## Appendix 2

Additional data relating to variable definitions, models 1-3 and missing values

**Box 2.1: Variable definitions (source of data)**

| | |
|---|---|
| Response variables for smoking behaviour throughout pregnancy | 1- Non-smokers (N= 27050) include:<br>- No record of smoking, quitting, smoking cessation service (SCS) contact throughout pregnancy<br>- Record of not smoking consistent throughout pregnancy<br><br>2- Smokers during pregnancy (N= 10676) include:<br>- Recorded smokers at booking (maternity, SCS)<br>- Records of quit date/ having set a quit date<br>- Records of attending/refusing appointment(s) with SCS<br>- Referral/ referral date with SCS<br>- Recorded smoker at booking (maternity, SCS)<br>- Record of information sent or any contact by SCS<br>- Recorded status for quit at 4 weeks' by SCS (any but NA)<br>- Recorded smokers at delivery  (maternity)<br><br>From status of smokers at booking, we were able to identify smokers at delivery and those who had quit at delivery:<br>3- Smokers at delivery (N=6882) includes:<br>- Recorded smokers at delivery  (maternity)<br>4- Quitters by delivery (N= 3712) includes:<br>- Recorded smokers at booking that are not recorded as smokers at delivery<br>5- Unknown smoking status  (N= 82) includes:<br>- Smokers at booking with unknown smoking status at delivery (cannot determine whether they quit or not) |
| Engagement with smoking cessation services | Setting a quit date (N=881) includes records of having set a quit date(s), one or more quit date(s) recorded, SCS outcome as having set a quit date. |
| Referrals to smoking cessation services | N=5613 referrals, include all observations with any record with SCS of:<br>- Whether a quit date was set<br>- Whether appointment(s) were attended or booked<br>- Ever being referred to SCS, any referral date<br>- Being sent information or contacted by SCS<br>- Any record of smoking status for 'quit at 4 weeks' |
| Estimated first appointment date | First appointment reflects the first potential contact within babyClear©; booking dates were not included as a variable in the dataset. |

| | |
|---|---|
| | Estimated conception date = Delivery date – gestational age at delivery<br><br>Estimated first appointment date = Estimated conception date + 11 weeks |
| Before or after intervention | A response variable is needed that accounts for whether the first booking occurred before or after the start of the intervention. In some cases of first referrals occurring prior to the intervention, further referrals and appointments may have taken place after intervention introduction. This classification considers these pregnancies as "prior" which is to be interpreted as not having received the full intervention protocol. |
| Strategy used for initial contact and referral with smokers | Developed from information gathered during process evaluation (SJ, personal communication) regarding different approaches to arranging contact between women and smoking cessation services<br><br>Categories:<br><br>None: SCS contacted woman after first appointment with midwife<br><br>Appointment: Referred directly SCS by midwives during the first appointment<br><br>Early contact: A specific enhanced strategy for early contact with smokers before their first appointment with a midwife |

**Table 2.1: Individual explanatory variables definition**

| Variable name | Source | Format provided | Unit in analysis | Notes |
|---|---|---|---|---|
| Foundation Trust | Foundation Trust | String | Categorical | Anonymised (A to H) |
| Maternal age at delivery | Maternity services | Numeric (years) | Categorical (15-20 21-30 31-40 41-55) | |
| Date of Additional Training | | Date String | Month of Training | |
| Sex of the baby | Maternity services | String | Categorical | Male or Female |
| Birthweight of the baby | Maternity services | Numeric (grams) | Numeric (grams) | |
| Gestational age at delivery | Maternity services | Numeric (weeks) | Numeric (weeks) | Completed weeks of gestation |
| Maternal parity | Maternity services | Numeric (number of births previous registered stillbirths and live births) | Categorical (First child, Second child, Third child or more) | |
| Maternal weight | Maternity services | Numeric (kg) | Numeric (kg) | *Not used* |
| Maternal height | Maternity services | Numeric (m) | Numeric (m) | *Not used* |
| BMI | Maternity services | Numeric ($kg/m^2$) | Categorical (<20, 20-24.9, 25-29.9, 30) | *Calculated using weight height when provided, if not using value 'recorded'.* |
| Mother's ethnic origin | Maternity services | Categorical according to national code | Categorical (White non-White) | White British White Irish Any other white background Mixed – White and black Caribbean Mixed – White and black African Mixed - White and Asian Any other mixed background Asian – Indian Asian – Pakistani Asian - Bangladeshi Asian Other |

| | | | | |
|---|---|---|---|---|
| | | | | Black or Black British - Caribbean<br>Black or Black British - African<br>Black or Black British – any other Black Background<br>Chinese<br>Any other ethnic group<br>Not stated |
| IMD score (Quintiles) | Postcode matching | Numeric, 2007 IMD scores | Categorical (0-16 17-64 65-80) | Aggregated score and scores for each domain downloaded from: http://data.gov.uk/data set/index_of_multiple_ deprivation_imd_2007 |

We used an area based measure of deprivation based on lower super output area (LSOA). The LSOA was linked directly to maternal postcode and the overall score for Indices for Multiple Deprivation (IMD) was obtained. IMD scores for each mother were then partitioned into deprivation quintiles by dividing the range of scores into five equal groups. We partitioned the range of IMD scores based on LSOA for the northeast region as a means of generating a measure of deprivation that may be more representative of local area as opposed to national statistics where it has been suggested that the distribution of deprivation may unequal between geographical areas. The IMD quintiles were ranked and reclassified as ordinal variables according to the magnitude of deprivation. Quintiles were reclassified 1-5 from the least deprived to the most deprived scores.

**Models**

**Table 2.2.** Estimation of effect sizes and corresponding standard errors, on rate of monthly referral counts for model 1.

| Variable | Estimate | Standard Error | Z-value | Pr(>\|z\|) | IRR | 95% CI |
|---|---|---|---|---|---|---|
| Intercept: Baseline | -3.85 | 0.48 | -8.02 | <0.0001 | 0.02 | 0.01-0.06 |
| babyClear© intervention, compared to before intervention for reference | | | | | | |
| First month | 0.14 | 0.08 | 1.68 | 0.0934 | 1.15 | 0.98-1.35 |
| Second month | 0.41 | 0.08 | 5.30 | <0.0001 | 1.50 | 1.29-1.74 |
| Third month | 0.76 | 0.07 | 11.05 | <0.0001 | 2.14 | 1.87-2.45 |
| Fourth month and beyond | 0.90 | 0.07 | 13.50 | <0.0001 | 2.47 | 2.16-2.81 |
| Time since introduction of intervention, compared to before babyClear© for reference | | | | | | |
| Each additional month | 0.05 | 0.03 | 1.63 | 0.1031 | 1.06 | 0.99-1.13 |
| Strategy for early initial contact with smokers, compared to none | | | | | | |
| Appointment | 0.58 | 0.24 | 2.42 | 0.0156 | 1.78 | 1.12-2.84 |
| Early contact | 1.83 | 0.34 | 5.36 | <0.0001 | 6.21 | 3.18-12.11 |
| Month of training, compared to month without training for reference | | | | | | |
| On month of training | 0.14 | 0.04 | 3.48 | <0.0001 | 1.15 | 1.06-1.25 |

Generalized linear mixed-effects model of monthly referral counts with a Poisson error distribution and an offset for monthly number of deliveries per trust. The random-effect structure contained a random intercept for trust which allows for heterogeneity between trusts in their baseline number of referrals, and a random slope for time correlated with trust intercept which allows heterogeneity between trusts in the deviation from the overall baseline in referral counts through time. The exponential of the coefficient estimates are used to calculate Incidence Rate Ratio's (IRR). Table 2.3 illustrates the variation between Trusts in the effect on referrals. The Trust Incidence Rate Ratio (IRR) is calculated from random intercept and random slope for each trust, whereby the trust effect IRR is the sum of the IRR from base-line, random intercept and slope.

**Table 2.3.** Trust effect on referrals.

| | Incidence Rate Ratio for Each Trust | | | |
|---|---|---|---|---|
| Trust | Base-line IRR | Trust IRR | Slope IRR | Trust Effect IRR |
| A | 0.02 | 2.277 | 0.935 | 3.232 |
| B | 0.02 | 2.346 | 0.951 | 3.317 |
| C | 0.02 | 1.011 | 1.020 | 2.051 |
| D | 0.02 | 0.072 | 1.193 | 1.285 |
| E | 0.02 | 1.593 | 0.960 | 2.573 |
| F | 0.02 | 0.602 | 1.052 | 1.674 |
| G | 0.02 | 5.321 | 0.871 | 6.212 |
| H | 0.02 | 0.514 | 1.050 | 1.584 |

**Table 2.4:** Estimation of effect sizes and corresponding standard errors on probability of quitting by delivery for the full model 2.

| Variable | Estimate | Standard Error | z value | Pr(>\|z\|) | Odds Ratio | 95% CI |
|---|---|---|---|---|---|---|
| Intercept: Baseline | -2.05 | 0.19 | -10.66 | <0.0001 | 0.1284 | 0.09-0.19 |
| After introduction of intervention, compared to before | | | | | | |
| After intervention | 0.59 | 0.08 | 7.35 | <0.0001 | 1.8104 | 1.55-2.12 |
| Time since start of intervention | | | | | | |
| Each additional month | 0.02 | 0.01 | 2.18 | 0.0157 | 1.016 | 1.00-1.03 |
| Ethnic group, compared to White for reference | | | | | | |
| Non white | 0.92 | 0.16 | 5.75 | <0.0001 | 2.52 | 1.84-3.44 |
| IMD category, compared to category of IMD scores 17-84 for reference | | | | | | |
| [0, 16]: Least deprived | 1.01 | 0.07 | 13.88 | <0.0001 | 2.75 | 2.39-3.18 |
| [65, 80]: Most deprived | -0.66 | 0.11 | -5.76 | <0.0001 | 0.52 | 0.42-0.65 |
| Maternal age category, compared to 21-30yr for reference | | | | | | |
| age [15, 20] | -0.28 | 0.07 | -3.94 | <0.0001 | 0.75 | 0.66-0.87 |
| age [31, 40] | 0.36 | 0.06 | 6.47 | <0.0001 | 1.43 | 1.29-1.60 |
| age [41, 55] | 0.13 | 0.21 | 0.63 | 0.5251 | 1.14 | 0.76-1.71 |
| Engagement with SSS, compared to not referred to SSS for reference | | | | | | |
| Referred & quit date | 1.43 | 0.09 | 16.68 | <0.0001 | 4.18 | 3.53-4.94 |
| Referred, no quit date | 1.20 | 0.06 | 21.88 | <0.0001 | 3.33 | 2.99-3.71 |

Generalized linear mixed-effects model analysing the probability of quitting by delivery. The model assessed the smoking status of each individual mother at delivery (smoker or quitter) following assessment of smoking status at booking. We used a binomial error distribution. A random intercept for trust which allows for heterogeneity in the baseline probability of quitting by delivery between observations recorded at different trusts.

**Table 2.5:** Estimation of effect sizes and corresponding standard errors on probability of quitting by delivery for the parsimonious model 2.

| Variable | Estimate | Standard Error | z value | Pr(>\|z\|) | Odds Ratio | 95% CI |
|---|---|---|---|---|---|---|
| Intercept: Baseline | -2.05 | 0.16 | -13.22 | <0.0001 | 0.13 | 0.09-0.17 |
| After introduction of intervention, compared to before | | | | | | |
| After intervention | 0.59 | 0.08 | 7.35 | <0.0001 | 1.80 | 1.56-2.17 |
| Time since start of intervention | | | | | | |
| Each additional month | 0.02 | 0.01 | 2.18 | 0.0293 | 1.01 | 0.97-1.05 |
| Ethnic group, compared to White for reference | | | | | | |
| Non white | 0.93 | 0.16 | 5.76 | <0.0001 | 2.53 | 1.84-3.46 |
| IMD category, compared to category of IMD scores 17-84 for reference | | | | | | |
| [0, 16]: Least deprived | 1.01 | 0.07 | 13.91 | <0.0001 | 2.76 | 2.39-3.18 |
| [65, 80]: Most deprived | -0.65 | 0.11 | -5.71 | <0.0001 | 0.52 | 0.42-0.65 |
| Maternal age category, compared to 21-30 years for reference | | | | | | |
| age [15, 20] | -0.28 | 0.07 | -3.94 | <0.0001 | 0.75 | 0.66-0.87 |
| age [31, 40] | 0.36 | 0.06 | 6.43 | <0.0001 | 1.43 | 1.28-1.60 |
| age [41, 55] | 0.14 | 0.21 | 0.69 | 0.4926 | 1.15 | 0.77-1.74 |
| Engagement with SSS, compared to not referred to SSS for reference | | | | | | |
| Referred & quit date | 1.44 | 0.09 | 16.48 | <0.0001 | 4.23 | 3.56-5.02 |
| Referred, no quit date | 1.17 | 0.06 | 21.01 | <0.0001 | 3.21 | 2.88-3.58 |

**Table 2.6:** Estimation of effect sizes and corresponding standard errors of changes in birthweight (g) for the full model 3.

| Variable | Estimated effect size on log(birthweight) | | | | Estimated Change in birthweight (g) | |
|---|---|---|---|---|---|---|
| | Estimate | Standard Error | t-value | Pr(>\|t\|) | Mean | 95% CI |
| Intercept: Baseline 40wk | 8.08 | 0.00 | 1810.9 | <0.0001 | 3226.98 | 3198.88-3255.32 |
| Gestational age at birth, centred at 40 weeks gestational age at birth | | | | | | |
| Each additional week past 40 | 0.05 | 0.001 | 71.44 | <0.0001 | 158.12 | 152.27-164.07 |
| Squared | -0.003 | 0.00 | -49.71 | <0.001 | -11.94 | -12.48 to-11.72 |
| Smoking status at delivery (compared to smoker for reference) | | | | | | |
| Non-smoker | 0.08 | 0.00 | 32.49 | <0.001 | 261.38 | 243.11-280.28 |
| Quitter | 0.06 | 0.00 | 18.61 | <0.001 | 212.34 | 187.45-237.31 |
| Maternal age category, compared to 21-30 year for reference | | | | | | |
| age [15,20] | 0.003 | 0.003 | 1.27 | 0.3410 | 13.23 | -7.04 to 34.18 |
| age [31,40] | 0.001 | 0.002 | 0.76 | 0.4796 | 4.84 | -7.36 to 16.93 |
| age [41,55] | -0.002 | 0.01 | -0.45 | 0.7511 | -9.68 | -51.82 to 33.53 |
| Parity (compared to second child for reference) | | | | | | |
| First child | -0.03 | 0.002 | -16.45 | <0.0001 | -105.84 | -117.08 to -94.08 |
| Third or more | 0.01 | 0.002 | 2.74 | <0.0067 | 20.65 | 5.76-35.81 |
| Ethnicity (compared to White for reference) | | | | | | |
| Non White | -0.04 | 0.003 | -13.96 | <0.0001 | -140.7 | -158.34 to -122.4 |
| Deprivation (IMD score compared to 3 central quintiles [17-64] for reference) | | | | | | |
| [65-80] Most Deprived | -0.004 | 0.00 | -1.17 | 0.2917 | -15.49 | -40.95 to 10.42 |
| [0-16] Least Deprived | 0.01 | 0.00 | 4.11 | <0.0001 | 28.4 | 14.71-42.32 |
| BMI (compared to healthy weight for reference) | | | | | | |
| Underweight | -0.04 | 0.01 | -7.15 | <0.0001 | -116.49 | -146.51 to -85.61 |
| Overweight | 0.02 | 0.002 | 11.81 | <0.0001 | 79.06 | 65.26-93.1 |
| Obese | 0.04 | 0.002 | 18.58 | <0.0001 | 135.21 | 117.64-151.05 |
| Sex of baby (compared to Female for reference) | | | | | | |
| Male | 0.04 | 0.002 | 23.2 | <0.0001 | 130.37 | 118.04-142.58 |
| Effect of Time | | | | | | |
| cos(pi*month* 2/12) | -0.002 | 0.001 | -1.34 | 0.1311 | -5.49 | -13.44 to 2.6 |
| sin(pi*month* 2/12) | -0.00 | 0.001 | -0.33 | 0.7414 | -1.61 | -8.96 to 5.86 |

A linear mixed-effects model of the log value of weight at birth for each child. A random intercept for trusts allows for heterogeneity in the baseline weight between observations recorded at different trusts.

**Table 2.7:** Estimation of effect sizes and corresponding standard errors of changes in birthweight (g) for the parsimonious model 3.

| Variable | Estimate | Standard Error | t-value | Pr(>\|t\|) | Mean | 95% CI |
|---|---|---|---|---|---|---|
| | Estimated effect size on log(birthweight) | | | | Estimated Change in birthweight (g) | |
| Intercept: Baseline 40wk | 8.08 | 0.00 | 1929.04 | <0.0001 | 3233.1 | 3206.66-3259.75 |
| Gestational age at birth, centred at 40 weeks gestational age at birth | | | | | | |
| Each additional week past 40 | 0.05 | 0.00 | 71.58 | <0.0001 | 156.81 | 151.03-162.66 |
| Squared | -0.00 | 0.00 | -53.43 | <0.0001 | -12.61 | -13.15 to -12.39 |
| Smoking status at delivery (compared to smoker for reference) | | | | | | |
| Non-smoker | 0.08 | 0.00 | 33.35 | <0.0001 | 259.62 | 241.78-277.73 |
| Quitter | 0.06 | 0.00 | 18.76 | <0.0001 | 210.15 | 186.31-235.03 |
| Parity (compared to second child for reference) | | | | | | |
| First child | -0.03 | 0.00 | -16.76 | <0.0001 | -104.43 | -115.44 to -92.9 |
| Third or more | 0.01 | 0.00 | 3.04 | <0.0024 | 22.31 | 7.70-37.16 |
| Ethnicity (compared to White for reference) | | | | | | |
| Non White | -0.04 | 0.00 | -14.24 | <0.0001 | -141.61 | -159.37 to -123.54 |
| Deprivation (IMD score compared to 3 central quintiles [17-64] for reference) | | | | | | |
| [65-80] Most Deprived | 0.00 | 0.00 | -1.20 | 0.2316 | -15.52 | -40.4 to 10.11 |
| [0-16] Least Deprived | 0.01 | 0.00 | 4.15 | <0.0001 | 27.8 | 14.43-41.07 |
| BMI (compared to healthy weight for reference) | | | | | | |
| Underweight | -0.04 | 0.01 | -7.28 | <0.0001 | -116.71 | -146.54 to -86.38 |
| Overweight | 0.02 | 0.00 | 12.00 | <0.0001 | 79.53 | 65.74-93.23 |
| Obese | 0.04 | 0.00 | 18.74 | <0.0001 | 134.5 | 119.29-150.27 |
| Sex of baby (compared to Female for reference) | | | | | | |
| Male | 0.04 | 0.00 | 23.24 | <0.0001 | 129.00 | 117.04-141.5 |

A quadratic term was used to describe the relationship between gestational age at birth and birthweight. The results show that up to 40 weeks gestation, birthweight increases significantly until a threshold is reached. Beyond this 40-week threshold, birthweight significantly decreases. The linear term in the model, described by each additional week beyond 40 weeks gestation provides an assessment of the increase in birthweight. In contrast, the squared term, which is used additively in the model, describes the downward inflection of the curve and is therefore negative.

**Missing values**

**1. Model of variation in monthly count of referrals**

Data were aggregated by month for this analysis, resulting in a total of 132 observation points through time across all trusts 8 trusts. The response variable was concerned with a subset of the population (count of smokers referred), however the model structure included an offset for the monthly sum of observations per trust. In the initial (non-aggregated data), from the total of N=37726 observations, N=36907 were included in the analysis.

From the initial dataset, a total of N=819 records of women were omitted due to either missing records (gestational age) or because information was unavailable to allow initial booking dates to be estimated.

Missing information on gestational age at delivery (N=672, information required to estimate relation to intervention in time, see table 2.7 and 2.8)

Observations during the initial months of data collection in each trust were omitted when information for estimated first booking dates was incomplete (N=41 Table 2.7). Incomplete data during the last four months of estimated first booking date (N=106 observations omitted (Table 2.7).

**Table 2.8:** Number of records of women omitted from the analyses of monthly referral counts.

| Description | Number of Mothers omitted |
|---|---|
| Gestational age unknown | 672 |
| Incomplete information relating to first booking dates | |
| Beginning of the study period to initiation of study | 41 |
| End of the study period | 106 |
| Total | 819 |

**Table 2.9:** Number and percentage of missing records for gestational age at delivery, within each trust and overall.

| Trust | Number of Records | Missing Records | Missing Records (% Total) |
|---|---|---|---|
| A | 9187 | 397 | 4.32% |
| B | 2127 | 0 | 0.0% |
| C | 3017 | 7 | 0.23% |
| D | 3875 | 99 | 2.55% |
| E | 9023 | 20 | 0.22% |
| F | 3712 | 3 | 0.08% |
| G | 5116 | 9 | 0.18% |
| H | 1669 | 142 | 8.50% |
| Total | 37726 | 672 | 1.78% |

**Model of probability of quitting by delivery**

The number of smokers at booking was N= 10676. This cohort was reduced to N= 9967 observations due to N=709 missing records (Table 2.9).

**Table 2.10:** Number of observations removed from data for variables used in the analysis of probability of quitting by delivery due to missing records.

| Variable | Number of Missing Records |
|---|---|
| Smoking status at delivery | 82 |
| Gestational age at delivery | 200 |
| Ethnicity | 329 |
| IMD score | 131 |
| Maternal age | 1 |
| Delivery date | 0 |
| Engaged with Stop-smoking Services | 0 |

**Model of birthweight**

The initial dataset consisted of N=37726 deliveries. This was reduced to N=22826 deliveries due to N=14900 missing records (Table 2.10).

**Table 2.11:** The number of missing records for birthweight and associated variables.

| Variable | Number of missing records |
|---|---|
| Birthweight >2000g and gestational age < 30wks | 8 |
| Birthweight >1000g and gestational age < 20wks | 1 |
| Gestational age > 45wks | 6 |
| Gestational age < 17wks | 13 |
| Gestational age | 672 |
| Birthweight | 150 |
| Sex | 94 |
| IMD score | 659 |
| Smoking status | 82 |
| Parity | 5721 |
| Ethnicity | 1376 |
| BMI | 12239 |
| Maternal height | 12239 |
| Maternal weight | 12135 |