Moreover, women interviewed who had social services involvement describe poor experiences of maternity services such as a lack of confidentiality and lack of support post-separation. Birth Companions' experience of supporting women in the situations above is that there are many practical steps that care-givers can take to ensure that women going have the best experiences possible given the circumstances, and recommendations in this area will be included in the final report. In addition Birth Companions/Birthrights' investigation of the human rights challenges faced by women experiencing severe, multiple disadvantage will also examine the intersection of maternity and social services during the perinatal period, and if	

		appropriate make rights-based recommendations in this area. Broadhurst, K et al's study also identifies the very high proportion of unplanned pregnancies and advocate that "new preventative projects and mainstream services need to engage closely with the particular reasons why women may be vulnerable to unplanned pregnancy if they are to enhance women's capacity to make better use of reproductive health services". For example, for some women it may be appropriate to refer them to programmes that enable them to examine and address some of the factors that contribute to their situation. The Pause Project is a national programme that works in this way. Many of the needs of the women described above would helpfully be understood within the framework of severe, multiple disadvantage described above, but because of the specific nature of their experiences we believe it is also appropriate to have a separate section outlining best practice in this area within guideline CG110.	
Maternity Action	No	No comment provided	Thank you.
National Organisation for Foetal Alcohol Syndrome-UK (NOFAS-UK)	Yes	NICE should prepare a separate guidance on alcohol, pregnancy and FASD, to bring the UK in line with international best practices and to take advantage of some of the work being done in the UK where there are pockets of excellence. The BMA "Alcohol and Pregnancy" publication (2007/2016) provides some details about how this	Thank you for your suggestion to develop a separate guidance on alcohol, pregnancy and Fetal Alcohol Spectrum Disorders (FASD). The NICE Centre for Guidelines receives a work programme from the Department of Health and Social Care which focuses on the need for guidelines in priority areas. We will pass your feedback onto the relevant group for consideration.

		might be shaped. Stakeholders are ready to engage in this process. Please see, "Hear Our Voices: FASD Stakeholders Share Their Experiences With Policy Makers" – a new report by the FASD UK Alliance, prepared by NOFAS-UK. While this is anecdotal, it demonstrates the huge discrepancies that exist in FASD diagnosis and support across the country. The government has clearly emphasised the important of early intervention for FASD and placed responsibility on the CCGs to deliver relevant services. See for example Lord O'Shaughnessy's reply, "Early intervention services can help reduce some of the effects of Fetal Alcohol Spectrum Disorders (FASD) and prevent some of the secondary disabilities that result. Responsibility for commissioning these services lies with clinical commissioning groups." (This has been repeated multiple times in other more recent written questions): https://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Lords/2017-01-27/HL5052/) However, the provision is patchy at best and in some places non-existent. Due to the significant under-training in this area, there is a need for NICE to work with stakeholders and experts to understand best practices that exist across the UK and to establish guidelines to help CCGs fulfil their role. See for example: Our Forgotten Children: The Urgency of Aligning Policy with Guidance on the Effects of Antenatal Exposure to Alcohol (PDF), a report from a roundtable discussion with FASD stakeholders, co-	Thank you for highlighting the latest UK Chief Medical Officers' Low Risk Drinking Guidelines published in 2016. As the CMOguidelines adrdess low risk drinking as opposed to alcohol misuse as adressed in CG110, we feel a cross-referral to CMO recommendations is not appropriate. However, the information around drinking in pregnancy will be considered as part of the ongoing update to Antenatal care for uncomplicated pregnancies (CG62). In addition, the NICE guideline on Antenatal and postnatal mental health (CG192) includes recommendations on identification and management of alcohol misuse in pregnancy. Both CG62 and CG192 are listed as related guidelines to CG110.

		chaired by Professor Sheila the Baroness Hollins and Mr Bill Esterson, MP in the Houses of Parliament on 23 May 2018. NOFAS-UK stands ready to assist in these discussions. The 2016 CMO guidance on alcohol and pregnancy should be on display in every doctor's surgery and the information about this guidance should be brought up to date on all NHS electronic systems without delay (NICE has been very slow to update its own website). Your guidance should note elsewhere that ALL pregnant women and women of child bearing years should be given information about the risks of alcohol in pregnancy as a routine matter.	
Royal College of Obstetricians and Gynaecologists	Yes	Page 2 of 6 provides the views of topic experts. The experts recommended that CG110 could be expanded to include wider groups of women with social factors in pregnancy. Whilst the RCOG appreciates NICE has published other guidance that covers some of these areas, it would be helpful to explain why those that are not covered elsewhere will not be addressed. For example, victims of trafficking are not considered in this guidance nor any other but experience very complex social factors.	Thank you for highlighting victims of trafficking as potentially being an omission from the guideline. The groups of women were identified for the scope of CG110 using national maternal and perinatal mortality reports indicating those at increased risk of poor pregnancy outcomes. The most recent clinical report from 2017 (and the MBRRACE-UK Perinatal Mortality Surveillance Report 2016. do not suggest a significant change in complex social factors that could have an influence on poor birth outcomes for mothers and babies since the guideline was developed. However, the populations described in CG110 are exemplar populations of pregnant women and principles of care can be extrapolated to all women experiencing complex social factors.
British Pregnancy Advisory Service	Yes	Women in the justice system (in prison, on probation, and on remand) should be included in the guidance.	Thank you for your comment. The focus of CG110 is about improving access to antenatal care and improving service organisation. Pregnant women in the criminal justice system

		There are around 600 pregnant women in prison every year, compared to an overall figure of female prisoners of 4,035 in November 2017 (L Abbott, Becoming a Mother in Prison, The Practising Midwife, October 2016, vol.19, issue 9). Women in prison are disproportionately likely to suffer from other forms of disadvantage, notably ('Women in Prison' research figures): • 46% of women in prison report having suffered domestic abuse • 53% of women in prison report having experienced emotional, physical, or sexual abuse during childhood • 31% of women in prison have spent time in local authority care as a child • 46% of women in prison report having attempted suicide at some point in their lives (7 times higher than the general population) • At least 20% of women prisoners are lone parents before imprisonment, compared to 9% of the general population • Only 9% of children whose mothers are in prison are cared for by their fathers in their mother's absence • Foreign nationals make up 11% of the women's prison population. Women are also disproportionately likely to serve short sentences – 70% of sentenced women entering prison in 2016 were serving 6 months or less. This	are within the scope of NICE's guideline on the Physical health of people in prison (NG57) which includes guidance on referring a woman to a GP and midwife if they think they are pregnant or have a confirmed pregnancy. We will add your comments to the issues log for NG57 so they can be considered fully when this guideline undergoes surveillance.

		makes it likely that women who are pregnant in prison will also experience pregnancy and/or birth in the community. Women face significant obstacles to accessing services on release. Given that the majority of women do not have fixed place of residence, registering with a GP can prove extremely difficult, and is often low-priority when compared with more immediate issues such as re-establishing relationships with children and securing financial support. (Prison Reform Trust, Home truths: housing for women in the criminal justice system, Sept 2016) Women in prison are therefore experiencing pregnancy in a situation of mixed, multiple, and complex needs and disadvantage – with the particular complication that they may not be able to access treatment when and where they choose because of constraints on their movement or behaviour. A period of incarceration provides a vital opportunity to address women's healthcare needs during pregnancy – but specific guidelines are needed for adequate practice to effectively treat women in these circumstances. These NICE guidelines should seek to address clinical guidance for these vulnerable women.	
National Childbirth Trust	No response provided	See above	Thank you, please see the response to your comment above.

Action on Smoking and Health	Yes	The Government has set itself an ambitious target of reducing the smoking in pregnancy rate to less than 6% by 2022. New evidence from the Smoking in Pregnancy Challenge group suggests that achieving this objective would mean that around 30,000 fewer women would be smoking in pregnancy. In turn, this would lead to: • 45 – 73 fewer babies stillborn • 11 – 25 fewer neonatal deaths • 7 – 11 fewer sudden infant deaths • 482 – 796 fewer preterm babies and • 1455 – 2407 fewer babies born at a low birth weight. Achieving this will require a concerted effort to support women in disadvantaged situations where smoking rates are high to quit. Many of these groups are identified in this guideline. For example, young women and/or women who experience poverty, homelessness or substance misuse have higher smoking prevalence than the rest of the population. As a result, the health outcomes for both these women and their babies are worse than for the general population. Unfortunately, even though this guideline exists precisely to support pregnant women in complex situations, no reference is made to smoking cessation support. For example, young women are more likely to smoke throughout pregnancy and are less likely to	Thank you for your comment. The focus of CG110 is about improving access to antenatal care and improving service organisation. The NICE guidelines Antenatal care for uncomplicated pregnancies (CG62) and Stopping smoking in pregnancy and after childbirth (PH26) both include recommendations on identifying women who smoke during pregnancy and interventions to help them stop. These guidelines are listed as a guideline related to CG110.

		quit during their pregnancy, bringing increased risk of adverse outcomes. Yet the section on 'Young pregnant women aged under 20' makes no reference to supporting women who smoke to quit. This is despite the fact that the guidance covers women who experience, for example, alcohol misuse. The highest rates of smoking are consistently found among those who are most disadvantaged. Moreover, people in these groups tend to display a higher level of addiction, making it harder for them to quit, and meaning they need more support to quit. For example, approximately 40% of people with a mental health condition smoke, suggesting this group has not benefitted from the suite of tobacco control measures which have resulted in a decline in smoking rates across the general population. Similarly, in 2013, 73% of the single homeless clients supported by St Mungo's in London smoked. It is therefore essential that healthcare professionals have the ability to help pregnant women in complex situations to quit smoking, and avoid the resulting physical health problems associated with high smoking prevalence. ASH therefore believes the guidance should be updated to reflect: 1. New evidence from the Smoking in Pregnancy Challenge Group that demonstrates the success of incentive schemes in supporting women from disadvantaged backgrounds to successfully quit smoking.	

		2. Evidence from the Smoking in Pregnancy Challenge Group (endorsed by the Royal Society for Public Health, the Royal College of Paediatricians and Child Health and the Royal College of Obstetricians and Gynaecologists) illustrating the benefits of alternative sources of nicotine to support pregnant women in their quit attempts, since health professionals and women often hold misconceptions about using Nicotine Replacement Therapy and e-cigarettes. Failure to update this guideline would constitute a missed opportunity to tackle smoking prevalence in these groups. The guidance explicitly highlights the need to offer women information about services they can access to help them throughout their pregnancy, but without including smoking cessation support as part of this, entrenched intergenerational health inequalities are not being adequately challenged. [1] Tobacco Control Plan for England: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/630217/Towards_a_Smoke_free_Generation_-_A_Tobacco_Control_Plan_for_England_2017-2022__2_.pdf [1] Smoking in Pregnancy Challenge Group, Review of the challenge, 2018: http://smokefreeaction.org.uk/download/1071/ [1] Szatkowsk Li & McNeill A. Diverging trends in smoking behaviours according to mental health	

		status. Nicotine & Tobacco Research 2015; 3: 356-60. [1] St Mungo's Client Needs Survey 2013 (personal communication) [1] Smoking in Pregnancy Challenge Group, Review of the challenge, 2018: http://smokefreeaction.org.uk/download/1071/ [1] Smoking in Pregnancy Challenge Group, Use of electronic cigarettes in pregnancy: http://smokefreeaction.org.uk/wp-content/uploads/2017/06/eCigSIP.pdf	
Birthrights	Yes	See comment (1) above.	See our response to your comment above.
The Birmingham City University	No response provided	There perhaps needs to be some reference to the new data protection act and the need for sharing information in cases of potential harm.	Thank you for your comment. The focus of CG110 is about improving access to antenatal care and improving service organisation. The GDPR is an important new act that in effect applies across all situations and is not specific to the guideline on pregnancies with complex social factors; it is expected that all healthcare professionals across all situation will act on the recommendations of the GDPR
Do you have any comments on equalities issues?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
The Survivors Trust	No response provided	No comment provided	Thank you.
NICE Quality & Leadership team	No	No comment provided	Thank you.

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Cardiff and Vale University Health Board	No	No comment provided	Thank you.
Birth Companions	No	No comment provided	Thank you.
Maternity Action	No	No comment provided	Thank you.
National Organisation for Foetal Alcohol Syndrome-UK (NOFAS-UK)	No	No comment provided	Thank you.
Royal College of Obstetricians and Gynaecologists	Yes	Some of the excluded groups will be at considerable social disadvantage, so should be included in any update of this guideline.	Thank you for your comment. Thank you for highlighting victims of trafficking as potentially being an omission from the guideline. The groups of women were identified for the scope of CG110 using national maternal and perinatal mortality reports indicating those at increased risk of poor pregnancy outcomes. The most recent clinical report from 2017 (and the MBRRACE-UK Perinatal Mortality Surveillance Report 2016. do not suggest a significant change in complex social factors that could have an influence on poor birth outcomes for mothers and babies since the guideline was published.
British Pregnancy Advisory Service	No	No comment provided	Thank you.
National Childbirth Trust	No response provided	No comment provided	Thank you.

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Action on Smoking and Health	No	No comment provided	Thank you.
Birthrights	Yes	1. In order to understand the equalities impact of the current guidance and the recommendation not to revise, it is important to understand the extent to which the general recommendations set out for CG110 are being met at present, particularly in relation to needs monitoring and women's satisfaction with services in CCG/LMS areas. To note that this monitoring should include numbers of women with any and all social factors included in comment (1) above (Birthrights note that the Guideline refers to women presenting "with any complex social factor") and should ensure that it includes monitoring of the number of women with multiple co-presenting complex needs. It is very important that the needs of women with multiple co-presenting needs, or with specific needs not currently addressed in CG110 are not lost within this monitoring. Birthrights is not aware of this monitoring data being maintained centrally and has no evidence on whether or not it is held at CCG/LMS level. Birthrights is aware of work by Birth Companions looking at maternity care provision, including service mapping, in North Central London, and work to understand women's experience of maternity care in North East London. This is very important work, but does suggest that data on local needs and on service provision/satisfaction is not reliably and	Thank you for your comment relating to monitoring satisfaction with services. We acknowledge the importance of collecting data in this area to inform future practice. The guideline does recommend monitoring and data capture for a needs assessment purpose under service organisation in section 1.1 General recommendations. Thank you for highlighting concerns over the charging policy. This was not identified as an issue in the equalities impact assessment developed for the guideline. The 2018 Summary of changes made to the way the NHS charges overseas visitors for NHS hospital care states that within England, free NHS hospital treatment is provided on the basis of someone being 'ordinarily resident' and is not dependent upon nationality, payment of UK taxes, national insurance contributions, being registered with a GP, having an NHS number or owning property in the UK. Treatment in A&E departments and at GP surgeries remains free for all. We believe this issue is covered under recommendation 1.3.6 which states that healthcare professionals should be given training on the most recent government policies on access and entitlement to care for recent migrants, asylum seekers and refugees.

		regularly collected elsewhere within NHS/CCG data programmes. 2. Birthrights has particular concerns over the impact of current NHS charging policy and requirements to provide identification ahead of receiving care on access to care for both vulnerable migrant women who are (correctly or incorrectly) afraid of charging, and on women who are entitled to free care who lack identification and/or may be subject to profiling in hospitals and dissuaded from accessing care. This is not currently reflected in Guideline recommendations but is likely to have serious equalities impacts. All aspects of the Guideline need to be updated to better reflect the current policy and regulatory environment.	
The Birmingham City University	No response provided	No comment provided	Thank you.