BMJ Open Quantitative assessment of pregnancy outcome following recurrent miscarriage clinic care: a prospective cohort study

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ABSTRACT

Objectives To measure pregnancy outcome following attendance at a recurrent miscarriage service and identify factors that influence outcome.

Design Prospective, observational electronic cohort study. Setting Participants attending a specialist recurrent miscarriage clinic, with a history of two or more pregnancy losses, 857 new patients attended over a 30-month period and were invited to participate. Participant data were recorded on a bespoke study database, 'Tommy's Net'. Participants 777 women consented to participate (90.7% of new patients). 639 (82%) women continued within the cohort, and 138 were lost to follow-up. Mean age of active participants was 34 years for women and 37 years for partners, with a mean of 3.5 (1–19) previous pregnancy losses. Rates of obesity (maternal: 23.8%, paternal: 22.4%), smoking (maternal:7.4%, paternal: 19.4%) and alcohol consumption (maternal: 50%, paternal: 79.2%) were high and 55% of participants were not taking folic acid. **Outcome measures** Biannual collection of pregnancy outcomes, either through prompted self-reporting, or

Results 639 (82%) women were followed up. 404 (83.4%) reported conception and 106 (16.6%) reported no pregnancy, at least 6 months following registration. Of those that conceived, 72.8% (294/404) had a viable pregnancy. Maternal smoking and body mass index (BMI) over 30 were significantly higher in those who did not conceive (p=0.001)

Conclusions Tommy's Net provides a secure electronic repository on data for couples with recurrent pregnancy loss and associated outcomes. The study identified that subfertility, as well as repeated miscarriage, maternal BMI and smoking status, contributed to failure to achieve live birth. Study findings may enable comparison of clinic outcomes and inform the development of a personalised holistic care package.

INTRODUCTION

existing hospital systems.

Miscarriage, the loss of a pregnancy prior to viability (24 weeks gestation) is common, with 15% of pregnancies ending in miscarriage. 1 2 Most miscarriages are sporadic and occur before 12 weeks gestation.³ Recurrent miscarriage (RM) is defined as two or three (or more) consecutive miscarriages. 4 5 It is

Strengths and limitations of this study

- ► The 'Tommy's Net' e-repository and associated database contains baseline and prospective pregnancy outcome data from the largest known population of couples with recurrent miscarriage in the UK.
- Time to conception and viable pregnancy can be calculated from this data using time to event analysis.
- Obtaining follow-up data is challenging but can be improved by using a variety of data collection methods.
- Follow-up data is only requested biannually, therefore, there is an inevitable lag in data collection.
- Limited use of the English language can be a barrier for participants completing the initial lengthy questionnaire.

estimated that 1.9% of women experience two consecutive miscarriages, and approximately 0.7% suffer three or more consecutive miscarriages. 167 In RM, the incidence of euploid fetal loss increases with each additional miscarriage, and the likelihood of a future successful pregnancy gradually decreases.⁸ RM is a debilitating disorder, associated with considerable psychological morbidity.

European and national miscarriage care guidelines recognise the importance of providing good physical care and psychological support, 4 5 however, there are no standardised outcomes to assess care within clinics. The recent Lancet series on miscarriage which brought together best evidence and expert opinion, clearly outlines essential investigations for couples, dependent on their history, together with a graded model of care to optimise outcome. This could address deficiencies identified by couples in a systematic review by van den Berg et al, 10 which evaluated features of care that couples valued within miscarriage services. The review identified that explaining potential causes of





pregnancy loss and planning for future pregnancies were specific areas couples felt could be improved .

Accurate information following attendance at an RM clinic is important for couples' counselling, stratifying care and directing research. While data does exist around outcomes in an RM setting, ^{3 11 12} prospective updates from clinics working under standardised guidance, ⁴ including all couples regardless of their outcome and not only those who conceived or who participate within a research trial, is required.

The Tommy's National Centre for Miscarriage Research brings together an interdisciplinary Translational Medicine research grouping jointly at the University of Warwick, University of Birmingham and Imperial College London. The centre is dedicated to research across all aspects of miscarriage and early pregnancy complications including medical, basic scientific, social and ethical issues. A secure electronic data collection tool and e-repository (with associated database), Tommy's Net, has been developed to facilitate recording of participant data, including follow-up. ¹³

OBJECTIVES

Our objective was to quantify the long-term cumulative live birth rate after first attendance at an RM clinic. A cohort of couples was developed, with prospective data collection of the medical and obstetric histories of both partners, investigation results and pregnancy and neonatal outcomes. The tool for collecting data on this cohort is designed to be used in multiple clinics so that success rates between clinics can be benchmarked. This objective will also allow clinics to support and assess new care pathways, identify areas needing further research, develop outcome prediction modelling and investigate new tests in future clinical trials.

METHODS

The e-repository and associated database has been developed over several years by a team with representation from University Hospital Coventry and Warwickshire (UHCW) National Health Service (NHS) Trust and University of Warwick, Imperial College and University of Birmingham. The cohort was initiated at UHCW but designed so other clinics can join. This paper summarises data collected only from couples attending UHCW RM service.

The study database complies with the regulatory requirements for Good Clinical Practice.

Patient and public involvement

An established patient and public involvement (PPI) group from within the Tommy's centre at UHCW was consulted during initial protocol development. Two further PPI sessions with 10 service users, each including 9 women and 1 partner, where consulted to ensure

follow-up methods where acceptable to participants and to optimise response rates.

Setting

This cohort is from a specialist RM clinic in a tertiary referral centre (UHCW) within the UK. Miscarriage care followed European Society of Human Reproduction and Embryology (ESHRE) guidelines.⁴

Eligibility

All couples with a history of two or more pregnancy losses (including biochemical loss: defined as a positive pregnancy test, without ultrasound evidence of pregnancy), miscarriage, molar pregnancy, ectopic pregnancy and stillbirth) were eligible (online supplemental file 1).

Recruitment

Couples are referred to the RM clinic by their General Practitioner (family doctor). Signposting prior to referral can occur from other hospital departments (eg, early pregnancy assessment unit, acute gynaecology, fertility unit) or charities (eg, Tommy's, The Miscarriage Association). Couples are then sent information about Tommy's Net by post along with a baseline questionnaire (online supplemental file 2). At their first clinic visit a member of the research team explains Tommy's Net and asks them to consent to storage of their data.

Data collection

Both partners complete initial baseline questionnaires including demographic details, obstetric and medical history. Investigation results, blood pressure and body mass index (BMI) are recorded by clinic staff and entered into Tommy's Net (online supplemental file 2).

The Tommy's Net e-repository and database system, used for data collection and storage in the study, is based on the CURe framework, ¹³ ¹⁴ a modular system for collecting research data in secondary care settings. The framework includes methods for the standardised, flexible capture and storage of data. The system is intended to link to the participating centre's clinical information systems where possible to access relevant data already collected, such as laboratory test results. Tommy's Net includes a database to organise data collected as part of the study and a web application for healthcare professionals to use for data entry, review and use in clinic (online supplemental file 3). Data in Tommy's Net can be exported for analysis. The development of Tommy's Net has seen continuous improvements based on feedback from clinicians, researchers and patients. The design of the system is intended to promote interoperability with existing hospital systems to allow researchers to use information already collected, collect pregnancy outcomes to benchmark clinics and allow researchers to identify high risk groups of patients for future research.

Statistical analysis

Statistical analysis was performed using IBM SPSS (V 27) Statistics. Time-to-event analysis was performed



using Kaplan-Meier curves, a non-parametric method for assessing the probability of an event occurring over time. Multivariant analysis was conducted using age, BMI, cigarette smoking status, alcohol consumption and use of folic acid.

Retention and pregnancy outcomes collection

A variety of methods were assessed to collect patient reported pregnancy outcomes after the first clinic visit. Initially, women were encouraged to self-report outcomes by telephoning the clinic or completing an outcome collection form sent by email. Subsequently, automated invitations to complete this form are sent via short message service (SMS)/text message every 6 months requesting information for follow-up. This invitation consists of a single use link allowing the research team to trace the responses back to the patient identifiable baseline information.

Further outcome data are collected through viability scan visits, which can be accessed following initial review in the RM service and using existing hospital systems. Researchers used a maternity database, Evolution, and a local intranet service to improve follow-up and to validate participant reported information.

Using a variety of methods to collect outcomes improves follow-up rate, however, this does require researcher vigilance to avoid duplicate data entry. 17.8% of participants are still lost to follow-up, therefore, more work is needed in this area to encourage continuous engagement of participants (figure 1).

Improving baseline data

In the first 3 months of recruitment, a number of couples (n=83) consented to the study but did not complete the baseline questionnaire. This resulted in their data being marked as 'inactive' within the database (ie, consented to the cohort study but not returned initial baseline questionnaires). On receipt of the baseline questionnaires, participants are 'activated' and followed up 6 monthly (n=10/83 to date). Our process has been updated so critical data items are collected by the clinician from all couples who consent before leaving the initial clinic appointment. Participants are no longer registered within the database until they have completed the initial baseline questionnaire.

Improving pregnancy outcome data collection

Initial pregnancy outcome data collection was poor with only 25% reporting their outcome, mainly due to technical difficulties in completing electronic versions of the forms for the participants. The response rate has gradually improved with development of a text message system. This was followed by other improvements such as a series of changes to the text message wording, by including partners in the messages, and changing the timing of the texts (with the majority sent in the afternoon or evening). Reminder messages are sent after 48 hours and 1 week (if no responses from the initial text are received). Changes

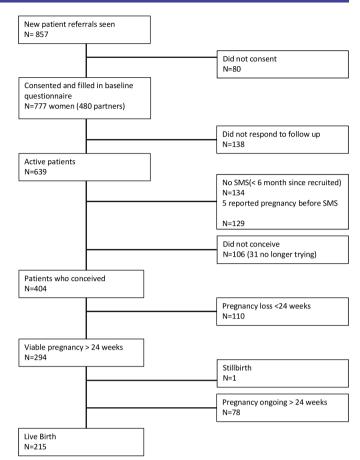


Figure 1 Flow diagram of cohort.

have been informed by PPI groups, which were used to understand further why participants fail to respond to follow-up SMS text message. Some explained that once they had had a baby they were busy - and forgot to reply. Conversely, repeated reporting of no pregnancy, or miscarriage was felt to be disheartening, or less important. We hope through education and careful wording of the questionnaire the response rate will continue to improve.

These approaches have contributed to an increase in response rate and combined with data from existing hospital systems, the response rate for pregnancy outcomes was 82.2%.

Data linkage with a general practice database was not deemed useful, because few miscarriages are recorded on the local general practice databases. Furthermore, there was a lack of standardisation in pregnancy data in primary care, though automated links with both primary and secondary care electronic health systems are still planned. The maternity services database may provide a fruitful source of pregnancy outcome data in the future.

RESULTS

Analysis of cumulative live birth rate

Between May 2017 and January 2020, 777 women (and 480 partners) who attended the RM clinic completed a baseline questionnaire and consented for their data to be included in the database (figure 1). One hundred and

Table 1 Comparison of demographics for all active participants, participants that did not conceive and those that were lost to follow-up

	Total no active patients continuing in cohort	Those that did not conceive within the continuing cohort	P value
No	639	106	
Age mean (range)	33.7 (18-46)	34.03 (22-47)	0.092
Ethnicity	White: 84% (436/519)	White 85.5% (65/76)	
	Mixed: 2.1% (11)	Mixed: 2.6% (2)	
	Asian: 8.9% (46)	Asian: 6.6% (5)	
	Black: 3.3% (17)	Black: 3.9% (3)	
	Other: 1.7% (9)	Other: 1.3% (1)	
	Unknown (120)	Unknown (30)	
Average no of previous live birth	0.6	0.15	0.36
Average no of previous miscarriages	3.5	3.6	
BMI over 30	23.8% (n=126/530)	30% (n=26/87)	0.001
Smoking Y/N	Yes:41 (7.4%)	Yes: 12 (13.5%)	0.001
Alcohol Y/N	Yes: 278 (50%)	Yes: 51 (58%)	0.083
Units	5.54 (0.5–30)	5.03 (0.5–35)	<0.001
Folic acid	Yes: 292 (45.5%)	Yes: 35 (47.17%)	< 0.001

thirty-eight (17.8%) participants were lost to follow-up (no response to SMS, or information obtained for hospital databases), therefore 639 women are active within Tommy's Net. One hundred and thirty-four of these women are within 6 months of consenting to the study and have not yet received a scheduled SMS. Five of these women have reported conceiving out with the SMS system with the data captured through early pregnancy scan clinics. Of the active women, their mean age was 34 years (table 1) and mean number of previous pregnancy losses was 3.5 (range 1–19). Demographic characteristics including age, ethnicity, alcohol intake, folic acid use and previous live births were not statistically different between participants who conceived and those who did not (table 1). Statistically more participants who did not

conceive smoked and had a BMI over 30.

Pregnancy results

Four hundred and four of these women reported conceiving. One hundred and six (16.6%) women reported no pregnancy at least 6 months following registration, 31 (4%) of whom are no longer trying to conceive. Of those that conceived 72.8% (294/404) had a viable pregnancy (215 live births, 1 stillbirth, remainder currently >24 weeks at time of initial analysis). Analysis of data exported from the database in January 2020, revealed a conception of rate of 81% after 2 years within the cohort and viable pregnancy rate (pregnancy over 24 weeks or live birth at time of export) of 60% 2 years after attending the RM clinic (figure 2). Age does impact on time to conception and time to viable pregnancy,

with women of 25–34 years being more likely to have a viable pregnancy 2 years after initial review than other age groups (figure 3). Partner age within this cohort did not have a marked effect on time to conception or viable pregnancy, particularly within the first year after initial consultation.

After 1 year in the cohort, there is a 30% difference between the number of couples who conceive and those who reach viable pregnancy. This difference/gap gradually decreases and plateaus after 900 days to a difference of 19% (conception rate 82% with 63% reaching over 24 weeks gestation). The couples within this 'gap' represent those within our clinic who conceive but miscarry prior to viability despite current intervention and support. This

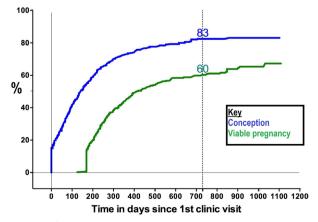


Figure 2 Cumulative rate over time, from initial consultation to conception and viable pregnancy (>24 weeks gestation).

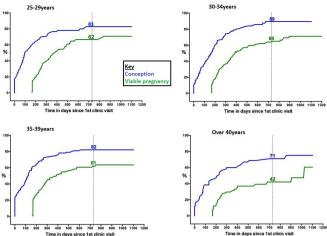


Figure 3 Comparing conception to >24 weeks gestation by age.

gap is maintained within the 30–39 years age group but is less pronounced within those who conceive aged 25–29 years (figure 3). Female BMI over 30 and female smoking status along with miscarriage history increases the time from initial consultation to conception and viable pregnancy within this patient group (figures 4–6). Partner BMI, smoking status or alcohol intake did not impact on time to conception or time to viable pregnancy.

A healthy BMI increases the chance of viable pregnancy, particularly when compared with a maternal BMI over 30 kg/m2 (figure 4). Having a BMI over 30 increases the time taken to viable pregnancy by 100–200 days. Within this population BMI does not appear to significantly change the time to conception (figure 7), particularly within the first 300 days.

Couples who have had four or more miscarriages take longer to conceive, compared with couples who have has three or less miscarriages (figure 5). There is a 17% gap within couples who have had four or more losses when comparing the rate of conception with viable pregnancy.

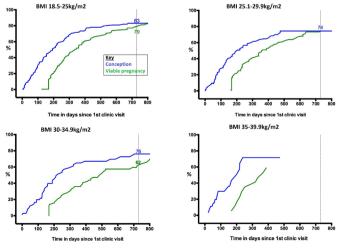


Figure 4 Time from initial consultation to conception/>24 weeks gestation by female BMI range. BMI, body mass index.

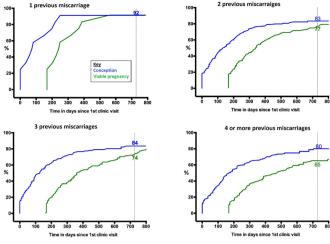


Figure 5 Time from initial consultation to conception/>24 weeks gestation by miscarriage history.

This gap represents those that continue to miscarry and should be a population where research should be focused.

Smoking status impacts on time to conception (figure 6). Females that smoke take longer to conceive with significantly more never conceiving.

DISCUSSION Database

We have developed an electronic method of obtaining outcomes from women following attendance at an RM clinic. These outcomes can be used to assess RM care and form a 'benchmark' to compare clinical services and interventions. The electronic cohort provides clinic outcome data in real time (online supplemental file 3), and can be used for counselling couples as to both the chance of their next pregnancy succeeding and their cumulative time to live birth. This is novel, as data^{3 11 12} identified at literature review could not be generalised to the UK population. Lund *et al*¹¹ used a national, Danish registry to collect live birth data from attendees up to 5 years after their visit to an RM clinic. Registry data were collected retrospectively and lacks information from couples who moved to other countries. Brigham *et al*⁸

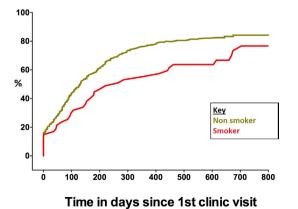


Figure 6 Time from initial consultation to conception by female smoking status.

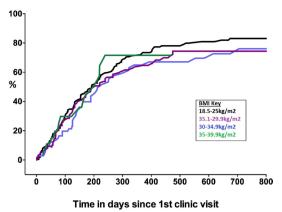


Figure 7 Time from initial consultation to conception by BMI. BMI, body mass index.

analysed 716 couples over a 10-year period in their Liverpool clinic, with pregnancy outcome data on 325 patients with unexplained RM. Data were only reported on those who conceived and had their pregnancy and birth care at the same hospital. These datasets are now over 20 years old. Kling et al¹² published more recent data based on a tertiary referral immunological centre within Germany. Seven hundred and nineteen couples were followed up for a median of 33.7 months, producing time to pregnancy and time to delivery over a 5-year period. While this is valuable data the study excluded couples who already had children within the partnership (25% within our clinic) and used immunotherapy in a proportion of couples which is not routinely used within the UK. It also asked for patient reported outcomes between 9 months to 4 years after the event which could be prone to recall bias. This database will continue to collect and provide prospective outcomes of all those who attend this RM clinic and, as use increases within the other sites it will allow comparison of outcomes with the aim of sharing good practice to improve patient care.

Infertility

The time to conception curve within our RM population is similar to that in the general population. ¹⁵ It is often assumed that the reason couples do not have a baby after attendance at RM services is because they have miscarried again. This however is only part of the picture. Analysis to date has identified that within our cohort 16.6% (n=106) of couples fail to conceive within the follow-up period. These patients are similar ethnicity when compared with all within the active cohort. They do have a trend to a higher BMI and are statistically more likely to smoke. Whist the mean age was similar in those conceived and those who did not, the expected effect of age on conception was demonstrated with a lower conception rate after 2 years in those over 40 years old.

Reasons why couples do not conceive are complex. Couples were encouraged to conceive immediately from first consultation, while investigation results are awaited. Anecdotal evidence from the text message system and PPI groups shows some couples feel unable to continue trying

to conceive due to the potential risk of repeat miscarriage. Recent research¹⁷ has highlighted an increased risk of post-traumatic stress disorder following pregnancy loss. We hypothesise that the psychological impact of miscarriage may stop couples from trying to conceive again. This is an important area on which to focus research and facilitate additional counselling and support.

Other couples may be unable to conceive despite actively trying. Identifying this subgroup of couples earlier could facilitate prompt referral to fertility services for assessment and treatment. Potentially increasing their chance of conception and ultimately live birth. Within this population, the rate of conception decreases significantly 1 year after initial consultation (figure 2). Sixty-five per cent of couples conceive within 1 year of initial consultation, with only an additional 15% conceiving in the second year. In view of this decrease in pace of conception we suggest referral to fertility services should be considered within this population after 1 year.

Throughout the UK, access to NHS-funded fertility treatment is dependent on maternal weight, smoking status, as well as age and parity. Addressing these factors early in the couple's fertility journey may help to manage expectations prior to referral and reduce any delay in starting treatment. We recognise that weight particularly can be a sensitive issue and difficult to manage. Open and honest discussion, without blame, along with support and advice that, for example, joining group programmes for exercise and dietary modification can lead to more pregnancies than weight loss alone 17 should be given. Referral to specialised weight management services including bariatric dietetic and surgical teams could be discussed if appropriate.

There may be a role for ovarian reserve assessment for women who have previously taken over 12 months to conceive. Having strong links, or an integrated multidisciplinary preconception service including miscarriage and fertility specialists along with psychologist and counsellors may allow a more cohesive approach to these couples and increase their chance of having a viable pregnancy as well as providing continuity of medical and psychological care.

Outcome data

Comparing the 'time to conception' and 'time to viable pregnancy' curves illustrate the importance of assessing cumulative data. There is by definition a lag between conception and reaching 24 weeks pregnant, but following this the difference between the curves represents delay in live birth due to miscarriage. This gap decreases initially and may represent an impact from interventions and support within the RM service. The importance of support to couples will be studied further during a planned qualitative study using semi-structured interviews of affected couples. After 900 days the gap between the curves is static and represents those whom despite conceiving have not yet had a child. This is a



group which resources and research should be targeted to further understand reasons for miscarriage.

Health education

It is well documented that miscarriage risk increases with BMI over 30 kg/m 2 and smoking status. 16 $^{18-21}$ Despite this 23.8% of women within the cohort have a BMI over 30 kg/m 2 and 7.4% smoke tobacco. Modifying these lifestyle factors through preconception counselling may reduce the chance of miscarriage and improve pregnancy outcome by reducing the incidence of, for example, gestational diabetes. Future research could be targeted at support in weight loss and smoking cessation.

Limitations and strengths

The Tommy's Net e-repository and associated database contains baseline and prospective pregnancy outcome data from the largest known population of couples with RM in the UK. It allows calculation of 'time to conception' and 'time to viable pregnancy' using time to event analysis. This large dataset aims to facilitate future studies within an RM population.

Obtaining follow-up data is challenging. Using a variety of methods including self-reporting through the text message link and local hospital systems has improved our follow-up rate.

Couples with limited English were unlikely to complete the lengthy questionnaire, which is currently only available in English. This means that this study is likely to miss high risk groups within our community

The introduction of the maternity services database could provide a valuable resource to enable improved follow-up. Couples attend this RM clinic from all over the UK. Currently couples who deliver within our trust have at least two ways in which we can capture their outcome (short message service (SMS) text message and hospital database with or without scan clinic information). These checks are not available to couples who have travelled some distance to attend and therefore may be underrepresented within the active participants group.

SMS text message requests for follow-up are only sent every 6 months. This means that for the first 6 months that participants are within the study we do not expect to collect any outcome data. Some of these participants may go on to become 'inactive' and be removed from analysis.

CONCLUSION

We have developed a user-friendly electronic database, storing comprehensive data, which can provide accurate time to conception and data on viable pregnancies to facilitate analysis into factors contributing to RM. 16.6% of women within our clinic did not conceive and early referral to fertility services should be facilitated. Over 20% of women within the cohort have a BMI of over 30% and 7.4% smoke. Preconception counselling should be targeted at weight and smoking status with an aim of reducing miscarriage.

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Contributors SDQ had the initial concept. OK, SLCK and TNA designed and developed Tommy's net database and extracted initial data. RS analysed the data and interpreted it along with SDQ. RS wrote the initial draft, which was revised by SDQ and DB, and reviewed by AJH, OK, SLCK, TNA, AB, AJD, SDQ and SDK. All commented on initial drafts and approved the final version. RS is the guarantor for the article.

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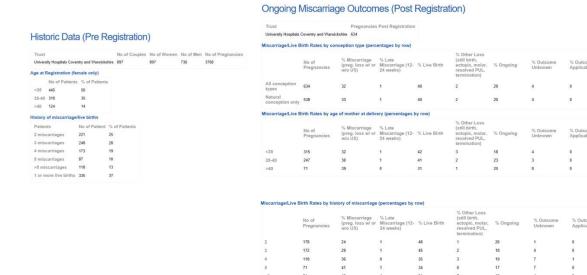


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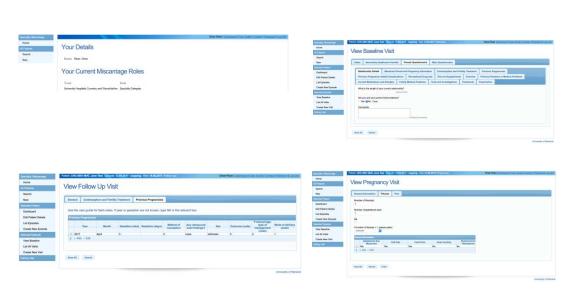
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- 18 Mishra GD, Dobson AJ, Schofield MJ. Cigarette smoking, menstrual symptoms and miscarriage among young women. Aust N Z J Public Health 2000;24:413–20.
- 19 Kmietowicz Z. Smoking is causing impotence, miscarriages, and infertility. BMJ 2004;328:364.2.
- 20 Pineles BL, Park E, Samet JM. Systematic review and meta-analysis of miscarriage and maternal exposure to tobacco smoke during pregnancy. Am J Epidemiol 2014;179:807–23.
- 21 Matjila MJ, Hoffman A, van der Spuy ZM. Medical conditions associated with recurrent miscarriage-Is BMI the tip of the iceberg? Eur J Obstet Gynecol Reprod Biol 2017;214:91–6.

1

1 Dashboard



2



3

4





Registration form

Male details

Title	Date of birth
Surname	Ethnic group (see last page)*
First and forename(s)	Religion (see last page)*
Address	Marital status (see last page)*
	Education (see last page)*
	Occupation
	NHS number
	Hospital number
City/town	GP name
County	GP address
Telephone (Home)	
Telephone (Mobile)	GPtelephone
E-mail address (we will use this to correspond with you):	·

Data Disclosure and Protection: By completing this form, you hereby give your consent for the data to be held within the NHS in accordance with the requirements of the 1998 Data Protection Act (UK).

Male signature:	
Date:	

 $Tommy's\ Net\ question naire\ (Male)\ v2.1\ 26/06/2017$

^{* -} enter the relevant code from the list of tables on the last page of this form



Please complete this form with as much information as you are able to. If you are uncertain about any of the questions you will be able to check these with your healthcare provider at your clinic appointment. Please include all medical information in your history even if you think it may be unimportant.

Previous illnesses or medical problems

Have you had any serious illnesses or	redical problems?
If yes, tick all applicable:	
Diabetes	Rheumatism or painful joints
Thyroid problems	Skin rashes or other skin disorders
Cancer	Irritable Bowel Syndrome
Heart problems	Coeliac disease
Liverproblems	Crohn's disease
Migraines	Autoimmune disease
Epilepsy	Other inflammatory disorder
Depression	Thrombosis (clot in the leg or chest)
High blood pressure	Candida
Lupus(SLE)	Bacterial urethritis
_	Abnormal urethral discharge
Other illnesses	Please state:
If you have ticked any of the boxes abo	ove, please provide further details below:
Current medications and allergies	
Please provide details on any allergies	you have and medication you are currently taking below:

Tommy's Net questionnaire (Male) v2.1 26/06/2017



Andrological history

Have you had a testicular examination before? Yes	No No
What was found?	<u> </u>
Have you had any of the following diagnosed?	
Please tick all applicable options	<u></u>
Absence of a testicle	Mumps
(cryptorchidism)	Tuberculosis (TB)
Testicular pain	Impotence/erectile dysfunction
Twisted testicles (torsion)	Ejaculatory dysfunction
Testicular cancer	Infertility
Varicose veins in your scrotum	STI's
If you have ticked any of the boxes above, please pro	vide further details below:
Have you had any of the following surgeries?	
Please tick all applicable options	
Groin surgery]
Varicocelectomy]
Orchidectomy]
Orchidopexy	- 1
Surgery for hernia	j

Family medical problems

ranniy medicai problems					
Has your mother, father, sibling. If yes, tick all applicable:	s or maternal aunt(s) ha	ad any medical compl	Yes	No	
Miscarriage Recurrent (3 or more) miscarriages	If yes:	Number of 1st trimester losses (<12 weeks)	Number of 2nd trimester losses (>12 weeks)		I don't know
Obstetric complications (such as pre-eclampsia and growth restriction)			Still birth Pre-term birth		
Genetic or developmental problems Heart problems under the age of 50			Infertility High blood pressure Diabetes		
Stroke under the age of 50			Blood clots (thrombosis) Depression Other		
			Please state:		
If you have ticked any of the box	es above, please provid	de further details belo	w:		

Tommy's Net questionnaire (Male) v2.1 26/06/2017

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Previous paternal history

1 revious paternal instory	
Have you had children in another relationship? If yes, number of children:	
Have you ever had a delay (>12 months) trying to father a child?	
What age did you enter puberty? years	
What is your current average ejaculatory frequency per week? times/week	
What is your usual ejaculatory frequency per month (4 weeks)? times/month	
Occupational exposure	
Have you been exposed to any harmful substances during your current or previous jobs? (see below for examples of such substances) Exposure Type/Substance: (Years of exposure) Dust Asbestos Noxious Gases Noxious Gases Other (please specify): Other (please specify): Please provide further details:	
	-

Tommu's

1	National Centre for Miscarriage Research
	Typeofunderwear
	What type of underwear do you wear?
	Tick one option

Tick one option
Boxer shorts Long underwear
Boxer briefs/trunks Jockstraps
Briefs None
Thongs/Bikinis/G-strings
What type of fabric is the underwear most commonly made from?
Tick one option Cotton
Synthetic
Lycra
Other (please specify)
Do they hold your testicles to the body, or are they loose?
Tick one option
Tight
Loose
Unsure
Is the tightness of your underwear similar to before the last time your partner fell pregnant?
Tick one option
Yes No Don'tknow
Technology habits
Do you ever sit with a laptop computer on your lap? Yes No
How many hours per day? hours minutes
Do you keep your mobile phone (that's switched on) in your trouser pocket?
Front pocket? Yes No Back pocket? Yes No
↓ ↓
How many hours a day? hours/day How many hours a day? hours/day

Tommy's Net questionnaire (Male) v2.1 26/06/2017

Diet and supplements

and supplements									
ow many days a week do you ea	t the following	foods:							
k one box per food type									
			Number	of days p	er week				
	0	1	2	3	4	5	6	7	
Red meat									
White meat		П							
Fish		П			П				
Eggs								П	
Fresh fruit						П		П	
Fresh vegetables						П		П	
Dairy products								П	
Soya products								П	
Chocolate								П	
Nuts (almonds/walnuts)						П		П	
How many cups of coffee* do you How many cups of tea* do you How many cans (or equivalent) per day (e.g. energy drinks, col	ı drink in a typi) of soft drink c	ical day?		cup	s of coffe os of tea/c				
Do you currently take any vita If yes, please provide details:	mins or supple	ments?	Yes	□ N	No				
Name of p	roduct		Frequency	(times/w	eek)	How lo	ong have yo	ou been taking eks)	git?
1									
2									
3									

Tommy's Net questionnaire (Male) v2.1 26/06/2017

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^{*} Do not count decaffeinated drinks

	Name of product	Frequency(times/week)	Duration (weeks)
l			
2			
3			
1			
	urrently taking any protein shakes or ase provide details:	r protein bars? Yes	No No
) yes, pree	Name of product	Frequency(times/week)	Duration (weeks)
2			
3			
1			
	ollow a regular routine of physical ex ny days a week do you exercise? option 0 1-2 3-4 5-6	rercise? Yes If you exercise, how many hours a data and an arrive trick one option	No ay do you exercise? < 30 min 30 min - 1 hr 1 hr - 1.5 hrs 1.5 hrs - 2 hrs

Tommy's Net questionnaire (Male) v2.1 26/06/2017

Recreational drug use

Do you currently drink alcohol?	Yes No
	How many units per week? units per week
Do you currently smoke?	
	•
How many ciga	arettes? per day Have you recently stopped? Yes No
	per week If yes, how recently did you stop? < 1 month
How many vapasessions?	per day per day
One session is c	
as 5 or more ini	per week Yes No
Do you take any other recreational dru	ugs?
If yes, please complete table:	↓
Туре	Frequency of use (tick one option)
	☐ Daily ☐ 2-3 times per week ☐ Weekly ☐ Bi-weekly ☐ Monthly
	☐ Every 2-3 months ☐ Every 6 months
	☐ Daily ☐ 2-3 times per week ☐ Weekly ☐ Bi-weekly ☐ Monthly
	☐ Every 2-3 months ☐ Every 6 months
	☐ Daily ☐ 2-3 times per week ☐ Weekly ☐ Bi-weekly ☐ Monthly
	☐ Every 2-3 months ☐ Every 6 months
	□ Daily □ 2-3 times per week □ Weekly □ Bi-weekly □ Monthly
	□ Every 2-3 months □ Every 6 months
	□ Daily □ 2-3 times per week □ Weekly □ Bi-weekly □ Monthly
	☐ Every 2-3 months ☐ Every 6 months
	☐ Daily ☐ 2-3 times per week ☐ Weekly ☐ Bi-weekly ☐ Monthly
	☐ Every 2-3 months ☐ Every 6 months

Tommy's
National Centre for
Miscarriage Research

Tests and investigations

Please give details of any tests or investigations you've had as a part of your treatment.

Test/investigations	Date of test	Result	Which hospital or clinic did you have the test at?
Semen analysis			
Sexually transmitted infection screening			

If other tests, please state below:

Test/investigation	Date of test	Result	Which hospital or clinic did you have the test at?



Treatments

Please give details of any treatments you've previously received or are currently receiving as a part of your miscarriage management. Please also include any medications that you've bought yourself.

Treatment (please include medicines and operations)	Dose	Date from*	Date to	Tick if ongoing	Additional clinician's notes

^{*} If an operation, please give the date of operation

Tommy's Net questionnaire (Male) v2.1 26/06/2017

Examination

This section should be completed in conjunction with the a member of the research team who attends to you in the clinic
Weight:
Blood pressure:
Examination findings (if appropriate)
For Tommy's research office use only if patient is consented and registered to take part in Tommy's research
Date of consent: d d - m m m - y y y y
Patient ID: P A T
Recruiting site:
Date entered onto database:// Entered by: Date checked:// Checked by:

Tommy's Net questionnaire (Male) v2.1 26/06/2017

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Ethnicity codes

******	nerty codes	
WHIT	T	Category includes
A	White British	English, Scottish, Welsh, Cornish
В	White Irish	
С	Any other white background	Former USSR, Baltic States, Former Yugoslavia, Other European, White South African, American, Australian, New Zealander, Mixed White
CF	Greek	
CG	Greek Cypriot	
СН	Turkish	
CI	Mediterranean	Italian, Portuguese and Spanish
CJ	Turkish Cypriot	
CN	Jewish	
CY	Other White European	
MIXE	ED .	
D	White & Black Caribbean	
Е	White & Black African	
F	White & Asian	
G	Any other mixed background	
ASIA	NOR ASIANBRITISH	
Н	Indian	British Indian, Punjabi
J	Pakistani	British Pakistani, Kashmiri
K	Bangladeshi	British Bangladeshi
L	Any other Asian background	British Asian, East African Asian, Sri Lankan, Tamil, Sinhalese, Caribbean Asian, Nepalese, Mixed Asian
BLAC	K OR BLACK BRITISH	
M	Black Caribbean	Caribbean, West Indian Islands (and also Guyana) apart from Puerto Rican, Dominican and Cuban, which are Latin America
N	Black African	Nigerian, Kenyan, Black South African, Other Black African Countries
P	Other Black background	Black American, Mixed Black
PA	Somali	
PE	Black British	
OTHE	R ETHNIC GROUPS	
R	Chinese	inc. Hong Kong
S	Any other ethnicity	Japanese, Filipino, Malaysian, Aborigine, Afghani, Burmese, Fijian, Inuit, Maori, Native American Indian, Thai, Tongan, Samoan, Iranian, Israeli, Kurdish, Latin American (inc. Cuban, Puerto Rican, Dominican, Hispanic), Moroccan, Multi Ethnic Islands (inc. Seychellois, Maldivian, St. Helena), Other Middle Eastern (inc. Iraqi, Lebanese, Yemeni), Other North African, South American (inc. Central America).
SA	Africa—colour not defined	
SC	Arab	
SD	Vietnamese	
Z	Not stated	
L	INOL STATEG	

Tommy's Net questionnaire (Male) v2.1 26/06/2017

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Religion codes

A	Christian (all denominations)
В	Buddhist
C	Hindu
D	Jewish
Е	Muslim
F	Sikh
G	Agnostic
Н	Atheist
I	I'd rather not say
J	Other (please specify)

Marital status codes

A	Single
В	Married
C	Separated
D	Divorced
E	Widowed

Education codes

A	No formal qualifications
В	1-4 GCSEs (A*-C) or equivalent
С	5+ GCSEs (A*-C) or equivalent
D	Apprenticeship
Е	2+ A-levels or equivalent
F	Degree or above
G	Other (please specify)

Tommy's Net questionnaire (Male) v2.1 26/06/2017





Registration form

Female details

Title	Date of birth
Surname	Ethnic group (see last page)*
First and forename(s)	Religion (see last page)*
Address	Marital status (see last page)*
	Education (see last page)*
	Occupation
	NHSnumber
	Hospital number
City/town	GP name
County	GP address
Telephone (Home)	
Telephone (Mobile)	GP telephone
E-mail address (we will use this to correspond with you):	

Data Disclosure and Protection: By completing this form, you hereby give your consent for the data to be held within the NHS in accordance with the requirements of the 1998 Data Protection Act (UK).

Female signature:	
Date:	

Tommy's Net questionnaire (Female) v2.1 26/06/2017

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 $[\]ensuremath{^*}$ - enter the relevant code from the list of tables on the last page of this form

Please complete this form with as much information as you are able to. If you are uncertain about any of the questions you will be able to check these with your healthcare provider at your clinic appointment. Please include all medical information in your history even if you think it may be insignificant.

Relationship details		
What is the length of your currentrelationship? years months	Yes	No
Are you and your partner blood relatives?	\Box	
Please describe:		
	<u> - </u>	
Menstrual period and pregnancy information		
What was the first date of your last menstrual period?	у у	У
What age did your periods start? years	Yes	No
Are your periods regular?		
If yes, what is your cycle length (time from the beginning of one period to the beginning of the next)?		
If no, what is your cycle length? MIN days		
MAX days		
How many days do you bleed for?		
Do you get any bleeding in between your periods?		
Do you have any problems with intercourse?		
How frequently do you have intercourse? per/wk		
or per/month		
Have you ever had a delay (>12 months) in trying to get pregnant?		
Are you currently pregnant?		
↓		
Are you currently trying to become pregnant?		
How long have you been trying to conceive?	*	years months
		Page 2 of 10

Tommy's Net questionnaire (Female) v2.1 26/06/2017



Contraception and fertility treatment

Please complete the table below with all forms injection, oral contraceptive pill). Use of conde			ICD), Depo-Provera						
Type of contraception	How long did you use it (years)?	How long ago did you stop using it (years)?							
			_						
Have you ever used fertility treatment to try	and get pregnant?	Yes	No						
Please tick all treatments y	ou've had, and enter the num	ber of attempts							
	Clomid/other o	vary stimulation	attempts						
		IVF/ICSI	attempts						
	IUI attempts								
	Donor sperm treatment attempts								
	Donor egg treatment attempts								

Tommy's Net questionnaire (Female) v2.1 26/06/2017

Previous pregnancies



Use the key opposite to complete the fields marked with *. If year or gestation are not known, state NK in the relevant box

Year	Gestation (wks)	Time taken to get pregnant (months)	Method of conception*	Any ultrasound scan findings? (e.g. please tell us if the baby's heart- beat was seen)	Sex (MorF,if known)	Outcome** (enter code)	Ifmiscarriage, type of management*** (enter code)	Mode of delivery**** (enter code)	With current partner (Yes or No)	Additional clinician's notes



* Method of conception

1	Natural
2	IVF/ICSI
3	IUI
4	Donor sperm treatment
5	Donor egg treatment
6	Ovarian stimulation

**Outcome

1	Live birth
2	Stillbirth
3	Pregnancy loss without ultrasound confirmation of pregnancy
4	Miscarriage after ultrasound confirmation of pregnancy
5	Late miscarriage (>12 weeks to <24 weeks)
6	Ectopic pregnancy
7	Molar pregnancy
8	Resolved pregnancy of unknown location
9	Termination

$***Type\ of\ management$

1	Expectant (waited for nature to take its course)
2	Surgical (operation)
3	Medical (took a tablet(s))

**** Mode of delivery

1	Unassisted vaginal				
2	Instrumental vaginal (forceps or suction cup delivery)				
3	Elective caesarean section				
4	Emergency caesarean section				
5	Vaginal breech				
6	Not applicable				

$\label{lem:previous pregnancy-related complications} Previous \ pregnancy-related \ complications$

Do you have a history of polycystic ovaries? Do you have a history of fibroids?	Yes No
	If yes: Distorting womb cavity Not distorting womb cavity I don't know
Do you have a history of endometriosis?	
Do you have a history of pelvic inflammatory disease?	
Do you have a history of uterine (womb) abnormalities?	
Have you ever had a sexually transmitted disease?	\Box
If yes, when: m m - y y Have you ever had any previous gynaecological surgeries?	y y Was it treated?
If yes, tick all applicable:	
Laser or loop excision of the cervix (LLETZ) Removal of fibroids Endometriosis surgery If yes, how ma Removal of sca Womb septum	ny operations? operations artissues in the womb removal logical surgeries If yes, state:
Removal of ovarian cyst(s) Surgical management of miscarriage Other gynaeco I don't know	logical disorders If yes, state:
Date of last cervical smear test?	у у у
Result? Normal	Abnormal

Tommy's Net questionnaire (Female) v2.1 26/06/2017

Recreational drug use

Do you currently drink alcohol?	Yes No How many units per week? units per week
Do you currently smoke?	
How many ciga	rettes?
How many vaping sessions? One session is classical description.	per day
as 5 or more inh Do you take any other recreational dru	Yes No
If yes, please complete table:	↓
Туре	Frequency of use (tick one option)
	☐ Daily ☐ 2-3 times per week ☐ Weekly ☐ Bi-weekly ☐ Monthly ☐ Every 2-3 months ☐ Every 6 months
	□ Daily □ 2-3 times per week □ Weekly □ Bi-weekly □ Monthly □ Every 2-3 months □ Every 6 months
	□ Daily □ 2-3 times per week □ Weekly □ Bi-weekly □ Monthly
	☐ Every 2-3 months ☐ Every 6 months ☐ Daily ☐ 2-3 times per week ☐ Weekly ☐ Bi-weekly ☐ Monthly
	□ Every 2-3 months □ Every 6 months
	☐ Daily ☐ 2-3 times per week ☐ Weekly ☐ Bi-weekly ☐ Monthly
	☐ Every 2-3 months ☐ Every 6 months
	☐ Daily ☐ 2-3 times per week ☐ Weekly ☐ Bi-weekly ☐ Monthly ☐ Every 2-3 months ☐ Every 6 months

Diet and supplements

ind supprements							
w many days a week do you eat	the following	g foods	:				
k one box per food type							
			Number	of days per week	X.		
	0	1	2	3 4	5	6	7
Red meat				$\neg \sqcap$			
White meat				\dashv \sqcap			
Fish				\dashv \sqcap			
Eggs				\neg			
Fresh fruit				\neg			\neg
Fresh vegetables	П			\sqcap			
Dairy products				\sqcap			
Soya products	П			\sqcap			
Chocolate				\sqcap			
Nuts (almonds/walnuts)	П			\sqcap			
How many cups of coffee* do you How many cups of tea* do you How many cans (or equivalent) per day (e.g. energy drinks, cola	drink in a typ	pical da	y?	cups of coff			
Do you currently take any vitant If yes, please provide details:	nins or suppl	ements	? Yes	No No			
Name of pr	oduct		Frequency(times/week)	How lo	ong have you be (weeks)	en taking it?
1							
2							

Tommy's Net questionnaire (Female) v2.1 26/06/2017

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^{*} Do not count decaffeinated drinks

If you are	not taking vitamins or minerals curr	ently but have taken them in the last four i	months please complete this table.
,	Name of product	Frequency(times/week)	Duration (weeks)
1			
2			
3			
4			
	urrently taking any protein shakes or	protein bars? Yes	No No
If yes, piec	se provide details: Name of product	Frequency(times/week)	Duration (weeks)
1	*	1	, ,
2			
3			
4			
cise			
Do you fo	ollow a regular routine of physical ex	ercise? Yes	No No
How man	y days a week do you exercise?	If you exercise, how many hours a co	lay do you exercise?
Tick one o	option 0	Tick one option	< 30 min
	1-2		30 min - 1 hr
	3-4		> 1 hr - 1.5 hrs
	5-6		> 1.5 hrs - 2 hrs
	7		> 2 hrs - 2.5 hrs
	_		> 2.5 hrs
On averag	e how many hours do you spend sitt	ing on a chair per day?	

Tommy's Net questionnaire (Female) v2.1 26/06/2017

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Previous illnesses or medical problems

Have you had any serious illnesses or r	medical problems?	
If yes, tick all applicable:		
Diabetes	Rheumatism or painful joints	
Thyroid problems	Skin rashes or other skin disorders	
Cancer	Irritable Bowel Syndrome	
Heart problems	Coeliac disease	
Liverproblems	Crohn's disease	
Migraines	Autoimmune disease	
Epilepsy	Other inflammatory disorder	
Depression	Thrombosis (clots in legs or chest)	
High blood pressure	Candida (thrush)	
Lupus(SLE)	Bacterial vaginosis	
Abnormal vaginal discharge		
Other illnesses	Please state:	
If you have ticked any of the boxes above	ve, please provide further details below:	
Current medications and allergies		
Please provide details on any allergies yo	ou have and medication you are currently taking below:	

Family medical problems

ranniy medicai problems					
Has your mother, father, sibling	gs or maternal aunt(s) ha	nd any medical compli	Yes	No	
If yes, tick all applicable: Miscarriage Recurrent (3 or more) miscarriages Obstetric complications (such as pre-eclampsia and growth restriction) Genetic or developmental problems Heart problems under the age of 50 Stroke under the age of 50	If yes:	Number of 1st trimester losses (<12 weeks)	Number of 2nd trimester losses (>12 weeks) Stillbirth Pre-term birth Infertility High blood pressure Diabetes Blood clots (thrombosis) Depression Other		I don't know
If you have ticked any of the box	xes above, please provid	le further details belov	Please state:		

Tommy's Net questionnaire (Female) v2.1 26/06/2017



$Tests\, and\, investigations$

Please give details of any tests or investigations you've had as a part of your miscarriage treatment.

Test/investigations	Date of test	Result	Which hospital or clinic did you have the test at?
FSH			
LH			
Oestradiol			
Haemoglobin			
Platelets			
Rubellaimmunity			
Thrombophilia screening			
Thyroid antibodies			
Thyroid function test			
Sexually transmitted disease			
Ultrasound			

If you've had any other tests, please state below:

Test/investigation	Date of test	Result	Which hospital or clinic did you have the test at?

Tommy's Net questionnaire (Female) v2.1 26/06/2017

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Treatments

Please give details of any treatments you've previously received or are currently receiving as a part of your miscarriage management. Please also include any medications that you've bought yourself.

Treatment (please include medicines and operations)	Dose	Date from*	Date to	Tick if ongoing	Additional clinician's notes
				Ш	

^{*} If an operation, please give the date of operation

Examination

This section should be complete	ted in conjunction wit	th a member of the	research team wh	no attends to yo	u in the clinic	
Weight: kg	Height:	ст	1	вмі:		
Blood pressure: Systolic	/ Diastolic	mmHg				
Examination findings (if approp	riate)					
For Tommy's research offic	ee use only if patient is	consented and regi	stered to take part i	in Tommy's res	earch	
Date of consent:	d d - m	m m y	ууу			
Patient ID:		■ M A	Т			
Recruiting site:	-					
Date entered onto database: _	// Enter	red	Date checked:	//		Page 14 of 1

Ethnicity codes

WHIT	TE	Category includes
A	White British	English, Scottish, Welsh, Cornish
В	White Irish	
С	Any other white background	Former USSR, Baltic States, Former Yugoslavia, Other European, White South African, American, Australian, New Zealander, Mixed White
CF	Greek	
CG	Greek Cypriot	
СН	Turkish	
CI	Mediterranean	Italian, Portuguese and Spanish
CJ	Turkish Cypriot	
CN	Jewish	
CY	Other White European	
MIXE	ED	
D	White & Black Caribbean	
Е	White & Black African	
F	White & Asian	
G	Any other mixed background	
ASIAN	NOR ASIANBRITISH	
Н	Indian	British Indian, Punjabi
J	Pakistani	British Pakistani, Kashmiri
K	Bangladeshi	British Bangladeshi
L	Any other Asian background	British Asian, East African Asian, Sri Lankan, Tamil, Sinhalese, Caribbean Asian, Nepalese, Mixed Asian
BLAC	K OR BLACK BRITISH	
M	Black Caribbean	Caribbean, West Indian Islands (and also Guyana) apart from Puerto Rican, Dominican and Cuban, which are
N	Black African	Nigerian, Kenyan, Black South African, Other Black African Countries
P	Other Black background	Black American, Mixed Black
PA	Somali	
PE	Black British	
OTHE	R ETHNIC GROUPS	
R	Chinese	inc. Hong Kong
S	Any other ethnicity	Japanese, Filipino, Malaysian, Aborigine, Afghani, Burmese, Fijian, Inuit, Maori, Native American Indian, Thai, Tongan, Samoan, Iranian, Israeli, Kurdish, Latin American (inc. Cuban, Puerto Rican, Dominican, Hispanic), Moroccan, Multi Ethnic Islands (inc. Seychellois, Maldivian, St. Helena), Other Middle Eastern (inc. Iraqi, Lebanese, Yemeni), Other North African, South American (inc. Central America).
SA	Africa—colour not defined	
SC	Arab	
SD	Vietnamese	
Z	Not stated	



Religion codes

A	Christian (all denominations)		
В	Buddhist		
С	Hindu		
D	Jewish		
Е	Muslim		
F	Sikh		
G	Agnostic		
Н	Atheist		
Ι	I'd rather not say		
J	Other (please specify)		

Marital status codes

A	Single
В	Married
C	Separated
D	Divorced
Е	Widowed

Education codes

A	No formal qualifications
В	1-4 GCSEs (A*-C) or equivalent
С	5+ GCSEs (A*-C) or equivalent
D	Apprenticeship
Е	2+ A-levels or equivalent
F	Degree or above
G	Other (please specify)

- 1 Referral criteria for Recurrent miscarriage clinic care UHCW
- 2 o Actively trying to conceive
 - 2 or more pregnancy losses, including biochemical loss, miscarriage, molar pregnancy, ectopic pregnancy and stillbirth

3

6