

Health and Social care Committee

Inquiry into stillbirths in Wales

SB 5 – Public Health Wales



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Health and Social Care Committee. Evidence for Inquiry into still births in Wales

Author: Ms Siobhan Jones, Consultant in Public Health, Dr Shantini Paranjothy, Senior Clinical Lecturer in Public Health Medicine

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Purpose and Summary of Document: The purpose of this paper is to provide evidence on the preventable causes of stillbirth for consideration by the Health and Social Care Committee during their one day inquiry into the prevention of still births in Wales.

Work Plan reference:

Key Messages

- Maternal overweight and obesity, advanced maternal age and maternal smoking are the highest ranking modifiable risk factors for still birth
- Rates of stillbirth are persistently higher in areas with high levels of deprivation
- Wales has highest rates of smoking and obesity in pregnancy than any other UK country
- The cause of still birth is unknown in the majority of cases. It is important to understand the impact of smoking and obesity on still birth rates, particularly in light of the known epidemiology of these risk factors such as rising levels of obesity in the population, and the higher rates of smoking in areas of deprivation.
- Supporting women to give up smoking during pregnancy through improved access to advice and NHS Stop Smoking services, and implementation of the NICE guidance systematically across Wales should be given the highest priority by the NHS and partners
- Women with a high BMI at the start of pregnancy should receive clinical care in line with NICE guidance⁶ and CMACE⁵ recommendations to minimise risks to mother and baby. This should include dietary interventions and advice on physical activity to minimise weight gain, improving outcomes for the pregnancy and subsequent pregnancies
- The public health role of the midwife and maternity services is vital to ensure the delivery of evidence based public health interventions and partnership working to reduce the inequality that exists in still birth rates and other maternal and neonatal outcomes

- Partnership programmes targeted at areas of high deprivation such as Flying Start and Families First should ensure maternal obesity and maternal smoking are given a high priority within their work with communities and families. The NHS should work with partners to ensure accessible services exist in communities to support women before, during and after pregnancy
- Many health factors such as smoking and obesity in pregnancy are difficult to address once a pregnancy has started. The profile of the importance of preconception advice and support should be raised and opportunistic contacts with primary care, family planning and sexual health services should be maximised
- A detailed study of stillbirths is required if we are to understand the reasons for stillbirth and identify modifiable risk factors that can be addressed to prevent them from occurring. A confidential enquiry focused on stillbirths is recommended, to gain insights into the main causes of stillbirth, to identify avoidable causes and to recommend improvements in clinical care and service provision.

Background

The still birth rate in Wales is about 5 per 1,000 births and the rate has remained steady over the last 5 years, (about 200 babies a year in Wales)¹. This is in contrast to the neonatal mortality rate in Wales which has declined from 4.1 per 1,000 live births in 1999 to 2.9 per 1000 live births in 2005 and has remained around this rate for the last 5 years. In the majority of cases the cause of stillbirth is not known. Stillbirth rates in Wales remain higher than in other European countries¹

Rates of stillbirth are persistently higher in areas with high levels of deprivation^{1,2}. Lifestyle factors are linked to deprivation and are an important contribution to health inequalities. Rates of smoking and obesity (both risk factors for stillbirth) have been shown to be higher in areas with high levels of deprivation².

A systematic review of major risk factors for stillbirth in high income countries has identified maternal overweight and obesity (body-mass

index >25 kg/m²), advanced maternal age and maternal smoking as the highest ranking modifiable risk factors³. In the UK smoking accounts for up to 7% of all stillbirths but it is estimated that in disadvantaged populations maternal smoking contributes to up to 20% of stillbirths¹.

Smoking and obesity in particular have a high prevalence in the population and not only impact on rates of still birth, but are also linked to higher rates of miscarriage, maternal death, neonatal deaths, admission to neonatal care and low birth weight. The impacts on the use of maternity and neonatal services are significant². These findings highlight the importance of public health initiatives to tackle smoking and obesity in women of reproductive age

In this paper we present the evidence for preventable risk factors associated with stillbirth and make recommendations for addressing these.

Smoking in pregnancy

Wales has higher rates of smoking in pregnancy than any other UK country. Around a quarter (26%) of mothers in the UK smoked directly before or during their pregnancy. Smoking levels before or during pregnancy were highest in Wales (33%) and lowest in England (26%). Across the UK, one in eight mothers (12%) continued to smoke throughout pregnancy, and were still smoking after the baby was born. Mothers in Wales were most likely to smoke throughout their pregnancy (16%)⁴.

Smoking in pregnancy is linked to a range of poor outcomes for mother and baby, including increased risk of stillbirth. A recent report by Public Health Wales, prepared as part of the Early Years Pathfinder Programme (see Appendix 2), has identified the population attributable risks associated with smoking in pregnancy from the available evidence⁴ (see Table 1). This evidence suggests that 4-7% of all stillbirths can be attributed to maternal smoking.

Table 1 – Outcomes associated with smoking during pregnancy⁴

Outcomes associated with cigarette smoking during pregnancy	Population attributable risk (Proportion of outcomes that could be attributed to maternal smoking in pregnancy based on data from studies carried out in the UK.
Ectopic pregnancy	8%
Low birth weight	10%
Preterm birth	13%
Premature rupture of the membranes	11%
Placenta praevia	14%
Placental abruption	13%
Low birth weight	10% - 27%
Small for gestational age	25%
Stillbirth	4-7%*
Sudden Infant death syndrome	26%
Respiratory distress	10%

*Based on results from a range of studies in high income countries

The evidence review conducted as part of the Public Health Wales report found that high quality evidence exists to support the effectiveness of interventions for promoting smoking cessation in pregnancy⁴. This evidence base, set out in NICE guidance, is not currently being fully implemented in a robust, coordinated and systematic way by the NHS in Wales. The report makes a series of recommendations including the need to ensure:

- Smoking in pregnancy is the highest priority area for public health action for the NHS in Wales.

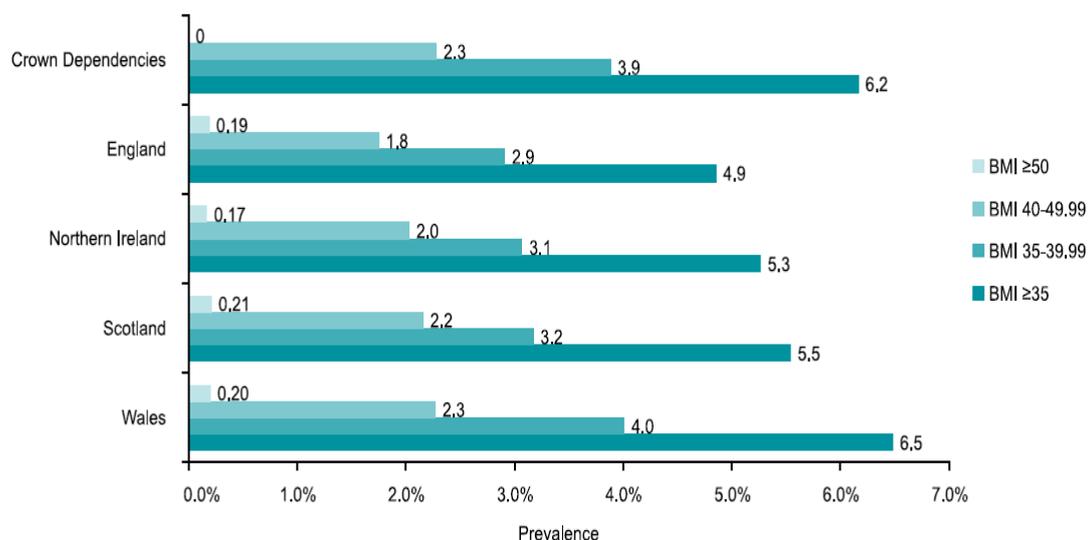
- Health Boards, Public Health Wales/Stop Smoking Wales and Welsh Government work together in an integrated way to ensure the robust, systematic and coordinated implementation of the evidence base on smoking in pregnancy

The recommendations arising from this report are being taken forward by Public Health Wales, in partnership with Health Boards. It is vital that these actions be prioritised by all partners and strongly supported by Welsh Government to ensure systematic implementation of NICE guidance and the development and implementation of better service models to increase uptake of Smoking Cessation services by pregnant women

Maternal Obesity

Over half the population of Wales are currently overweight or obese (BMI >25). The 2010 Centre for Maternal and Child Enquiries report Maternal Obesity in the UK found that 6.5% of pregnant women in Wales had a BMI of 35 or more, compared to the UK average of 5% (see figure 1)⁵. Wales has the highest prevalence of maternal obesity of all the UK countries⁵. Obesity in pregnancy is currently one of the biggest threats to maternal and child health in developed countries. Women who are obese are more than twice as likely to have a stillborn baby, and the risk increases with increasing maternal BMI (see Table 2). Babies born to obese mothers are less likely to be breast fed, more likely to have congenital anomalies, especially neural tube defects, and to require admission to neonatal units. It is also more difficult to monitor the health of these babies during pregnancy and birth⁵.

The mother's health is also at risk, as they are more likely to have pregnancy-related complications such as gestational diabetes, pre-eclampsia, haemorrhage following birth, thromboembolism and deliver their babies by caesarean section⁵.

Figure 1: Rates of Maternal Obesity in the UK

Source: CMACE 2010

Table 2: Fetal Risks associated with Maternal BMI >30

Risk	Odds Ratio
Birth Defects	1.6
Prematurity	1.2
Macrosomia	2.4 – 3.1
Admission to NNU	1.3 – 1.5
Still Birth	2.1
Neonatal Death	2.6

Source: CMACE

The recent CMACE 3 year study into maternal obesity in the UK, highlights the scale of the issue and makes a series of recommendations in relation to the safe clinical management of pregnant women with raised BMI in

pregnancy⁵. It is important that Health Boards are taking forward these recommendations as part of clinical pathways in order to ensure risks of still birth (and other adverse outcomes associated with raised BMI) are minimised.

The Public Health Wales Early Years pathfinder programme is currently preparing a briefing paper, similar to that completed for Smoking in pregnancy which will set out the epidemiology, evidence base, population health impact and current situation in Wales in relation to maternal obesity. It will be important for the NHS to work in partnership to take forward these recommendations.

The Way Forward

Still birth rates in Wales have not fallen in recent years. In the majority of cases, the cause of still birth is unknown. It is important to understand the impact that some of these preventable risk factors are having on still birth rates, particularly in light of the known epidemiology of these risk factors such as rising levels of obesity in the population, and the higher rates of smoking in areas of deprivation. A confidential enquiry into still birth rates in Wales would facilitate this understanding and identify areas for improvement.

Supporting women to give up smoking during pregnancy through improved access to advice and services, and implementation of the NICE guidance systematically across Wales should be given the highest priority by the NHS and partners.

Women with a high BMI at the start of pregnancy should receive clinical care in line with NICE guidance⁶ and CMACE⁵ recommendations to minimise risks to mother and baby. This should include dietary interventions and advice on physical activity to minimise weight gain, improving outcomes for the pregnancy and subsequent pregnancies^{5,6}.

The public health role of the midwife and maternity services is vital to ensure the delivery of evidence based public health interventions and partnership working to reduce the inequality that exists in still birth rates and other maternal and neonatal outcomes such as miscarriage, low birth weight and pre term births. There is a strong policy context for this^{7,8} and a high priority should be given to ensuring staff working in maternity services have the skills and time to deliver the public health agenda.

Partnership programmes targeted at areas of high deprivation such as Flying Start and Families First should ensure addressing maternal obesity and maternal smoking is given a high priority within their work with communities and families. The NHS should work with partners to ensure accessible services exist in communities to support women before, during and after pregnancy

It is vital for women to be healthy at the start of pregnancy. This will significantly impact on the outcome of the pregnancy for both mother and baby. Many health factors such as smoking and obesity in pregnancy are difficult to address once a pregnancy has started. It is more effective if advice and behaviour change occur before conception. The latest Centre for Maternal and Child Enquiries report on maternal deaths highlights the benefits of providing targeted support and pre-pregnancy counselling to women with epilepsy, obesity, known significant mental ill health and congenital heart disease⁹. Whilst this advice is available from all GPs, midwives and health visitors there is a need for more proactive targeting of this advice to those who need it most. The profile of the importance of preconception advice and support should be raised and opportunistic contacts with primary care, family planning and sexual health services should be maximised.

Recommendations arising from the work of the Early Years Pathfinder Programme will support Health Boards in the implementation of the evidence base in relation to maternal smoking, obesity and preconception.

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Appendix 1 – Background: Public Health Wales

Public Health Wales is an NHS organisation providing professionally independent public health advice and services to protect and improve the health and wellbeing of the population of Wales. Public Health Wales has four statutory functions:

- To provide and manage a range of public health, health protection, healthcare improvement, health advisory, child protection and microbiological laboratory services and services relating to the surveillance, prevention and control of communicable diseases;
- To develop and maintain arrangements for making information about matters related to the protection and improvement of health in Wales available to the public; to undertake and commission research into such matters and to contribute to the provision and development of training in such matters;
- To undertake the systematic collection, analysis and dissemination of information about the health of the people of Wales in particular including cancer incidence, mortality and survival; and prevalence of congenital anomalies; and
- To provide, manage, monitor, evaluate and conduct research into screening of health conditions and screening of health related matters.

Public Health Wales is currently taking forward an **Early Years Pathfinder Programme** to drive forward improvements in early years outcomes in Wales.

Appendix 2: Smoking in Pregnancy: Briefing Paper

Smoking in Pregnancy: Briefing Paper Reproductive and Early Years Pathfinder Project

Author: Siobhan Jones, Consultant in Public Health, Eleri Tyler, Clinical Information Analyst ATTRACT, Jon Brassey (Support Manager, ATTRACT), Sikha De Souza, Specialty Registrar, Roslind Reilly, Specialty Registrar, Shantini Paranjothy, Senior Clinical Lecturer Public Health Medicine

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Purpose and Summary of Document:

- Summarise evidence base on smoking in pregnancy
- Summarise likely impact of implementing evidence base on population health outcomes
- Provide overview on current service delivery in Wales

Work Plan reference: Reproductive and Early Years Pathfinder Programme

Summary of key findings

- Smoking in pregnancy is associated with increased risk of miscarriage, perinatal death, prematurity, low birth weight and congenital anomalies in the baby in particular of the heart, face and limbs
- Wales has higher rates of smoking in pregnancy than any other UK country
- Estimation of trends in cigarette smoking prevalence in Wales and in sub-sections of the population are hampered by the lack of good quality routinely collected information

Evidence Base

- High quality evidence exists on the effectiveness of interventions for promoting smoking cessation in pregnancy. This evidence base is not currently being fully implemented in a robust, coordinated and systematic way by the NHS in Wales
- Smoking cessation interventions can reduce smoking in late pregnancy by 3-6%
- Smoking cessation interventions can reduce low birthweight (RR 0.83, 95% CI 0.73 to 0.95) and preterm birth (RR 0.86, 95% CI 0.74 to 0.98), and increase mean birth weight by 53.91g (95% CI 10.44 g to 95.38 g). Four week quit rates for pregnant women using NHS Stop Smoking Services are 32-48%
- Smoking cessation interventions should be implemented in all maternity care settings and population based measures to reduce smoking and social inequalities should be supported
- Women in the UK under report smoking and CO monitoring can aid in the identification of smokers and support referral into NHS Stop Smoking Services
- There is insufficient evidence to conclude whether or not NRT is effective when used in pregnancy

- Financial incentives have been shown to be significantly more effective than other intervention strategies in US based research. Rigorous UK-based research is needed
- Professional barriers to supporting pregnant women include; health professionals not asking about smoking status for fear of damaging the relationship with the pregnant woman, limited knowledge on guidelines/protocols, staff perception that they have limited skills and knowledge, staff perception of lack of time and staff perception of the limited effectiveness of interventions
- Barriers for pregnant women are length of sessions, difficulty making phone contact, lack of transport or child care. Fear of failure, beliefs about control and concerns about being stigmatised have also been described as important barriers
- There is limited high quality evidence that the site or setting of the intervention (e.g. clinic based or home) influences the effectiveness of smoking cessation interventions for pregnant women in the UK
- There is limited high quality evidence in relation to effectiveness of midwives in delivering the intensive support as part of the Stop Smoking team
- Service evaluations from England and Scotland suggest flexibility around the site and setting and clinical staff delivering the intervention can improve engagement with the client, facilitate access to NRT and subsequently improve outcomes. Further high quality evidence is needed on this
- Using the NICE costing model⁶ we estimate that 23 of 3368 cases of complications for the mother and the baby could be avoided each year (cost avoided to the NHS of £443,064), if uptake of stop smoking services for pregnant women increased from 11% to 25%.

Summary of Key Recommendations

Due to the health, social and economic impacts smoking in pregnancy should be the highest priority area for public health action for the NHS in Wales.

- Health Boards, Public Health Wales/Stop Smoking Wales and Welsh Government should work together in an integrated way to improve services and ensure uptake of smoking cessation in pregnancy are increased to 25%.

In particular ensuring:

- Strong leadership from maternity services with a senior midwife identified in each Health Board area to work with Public Health Wales and Stop Smoking Wales to implement the evidence base.
- Establish consistent data recording and collection to establish the baseline, monitor outcomes and the impact of service changes.
- Improved referral systems and processes in place for all pregnant smokers to
- Access to brief intervention/motivational interviewing training for midwives and support staff in all Health Boards, to address a suite of behavioural risks including smoking during pregnancy, as part of making every contact count
- A review of the service model delivered by SSW to pregnant smokers, ensuring implementation of evidence base in order to maximise outcomes.

ACTION: A task and finish (5x5) group on tobacco has been set up to take this work forward.

- Consideration should be given to undertaking a social profiling exercise in Wales in order to establish who the different groups of women who smoke are and what are the individual motivations/barriers, in order to target evidence based interventions accordingly.

ACTION: Once the data issues above are resolved we aim to complete this work by June 2013

- Consideration should be given to how the NHS works in a more and integrated way on this key priority area, with a seamless approach to joint working across all NHS services and partner agencies. In particular the value of working with other agencies such as ASH Wales needs to be explored.

ACTION: Implementation plan to be developed autumn 2012.

1 Background

The prevalence of smoking in the female population and the variation of smoking levels between the most and least deprived areas are important factors influencing maternal and child health outcomes within a population¹. Maternal smoking is a key cause of poor outcomes for mothers, babies and children. Smoking in pregnancy is associated with increased risk of miscarriage, perinatal death, prematurity, low birth weight and congenital anomalies in the baby in particular of the heart, face and limbs². In developed nations, the single most important factor that affects low birth weight is cigarette smoking during pregnancy^{1,2}.

Wales has higher rates of smoking in pregnancy than any other UK country. Around a quarter (26%) of mothers in the UK smoked directly before or during their pregnancy. Smoking levels before or during pregnancy were highest in Wales (33%) and lowest in England (26%). Across the UK, one in eight mothers (12%) continued to smoke throughout pregnancy, and were still smoking after the baby was born. Mothers in Wales were most likely to smoke throughout their pregnancy (16%)³.

The smoking habits of teenage girls are a particular cause for concern as smoking rates in this group continue to increase despite a downward trend in all other areas. This will have a direct impact on future smoking in pregnancy rates².

Supporting pregnant women to stop smoking is a challenging area of public health and the numbers of women supported by NHS stop smoking services is low^{4,5}. A study from Scotland found that in 2006 only 3.2% of identified pregnant smokers quit⁵.

This briefing paper, developed as part of the Public Health Wales, Reproductive and Early Years Pathfinder Project, aims to give an overview of the evidence base on what works to support pregnant smokers to quit, what the implications would be for population health in Wales if this evidence was implemented in a robust and systematic way and an overview of how services are currently configured in Wales and progress towards implementing evidence based practice. It is hoped this paper will

guide the future development of services and support for pregnant women in order to maximise health outcomes for mothers and babies.

Epidemiology of cigarette smoking during pregnancy in Wales

Cigarette smoking during pregnancy is associated with adverse perinatal outcomes for the mother and baby as illustrated in Table 1 below.

Table 1 – Outcomes associated with smoking during pregnancy

Outcomes associated with cigarette smoking during pregnancy	Population attributable risk (Proportion of outcomes that could be attributed to maternal smoking in pregnancy based on data from studies carried out in the UK.
Ectopic pregnancy	8% ⁽⁶⁾
Low birth weight	10% ⁽⁶⁾
Preterm birth	13% ⁽⁷⁾
Premature rupture of the membranes	11% ⁽⁶⁾
Placenta praevia	14% ⁽⁶⁾
Placental abruption	13% ⁽⁶⁾
Low birth weight	10% ⁽⁶⁾ , 27% ⁽⁷⁾
Small for gestational age	25% ⁽⁷⁾
Stillbirth	4-7%* ⁽⁹⁾
Sudden Infant death syndrome	26% ⁽⁶⁾

Respiratory distress	10% ⁽⁶⁾
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*Based on results from a range of studies in high income countries⁹

The longer term impacts on the child from smoking during pregnancy include asthma¹⁰, upper respiratory infections¹⁰, behavioural problems¹⁰, the effects of preterm birth such as neuro-developmental problems¹¹, the effects of low birth weight such as coronary heart disease and diabetes in adulthood¹¹.

Women who did not smoke during pregnancy were less likely to have a preterm birth (5.9% vs. 8.2%) or to give birth to a low birth weight baby (5.5% vs. 8.9%) than women who smoked at some time during the year before birth⁽¹⁰⁾. There was a reduction in the proportion of preterm births (6.7% vs. 9.1%) and low birth weight infants (7.9% vs. 9.6%) for women who quit smoking within the first trimester, compared with women who smoked beyond the first trimester⁽¹⁰⁾. Women who smoked during the first two trimesters of pregnancy had a 90% increase in risk for placenta praevia (OR = 1.9 [95% CI, 1.2–3.0]) than women who did not smoke during pregnancy⁽¹⁰⁾. The risks of small for gestational age births increased with the number of cigarettes smoked during the third trimester. The impact of smoking on low birth weight can be lessened if women quit before their third trimester. Similarly, for studying fetal growth restrictions, knowledge of smoking habits during the third trimester, the time when most of the growth in the fetus occurs, is of critical importance⁽¹⁰⁾.

Emerging evidence suggests that reducing exposure to smoke during pregnancy improves outcomes at a population level, with a recent Scottish study highlighting findings suggesting that the introduction of national, comprehensive smoke free legislation was associated with significant reductions in pre term births and babies being born small for gestational age²⁰

The UK Infant feeding survey estimates 33% of women in Wales smoke before or during pregnancy, and 16% smoke throughout pregnancy. This varies according to social class with higher prevalence in lower social classes. Across the UK, mothers in managerial and professional occupations were the least likely to have smoked before or during pregnancy (14%) whilst those in routine and manual occupations were the most likely to have done so (40%). Mothers in routine and manual occupations were five times more likely than those in managerial and

professional occupations to have smoked throughout pregnancy (20% and 4% respectively)³.

Estimation of trends in cigarette smoking prevalence in Wales and in sub-sections of the population are hampered by the lack of good quality routinely collected information. Although all women are usually asked at their antenatal booking appointment about cigarette smoking and this information is recorded in their hand-held antenatal notes, this is not consistently reported to the local Child Health Systems across Health Boards, resulting in patchy completeness of data collected at a national level within The National Community Child Health Database (NCCHD) (Table 2). This data completeness issue is being addressed by an ongoing data quality improvement agenda by the NCCHD Steering Group. Further information of referral to smoking cessation services, or smoking status during late pregnancy is not recorded. It is important that we resolve these issues around data quality and completeness at a national level to enable more detailed analysis and social profiling of smoking during pregnancy to inform the targeting of services.

Table 2 – Data completeness and maternal smoking prevalence by Health Board, Wales

Health Board	Total births	Data completeness (%)	Smoking prevalence (%)
Cwm Taf	4253	94%	26%
BCU	6939	91%	21%
Hywel Dda	3438	52%	14%
ABMU	6365	23%	8%
CVU	6233	9%	99%
AB	6088	1%	14%

Powys	157	99%	21%
Source: NCCHD 2010			

2 Methodology

Overview of the evidence

The overview of the evidence presented in this paper was undertaken using a pragmatic high level search of key sources.

The Public Health Wales ATTRACT team undertook a series of literature searches to answer the following questions:

- What are the most effective interventions to support women to stop smoking during pregnancy?
- How effective are midwives at delivering smoking cessation interventions to pregnant women?
- What are the best models of service delivery for smoking in pregnancy services?
- Are home visits to support women to stop smoking in pregnancy more effective than clinic based interventions?
- How effective are pharmacists in supporting pregnant women to give up smoking?

In addition, the recently published National Institute for Health and Clinical Excellence (NICE) public health guidance 26 – How to stop smoking in pregnancy and following childbirth⁴ was reviewed at length by the ATTRACT team and authors of this paper, and the key findings from the NICE evidence review are highlighted.

Impact of implementing the evidence base on population health outcomes

The NICE Costing Template, a tool published as part of the NICE guidance 26 was used to estimate the economic and population health impact of smoking in pregnancy.⁶ The template estimates the potential number of cases and cost savings that would result in Wales, assuming there is no difference in the prevalence of these outcomes between England and Wales or uptake of smoking cessation services. We acknowledge that this model is limited as it does not take account of the wider health and social impacts of cigarette smoking and at best will provide a conservative estimate.

Overview on current service delivery and outcomes in Wales

A mapping exercise was completed in August 2011 as part of the pathfinder project. This involved asking all Health Board's in Wales about the early years' interventions currently in place. This included smoking in pregnancy interventions and the mapping document is used to describe current practice in Wales and progress with implementation of the evidence base (Appendix 1). There were several limitations to this exercise. It was extremely difficult to compile a list of early interventions across Wales as there is no system or resource that captures this information. Collecting the information took a huge amount of chasing and the accuracy very much depended on interviewing the right individual in each Health Board about each intervention. Consequently there were some gaps, and it isn't possible to know if this is because interventions are not in place or that the right individual was not interviewed. Also the information provided by Health Board's was a snap shot, and developments in the individual areas are happening all the time. Regular surveys would be needed to capture progress on key programmes.

3 Overview of Evidence Base

3.1 Effectiveness of smoking cessation interventions in pregnancy

The evidence on the effectiveness of smoking cessation interventions has recently been reviewed and described in detail by NICE in public health guidance 26 – How to stop smoking in pregnancy and following childbirth⁴. The NICE evidence review found that there is high quality evidence on the effectiveness of interventions for promoting smoking cessation in pregnancy. A recently updated Cochrane review, showed a significant reduction in smoking in late pregnancy following interventions (risk ratio (RR) 0.94, 95% confidence interval (CI) 0.93 to 0.96), an absolute difference of six in 100 women who stopped smoking during pregnancy. When the review looked at the studies with the lowest risk of bias only, the interventions had less effect (RR 0.97, 95% CI 0.94 to 0.99). Using the results of this systematic review it can be estimated that smoking cessation interventions can reduce smoking in late pregnancy by 3-6%¹¹.

The Cochrane review found that smoking cessation interventions reduced low birthweight (RR 0.83, 95% CI 0.73 to 0.95) and preterm birth (RR 0.86, 95% CI 0.74 to 0.98), and there was a 53.91g (95% CI 10.44 g to 95.38 g) increase in mean birthweight. There were no statistically significant differences in neonatal intensive care unit admissions, very low birthweight, stillbirths, perinatal or neonatal mortality but these analyses had very limited power. Appendix 2 gives a summary of the evidence on effect sizes resulting from individual smoking cessation interventions in pregnancy.

The Cochrane review concludes that smoking cessation interventions should be implemented in all maternity care settings and that population based measures to reduce smoking and social inequalities should be supported¹¹.

NICE reports good evidence to support that women in the UK under report smoking and that CO monitoring can aid in the identification of smokers and support referral into NHS Stop Smoking Services⁴. The evidence supports the role of NHS Stop Smoking Services and indicates that they are effective in supporting women to stop smoking. Four UK studies on outcomes, reported 4 week quit rates of 32-48% for pregnant women using NHS Stop Smoking Services⁴. A Scottish review of smoking cessation services for pregnancy did find that there was large variation in the reach and effectiveness of services, with some areas offering no tailored support⁴.

The evidence supports the use of self help interventions to aid cessation in pregnant women, although the extent of UK evidence was found to be limited⁴.

Effectiveness of Nicotine Replacement Therapy in Pregnancy (NRT)

The NICE review found that there was mixed evidence on the effectiveness of Nicotine Replacement Therapy (NRT) in pregnancy⁴. The Cochrane review conducted a meta-analysis on five trials and found NRT to be effective (RR 0.95, 95% CI 0.92 to 0.98). However a subsequent meta-analysis carried out to support development of the NICE guidance¹² concluded that the Cochrane review does not provide the most accurate possible estimate for the safety and effectiveness of NRT as:

- A large double blind placebo randomised trial has been published since and its findings need to be considered.
- The Cochrane reviews synthesises data from trials with multi-modal intervention strategies which often involve a number of different interventions being delivered. Whilst this permits maximum use of available research data, it is not necessarily an appropriate strategy for determining the effectiveness of the individual interventions.
- Cochrane analyses include one trial in which NRT was offered to women as part of a multi-modal treatment strategy and in which the level of behavioural support for smoking cessation offered in addition to NRT in the intervention group was substantially higher than the amount offered in the "routine care control group". As behavioural support is an effective treatment for smoking cessation in pregnancy, the inclusion of this trial has probably resulted in an over-estimate of the effectiveness of NRT in both the current and previous Cochrane reviews.

In the updated meta-analysis¹² findings of all trials suggest that NRT is effective for reducing smoking in later pregnancy [RR, 95% CI = 0.92 (0.87, 0.98)], but that all of the evidence for NRT being effective comes exclusively from the trials which are at highest risk of bias (non-placebo randomised studies [RR, 95% CI = 0.87 (0.81, 0.94)]). The most robustly designed trials (placebo randomised,) provide no evidence that

NRT is effective for smoking cessation in pregnancy [RR, 95% CI = 0.94 (0.87, 1.02)]. See Appendix 3 for results of this meta analysis.

The NICE evidence briefing also concluded that there is no evidence that NRT either increases or decreases low birth-weight and that there are insufficient data to form judgements about any impact of NRT on stillbirth or special care admissions¹². Consequently there is currently insufficient evidence to conclude whether or not NRT is effective when used in pregnancy. A recent large, double blind placebo controlled trial of NRT in pregnancy conducted in England (SNAP) found that adding a nicotine patch (15 mg per 16 hours) to behavioural cessation support for women who smoked during pregnancy did not significantly increase the rate of abstinence from smoking until delivery or the risk of adverse pregnancy or birth outcomes. However, low compliance rates substantially limited the assessment of safety²¹

A statement from the UK teratology service on the use of NRT in pregnancy states¹³:

“Tobacco use and exposure through passive smoking during pregnancy is associated with an increased risk of intrauterine growth retardation, cleft lip and/or palate, ectopic pregnancy, spontaneous abortion, premature delivery, perinatal mortality and poor postnatal development.

The first choice treatment for tobacco use cessation during pregnancy would be through cognitive behavioural therapy (CBT). In non-pregnant populations, CBT combined with nicotine replacement therapy (NRT) has been shown to increase rates of tobacco use cessation.

Concerns exist over the efficacy and safety of NRT in pregnancy. An advantageous risk vs. benefit ratio has not, as yet, been adequately proven, however use of NRT may be preferable to continued fetal exposure to the many harmful constituents of tobacco smoke. The available data which investigate pregnancy outcomes, although limited, do not yet provide substantial evidence of an increased risk of adversity when NRT has been used during pregnancy.

Should CBT measures fail to control a patient’s urge to use tobacco, NRT could be considered provided concomitant tobacco use is kept to an absolute minimum. When NRT is indicated it should be used at the lowest effective dose which controls symptoms of withdrawal and cravings”.

Effectiveness of financial incentives.

The NICE guideline highlights that there is good evidence from the recent Cochrane review to support use of financial incentives in promoting smoking cessation in pregnancy. The meta analysis of the US based trials found that financial incentives were significantly more effective than other intervention strategies (RR 0.76, 95% CI 0.71 – 0.81)^{4,11}. NICE state that rigorous UK-based research is needed to take account of cultural differences and stress the need to avoid a proliferation of local evaluations which may be insufficiently powered or inappropriately designed to determine whether incentives are effective⁴.

3.2 Barriers to smoking cessation in pregnancy

There have been a number of qualitative studies looking at the barriers to pregnant women stopping smoking^{4,11,14,15,16}. The professional barriers to supporting pregnant women to stop smoking have been described as; health professionals not asking about smoking status for fear of damaging the relationship with the pregnant woman, limited knowledge on guidelines/protocols in place, staff perception that they have limited skills and knowledge to implement successful interventions, staff perception of lack of time and staff perception of the limited effectiveness of interventions^{4,11}. It has been suggested that the use of Numbers Needed to Treat (NNT) rather than absolute risk reduction data to express the efficacy of smoking cessation in pregnant women could help to overcome the pessimism of staff over the high failure rate. Data from systematic reviews suggest NNT's of between 17 and 33¹¹ which could be used in conjunction with data on success rates of NHS specialist services to encourage referral by staff^{4,11}. The barriers for pregnant women to stopping smoking have been described as length of sessions, difficulty making phone contact, lack of transport or child care^{4,14,15}. Home visits or very local services and the provision of crèche facilities have been suggested as possible service options in order to address some of these barriers¹⁴. This is supported by NICE who recommend that home visits or alternative venues should be considered for those women who are reluctant to or find it difficult to attend the clinic⁴. Fear of failure, beliefs about control and concerns about being stigmatised have also been described as important barriers^{15,16}.

Consideration should be given to undertaking a social profiling exercise in Wales in order to establish who the different groups of women who smoke are and what are the individual motivations/barriers, in order to target the evidence based interventions accordingly

3.3 Models of service delivery

Following an extensive review of the evidence, NICE make the following recommendations in relation to the model of service delivery that should be in place to support women to stop smoking during pregnancy⁴:

Role of Midwives at booking and subsequent appointments:

- Assess woman's exposure to tobacco smoke through discussion and use of CO monitoring.
- Discuss health risks, benefits of stopping smoking and provide information.
- Refer all pregnant smokers, those with CO reading >7 ppm and those stopped in previous two weeks to NHS Stop Smoking Services on opt out basis using NICE referral pathway.
- All midwives should be trained in assessing and recording smoking status and readiness to quit, discussing health risks and making a referral into the local Stop Smoking Service. Midwives are not advised to carry out brief interventions, but should use their skills to initiate a referral into NHS Stop Smoking Services.

Other staff in wider health care team (GP's, Practice Nurses, HV's, Obstetricians, Paediatrician, Sonographers) should ask about smoking status at every opportunity and refer those who want to stop to the NHS Stop Smoking Service using local arrangements⁴.

Role of NHS Stop Smoking Services:

- Attempt to contact woman by telephone twice and follow up with a letter.
- Attempt to see those who can't be contacted by phone. For example in a routine antenatal contact.
- Address any barriers to taking up smoking cessation services. Consider offering home visits or alternative locations for those who are reluctant or find it difficult to attend clinic.
- Feedback on individual clients should be given to the midwife.
- Provide intensive interventions and ongoing support throughout pregnancy and beyond (as detailed in NICE guidance).
- Discuss risks and benefits of NRT.
- For those women who are disadvantaged, the service should be offered in a flexible, client centred way. Interventions should be delivered in locations and times that mean they are accessible and tailored to individual needs. Services should work in an integrated way with other services such as substance misuse and teenage pregnancy support.

Evidence searches were undertaken by the ATTRACT team in order to answer the following questions:

- What are the most effective interventions to support women to stop smoking during pregnancy?
- How effective are midwives at delivering smoking cessation interventions to pregnant women?
- What are the best models of service delivery for smoking in pregnancy services?

- Are home visits to support women to stop smoking in pregnancy more effective than clinic based interventions?
- How effective are pharmacists in supporting pregnant women to give up smoking?

These searches found that there is limited high quality evidence that the site or setting of the intervention influences the effectiveness of smoking cessation interventions for pregnant women in the UK. There also appears to be little high quality evidence in relation to effectiveness of midwives in delivering the intensive support as part of the Stop Smoking team. The ATTRACT team found three papers^{5,17,18} describing midwives delivering interventions, as part of the service. Two of these were evaluations of service delivery and one was an RCT of motivational interviewing approaches by midwives, which did not show significant increases in smoking cessation. NICE highlight that where midwives do deliver the intensive interventions they should be trained to the same standard as NHS stop smoking advisors⁴.

There are a number of published evaluations of outcomes for smoking in pregnancy services in the UK. One mixed methods evaluation undertaken in Scotland found that most stop smoking services in Scotland offered home visits by trained advisers to pregnant women. An analysis of routine service data, suggested that for home based services for which data on engagement (whether a woman attended the first appointment with a specialist advisor) were available, about 50% of those referred engaged compared with 20% for clinic-based services¹⁹.

An evaluation undertaken on the three beacon services in England found that those services that were delivering the best outcomes had several common features¹⁷;

- Interventions delivered by small number of dedicated clinical staff (nurses or midwives)
- Full support from Heads of Midwifery
- Receive bulk of referrals from midwives

- Offer NRT to almost all pregnant smokers and have an efficient system for providing the prescriptions (eg PGD's)
- Offer flexible home visits
- Provide intensive multi session treatment delivered by small number of full time staff

Another evaluation of a service for young pregnant smokers highlighted the importance of good integration between maternity services and Stop Smoking Services. Although numbers participating were small, the project pointed to the value of midwife led home visits in engaging this group of women¹⁸.

An observational study undertaken in Scotland, using routinely collected data found that a very low proportion of pregnant smokers are supported to quit in Scotland (3.2%)⁵. Poor outcomes were attributed to issues along the whole pathway in relation to identification, engagement and treatment⁵. The study suggests CO monitoring can be useful in encouraging midwives to ask about smoking and in addressing under reporting. A greater proportion of women set a quit date and quit when interventions were delivered at home. Costs were higher with home visits⁵.

The ATTRACT team found very little evidence on the effectiveness of pharmacists in supporting pregnant women to stop smoking. This is one of a number of areas identified as needing further research.

3.4 Population health and economic impacts of implementing evidence base on smoking cessation in pregnancy

Using the NICE costing template it is possible to model the population health and economic impacts of increasing the uptake of women receiving NHS stop smoking support⁶. Table 3 models how many more women could be supported to quit in Wales if the uptake of smoking services increased to 25%. There are several assumptions that have been used in this model. Smoking prevalence is assumed to be 33%, taken from the infant feeding survey³ and the current uptake of pregnant women

receiving support has been estimated at 11% using data from NHS Stop Smoking services in England. Data from one Health Board in Wales suggests that uptake of Stop Smoking Services by pregnant women is currently a lot lower than England (<5%). More work is being done to develop more robust data on uptake at an all Wales level. A sensitivity analysis has been carried out to model the assumptions at different levels of smoking prevalence and uptake of smoking cessation services (see Appendix 4)

Table 3 Service delivery Statistics – Local assumptions

	Percentage	Number of people
Number of pregnant women	100%	34937
Smoking prevalence in pregnancy ¹	33%	11529
Current uptake of pregnant women receiving NHS stop smoking support ²	11%	1268
Future uptake of women receiving NHS Stop Smoking support ³	25%	2882
Additional pregnant women receiving NHS support	14%	1614
Number of women successfully quitting smoking as a result of contact with NHS services ⁴	45%	726
Pregnant women who stopped as a % of all women who smoke ⁵	6.3%	726 / 11,529
Estimated number of births to women who smoke	33%	11,529

1. This is the percentage of women who smoked before or during pregnancy in Wales in 2010 from the Infant Feeding Survey 2010
http://www.ic.nhs.uk/webfiles/publications/003_Health_Lifestyles/IFS_2010_early_results/IFS_2010_headline_report_tables2.pdf

2. This is an estimate based on 188,023 pregnant women smoking in England (26% of 723,165 live births) in England in 2010 and 21,839 pregnant women in England setting a quit date in 2010/11 from Statistics on NHS Stop Smoking Services: England, April 2010-March 2011
http://www.ic.nhs.uk/webfiles/publications/003_Health_Lifestyles/NHS%20Stop%20Smoking%20Services%20201011/SSS_2010_11.pdf
3. This is an estimate for future uptake of NHS Stop Smoking services
4. This is an estimate for Wales based on the percentage of pregnant women who are successful quitters at 4 weeks in England from the NHS Stop Smoking Services report above. The number is 45% of 2306, the additional women who contact Stop Smoking Services if uptake is increased to 25%.
5. This is calculated by taking 1,038 as a percentage of 11,529, the number of additional quitters as a percentage of those women who smoke during pregnancy. we have used the number of live births
6. The number of pregnant women was taken as the number of live births, so the number of births to women who smoke is the same as the number of pregnant women who smoke.

Assuming that the prevalence of the complications is the same in Wales as in England, the following table estimates the number of cases with infant and maternal complications. It also estimates the number of cases due to smoking using Population Attributable risks. If the uptake of stop smoking services for pregnant women increased to 25% then it is estimated that 6.3% of all pregnant women who smoke will quit. Population Attributable risks have been calculated from these figures and used to estimate the number of complications due to smoking. The calculations below estimate that an uptake of 25% would result in 234 out of 3368 maternal or infant complications being avoided.

Table 4 Maternal and infant complications: general cases in pregnancy and associated cases due to smoking.

		Estimate of number of cases based on births ¹	Cases due to smoking
Maternal Complications	Ectopic pregnancy	182.80	9.71
	Premature rupture of membranes	1045	79.23

	Placenta Praevia	70	7.32
	Abruption placenta	43	3.97
	Pre-term delivery	614	46.46
	Pre-eclampsia	214	-5.56
	Total Maternal complications	2171	141.01
Infant Complications	Low birth weight	791	55.56
	Respiratory distress	336	23.62
	Sudden Infant Death Syndrome (SIDS)	70	13.71
	Total Infant complications	1197	92.89
	Total	3368	233.89
	Total cases that could be avoided		234

These calculations estimate that £443,064 could be saved in a year in Wales if uptake of stop smoking services for pregnant women increased to 25%. This is illustrated in Table 5. The NICE costing templates are set up to calculate direct costs to NHS, they do not take into account the medium and long term implications of some of these complications. The overall cost to society from smoking and pregnancy will be higher. An economic evaluation of smoking in pregnancy undertaken to support the NICE review found that all effective interventions were shown to reduce costs and increase Quality Adjusted Life Years (QALY), for both the mother and the child²². Furthermore, at a societal level, the net benefit (i.e. accounting for money and health gains), could be in excess of £500 million²².

Table 5 Savings from cases of maternal and infant complications avoided

		Cases due to smoking	Unit cost £ ¹	Total cost £
Maternal Complications	Ectopic pregnancy	9.71	1081	10497
	Premature rupture of membranes	79.23	2679	212257
	Placenta Praevia	7.32	2679	19610
	Abruption placenta	3.97	2679	10636
	Pre-term delivery	46.46	2679	124466
	Pre-eclampsia	-5.68	2679	-15217
	Total Maternal complications	141.01		362,249
Infant Complications	Low birth weight	55.56	870	48337
	Respiratory distress	23.62	870	20549
	Sudden Infant Death Syndrome (SIDS)	13.71	870	11928
	Total Infant complications	92.89		80,814
	Total savings	233.9		443,064

1 The unit costs are based on the NHS national tariff for 2010/11

The limitations of the NICE costing models for public health interventions are a subject of debate particularly due to the difficulty of obtaining robust utility scores for use in cost-effectiveness models. Further work is required to develop a more robust model that addresses the current limitations.

4.0 What is currently happening in Wales?

The mapping exercise carried during 2011 and completed in Aug 2011 asked all Health Boards in Wales to report progress on Smoking in Pregnancy. Three out of seven Health Boards reported to have the NICE opt out referral pathway in place, with one additional Health Board reporting that it is in place in 1 out of 3 of the locality areas. Three out of seven Health Boards reported having a lead midwife identified to champion implementation of the NICE guidance and act as a link between Stop Smoking Wales and the maternity service. One additional Health Board reported that this is in place in 1 out of 3 of the locality areas. Two out of seven Health Boards reported having bespoke smoking in pregnancy training for midwives in place (See Appendix 1). There were some limitations to this exercise (see methodology section) and caution should be applied to the interpretation of these findings.

In relation to the delivery of interventions to pregnant women by Stop Smoking Wales, the service currently offers the following:

- Referrals received by SSW from midwives. Advisors contact the pregnant women to discuss benefits of quitting, offer support and arrange assessment session
- SSW attempt to contact client twice by telephone, and send follow up letter if no response. Clients are fast tracked into an appointment to allow for the longest cessation period during their pregnancy
- Clients are offered sessions for intensive support at existing community based groups, on a one to one basis at a clinic/venue where SSW usually hold sessions, or support over the phone.
- Women are given 7 sessions of intensive support. If the client feels they are not ready to quit at the assessment session there is a four week flexibility within which time treatment can start.
- Risks/benefits of NRT are discussed in the sessions.
- If the client requires additional support following the seven sessions, the advisor will arrange to telephone in two weeks time to check progress.

There are several areas in relation to the service delivery model that are recommended by NICE that are not currently being implemented in Wales. These are:

- Carbon monoxide monitoring is not done routinely in Wales as part of the booking visit and NICE referral pathway.
- No attempts are made to see women i.e in antenatal clinics, if they are unable to be contacted by SSW.
- Women are not currently supported throughout their pregnancy and after delivery.
- There is variable practice in relation to feedback on the progress of individual clients from SSW to midwives.
- There is currently very little flexibility in the model of support for pregnant women in relation to offering sessions at home or at alternative venues for women who are disadvantaged, are reluctant or find it difficult to access the services on offer.

5.0 Conclusions

Smoking in pregnancy is a major preventable cause of poor outcomes and inequalities in maternal and child health in the short, medium and long term. Wales is doing worse than any other UK country in relation to the number of women that continue to smoke throughout pregnancy.

High quality evidence exists to support smoking cessation interventions in pregnancy, and there are key recommendations from NICE highlighting what NHS and partners should be providing as part of an effective, cost effective integrated system to support women to stop smoking during pregnancy. This evidence base is not currently being fully implemented in a robust, coordinated and systematic way across by the NHS in Wales.

Smoking in pregnancy is an extremely challenging area of public health. Evidence on the barriers to smoking cessation in pregnancy suggests that pregnant smokers are different to other adult smokers who are motivated to quit and self refer to SSW. There are practical issues with access to services, such as childcare. Rurality is a big issue for the population in Wales and services such as smoking cessation services need to be

provided as locally as possible. In addition, stigma, beliefs about control and the fear of failure are often reported by pregnant women as barriers to engaging with smoking cessation services. The NICE guidance and evaluations of services from other UK countries suggest that a flexible approach is needed for pregnant women, particularly those who are disadvantaged, with the services being offered in a client centred way throughout pregnancy and following childbirth.

Flexibility may also be required in relation to thinking about innovative and alternative ways to decrease levels of smoking in pregnancy at a population level, including the role of joint working with Welsh Government and agencies such as ASH Wales. There may be a number of different ways to support pregnant women to stop smoking. Strong evidence is emerging on financial incentive schemes which highlight an urgent need to evaluate these schemes in a UK setting. Other health professionals, such as pharmacists or other primary care staff, may have a role, particularly in rural or remote areas. Again, this needs further research. There are a number of areas where we don't have high quality evidence to support practice such as the site or setting of the interventions or the professional delivering the interventions (i.e. midwife vs. smoking cessation advisor). There are evaluations from England and Scotland that suggest that flexibility around the site and setting and clinical staff delivering the intervention can improve engagement with the client, facilitate access to NRT and subsequently improve outcomes; further high quality evidence is needed on this.

6.0 Recommendations

The following are the key recommendations arising from this paper:

- Due to level of harm to maternal and child health, and the evidence on effectiveness of cessation, smoking in pregnancy should be the highest priority area for public health action for the NHS in Wales.
- Health Boards, Public Health Wales/Stop Smoking Wales and Welsh Government should work together in an integrated way to ensure the robust, systematic and coordinated implementation of the evidence base on smoking in pregnancy. In particular ensuring:

- Strong leadership from maternity services with a senior midwife identified in each Health Board area to work with Public Health Wales and Stop Smoking Wales to implement the evidence base⁴.
 - Opt out referral pathways based on NICE guidance in place in each Health Board area to facilitate referral of all pregnant smokers into SSW⁴.
 - CO monitors are routinely used as part of the NICE referral pathway⁴.
 - Access to bespoke smoking in pregnancy training for midwives and support staff in all Health Boards⁴.
 - A review of the service model delivered by SSW to pregnant smokers, ensuring implementation of evidence base in order to maximise outcomes.
 - A review of the availability of accurate data in order to establish the baseline, monitor outcomes and the impact of service changes.
-
- NHS and partners in Wales need to urgently consider areas for innovation and evaluation. Section 7 of this report includes areas for potential research and evaluation within smoking cessation in pregnancy.
 - Consideration should be given to undertaking a social profiling exercise in Wales in order to establish who the different groups of women who smoke are and the differentials in uptake and prevalence among different socio-economic groups. Including what are the individual motivations/barriers, in order to target evidence based interventions accordingly.
 - Consideration should be given to how the NHS works in a more and integrated way on this key priority area, with a seamless approach to joint working across all NHS services and partner agencies. In

particular the value of working with other agencies such as ASH Wales needs to be explored.

7.0 Areas for further research

This evidence review and that undertaken by NICE highlighted a number of important areas that require further high quality research to be undertaken in order to determine effectiveness:

- Site or setting used to deliver interventions for pregnant women.
- Financial incentive schemes in a UK setting.
- Increasing contact of smoking cessation services with pregnant women who smoke.
- Role of pharmacists in supporting pregnant women to stop.
- Self help interventions in a UK setting.
- How and why some women spontaneously quit smoking when they become pregnant
- Interventions across different socio-economic groups

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Appendix 1 – Mapping of Smoking in Pregnancy Interventions in Health Boards across Wales

Health Boards (HB)	Progress with maternal smoking interventions
HB A	<ul style="list-style-type: none"> - Smoking Cessation in pregnancy implementation group in place - BI Training programme for midwives/HVs set up - Lead midwife identified - NICE Pathway agreed - Fax referral mechanism has commenced - Systems for data sharing between Stop Smoking Wales & midwives are starting to be set up
HB B	<ul style="list-style-type: none"> - Smoking and Maternity Smoking Cessation agreed as an outcome to 'Smoke Free UHB' Action Plan 2010-2011 - Midwifery Service has agreed to implement the SSW Maternity Smoking Cessation Programme and use the 'opt out' referral form at booking appointment which is carried out in a hospital setting - Agreed to use SSW standardised 'opt out' referral form but want additional 'carbon copies' added to this - Lead Midwife agreed - 2 Brief Intervention for Smoking Cessation Training Courses held for Midwifery Care Assistants (MCAs) (who carry out 'booking' clinics) and Community Midwives. - Programme officially launched February 2011 <p><i>Smokebugs, Assist and Smokefree Class Competition</i> initiatives in place for generic smoking prevention</p>
HB C	<ul style="list-style-type: none"> - <u>Locality 1</u> <ul style="list-style-type: none"> o Brief Intervention Training delivered to: <ul style="list-style-type: none"> ▪ 1st, 2nd and 18 month undergraduate student midwives at Swansea University August 2010, and a lecture was given to the new 1st year intake in December 2010

	<ul style="list-style-type: none"> ▪ Teenstart Team (Midwives, Health visitors, Students, Community Nurses, Link Workers, etc. ○ Awareness Raising Session delivered to Antenatal Day Assessment Unit - <u>Locality 2</u> <ul style="list-style-type: none"> ○ Task and Finish group established ○ Awareness Raising Session delivered to Community Midwives and staff ○ Launch of maternity referral pathway – August 2010 and ongoing - <u>Locality 3</u> <ul style="list-style-type: none"> ○ Deputy Head Midwife – Lead, member of Task and Finish Group ○ Raising Awareness Sessions currently being delivered by SSW Practitioner ○ Awaiting launch of referral pathway
HB D	<ul style="list-style-type: none"> - Working with Stop Smoking Wales - Training in how to deliver 'brief interventions for smoking cessation' delivered to Sure Start Health Visitors <p>Midwives provide systematic brief interventions for smoking cessation</p>
HB E	<ul style="list-style-type: none"> - Direct referral pathway in place to SSW - Bespoke training delivered to midwifery staff. BI training programme for midwife/HV available - Consultant midwife lead identified - Systems for data sharing between SSW & midwives currently being established <p>Pharmacy-based generic community smoking cessation scheme also open to pregnant women</p>
HB F	<ul style="list-style-type: none"> - Working with SSW for individual referrals. - Roll out of National Smoking Cessation Pathway

	All Midwives & Health Visitors give information and support/signposting to cessation services and inform about the risks of passive smoking with infants.
HB G	Routine referral to Stop Smoking Wales but no follow-up undertaken

Appendix 2 – Overview of evidence base on effect sizes of smoking cessation interventions in pregnancy

Life course stage	Intervention	Effect size	Type of study	Comments	Source
Antenatal	All smoking cessation interventions	Absolute difference of 6% of women in intervention groups who quit smoking during pregnancy (RR 0.94, 95% CI 0.93, 0.96)	Meta-analysis of 65 RCTs, quasi-RCTs and cluster RCTs	High heterogeneity between interventions, even after subgroup analysis	Lumley et al, 2009
Antenatal	Incentives to stop smoking	24% reduction in smoking in intervention group (RR 0.76, 95% CI 0.71, 0.81)	Meta-analysis of 4 RCTs and quasi-RCTs	USA setting. Financial incentives might have a different impact in UK and further research required to explore applicability in UK (Bauld and Coleman, 2010).	Lumley et al, 2009
Antenatal	Cognitive behaviour strategies	5% reduction in smoking in intervention group (RR 0.95, 95%CI 0.93-0.97)	Meta-analysis of 31 RCTs, quasi-RCTs and cluster RCTs		Lumley et al, 2009
Antenatal	Nicotine replacement therapy	5% reduction in smoking in intervention group (RR 0.95, 95%CI 0.92-0.98)	Meta-analysis of 5 RCTs and quasi-RCTs	No clear evidence of safety of nicotine replacement therapy in terms of perinatal outcomes	Lumley et al, 2009

		No reduction in smoking (RR 0.96, 95% CI 0.85-1.09)	RCT	Not included in Cochrane meta-analysis (Lumley et al, 2009).	Oncken et al, 2008 in Bauld and Coleman, 2010
Antenatal	Stages of change theory (precontemplation, contemplation, preparation and action)	No evidence of effectiveness (RR 0.99 95%CI 0.97, 1.00)	Meta-analysis of 11 RCTs, quasi-RCTs and cluster RCTs		Lumley et al, 2009
Antenatal	Feedback	No evidence of effectiveness (RR 0.92, 95% CI 0.84-1.02)	Meta-analysis of 4 RCTs and quasi-RCTs		Lumley et al, 2009
Antenatal	Self-help interventions	Intervention group more likely to quit smoking compared with usual care 13.2% vs 4.9% (OR 1.83, 95% CI 1.23-2.73)	Meta-analysis of 12 RCTs and quasi-RCTs	All studies involved dissemination of written materials to participants	Naughton et al, 2008 in Bauld and Coleman, 2010
Antenatal	NHS smoking cessation services	Quit rate of 20% at 3 months and 12.7% at one year (CO validated)	Mixed methods	Intervention consisted of behavioural support and motivational interviewing and NRT (Scotland)	Bryce et al, 2007 in Bauld and Coleman, 2010

		Quit rate 32% at 4 weeks (self reported)	Mixed methods	Intervention consisted of behavioural support and motivational interviewing and NRT (Scotland)	McGowan et al, 2008 in Bauld and Coleman, 2010
		Quit rate 0.4-5.4% at 4 weeks	Mixed methods	Reach and type of interventions varied (Scotland)	Macaskill et al, 2008 in Bauld and Coleman, 2010
		Quit rate 37-48% at 4 weeks at three Stop Smoking services	Qualitative	England	Lee et al, 2006 in Bauld and Coleman, 2010
Antenatal	Exercise with behavioural support	Quit rate 25% at eight months gestation	Cross sectional study	Pilot study - 32 participants	Ussher et al, 2008 in Bauld and Coleman, 2010

Bauld L and Coleman T. The effectiveness of smoking cessation interventions during pregnancy: A briefing paper. *UK Centre for Tobacco Control Studies* 2010. Available from <http://guidance.nice.org.uk/PH26>.

Lumley J, Chamberlain C, Dowsell T, Oliver S, Oakley L, Watson L. Interventions for promoting smoking cessation during pregnancy. *Cochrane Database of Systematic Reviews* 2009, Issue 3. Art. No.: CD001055. DOI: 10.1002/14651858.CD001055.pub3.

SNAP – Smoking, Nicotine and Pregnancy – trial underway

LEAP – London Exercise and Pregnant Smokers – trial underway

Trial of financial incentives for smoking cessation during pregnancy under proposal

Appendix 3 – Results of meta-analysis of trials assessing effectiveness of NRT in pregnancy¹²

Table 2 Nicotine replacement therapy for smoking cessation in pregnancy: all trials

Intervention	Total	Control Events	Total	Risk Ratio Weight	MH, Fixed 95% CI
Kapur 2001	13	17	13	5.0%	0.78 [0.58, 1.03]
Hotham 2005	17	20	20	6.7%	0.85 [0.70, 1.05]
Pollak 2007	105	122	58	25.7%	0.88 [0.81, 0.95]
Wisborg 2000	102	124	109	35.5%	0.95 [0.85, 1.06]
Oncken 2008	82	100	80	27.1%	0.96 [0.85, 1.09]
Total (95% CI)	383	312	100.0%	280	0.92 [0.87, 0.98]
Total events		319		280	
Heterogeneity: Chi ² = 4.26, df = 4 (P = 0.37); I ² = 6%					
Test for overall effect: Z = 2.80 (P = 0.005)					

Table 3 Nicotine replacement therapy for smoking cessation in pregnancy: placebo controlled trials

Intervention	Total	Control Events	Total	Risk Ratio Weight	MH, Fixed 95% CI
Kapur 2001	13	17	13	2.5%	0.78 [0.58, 1.03]
Oncken 2008	82	100	80	13.3%	0.96 [0.85, 1.09]
Wisborg 2000	102	124	109	17.4%	0.95 [0.85, 1.06]
Total (95% CI)	241	233	33.1%	201	0.94 [0.87, 1.02]
Total events		198		201	
Heterogeneity: Chi ² = 1.89, df = 2 (P = 0.39); I ² = 0%					
Test for overall effect: Z = 1.47 (P = 0.14)					

Table 4 Nicotine replacement therapy in pregnancy for smoking cessation: non-placebo controlled trials

Intervention	Total	Control Events	Total	Risk Ratio Weight	MH, Fixed 95% CI
Hotham 2005	17	20	20	6.7%	0.85 [0.70, 1.05]
Pollak 2007	105	122	58	25.7%	0.88 [0.81, 0.95]
Subtotal (95% CI)	142	79	32.4%	78	0.87 [0.81, 0.94]
Total events		122		78	
Heterogeneity: Chi ² = 0.05, df = 1 (P = 0.82); I ² = 0%					
Test for overall effect: Z = 3.60 (P = 0.0003)					

Appendix 4 – Sensitivity Analysis – economic modelling

The following table shows the number of maternal and infant complications that could be avoided and the cost savings that could be made, with different variables used in the calculations.

- Smoking prevalence is taken as being 16% (number of women who smoked throughout pregnancy) or as 33% (number of women who smoked before or during pregnancy)³.
- A current uptake of 11% is used which mirrors the estimates for England, and 5% is also used which perhaps better reflects the current situation in Wales
- A number of figures are used for future uptake, demonstrating varying levels of increase in service uptake.

Smoking prevalence	Current uptake	Future uptake	No. smoking related adverse events avoided	Total cost saving
Smoking prevalence at 16% with low estimate of current uptake				
16%	5%	10%	43	81,261
16%	5%	15%	83	157,514
16%	5%	20%	121	228,708
16%	5%	25%	156	296,439
Smoking prevalence at 16% with high estimate of current uptake				
16%	11%	15%	35	65,547
16%	11%	20%	75	142,156
16%	11%	25%	113	241,840
Smoking prevalence at 33% with low estimate of current uptake				
33%	5%	10%	88	166,973
33%	5%	15%	171	324,382
33%	5%	20%	249	471,936
33%	5%	25%	323	611,622
Smoking prevalence at 33% with high estimate of current uptake				
33%	11%	15%	71	134,928
33%	11%	20%	155	293,682
33%	11%	25%	234	443,064