

Supporting Smoking Cessation in Pregnancy

Pregnancy Calendar			
January	February	March	April
May	June	July	August
September	October	November	December

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CORREPRINT

PREFACE

This study was motivated by a personal belief that as a health professional whose primary role was intensive one to one support to enable individuals to quit smoking there appeared to be a barrier to a high percentage of pregnant women who smoke accessing the SCS (smoking cessation service) compared to the population in general.

In consultation with the midwives who also expressed similar concerns we agreed to work in partnership to review our current practice and identify strategies to enable us to support pregnant women who smoke more effectively.

This study would not have been possible but for the diligence, dedication and commitment of the midwives in the antenatal clinic Sligo General Hospital who embraced any opportunity to improve the health and well being of both mother and baby. On behalf of the working group and in particular on behalf of mothers who you helped

Thank You

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Abbreviations:

CO;	Carbon monoxide
CI;	Confidence interval
DNA;	Did not attend
FCOHb;	Foetal carboxy haemoglobin
PPM;	Parts per million
NRT;	Nicotine replacement therapy
SGH;	Sligo General Hospital
SCS;	Smoking cessation service
NICE;	National institute for clinical excellence

Pre amble;

Quotation from a participant in the study;

“In my previous pregnancy the midwife got onto me about smoking, her manner made me just want to leave and certainly not give up. This time round I received the invite letter and decided “no way” but the antenatal midwife was so nice and caring, asked me if I would like to know a little more, put me under no pressure, was really kind. So I decided there and then I would give it a go, it was totally because of her manner that I attended today’s clinic and I am so glad I did because I did not know about nicotine replacement therapy (NRT) and now believe I can quit”

Executive Summary

Tobacco use during pregnancy remains the single most preventable cause of perinatal morbidity and mortality. Smoking status is routinely recorded at antenatal clinics however under-reporting of smoking in pregnancy is well documented. In 2008, 11% (201) of pregnant women attending the Antenatal Clinic at Sligo General Hospital (SGH) reported smoking during pregnancy of which 5% (11) agreed to referral to the Smoking Cessation Service (SCS).

The primary aim of this study was to determine the effectiveness of introducing a Midwife-led brief intervention approach with advice on smoking cessation, urine Cotinine and Carbon monoxide (CO) breath testing to ascertain the smoking status of pregnant women and following this intervention the midwives then offered referral to the SCS. The women referred to the SCS received the standard Smoking Cessation Programme

All pregnant women (716) aged >16 attending the public Ante natal Clinic at SGH from October 2009 to September 2010 were invited to participate in the study. 86 (12%) of all pregnant women who smoked consented to taking part in the study. In this study group, 49 (57%) were smokers. In total, 114 of all pregnant women were recorded as smokers (16%) [95% CI: 13% - 19%]. The total number of referrals to the SCS was 56 (referral rate: 49% of recorded smokers [95%CI 40%-59%]). This represents an increase in the referral rate of 44% [95%CI 34%-53%] compared to 2008 figures (Odds ratio = 17; [95%CI: 10 to 29]). In total 41 pregnant women attended the SCS. Of those referred, 28% (n=15) did not attend (DNA) their SCS appointment. The outcome for the 41 women who attended the SCS was as follows: 68% quit smoking, 27% reduced consumption and 5% had no quit attempt.

The combined interventions of midwife led brief advice and clinical validation of smoking status has resulted in a dramatic increase in the referral rate of pregnant women who smoke to the SCS. A key recommendation of this study is the introduction of clinical tools such as carbon monoxide monitoring into routine obstetric and ante natal care. This is in line with the recommendations in the National Institute clinical excellence (NICE) guidelines "How to stop smoking in pregnancy and following childbirth" published in June 2010.

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1. Background

1.1 Context

Cigarette smoking during pregnancy remains the single most preventable cause of perinatal morbidity and mortality (Dietz et al., 2010). Women who stop smoking before conception or during the early stages of pregnancy significantly reduce the risk of adverse outcomes as a result of smoking. It is a significant public health problem as prevalence studies in the 1990's show that between one in five and one in three pregnant women in developed countries report smoking throughout their pregnancies (Campion., 1994; Tappin., 1997). The literature review revealed limited national statistics for pregnant smokers in Ireland. A small scale survey (n.100) in the Coombe, s Women's Hospital in 1999 reported that 27% of pregnant women smoked throughout their pregnancy however this was self reported rather than validated (Dr Mary Laffoy 2000). A more recent publication identified that 18% of pregnant women in Ireland stated they smoked at some stage during their pregnancy (Growing up in Ireland 2010)...

1.2 Introduction

There is overwhelming evidence that smoking is implicated as a major risk factor for poor outcomes in pregnancy. Such poor outcomes can have long and debilitating consequences affecting not only the unborn but extending into childhood and beyond (Dietz et al., 2010; The Advisor, 2010).

The main constituent in tobacco is CO, this interferes with tissue oxygenation therefore it carries a significant risk to maternal and foetal well being and subsequently has potentially damaging effects on the foetus. The adverse outcomes of smoking during pregnancy include increased risk of miscarriage and stillbirth, increased risk of ectopic pregnancy, increased risk of preterm birth and low birth weight, leading to increased perinatal morbidity (Royal College of Physicians, 1992; Di Franza et al.), an increased risk of attention-deficit hyperactivity disorder and other learning difficulties in childhood (Bastra

et al., 2003; Langley et al., 2005). A further study in the Coombe Hospital demonstrated the highest rates of low birth weight babies were among babies whose mother smoked at 16.6% compared to non smoking mothers 5.1% (Barry et al 2007).

There are marked social differences between women who smoke and those who do not, with continued smoking and high daily consumption showing a strong association with social disadvantage, high parity, being without a partner, and low income (Frost 1994; Graham., 1996). 56% of women in social class 5-6 aged 18-29 are smokers, according to the SLAN survey (Department of Health & Children, 2009). In addition to the social factors associated with continued smoking, there are common psychosocial associations, especially depression, job strain/workload, exposure to intimate partner violence and low levels of practical support (Borelli 1994; Karlsson 1996; Mc Nutt 2002). Fear of weight gain is another factor in continued smoking, with women being more likely to smoke to control their weight (Department of Health & Children, 2009) and female body image being extensively targeted by tobacco marketing campaigns (CDCP, 2002). The rate of quits among women is lower than men, according to the data from SLAN (Department of Health & Children, 2009). 16% of women reported to have quit smoking compared to 23% of men. However, more women tend to cut down on pregnancy (Department of Health & Children, 1994).

It is important clinically to have knowledge of patients' smoking habits since it enables appropriate smoking cessation advice to be given. Pregnancy is seen as a window of opportunity to provide this, rarely is there any other opportunity where an individual will have access to frequent health professional advice over a 9 month period (Bryce et al., 2009; Usmani et al., 2008; Lumley et al., 2009). Meta-analyses, including a Cochrane review, show that appropriate screening plus active intervention, in the form of advice and the provision of written materials, increases the percentage of pregnant women who stop smoking. This, in turn can reverse the adverse effects of smoking on perinatal outcomes by up to 20% (Lumley et al., 2004; Dolan-Mullen et al., 1994).

It has also been emphasised that, in pregnancy, biochemical validation can increase women's motivation to stop smoking and increase their utilization of available treatment services (Bize et al., 2007; Campbell et al., 2009). Research indicates that self-reported smoking during pregnancy is not an accurate reflection of true tobacco smoking status (Campbell et al., 2001; Tobacco Control, 2003; Webb et al., 2003; Walsh et al., 1997; Burystyn et al., 2009; Lumley et al., 2009; McGowan et al., 2007; Garber et al., 2009; Usmani et al., 2008). In pregnancy, women who smoke can experience intense social and clinical pressure that results in false declaration of non-smoking. This inaccuracy of self-reported smoking makes appropriate counselling difficult and stresses the need for reliable biochemical confirmation of smoking status (Ford et al. 2007).

Carbon monoxide breath testing is a useful non-invasive, inexpensive testing tool for midwives to implement as part of routine antenatal care (Hermon, 2009; Usmani et al., 2008). The result is displayed visually, showing pregnant women the amount of CO circulating in their bodies and the associated level in the foetus; this recording may act as a motivator to empower pregnant women to quit smoking. Carbon monoxide has a half life of around 3-5 hours measured using exhaled air from the general population of smokers. However, due to an increased maternal metabolic rate producing a shorter half-life of CO and therefore lower CO readings; this limits its use as a biomarker for tobacco use and is therefore not clinically robust enough to use as a stand alone risk assessment tool (Usmani et al., 2008; McGowan et al., 2007; Campbell et al., 2001).

Cotinine testing is considered to be the 'gold standard' for measuring tobacco consumption (Hermon, 2009; Gorber et al., 2009). Therefore, urine cotinine testing is proposed as the measurement of choice for pregnancy due to its accuracy and the fact that analysis is routinely taken this should not impact negatively on time management (Gorber et al., 2009; Walsh et al., 1997). Cotinine is a major nicotine metabolite and has a longer elimination half life of around 16 hours in the general population of smokers and around 9 hours in pregnant women. It can be measured to a high degree of sensitivity.

Using both methods of testing is the perfect combination and provides a consistently strong message to women about the adverse outcomes of smoking during pregnancy (Hermon, 2009).

CO and/or Cotinine testing is not part of current routine antenatal care in the Republic of Ireland.

Raising the issue of smoking with pregnant women may present with some challenges and ambivalence; getting the balance right in imparting information and increasing motivation without making them feel under siege can require skill. Training midwives who provide routine ante natal care to give them confidence to raise the issue of smoking in a client-centred, non confrontational, non judgmental manner has been demonstrated to increase the numbers identified as smokers by health professionals during routine consultations (Lancaster et al., 2000). Midwives can be empowered to enable them to deliver individual and impacting advice to pregnant women who smoke and help them to make the decision to quit (Bryce et al., 2009). Motivational interviewing skills are an important and useful tool in smoking cessation & pregnancy (Bryce et al., 2009; Hermon, 2009; McGowan et al., 2007).

Smoking cessation interventions by health professionals is crucial to reducing smoking prevalence in pregnancy and extending into post partum period. Furthermore a systematic review found evidence that individual counselling offering intensive cessation support from a health professional not involved in routine care can increase smoking cessation rates (Lancaster and Stead, 2005).

Obstetric data show that 1767 births took place in Sligo General Hospital in 2008 with 201 (11.4%) of this group reporting to have smoked throughout their pregnancy. In the same year, there were 11 referrals of pregnant women to the SCS in SGH corresponding to a referral rate of 5.5% (11/201). In contrast the referrals in 2008 from other sources within the hospital totalled 475.

2. Aims & Objectives

Aim of study:

The primary aim of this study is to determine the effectiveness of introducing midwife-led brief advice on smoking cessation and clinically validated smoking status-testing in increasing the referral rate to the Smoking Cessation Service.

Objectives:

- To ascertain the validated smoking status of pregnant women by measuring expired air CO and levels of Cotinine in the urine.
- To educate pregnant women on the effects of smoking on their unborn babies' health by distributing information resource packs and reporting the % of foetal carboxy haemoglobin (FCOHb)
- To compare self-reported smoking status with validated smoking status
- To assess if there is a change in the rate of referrals from the antenatal clinic to a smoking cessation service as a result of this intervention.
- To determine if such an intervention influences smoking habit by recording a pre and post intervention CO and cotinine level.
- To record the outcome of the SCS provided to the pregnant women in this study.
- To evaluate midwives experiences of using this intervention in their work practices.

The study is divided into two components:

- (A): A quantitative study involving pregnant women attending SGH.
- (B): A qualitative study involving midwives working in the antenatal clinic (see appendix E & F).

3. Methodology

3.1: Study population

Inclusion criteria:

- Pregnant women attending their first booking clinic at SGH
- Aged 16 or over
- Public patients only (private patients attended external clinics which would be challenging for implementation and recording purposes)

3.2: Sample size

Assumptions:

- 1767 births per annum at SGH, according to 2008 data
- Estimated 1600 births at SGH in 2009
- 201 (11.4 %) of pregnant women reported to be smokers at the time of the initial antenatal booking clinic (2008 figures)
- 11 referrals of pregnant women reporting to be smokers to the SCS at SGH in 2008

Sample size required to assess an increase in the rate of referral to the SCS:

Based on the above data, 201 pregnant women were smokers in 2008 with 5.5% (11/201) of those women accepting a referral to the SCS at SGH.

In order to detect an increase of this referral rate to 16.5% of pregnant women who smoke (with a power of 80% and 5% significance level) the number of smokers required for the study is 102. This increase would reflect a three-fold increase in the referral rate.

Assuming a smoking level 11.4% as above, the total number of pregnant women to be recruited is 910. This number will be less if the percentage of pregnant women who smoke is higher than the self-reported rate in 2008.

On average about 25 first time visits are seen weekly at the antenatal clinic at SGH In order to reach the sample size, recruitment will take place over 37 weeks.

Sample size required to assess the proportion of pregnant women who smoke:

A sample size of 910 will enable the study to detect a worst case confidence interval (at 95%) of the proportion of smokers of 0.114 (11.4%) with a 2.1% margin of error. A worst case proportion of 15% can be detected with a 2.3% margin of error with a sample size of 910.

3.3: Recruitment

Potential participants receive an invite letter to take part in the research study together with their first antenatal booking appointment (see appendix A). The study would aim to identify if they had been exposed to active or passive smoking. On arrival at the booking clinic they received an information sheet (see appendix B) together with their medical records. There is adequate time for them to read the letter before they meet with the midwife who then discusses the study and answers any queries they might have in relation to the study. Following discussion the midwife ascertains if the individual is willing to consent to be part of the study or not, formal written consent (see appendix C) is obtained from those who are interested in being a participant.

3.4: Interventions

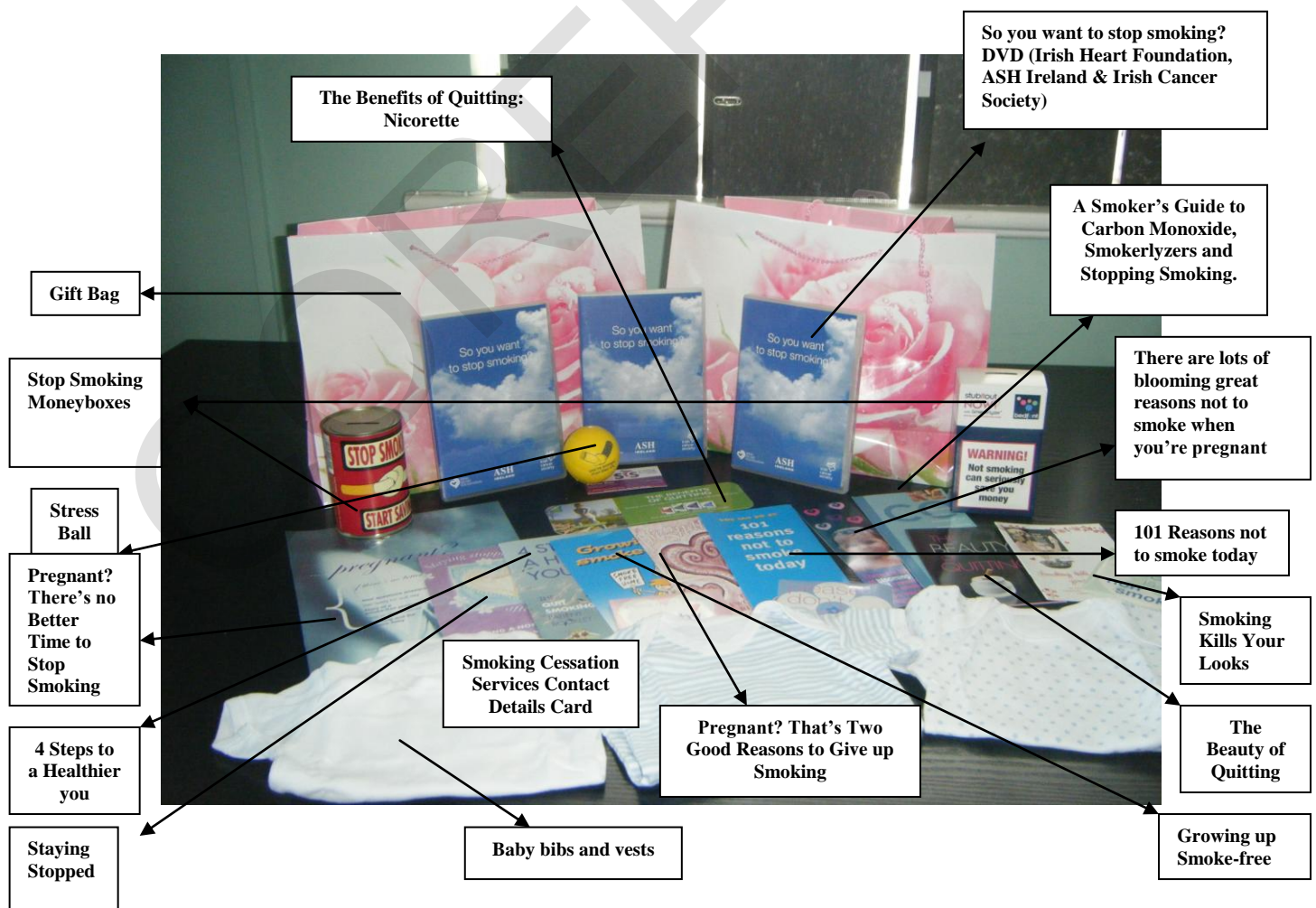
In routine antenatal care, initial consultation at the booking clinic requires the pregnant woman to answer a set of screening questions which are then recorded by the midwife. The screening questions include recording smoking status.

Those who consent to participate in the study provide a carbon monoxide (CO) breath test using a baby CO micrometer to validate smoking status and permit the pregnant women to see a physical measure of their smoking. Results are instantaneous and shared with the woman showing the reading in parts per million (ppm) and estimating the % FCOHb circulating. A CO guide chart demonstrates to the woman her results.

A urine sample is collected in order to test the presence of cotinine which further validates smoking status. The cotinine is a dip-stick test which gives instantaneous measurement of cotinine levels, which will ascertain smoking status again a Cotinine guide chart is used to show the woman her results.

The second consultation takes place at next follow up clinic which may be between 6 and 10 weeks. At this stage, repeat tests of both CO and cotinine were performed and the results would demonstrate the effectiveness of the intervention.

When an individual self-reported as being a smoker and/or had a carbon monoxide breath test result >6 ppm and had a positive test for the presence of cotinine in the urine, they will receive advice from the midwife, together with their results, an information pack to help motivate them to quit smoking and offer of referral to the SCS. The information packs contained a variety of tailored leaflets which address lifestyle change and smoking cessation, a smoke-free baby bib, a pen and pencil, a stress relief ball, a bookmark, a moneybox, and a cot mobile, contact details of smoking cessation advisor (view caption below for an example of what is contained in the information pack).



A pre-requirement for referral to the service is consent at the antenatal clinic or the individual may self refer after having a period of time to consider the advice and material which was delivered to her.

The programme on offer is the standard Smoking Cessation Programme offered to patients and staff of SGH. It is an intensive one to one consultation with follow up for up to one year post-cessation. The advice offered includes: Behavioural change, pharmacotherapy, Health & lifestyle, fagerstrom scoring, demonstration model of health effects, addressing environmental & social influences, dietary advice and information on alternative coping mechanisms and an individual exercise programme.

3.5: Study Preparation - Training midwives

Midwives involved in the study offered brief advice on smoking cessation to all pregnant women who report to be smokers. The midwives were all trained in the necessary skills to enable them to approach the subject in a non-confrontational, non-judgemental manner. Midwives working in the antenatal clinic at SGH had previously received training in brief intervention specific to pregnant women.

Additional training was delivered on site and the training covered health impact of maternal smoking, motivational interviewing skills, demonstration and skills training in the use of CO monitor, demonstration of Cotinine test, knowledge of levels and its influence on health of pregnant women and foetus (see training details document in appendix D). Individual information packs were also made available for each midwife plus a resource pack with additional information located in the Antenatal OPD. A link person was selected amongst the midwives in the antenatal clinic and acted as the contact person to the group of midwives for the Smoking Cessation Officer.

3.6 Focus Group study of Midwives' Perspective

Upon conclusion of the study in August 2010 the midwives were invited to take part in a focus group to evaluate their experiences of using this intervention in their work practices. A purpose designed interview guide was developed (appendix E). The focus group was tape-recorded and analysed using thematic analysis.

3.7 Ethical Considerations

Ethical approval was granted by the Research Ethics Committee at SGH

4. Results

4.1 Sample

The study took place over a 10.5 month period between 12th October 2009 and September 1st 2010 at which point recruitment to the study was terminated.

The total number of pregnant women aged >16 yrs attending the public clinic at SGH in the study period was 716. All were invited to participate in the study.

Eighty six (12%) women consented to the study, i.e. 630 (88%) chose not to take part in the study.

A statistically significant outcome of the study was obtained with a sample less than the one estimated in section 3.2 (910). Hence recruitment to the study was terminated early.

4.2. Smoking Status of Pregnant Women

Routine recording of smoking status was carried out for all women attending the clinic (n=716). 16% (n=114) were recorded as smokers [95% CI: 13% - 19%]. 596 women were recorded as non-smokers (83%) and data was unrecorded for 6 women (1%). Included in the non smoking group are 3 women, who spontaneously quit smoking when they found out they were pregnant.

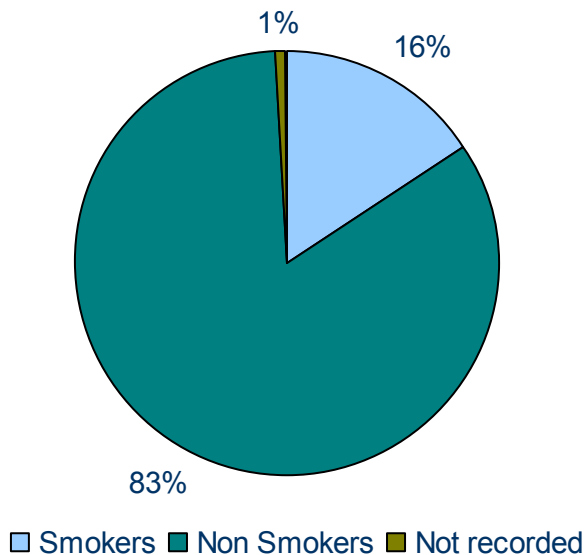


Fig 4.1: Smoking status (unvalidated) of women (n=716) attending the antenatal clinic in the study period

A total of 86 women consented to the study. 49 (57%) in this group were smokers and 37 (43%) were non-smokers.

49 (43%) of the women who reported to be smokers consented to the study while 65 (57%) of the smokers did not consent.

4.3 Referrals to SCS

The total number of referrals to the SCS in the study period was 56 out of 114 smokers; i.e. the referral rate was 49% [95%CI 40%-59%] of recorded smokers (Figure 4.2). This represents an increase in the referral rate of 44% [95%CI 34%-53%] compared to 2008 figures (Odds ratio = 17; [95%CI: 10 to 29]). The vast majority of referrals (53 out of 56) were by way of referral from the antenatal clinic. The remainder were self referrals, i.e. the SCS was contacted by the women themselves subsequent to receiving brief intervention in the antenatal clinic.

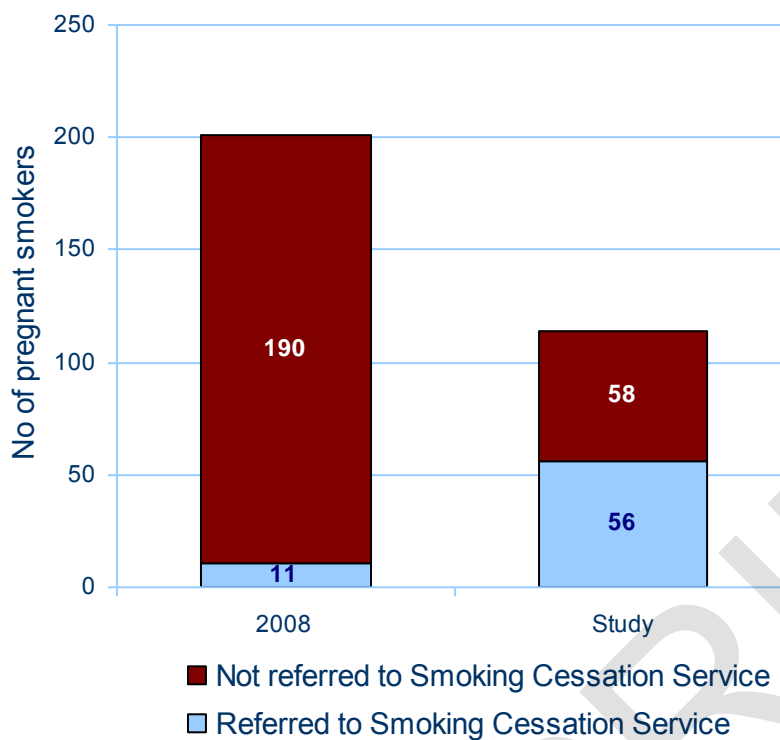


Fig 4.2: The number of pregnant women reporting to be smokers who were referred/not referred to the SCS at SGH. Referral rate 2008: $11/201 = 5\%$; referral rate study period: $56/114 = 49\%$.

Of the referrals made from the antenatal clinic ($n=53$), 41 women attended the SCS either in person or by phone consultation. 15 women did not attend their appointment, corresponding to a DNA rate of 28%.

4.4 Outcome of Referrals to SCS during the study period.

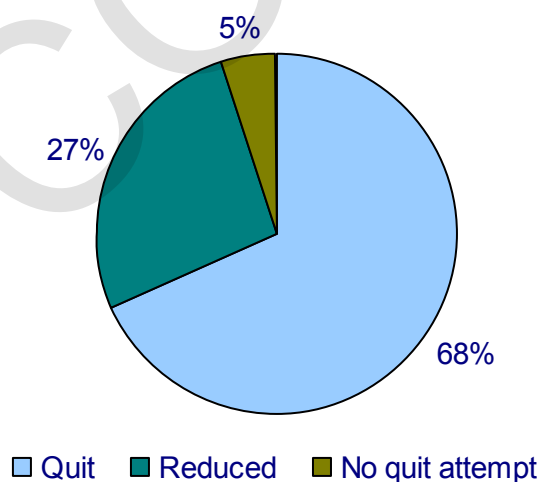


Fig 4.3: Outcome of the SCS for the 41 women who attended the service in the study.

The women that attended the SCS received the standard smoking cessation programme available in addition specific smoking cessation leaflets in relation to pregnancy were distributed. A quit rate of 68% was achieved for the 41 women that attended (figure 4.3).

4.5 Validated Smoking status results

CO and cotinine tests were performed on all women consenting to the study (n=86). 49 women in this group had indicated they were smokers.

The distribution of CO breath test results for this group is shown in Figure 4.4. The categories are defined as follows (<http://www.micromedical.co.uk>):

CO content (ppm)	Category
0 – 6	Non smoker
7 – 10	Light smoker
11 – 19	Smoker
> 19	Heavy smoker

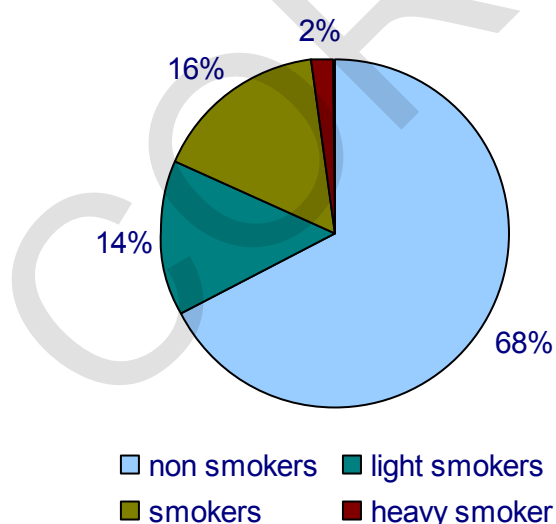


Fig 4.4: Validated smoking status using CO breath testing of the 49 women that indicated they smoked and who consented to the study.

The distribution of Cotinine results for this group is shown in Figure 4.5. The categories are defined as follows (<http://www.micromedical.co.uk>):

Cotinine content in urine (ppm)	Category
0	Non smoker
1 – 7	Light smoker
> 7	Heavy smoker

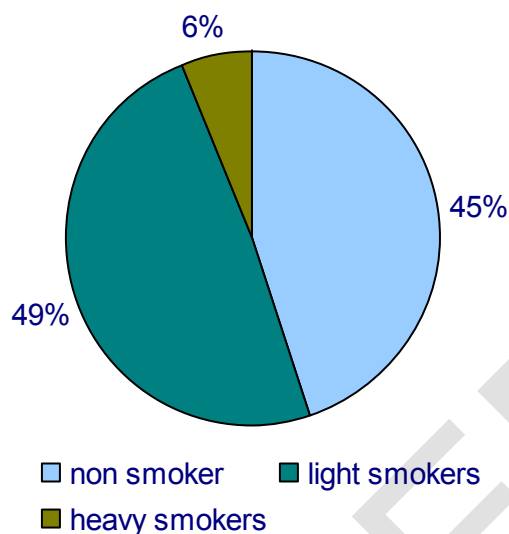


Fig 4.5: Validated smoking status using Cotinine urine testing of the 49 women that indicated they smoked and who consented to the study.

A high percentage of those consenting to the study did not undergo CO and Cotinine testing at their follow up visit in the antenatal clinic. Therefore these results are not included in the study results (see section 4.6)

4.6 Focus Group on Midwives perspective

Four midwives participated in the focus group. The following themes were identified by thematic analysis:

- **Information and Awareness;** Initial training was key however an in-term report midway through study re-energised and re focussed staff.

- **Study Barriers;** Challenge due to having to change practice, time factor, staff shortages, and inexperienced staff providing cover, reluctance of pregnant women who smoke to partake in the study. It was also acknowledged that the women attending the ante natal clinic are at 20 weeks gestation so they have been smoking for at least half of their pregnancy therefore earlier intervention is crucial to working with this specific group.
- **Working Environment;** Study was held during a particular challenging time in the acute sector with staff shortages and this had a negative impact on both the running of clinics and the study.
- **Testing Procedures:** Both methods were straight forward.
- **Benefits of the Study:** With familiarity of the process involved time factor less of a barrier, seeing the increase in consenting referrals and the amount of women who quit was positive reinforcement.
- **Midwives Perceptions of the Participants:** The midwives experienced empowerment at been able to give accurate information plus introducing clinical tools to support the pregnant women to quit however there was disappointment expressed at the high % of smokers who refused to consent to the study or consent to referral to the SCS.

The midwives suggested the following recommendations on completion of the study:

- a) A multidisciplinary approach to smoking cessation in pregnancy should be implemented and all team members should receive brief intervention and motivational skills training.
- b) Information on smoking cessation in pregnancy should be highlighted through the media and other channels. In addition, HSE website and posters in the antenatal clinic demonstrating the results of the study.
- c) A clinic should be delivered by the Smoking Cessation Services to coincide with when the antenatal clinics are operating.
- d) Routine carbon monoxide testing should be carried out as part of routine obstetric care in particular should be recorded at booking and and each subsequent visit as recommended by NICE guidelines (2010)

5. Discussion:

The recorded percentage of smokers in the study (16%) is, although higher than the recorded rate in 2008, likely to be less than the true value. Under-reporting of smoking status is frequent, particularly in pregnancy, and considering the low consent rate to the study of 12% this is most likely to be the case in this study.

The combined interventions of midwife led brief advice and smoking status testing has resulted in a dramatic increase in the referrals to the Smoking Cessation Service of 44%: From 5% of reported smokers referred in 2008 to 49% in the study period. This confirms the effectiveness of implementing a combined brief intervention and validated smoking status testing in the antenatal setting.

The percentage of pregnant women that did not attend (DNA) their SCS appointment was 28%. However, the DNA rate is less than recorded for pregnant women in 2008 (11 referrals, 6 DNA's i.e. DNA rate 55%).

Cotinine and Carbon Monoxide testing are recognised as valuable tools to validate smoking status. 49 women who consented to the study said that they were smokers. However, the Carbon monoxide tests showed that a total of 33 women were in the non smoker category. In the Cotinine test, 22 out of the 49 confirmed smokers were in the non smoker category. This discrepancy between unvalidated and validated smoking status differs from other studies which showed the opposite effect (Tappin et al., 2010; Ford et al., 2007; Gorber et al., 2009; Buystyn et al., 2009; McGowan et al., 2007).

The combined factors of an early morning clinic resulted in some women not smoking in the previous 3-9 hours. This phenomenon which would effect readings had been recorded as was the case in another study carried out by Campbell et al. (2001). Carbon monoxide readings may only show up 3-5 hours after the woman smokes and Cotinine, 9 hours post smoking. A further factor to be considered in pregnancy is the increased metabolic rate which will also influence results. Implementations of both tests demonstrate a more

accurate reflection of smoking status than implementation a sole test. Where the tests demonstrate that the individual is a smoker then this can offer an opportunity for an intervention in motivating them to making a behaviour change.

The quit rate for pregnant women in this study (68%) is higher than that achieved in the general population (average quit rate of clients attending the SCS at SGH is approximately 35 - 40%) The authors believe that a possible explanation for this is that the individual's motivation for behaviour change was present following consultation with midwife and their consenting to referral to the SCS and attending clinic is testimony to that motivation.

Conclusions & Recommendations:

A key recommendation following conclusion of this study is that the clinical tools (Brief intervention and validated smoking status testing) should be incorporated into routine obstetric and anti natal care. This would be in line with the recommendations in the NICE guidelines 'How to stop smoking in pregnancy and following childbirth' published June 2010. The perception that introducing a new approach to care may impact negatively on time was not demonstrated in this study and the experience was embraced fully by all midwives involved.

In considering the % of pregnant women who smoke there is a need for the authors to acknowledge the low numbers that consented to participate in the study and to have chemical validation of smoking status. The recorded percentage of smokers (16%) is, although higher than the 2008 rate, likely to be less than the true value. There appear to be some barriers to pregnant women seeking support for smoking cessation however the authors believe that delivering appropriate advice and support in a non confrontational and non judgemental manner will be effective in reducing mortality and morbidity as a consequence of smoking.

The combined interventions resulted in a dramatic increase in the referral rate to the SCS of pregnant women who smoke. In addition, the quit rate status for pregnant women in this study (68%) is higher than that achieved in the general population. This specific study involved patients attending first antenatal booking which generally took place at 20 weeks gestation a key recommendation from this study is that earlier intervention to support smoking cessation takes place e.g. on confirmation of pregnancy.

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Appendix A



INVITATION LETTER

Dear Madam,

You are invited to participate in a research study to find out if you have been exposed to tobacco smoke through self use or through exposure from others. We will achieve this by introducing some new measures, which may also motivate those who smoke to quit.

All pregnant women attending the antenatal clinic at Sligo General Hospital for the first time are invited to participate. It involves testing your urine for the presence of nicotine and asking you to blow into a meter, which can detect if you have been exposed to smoke.

You will receive further information at your first antenatal clinic. You may then decide if you would like to partake in the study and your written consent will be asked for by the midwife. The research will ensure your full confidentiality. You can change your mind at anytime and withdraw from the study without giving a reason. The standard of antenatal care you receive will not change whether or not you decide to partake in the study.

Please do not hesitate to contact me if you need further information.

Yours Sincerely,
Pauline Kent

Smoking Cessation Officer
Sligo General Hospital
Email: Pauline.kent@hse.ie
Tel: 071914548

Note: This research is carried out by the Smoking Cessation Service and the Research and Education Foundation at Sligo General Hospital.

Appendix B

“Smoking Cessation in Pregnancy”

INFORMATION SHEET FOR PARTICIPANTS

Dear Client/Patient,

You are invited to take part in a research study to find out what the percentage of pregnant women are smokers and if introducing some new measures can motivate pregnant women to quit smoking. All pregnant women attending the ante natal clinics at Sligo General Hospital for the first time are invited to participate. This study is being conducted by the Research and Education Foundation and the Smoking Cessation Services at Sligo General Hospital.

Before you decide whether to take part in the study it is important that you understand what the research is for and what you will be asked to do. Please take time to read the following information and discuss it with others if you wish. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep. You will also be asked to sign a consent form. You can change your mind at any time and withdraw from the study without giving a reason. The standard of ante natal care you receive will not change whether or not you decide to participate in this study.

The purpose of the study is two fold. We wish to find out what percentage of pregnant women attending the antenatal clinic are smokers and what the level of smoking is e.g. light smoker, heavy smoker etc. Secondly, for those pregnant women who do smoke, we wish to establish if we can motivate them to quit.

You will be asked if you are a smoker as part of the routine questions asked at the antenatal clinic. You will be asked to blow into a simple breath test device, which will indicate if you are smoker. We will also perform a test of the urine sample you will be supplying as part of your routine care. This test will measure the levels of cotinine, a measure of nicotine in your system. Women who smoke will receive along with their results an information pack on quitting smoking. Those women will be offered a referral to the Smoking Cessation Services at Sligo General Hospital.

You have been chosen because you are booked in for antenatal care at Sligo General Hospital for your first visit. The study will involve approximately 900 pregnant women attending Sligo General Hospital.

The information we get from this study may help us to develop appropriate smoking cessation services for pregnant women who smoke. This information sheet is for you to keep. Your response will be treated with full confidentiality. This study has been reviewed and approved by the Research Ethics Committee at Sligo General Hospital. The information gained from this study may be published in journals and conference presentations. No research participant will be identifiable from any publications.

Please do not hesitate to contact me if you need further information

Yours sincerely,

Pauline Kent

Smoking Cessation Officer

Sligo General Hospital

Pauline.kent@hse.ie

Appendix C

CONSENT FORM

Title of Protocol:

Smoking cessation in pregnancy

Principal Investigator: Pauline Kent, Smoking Cessation Officer, SGH

1. I confirm that I have received a copy of the Information Sheet for the above study. I have read it and I understand it. I have received an explanation of the nature, purpose, duration of the study and what my involvement will be.
2. I have had time to consider whether to take part in this study and I have had the opportunity to ask questions.
3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
4. I agree to take part in the above study_____

Name of patient

Date

Signature

Name of person taking consent

Date

Signature

1 copy for patient, 1 copy for medical records

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Appendix D Training

**Empowering Midwives to deliver effective
Smoking cessation interventions to
Pregnant women and their partners who smoke**

Pauline Kent, Smoking Cessation Co-ordinator.

September 2009

AIM:

To assist midwives in raising the issue of smoking with pregnant women and their partners who smoke as an integral component of their working practice.

OBJECTIVES:

- To empower midwives to engage in a non confrontational, non judgemental manner when raising the issue of smoking with pregnant women who smoke and their partners.
- To enhance current skills by increasing knowledge of brief intervention and motivational interviewing techniques.
- To understand the effects of both active and passive smoking in relation to the health and well being of both the mother and her unborn child.
- To understand the behaviour change process when considering stopping smoking in pregnancy.

2. Training Plan

Timing	Content	Method
09.00 - 09.15	Registration/ Name badges	Sign in.
09.15 - 09.30	Introduction of facilitators. Welcome. Housekeeping/ mobile phone/ facilities/breaks/ respect for each other.	Introduce self to group with some background information of your current position in the workplace.
	Introduction by Attendees	Name, describe how your feeling this am in terms of weather i.e. calm, turbulence etc
09.30 - 09.45	Icebreaker – Identify the composition of a cigarette.	Group work, work in pairs. Feedback to larger group. Facilitator scribes on flip chart. Information leaflet in pack.
09.45 - 10.00	Aims & Objectives.	Power point presentation. Handout in pack.
10.00 - 10.15	Smoking in Ireland today 'Setting the scene' Recent data on smoking cessation in pregnancy.	Power point.
10.15 - 11.00	Start/Continue/Stop smoking 'Why'	Group work; divide into three groups to look at a particular stage. One team member scribe on flip chart sheet and one member feedback to larger group. Handout in pack.

11.00 - 11.15	Break	
11.15 - 11.45	Effects of smoking on health and benefits of quitting.	Interactive presentation, Group work brainstorm on health effects of active/passive smoking. Feedback to larger group on flip chart. Power point. Handout in pack.
11.45 - 12.15	Stages of change model 'Relapse'	Power point. Interactive, Handout in pack. Divide into groups of three, deliver scenarios and group to feedback on stages of change. Brainstorm thoughts in relation to why people relapse.
12.15 - 12.45	Tools for change	Interactive presentation, Flip chart, Blank tool in pack to fill out own personal change. Demonstrate readiness to change.
12.45 - 01.00	Questions & Answer session	
13.00 – 14. 00	Lunch	
14. 00 – 14.40	Brief intervention & Motivational interviewing techniques. Communication skills verbal/non verbal. Reflective listening skills	Video presentation & discussion. Handout.

14.40 – 15.30	Skills practice with scenarios. Tools provided	Demonstration. Group select preferred scenario. Group work in three, Practitioner/client/observer Each participant to have an opportunity in each role play, 8 minutes for each role play. Feedback by each observer to larger group and material inserted on flip chart, divided into what worked/ what did not work.
15.30 – 15.45	Feedback from skills practice.	Discussion
15.45 – 16.15	Break 10 minutes, Nicotine dependence therapy.	Discussion and display of products with direction on use of same. Contraindications discuss. Handout in pack
16.15 – 16.30	Summary main learning points of the day. Referral pathways to the service. Questions & answers	Handout in pack
16.30 - 16.45	Evaluation – participant reactions.	
16.45 - 17.00	Closure	Group to feedback on one main piece of learning from the day.

Appendix E

Topic Guide for Focus Group

Rationale; *To explore midwives interpretation of the effectiveness of introducing new measures to address smoking in pregnancy*

Broad questions to more specific -'run on' questions will inevitably be generated by each of the following questions and the participant's reactions

1. What springs to mind when you think about managing smoking cessation amongst your pregnant clients at the antenatal clinic? (From previous experience i.e. before intervention)
2. When you were first approached by the Research investigator, what were your initial thoughts about the proposed project?
3. Did you feel that there was a need for a more comprehensive system in delivering/tackling smoking (cessation) in pregnant women at the antenatal clinic?
4. How did you find the training day? (pose 'run on' questions to gauge its usefulness/adequate/satisfactory training e.g. did you feel you could communicate effectively with the client?)
5. What experiences did you have with respect to the women's reactions during the recruitment process (negative and positive)?
6. In your opinion did introducing this project into routine ante natal care influence the nurse / patient relationship positively or negatively?
7. Did any conflicting issues arise and how did you manage these? How did you feel during the situation?

8. How do you feel the introduction of new clinical practice i.e. CO & cotinine testing impact on time management? (Gage was there additional pressure on the midwife)

9. Did you feel supported and empowered whilst delivering this intervention? What supports were in place/not in place and how did these assist/not assist you in deliverance? Do you feel that anything could have been done to feel more supported and empowered?

10. In essence, how do you think the intervention benefited/disadvantaged you as a health professional, and also the pregnant client?

11. Have you any thoughts on the effectiveness of the intervention in terms of reducing smoking in pregnancy?

12. What would you like to see happen as a result of the intervention?

13. Would you like to continue this intervention? / In your opinion do you believe the outcome of this intervention should influence us to introduce such an intervention routinely into all obstetric care?

Appendix F

Standards for the Smoking Cessation programme offered to pregnant women (survey conducted by researcher 6 months post completion of study May 2011);

Question 1, 6, 7 & 8

Service providers should continuously evaluate client's experience of the service, and improve service experience based on the feedback of service users. (Criteria 1.1.5 of the Draft National Standards for Safer Better Health Care, HIQA, 2010)

Question 2

All pregnant smokers should be satisfied with the location of the smoking cessation service, appropriate to their circumstances (Adapted from WHO, 2009).

Question 3 & 4

Pregnant smokers should receive clear, accurate, and specific information on the risks of smoking to the foetus and themselves and be advised to stop smoking. Pregnant smokers should be offered specialist support with stopping smoking. (West et al, 2000).

Tobacco control messages in maternal health programmes should not just focus on the health of the foetus but also on the health benefits for the mother, which could support long term quitting (WHO, Cessation services and support (Article 14) – Tailored approach)

Question 5

Smoking status should be monitored throughout the pregnancy and beyond (NICE, 2008)

Evaluation of Smoking Cessation in Pregnancy Programme.

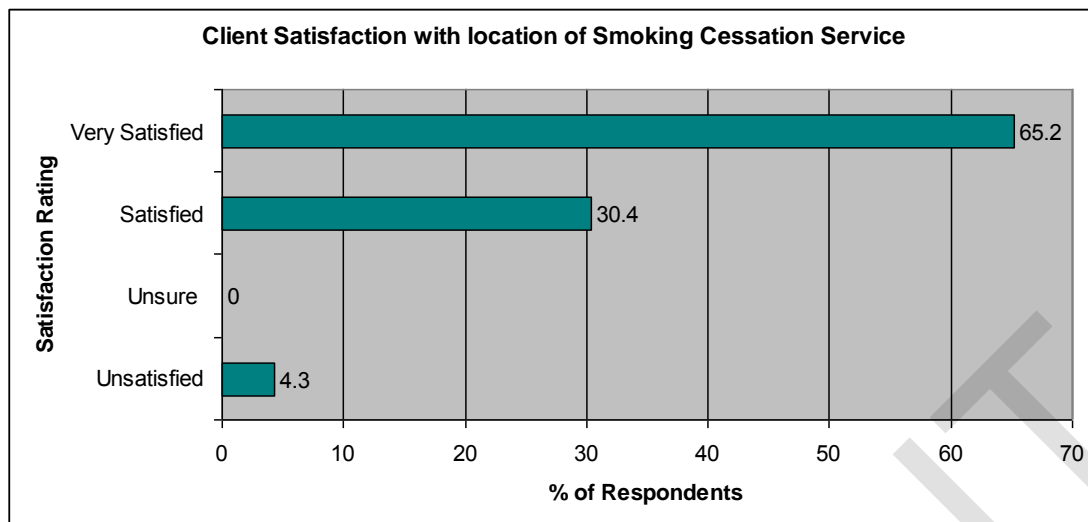
1. Clients were asked to describe their overall experience with the smoking cessation support they received from the intervention programme. Overall clients experienced a very positive experience from the programme.

Key recurrent themes identified

- **Helpful** – ‘Found the service very helpful, I was not ready to quit at the time but once I removed the stresses in my life I quit with the information I received’.
‘I managed to quit smoking; the information given to me was very helpful’.
- **Supportive** – ‘Very supportive and non judgemental service’.
- **Informative** – ‘Found it very informative and friendly’.
‘It was most informative, helpful and supportive all which helped me give up smoking’.

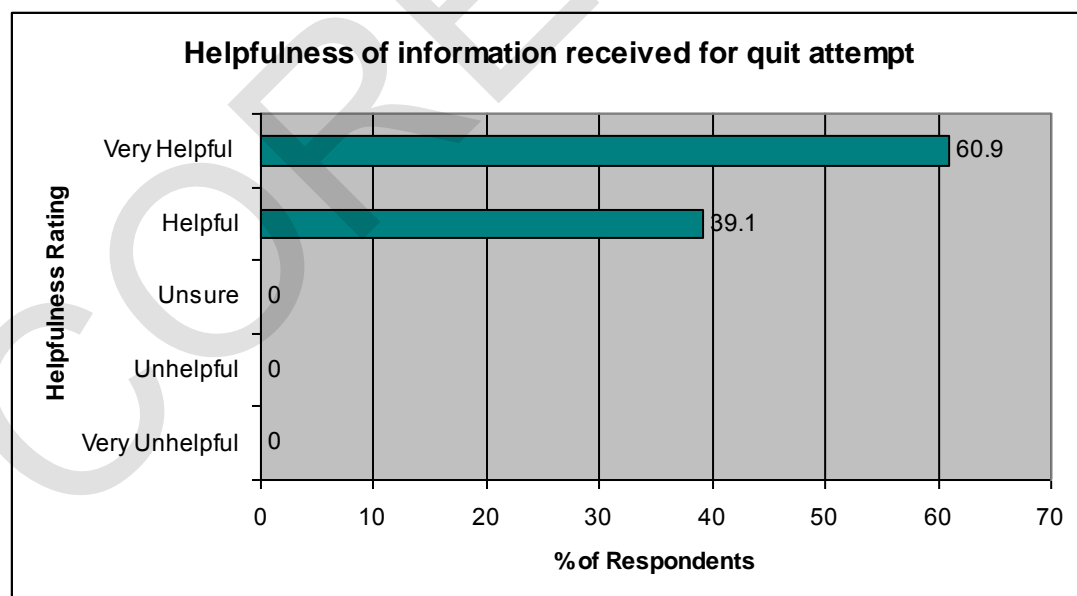
2. Clients were asked to rate how satisfied they were with the location of the smoking cessation service.

- Of the 23 women who responded to the questionnaire, 65.2% (n= 15) of respondents were ‘Very Satisfied’ and 30.4% (n= 7) were ‘Satisfied’.
- 4.3% (n= 1) of Clients were ‘Unsatisfied’ with the location of the smoking cessation service.



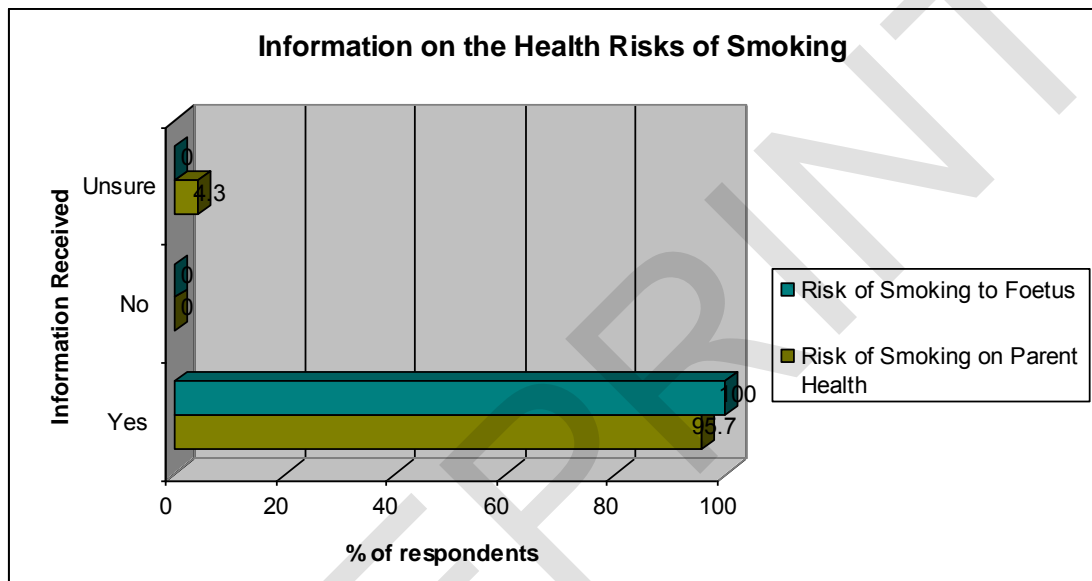
3. Clients were asked to rate how helpful the information they received in the cessation intervention was in their quit attempt.

- Six in ten respondents (60.9%, $n = 14$) found the information they received as very helpful in their quit attempt. 39% ($n = 9$) of client respondents reported to find the information helpful. None of the clients rated the information as 'Very Unhelpful' or 'Unhelpful'.



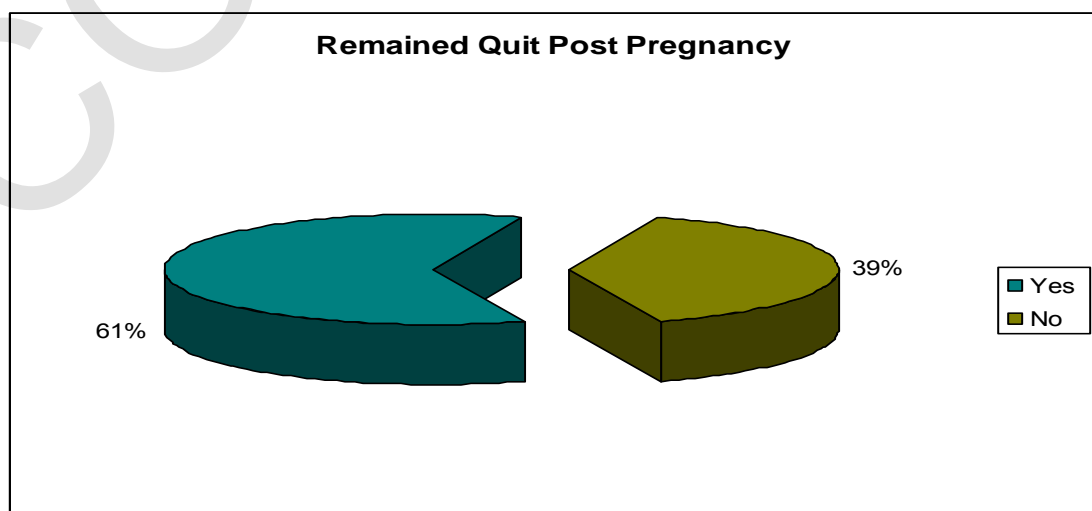
4. Clients were asked whether they received information on the health risks of smoking on the health of the parent and to the foetus.

- 95.7% (n= 22) of the clients who received smoking cessation support during pregnancy received information to the health effects of smoking on their health. 4.3% (n=1) were unsure if they received information.
- 100% (n=23) of the clients received information on the health risks of smoking to the Foetus.



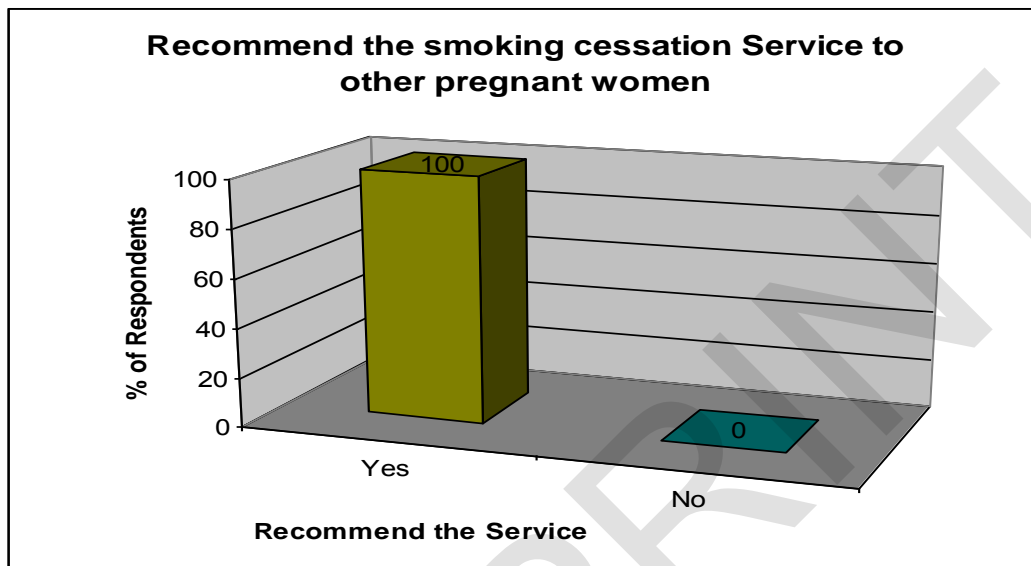
5. Clients surveyed were asked if they had remained quit post pregnancy.

- 61% of respondents (n=14) have remained quit following the intervention.
- 39% of respondents have not remained quit.



6. Clients were asked if they would recommend the smoking cessation service to other pregnant women who smoke.

- 100% (n=23) of clients said they would recommend they service.



Some of the common responses when asked why they would recommend the service were:

- 'It is good to let women know the benefit of giving up smoking while pregnant'.
- 'Service provides education and support needed and encouragement to quit'.
- 'It was the first step to helping me quit'.
- 'The pamphlets and information I received was very good, the information I was given was unbiased'.
- 'Anyone who is looking to give them up would find the service helpful'.

7. Clients were asked if they had any suggestions on how the service could be improved to provide other pregnant women with better care during their quit attempt. Of the respondents who answered this question (74%, n=17). Thirty four percent (n=8) were very satisfied with the service and said the support received could not have been improved.

'Very happy with the care I received, Staff very helpful'.

‘Attended the once, support could not have been improved’.

‘None very satisfied’.

‘Very satisfied with the service as it helped me to quit smoking’.

Some suggestions as how to improve the service:

- **Group Support** – ‘More contact with other pregnant women going through the same thing’.

‘I would like to take part a group, even if it was only once a month’.

- **Increase Contact** – ‘More follow up appointments, prenatal and postnatal’.

‘I would have liked more contact with smoking cessation advisor’.

- **Increased Availability** – ‘Suggest and offer the service to patients more frequently’.

‘If the smoking cessation advisor could issue prescription for the cessation method’.

9. Clients were also asked if they found any one aspect of the service particularly satisfactory . A range of issues were identified.

- **Service given** – ‘All very good, all on the same level’.
‘Overall it was very satisfactory’.

- **Staff** – ‘Treated perfectly by staff’.

‘Very approachable advisor, down to earth. She made me feel at ease as there was no medical jargon involved’.

‘Very supportive and non judgemental’.

‘The co-ordinator has the ability to instil positive motivation’.

- **Follow up** – ‘The follow up after the clinic’.

- **Cessation Method** – ‘Until then I never knew that it was ok to use NRT while pregnant’.

- **Information received** – ‘Information regarding the medical effects of smoking, I had not known the extent of the damage’.

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