Purpose and Summary of Document:
This report summarises the findings of the Models for Access to Maternal Smoking cessation Support (MAMSS) project. The project aimed to increase engagement of pregnant women with stop smoking services in intervention sites, by providing flexible, women focused services. This report outlines the findings of this project in relation to the effectiveness of the new models for service, a process evaluation and cost analysis. Based on the discussion of these findings, a set of recommendations and actions are proposed.

Acknowledgements:
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# List of abbreviations

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<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>AB</td>
<td>Aneurin Bevan</td>
</tr>
<tr>
<td>ABM</td>
<td>Abertawe Bro Morgannwg</td>
</tr>
<tr>
<td>BC</td>
<td>Betsi Cadwaladr</td>
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<tr>
<td>CI</td>
<td>Confidence Interval</td>
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<tr>
<td>CO</td>
<td>Carbon Monoxide</td>
</tr>
<tr>
<td>CT</td>
<td>Cwm Taf</td>
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<td>MAMSS</td>
<td>Models for Access to Maternal Smoking cessation Support</td>
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<td>MoU</td>
<td>Memorandum of Understanding</td>
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<tr>
<td>MSW</td>
<td>Maternity Support Worker</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service</td>
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<tr>
<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
</tr>
<tr>
<td>NRT</td>
<td>Nicotine Replacement Therapy</td>
</tr>
<tr>
<td>PAS</td>
<td>Patient Administration System</td>
</tr>
<tr>
<td>PPM</td>
<td>Parts per million</td>
</tr>
<tr>
<td>SSW</td>
<td>Stop Smoking Wales</td>
</tr>
<tr>
<td>UHB</td>
<td>University Health Board</td>
</tr>
<tr>
<td>WIMD</td>
<td>Welsh Index of Deprivation</td>
</tr>
<tr>
<td>WTE</td>
<td>Whole Time Equivalent</td>
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</tbody>
</table>
Models for Access to Maternal Smoking Cessation Support

1 Introduction and background

A third of pregnant women living in Wales smoke before or during their pregnancy compared to just over a quarter of women living in other areas of the UK.

(Infant Feeding Survey, 2010)

This is a major concern since maternal smoking is a key cause of poor outcomes for mothers, babies and children; including increased risk of miscarriage, perinatal death, prematurity, low birth weight and congenital abnormalities (Delpisheh et al, 2007; Kramer, 1987). Supporting pregnant women to stop smoking is a key public health priority.

There is high quality evidence of effective interventions to promote smoking cessation in pregnancy.

A Cochrane review found that psychosocial interventions to support women to stop smoking during pregnancy were associated with a significant reduction in smoking during pregnancy (Chamberlain et al, 2013). The same review reported an 18% reduction in pre-term birth (CI 4% to 30%) among women who received psychosocial interventions, an 18% reduction in the proportion of babies born with a low birth weight (CI 6% to 29%) and a significant increase in mean birth weight (41g, CI 18g to 63g) (Chamberlain et al, 2013).

UK public health guidance on interventions aimed at stopping smoking in pregnancy and following childbirth provides a clear pathway and referral mechanism for pregnant smokers into NHS Stop Smoking Services (NICE, 2010). A key component of this guidance is carbon monoxide (CO) testing for all pregnant women to assess their level of exposure to CO either as smokers themselves or from other sources. Test results are used to ensure the appropriate identification of smokers for onward referral to specialist support services. It has been estimated that 20 per cent of smokers deny their habit when cotinine measurements are compared with self-report (Ford et al, 1997), leaving these pregnant smokers without the information available to facilitate a quit attempt. UK based research has found that employing the carbon monoxide test in conjunction with self-report improves the identification of smokers, but that maternity staff have found it difficult to discuss smoking and administer the test (McGowan et al, 2010).

Another key element of UK national guidance for smoking cessation during pregnancy is to provide a flexible and tailored service for pregnant women to help increase levels of engagement. This is due to the fact that pregnant women may not feel comfortable nor have all their needs met when attending generic services.
Many stop smoking services in England offer a flexible service for pregnant women (Fahy et al, 2014). There are evaluations from England and Scotland which 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. However, there is still a lack of high quality evidence about what works in implementing a flexible service, such as where this should be provided or what type of professional should deliver the interventions (e.g. midwife vs. smoking cessation advisor) (Public Health Wales, 2012).

Within Stop Smoking Wales (SSW), the national smoking cessation service, various service improvements have occurred since 2009 to strengthen the referral system for pregnant women who smoke from antenatal clinics to the stop smoking service. These service improvements have included additional training of midwifery staff, in line with National Institute for Health and Care Excellence (NICE) guidance, to encourage the use of CO testing.

Despite this, referral into the service and engagement with pregnant women has continued to remain extremely low. For example, data from SSW show that in the referral period May 2012-March 2013, 1,817 pregnant smokers were referred to the service from maternity services, but only 529 went on to accept an appointment. At this time, there were around 32,000 births in Wales (Office for National Statistics, 2012).

Assuming a smoking prevalence of 33% (Infant Feeding Survey, 2010), 5.6% of smokers were referred to the service, and 1.6% of smokers accepted an appointment. In response, a national group was created to consider a way forward.

This group developed the Models for Access to Maternal Smoking cessation Support (MAMSS) project with the aim of implementing NICE guidance systematically across project areas and testing the effectiveness of three different models of service delivery to address the gap in the evidence base about how to deliver a flexible tailored smoking cessation service to pregnant women.
2 Aim and objectives

The overall aim of MAMSS was to implement different service delivery models for smoking cessation services for pregnant women and evaluate the extent to which these could increase the proportion of pregnant smokers who engaged with stop smoking services and reduce the number of women smoking during pregnancy.

The objectives were to:

- Fully implement NICE guidance for smoking services for pregnant women in selected intervention and usual care sites
- Design and deliver different models of service delivery for smoking cessation services for pregnant women in intervention sites
- Compare the effectiveness and costs of new models of service delivery with usual care
3.1 Introduction

A full description of the methods used for MAMSS is described in the peer-reviewed protocol paper (see appendix 1). This section of the report summaries the study design; describes what was delivered within intervention and usual care sites; outlines the data sources, outcome measures and the statistical analysis. It also provides information about the process and health economic evaluations as well as research governance approvals from the NHS Research and Development Offices.
3.2 Study design

The MAMSS project was undertaken as a quasi-experiment involving both intervention and usual care sites. The four Health Boards involved were Abertawe Bro Morgannwg University Health Board (UHB), Aneurin Bevan UHB, Betsi Cadwaladr UHB and Cwm Taf UHB.

The project took place over a 12-month period (9 months in Cwm Taf) using an integrated approach between maternity services, local public health teams and SSW. The intervention and usual care sites were selected from existing midwifery teams (see Table 1) and selected on the basis of high rates of pregnant smokers and similar demographic profiles. Areas that fell outside intervention or usual care continued to provide services according to existing arrangements. Data from these areas have not been included in the analysis.

Table 1: Overview of intervention and usual care sites

<table>
<thead>
<tr>
<th>Health Board Area</th>
<th>Intervention delivered by</th>
<th>Intervention Sites</th>
<th>Usual Care Sites</th>
<th>Intervention period (date of first referral to date of last referral)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aneurin Bevan University Health Board</td>
<td>Specialist stop smoking advisor (Band 5)</td>
<td>County Hospital, Pontypool</td>
<td>Ysbyty Ystrad Fawr, Ystrad Mynach</td>
<td>12/6/13 – 1/5/14</td>
</tr>
<tr>
<td>Abertawe Bro Morgannwg University Health Board</td>
<td>Specialist smoking in pregnancy midwife (Band 6)</td>
<td>Princess of Wales Hospital, Bridgend</td>
<td>Singleton Hospital, Swansea Neath Port Talbot Hospital</td>
<td>20/5/13 – 14/2/14</td>
</tr>
<tr>
<td>Betsi Cadwaladr University Health Board</td>
<td>Specialist maternity care support worker (Band 3)</td>
<td>Denbighshire Community Midwifery Teams (Rhyl and Denbigh)</td>
<td>Wrexham and Flintshire Community Midwifery Teams (East)</td>
<td>16/7/13 – 30/5/14</td>
</tr>
<tr>
<td>Cwm Taf University Health Board</td>
<td>Specialist maternity care support worker (Band 3)</td>
<td>Rhondda Community Midwifery Team</td>
<td>Merthyr Tydfil Community Midwifery Team</td>
<td>12/6/13 – 4/2/14</td>
</tr>
</tbody>
</table>

In both intervention and usual care sites, maternity services and stop smoking services were asked to implement and adhere strictly to NICE guidance for quitting smoking during pregnancy and following childbirth including CO monitoring for all pregnant women and an opt out smoking cessation pathway (NICE, 2010).
3.3 Description of the intervention

Pregnant smokers (i.e. those who self-reported as current smokers, had a CO reading of $\geq 7$ parts per million (ppm) or who had quit in the two weeks prior to their booking appointment) were referred to the intervention on an opt-out basis, in accordance with NICE guidance. This means midwives were directed to routinely refer to the stop smoking service.

In intervention sites, the referral process could take place at any stage during pregnancy or during the two-week period immediately following the birth of the baby whilst still under the care of a midwife.

Pregnant smokers were referred to one of three models of service delivery dependant on the Health Board area: either a whole time equivalent (WTE) maternity support worker (employed by the UHB), or a midwife (employed by the UHB) or a smoking cessation advisor working with pregnant women (employed by SSW) (see Table 1).

The staff in intervention sites received referrals directly from midwives to provide an intensive smoking cessation intervention at times and settings of the women’s choice, including home visits.

During every subsequent antenatal appointment, midwives were prompted to ask women about their smoking status and refer as appropriate.

If a woman declined treatment (i.e. she opted-out by not answering the telephone to stop smoking services or refused an assessment appointment) midwives were encouraged to ask the woman during each follow up appointment if she would like to be re-referred.

Clients in intervention sites were offered smoking cessation support for the duration of their pregnancy if required. The support they received followed an adapted behavioural intervention model documented in the NHS Stop Smoking Service delivery manual, which is based on withdrawal-oriented therapy (Maudsley model) (Hajek, 1989). This may have involved a combination of telephone and face-to-face support as well as motivational support by email and or text, dependent upon the needs of the client (see Figure 1). A detailed manual for specialist smoking cessation staff was developed for use in all intervention sites detailing the referral pathway, intervention programme, policies, procedures and support materials.

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All models offered a flexible service designed to meet the needs of the women, which incorporated the following core elements:

- Smoking cessation services embedded within maternity services (provided as part of the package of maternity care)
- Referral from midwife to smoking cessation support within 48 hours
- Flexibility in service model with a women centred approach.
3.4 Description of usual care

Pregnant smokers in usual care areas were referred to the usual care stop smoking service on an opt-out basis, in accordance with NICE guidance. This means midwives were asked to routinely refer smokers to the Stop Smoking Wales service.

The core elements of the usual care service are:

- Referrals received by SSW from midwives via fax or phone call.
- SSW staff make an attempt to contact the pregnant women within 48 hours to discuss benefits of quitting, offer support and arrange an assessment session.
- SSW staff attempt to contact the client by telephone twice more if contact has not been established, and send a follow up letter if no response.
- Clients who do not opt out are offered community based behavioural support at a one-to-one appointment, which consists of an initial assessment session followed by treatment sessions throughout their pregnancy if required. If there are a limited number of one-to-one appointments available the client may be offered an appointment in a group but this is only provided if the client is happy to attend. In some circumstances the client will receive behavioural support via the telephone, this would be offered if the client felt they would struggle to regularly attend community based appointments or they lived a significant distance from the nearest community based appointment.

For an overview of referral and treatment in intervention and usual care sites see figure 1.

3.5 Data sources

The data analysis used routinely collected healthcare data from: i) the UHB’s electronic Patient Administration System (PAS)\(^1\) and Maternity Information System (which contain information about expectant mothers smoking status and birth outcomes) and ii) the Stop Smoking Wales database which recorded referral and treatment information for all intervention and usual care clients (see appendix 2 for data requirements for MAMSS). In intervention sites information about the referral pathway and stop smoking treatment programme was entered onto Quit Manager (the database used by SSW).

To facilitate the data collection process, Memoranda of Understanding (MoU) were established between Public Health Wales Informatics team and the four participating UHBs, and between Public Health Wales Informatics and SSW. This enabled Public Health Wales Informatics to receive extracts of the data required and produce an anonymised linked dataset for analysis (with linkage between the UHB maternity system data and the SSW data).

However, due to the lack of NHS numbers on the maternity data and SSW data, linkage was only possible for a proportion of the data and this varied across Health Boards. Therefore we have presented the un-linked data in this report. Analysis of the linked data (where available) is shown in appendix 5.

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\(^1\) No electronic system for routinely recording maternity data is in place in BC UHB therefore analysis is based on paper records which were recorded electronically for the purposes of MAMSS.
Methods

Figure 1: Referral and treatment in usual care and intervention sites

First antenatal appointment: midwives follow a standardised protocol
- Measure women’s carbon monoxide (CO) level
- Ask smoking status
- Ask if anyone else in the household smokes
- Record (CO) level and smoking status in notes

If identified as a smoker, or quit within last 2 weeks, referral is made for smoking cessation support

Usual care
- Referral from midwife to NHS Stop Smoking Service (Stop Smoking Wales) via fax or phone call.
- Stop smoking staff make an attempt to contact the pregnant women within 48 hours to discuss benefits of quitting, offer support and arrange an assessment session.
- NHS Stop Smoking Service staff attempt to contact the client by telephone twice more if contact has not been established, and send a follow up letter if no response.

Intervention
- Referral from midwife to smoking cessation support within 48 hours
- MAMSS clinician attempts to contact pregnant woman by telephone (or face-to-face at clinic) within 48 hours to discuss support and to arrange an appointment for an assessment session.
- MAMSS clinician attempts to contact the client by telephone at least twice more if contact has not been established.

Woman unable to be contacted or refuses treatment
- Women are fast tracked into a one-to-one assessment session appointment within 48 hours. Assessment sessions are conducted in community venues.
- Women are offered six further sessions of intensive behavioural support in community venues or by telephone, each lasting around 30 minutes.
- Women are CO monitored at all treatment sessions and at 4-6 weeks after their quit date.
- If the client requires additional support following the seven sessions, the advisor will arrange to make contact by telephone in two weeks to provide an additional follow up.

Woman accepts appointment

Woman unable to be contacted or refuses treatment

Woman accepts appointment

Approach: Flexibility in service model with a women centred approach.
- Face-to-face assessment session, within 1 week of contact, in location of woman’s choice
- Women are offered intervention sessions at a location of their choice, each lasting around 30-60 minutes
- The number and frequency of treatment sessions will be according to the woman’s choice, including the option of support by text message or telephone.
- Women are CO monitored during face-to-face treatment sessions and at 4-6 weeks after their quit date
3.6 Outcome measures

The primary outcome measure was engagement with stop smoking services (i.e. treated smoker, defined as attending the initial assessment session and at least one treatment session and setting a quit date). Secondary outcome measures were referrals received by the specialist stop smoking service\(^2\), pregnant smokers who accepted an appointment\(^3\), and pregnant smokers who quit at four weeks follow up (self-report and CO verified).

We also assessed fidelity to protocols, feasibility, acceptability, maintenance and sustainability (process measures) should the interventions be rolled out on a wider scale using data available within the maternity services and SSW on specific aspects of the referral pathway and treatment programme.

3.7 Statistical analysis

Routine data from each UHB were analysed to examine the effectiveness of each model in comparison to usual care. Baseline characteristics and outcomes for women in intervention sites were compared with those in usual care using percentages and chi-squared tests for statistical differences in the distribution of characteristics between the two groups. We used a fisher’s exact test in cases where the assumptions for chi-squared test were not met.

3.8 Process evaluation

A process evaluation was undertaken in order to understand the feasibility, acceptability and compliance to intervention, using the Medical Research Council complex intervention evaluation guidelines (Craig et al., 2008). Semi-structured interviews were undertaken with those delivering and receiving the intervention (Oakley et al, 2006). Full details of those who were invited to participate and who participated in the interviews can be seen in appendix 3.

Alongside this, minutes of the MAMSS Steering Group were subjected to a documentary analysis (Gill, 2006). Meeting minutes were analysed from the inception of the project in September 2012 until February 2014, when no new implementation issues were being encountered, a total of 17 sets of minutes. Data were analysed using framework analysis (Spencer et al, 2014) in order to identify key trends. Additional information was sought from MAMSS leads in each UHB where these sources of data were unable to fully detail all issues relating to feasibility, acceptability and compliance to intervention.

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2 Referral from midwife(or other health professional) has been received by Stop Smoking Wales or MAMSS Practitioner.

3 Client has been contacted successfully by SSW or MAMSS Practitioner and has made an appointment for support to quit smoking.
3.9 Health economic evaluation

A health economic analysis was undertaken using a cost-consequences analysis approach. A detailed list of resources and consumables/supplies compiled by those engaged in developing the projects was used as the basis for estimating the costs. Discussions were held with those leading the projects locally to collate actual costs for the intervention period against each item for each UHB area, with additional data subsequently provided by some of the specialist smoking cessation advisors.

Each item was costed for the periods May 2013 to June 2014, although the actual dates of employment (and consequent use of consumables) varied across the areas. Staff costs were taken directly from the UHB associated sources, or where this was not available was estimated at ‘top-of-scale’ so as not to underestimate the expenditure incurred. On-costs were also included in the staff costs, to present a more accurate estimation of expenditure; these on-costs cover pension and national insurance contributions and associated costs.

Where appropriate the costs associated with travel for each intervention/home visit were recorded. The distances travelled are not reported here but they will have a direct impact on the associated costs and there will be a degree of variability around them as well as a potential impact on ability to recruit/support clients as more travel time means less ‘intervention’ time.

Costs were categorised by agreement as related to the interventions or evaluation thereof and those associated with the latter were excluded.

3.10 Ethics and research and development approval

In three of the four UHBs, the project was considered a service evaluation and we obtained the necessary NHS research and development permissions required. In Cwm Taf UHB, the project was considered a research project and ethical approval was sought from South East Wales Research Ethics Committee in addition to research and development permissions.
4 Results

This section of the report provides a description of study participants, process measures (referrals received by SSW or the MAMSS practitioners of pregnant smokers into stop smoking services and referrals accepted) and outcome measures (treated smokers and four week quit rates). The final two parts of this section present the findings from the qualitative interviews and cost analysis.

4.1 Description of study participants

Figure 2 provides an overview of the sample for the study.

In total, there were 2756 smokers eligible to participate in the study across the four UHB areas. This represents a 24% smoking prevalence overall.

Data on the number of pregnant smokers at booking were not available in Betsi Cadwaladr UHB, therefore we estimated this by applying the average smoking prevalence of other participating Health Boards (24%) to the number of bookings in both the intervention and usual care sites in this area.

Data on the number of smokers at booking were available from the maternity information systems in the other three UHBs.
Figure 2: Study sample in intervention and usual care sites

Data on the number of pregnant smokers at booking were not available in BC UHB, therefore we estimated this by applying the average smoking prevalence of other participating Health Boards (24%) to the number of bookings in both the intervention and usual care sites in this area.

Total number of pregnant women in study period
n= 11,605

Number of pregnant smokers in study period (% prevalence)
n= 2756 (24%)

Number of pregnant non-smokers in study period
Total= 8849

Number of pregnant smokers in study period

Number of pregnant smokers in Abertawe Bro Morganwg UHB
n = 883

Number of pregnant smokers in Aneurin Bevan UHB
n = 553

Number of pregnant smokers in Betsi Cadwaladr UHB
n = 912*

Number of pregnant smokers in Cwm Taf UHB
n = 408

Number of pregnant smokers in intervention site (% prevalence)

n = 284 (24%)

n = 599 (19%)

n = 239 (29%)

n = 314 (23%)

n = 274 (24%)*

n = 638 (24%)*

n = 181 (33%)

n = 227 (30%)

Total number of pregnant women in study period
n= 11,605

Number of pregnant smokers in study period (% prevalence)
n= 2756 (24%)
4.2 Baseline characteristics

Demographic information was available from three of the UHBs involved in the study: Aneurin Bevan, Abertawe Bro Morgannwg and Cwm Taf UHBs. Analysis of these data showed no significant differences in the age of pregnant women who received antenatal care between the intervention and usual care sites in two of the UHBs (Table 2). The majority of smokers in usual care and intervention sites were aged between 20 to 29 years.

In Aneurin Bevan UHB, there was a significant difference in the age of pregnant women with a higher proportion of women aged 29 and under in intervention sites (67%) compared to usual care (61%).

The distribution of pregnant women varied according to deprivation quintile, with the largest proportion of pregnant women in WIMD quintiles 1 and 2 (most deprived) across all UHB areas in both usual care and intervention sites. This reflects the demographic characteristics of the local population.

The prevalence of smoking amongst pregnant women was significantly higher in intervention sites compared to usual care in two UHBs (Table 2). There was no significant difference in smoking prevalence between the usual care and intervention site in Cwm Taf UHB with 30% and 33% smoking prevalence respectively. Overall smoking prevalence ranged from 19% (Abertawe Bro Morgannwg usual care site) to 33% (Cwm Taf intervention site) amongst pregnant women during the intervention period.

There were no statistically significant differences in relation to the age of pregnant smokers in the intervention and usual care sites across all the UHBs where such data were available (Table 2).

In line with the known association between higher levels of deprivation and smoking behaviour, a greater proportion of pregnant smokers came from Wales’ most deprived communities according to the Welsh Index of Deprivation (WIMD) (Welsh Government, 2014) across all UHB areas. In Cwm Taf and Aneurin Bevan, there were no differences between intervention and usual care sites in the proportion of smokers from each WIMD deprivation quintile. However, in Abertawe Bro Morgannwg, there were significant differences in the proportion of pregnant smokers across deprivation quintiles: more pregnant smokers came from quintile 1 (most deprived) in the usual care site compared to their intervention comparator (54% v 48%).
<table>
<thead>
<tr>
<th></th>
<th>Abertawe Bro Morgannwg</th>
<th>Aneurin Bevan</th>
<th>Cwm Taf</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total number of pregnant women</strong> during intervention period</td>
<td>4323</td>
<td>2166</td>
<td>1315</td>
</tr>
<tr>
<td><strong>Total number of pregnant women</strong> as % of total</td>
<td>3139 (73%)</td>
<td>1184 (27%)</td>
<td>814 (38%)</td>
</tr>
<tr>
<td><strong>Number by age (%)</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Age under 20</td>
<td>183 (6%)</td>
<td>68 (6%)</td>
<td></td>
</tr>
<tr>
<td>Age 20 to 29</td>
<td>1636 (52%)</td>
<td>634 (54%)</td>
<td></td>
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<tr>
<td>Age 30 or over</td>
<td>1320 (42%)</td>
<td>482 (41%)</td>
<td></td>
</tr>
<tr>
<td>Not stated</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td><strong>Number by Wales WIMD 2011 quintile (1 most deprived) (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WIMD Wales quintile 1</td>
<td>1084 (35%)</td>
<td>313 (26%)</td>
<td></td>
</tr>
<tr>
<td>WIMD Wales quintile 2</td>
<td>658 (21%)</td>
<td>326 (28%)</td>
<td></td>
</tr>
<tr>
<td>WIMD Wales quintile 3</td>
<td>535 (17%)</td>
<td>163 (14%)</td>
<td></td>
</tr>
<tr>
<td>WIMD Wales quintile 4</td>
<td>307 (10%)</td>
<td>146 (12%)</td>
<td></td>
</tr>
<tr>
<td>WIMD Wales quintile 5</td>
<td>550 (18%)</td>
<td>231 (20%)</td>
<td></td>
</tr>
<tr>
<td>Not available</td>
<td>5 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td><strong>Number of smokers (%)</strong></td>
<td>599</td>
<td>284</td>
<td></td>
</tr>
<tr>
<td>Smokers as % of total</td>
<td>19%</td>
<td>24%</td>
<td></td>
</tr>
<tr>
<td><strong>Smokers by age (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age under 20</td>
<td>75 (13%)</td>
<td>28 (10%)</td>
<td></td>
</tr>
<tr>
<td>Age 20 to 29</td>
<td>352 (59%)</td>
<td>172 (61%)</td>
<td></td>
</tr>
<tr>
<td>Age 30 or over</td>
<td>172 (29%)</td>
<td>84 (30%)</td>
<td></td>
</tr>
<tr>
<td>Not available</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td><strong>Smokers by Wales WIMD 2011 quintile (1 most deprived) (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WIMD Wales quintile 1</td>
<td>309 (54%)</td>
<td>125 (48%)</td>
<td></td>
</tr>
<tr>
<td>WIMD Wales quintile 2</td>
<td>137 (23%)</td>
<td>84 (28%)</td>
<td></td>
</tr>
<tr>
<td>WIMD Wales quintile 3</td>
<td>89 (14%)</td>
<td>34 (15%)</td>
<td></td>
</tr>
<tr>
<td>WIMD Wales quintile 4</td>
<td>34 (3%)</td>
<td>29 (6%)</td>
<td></td>
</tr>
<tr>
<td>WIMD Wales quintile 5</td>
<td>30 (6%)</td>
<td>10 (3%)</td>
<td></td>
</tr>
<tr>
<td>Not available</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
</tbody>
</table>
4.3 Referrals received by smoking cessation services

Table 3 and Figure 4 show the number of referrals received by SSW or MAMSS Practitioners and the number who accepted the offer of an appointment across all sites. The proportion of pregnant smokers for whom a referral was received in intervention sites and the proportion of pregnant smokers who accepted the offer of an appointment was statistically significantly higher in intervention sites compared with their usual care comparator. Amongst the four intervention sites, the proportion of pregnant smokers for whom a referral was received ranged from 61% (CI 55%-66%) in Abertawe Bro Morgannwg UHB (Midwife) to 91% (CI 87%-93%) in Betsi Cadwaladr UHB (MSW).

In usual care sites the proportion of pregnant smokers for whom a referral was received ranged from 6% (CI 3%-10%) of smokers in Cwm Taf UHB to 36% (CI 32%-40%) in Abertawe Bro Morgannwg UHB.

In relation to accepted referrals the pattern is similar. The proportion of pregnant smokers who accepted the offer of an appointment in all intervention sites was significantly higher than their usual care comparator. The proportion of pregnant smokers who accepted a referral ranged from 39% (CI 33%-46%) in Aneurin Bevan UHB’s intervention site to 75% (CI 69%-79%) of pregnant smokers in Betsi Cadwaladr UHB intervention site.

---

4 “Referral received” indicates a referral from a midwife (or other health professional) has been received by Stop Smoking Wales or MAMSS Practitioner. “Referral accepted” indicates a client has been contacted successfully by Stop Smoking Wales or MAMSS Practitioner and has made an appointment for support to quit smoking.
### Table 3: Results table

<table>
<thead>
<tr>
<th></th>
<th>Abertawe Bro Morgannwg (Midwife)</th>
<th>Aneurin Bevan (Specialist SSW Advisor for pregnant women)</th>
<th>Betsi Cadwaladr (Maternity Support Worker)</th>
<th>Cwm Taf (Maternity Support Worker)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Usual care site</td>
<td>Intervention site</td>
<td>p-value</td>
<td>Usual care site</td>
</tr>
<tr>
<td><strong>Total number of pregnant women</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>As a % of total</td>
<td>73%</td>
<td>27%</td>
<td>62%</td>
<td>38%</td>
</tr>
<tr>
<td><strong>Number of smokers</strong></td>
<td>599</td>
<td>284</td>
<td>314</td>
<td>239</td>
</tr>
<tr>
<td>As a % of all pregnant women</td>
<td>19%</td>
<td>24%</td>
<td>23%</td>
<td>29%</td>
</tr>
<tr>
<td>(95% confidence interval)</td>
<td>(18%-21%)</td>
<td>(22%-27%)</td>
<td>(21%-26%)</td>
<td>(26%-33%)</td>
</tr>
<tr>
<td><strong>Number of referrals received</strong></td>
<td>215</td>
<td>173</td>
<td>83</td>
<td>185</td>
</tr>
<tr>
<td>As % of all smokers</td>
<td>36%</td>
<td>61%</td>
<td>26%</td>
<td>77%</td>
</tr>
<tr>
<td>(95% confidence interval)</td>
<td>(32%-40%)</td>
<td>(55%-66%)</td>
<td>(22%-32%)</td>
<td>(72%-82%)</td>
</tr>
<tr>
<td><strong>Number of referrals accepted</strong></td>
<td>108</td>
<td>133</td>
<td>23</td>
<td>94</td>
</tr>
<tr>
<td>As % of all smokers</td>
<td>18%</td>
<td>47%</td>
<td>7%</td>
<td>39%</td>
</tr>
<tr>
<td>(95% confidence interval)</td>
<td>(15%-21%)</td>
<td>(41%-53%)</td>
<td>(5%-11%)</td>
<td>(33%-46%)</td>
</tr>
<tr>
<td><strong>Number of treated smokers</strong></td>
<td>28</td>
<td>93</td>
<td>8</td>
<td>42</td>
</tr>
<tr>
<td>As % of all smokers</td>
<td>5%</td>
<td>33%</td>
<td>3%</td>
<td>18%</td>
</tr>
<tr>
<td>(95% confidence interval)</td>
<td>(3%-7%)</td>
<td>(28%-38%)</td>
<td>(1%-5%)</td>
<td>(13%-23%)</td>
</tr>
<tr>
<td><strong>Number quit at 4 weeks</strong></td>
<td>9</td>
<td>29</td>
<td>1</td>
<td>18</td>
</tr>
<tr>
<td>As % of all smokers</td>
<td>2%</td>
<td>10%</td>
<td>0%</td>
<td>8%</td>
</tr>
<tr>
<td>(95% confidence interval)</td>
<td>(1%-3%)</td>
<td>(7%-14%)</td>
<td>(0%-2%)</td>
<td>(5%-12%)</td>
</tr>
<tr>
<td><strong>Number quit at 4 weeks (CO confirmed)</strong></td>
<td>2</td>
<td>27</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>As % of all smokers</td>
<td>0%</td>
<td>10%</td>
<td>0%</td>
<td>3%</td>
</tr>
<tr>
<td>(95% confidence intervals)</td>
<td>(0%-1%)</td>
<td>(7%-14%)</td>
<td>(0%-2%)</td>
<td>(1%-6%)</td>
</tr>
<tr>
<td>As % treated smokers</td>
<td>7%</td>
<td>29%</td>
<td>13%</td>
<td>17%</td>
</tr>
<tr>
<td>(95% confidence intervals)</td>
<td>(2%-23%)</td>
<td>(21%-39%)</td>
<td>(2%- -47%)</td>
<td>(8% - 31%)</td>
</tr>
</tbody>
</table>

*Referral received = Referral from Midwife (or other health professional) has been received by Stop Smoking Wales or MAMSS Practitioner

**Referral accepted = Client has been contacted successfully by Stop Smoking Wales or MAMSS Practitioner and has made an appointment for support to quit smoking.
A treated smoker, defined as someone who has set a quit date and attended at least one treatment session, was the primary outcome in this study. The proportion of smokers who went on to become a treated smoker was statistically significantly higher in all intervention sites compared to their usual care comparator (Figure 3).

Figure 3: Treated smokers (as a % of all pregnant smokers) by UHB

<table>
<thead>
<tr>
<th>Service Provider</th>
<th>Usual Care Sites</th>
<th>Intervention Sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abertawe Bro Morgannwg (Midwife)</td>
<td>5%</td>
<td>33%</td>
</tr>
<tr>
<td>Aneurin Bevan (Specialist SSW Advisor)</td>
<td>3%</td>
<td>18%</td>
</tr>
<tr>
<td>Betsi Cadwaladr (Maternity Support Worker)</td>
<td>1%</td>
<td>32%</td>
</tr>
<tr>
<td>Cwm Taf (Maternity Support Worker)</td>
<td>1%</td>
<td>35%</td>
</tr>
</tbody>
</table>
The highest proportion of treated smokers was observed in Cwm Taf UHB where 35% (CI 29%-43%) of pregnant smokers went on to set a quit date and attend at least one treatment session compared with just 1% (CI 0%-3%) in their usual care site.

In Abertawe Bro Morgannwg UHB just 5% (CI 3%-7%) of all pregnant smokers in the usual care site became treated smokers compared with 33% (CI 28%-38%) of all pregnant smokers in the intervention sites. The lowest proportion of treated smokers in an intervention site was observed in Aneurin Bevan UHB with 18% of pregnant smokers (CI 13%-23%).

Although overall the number of CO validated quitters was small, the proportion of pregnant smokers who ultimately went on to quit a 4 weeks (CO confirmed) was significantly higher across all intervention sites compared to usual care comparators.

The proportion of pregnant smokers who quit at 4 weeks (CO confirmed) ranged from 3% (CI 1%-6%) in Aneurin Bevan UHB’s intervention site to 12% (CI 9%-16%) of pregnant smokers in Betsi Cadwaladr UHB intervention site.

The proportion of treated smokers who went on to quit (CO validated) is also illustrated in Table 3. The highest proportion of treated smokers who went on to quit at 4 weeks was observed in Betsi Cadwaladr UHB, where 38% of treated smokers quit at 4 weeks (CI 29%-48%). However, this was not significantly different from their usual care comparator.

Only Abertawe Bro Morgannwg HB had a significantly higher proportion of treated smokers who quit at weeks in their intervention site with 29% (CI 21%-39%) of treated smokers quit at 4 weeks compared to 7% (CI 2%-23%) in their usual care comparator.
Figure 4: Summary of main outcomes between intervention and usual care sites in all MAMSS Health Boards

<table>
<thead>
<tr>
<th>% of total number of pregnant smokers</th>
<th>Referrals received by SSW or MAMSS</th>
<th>Accepted referrals</th>
<th>Treated smokers</th>
</tr>
</thead>
</table>
| **Abertawe Bro Morgannwg** (Midwife)**
Usual care                          | 36%                               | 18%                | 5%             |
| Intervention                         | 61%                               | 47%                | 33%            |

| **Aneurin Bevan** (Specialist SSW advisor)**
Usual care                          | 26%                               | 7%                 | 3%             |
| Intervention                         | 77%                               | 39%                | 18%            |

| **Betsi Cadwaladr** (Maternity Support Worker)**
Usual care                          | 18%                               | 6%                 | 1%             |
| Intervention                         | 91%                               | 75%                | 32%            |

| **Cwm Taf** (Maternity Support Worker)**
Usual care                          | 6%                                | 3%                 | 1%             |
| Intervention                         | 88%                               | 59%                | 35%            |
4.5 Qualitative evaluation

Findings will be presented chronologically, focusing on: compliance with NICE guidance, i.e. carbon monoxide testing all pregnant women and referring all smokers to stop smoking services; the provision of stop smoking support for pregnant women; and data collection. An overview of key findings is presented below; a full overview of the results can be found in appendix 4.

4.5.1 Adherence to NICE guidance

As part of this project, referring midwives in both intervention and usual care sites were invited to participate in training. As may have been expected due to the pressures on maternity services, there were some delays and difficulties in training all midwives; some staff remained untrained towards the end of the project. Some midwives who had not received training reported that they could ask their local MAMSS Practitioner(s) for support. The referring midwives who took part in interviews reported that they were confident discussing smoking with women. Moreover, midwives reported that the majority of women who were approached consented to CO testing. However, this was not always reflected in process data, with CO test results absent on MAMSS referral forms in one site, and varying compliance in other sites. This was in part due to a shortage of carbon monoxide monitors and a lack of replacement batteries for the monitors. In addition to removing environmental barriers, additional training and ongoing support was provided by MAMSS Practitioners and SSW to attempt to address this issue.

It appeared that midwives did not always adhere to a true opt out referral process (whereby a referral was made regardless of the patient’s belief, with the option to opt out when they spoke to the MAMSS Practitioner). Referring midwives in both usual care and intervention sites stated that patients reported that they were cutting down and thus felt that they did not need to access stop smoking support. In addition, following referral to SSW midwives reported that patients said that they were not usually contacted, and the referring midwife had no further contact from the service regarding that patient. This resulted in low motivation to refer patients, despite SSW making three attempts to telephone each pregnant woman, with the first call within 48 hours of referral.

A strong relationship was reported between referring midwives and MAMSS Practitioners, with regular communication, including informal discussions resulting from shared working space, and this was felt to support the adherence to NICE guidance.

However, interviewees noted that the costs of providing CO testing (monitors, mouth pieces and batteries) could not be met from within midwifery budgets at the beginning of the project.

4.5.2 Stop smoking support within intervention areas

Recruitment to the Band 3 MSW roles in one site was challenging. As none of the staff had previous experience in delivering smoking cessation support, all staff delivering specialist stop smoking support underwent comprehensive smoking cessation training.

When MAMSS Practitioners received a referral, they telephoned women within 48 hours, as per the protocol. When the Practitioner made contact, an appointment for an assessment session was offered. Following a high level of cancellations earlier in the project, the appointment was usually confirmed by text message. Cancellations remained higher than for routine midwifery care appointments. The initial telephone calls were often unanswered; MAMSS Practitioners left voicemail messages at these times.
Assessment and treatment sessions often took place in the women's home, and interviewees felt that this resulted in a higher level of engagement with the service. However, MAMSS Practitioners reported that many patients aimed to ‘cut down’, rather than quit smoking, and this was challenging within a treatment model which focused on abstinence.

Data presented in Figure 5 and Table 4 shows service usage. Figure 5 presents data regarding the number of treatment sessions received within a quit attempt, where an assessment session is equal to one and all subsequent sessions are treatment sessions, can be seen. In three of the four sites, the highest frequency of women attended for one session only. In Abertawe Bro Morgannwg HB, the highest frequency of women attended two sessions. The most sessions received within a treatment episode was 12. The mean number of sessions attend was 3.3.

Where women undertook multiple quit attempts, this is defined as having more than one treatment ‘episode’. For example, Mary attended for four sessions, but did not make a quit attempt on her planned quit date. As such, her MAMSS Practitioner closed that treatment episode and began a new (second) treatment episode when Mary felt ready to try to quit again. Table 4 shows that the number of additional treatment episodes varied by HB, with 17 new treatment episodes used in Betsi Cadwaladr, but only three in Cwm Taf. Accordingly, 32 treatment episodes were not related to unique individuals and this is not adjusted for in the analysis.

Figure 5: Number of sessions (assessment session, plus treatment sessions) attended:

![Graph showing the number of sessions attended across different treatment episodes.](image-url)
Table 4: The number of treatment episodes:

<table>
<thead>
<tr>
<th>Health Board</th>
<th>2 episodes</th>
<th>3 episodes</th>
<th>4 episodes</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>AB</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>ABM</td>
<td>8</td>
<td>0</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>BC</td>
<td>13</td>
<td>3</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td>CT</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>28</strong></td>
<td><strong>3</strong></td>
<td><strong>1</strong></td>
<td><strong>32</strong></td>
</tr>
</tbody>
</table>

As part of intensive behavioural support, MAMSS Practitioners provided documents (letters or cards) which enabled participants to access NRT. MAMSS Practitioners did not appear to provide consistent evidence-based advice regarding whether women should use NRT.

3 of the 5 Practitioners reported a need for additional training and ongoing support.

There were some issues with participants being able to exchange documents for NRT.

Patients and MAMSS Practitioners identified that stress, social barriers and addiction played a role in failed quit attempts. Alongside face-to-face support, MAMSS Practitioners contacted patients by telephone and text message, and this was usually initiated by the patient in relation to one of the above barriers to quitting.

4.5.3 Data collection

There were significant challenges and delays in the development of a MAMSS specific data management programme, Quit Manager. MAMSS Practitioners reported that challenges persisted as the system did not always perform as expected. This resulted in a high level of data entry error and additional support being provided by SSW, in order to train Practitioners and remove errors. In some areas, iPads were loaned from SSW to allow data collection within clients’ homes, but it was not possible to use the iPads to collect data on site without an internet connection.

MAMSS Practitioners were instructed to support women to set a quit date within their first few weeks of treatment, as is usual within UK Stop Smoking Services (West, 2005). Practitioners reported that some clients were reluctant to set a quit date. In addition to setting a quit date, all participants should have been followed up to assess their quit status four weeks from the quit date. Ideally follow up should be face-to-face to allow for CO verification, but within a flexible service this was not always possible. Moreover, it was reported that the Quit Manager system did not always provide advisors with reminders at the appropriate time to telephone participants to assess their self-reported quit status.
4.6 Intervention costs

The cost per treated smoker for each of the intervention sites was calculated from the total (actual) costs and the number of treated smokers for each site. Salary costs were modelled at the top of the relevant band for consistency across all four sites.

The main variables of interest are outlined in table 5. The highest cost per treated smoker was in Aneurin Bevan UHB who employed a Specialist SSW advisor for pregnant women at £1,171. The second highest cost per treated smoker was Abertawe Bro Morgannwg UHB who used the specialist midwife model at £777 per treated smoker.

It should be noted, however, that Abertawe Bro Morgannwg UHB employed 1.2 WTE Band 6 midwives whereas the other intervention sites employed 1 WTE practitioner. The numbers of treated smokers and other costs have not been adjusted to account for the higher staff ratio in Abertawe Bro Morgannwg UHB.

The lowest costs per treated smoker were calculated in Betsi Cadwaladr UHB (£484) and Cwm Taf UHB (£514). Both Cwm Taf UHB and Betsi Cadwaladr UHB employed Maternity Support Workers to deliver specialist smoking cessation support, with Cwm Taf UHB having one full time MSW, and Betsi Cadwaladr UHB employing two 0.5 WTE MSWs.

The start up costs and costs during the intervention period varied considerably between interventions and are not directly comparable.
### Table 5: Summary of costs of each MAMSS intervention per treated smoker

<table>
<thead>
<tr>
<th>Costs for 12 months*</th>
<th>Abertawe Bro Morgannwg</th>
<th>Aneurin Bevan</th>
<th>Betsi Cadwaladr</th>
<th>Cwm Taf **</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Start-up costs for staffing</strong></td>
<td>£1,850 (does not include training and consumables)</td>
<td>(itemised in separate rows)</td>
<td>£2,650 (does not include training and consumables)</td>
<td>£1,850 (does not include training or consumables)</td>
</tr>
<tr>
<td><strong>Salary cost (modelled at top of band)</strong></td>
<td><strong>£51,268 (1.2 WTE Band 6 midwife)</strong>&lt;br&gt;Two part-time (0.6 WTE) roles</td>
<td><strong>£34,521 (1 WTE Band 5 SSW advisor)</strong>&lt;br&gt;One full-time role</td>
<td><strong>£23,840 (1 WTE Band 3 MSW)</strong>&lt;br&gt;Two part-time (0.5) roles</td>
<td><strong>£23,840 (1 WTE Band 3 MSW)</strong>&lt;br&gt;1 full-time role</td>
</tr>
<tr>
<td><strong>Other staffing costs</strong>&lt;br&gt;(e.g. local support, national support, data validation and admin):</td>
<td>£7,660</td>
<td>£5,850</td>
<td>£5,933 (no holiday cover provided)</td>
<td>£8,880 (incl supervising MSW, admin and holiday cover)</td>
</tr>
<tr>
<td><strong>Travel</strong></td>
<td>£3,000</td>
<td>£1,200</td>
<td>£3,229</td>
<td>£2,424</td>
</tr>
<tr>
<td><strong>Training, internal and external</strong></td>
<td>£524</td>
<td>£1,100</td>
<td>£2,564</td>
<td>£1,100</td>
</tr>
<tr>
<td><strong>Consumables (phone, laptops etc)</strong></td>
<td>£7,965</td>
<td>£6,492</td>
<td>£3,920</td>
<td>£5,563</td>
</tr>
<tr>
<td><strong>Total 12 month cost</strong></td>
<td><strong>£72,267</strong></td>
<td><strong>£49,163</strong></td>
<td><strong>£42,136</strong></td>
<td><strong>£43,657</strong></td>
</tr>
<tr>
<td><strong>Number of treated smokers</strong></td>
<td>93</td>
<td>42</td>
<td>87</td>
<td>85</td>
</tr>
<tr>
<td><strong>Cost per treated smoker</strong></td>
<td><strong>£777</strong></td>
<td><strong>£1,171</strong></td>
<td><strong>£484</strong></td>
<td><strong>£514</strong></td>
</tr>
</tbody>
</table>

* Rounded to nearest £.

** Costs and number of treated smokers were available for 9 months only. Costs have been scaled up to 12 months.
Each UHB was asked to estimate its costs based on the following parameters at start up and during the intervention period:

- **Staffing** including local support, national support, data validation and admin
- **Consumables** including phones, laptops, monitors, printing
- **Travel**
- **Training** internal and external

Each of the UHBs have recorded and calculated costs in different ways making a direct comparison of cost per treated pregnant smoker less meaningful.

The costs were on occasion gathered in retrospect so are based on memory and sometimes assumptions. Only Cwm Taf UHB included printings costs at a total of £300.

Costs relating to validation of intervention data were not included as these were considered to be an evaluation cost as opposed to a cost of the intervention.
Pregnancy has been recognised as a ‘window of opportunity’ for smoking cessation (McBride, 2003). The MAMSS project uses this opportunity to provide a novel way of delivering stop smoking services to pregnant women.

The findings from this study have shown that pregnant smokers who received any type of MAMSS intervention were significantly more likely to be referred and engage with specialist stop smoking services (measured by the proportion of pregnant smokers defined as treated smokers) compared with the usual care service. The low percentage of referrals received in the usual care arm of the study possibly reflects the benefits of having the provision of the smoking cessation service embedded within the maternity service, which allows for regular feedback to midwives and maintaining the profile of the service in the intervention areas.

Based on our primary outcome measure, Cwm Taf UHB (MSW model) had the highest proportion pregnant smokers who went on to become a treated smoker (35%) followed by Abertawe Bro Morgannwg UHB (midwifery model, 33%).

Taking into account the costs and consequences analysis, the most cost effective model was the maternity support worker model, which in Betsi Cadwaladr UHB cost £484 per treated smoker and in Cwm Taf UHB cost £514 per treated smoker to implement.

A key finding of the evaluation was the lack of consistent adherence to NICE guidance, especially the opt-out referral pathway. This was particularly evident from the low number of referrals received in the usual care arm. Although the proportion of pregnant smokers for whom a referral was received was consistently higher in interventions sites, these were below 90%. The academic study of discretion (Lipsky, 2010) has identified that inconsistent application of guidance is as a result of the need to make quick, face-to-face, decisions; inadequate resources (including time) and unclear or conflicting organisational policies. In addition to this, research with nurses has identified that if a Practitioner’s beliefs conflict with organisational policy, they may not apply it (Provis and Stack, 2004).
Applying this theory to the results of the process evaluation, we can begin to understand why NICE guidance and the Russell Standard may not have been consistently implemented.

Due to the demands of busy maternity services, it was not possible for all midwives to be trained in the NICE referral pathway.

Moreover, midwives identified that their role in booking clinics was fast paced, and thus they may have been short of time to undertake CO testing and to offer a referral. In addition to this, for at least some of the study period, there were inadequate numbers of functioning carbon monoxide monitors, to enable testing. There were challenges in releasing midwives from their routine workloads to enable training in how to identify and refer pregnant smokers in both intervention and usual care areas, and some midwives remained untrained at the end of the project. Accordingly, midwives may not have been clear what their role was in implementing NICE guidance. Moreover, in not enabling all midwifery staff to attend training and not providing funding for CO monitors and associated consumables, it can be seen that maternity services support for the policy was not absolute and midwives may thus have not received clear and consistent messages.

Whilst most midwives reported that they did not find it difficult to discuss smoking with patients, one midwife highlighted concerns that her relationship with patients may be jeopardised by discussing smoking, and this may lead to a rejection of NICE guidance. It is also recognised that midwives offer a range of screening tests and interventions, all of which require informed consent, whilst the opt-out referral process for smoking cessation takes a different approach.
Within usual care areas, a lack of apparent action from stop smoking services following a referral was highlighted as reducing motivation to refer patients. Moreover, in both intervention areas and usual care areas, there was little oversight of the implementation of NICE guidance from within the maternity team, and this may have reduced the perceived importance of conducting this work within a work environment with significant time pressures.

In relation to the intervention, MAMSS Practitioners were expected to facilitate the setting of quit dates, and to monitor abstinence four weeks after the quit dates. Regarding setting quit dates, MAMSS Practitioners stated there were no challenges with resources. Accordingly, it is likely that unclear or inconsistent guidance - alongside client reluctance – was likely to have played a role in some Practitioners not supporting clients to set a quit date. Moreover, some Practitioners reported they found it difficult to discharge clients who did not set a quit date (the guidance to which they should have worked within), because it did not appear to fit within the ethos of a flexible service and they were hopeful that the woman would go on to set a quit date in the future.

Challenges were also identified which influenced the monitoring and recording of four week quit dates.

Whilst time to undertake four week reviews was not an issue, a technical failing within the Quit Manager system resulted in Practitioners not being reminded to make telephone calls to clients. In addition to this, it appeared that some Practitioners were not aware of the importance of undertaking four-week reviews at the outset of the pilot, due to unclear guidance and a lack of pro-active supervision from a stop smoking specialist. As such, there may have been higher rates of four-week quits than were recorded.

This study has addressed several areas where there are key evidence gaps relating to pregnant women and stop smoking interventions. Specifically, how best to encourage pregnant women to attend a specialist stop smoking support service, how to deliver the service and who should provide it.

The study has revealed important findings in relation to service delivery and in doing so will enable local services to improve their effectiveness in a challenging area of public health.

Ensuring better identification of pregnant smokers and providing access to timely support from smoking cessation specialists is crucial to reducing the number of women smoking during pregnancy in Wales. Investigating ways to provide a more flexible, women-centred approach is an important development which will assist in reducing the range of adverse factors for both mother and baby associated with maternal smoking behaviour.

This study adopted a quasi-experiment design for practical and logistical reasons. The use of a comparison (usual care) group helped to prevent certain threats to validity including the ability to statistically adjust for confounding variables. It should be noted, however, that data presented in this report is unadjusted to account for baseline differences (e.g. smoking prevalence) as the data analysis was not undertaken at the individual level.
Limitations of the cost-analysis can be summarised as follows:

- Abertawe Bro Morgannwg UHB employed 1.2 WTE midwives whereas the other sites employed 1 WTE practitioner. Outcomes and costs have not been adjusted to account for the higher staff ratio in Abertawe Bro Morgannwg UHB.

- The analysis does not account for costs avoided.

- Phone calls / texts not recorded.

- To begin with, the practitioners had not developed skills in identifying those women who really wanted to quit compared to those who were not motivated enough.

- It is not possible to compare this service with other stop smoking services (i.e. those for general population or other pregnancy services) as this was a developmental stage.

- The cost per treated smoker is not comparable to cost per quitter. Therefore, it is not possible to compare to SSW or pharmacy as the services are very different.

It is important to recognise the complexity of social and political forces that exist which might have accounted for the effects seen.

For example, during the intervention period there were several service improvements, which occurred in the usual care service and were beyond the control of the MAMSS steering group. Such changes might have affected associated outcomes. Similarly, although it was understood that usual care was delivering services in line with NICE guidance (for example, training for maternity staff and the use of CO monitoring) evidence from the process evaluation suggests a level of inconsistency in implementation.

Therefore, results might have been confounded by different practices in usual care sites. Despite this, we feel from the outcomes demonstrated, the process evaluation and cost analysis that the benefit seen is likely due to the intervention and changes in service delivery put in place.
# Recommendations

1. **Strict adherence to NICE guidance across all maternity and stop smoking services in Wales including:**
   a. Provision of CO monitors and necessary consumables to every midwife in Wales
   b. An audit of midwives’ training needs
   c. Provision of training (where required), ongoing support and regular feedback for all midwives
   d. Consistent opt out referral system
   e. Regular audit of CO monitoring and opt-out referral system

2. **Specialist stop smoking support to become a key component of antenatal care rather than ‘add-on’ service. Stop smoking specialist embedded within antenatal care, visible to midwives and maternity support workers.**

3. **Recruitment of specialist maternity support workers within maternity services who specialise in supporting women to stop smoking during pregnancy with dedicated administration support.**

4. **Regular supervision of specialist staff by both midwifery and stop smoking services.**

5. **Flexible method of treatment delivery to include home based, one-to-one appointments and unlimited treatment throughout pregnancy. Text and telephone support if required.**

6. **Consistent and bespoke data collection / recording to reflect the flexible model of delivery required for pregnant women and use of electronic data management systems. In particular, the recording of CO monitoring outcome is vital as self-report smoking status is unreliable and is important for evaluation purposes.**

7. **Collection, recording and evaluation of data on smoking status at booking and in the third trimester and birth outcomes (low birth weight (<2500 g), preterm birth <37 weeks).**

8. **Opportunity for referral to specialist stop smoking service at any point during pregnancy.**

9. **Feedback to referring midwives on progress and outcomes of women referred to the stop smoking service.**

10. **Provision of consistent evidence-based advice regarding whether women should use NRT and to facilitate the process of accessing NRT for women who require it.**
Next steps

1. Audit implementation of NICE guidance
   across all maternity and stop smoking service in Wales.

2. Secure funding
   to employ specialist stop smoking Maternity Support Workers
   for pregnant women across Wales and to provide all necessary
   equipment. Staff to be embedded within antenatal care and
   have strong links with the national stop smoking service.

3. Review methods and systems
   for consistent data collection and data recording,
   reflecting the flexible delivery model.

4. Ongoing evaluation
   of new services examining outcomes including treated
   smoker and quit status of pregnant women during
   pregnancy and birth outcomes.
Supporting pregnant women to engage with stop smoking services and to quit smoking is a challenging area of public health.

The importance of targeting pregnant women who smoke within the antenatal clinic setting has been described previously (Fendall et al, 2012). This is due to the fact that even hard-to-reach women attend the antenatal clinic as non-attendance is seen as a child protection issue.

Our study supports this view since the service delivery model developed for MAMSS, including the recruitment of specialist stop smoking practitioners who based themselves within the antenatal setting, has produced positive results in terms of referrals to services and engagement.

Due to the known difficulties in quitting smoking amongst pregnant women, we did not expect quit rates to be high. However, based on data received to date, an increase in quit rates was observed and any reduction in smoking behaviour amongst this population will be extremely beneficial to both women’s and babies’ health. The new models developed by MAMSS therefore have the potential to deliver improved health for women and their babies at a reasonable cost.
References


# Appendices

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Appendix 1

**STUDY PROTOCOL**

Models for Access to Maternal Smoking cessation Support (MAMSS): a study protocol of a quasi-experiment to increase the engagement of pregnant women who smoke in NHS Stop Smoking Services

Lorna Bennett, Aimee Grant*, Siobhan Jones, Mererid Bowley, Christian Heathcote-Elliott, Catrin Ford, Angela Jones, Rachel Lewis, Margaret Munkley, Carol Owen, Annie Petherick and Shantini Paranjothy

Abstract

**Background:** Maternal smoking is a key cause of poor outcomes for mothers, babies and children and Wales has higher rates of smoking in pregnancy than any other UK country. Despite various improvements within the NHS Stop Smoking Service to strengthen the intervention for pregnant women, referrals and successful quit attempts for this group have continued to remain extremely low. A key element of UK national guidance for smoking cessation during pregnancy is to provide a flexible and tailored service to help increase levels of engagement. This study aims to test the effectiveness of three different models of service delivery to address the gap in the evidence base about how to deliver a flexible, tailored smoking cessation service to pregnant women.

**Methods:** This study will adopt a quasi-experimental design over a 12 month period. The setting is four of Wales’ seven Health Boards using an integrated approach between maternity services, local public health teams and the NHS Stop Smoking Service. Core recommendations from UK public health guidance are being implemented across intervention and usual care sites. Stop smoking support for pregnant women in intervention sites is being delivered more flexibly than in usual care sites. Both qualitative and quantitative approaches will be adopted to capture important contextual information and consider multiple perspectives. A health economic analysis will be undertaken using a cost-consequences analysis approach. The primary outcome measure is engagement with stop smoking services (defined as having at least one face-to-face therapeutic contact with a clinician).

**Discussion:** Supporting pregnant women to stop smoking is a challenging area of public health. The proposed study will address several areas where there are key evidence gaps relating to smoking cessation interventions for pregnant women. Specifically, how best to encourage pregnant women to attend a specialist stop smoking support service, how to deliver the service and who should provide it.

**Keywords:** Smoking, Smoking cessation, Stop smoking services, Pregnant women, Pregnancy, Midwife, Maternity support worker, Quasi-experiment, Service delivery

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Models for Access to Maternal Smoking Cessation Support

Background
A third of pregnant women living in Wales smoke before or during their pregnancy compared to just over a quarter of women living in other areas of the UK [1]. This is a major concern since maternal smoking is a key cause of poor outcomes for mothers, babies and children. It is associated with increased risk of miscarriage, perinatal death, prematurity, low birth weight and congenital abnormalities in the baby in particular of the heart, face and limbs [2,3]. Supporting pregnant women to stop smoking is thus an important area of public health.

High quality evidence exists for interventions to promote smoking cessation in pregnancy. A Cochrane review found that psychosocial interventions led to a reduction in smoking during pregnancy and reduced the risk of low birth weight and pre-term birth [4]. UK public health guidance on interventions aimed at stopping smoking in pregnancy and following childbirth provides a clear pathway and referral mechanism for pregnant smokers into NHS Stop Smoking Services [5].

A key component of this guidance is carbon monoxide (CO) testing for all pregnant women to assess their level of exposure to CO either as smokers themselves or from other sources. Test results are used to ensure the appropriate identification of smokers for onward referral to specialist support services. It has been estimated that 20 per cent of smokers deny their habit when cotinine measurements are compared with self-report [6], leaving these pregnant smokers without the information available to facilitate a quit attempt. It has been reported in UK based research that employing the carbon monoxide test in conjunction with self-report improves the identification of smokers, but that maternity staff have found it difficult to discuss smoking and administer the test [7].

A further key element of UK national guidance for smoking cessation during pregnancy is to provide a flexible and tailored service for pregnant women to help increase levels of engagement. This is due to the fact that pregnant women may not feel comfortable or have all their needs met when attending generic services. Many English stop smoking services offer a flexible service for pregnant women [8]. However, it is not known how best to deliver such a service or who should provide it.

Within the Welsh NHS Stop Smoking Service, various service improvements have occurred since 2009 with a view to strengthening the referral system for pregnant women who smoke from antenatal units to the stop smoking service. These service improvements have included additional training of midwifery staff, in line with National Institute for Health and Care Excellence (NICE) guidance, to encourage the use of CO testing. Despite this, referrals into the service and engagement with pregnant women has continued to remain extremely low. For example, data from the Stop Smoking Service show that in the referral period May 2012-March 2013, 1,817 pregnant smokers were referred to the service from maternity services, but only 529 went on to accept an appointment. At this time, there were around 32,000 births in Wales [9] based on a smoking prevalence of 33% [1], 5.6% of smokers were referred to the service, and 1.6% of smokers accepted an appointment. In response, key partners were brought together across Wales to develop a public health study, Models for Access to Maternal Smoking cessation Support (MAMSS) with the aim of testing the effectiveness of three different models of service delivery to address the gap in the evidence base about how to deliver a flexible tailored smoking cessation service to pregnant women.

Methods
This study will be undertaken as a quasi-experimental design. Donabedian’s conceptual model for examining health services and evaluating quality of care as a framework for examining structures, processes and outcomes will be applied [10]. The setting will be four of Wales’ seven Health Boards. These are single local health organisations responsible for planning, securing and delivering all healthcare services within a geographical area. The Health Boards involved in the study are self-selected and are geographically diverse. Total population figures range from 294,497 to 690,434 [11] and live births range from 63.9 to 66.3 per 1000 women aged 15-44 [9] (see Table 1).

Interventions
The study will take place over 12 months using an integrated approach between maternity services, local public health teams and the NHS Stop Smoking Service. In each Health Board, an intervention and a usual care site will be selected from existing community midwifery teams. Sites will be selected on the basis of high rates of pregnant smokers, and a similar demographic profile in intervention and usual care sites within each Health Board. Pregnant smokers (i.e. those who are self-reported current smokers or have a CO reading ≥ 7 ppm) or who have quit in the two weeks prior to their booking appointment [5]) will be referred to the intervention or usual care NHS Stop Smoking Service on an opt out basis (see Figures 1 and 2). This automatically refers pregnant smokers to the service. The two main points for referral are the first antenatal appointment (at home or in a community antenatal clinic by the midwife) or subsequent scheduled antenatal care visits (by the midwife). However, the referral process can take place at any stage during pregnancy, for example, during the postpartum period whilst under the care of a midwife.

In intervention sites, pregnant smokers will be referred to one of three different models of service delivery where smoking cessation services are provided by maternity support workers, midwives or smoking cessation advisors dedicated to working with pregnant women, all offering a
flexible service designed to meet the needs of the women. The core elements of the evidence base to be implemented in all intervention sites will include:

- Strict adherence to NICE opt out smoking cessation pathway for pregnant women, including CO monitoring.
- Smoking cessation services being more closely aligned to maternity services (provided as part of the package of maternity care).
- Referral from midwife to smoking cessation support within 48 hours.
- Flexibility in service model with a women centred approach.

Each intervention site will recruit a whole-time equivalent (WTE) maternity support worker (employed by the Health Board), midwife (employed by the Health Board) or dedicated Stop Smoking Advisor for pregnant women (employed by the NHS Stop Smoking Service) who will deliver stop smoking support to pregnant women. These staff will receive referrals directly from midwives to provide an intensive smoking cessation intervention at times and settings of the women’s choice, including home visits. During every subsequent antenatal appointment, women will be asked about their smoking status and referred as appropriate. If a woman has declined treatment (i.e. she opts-out by not answering the telephone to stop smoking services or refuses an assessment appointment) she will be asked if she would like to be re-referred during each follow-up appointment.

Clients in intervention sites will be offered smoking cessation support for the duration of their pregnancy if required. The support they receive will follow an adapted behavioural intervention model documented in the NHS Stop Smoking Service delivery manual, which is based on withdrawal oriented therapy (Maudsley model) [12]. This may involve a combination of telephone and face to face support as well as motivational support by email and or text, dependent upon the needs of the client (see Figure 1). A detailed manual for specialist smoking cessation staff has been developed for use in all intervention sites detailing the referral pathway, intervention programme, policies, procedures and support materials.

### Comparison group (usual care)

Pregnant smokers will be referred on an opt out basis to NHS Stop Smoking Services in usual care sites. The core elements of this service are:

- Referrals received by NHS Stop Smoking Service from midwives via fax or phone call.
- Stop smoking staff make an attempt to contact the pregnant women within 48 hours to discuss benefits of quitting, offer support and arrange an assessment session.
- NHS Stop Smoking Service staff attempt to contact the client by telephone twice more if contact has not been established, and send a follow up letter if no response.
- Clients who do not opt out are fast tracked into a one-to-one assessment session appointment within 48 hours. Assessment sessions are conducted in community venues.
- Women are offered six further sessions of intensive behavioural support in community venues or by telephone.
- If the client requires additional support following the seven sessions, the advisor will arrange to make contact by telephone in two weeks to provide an additional follow up.

### Outcome measures

The primary outcome measure is engagement with stop smoking services (defined as having at least one face-to-face therapeutic contact with an advisor) and secondary outcome measures are pregnant smokers who set a quit date; pregnant smokers who quit at four weeks follow-up (CO verified); smoking status at the time of birth or third trimester and 52 weeks; and birth outcomes (low birth weight (<2500 g), preterm birth <37 weeks).

Process measures will assess fidelity to protocols, feasibility, acceptability, maintenance and sustainability should the interventions be rolled out on a wider scale. Data will be obtained from available data sources within maternity services and the NHS Stop Smoking Service on specific aspects of the referral pathway and treatment programme.

### Sample

Women who are pregnant and smoke or who have quit smoking in the two weeks prior to their initial antenatal booking appointment will be eligible to participate. The inclusion criteria are pregnant or postnatal women, under the care of a midwife, who are either a current smoker (self-report or verified through CO reading of ≥7 ppm) or ex-smoker (quit within two weeks prior to booking appointment). The exclusion criteria are pregnant women who are not smokers or who have reduced mental capacity.

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**Table 1 Total population and live births per 1000 for Health Boards participating in MAMSS**

<table>
<thead>
<tr>
<th>Health board</th>
<th>Total population</th>
<th>Live births per 1000 women aged 15-44</th>
</tr>
</thead>
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<tr>
<td>Health board 1</td>
<td>519,781</td>
<td>60.0</td>
</tr>
<tr>
<td>Health board 2</td>
<td>577,981</td>
<td>61.8</td>
</tr>
<tr>
<td>Health board 3</td>
<td>690,704</td>
<td>64.8</td>
</tr>
<tr>
<td>Health board 4</td>
<td>294,497</td>
<td>61.7</td>
</tr>
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Bennett et al. BMC Public Health 2014, 14:1041
http://www.biomedcentral.com/1471-2458/14/1041
**Models for Access to Maternal Smoking Cessation Support**

First antenatal appointment: midwives follow a standardised protocol
- Measure women’s carbon monoxide (CO) level
- Ask smoking status
- Ask if anyone else in the household smokes
- Record (CO) level and smoking status in notes

If identified as a smoker, referral is made for smoking cessation support

**Usual care**
- Referral from midwife to NHS Stop Smoking Service via fax or phone call.
- Stop smoking staff make an attempt to contact the pregnant woman within 48 hours to discuss benefits of quitting, offer support and arrange an assessment session.
- NHS Stop Smoking Service staff attempt to contact the client by telephone twice more if contact has not been established, and send a follow up letter if no response.

**Intervention**
- Referral from midwife to smoking cessation support within 48 hours.
- MAMSS clinician attempts to contact pregnant woman by telephone (or face-to-face at clinic) within 48 hours to discuss support and to arrange an appointment for an assessment session.
- MAMSS clinician attempts to contact the client by telephone at least twice more if contact has not been established.

**Figure 1** Referral and treatment in usual care and intervention sites.

- Woman does not answer telephone or refuses treatment
- Woman accepts appointment

- Women are fast tracked into a one-to-one assessment session appointment within 48 hours. Assessment sessions are conducted in community venues.
- Women are offered six further sessions of intensive behavioural support in community venues or by telephone, each lasting around 30 minutes.
- Women are CO monitored at all treatment sessions
- If the client requires additional support following the seven sessions, the advisor will arrange to make contact by telephone in two weeks to provide an additional follow up.

**Approach: Flexibility in service model with a women centred approach.**
- Face-to-face assessment session, within 1 week of contact, in location of woman’s choice
- Women are offered intervention sessions at a location of their choice, each lasting around 30-60 minutes
- The number and frequency of treatment sessions will be according to the woman’s choice, including the option of support by text message or telephone.
- Women are CO monitored during face-to-face treatment sessions and at 4-6 weeks after their quit date.
Sample size
We hypothesise that the flexible models of service delivery can increase the percentage of pregnant women who engage with smoking cessation services from 10 per cent (current rate of engagement in NHS England smoking cessation services) to 25 per cent. A sample size of 146 pregnant smokers in each group within each Health Board will allow a 15 per cent difference to be detected in the proportion of pregnant smokers who engage, with a five per cent type I error rate and 90 per cent power.

Quantitative data collection
Quantitative data collection will principally utilise routine data from: i) the Health Board’s electronic Patient Administration System (PAS) and Maternity Information System, which contain information about expectant mothers smoking status and birth outcomes and ii) the NHS Stop Smoking Service database which will record referral and treatment information for all intervention and usual care clients. Each Health Board uses a national standardised maternity record. The maternity record aims to improve quality and safety of maternity care and is updated regularly according to national guidelines to represent the latest recommendations for best practice. Within the record, there is a comprehensive risk assessment which identifies individual risk factors, including smoking status, for the expectant mother. Data from the patient hand-held record is entered into each Health Board’s electronic PAS and Maternity Information System (where available). Additional file 1 provides detail about the specific data items to be extracted from the PAS and Maternity Information System for this study.

Information about the referral pathway and stop smoking treatment programme will be entered onto a separate database used by the existing NHS Stop Smoking Service which has recently undergone developments including the ability to conduct e-referrals. Data items to be extracted are detailed in Additional file 1. To facilitate this process, Memoranda of Understanding (MoU) will be established between Public Health Wales Informatics team and the four participating Health Boards and between Public Health Wales Informatics and the NHS Stop Smoking Service which will allow Public Health Wales to hold and process Health Board and NHS Stop Smoking Service data on their behalf. Approval will be sought from each Health Board and the NHS Stop Smoking Service to allow Public Health Wales Informatics to release anonymised data to specified analysts for use in accordance with an agreed
analysis plan. The Public Health Wales Informatics team will act as the NHS Stop Smoking Service’s and the Health Board’s agent in this process and undertake any linking that has to be undertaken before anonymising the data and providing it to analysts. All data will be anonymised, therefore patient confidentiality will be maintained. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act which requires data to be anonymised as soon as it is practical to do so.

Analysis
Baseline demographic and social characteristics of pregnant smokers in both intervention and usual care sites will be summarised using descriptive statistics. Comparisons between the two groups will be carried out using a Student’s t-test or a non-parametric test for continuous data and a chi-squared test or a Fisher’s exact test for categorical data. Characteristics of women who do not opt out of the referral will be compared to those who do. Continuous data will be expressed as mean values with standard deviations and categorical data will be presented as counts with percentages. A single logistic regression model will be developed to obtain odds ratios for the comparison of different interventions with usual care, and for comparisons between interventions. Differences in baseline characteristics of individuals and referral rates for Stop Smoking Services will be adjusted for. To account for the geographical clustering of individuals, robust standard errors will be calculated.

Qualitative evaluation
Staff delivering treatment or referring women for treatment in all usual care areas and in three of the intervention areas will be invited to take part in semi-structured interviews. All 32 usual care advisors will be emailed with an information sheet and asked to contact the researcher if they are experienced in supporting pregnant women. If low response occurs, further invitations will be sent by email. Staff in selected intervention areas will be recruited via the Health Board’s lead or co-lead for the study. Staff will have the opportunity to undertake an interview either face-to-face within a private room in their workplace, or by telephone at a time that is convenient for them.

Clients who receive treatment will be invited to take part in the study by the staff delivering their treatment. If a client expresses an interest in the study, staff will provide them with an information sheet, containing contact details for the researcher. The client can then opt in by contacting the researcher. Whilst staff introduction will introduce bias into the sample, and a low response rate is likely due to the opt-in procedure, it will allow vulnerable women the opportunity to take part in research. In order to minimise data collection costs in a large research site, ensure researcher safety and to encourage clients to be open about their treatment, interviews will be conducted by telephone. Whilst traditionally face-to-face interviewing has been seen as important for health research, the advantages of telephone interviewing are increasingly recognised [13].

If participants consent, interviews will be audio recorded and transcribed verbatim. Comprehensive notes will be taken if consent is refused. Qualitative data will be analysed using a structured approach. Framework analysis, which involves five stages: familiarisation, constructing an initial framework, coding, reviewing data extracts and conclusion drawing [14]. Transcripts will be coded by hand, before being displayed in tables, with all instances of one code examined together. Finally conclusions will be drawn by identifying salient themes in the tables. The use of a structured approach aims to minimise researcher bias. Moreover, each stage of the analysis will be agreed by two researchers, with inconsistencies discussed and resolved.

Economic evaluation
A health economic analysis will be undertaken using a cost-consequences analysis approach. Over a period of 12-months, cost data will be collected on wages, travel, training, NRT prescribing and average length of intervention per client. Summary information for these costs will be presented in a tabular format against the consequences of each intervention. Consequences are defined as the primary and secondary outcome measures previously described.

Ethical considerations
We contacted the Research and Development manager for all four sites. One Health Board, Cwm Taf Health Board, received NHS ethical approval (South East Wales Research Ethics Committee). In the other three sites the research was declared service evaluation by the Research and Development manager (Abertawe Bro Morgannwg University Health Board ), the Clinical Audit and Effectiveness Manager (Betsi Cadwaladr University Health Board) and the Aneurin Bevan Health Board Research Risk Review Committee (Aneurin Bevan Health Board). As a result the project did not require NHS ethical approval. This decision was approved by the NHS Research Ethics Committee (REC) for Wales. Research and development approvals were obtained from all four Health Boards and Public Health Wales NHS Trust.

Discussion
A quasi-experimental design for the proposed study was adopted as it was not logistically feasible to conduct a cluster randomised controlled trial in the desired timescales and within the available budget [15]. Although the
randomised controlled trial is generally considered to have the highest level of credibility with regard to assessing causality, the use of a comparison group helps prevent certain threats to validity including the ability to statistically adjust for confounding variables.

The proposed study will address several areas where there are key evidence gaps relating to pregnant women and smoking cessation interventions. Specifically, how best to encourage pregnant women to attend a specialist stop smoking support service, how to deliver the service and who should provide it. The study will reveal important findings in relation to service delivery and enable local services to improve their effectiveness in a challenging area of public health. Ensuring better identification of pregnant smokers and providing access to timely support from smoking cessation specialists is crucial to reducing the number of women smoking during pregnancy in Wales. Investigating ways to provide a more flexible, women-centred approach is an important development which will assist in reducing the range of adverse factors for both mother and baby associated with maternal smoking behaviour.

Endnotes

1 The NHS Stop Smoking Service in Wales is known as Stop Smoking Wales. The service is funded and run by Public Health Wales NHS Trust - an NHS organisation providing professionally independent public health advice and services to protect and improve the health and wellbeing of the population of Wales. It contributes to national and local tobacco control initiatives and has a key role in reducing the impact of tobacco on the health of people in Wales.

2 A lower level (e.g. 3 ppm) may apply for light/in frequent smokers. A higher level might apply if prior exposure to other sources of pollution e.g. traffic fume, leaky gas appliances [5].

3 The use of 7 ppm was adopted as it was accepted best practice, contained in NICE guidance, at the time of the research design. It is likely that NICE will move to 4 ppm in the future, and some existing research is already using this definition. We recommend that future research use a definition of 4 ppm.

Additional file

Additional file 1: Data items to be extracted from NHS systems.

Abbreviations

CO: Carbon monoxide; MAMSS: Models for access to smoking cessation support; MoU: Memorandum of understanding; NHS: National Health Service; NICE: National Institute for Health and Care Excellence; NRT: Nicotine replacement therapy; PAS: Patient administration system; UK: United Kingdom; WTE: Whole time equivalent.

Competing interests

The authors declare they have no competing interests.

Authors’ contributions

SJ provides the overall lead for the development, implementation and coordination of the MAMSS study. LB and SP have designed the data collection and developed the study protocol. MB, AJ, CH, SJ, RL, AP, MM and CF have led the development and implementation of the study in each Health Board area. CO has provided expertise on stop smoking services. CH has provided expertise in economic evaluation. AG has led the qualitative research components in the study. All authors have contributed to the development of the study, writing the protocol and approved the final version.

Acknowledgements

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### Appendix 2: Data requirements for Models for Access to Maternal Smoking Cessation Support (MAMSS)

#### Data required from all pregnant women who smoke (and those quit in past 2 weeks):

**Data source: Health Board Maternity System**
- NHS number
- Age (taken at book in, will include book in date)
- Postcode
- Agreed estimated date of delivery
- Employment
- Occupation
- Do you smoke?
- If yes, how many cigarettes do you smoke each day?
- Have you smoked in the last 2 weeks?
- When did you stop smoking?
- Have you been offered advice on how to stop smoking?
- Have risks of smoking been explained to you?
- Have you received written information on how to stop smoking?
- CO reading
- Date of referral
- Does your current partner smoke?
- Are you exposed to cigarette smoke at home?
- Which groups do you most identify with? (Ethnicity)

#### Data required for all pregnant smokers (and those quit in past 2 weeks) WHO OPT OUT:

**Data source: Stop Smoking Wales Quit Manager/ Interim Excel spreadsheet**

**Referral information:**
- NHS number
- Date received
- Name of midwife
- Hospital
- Local Area
- Smoker?
- If ex smoker date when stopped
- For smokers only, permission to pass details to SSW
- Name
- Address
- Postcode
- Contact telephone

#### Data required from pregnant smokers (and those quit in past 2 weeks) who DO NOT OPT OUT:

**Data source: Stop Smoking Wales Quit Manager/ Interim Excel spreadsheet**

**Referral information:**
- NHS number
- Mobile
- Due date
- CO Reading
- Attempt 1
- Attempt 2
- Attempt 3 (Letter to be sent)
- Letter Sent
- Details of conversation
- Client Code
- Date & Venue of Appt
- Advisor

**All treatment programme information**

---

**Data required for all pregnant smokers (and those quit in past 2 weeks) WHO OPT OUT:**

**Data source: Stop Smoking Advisor (pregnancy) spreadsheet or Health Board Maternity system**
- NHS number
- Full name
- Postcode
- DOB

**Data required from pregnant smokers (and those quit in past 2 weeks) who DO NOT OPT OUT:**

**Data source: Health Board Maternity system**
- Date and time of birth
- Live / still birth
- Birth weight
- Smoking status during third trimester
- Gestational age

---

**Public Health Wales Data Warehouse**
Appendix 3: Details of those invited to take part in qualitative interviews, and interview participants

<table>
<thead>
<tr>
<th>Participant type</th>
<th>Referring midwife</th>
<th>Treat ing clinician</th>
<th>Smoking cessation service user</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site</td>
<td>Invited</td>
<td>Participated</td>
<td>Invited</td>
</tr>
<tr>
<td>ABHB</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>ABMU</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>BCU</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Cwm Taf</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Usual care/Stop Smoking Wales</td>
<td>4</td>
<td>4</td>
<td>32</td>
</tr>
<tr>
<td>TOTAL</td>
<td>10</td>
<td>9</td>
<td>37</td>
</tr>
</tbody>
</table>

1 The service user and her partner, who had also been supported, took part in interviews, although this has only been counted as one interview.
2 One of the treating clinicians took part in an interview on two occasions, as the clinicians were initially interviewed near the start of the project.
3 Both clinicians took part in a single interview
4 It was not known how many of the 32 advisors had experience of supporting pregnant women
Appendix 4: Detailed description of process evaluation findings

Findings are presented chronologically, focusing on: setting up the pilot sites; training; compliance to NICE guidance, i.e. carbon monoxide testing all pregnant women and referring smokers to stop smoking services; the provision of stop smoking support for pregnant women; and data collection. Throughout this appendix, the staff delivering MAMSS smoking cessation support (midwives, midwifery support workers and specialist stop smoking advisors) will be jointly referred to as MAMSS Practitioners to protect their anonymity. Midwifery staff referring patients to MAMSS will be referred to as referring midwives or midwives.

1. Setting up the pilot sites

1.1 MAMSS Intervention sites
Recruitment of specialist smoking Practitioners into the band 3, Maternity Support Worker, roles was challenging in one site, but non-problematic in other sites. None of the MAMSS Practitioners had previous experience of delivering smoking cessation, although most had some interest in the area of smoking cessation. MAMSS Practitioners reported they had very good relationships with midwifery staff, and in the site where the MAMSS Practitioner was new to the department, an induction was provided by the midwifery team.

In some pilot areas, promotional posters were created and displayed in maternity waiting areas, in order to inform women that the project was running, before they were invited to participate.

MAMSS Practitioners and referring midwives reported a very strong working relationship, which enabled frequent (often face-to-face) communication about women who had been referred to MAMSS. MAMSS Practitioners were also directly contactable by email and mobile telephone. This was viewed as highly beneficial, and enabled women who may have been lost at the referral stage, due to lack of engagement, to be re-referred by the midwife.

All Practitioners noted that they had support from within maternity teams, their local public health team or Stop Smoking Wales. As such, if a difficulty arose, they felt confident that they could solve it.

1.2 Usual care sites: service improvements
During the intervention period, service development occurred within the usual care service. Advisors were interviewed near the start of the research project, and thus improvements have already occurred in some areas. For example, a new e-referral process was put in place to ensure referrals were not lost, a new target was put in place to contact all women within 48 hours of referral, to book four women to attend each one-to-one appointment in order to reduce waiting lists and the number of wasted advisor hours due to non-attendance. All advisors had also been asked to undertake the online pregnancy training module created by the National Centre for Smoking Cessation and Training.
2. Training

2.1 Referring midwives
The project aimed to provide referring midwives in intervention and usual care sites with training in brief intervention for smoking cessation and how to CO test pregnant women. There were some delays and difficulties in achieving this, with some maternity staff remaining untrained towards the end of the project. Referring midwives reported different levels of training; some reported attending a short course (‘hours not days’), but others had not received any training related to smoking in recent years. Some midwives who had not attended training noted that they could ask for support from MAMSS Practitioners working in their area. Referring midwives varied in the extent they desired further training, with some midwives concerned that further training may lead to them having to undertake a specialist smoking cessation role within routine maternity services, which they objected to.

2.2 MAMSS Practitioners
MAMSS Practitioners attended comprehensive smoking cessation training, provided either by the National Centre for Smoking Cessation and Training (NCSCT) or the Maudsley Clinic. All reported feeling qualified for their role. However, some staff found the online component of the NCSCT training challenging due to their lack of experience in smoking cessation. Some staff received regular updates from SSW advisors working in their area, but others did not report this.
3. Adherence to NICE guidance: identification and referral of pregnant smokers

The referring midwives who took part in interviews reported that they were confident discussing smoking with women, but that these conversations could be difficult to manage. However, this should be seen in the context of a sample of midwives who chose to take part in an interview about smoking in pregnancy.

3.1 Carbon monoxide testing all pregnant women

All pregnant women should have been carbon monoxide tested at booking in order to determine their smoking status. Adherence varied in both intervention and usual care sites. For example, early in the project it was relatively common in all sites for referrals to be entered onto the MAMSS project database without a CO reading, and additional training was provided. Some MAMSS local leads identified referring midwives who were not routinely CO monitoring women and provided further training. It was not possible to quantify the extent of the issue as none of the Health Boards were collecting data on this at the time of the study.

However, environmental and social barriers existed resulting in low fidelity to CO testing. For example, early in the project, some of the CO monitors were producing false readings, which may have led to distrust of the equipment. The service delivery model relied on each midwife who was booking women to have a CO monitor. Consumables associated with monitoring women included batteries, mouth pieces and wipes. Throughout the project, maternity departments reported a lack of funds to purchase the necessary equipment and consumables associated with CO testing. Charitable funds were secured in some areas, whilst in others the cost was met from within Public Health Wales. Some referring midwives noted that budgets in their departments were stretched and that they would struggle to meet these costs if the use of routine CO monitoring were introduced more widely. Finally, a minority of midwives identified that CO testing women could jeopardise their relationship with women.

In one site, the MAMSS Practitioner was based within the maternity department during booking clinics, and it was suggested that this made it easier for midwifery staff to refer patients to MAMSS. However, referral relied on the patient’s self-reported smoking status, rather than the use of the CO test to secure a referral. The MAMSS Practitioner then conducted the CO test on most patients, but some who did not want smoking cessation support did not undertake CO testing. Midwifery staff suggested that having face to face contact with a stop smoking advisor shortly after their 12 week scan could facilitate engagement.

It was reported that the majority of women who were approached consented to a CO test. Two of the women who were interviewed noted that their CO test result prompted their quit attempts. Among midwives who CO tested women using specialist monitors which displayed the CO level of the foetus, it was reported that this could be shocking and highly motivating. Some referring midwives also highlighted the role of undertaking CO testing and potential referral to stop smoking services alongside their first scan. It was argued that ‘seeing’ their baby for the first time could increase the motivation to undertake cessation support.
3.2 Opt out referral to smoking cessation services

Following CO testing, midwives referred women to MAMSS in intervention sites or Stop Smoking Wales in usual care sites. It was reported that the majority of women agreed to being referred. Among the minority who refused a referral, an information leaflet was provided and women were reminded that they could change their mind at a later stage. However, some midwives stated that the information leaflet was given as part of a large ‘pack’ of leaflets; the risks of smoking were not always discussed.

Referring midwives and MAMSS Practitioners reported that the majority of pregnant smokers said that they were already ‘cutting down’ when they met with midwifery staff. Accordingly, for those who wanted to cut down or quit, a belief in their ability to successfully cut down the number of cigarettes smoked without support may have resulted in a lack of engagement. For others who did not want to quit, referring midwives believed that this provided a way of opting out of treatment, as the women prevented a further discussion by showing her positive action towards a quit attempt.

Midwives in two MAMSS intervention sites used paper based forms to refer women to specialist smoking cessation support, with MAMSS Practitioners collecting the forms from areas on the ward. In the third area, the MAMSS Practitioner was provided with a sticky label with the patients name and address, and then completed the referral form as part of a face-to-face brief referral session with the patient. It appeared that both strategies were working well. Referring midwives reported a strong working relationship with MAMSS Practitioners, and receiving regular feedback on patients undergoing treatment, which was viewed positively.

Two of the interviewees who had been referred to a MAMSS intervention highlighted that the opt-out procedure had been working well. One woman who had initially opted out at booking agreed to being referred in week 16, showing high levels of engagement in the referral process by her midwife. In contrast, one woman was not sure when she had been referred or by whom, but this shows that the opt-out referral process was being used.

Midwives in usual care sites, and those who had previously worked in usual care sites, reported that they had experience of referring pregnant women to Stop Smoking Wales. One midwife praised the friendly nature of the Stop Smoking Wales staff. However all of the midwives noted that their patients reported that following referral they had not been contacted. In addition, midwives did not receive any feedback on their clients’ engagement or treatment. As such, the midwives reported a lack of understanding of how the service could support their patients.

3.3 Making contact with patients

Following receipt of a referral, MAMSS Practitioners telephoned women within 48 hours wherever possible, using their work mobile telephone. The use of a number which would not display as ‘no number’ on women’s telephones was viewed as important to engagement. It was reported that some women were very positive during these calls, but others were less so. However, the initial telephone call was not answered in the majority of cases, and it was suggested that some clients had chaotic lifestyles, others may not have told their families that they were pregnant and others remained in work.

MAMSS Practitioners reported that they would leave messages with women who did not answer their telephone, although few women returned the MAMSS Practitioners’ calls at this stage.
4. Treating pregnant women

4.1 Intensive Behavioural Support

As part of the initial telephone call, the MAMSS Practitioner would make an appointment for an assessment session at a time and location of the woman’s choice. These assessment sessions were usually scheduled for a few days from the telephone call. Prior to attending the appointment, the MAMSS Practitioners usually sent clients a text message to remind them that they had an appointment. In all sites, the majority of appointments took place in women’s homes, and referring midwives, MAMSS Practitioners and service users reported this as one of the key strengths of the intervention. Other clients preferred to have their support delivered in midwifery clinics or occasionally by telephone. MAMSS Practitioners reported that they usually had face-to-face support sessions with clients about once a week for 6-12 weeks, and they felt they had been holding an appropriate case load.

Alongside the mainstream intensive behavioural support, MAMSS Practitioners reported text message and telephone contact between themselves and clients, usually initiated by the Practitioner between scheduled treatment sessions. This informal contact was used to resolve problems with Nicotine Replacement Therapy. In addition to this, some MAMSS Practitioners reported that they continued to maintain contact with clients beyond their treatment using text messages to provide informal support. The current Quit Manager system was not seen as suitable to record every interaction by text message or telephone, but MAMSS Practitioners stated that if therapeutic advice had been given, they tried to remember to record it on the system.

Women described their MAMSS Practitioner very positively, as friendly, unhurried and having a non-judgemental approach. Some mothers reported already feeling intensely guilty about smoking and not adding to this guilt was central to continuing engagement. Others contrasted the MAMSS service with NRT alone, and suggested that the intensive behavioural support was highly motivating. For some women, their MAMSS Practitioner praising their moves towards quitting was motivating.

Setting a quit date is a key part of intensive behavioural therapy for smoking cessation, and MAMSS Practitioners were encouraged to support participants to set a quit date. Overall 71% of those who attended at least an assessment session had a quit date recorded. However, this varied by site from 94% to 56%.

4.2 Nicotine Replacement Therapy

As part of intensive behavioural support sessions, MAMSS Practitioners provided information about NRT products and a letter to enable clients to access NRT. In some areas, receipt of the NRT letter was tied to continuing engagement in behavioural support. In other areas, women who had reached their four week quit date were sometimes posted letters to enable continued access to NRT. One MAMSS Practitioner, working in a rural area, reported that she collected NRT from the pharmacy for some clients who would be unable to make the journey themselves, when the client had spoken to the pharmacist by telephone.

There appeared to be some confusion about the desirability of using NRT in pregnancy among partner organisations. Despite MAMSS staff visiting local pharmacies early in the project, in several interviews with MAMSS Practitioners, it was reported that pharmacists would not issue or prescribe NRT or would only prescribe NRT when the client had had a failed quit attempt without NRT or had been very assertive. Other pharmacists wanted MAMSS Practitioners to determine the product or dosage of NRT, which was not allowed at the time of the research. Other women had to receive intensive behavioural support from pharmacy schemes (in addition to their MAMSS support) in order to receive their NRT, which was described as unhelpful.
One MAMSS Practitioner noted that the volume of pharmacy staff compared to MAMSS clients meant that each pharmacy worker saw very few MAMSS clients, and thus were not always familiar with the treatment pathway. Clients who took part in interviews mostly reported using two NRT products together, such as a patch and an inhalator. Whilst most (5/7) found it unproblematic to obtain NRT, one woman felt embarrassed by a lack of discretion by the staff dispensing her prescription and another struggled to get the pharmacist to agree to dispense her prescription.

In one area, a strong relationship was noted with pharmacy staff, where the local pharmacy lead wrote to all pharmacies ahead of the go live date. In this area, a pharmacy had referred a pregnant smoker in to the MAMSS project. Throughout the steering group meetings, the issues encountered in other areas did not appear to be apparent here.

Alongside challenges accessing NRT, MAMSS Practitioners reported regular issues with providing pregnant women the correct NRT to ‘keep them comfortable’ during their quit attempt. In many cases, this resulted in changing methods or doses of NRT until the best treatment was found.

Finally, one MAMSS Practitioner reported they told women it was desirable for them not to use any NRT in their quit attempt and another mentioned it was desirable for pregnant women not to use any NRT once they had quit. One of these Practitioners reported that some clients did not want to use NRT because of the potential risk to their baby, which the Practitioner contrasted with the harm from their continuing smoking behaviour.

Three MAMSS Practitioners highlighted a need for regular updates on changes to advice regarding NRT, in order to keep their knowledge up to date. Particular issues included new NRT products and how to respond when women ask about dosage or how to come off NRT. Alongside discussions of pharmacological support, one MAMSS Practitioner noted that some mothers were using e-cigarettes. The Practitioner highlighted her concern about the lack of regulation and stated they told women not to use e-cigarettes. No other Practitioner mentioned the use of e-cigarettes.

### 4.3 Client engagement

MAMSS Practitioners reported that whilst many of their clients engaged with treatment and wanted to quit, their main motivation was linked to protecting their baby, with a secondary motivation provided by saving money. Accordingly, midwives and service users reported that mothers often planned to resume smoking following the birth of their baby.

All MAMSS Practitioners suggested that engagement was fostered by the use of treatment that was scheduled at the mothers’ convenience, and in a location of their choice. Practitioners reported that they had met women at home and in clinics, removing the necessity to undertake difficult journeys to attend for treatment. Moreover, if a client had forgotten their appointment but wanted to attend, the MAMSS Practitioners attempted to meet with them at a convenient location, including a supermarket. It was also reported that many mothers had young children who were present during treatment sessions.

Two of the MAMSS Practitioners who held a dual role (that is simultaneously working part time as a MAMSS Practitioner, and part time in a mainstream maternity role) reported that women responded more positively to them when they were attending in a midwifery capacity compared to a smoking cessation capacity. However, two other MAMSS Practitioners with a dual role did not report this and suggested that ‘everybody’ referred for treatment had been very positive about receiving support from MAMSS. All MAMSS Practitioners reported a higher rate of non-attendance than in usual maternity care.

Following the end of their treatment episode, MAMSS clinicians noted several clients had maintained informal ad hoc contact by text message, and notified MAMSS Practitioners of when their babies had been born. This was very motivating for MAMSS Practitioners.
5. Data collection

5.1 Quit Manager system

There were significant challenges in the external development of the MAMSS specific stop smoking database, Quit Manager, so it was suitable for a flexible maternal cessation service. This resulted in delays in the system being ready, and temporary data collection arrangements being used in all sites for several months. When the Quit Manager system was ready, MAMSS Practitioners, local project leads and administrative staff spent considerable amounts of time inputting the paper records onto the system.

Following the role out of the data collection tool, Quit Manager, it was anticipated that MAMSS Practitioners would receive training and be able to record all treatment on the system. Some difficulties in recording client information and treatment sessions occurred following initial training, with MAMSS Practitioners struggling to use the system and seven extra face-to-face training sessions were delivered by Stop Smoking Wales. Stop Smoking Wales also sent guidance electronically to MAMSS Practitioners who were encountering specific issues with Quit Manager. Alongside this, additional support was provided by Stop Smoking Wales and Public Health Wales to ensure data was accurate and complete prior to analysis.

Additional issues with the Quit Manager system identified by MAMSS Practitioners during interviews were: ‘call backs’ not automatically popping up on the system, relating to missed phone calls to establish four week quit status and a need to input the client’s address on every page of their treatment episode. Also iPads loaned from Stop Smoking Wales to Practitioners in some areas did not work well in practice, as Practitioners could not enter data without an internet connection. As such, MAMSS Practitioners wrote on paper notes when in the community and updated the records electronically in the office or at home.

For clients who lapsed during a quit attempt, a new ‘treatment episode’ (and quit date) was supposed to be recorded. Some MAMSS Practitioners found this distinction to be artificial in practice, and they were not always confident in recording this accurately on Quit Manager.

Despite these difficulties, some of the MAMSS Practitioners felt they were improving their confidence and ability over time, and the system was working well. Others, however, did not feel they were improving and continued to find the system frustrating.

5.2 Russell Standard

The project worked to the accepted standard of reporting in NHS Stop Smoking Services, the Russell Standard (West, 2005). This required particular elements to be entered onto the quit manager system, including a ‘quit date’ for a client to become a ‘treated smoker’, and for details relating to their four week quit to be input within a particular timeframe.

This was problematic, to some extent, within a flexible service where some women withdrew from treatment prior to their ‘four week quit date’. A training need was also identified within steering group minutes for MAMSS Practitioners to understand the importance of timely data entry, and following this training, adherence to four week carbon monoxide testing improved.

Moreover, among women who took part in the treatment, it was reported that not all clients were motivated to quit. It was difficult to identify ways to support these women within the context of a prescribed intervention which relied upon clients setting a quit date.
6. Barriers to ongoing service delivery

6.1 Resources

The delivery of MAMSS required co-ordination from a number of PHW departments, and providing resource to allow this without dedicated funds was challenging. Alongside this, funds were provided from the early years budget to deliver the intervention services. However, due to delays in setting up the sites and receiving training, it was challenging to secure funds to complete the planned intervention delivery. Alongside this, administrative support was required to support the MAMSS Practitioners to enter data onto Quit Manager.

The delivery of stop smoking support relied on a small number of specialist staff, and there were concerns that staff sickness and annual leave were challenging to manage. Moreover, concerns were raised regarding capacity if the number of referrals increased, in order to provide high quality treatment.
## Appendix 5: Results of linked data analysis

<table>
<thead>
<tr>
<th></th>
<th>Abertawe Bro Morgannwg (Midwife)</th>
<th>Aneurin Bevan (Specialist SSW Advisor for pregnant women)</th>
<th>Cwm Taf (Maternity Support Worker)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of pregnant women (Usual care site)</td>
<td>3139</td>
<td>1352</td>
<td>766</td>
</tr>
<tr>
<td>As % of total</td>
<td>73%</td>
<td>62%</td>
<td>58%</td>
</tr>
<tr>
<td>Number of smokers (Usual care site)</td>
<td>599</td>
<td>314</td>
<td>227</td>
</tr>
<tr>
<td>As % of all pregnant women</td>
<td>19%</td>
<td>23%</td>
<td>30%</td>
</tr>
<tr>
<td>(95% confidence interval)</td>
<td>(18%-21%)</td>
<td>(21%-26%)</td>
<td>(27%-33%)</td>
</tr>
<tr>
<td>Number of referrals received (Usual care site)</td>
<td>138</td>
<td>10</td>
<td>46</td>
</tr>
<tr>
<td>As % of all smokers</td>
<td>23%</td>
<td>3%</td>
<td>20%</td>
</tr>
<tr>
<td>(95% confidence interval)</td>
<td>(20%-27%)</td>
<td>(22%-32%)</td>
<td>(15%-26%)</td>
</tr>
<tr>
<td>Number of referrals accepted (Usual care site)</td>
<td>100</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>As % of all smokers</td>
<td>17%</td>
<td>3%</td>
<td>4%</td>
</tr>
<tr>
<td>(95% confidence interval)</td>
<td>(14%-21%)</td>
<td>(22%-32%)</td>
<td>(2%-8%)</td>
</tr>
<tr>
<td>Number of treated smokers (Usual care site)</td>
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<td>2</td>
<td>6</td>
</tr>
<tr>
<td>As % of all smokers</td>
<td>5%</td>
<td>1%</td>
<td>3%</td>
</tr>
<tr>
<td>(95% confidence interval)</td>
<td>(3%-7%)</td>
<td>(0%-2%)</td>
<td>(1%-6%)</td>
</tr>
<tr>
<td>Number quit at 4 weeks (Usual care site)</td>
<td>8</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>As % of all smokers</td>
<td>1%</td>
<td>0%</td>
<td>1%</td>
</tr>
<tr>
<td>(95% confidence interval)</td>
<td>(1%-3%)</td>
<td>(0%-1%)</td>
<td>(0%-3%)</td>
</tr>
<tr>
<td>Number quit at 4 weeks (CO confirmed) (Usual care site)</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>As % of all smokers</td>
<td>0%</td>
<td>0%</td>
<td>1%</td>
</tr>
<tr>
<td>(95% confidence intervals)</td>
<td>(0%-1%)</td>
<td>(0%-1%)</td>
<td>(0%-3%)</td>
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