FACULTY OF SEXUAL & REPRODUCTIVE HEALTHCARE

ROYAL COLLEGE OF OBSTETRICIANS & GYNAECOLOGISTS

# Faculty of Sexual & Reproductive Healthcare Clinical Guidance



# Fertility Awareness Methods

## Clinical Effectiveness Unit

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## ABBREVIATIONS USED

| | |
|---|---|
| BBT | basal body temperature |
| CEU | Clinical Effectiveness Unit |
| CI | confidence interval |
| FA | fertility awareness |
| FAM | fertility awareness methods |
| FSH | follicle-stimulating hormone |
| FSRH | Faculty of Sexual & Reproductive Healthcare |
| GnRH | gonadotropin-releasing hormone |
| HIV | human immunodeficiency virus |
| LAM | lactational amenorrhoea method |
| LARC | long-acting reversible contraception |
| LH | luteinising hormone |
| RCT | randomised controlled trial |
| SDM | Standard Days Method® |
| STI | sexually transmitted infection |
| UPSI | unprotected sexual intercourse |
| WHO | World Health Organization |

## GRADING OF RECOMMENDATIONS

**A** Evidence based on randomised controlled trials

**B** Evidence based on other robust experimental or observational studies

**C** Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

✓ Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the guideline group

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NICE has accredited the process used by the Faculty of Sexual & Reproductive Healthcare to produce its Fertility Awareness Methods guidance. Accreditation is valid for 5 years from May 2011. More information on accreditation can be viewed at www.nice.org.uk/accreditation.

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## SUMMARY OF KEY RECOMMENDATIONS

C Women wishing to use fertility indicators for contraceptive purposes should receive support and instruction on the method from a trained practitioner.

C Women should be informed that combining fertility indicators is considered more effective than using single fertility indicators alone.

B Sexual intercourse on days when cervical secretions are present increases the likelihood of pregnancy. Women wishing to avoid pregnancy should not have sexual intercourse, or they should use an additional contraceptive method until three consecutive dry days are noted.

B Over 1 year, fewer than 1 in 100 women would be expected to fall pregnant with perfect use of the symptothermal method [monitoring of cervical secretions and basal body temperature (BBT) used with a calendar calculation].

B When sexual intercourse only occurs in the identified post-ovulatory phase, the failure rate of BBT as a single indicator is estimated to be approximately 6.6%.

C The effectiveness of changes to the cervix as a sole indicator for contraceptive purposes is unknown and therefore is not recommended.

B Women may be advised that if they are <6 months postpartum, amenorrhoeic and fully breastfeeding, the lactational amenorrhoea method (LAM) is over 98% effective at preventing pregnancy.

B Women using LAM should be advised that the risk of pregnancy is increased if the frequency of breastfeeding decreases (stopping night feeds, supplementary feeding, use of pacifiers/dummies), when menstruation returns or when >6 months postpartum.

✓ Women may be informed that the effect of expressing breast milk on the efficacy of LAM is not known but it may potentially be reduced.

B Barrier methods can be considered as an alternative to sexual abstinence during the fertile window of the menstrual cycle in women, provided couples have been properly instructed in their use and accept a potentially higher failure rate if using barrier contraception around the time of ovulation (peak fertile time).

C Women stopping hormonal contraception should not rely on fertility indicators until regular menstrual cycles have been established and they have had a minimum of three cycles after stopping.

C Women using drugs that are known to have a teratogenic effect should not rely solely on fertility indicators for prevention of pregnancy.

C In women for whom pregnancy poses a significant health risk, the reliance on fertility indicators for the prevention of pregnancy is not recommended. Contraceptive options should be discussed with the woman and specialists involved in the management of the condition.

C Withdrawal is not advised as a method of contraception on its own or as an alternative to condom use or abstinence in women using fertility indictors to avoid pregnancy.


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**Faculty of Sexual & Reproductive Healthcare Clinical Effectiveness Unit**

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# FSRH Guidance (June 2015)
# Fertility Awareness Methods

(Revision due by June 2020)

## 1 Purpose and Scope

This is a new guidance document that provides evidence-based recommendations and good practice points on the use of fertility awareness methods (FAM) for the purpose of preventing and/or spacing pregnancies. It is intended for any health care professional or health service providing contraception or conception advice in the UK.

Natural family planning is a term used to describe fertility awareness (FA) indicators used in conjunction with abstinence. This guidance does not cover abstinence as a contraceptive method other than in the context of avoiding sex at certain times during the menstrual cycle.

For the purposes of this guidance, FAM will cover all practices irrespective of whether abstinence or other forms of contraception, such as barrier methods, are used during the fertile window. The lactational amenorrhoea method (LAM) will also be covered within this document. Coitus interruptus/withdrawal is not a FAM but it is mentioned in this guideline as it is used by many couples and is considered a natural method.

Fertility indicators can also be used for the purpose of conceiving a pregnancy but such use is outside the scope of this guidance. In this document the term 'fertile window' is used to describe the time that a woman is presumed to be at her most fertile based on the most likely timing of ovulation.

While this guidance seeks to provide an overview of FAM, it is not a substitute for training in FAM. UK health professionals with an interest in accessing specialist training or wishing to signpost women to a locally trained practitioner can find further details on the Fertility UK website (www.fertilityuk.org).

The recommendations included in this document should be used to guide clinical practice but they are not intended to serve alone as a standard of medical care or to replace clinical judgement in the management of individual cases. A key to the Grading of Recommendations, based on levels of evidence, is provided on the inside front cover of this document. Details of the methods used by the Clinical Effectiveness Unit (CEU) in developing this guidance are outlined in Appendix 1 and in the CEU section of the Faculty of Sexual & Reproductive Healthcare (FSRH) website (www.fsrh.org).

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## 2 Background

There are four key phases of the menstrual cycle:

1 **Follicular/proliferative phase (pre-ovulation):** This phase can vary in length. It is the phase prior to ovulation and is characterised by the maturation of follicles in the ovary as a result of follicle-stimulating hormone (FSH) being released from the pituitary gland.

2 **Ovulatory phase:** During the follicular phase there is a rise in estrogen levels, resulting in pulsatile secretion of gonadotropin-releasing hormone (GnRH). Consequently the production of both luteinising hormone (LH) and FSH from the pituitary gland is increased, stimulating ovulation. This generally occurs 12–16 days before a woman's next menses.

3 **Luteal phase (post-ovulation):** Following ovulation, progesterone from the newly formed corpus luteum in combination with estrogen promotes secretory changes in the endometrium. If fertilisation does not occur, the corpus luteum disintegrates, progesterone levels fall, and the endometrium is shed.

4 **Menstruation:** Menstruation is the bleeding that occurs when the endometrium is shed. A woman's menstrual period usually lasts for 3–7 days.

There are limited data on the survival time of the human ovum. One study suggested an average lifespan of around 17 hours (0.70 days),[1] although 24 hours is more commonly quoted. Sperm is said to remain viable for up to 7 days, although research suggests there is only a 1% probability of sperm lasting this long.[1] The mean survival time has been estimated to be 1.47 days[1] with less than 5% probability of sperm surviving more than 4.4 days. Therefore at most, a woman's fertile window lasts for around 8–9 days each menstrual cycle, extending from the earliest time in the cycle that an act of unprotected sexual intercourse (UPSI) could result in pregnancy until the demise of the ovum. An individual woman's risk or chance of pregnancy will be influenced by her age, her fertility, her partner's fertility, and how often they have intercourse.

UPSI that occurs in the pre-ovulatory phase (follicular/proliferative) of the menstrual cycle carries a risk of pregnancy, although the probability of pregnancy from a single act of intercourse in the first 3 days of the menstrual cycle appears to be negligible.[2] Conception is most likely to occur following UPSI on the day of ovulation or in the preceding 24 hours.[3,4] Having an awareness of fertility indicators enables women to identify when in their menstrual cycle they are likely to be fertile.[5]

In the post-ovulatory phase, there is an extremely low risk of pregnancy. Data have shown that there is a high degree of natural variation in the timing of ovulation. Consequently the timing of the fertile window is variable and can be difficult to identify: in shorter cycles it will occur earlier, and in longer cycles will occur later. Effective use of FA is dependent on allowing for this individual variation and on correctly identifying various fertility indicators. Therefore, women practising FA for contraceptive purposes may be required to avoid UPSI for at least 8–9 days per cycle. The physiological changes in the indicators of fertility during the menstrual cycle are summarised in Figure 1.

Figures from a sample of women aged 18–49 years (married or in a partnership), in the UK during 2008/2009, suggest that 2% of women used FAM for contraception.[6]

Table 1 outlines the different fertility indicators and methods identified in the literature.


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**Figure 1** The physiological changes in the indicators of fertility during the menstrual cycle. FSH, follicle-stimulating hormone; LH, luteinising hormone. Copyright© Dr Cecilia Pyper and Jane Knight 2003 in collaboration with Fertility UK, The Institute for Reproductive Health, Georgetown University (figure reproduced with permission)

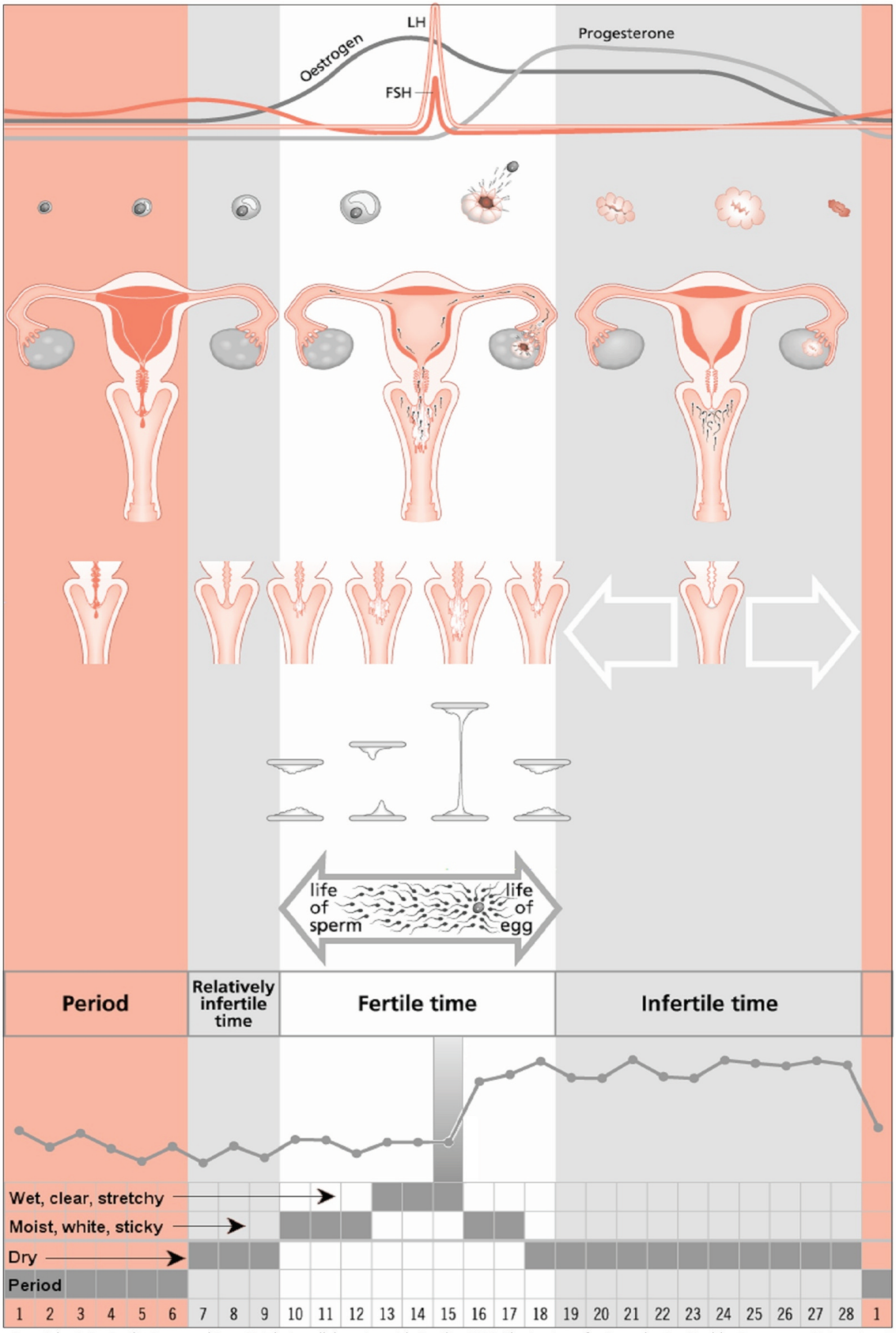


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**Table 1** Summary of different fertility and urinary hormone indicators and methods

| Indicator | Brief overview |
|---|---|
| Temperature | Basal body temperature is monitored to identify when ovulation has occurred. |
| Cervical secretions | Any cervical secretions are monitored. An increase in the volume of cervical secretions, which are wet, slippery and clear, is a sign that ovulation is approaching. Any secretions in the early part of the cycle indicate potential fertility. |
| Two-day method | If cervical secretions have been noted on the day of observation or the day before, sex should be avoided. |
| Calendar | The woman's menstrual cycle is tracked over a minimum of 12 cycles and the fertile window calculated using the shortest and longest cycle lengths. |
| Standard Days Method® | Sex is avoided on Days 8–19 in cycles that are regularly 26–32 days long. |
| Symptothermal method (combined indicators) | This method uses a combination of the above single indicators (e.g. calendar, cervical secretions and temperature). |
| Lactational amenorrhoea method (LAM) | Use of breastfeeding to provide contraceptive cover. Strict restrictions apply to this method. |

## 3 Measuring the Effectiveness of Fertility Awareness Methods for Contraception

There is limited good-quality evidence investigating the efficacy of FAM. Most of the reported studies have utilised an observational design. The few randomised controlled trials (RCTs) identified in the published literature are of poor quality with high attrition rates.[7] A Cochrane Review of RCTs was unable to determine pregnancy rates associated with FAM,[7] therefore the efficacy of FAM is very difficult to ascertain.

Women who choose to use FAM should be made aware of the different fertility indicators and the failure rate of different combinations in order to decide on the most appropriate method for them. In a study of women using either a combination of fertility indicators or cervical secretions alone, higher motivation resulted in higher efficacy.[8] The level of motivation women and/or their partners experience may change with time and circumstances.

The use of single fertility indicators is not recommended because the typical use pregnancy rate at 1 year is approximately 24%,[9] which is less effective than use of male condoms (typical use failure rate 18%).[9] One-year pregnancy rates for perfect use of the symptothermal method are noted as being comparable to those for perfect use of oral contraceptives: 0.4% and 0.3% for the symptothermal method and oral contraceptives, respectively.[9]

FAM teachers in the UK generally recommend combining fertility indicators to improve efficacy (see page 8).

**C** Women wishing to use fertility indicators for contraceptive purposes should receive support and instruction on the method from a trained practitioner and be informed that combining indicators is considered more effective than using single fertility indicators alone.

**B** Over 1 year, fewer than 1 in 100 women would be expected to experience a pregnancy with perfect use of the symptothermal method.


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## 4 The Different Individual Fertility Awareness Indicators and How They Predict Fertile Days

FA indicators include basal body (waking) temperature (BBT), changes in the cervical secretions (with an option to check the cervix), calculations based on menstrual cycle lengths and monitoring personal hormone levels (Table 1). Information on the efficacy of individual indicators is included for information but is not intended to imply or recommend that they should be used on their own.

### 4.1 Temperature

#### *4.1.1 Physiology*

Progesterone causes an increase in the BBT (the temperature before rising from bed after resting for at least 3 hours). Following ovulation, progesterone increases BBT and remains elevated until menstruation. This can help to identify ovulation retrospectively and the end of the fertile window. In a study investigating the probability of pregnancy associated with different days in the menstrual cycle, more than 6 days before or 2 days after the day of the rise in BBT the chance of conception was found to be negligible.[10] The post-ovulatory infertile phase of the cycle starts once temperatures on three consecutive days are a minimum of 0.2˚C higher than all the previous 6 days.[11]

Study findings have varied regarding the reliability of BBT. One study suggested that it is a relatively accurate measure of ovulation; in 75% of cases the thermal nadir (low point) was within 1 day of the LH surge and in 90% of cases within 2 days.[12] However, in practice this 'dip' is not present in many cycles. In addition it has been suggested that it is a poorer indicator of ovulation than other indicators such as LH detection kits and cervical secretions.[13]

#### *4.1.2 Instructions for use*

To use this indicator, women must monitor their BBT on a daily basis using a digital thermometer. It is advised that women take their temperature at the same time each day. The temperature should be taken before rising after at least 3 hours rest.

No additional contraceptive precautions are required for sex that has occurred from 3 days after the temperature rise until the start of menstruation. In women wishing to avoid a pregnancy, avoidance of sex, or use of additional contraceptive precautions, is then required until higher temperatures have again been recorded on three consecutive days in the next cycle. When used alone abstinence is required for about 16 days per cycle as UPSI is not permitted in the pre-ovulatory phase of the cycle.

#### *4.1.3 Efficacy of BBT as a single fertility indicator for contraception*

In a study of 502 couples who used BBT for fertility control through 8294 cycles, the overall failure rate was lower amongst those who only had sex during the post-ovulatory phase (*n* = 321) compared to those who had sex in the pre- and post-ovulatory phases (*n* = 225) (6.6 vs 19.3 per 100 woman-years).[11] Amongst those who only had sex in the post-ovulatory phase, efficacy was increased with increasing age, duration of marriage, and family size but these variables were not controlled for to determine their individual importance/significance.[11]

**B** When sexual intercourse only occurs in the identified post-ovulatory phase, the failure rate of BBT as a single indicator is estimated to be approximately 6.6%.

### 4.2 Cervical secretions

#### *4.2.1 Physiology*

Hormonal changes during the menstrual cycle result in changes in the quantity and appearance of cervical secretions.[14] Sperm motility is either supported or impeded by the

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quality and quantity of cervical secretions.[15] The survival of sperm is largely dependent on the presence of alkaline cervical secretions.

Cycle length and type will influence the number of days women experience the different characteristics of cervical secretions. Generally following menstruation women will have several days where the vulva feels dry with no visible secretions. As the follicles grow and estrogen levels increase in the lead up to ovulation, cervical secretions are sticky in texture and appear white/cream in colour. As the estrogen levels continue to rise, the secretions become increasingly slippery, wet, clear in colour and stretchy (like raw egg white) – these highly fertile alkaline secretions allow maximum sperm penetration. Following ovulation, the corpus luteum starts to produce progesterone and cervical secretions revert to being thick and sticky again, blocking sperm penetration, reducing sperm motility, and the risk of pregnancy.

In a prospective analysis[13] of ovulation detection, characteristics of cervical secretions yielded a 48.3% correlation with ultrasonographic diagnosis of ovulation. The probability of conception according to secretions observations was assessed in a prospective cohort study[16] of 193 women. In the absence of any secretions, the probability of pregnancy was reported to be negligible. However, in the presence of cervical secretions the probability was increased up to nearly 30% on the days where the most fertile secretions were present. Similarly a large European prospective study[17] found a strong increasing trend in the day-specific probability of pregnancy related to increases in secretion scores and sexual intercourse on days with the most fertile secretions. It would therefore be reasonable to assume the reverse is also true from the perspective of pregnancy prevention.

### 4.2.2 *Instructions for use*

The start and the end of the fertile window are monitored by observing changes in cervical secretions. Women can detect the presence of secretions by checking for signs of mucus on their underwear, on toilet paper and/or by feeling their genital area. As soon as they are no longer dry and notice any type of secretion, their fertile time has started. The last day they are aware of the highly fertile wetter, slippery secretions is known as peak day (this is generally the time closest to ovulation). The peak day can only be recognised retrospectively, as the day after this peak the secretions will revert to becoming thicker or absent.

The most fertile time is on the peak day and the 2 days preceding it, although women can conceive from UPSI that occurs at any time during the fertile window. The fertile time starts at the first sign of any secretions and continues for three full days after peak. The fertile time ends on the fourth day after peak day. It may take women at least three cycles of observing secretions to be confident in recognising these changes.

### 4.2.3 *TwoDay Method®*

The TwoDay Method is a simplified method of monitoring cervical secretions. It involves daily monitoring of cervical secretions, preferably in the afternoon or evening. If a woman does not note cervical secretions on that day or the day before then the probability of pregnancy is very low. If cervical secretions were noted on the day of observation or the day before, UPSI should be avoided. It can be used by women with any cycle length and it is relatively simple to learn.

**B** Sexual intercourse on days when cervical secretions are present increases the likelihood of pregnancy.

**B** When cervical secretions are present, women wishing to avoid pregnancy should not have sexual intercourse, or they should use an additional contraceptive method until three consecutive dry days are noted.


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*4.2.4 Efficacy of cervical secretions methods as a single fertility indicator for contraception*

A small prospective trial[18] reported an overall unintended pregnancy rate of 15.5 per 100 woman-years among 122 couples across 1626 cycles. A total of 21 unintended pregnancies were noted.[18] Only four pregnancies occurred in couples who followed the guidelines correctly (perfect use 2.9%). Nine pregnancies resulted in couples taking a conscious risk and a further eight from intercourse on pre-ovulatory days with scant sticky secretions. This reinforces the point that *any* secretions signify potential fertility. A large multicentre study[19] conducted by the World Health Organization (WHO), involving 725 participants, showed that if couples were provided with good tuition and followed the instructions correctly, the cervical secretions indicator has a failure rate of around 3%; with typical use the failure rates may be higher.[20]

The first-year pregnancy rate in a prospective non-randomised study[21] investigating the TwoDay Method was 3.5 per 100 woman-years in those who abstained on fertile days. Across all cycles, however, the pregnancy rate was 13.7 per 100 woman-years.

## 4.3 Calendar calculations

*4.3.1 Physiology*

As previously indicated, the length of the menstrual cycle can be highly variable with ovulation usually occurring between 12 and 16 days *before* menstruation. By plotting menstrual cycles over a period of time, women can establish the earliest and latest time they are at risk of conception.

*4.3.2 Instructions for use*

The calendar method requires the user to record their menstrual cycle length for a minimum of 12 cycles. The length of the shortest and longest cycles is used to calculate the fertile window. Day 1 of the menstrual cycle is the first day of bleeding. The total cycle length is the number of days from the start of bleeding in one cycle to the day before the bleeding starts in the next cycle.

To estimate the first fertile day, 20 days are subtracted from the shortest cycle length. The last fertile day is calculated by subtracting 10 days from the longest cycle length. This latter measurement is rarely used when calendar calculations are used in conjunction with other indicators because it tends to require more days of abstinence than other methods; for example, the fertile window for a woman whose shortest cycle is 26 days and longest is 32 days would be from Days 6 and 22 inclusive - additional precautions would be required during this period if pregnancy was to be prevented.

If a woman's longest or shortest menstrual cycle length changed, the fertile window would need to be recalculated. The calculation is always made on the most recent 12 cycles.

*4.3.3 Standard Days Method®*

The Standard Days Method (SDM) is a simplified form of the calendar method that uses a fixed formula. The SDM involves avoiding UPSI between Day 8 and 19 of each cycle. The rule[22,23] was developed by estimating, from a large existing data set,[19] the probability of pregnancy on different cycle days. The investigators showed that in women with cycle lengths between 26 and 32 days, the fertile time was most likely to occur within Days 8–19.[22,23] The SDM is not advised for women with cycle lengths less than 26 days, longer than 32 days or those with irregular cycles. This method should not be used if two or more cycles were outside this range in the last 12 months.

**Box 1** Calendar-based calculations

**Calculation based on previous cycle lengths (personal information)**
Shortest cycle length minus 20 = first fertile day
Longest cycle length minus 10 = last fertile day

**Standard Days Method® (fixed fertile time)**
Applies only to cycles that are 26–32 days
The first fertile day is Day 8
The last fertile day is Day 19

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*4.3.4 Efficacy of calendar-based methods as a single indicator for contraception*

A meta-analysis of eight studies investigating the efficacy of calendar methods reported an overall failure rate of approximately 20% (range 5–47%) at 12 months of observation.[24] Discrepancies have been shown between self-reported cycle days and hormonal data[25,26] suggesting that risk calculated from cycle days alone may, in some instances, not accurately reflect actual risk.

A prospective multicentre study[27] followed 478 women aged 18–39 years practising the SDM to assess efficacy. Only 218 women completed 13 cycles of method use (46%), with 28% removed from the study because they had two cycles outside the predefined range. Having no sexual intercourse on Days 8–19 was associated with a 1-year pregnancy rate of 4.8% [95% confidence interval (CI) 2.33–7.11]. Across all cycles and all pregnancies, the 'typical' 1-year pregnancy rate was 12% (95% CI 8.47–15.3).

### 4.4 Changes to the cervix

Changes to the cervix and the cervical os have been noticed during the menstrual cycle.[28–30] Two small studies of women experienced with FAM[28,31] have shown that cervical changes correlate with cervical secretions and temperature indicators in identifying the fertile window.

There is a risk of pregnancy when the cervical os dilates. The fertile window starts at the first sign of the cervix changing from being low and firm, and the cervical os closed, to the cervix being high and soft and the cervical os open. It ends when the cervix becomes low and firm and the cervical os has been closed again for 3 days.

*4.4.1 Instructions for use*

There is a risk of pregnancy when the cervix opens and widens. Those women wishing to prevent a pregnancy should use alternative contraception or avoid sex when the cervix feels high, soft and the cervical os open. Palpating the cervix should not be used alone as a form of contraception.

*4.4.2 Efficacy of changes to the cervix as a single measure for contraception*

No studies were identified that examined the effectiveness of using cervical changes alone.

**C** The effectiveness of changes to the cervix as a sole indicator for contraceptive purposes is unknown and therefore is not recommended.

## 5 Combination Indicator Methods

Using multiple fertility indicators helps to improve the effectiveness of FAM (Figure 2). The symptothermal method is a combined indicator method that uses a combination of monitoring cervical secretions and BBT, together with a calendar calculation to identify the fertile window. Another optional additional measure is to self-examine for cervical changes. There are other combination methods such as the Marquette method (http://nfp.marquette.edu/), which combines the observation of cervical secretions with a fertility monitor assessing urinary estrogen and LH; however, this is not widely used in the UK.

The symptothermal method has been shown to be an effective method of contraception, when used consistently and correctly. A prospective cohort study of 900 women found that when practised correctly (i.e. no incidence of UPSI during the fertile phase), the pregnancy rate over 13 cycles was 0.6 per 100 women.[32] The efficacy was reduced when UPSI did occur during the fertile phase, with a 13-month pregnancy rate of 7.47 per 100 women reported.[32]

A smaller 12-month prospective study[33] sought to determine the effectiveness of combining cervical secretions monitoring with use of an electronic fertility monitor. The study reported that the pregnancy rate over 12 months was 2.1% with correct use, and 14.2% with imperfect use.

Other studies have sought to investigate the effect of combining FA indicators on contraceptive efficacy; however, there are a number of methodological flaws that limit the findings.


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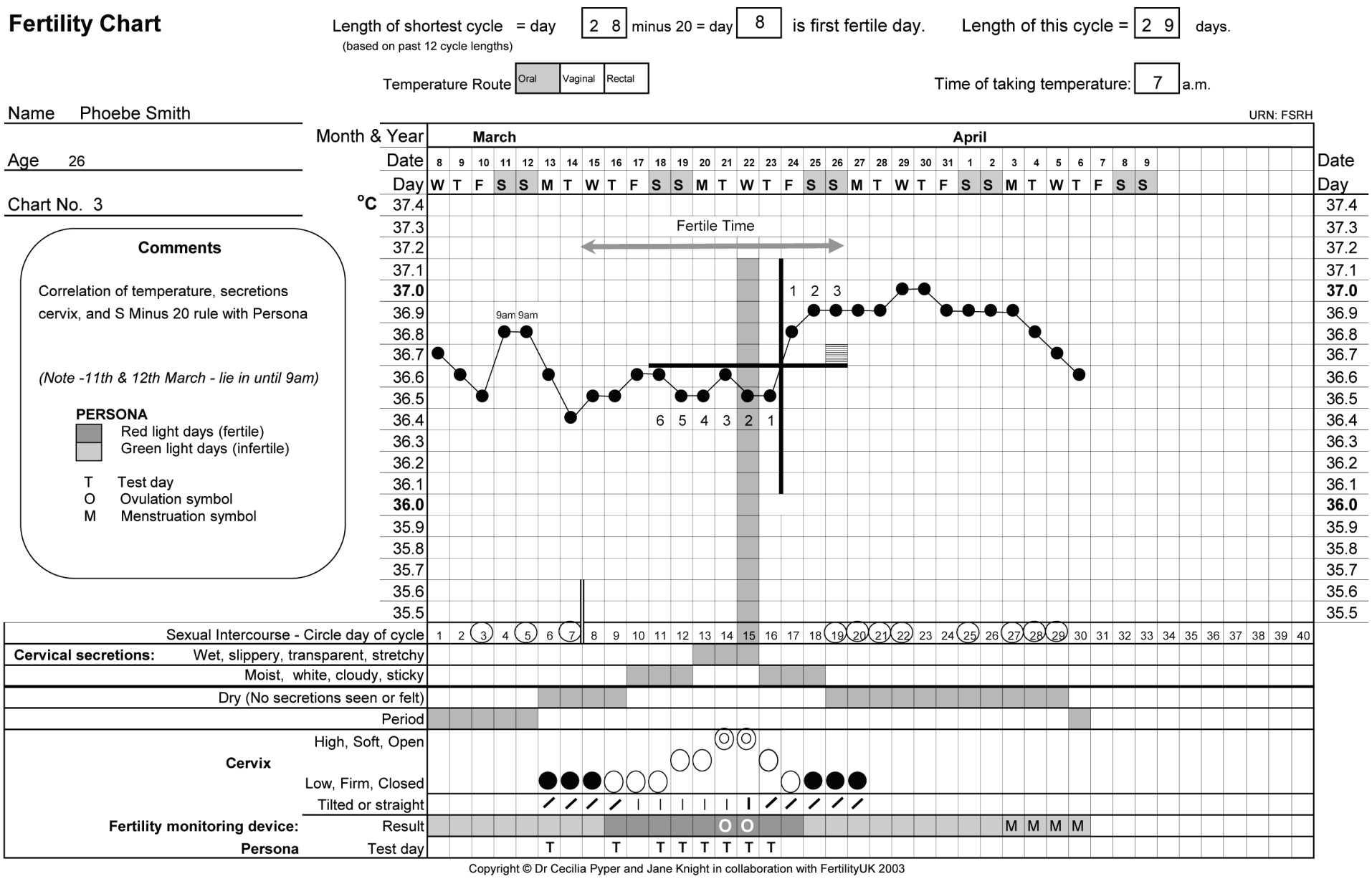


**Figure 2** Combining the indicators of fertility. Copyright © Dr Cecilia Pyper and Jane Knight 2003 in collaboration with Fertility UK (figure reproduced with permission)

# 6 Fertility Monitoring Devices

## 6.1 Urinary hormone monitoring

### *6.1.1 Physiology*

Urinary LH has been found to be a reliable measure for identifying ovulation.[13] In a small prospective study evaluating the efficacy of different FAMs in identifying ovulation, urinary LH correlated 100% with ovulation as diagnosed by ultrasound.[13]

### *6.1.2 Instructions for use*

Urine-based test strips with antibodies to estrone-3-glucuronide and LH are used to identify the fertile window. Women should avoid intercourse or use additional contraceptive precautions (e.g. condoms or other barrier methods) when increased levels of these hormones are detected.

### *6.1.3 Efficacy/effectiveness of fertility monitoring devices as a single indicator*

Many of the commercially available monitors are designed to identify the fertile time for the purpose of conception rather than contraception. Although there is evidence from prospective studies to support good correlation between detection of the LH surge and ovulation as identified by ultrasound, there are no data from RCTs evaluating the sole effectiveness of such monitors for contraception, rather than conception. Because these methods are primarily designed for identifying the most fertile window, they may underestimate the time of risk for those women who do not wish to become pregnant. In a study of 100 women such monitors were shown to identify the start of the fertile window on average almost 2 days later than cervical secretions observation.[34] Use of such methods for contraceptive purposes is outside the terms of the product licence.

While several contraceptive monitors are available, only one study[35] examining effectiveness was identified. This study examined the efficacy of the Persona® system in which disposable urine sticks are used to test the level of hormones (LH and estrone-3-glucuronide). A monitor interprets the information and displays a green or red light for the infertile and fertile phase, respectively. A large prospective study of 710 women with regular menstrual cycles (23–35 days) contributing 7209 cycles of use, reported 67 method-related pregnancies. This equated to a 13-cycle life-table method pregnancy rate of 12.1% (95% CI 9.3–14.8). After adjustment of the algorithm to increase the median warning of the LH surge to 6 days the calculated pregnancy rate was 6.2% (95% CI 4.2–8.3) and method efficacy of 93.8%.[35] There has been some criticism of the use of the method failure rate in this study rather than the perfect-use pregnancy rate, which may be higher.[36]

## 6.2 Other monitors

A number of computerised devices are available that identify the fertile and infertile times by combining temperature with cycle length. The devices may be available to buy commercially but are not widely used or recommended in the UK because of the lack of efficacy data.

Studies have been carried out which have sought to evaluate the effectiveness of three computerised thermometers, namely Ladycomp®, Bioself® and Cyclotest®.[37–39] More rigorous prospective research is required before conclusions can be drawn regarding the effectiveness of computerised thermometers.

Saliva testing for contraceptive purposes has been shown to be unreliable. In one small study favourable results were found in postmenopausal women and even in some men.[40]

# 7 Other Less Reliable Indicators of Fertility

Women sometimes experience abdominal pain, abdominal heaviness, breast changes, intermenstrual bleeding, back pain, skin changes and changes in libido and mood. While some women may experience these symptoms quite consistently and cyclically in association with

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their menstrual cycle, they should not be relied upon to indicate the fertile window. These highly subjective symptoms are the least reliable of all the indicators and show wide variability compared with objective signs of ovulation.[41] Women should not assume the changes are physiological as some symptoms may indicate underlying pathology and should be appropriately investigated.

## 8 Lactational Amenorrhoea Method

### 8.1 Physiology

The use of breastfeeding as a contraceptive is known as LAM (Figure 3). Suckling suppresses the resumption of ovarian activity and the return of menses postpartum.[42] Consequently women who are fully breastfeeding have reduced fertility, and breastfeeding can be used to provide protection against unintended pregnancy.[43] However, when the frequency and duration of suckling decreases, ovarian activity may be restored and the likelihood of experiencing the first postpartum bleeding increases.[44]

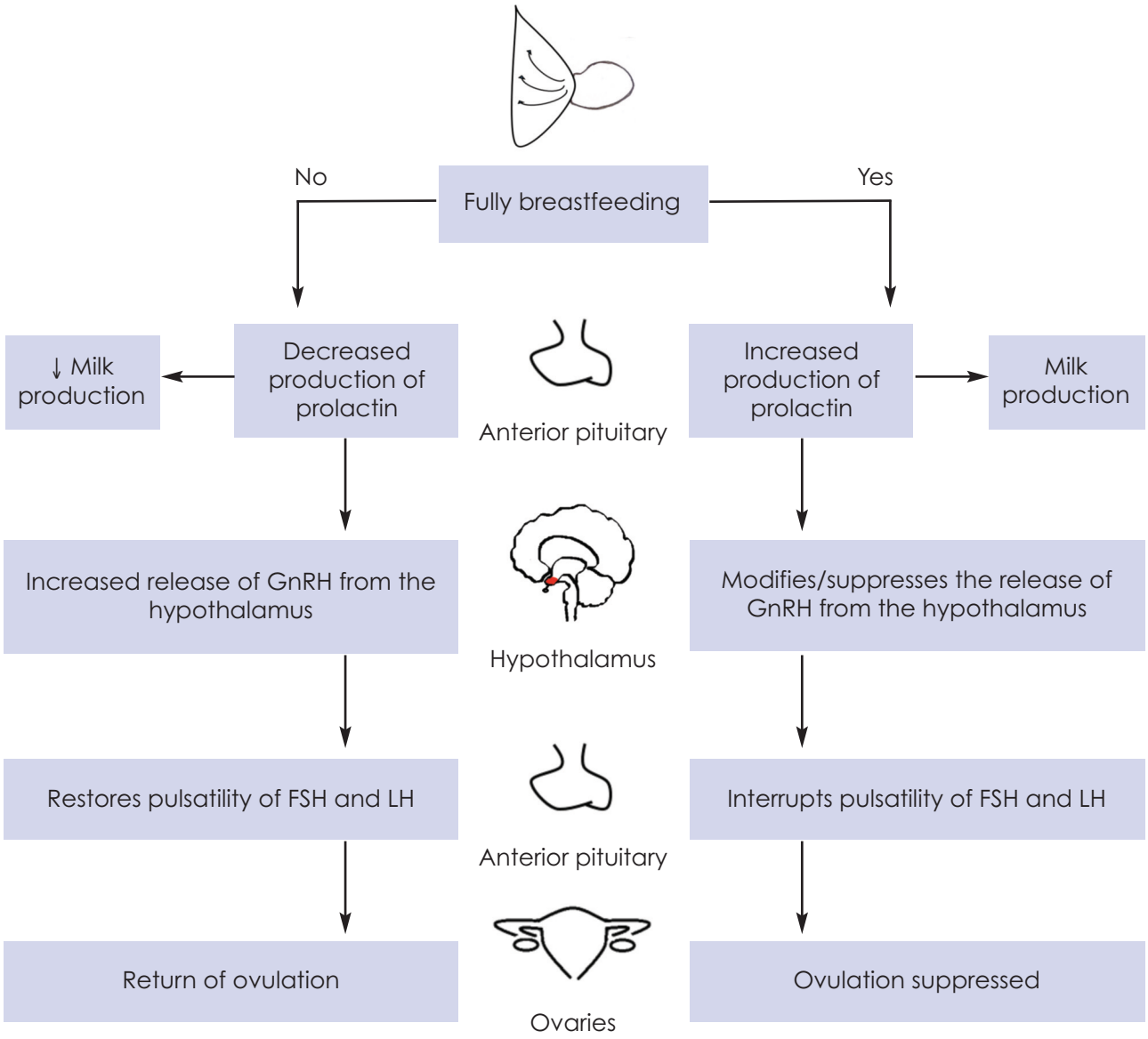
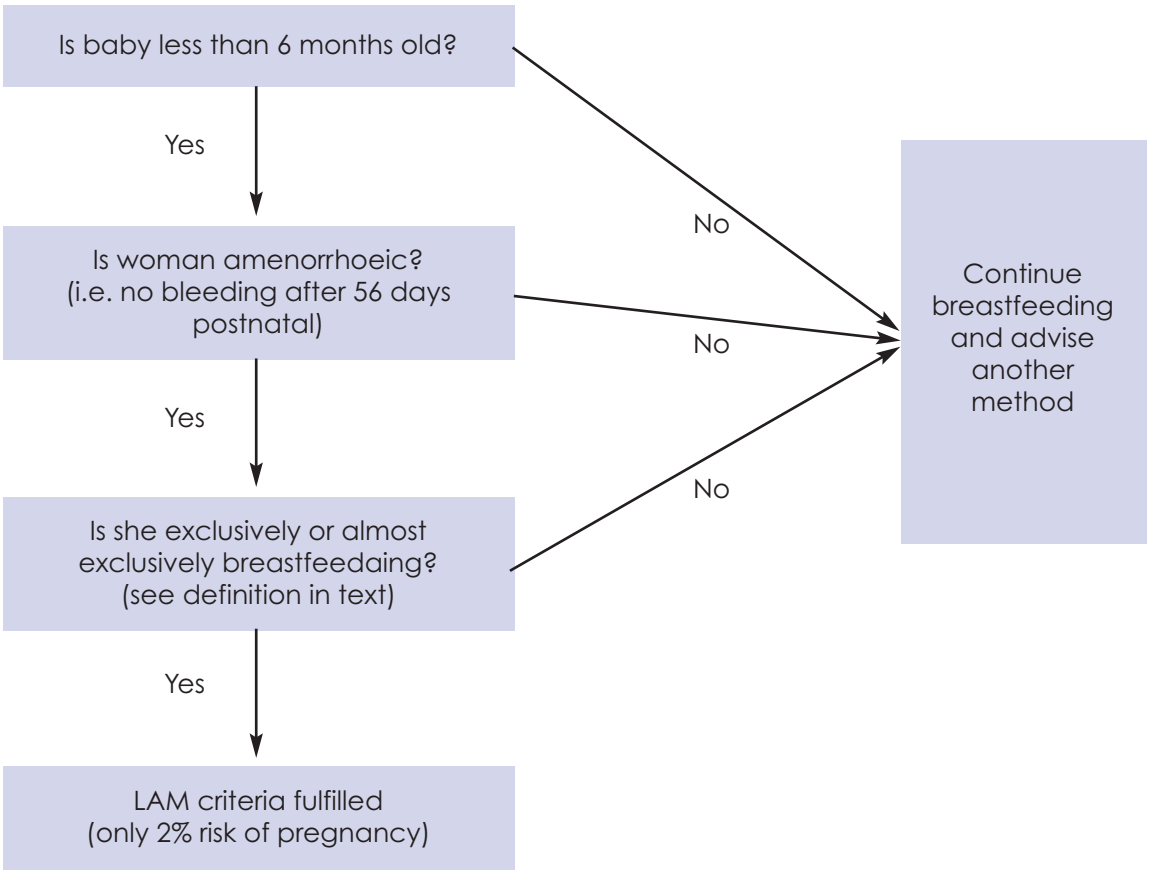



**Figure 3** Mode of action of lactational amenorrhoea. FSH, follicle-stimulating hormone; GnRH, gonadotropin-releasing hormone; LH, luteinising hormone.

**Figure 4** Criteria for relying on the lactational amenorrhoea method (LAM) for contraception.




### 8.2 Instructions for use

Breastfeeding women who experience a bleed in the first 6 months postpartum have been shown to have a higher risk of pregnancy than those who remain amenorrhoeic.[45] Therefore for breastfeeding to be used as a contraceptive (Figure 4) it is recommended that women must be:

- Fully or nearly fully breastfeeding day and night (no other liquids given or only water, juice or vitamins given *infrequently* in addition to breastfeeds). No long intervals between feeds day or night (e.g. >4 hours during day and >6 hours at night)
- Amenorrhoeic
- Less than 6 months' postpartum.

### 8.3 Efficacy/effectiveness of LAM

Studies have consistently shown that when the rules of LAM are applied, the associated failure rates are less than 2%.[46–48] When suckling frequency and duration decreases, perhaps as a result of the introduction of pacifiers/dummies, maternal or infant illness or introduction of supplementary feeding, ovarian activity and the risk of pregnancy increases.[44,49,50] In a multicentre prospective study[47] of 4118 breastfeeding women, cumulative pregnancy rates for fully breastfeeding amenorrhoeic women ranged between 0.9 (95% CI 0–2) to 1.2% (95% CI 0–2.4) in the first 6 months. In comparison, at 12 months the rates ranged from 6.6% (95% CI 1.9–11.2) to 7.4% (95% CI 2.5–12.3). Other studies[46] have similarly reported higher failure rates when the LAM criteria are not fully applied.

There are limited studies on the effect of 'expressing' on the effectiveness of LAM and therefore it is difficult to make recommendations in this area. A study[51] of 170 women designed to examine the effectiveness of LAM in working women who were manually expressing milk reported a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pregnancy rate of 5.2%. The study had a number of limitations including no comparative group, high drop-out rates and lack of information about sexual activity.

B Women may be advised that if they are <6 months postpartum, amenorrhoeic and fully breastfeeding, LAM is over 98% effective at preventing pregnancy.

B Women using LAM should be advised that the risk of pregnancy is increased if the frequency of breastfeeding decreases (stopping night feeds, supplementary feeding, use of pacifiers/dummies), when menstruation returns or when >6 months postpartum.

✓ Women may be informed that the effect of expressing breast milk on the efficacy of LAM is not known but it may potentially be reduced.

## 9 Use of Barrier Methods or Abstinence During the Fertile Window

If a woman does not wish to become pregnant, she should be advised to abstain from sexual intercourse, or use another form of contraception, for example, condoms. The decision to use barrier methods or to abstain from intercourse is a matter of personal preference and may be influenced by the woman's religious or cultural practices and/or partner preference.

The use of spermicides or barrier methods with additional lubricant can make it more difficult to identify changes in cervical secretions. This is less of a concern if cervical secretions are being used in combination with other fertility indicators. If a woman uses a diaphragm she may be well-suited to checking the changes in her cervix.

As barrier methods have the potential to be used incorrectly their use may be less effective than abstaining during the fertile window. Currently there is no evidence to support a statistically significant difference between abstinence and condom use. In the large prospective trial[32] examining the effectiveness of the symptothermal method in relation to couples' sexual behaviour, the rates of unintended pregnancy per 100 women were 0.43% and 0.59% for abstinence and protected intercourse in the fertile window, respectively (two pregnancies in each group). An efficacy trial[27] of the SDM found a lower 1-year pregnancy rate amongst the 218 women who completed 13 cycles and reported no intercourse on Days 8–19 than those who reported intercourse with use of a condom or withdrawal, 4.8% (95% CI 2.33–7.11) and 5.7% (95% CI 3.11–8.16), respectively. As condoms and withdrawal were included in the same analysis, it is not possible to differentiate the risks associated with these different approaches.

The use of barrier methods or sexual activities other than vaginal intercourse during the fertile window can be advised. Women should be advised that consistent use of condoms confers the best protection against sexually transmitted infections (STIs).

B Barrier methods can be considered as an alternative to sexual abstinence during the fertile window, provided couples have been properly instructed in their use and accept a potentially higher failure rate if using barrier contraception around the time of ovulation (peak fertile time).

## 10 Restrictions on the Use of Fertility Indicators for Contraception

In general, most women can use fertility indicators either for pregnancy prevention or planning. A number of factors such as illness and infection may influence body temperature. Lifestyle factors including alcohol consumption and stress may also result in poor adherence to these methods. Other considerations are discussed in the sections that follow.

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### 10.1 Menstrual and cycle irregularities

Menstrual irregularities are common immediately post-menarche and in the perimenopause. Such irregularities may complicate the teaching and interpretation of fertility indicators. Methods may be more difficult to learn at this time and women may require additional support, or the method may be deemed unsuitable.

Women with irregular cycles may find calendar indicators more difficult to adhere to because of the longer duration of abstinence that will be required.

### 10.2 Postpartum period

In the first 4 weeks postpartum women who are not breastfeeding (any births including stillbirths from 24 weeks' gestation) are not likely to have detectable fertility signs or hormonal changes. As the earliest expected ovulation in non-breastfeeding women is Day 28, contraception is not required until Day 21 postpartum in non-breastfeeding women.[52] Although the risk of pregnancy is low during this time, women wishing to use a method of contraception prior to 4 weeks postpartum should be offered a method suitable for this period (e.g. the progestogen-only pill). Postpartum women who are primarily breastfeeding are unlikely to have sufficient ovarian function to produce detectable fertility signs and hormonal changes during the first 6 months. Postpartum women should have three regular postpartum menses before switching to a FAM. Prior to this, women should be offered a method appropriate for the postpartum window.

### 10.3 Recent use of hormonal contraception

Following discontinuation of hormonal contraception, a woman's initial menstrual cycle may be altered. A retrospective cohort study[53] reported that women who had discontinued oral contraception in the previous 12 weeks had significantly poorer cervical secretions scores compared with matched controls that had not used oral contraceptives for 1 year. Estimated date of ovulation was also later and menses shorter compared to controls. In a study[54] examining use of the SDM following discontinuation of oral contraception, the authors reported that the first cycle post-discontinuation was not a reliable indicator of future cycle lengths and that women should not start this method in their first three cycles after stopping. This may also be the case for urinary monitors that rely on the first cycle of use.

There may be a delay in return of fertility following use of the progestogen-only injectable of up to 1 year.[55,56]

**C** Women stopping hormonal contraception should not rely on fertility indicators until regular menstrual cycles have been established and they have had a minimum of three cycles after stopping.

### 10.4 Use of drugs known to be teratogenic

Some drugs are known to have a teratogenic effect. Therefore effective contraception is strongly advised during use and for a period of time afterwards, depending on the washout period for the particular drug. Fertility indicators (including combined methods) should not be relied on as the sole method of contraception during these times due to the potential implications of an unplanned pregnancy and potential harmful effects of the drug in this context. Women who do not wish to use any other form of contraception need to be informed of the potential risk to the fetus should pregnancy occur and be advised to consider abstaining from sex until the drug has cleared from their system.

**C** Women using drugs that are known to have a teratogenic effect should not rely solely on fertility indicators for prevention of pregnancy.


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### 10.5 Antibiotics and other medications

Product information suggests that the Persona contraceptive monitor should not be used if a woman is taking tetracyclines. Other medications such as cold remedies, pain relieving drugs/analgesics, antihistamines or chemotherapy/cortisone treatment may affect different fertility indicators. Advice should be sought when using medications in conjunction with FAM.

### 10.6 Medical conditions for which pregnancy is high risk

Pregnancy poses a high risk of mortality to women with certain medical conditions, such as Eisenmenger syndrome. In women with such conditions, the disadvantage of using FAM with higher typical failure rates outweighs any advantages. Contraceptive options should be discussed with the woman and their specialists to ensure the most suitable, effective and safe method is provided.

### 10.7 Other medical conditions

According to the product information, women with impaired liver or kidney function, or polycystic ovarian syndrome should not use Persona.

**C** In women for whom pregnancy poses a significant health risk, the reliance on fertility indicators for the prevention of pregnancy is not recommended. Contraceptive options should be discussed with the woman and specialists involved in the management of the condition.

## 11 Advantages of Fertility Awareness for Contraception

As the methods rely on 'natural' indicators, there are no potential hormone-related side effects or health risks associated with use.

FAM do not alter women's menstrual cycles. Therefore, potential problems presenting with amenorrhoea or irregular bleeding may be more readily identified. Additionally, the lack of interference with a woman's natural cycle may be more acceptable and preferable to some women.

Having a better understanding of FA indicators may also assist women to conceive/plan a pregnancy in the future.

## 12 Disadvantages of Using Fertility Awareness for Contraception

With typical use, these methods are less effective than long-acting reversible methods of contraception (LARC). There is a greater reliance on the user and their partner to check BBT or cervical secretions each day and avoid vaginal intercourse or use condoms/barrier methods during the fertile window.

Hormonal contraceptives can offer a number of non-contraceptive benefits such as a reduction in ovarian/endometrial cancer risk;[57–74] menstrual bleeding;[75–78] dysmenorrhoea[75,76,79–89] and acne.[90] Such benefits are not conferred by the use of FA indicators.

While FA indicators can be used to avoid pregnancy, they offer no protection from human immunodeficiency virus (HIV) and other STIs. The consistent and correct use of condoms is the most efficient means of protecting against HIV and other STIs.

## 13 Coitus Interruptus/Withdrawal

Coitus interruptus or withdrawal requires the male partner to withdraw the penis from the woman's vagina prior to ejaculation.

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Data suggest that approximately 4-6% of women in the UK may be using withdrawal.[6,91] The efficacy of this method is largely dependent on the male partner withdrawing before any sperm are released into the vagina, and relies on the male being able to accurately identify when to withdraw and being compliant.

It is widely reported that pre-ejaculate contains sperm and therefore poses a risk should women not wish to conceive; however, few studies have examined this issue and most have failed to identify any motile sperm.[92–94] One study[95] found sperm in the pre-ejaculatory fluid samples of 11/27 men, 10 of which had motile sperm. This study analysed samples within 2 minutes of their production which may have aided identification of the sperm. A possible noted limitation of the study was the lack of confirmatory testing to ensure that the samples were pre-ejaculate. However, the authors reported that it demonstrated a potential risk, as nearly half of men either had pre-ejaculate containing sperm or were unable to accurately identify when ejaculation was imminent. The actual numbers of sperm in pre-ejaculate were low but the presence of motile sperm means there was a potential pregnancy risk.[95]

Men practising withdrawal are advised to urinate between successive ejaculations to remove any sperm from pre-ejaculatory fluid[96] but there is no evidence to support this practice. In the aforementioned study, in which motile sperm were identified in the pre-ejaculatory fluid, men had urinated several times since their last ejaculation prior to providing samples.[95]

Figures from the USA[9] suggest that with perfect use, 4% of women will have an unintended pregnancy at 1 year; with typical use, this increases up to 22%.

Withdrawal, if practised correctly, may work for some couples, particularly as a backup to other methods of contraception, including the use of fertility indicators. No studies were identified that sought to examine the efficacy of withdrawal as an alternative to abstinence or condoms and therefore this is not advised during the fertile window.

C Withdrawal is not advised as an alternative to condom use or abstinence during the fertile window of the menstrual cycle in women using fertility indictors to avoid pregnancy.

## 14 Training/Teaching/Additional Resources

FAM are more effective when women receive specialist training. Women interested in using FA for contraception purposes should be signposted to an organisation, service or local recognised practitioner offering teaching. Information is available on the Fertility UK website (www.fertilityuk.org).

## 15 Planning a Pregnancy

FAM may help women planning a pregnancy to better understand their fertility. Whilst women trying to conceive are generally encouraged to have sexual intercourse every 2–3 days throughout the menstrual cycle.[5] identifying the fertile window can help women to ensure that UPSI occurs around the time of ovulation. As temperature monitoring relies on retrospective identification of ovulation, it is not useful for women timing UPSI to achieve a pregnancy,[97] but it can provide an indication of ovulatory cycles when checking fertility.

Women wishing to achieve a pregnancy are more likely to conceive when intercourse takes place on days when cervical secretions are noticeable. Fertility monitors designed to aid conception may be useful in identifying the LH surge and impending ovulation. A prospective study[98] of a fertility monitor reported that of 149 cycles with an LH surge and ultrasonographically confirmed ovulation the fertility monitor detected peak fertility within 2 days of ovulation in 91.1% of cycles. Peak fertility, as identified by the fertility monitor, did not occur after ovulation or the serum LH surge day in any of the cycles.[98]

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# APPENDIX 1: DEVELOPMENT OF CEU GUIDANCE

**GUIDELINE DEVELOPMENT GROUP**

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**Ms Julie Craik** – Researcher, Clinical Effectiveness Unit

**Dr Sarwat Bari** – FSRH Meetings Committee Representative; Specialty Doctor, Guys and St Thomas Hospitals, London

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**Dr Debbie Hallott** – Clinical Lead/Head of Contraception and Sexual Health, Wakefield

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**Ms Sarah Panzetta** – Fertility Awareness Practitioner, London

**Dr Karin Piegsa** – FSRH Clinical Effectiveness Committee Representative; Consultant in Reproductive Health, Fife

**Dr Cecilia Pyper** – Honorary Senior Research Fellow, National Perinatal Epidemiology Unit, University of Oxford, Oxford

**Ms Jill Shawe** – Reader in Midwifery Practice/Director, Centre for Research in Nursing and Midwifery Education, University of Surrey, Guildford

**Dr Rachel Westwick** – FSRH Clinical Standards Representative; ST6 Community Sexual and Reproductive Health Trainee, Bristol Sexual Health Service, Bristol

**INDEPENDENT PEER REVIEWER**

**Professor Victoria Jennings** – Director and Professor, Department of Obstetrics and Gynecology, Institute for Reproductive Health, Georgetown University, Washington, DC, USA

**Declared Interests**

Ms Jane Knight has received payment for lectures and consultancy work for SPD who manufacture Persona. Fertility UK, which is headed by Jane Knight, has received sponsorship for postgraduate meetings from SPD.

Dr Karen Piegsa has received lecture fees for non-promotional update sessions to general practice.

Administrative support to the CEU team was provided by **Mr John Matthews**.

The illustrations in Figure 3 were kindly provided by **Miss Iqra Shahid.**

**Patient Consultation**

A questionnaire on the proposed guidance content was completed by a sample of potential users.

Clinical Effectiveness Unit (CEU) Guidance is developed in collaboration with the Clinical Effectiveness Committee (CEC) of the FSRH. The CEU Guidance development process employs standard methodology and makes use of systematic literature review and a multidisciplinary group of professionals. The multidisciplinary group is identified by the CEU for their expertise in the topic area and typically includes clinicians working in family planning, sexual and reproductive health care, general practice, other allied specialities, and user representation. In addition, the aim is to include a representative from the FSRH CEC, the FSRH Meetings Committee and FSRH Council in the multidisciplinary group.

Evidence is identified using a systematic literature review and electronic searches are performed for: MEDLINE (CD Ovid version) (1996–2015); EMBASE (1996–2015); PubMed (1996–2015); The Cochrane Library (to 2015) and the US National Guideline Clearing House. The Cochrane Library is searched for relevant systematic reviews, meta-analyses and controlled trials relevant to fertility awareness methods. Previously existing guidelines from the FSRH (formerly the Faculty of Family Planning and Reproductive Health Care), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO) and the British Association for Sexual Health and HIV (BASHH), and reference lists of identified publications, are also searched. Summary evidence tables are available on request from the CEU. The process for development of CEU guidance is detailed on the FSRH website (www.fsrh.org). The methods used in development of this guidance (CEU Process Manual version 2.0) have been accredited by NHS Evidence.

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# Questions for Continuing Professional Development

The following questions have been developed for continuing professional development (CPD).

The answers to the questions and information on claiming CPD points can be found in the 'members-only section' of the FSRH website (www.fsrh.org), which is accessible to all Diplomates, Members, Associate Members and Fellows of the FSRH.

**1 Which of the following statements is most accurate with regard to pregnancy risk:**

a. There is no risk of pregnancy from sex that occurs after the demise of an ovum
b. There is no time in the menstrual cycle when a woman is not at risk of pregnancy
c. The risk of pregnancy is greatest on Day 14 of women's cycles
d. The risk of pregnancy is negligible in the first 7 days of the menstrual cycle

**2 Sperm on average have been shown to survive for:**

a. 1–2 days
b. 3–5 days
c. 5–6 days
d. 6–7 days

**3 The Standard Days Method® of contraception involves abstaining or using additional precautions:**

a. From Day 5 until Day 19 of a 28–32 day menstrual cycle
b. From Day 8 until Day 19 of a 26–32 day menstrual cycle
c. From Day 1 until Day 19 of a 28–32 day menstrual cycle
d. From Day 7 until Day 19 of a 26–32 day menstrual cycle

**4 Which of the following statements most accurately reflects the timing of ovulation for the majority of women?**

a. Ovulation occurs 7 days after the end of menstruation
b. Ovulation occurs on Day 14 of the menstrual cycle
c. Ovulation occurs 12–16 days before menstruation
d. Ovulation occurs 12–14 days after menstruation starts

**5 Which of the following best reflects the cervix and cervical os during the fertile window?**

a. The cervix would be high and firm with a closed os
b. The cervix would be high and soft with an open os
c. The cervix would be low and firm with a closed os
d. The cervix would be low and soft with an open os

**6 Which of the following best reflects the changes to basal body temperature that occur following ovulation?**

a. It decreases and remains decreased until menstruation
b. It decreases by 0.2° for 6 days and then increases
c. It increases and remains elevated until menstruation
d. It increases by 0.2° for 6 days and then decreases

**7 Which of the following best describes the physiological changes that affect cervical mucus following ovulation?**

a. Estrogen decreases, progesterone increases, secretions lessen and become thick and sticky
b. Estrogen decreases, progesterone increases, secretions thicken and increase in volume
c. Estrogen increases, progesterone decreases, secretions lessen and become thick and sticky
d. Estrogen increases, progesterone decreases, secretions thin and increase in volume

**8 Which of the following best reflects the physiological mechanism by which breastfeeding offers contraceptive protection?**

a. Suckling decreases the production of prolactin, decreases the release of gonadotropin-releasing hormone (GnRH) and suppresses ovulation
b. Suckling decreases the production of prolactin, increases the release of GnRH and suppresses ovulation
c. Suckling increases the production of prolactin, decreases the release of GnRH and suppresses ovulation
d. Suckling increases the production of prolactin, increases the release of GnRH and suppresses ovulation

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**9 A woman presents enquiring about the use of breastfeeding as a contraceptive. Which of the following best describes the criteria that she would need to fulfil?**

a. Amenorrhoeic, fully or nearly fully breastfeeding
b. Amenorrhoeic, fully or nearly breastfeeding, less than 9 months postpartum
c. Amenorrhoeic, fully or nearly fully breastfeeding less than 6 months postpartum
d. Amenorrhoeic, less than 6 months postpartum, breastfeeding every 4–6 hours

**10 A woman presents asking to have her progestogen-only implant removed. She no longer wants to use hormonal methods of contraception and does not want an intrauterine device. She would like to start using a fertility awareness method of contraception and wonders if she can start immediately. She is amenorrhoeic. What is the most appropriate advice to offer her?**

a. Fertility indicators should not be relied on until regular menstrual cycles have been established.
b. Fertility indicators are ineffective for 6 months after use of hormonal contraception
c. She can start immediately following her first menses
d. She can start 3 months after removal of the implant

**What learning needs did this guidance address and how will it change your practice? (Please write below)**

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## DETAILS OF CHANGES TO ORIGINAL GUIDANCE DOCUMENT

The CEU has updated this guidance (which was first published online in June 2015) following receipt of feedback from Faculty Members. The only material amendments made to the document are as follows:

November 2015 update:

- Appendix 1: Development of CEU Guidance on page 21. Dr Farah Chaudhry's role as Guideline Chairperson has been acknowledged and her affiliation amended. The entries for Dr Louise Melvin and Mr John Scott have been removed from the Guideline Development Group listing since their names were erroneously included in the original document. Miss Iqra Shahid has been credited for the illustrations in Figure 3.

## COMMENTS AND FEEDBACK ON PUBLISHED GUIDANCE

All comments on published guidance can be sent directly to the Faculty of Sexual & Reproductive Healthcare (FSRH) at **mail@fsrh.org**

The FSRH is unable to respond individually to all feedback. However, the FSRH will review all comments and provide an anonymised summary of comments and responses, which are reviewed by the Clinical Effectiveness Committee and any necessary amendments made.