

School for Public Health Research

1.	Project reference:	Final report date:	
	SPHR-FUS-PES-BBC	19 th April, 2016	
2.	Project title:		
	Natural experimental evaluation of a complex intervention to promote increased smoking cessation rates among pregnant women in maternity care		
3.	Lead investigators on project:		
	Dr Ruth Bell, Clinical Senior Lecturer in Public Health, Newcastle University		
	Other NIHR School collaborators (name, School for Primary Care/Social Care Research) on project:		
	N/A		
	Names and roles of others involved in project (e.g. include fixed term contract researchers and external collaborators / partners):		
<p>This is a Fuse project involving the following investigators from Newcastle University and Teesside University:</p> <p>Prof Janet Shucksmith, Professor of Public Health, Teesside University Dr Sharon Hamilton, Reader in Nursing, Teesside University Prof Luke Vale, Professor of Health Economics, Institute of Health & Society, Newcastle University Dr Vera Araujo-Soares, Senior Lecturer in Health Psychology, Institute of Health & Society, Newcastle University Prof Steven Rushton, Professor of Biological Modelling, School of Biology, Newcastle University</p> <p>Prof Martin White, MRC Epidemiology Unit & CEDAR, University of Cambridge (formerly Fuse Director, Newcastle University) Mr Martyn Willmore, Performance Improvement Delivery Manager, Fresh (North East tobacco control centre) Professor Eugene Milne, Director of Public Health, Newcastle City Council Dr Svetlana Glinianaia, Team Scientist, Institute of Health & Society, Newcastle University Dr Andrew Close, Research Associate, School of Biology, Newcastle University Dr Zelda van der Zaal, Research Associate, School of Biology, Newcastle University Mr Eoin Moloney, Research Associate, Institute of Health & Society, Newcastle University Mrs Susan Jones, Research Associate, Teesside University</p>			
4.	Project start date:	Project end date:	Duration:
	1 st April, 2013	31 st July, 2015	28 months
5.	Project objectives originally outlined in proposal:		
	In August 2012, Fresh commissioned the Tobacco Control Collaborating Centre (TCCC) to deliver a comprehensive package of support (babyClear© intervention) to transform North East services in relation to supporting pregnant smokers to stop. The project aimed to evaluate the effectiveness and cost-effectiveness, and process of implementation, of this		



intervention.

The babyClear© intervention aims to result in a reconfiguration of services for pregnant smokers attending maternity services, leading to more effective delivery of smoking cessation services. It has been developed and tested by the Tobacco Control Collaborating Centre (TCCC), an independent organisation. The intervention is based on the evidence and recommendations of the NICE guidance and includes the following components:

1. A protocol driven referral pathway, based on universal carbon monoxide (CO) monitoring at booking by midwives as part of routine care, which specifies thresholds for referral and actions to be taken
2. Training of all midwives both in the use of CO monitors, thresholds and systems for referral, and also in delivering a brief intervention to encourage engagement with stop smoking services
3. Training of stop smoking services (SSS) advisors in giving effective advice to pregnant smokers
4. Training of SSS administrative staff in effective customer relationship management techniques, in order to convert more referrals into appointments
5. An intensive risk perception intervention (RPI), delivered by trained midwives at the second trimester ultrasound scan to smokers who have not engaged with SSS
6. Branded materials and equipment, including CO monitors, to support the referral pathway, training and stop smoking interventions for pregnant women.
7. Information systems to capture data on the implementation and delivery of the intervention.

Project aim:

To evaluate whether a complex, service reconfiguration intervention improves the delivery of smoking cessation interventions to pregnant smokers, whether the reconfigured service can be implemented and sustained effectively, and whether it cost-effectively results in improved pregnancy outcomes.

Objectives:

1. To assess the effect of the intervention on referral rates to stop smoking services, reported quit rates and pregnancy outcomes (low birthweight for gestational age and preterm delivery)
2. To assess the cost-effectiveness of the intervention (NHS costs per additional quit)
3. To assess the acceptability and fidelity of intervention implementation, the impact of the intervention on midwifery and stop smoking services and the extent to which these changes are sustained post intervention
4. To assess the acceptability and perceptions of the reconfigured service among pregnant women who are offered services on the pathway

Work package 1 led by Newcastle University addresses objectives 1 and 2; and work package 2 led by Teesside University addresses objectives 3 and 4.

6. Briefly describe and explain the reason(s) for any changes to the project originally outlined in proposal:

The intervention roll out was affected by reorganisations to public health services and subsequent recommissioning of stop smoking services. As a result, implementation did not proceed in a phased manner across the pre-defined clusters, but was overlapping and severely delayed. The risk perception element of the intervention was not implemented in most Trusts before the end of the data collection period. This had implications for the project design as follows:

WP1: The quantitative results relate to the cost-effectiveness of the 'core' babyClear intervention (training, referral pathway, CO monitoring and opt out referral) and does not evaluate any additional effect of the risk perception intervention. The step wedge design originally envisaged, using clusters of trusts, could no longer be used for analysis, and instead, individual Trust was used as a variable in the analysis. Dates of implementation

were identified for each Trust, based on training dates for midwives in that Trust, and deliveries classified as 'before' or 'after' implementation based on booking date.

WP 2 – The delay in full implementation of the intervention across the region resulted in a different pattern of data collection. The clustered, stepwise model was replaced by a more pragmatic approach, whereby as Trusts fully implemented the intervention and moved beyond the initial, introductory stage then data collection began.

An additional interview with a representative from FRESH NE has been included as the role of FRESH was realised to have more importance than originally understood.

Recruitment of pregnant women by the researcher directly in the clinics was not found to be feasible as women were unwilling to extend their appointment times further, bearing in mind the intervention itself already increased their expected length of stay. Therefore it was agreed that maternity staff would hand the invitations to the women instead.

7. Brief summary of methods, findings against objectives, and conclusions (2-4 pages max):

Please note that these findings are still subject to final agreement and should be regarded as provisional.

Work package 1

Methods

We conducted an interrupted time series analysis of longitudinal data collected before and after introducing the intervention across all eight acute NHS hospital Trusts.

We obtained electronic records of deliveries from Trust, encompassing a pre and post-intervention period with at least four months of data post intervention for each Trust. Data on referrals and quit attempts were obtained from smoking cessation services and linked using maternal NHS number where available, or by mothers' date of birth and postcode. Record linkage was undertaken either by the information departments of the participating Trusts (two Trusts), with release of an anonymised dataset to the research team, or by the study researcher (SG, six Trusts). Once matched, records were anonymised and combined into a single database, and multiple pregnancies were excluded.

Statistical analysis

We modelled three outcomes that we hypothesised would be influenced by the intervention. These were: 1) change in the monthly referrals to smoking cessation service per Trust; 2) change in individual maternal quit rates; and 3) the impact of quitting during pregnancy on birthweight.

We used a mixed-effects modelling approach to investigate how the intervention impacted on the monthly referral rate (model 1). We included time since the introduction of the intervention in each Trust as a proxy for changes that might have arisen through changes in efficiency as implementation progressed. We used a stepwise reduction approach to identify the most parsimonious model at each stage and analysed the error.

We investigated the effects of the intervention on the probability that an individual mother would quit smoking before delivery in a similar way, using a logistic regression mixed-effect modelling approach with random intercept for Trust (model 2). We used quitting as a binary response variable (yes/no) for individual pregnancies. We were able to adjust for maternal ethnicity, age, parity and socio-economic status (index of multiple deprivation based on maternal postcode of residence).

We investigated the effects of quitting on birthweight using linear mixed effect models with Trust as random effect, with the same maternal demographic covariates used in the model to assess individual quitting. We investigated the effects of quitting and smoking on birthweight as a continuous outcome.

All analyses were undertaken in the R using the Nonlinear Mixed Effects Models statistical package.

Economic analysis

We estimated the additional cost to the NHS of adopting the 'core' babyClear© intervention

(ie training and referral pathway implementation, but not including costs attributable to the 'risk perception' element). Costs included those for training of staff, investment in equipment and consumables and changes in workload, and were costed using routine sources. Costs were estimated over a five-year time horizon as costs are higher in the first year of use. Costs are presented as an average of costs for the participating trusts and are reported in UK £ sterling for 2013. Data on the typical number of pregnancies and the number of additional quitters were calculated by combining data on the average quit rate in the each Trust before implementation, combined with the estimated adjusted odds ratio for quitting after implementation and data on smoking prevalence at booking in the entire cohort. These data were combined with costs to produce the incremental cost per additional quit.

Key results

Study population

There were 37726 records of singleton delivery across the eight Trusts. Twenty eight percent of mothers were classified as smokers at booking.

Model 1: effect of intervention on referrals

The referral rate increased progressively in the first three months after the intervention was introduced in all Trusts. Introduction of the intervention was associated with a 2.47 (95% CI 2.16-2.81) fold increase in referrals beyond the fourth month after introduction, compared to the period before introduction. The referral rate varied across Trusts. Inclusion of a random intercept for Trust led to an improved model fit, indicating that there were differences in the baseline number of referrals across Trusts. Additional training sessions in any Trust were associated with an increase in referrals in the month of training (OR 1.15, 95% CI 1.06-1.25); availability of a system for early contact with smokers was associated with a 6.21 fold (95% CI 3.18-12.11) in referrals, and Trust holding booking-in appointments led to a 1.78 (95% CI 1.12-2.84) increase. The fitted values of the final model reflect the observed patterns in referrals rates (squared correlation of fitted and observed values was 89.29%).

Model 2: effect of intervention on quitting during pregnancy

Introduction of the intervention was associated with a 1.81 fold increase in quitting by delivery (OR 1.81, 95% CI 1.55-2.12) across Trusts. The odds of quitting were 3.33 (95% CI 2.99-3.71) fold higher for deliveries with a recorded referral to smoking cessation services and 4.18 (95% CI 3.53-4.94) times higher if there was a record of a quit date during the intervention period. Mothers resident in the most deprived areas were half as likely to quit as those living in the middle quartile of deprived areas (OR 0.52, 95% CI 0.42-0.65). Younger mothers (under 20 years) were less likely to quit and older mothers (aged 30-39) more likely to quit than those aged 20-29. Maternal ethnicity also influenced the odds of quitting being 2.52 (95% CI 1.84-3.44) times higher in women who were non-white. The odds of quitting were also dependent on aspects of service provision, being 1.02 (95% CI 1.001-1.03) fold higher on the month of additional training. The model classified approximately 72.23% of observations correctly (sensitivity was 66.8%, specificity was 75.2%).

Model 3: effect of quitting on birthweight

Babies born to non-smokers had a significantly higher birthweight than those born to smokers by about 259.62g for reference categories, amounting to an average of 8.04% (95% CI 7.54%-8.53%) over that birthweight of 3233.10g for a 40 week (term) baby. Babies born to women who quit smoking by delivery had a significantly higher birthweight by about 210.15g compared to those who continued smoking (6.50%, 95% CI 5.81%-7.21%), but lower by about 49g compared to non-smokers (decrease of 1.41%, 95% CI 1.96%-0.86%). The fitted values of the final model reflect the observed patterns in logged values of birthweight (squared correlation of fitted and observed values was 59.30%).

Economic analysis

The total cost of implementing the core intervention for the typical Trust in the North East of England through years 1-5 was £572,009. Over the same time period the total number of deliveries in a typical Trust would be 18,640, giving a cost per delivery of £30.69. Assuming the quit rate prior to babyClear© was 0.041 per delivery and given the odds ratio for quitting

with babyClear© was 1.81[1.54-2.12], this gives a quit rate with babyClear© of 0.073 per delivery and an incremental cost per additional quitter of £937 (30.69 / (0.073-0.041)).

Work package 2

Methods

Study design

A qualitative methodology was used. Normalisation Process Theory (NPT) was used to frame both enquiry tools and analysis, with Theory Domains Framework (TDF) also used to inform development of interview schedules.

Data collection

Training sessions were observed and noted, interviews/focus groups were audio-recorded and transcribed and a field diary maintained. NPT and TDF were used to design the interview guide. Trainers (n=3) and a representative from Fresh NE were interviewed, as were maternity and stop smoking staff (n=95) from all Trust areas. Pregnant women who smoked at time of booking from the four areas where full implementation had taken place were interviewed, first at around 16 weeks of pregnancy (n=17) and again several weeks later (n=8) or postpartum (n=3) as time allowed. Staff interviews and focus groups were conducted on work premises and generally took 30 – 40 minutes. Pregnant women were interviewed at home or in community settings or by telephone. Field notes were written up following data collection and throughout the study.

Participant selection

Senior managers were purposively selected through their role in employing organisations. They were recruited by email and telephone. Permission was sought from them to approach other staff members, again according to role. Pregnant women were recruited by maternity staff during appointments.

Staff participants

Maternity staff included senior managers (n=8), public health midwives (n=2), community midwives (n=20), midwives who carried out the RPI (n=14), midwifery students (n=3) and care assistants (n=13). Stop smoking service staff included senior managers (n=10), administration staff (n=7), pregnancy advisors (n=2), general advisors (n=7), mentors (n=3) and other advisors e.g. health trainers (n=1), outreach workers (n=2), public health nurses (n=3). In addition interviews were undertaken with the three trainers provided by TCCC and a representative from Fresh North East.

Service user participants

Of the 17 pregnant women smokers who agreed to interview, all were aged between 18 – 39 years (3 in their teens, 9 in their 20s and 5 in their 30s). Fifteen were single but had partners; 2 were married.

Data analysis

NVivo 10 software was used for data management. Framework Analysis was applied to the maternity and SSS data using the four NPT core concepts as themes. Double-checking was carried out by the team. In addition a preliminary framework analysis for a consultation exercise with commissioners and senior manager providers was undertaken. Selected transcripts were coded to key themes emerging from the data in relation to implementing the intervention.

Results

Acceptability of intervention to staff

The ethos of babyClear was seen as consistent with the purpose of maternity services, their developing public health role, and other social and professional norms. The training element was seen as excellent preparation, giving a new way of presenting smoking cessation

messages to women, which was non-stigmatising and emphasised health of mother and baby. BabyClear enabled staff to make challenging smoking into a maternity service norm, and staff felt they were able both to extend their reach to groups they usually felt unable to tackle and also to adapt babyClear to each pregnant smoker appropriately. Stop smoking staff were equally enthusiastic and made great efforts to adapt ways of working to really come behind the initiative.

However, applying a manualised pathway across very different local contexts was extremely challenging. In some areas/organisations there were high levels of buy-in by commissioners of services, senior maternity managers and staff, but in others there was a lack of engagement and systems were not fully implemented.

Fidelity of intervention implementation

BabyClear offered a manualised pathway encompassing many different elements. The training successfully built knowledge, confidence and skills in using the pathway; it was motivational and increased staff buy-in. However, inevitably, introducing this complex intervention into a number of complex and very different systems challenged fidelity.

Five factors that encouraged or discouraged fidelity were identified: organisation characteristics, organisation response, system context, quality of relationship and resources/system facilitators.

Impact of the intervention on midwifery and stop smoking services

Staff attitudes

The majority of midwives/ care assistants were on-board with the SS message and welcomed additional ways to intervene effectively. Stop smoking service staff were keen and felt better equipped, especially the least experienced ones. Changes to service as a consequence of the introduction of babyClear were seen as systematic and/or subtle rather than revolutionary, excepting the introduction of the risk perception intervention. There was some debate as to how much more babyClear offered compared to standard practice.

Staff behaviours

The intervention:

- Increased CO monitoring, referrals and re-referrals to stop smoking services
- Led to more robust engagement and follow up strategies amongst stop smoking services
- Encouraged changes to systems by streamlining information passing between agencies, allowing SSS to offer appointments within quicker timeframes
- Introduced a new professional discourse which most participants had begun to employ
- Introduced for the first time a 'tough love' risk perception tool with rapid stop smoking follow-up, including more home visits than previously
- Raised awareness of stop smoking as an issue and increased likelihood of staff having in-depth conversations with pregnant women.

Variable impact of babyClear on services

The natural experiment provided a real test of the robustness of the intervention pathway, since it had to be implemented in a range of very different contexts and at a time of great flux in services.

Structures and commissioning contracts varied, responsibilities for delivering the stop smoking agenda lay with various roles. Levels of internal and external support for babyClear varied.

Some services dealt with the challenges more successfully than others, relating partly to how easily babyClear fitted into existing systems and reflected existing priorities. Only some stop smoking services were able to provide follow up as per the pathway; others whose structures were very different worked at applying the principles of babyClear but adapted it to their localities.

The following list highlights the areas of greatest variability in terms of implementation:

- *Training.* Midwives, maternity care assistants and standard stop smoking advisors attended training in high numbers. However, in some areas, insufficient numbers of staff were trained to deliver the risk perception intervention. There was also low attendance from staff in alternative roles who would be delivering stop smoking follow up advice in the new service delivery models e.g. pharmacy employees, outreach workers, health trainers.
- *Resources.* Services that appointed an effective champion and gave them authority to trail-blaze and create bridges between services made better progress. However a significant point of delay everywhere was the implementation of the risk perception intervention. This was linked to negotiation for resources (clinic space, staffing, extra stop smoking follow up) and altered workloads, which were more easily provided in some places compared with others.
- *Integration of maternity and stop smoking services.* babyClear necessitated greater integration of maternity and stop smoking services than previously. It also required high quality data capture and management and the development of robust feedback loops. Levels of success in meeting these requirements varied widely.

Unanticipated costs and benefits

BabyClear brought a different group of more intransigent smokers to the stop smoking services. The intervention pathway required follow up staff to alter work patterns and accommodate extra visits and clinics into their workloads; this resulted in pressure in the system to cover all the work. Now that they were trying to engage women who were not initiating contact with the stop smoking service themselves but were being referred by healthcare staff there were time implications, as contacts with this new group of women took more time.

Initially the number of referrals shot up (although this was not fully sustained), an increase in effort was required to engage women, there was an increase in follow ups and associated paperwork, but also high levels of failure to attend and drop out.

The introduction of the babyClear pathway also offered more opportunities for other family members to be influenced to quit smoking and there was evidence that home environments were improving and becoming smoke free.

Extent to which these changes were sustained post intervention

Delays in implementation meant it was impossible in the lifetime of the evaluation project to assess fully whether the intervention (and its effectiveness) could be sustained.

Acceptability and perceptions of the reconfigured service among pregnant women

CO monitoring as a form of universal surveillance appeared to be acceptable and women were motivated to quit by being monitored. When linked to a professional discourse of caring and concern babyClear prompted some women to take action.

They were more guarded in their reaction to initial contact from the SSS. Women reported having appointments set up successfully or in some cases, having problems that put them off and made quitting harder. Where women continued to smoke or failed to attend SSS appointments they were then subject to the RPI. Most women accepted the need for a hard-hitting approach, and - while it distressed them at the time - they claimed that they were subsequently grateful for it. SSS intervention post RPI was seen as supportive, as it often involved home visits. Family inclusion in babyClear benefited women.

Where services were less focused on prioritising the SS message, where services were less well integrated or where maternity staff were not as adept at delivering the RPI women found babyClear less acceptable overall.

It is, of course, unclear how persistent the effects of babyClear will be postpartum; the timing

of the evaluation did not allow us to study this aspect because of delays in implementation.

Conclusions

This intervention package, aimed at improving skills and systems across a local health system, provides a feasible and cost-effective method of implementing evidence based guidelines for smoking cessation in pregnancy. We conclude that a system wide focus on routine identification and referral of pregnant smokers is likely to have an important impact on pregnancy outcome and should be adopted within all local health systems.

**8. Plain English Summary (400 words max)
Please provide a summary of the project, including background, findings and conclusions:**

Background

Smoking in pregnancy is an avoidable cause of stillbirth and low birth weight. Smoking rates among pregnant women in the North East are the highest in England. Fresh (the North East tobacco control office) commissioned the babyClear intervention across the region to address this problem. The intervention package included training for staff in maternity and stop smoking services (SSS) and a new referral pathway for pregnant smokers, based on universal testing for smoking using carbon monoxide monitors and automatic referral to stop smoking services. We aimed to evaluate the intervention's effectiveness and cost-effectiveness, and to explore how well the intervention was implemented.

Study design

We obtained routine information from Trust maternity services on deliveries, and data from Stop Smoking Services on referrals and quit attempts, before and after the introduction of babyClear©. We linked records to create a study cohort of 37,726 singleton deliveries. We assessed impact on referral rates, quit rates and birthweight. Interviews with midwives, stop smoking services staff and pregnant smokers explored experiences of implementing the intervention.

Findings

Referral rates to stop smoking services increased progressively after introduction of the intervention, and quit rates during pregnancy nearly doubled. Quit rates were higher in pregnancies with a recorded referral to stop smoking services or with a recorded quit date. Babies born to women who quit smoking during pregnancy were, on average, 6 per cent heavier than babies born to women who smoked throughout, equivalent to an additional 200g for a baby born at full term.

The cost of implementing the babyClear© core package over five years was estimated at £30 per delivery. Nine pregnant smokers needed to be treated for each additional quit, at a cost of £938.

Interviews discovered that there was variability in how the babyClear© package had been implemented in different Trusts. Nevertheless, all organisations were able to deliver the core intervention broadly as intended. Interviews with maternity staff emphasised the importance of leadership and champions to help embed the babyClear© approach locally. Pregnant women were not put off by being challenged on their smoking behaviour so long as they were approached sensitively; they responded well to support that was flexible, tailored and frequent.

Implications

This intervention package provides a feasible and cost-effective method of increasing the number of smokers who quit during pregnancy. Quitting smoking increased birthweight and is likely to have an important impact on maternal and infant health.

**9. Keywords
Please provide up to 8 keywords that relate to the research undertaken in this study:**

Smoking cessation; pregnancy; evaluation; qualitative; maternity services; cost-effectiveness; effectiveness; natural experiment

10. Dissemination – please detail planned or published articles in peer-reviewed journals (including web links):

Published paper:

Bell R, Glinianaia SV, Waal ZV, Close A, Moloney E, Jones S, Araújo-Soares V, Hamilton S, Milne EM, Shucksmith J, Vale L, Willmore M, White M, Rushton S. [Evaluation of a complex healthcare intervention to increase smoking cessation in pregnant women: interrupted time series analysis with economic evaluation](http://tobaccocontrol.bmj.com/cgi/content/full/tobaccocontrol-2016-053476). Tobacco Control. 2017 Feb 15. pii: tobaccocontrol-2016-053476. doi: 10.1136/tobaccocontrol-2016-053476. [Epub ahead of print] <http://tobaccocontrol.bmj.com/cgi/content/full/tobaccocontrol-2016-053476>

The publication of the above paper led to an NIHR Dissemination Centre Signal – *The “BabyClear” programme helped pregnant women stop smoking in North East England*. Commentary on Bell R, Glinianaia SV, Waal ZV, et al. *Evaluation of a complex healthcare intervention to increase smoking cessation in pregnant women: interrupted time series analysis with economic evaluation*. Tobacco Control. 2017.

Submitted paper:

Jones S, Hamilton S, Bell R, Araujo-Soares V, Glinianaia SV, Milne EM, White M, Willmore M, Shucksmith J. What helped and hindered implementation of an enhanced package of measures to reduce smoking in pregnancy: process evaluation guided by Normalisation Process Theory. Implementation Science (submitted)

Workshops and briefings:

Fuse Quarterly Research Meeting Smoking cessation in pregnancy: the North East leads the way. Workshop with stakeholders presenting results from the evaluation. Darlington July 2016.

Briefing to national stakeholders, PHE London, April 2016.

Case study in NIHR Dissemination Centre Themed Review – New Beginnings Improving Health for Pregnancy, February 2017.

Conference presentations:

Jones S on behalf of the evaluation team. *Implementing an effective system level intervention to promote smoking cessation in pregnant women*. UKCRC Public Health Research Centres of Excellence Annual Conference, London June 2017 (oral presentation)

Rutter A, on behalf of the BabyClear evaluation team. *Evaluation of the implementation of the babyClear© approach to promote smoking cessation among pregnant women in North East England* PHE North Region Quality Assurance Conference York, Feb 2017 (oral presentation)

Rutter A, on behalf of the BabyClear evaluation team. *Evaluation of the implementation of the babyClear© approach to promote smoking cessation among pregnant women in North East England* PHE Annual Conference Warwick, Sept 2016

Bell, Araujo-Soares, Close, Glinianaia, Hamilton, Jones, Milne, Moloney, Rushton, Shucksmith, Vale, van der Waal, White, Willmore. *Evaluation of the implementation of a complex intervention (babyClear©) to promote increased smoking cessation rates among pregnant women in maternity care*. Oral presentation at the Society for Social Medicine

Annual Meeting, York, September 2016.

Bell, Willmore, on behalf of the BabyClear evaluation team
Evaluation of the implementation of the babyClear© approach to promote smoking cessation among pregnant women in North East England. Oral presentation at the UK National Smoking Cessation Conference, London June 2016

Bell, Araujo-Soares, Close, Glinianaia, Hamilton, Jones, Milne, Moloney, Rushton, Shucksmith, Vale, van der Waal, White, Willmore. *Evaluation of the implementation of a complex intervention (babyClear©) to promote increased smoking cessation rates among pregnant women in maternity care.* Oral presentation at the School for Public Health Research Annual Scientific Meeting, Newcastle, March 2016.

Bell, Araujo-Soares, Close, Glinianaia, Hamilton, Jones, Milne, Moloney, Rushton, Shucksmith, Vale, van der Waal, White, Willmore. *Evaluation of the implementation of a complex intervention (babyClear©) to promote increased smoking cessation rates among pregnant women in maternity care.* Oral presentation at the UK Society for Behavioural Medicine Annual Conference, Newcastle, December 2015.

Bell, Araujo-Soares, Close, Glinianaia, Hamilton, Jones, Milne, Moloney, Rushton, Shucksmith, Vale, van der Waal, White, Willmore. *Evaluation of the implementation of a complex intervention (babyClear©) to promote increased smoking cessation rates among pregnant women in maternity care.* Oral presentation at the UK Public Health Research Centres of Excellence Annual Meeting, Edinburgh, November 2015.

Shucksmith, J Jones, S. Hamilton, S. *Process evaluation of a natural experimental intervention to improve smoking cessation rates in pregnancy.* Poster presentation at the UK Public Health Research Centres of Excellence Annual Meeting, Edinburgh, November 2015.

Jones, S. Hamilton, S. Shucksmith, J. *How can more pregnant women be supported to stop smoking? Evaluating the implementation of a stop smoking initiative across the north east of England.* Poster presentation at the UK Faculty of Public Health Annual conference, Gateshead, 23-24 June 2015.

Jones, S. Hamilton, S. Shucksmith, J. *Normalisation Process Theory: a useful method for informing the evaluation of complex interventions?* Oral presentation at the Royal College of Nursing International Research Conference, University of Nottingham, 20-22 March 2015.

Papers in preparation:

Women's responses to the intervention (qualitative)

Non-academic dissemination:

An event with policy makers was held on May 21 2015 (for details see question 11).

A briefing of the provisional results was held on February 29th 2016, at the request of local commissioners.

A briefing with Public Health England took place on April 26th 2016.

The findings were presented at the UK National Smoking Cessation Conference in June 2016 (invited presentation)

A Fusebrief was produced summarising the results and disseminated via the Fuse website and at Fuse events.

A Fuse blog post was published in February 2017

<http://fuseopscienceblog.blogspot.co.uk/2017/03/the-challenges-and-joys-of-evaluating.html>

A Fuse Quarterly Research meeting (researchers and practitioners) took place in July 2016

An infographic summarising the key findings has been produced with the aim to disseminate to healthcare professionals in the region.

News and Social Media:

A media release was developed in February for the publication of the main results paper. This resulted in coverage on regional TV news (Look North, Tyne Tees) and regional and national radio (BBC Radio 5 Live, Radio 4 Woman's hour, BBC Radio Newcastle, Wales, and Humberside).

11.

Public and participant involvement**Please provide comment on your experiences, any changes made and lessons drawn:****Service user reference panel**

A service user reference panel (SURP) was set up consisting of women who had had a baby in the last few years and were smoking at the time of conception. Two groups of three members each were recruited from toddler groups at two separate locations. All members were still smokers; they had continued to smoke during and after their pregnancies.

The purpose of the SURP was to give the researchers information about members' own experiences of smoking at the start of and/or during pregnancy; with the aim of providing information to be used in the study that recognised the experiences of service users and made the research and findings more relevant to pregnant women. Specifically it was hoped that the SURP would a) inform content of data collection tools; b) identify effective recruiting methods; c) provide insight on initial findings and d) comment on draft report findings. All discussions were recorded on flip charts during the meetings and written up, along with researchers' impressions, shortly afterwards.

Each group met four times with the researchers. All members made every meeting bar one member at the last meeting. The sessions were designed to be highly interactive. At the first meeting the intervention and evaluation methods were outlined and members were asked for their views on participation in the study. At the second meeting they were asked to comment on the proposed interview questions. Following these sessions their contribution was incorporated into the design of data collection tools and recruitment methods.

During a gap between meetings two newsletters were sent to keep in touch. They outlined progress on the project, how the members' input had been used, what had been found so far and plans for future meetings. A third newsletter was sent when we came to organise the third set of meetings to look at preliminary findings. Four key themes arising from the pregnant women's data were discussed. Our findings were checked against members' perspectives. In the final meeting, specific points of interest arising from the data were discussed in more detail, and used to inform the write-up of the findings.

Impact of the SURP

The SURP helped the researchers confirm that no significant topics had been missed, frame the interview questions with greater understanding of the participant's perspective and add a question on the influence of age on smoking behaviour. Another aspect of the usefulness of the SURP lay in its ability to confirm that the views expressed in the evaluation data were consistent with pregnant women who smoke as a broader group. Recruitment was expected to be challenging and discussions revealed a variety of views between groups. Suggestions of methods to try were made however the most helpful outcome was that the researchers gained an insight into what might be in women's minds and militate against recruitment at the scan appointment. Notes and reflections from the SURP have been incorporated into the understanding and validation of the data. This, along with the other aspects mentioned, is expected to strengthen the dependability of our data and findings and therefore any dissemination based on them.

Changes made

The changes made tended to be subtle rather than overt. For example the SURP provided more, accurate, background information about women's situations and how they felt about their smoking, rather than direct changes required. As a result of discussions some interview questions were slightly altered or expanded.

Lessons drawn

The purpose for which the SURP was set up was largely met: informing the development and use of data collection tools, assisting decisions around recruiting methods and providing insight on initial findings. One challenge we faced in desiring the members opinions on draft findings, was how they were presented in a meaningful but less academic way that also met the needs of the researchers. As a result, findings were presented in a selective way, based in the data, focusing on specific issues only, that related closely to the women, but were of particular interest to us.

Involvement with the SURP was successfully maintained. There may be a number of reasons for this. Women expressed pleasure in taking part in the sessions; they enjoyed discussing their smoking in pregnancy behaviours with a peer group in a non-judgemental atmosphere, where no-one was pressuring them to change and simply asking for their views and opinions. The members already knew one another to varying degrees as they attended the groups at the community venues. The SURP meetings were held at those same venues so they were readily accessible to members. A crèche was provided and times of meetings were at members' convenience. Vouchers were given for each attendance which appeared to be a bonus. The researchers kept in touch via newsletters and were available to text or call.

Consultation workshop with service decision-makers

A consultation workshop took place on 19th May 2015. All commissioners, senior managers and clinical managers of stop smoking and maternity services within the region were invited. The main group of attendees were stop smoking service managers (n=8); a few staff from maternity services (n=4) attended but no commissioners. Nevertheless, despite this rather skewed attendance, it gave the researchers an opportunity to hear the views of attendees on the preliminary findings, and to ascertain what they hoped for from the evaluation and also their preferred methods for dissemination of findings.

In preparation for the consultation event a short, online questionnaire seeking opinions on the relative importance of key elements of babyClear in enabling the intervention to reach its full, potential effectiveness had been sent out. The questions arose from the initial analysis of the qualitative data. It was sent to commissioning and providing organisations for whom ethical approval for this purpose had been received. Approval was received from 2 local pharmaceutical committees and 8 trusts, which also covered 8 SSS. Approval was not received from one trust, 2 SSS and all 6 Clinical Commissioning Groups. Fourteen responses were received, predominantly from stop smoking services/commissioners (n=11).

12. What impact has the research already achieved or what might it achieve? (i.e. policy, practice, academic):

The research has generated a steady stream of enquiries from practitioners in other parts of the country and from policy makers, indicating a high level of interest in the results, as evidenced by the request for an early briefing of the results to local commissioners.

A meeting took place to discuss the findings with PHE on April 26th 2016

Briefing meeting held at PHE in April 2016. Signatory on letter from the Pregnancy Challenge team to the Public Health Minister, July 2016.

Included as a case study in the NIHR Dissemination Centre Themed Review – New Beginnings Improving Health for Pregnancy, Feb 2017.

Put forward as a case study for National Tobacco Control plan, however this has not yet been published.

RB has joined the North East tobacco control task force with the remit of ensuring that findings from the evaluation are carried forward into local Sustainability and Transformation Plans regarding action to reduce smoking in pregnancy.

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Department of Health Disclaimer:

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