Scientific basis of Fertility Awareness-based Methods (FAM)

Yves Jacquemyn
UZA
UA

Overview
- Definitions
- A brief history
- Basic concept of FA
- Some remarks on contraceptive efficacy
- Conclusions

Definitions

Family Planning
- WHO: Family Planning implies
  - the ability of individuals and couples to anticipate and attain their desired number of children
  - and the spacing and timing of their births.
- It is achieved through
  - use of contraceptive methods
  - and the treatment of involuntary infertility

WHO 1997

Natural Family Planning

Natural Family Planning refers to techniques for planning or preventing pregnancies by observation of the naturally occurring signs and symptoms of the fertile and infertile phases of the menstrual cycle

WHO 2000

FAM is used
(Population reference bureau 2002)

In % for “more developed countries”

Jacquemyn: Scientific basis
Fertility Awareness-based Methods (FAM) involve
- identification of the fertile days of the menstrual cycle,
- whether by observing fertility signs such as cervical secretions
  and basal body temperature,
- or by monitoring cycle days.

- FAM can be used in combination with
  - abstinence or
  - barrier methods
  during the fertile time.

WHO 2004

A brief history

Bible: lapse of 7 days from the end of menstruation (Leviticus XV, 19-28)
- 15:19 And if a woman have an issue, [and] her issue in her flesh be blood, she shall be put apart seven days: and whosoever toucheth her shall be unclean until the even.
- 15:28 But if she be cleansed of her issue, then she shall number to herself seven days, and after that she shall be clean.

3rd century; Rabbi Jochanan (Bawli Nidda 31b): a woman gets pregnant only in the time close to the ritual bath

Time limited viability of sperm is known in Jewish tradition, but discussion on period
- 48 to 72 hours
  - Eg Maimonides (12th Century)
    (Hilg. Sjear Hattoem-a 5:11, 12): 12 hours

To achieve a pregnancy

- Discovery of basal body temperature shift
  - 1868 W. Squire
  - 1876 Mary Putnam Jacobi
  - 1905 Theodoro Hendrik Van de Velde

- Ovulation time
  - 1924 Kyusaku Ogino
  - 1929 Hermann Knaus

- Proved by
  - 1931 Lewis (during surgery)
  - 1930 Allan, Pratt Newel and Bland

To avoid a pregnancy

- Calendar method
  - 1930 Johannes NJ Smulders

- Temperature method
  - 1954 Gerhard Döring

- Mucus method
  - 1964 John and Evelyn Billings

- Symptothermal method
  - 1982 Anna Flynn
  - 1987 Arbeitsgruppe NFP

Jacquemyn: Scientific basis
Basic concept of FA

Scientific basis
- Double Concept
- Fertile period in a menstrual cycle
- Determine this fertile window in an easy way

Scientific basis
- Fertile period in a menstrual cycle
  - Timing of ovulation
  - Limited ovum viability
  - Limited sperm viability
  - Determine this fertile window in an easy way

Fertile period: sperm
- Viability of sperm?
- 1903 Birsch-Hirshfeld: autopsy after murder during coitus: vital sperm in tube 14-16 hours later
- 1923 Stecher (Zurich) in female genitals only vital sperm for 24 hours after coitus
- Mobile sperm has casuistically been found up to 8.5 days after coitus

Fertile period: ovum
- 1931 Lewis (during surgery) fresh undivided ovum in tube 14 days before next menstruation
- 1930 Allen, Pratt Newel and Bland: found 5 human ova during surgery 1 day 14, 1 day 16 and 3 day 15 after last menstrual period

Jacquemyn: Scientific basis
**Fertile period: ovum**

- Viability of the ovum was until recently a black hole in our knowledge: no direct observations possible until IVF
  - Immature human eggs recovered for IVF can be fertilized even after 36 hours of incubation
  - But IVF not representative of physiological state
  - 12 to 24 h is generally accepted

**Fertile period: timing of ovulation**

- The time from ovulation to the next menstruation is constant 12 to 16 days
- The time from the previous menstruation to ovulation is variable!!!
- There is no ovulation in the first 5 days of a cycle, endometrium is building up
- MOST WOMEN DO NOT HAVE REGULAR 28 DAYS CYCLES

**The cycle**

- Variability of cycle length
  - 70%: 25 – 31 days
  - 30%: 21 – 24 days
- Variability within same woman

**Possible influences on the cycle**

- Stress
- Joy
- Disease
- Travel
- Diet
- Night duty

**Ovulation and fertilization**

- Up to 4 days + 1 day
  - maximum 5 days common fertility of man and woman in a cycle
  - But when is ovulation?

**The physiologic reality**

- Variability of cycle length
  - n = 5 037 cycles
  - n = 423 women
  - 70%: 25 – 31 days
  - 30%: 21 – 24 days
- Variability within same woman
  - n = 5 037 cycles
  - n = 423 women
There is an important variability regarding ovulation, even within the same woman:

For high efficacy in preventing a pregnancy, a calendar method is unsafe.

Scientific basis

- Double Concept
- Fertile period in a menstrual cycle
  - Timing of ovulation
  - Limited ovum viability
  - Limited sperm viability
- Determine this fertile window in an easy way
  - Calendar
  - Symptoms
  - Biological measurements

 Symptoms: symptothermal methods

- Basal body temperature
- Cervical mucus
- Cervical position
- Cervical consistency

Biological measurements

- Microscopy saliva: ferning
- Urinary LH

Fertile ?
Yes, at least fertile!

Fertilization condition
- 1948 Erik Odeblad (Sweden): predictable cyclic mucus changes (while studying mycoplasma)
- 1962 Edward F Keefe: physical changes of the cervix throughout the menstrual cycle

Oestrogen
- Stimulates mucus production
- Builds up the endometrium
- Opens and softens the cervix and causes the cervix to rise in the vagina

Wenn in the 1st cycle phase you see first mucus
- It most is white, thick and sticky
- The more oestrogens, the clearer it becomes

Around ovulation it looks often like raw egg white and is very stretchy.
- After ovulation it soon becomes thick and disappears.

Under influence of oestrogens
Under influence of progesteron

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Progesteron

- Mucus plug
- Develops endometrium
- Suppresses a new ovulation
- Elevates basal body temperature

How it all fits together

FERTILE WINDOW

OVULATION

VIABILITY SPERM

VIABILITY OVUM

FERTILE WINDOW

PROGESTERON RISE

TEMPERATURE RISE

CHANGE IN CERVICAL MUCUS, POSITION, CONSISTENCY

FERTILE WINDOW

CONSTANT 12-16 DAYS

VARIABLE BUT 5 DAYS SAFE

FERTILE WINDOW

PROGESTERON RISE

TEMPERATURE RISE

CHANGE IN CERVICAL MUCUS, POSITION, CONSISTENCY

The fertility cycle

Increasing probability of pregnancy

Menstruation

Duration of a menstrual cycle

ovulation

relatively unfertile

fertile

absolutely unfertile

Jacquemyn: Scientific basis
Some remarks on contraceptive efficacy

What is the real failure rate of contraception?

- Users = real life population study
- In a population comparable to your own: US ≠ Europe
- An example (Moreau et al. Hum Reprod 2007)
- French population based study
- 1689 women, 18-44 years

What is the real failure rate of contraception?

- First year
  - Overall 2.9% failure
  - Failure rate per method
    - IUD 1.1%
    - Pill 2.4%
    - Condom 3.6%
    - FAM: 7.7%
    - Withdrawal 10.1%
    - Spermicides 21.7%

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Major difference with US (Kost et al, Contraception 2008)
- Pill 7%
- Condom 17%
- FAM 25%
- Withdrawal 18%

And no improvement between 1995 and 2002

This is no Pearl index or lifetimetable!

What is the real failure rate of contraception?

- Real life always higher compared to “studies”
  - Bias
    - People will be performing better as long as they are 
      “monitored”
    - Motivation in a study is high

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FAM: Cochrane review

- Grimes, Gallo, Halpern, Nanda, Schulz and Lopez
- 2004

FAM: cochrane review

- All RCT on any FAM
- Any language
- Compared with placebo, another method, alternative FAM

FAM: cochrane review

- Only 8 studies
- 3 methodologically acceptable for review
- Including < 2000 women in all 3 studies taken together
- None of the studies even mentions the randomization method
- Non compliant couples were encouraged to discontinue....
- > 50 % drop out (if > 20 %, trial validity extremely low)

FAM: Cochrane review

- Conclusion
  - Such poor quality that it is impossible to determine comparative efficacy
  - Just as every other method of contraception FAM should be properly evaluated, in RCT??, before adoption and dissemination
  - But, is an RCT acceptable for contraception in the 21st century?
  - Is an RCT the best method, are descriptive studies enough?

Problems when studying FAM

- Mixture of methods
  - Creighton model fertility care system
  - Billings ovulation method
  - Ogino-Knaus
  - Smulders Ogino
  - Perimon Standard Days method
  - TwoDay Method
  - NFP
  - Alone or in combination with, condom, Femidom, pessary, ....

Jacquemyn: Scientific basis
Problems when studying FAM

- Mixture of methods
- Often combined with condom etc. on fertile days
- Studies on contraception are always flawed: by the pharmaceutical industry, by religious authorities…
- Motivation, training etc.
- Combining in a review all FAM is like combining bycicles, cars, and trains to calculate the travel time "on wheels"

Conclusions

- FAM have a sound physiologic basis
- Calendar alone is useless
- Combination methods and training are necessary
Introduction into the Biomedical Aspects of Fertility Awareness-based Methods

Dpt. of Gynecological Endocrinology, University of Heidelberg

Petra Frank-Herrmann

Fertility Awareness based Methods (FAM)

• Determination of the fertile window of the cycle by the woman herself

• Couples use it
  – to avoid a pregnancy
  – to achieve a pregnancy

Main parameter:
cervical mucus pattern
temperature changes

The cervical mucus as estrogen marker and the basal body temperature as progesterone marker represent the complete picture of the hormonal ovarian cycle.

Controversy

• Do Fertility Awareness based Methods work?

Answer

• The German Arbeitsgruppe NFP started a subventioned project in the 80s
  – studies on the scientific, physiologic basis of NFP
  – development of a complete NFP methodology
    • easy rules for the couple
    • teaching skills for teachers
    • teacher training course
  – studies on the efficacy to avoid and to achieve a pregnancy (acc. to EBM criteria)

Fran-Herrmann: Biomedical Aspects
Contents

• The common FAM method of the German Arbeitsgruppe NFP, NFP-Vlaanderen and NFP-Nederland (NFP-DAG*)

• Current FAM methodology to avoid pregnancy: what is effective and evidence-based?

• Further application in Gynaecology and Reproductive Medicine

FAM methods

• Temperature Methods/Calculation methods: no longer used as single indicator, except: Standard days method (SDM)

• Cervical mucus methods
  - Billings-Ovulation Method (OM)
  - TwoDayMethod (TDM) = simplified mucus method

• Symptothermal Method (STM)
  - double-check: onset and end of fertile phase (NFP-DAG)
  - onset: mucus only, end: double-check

Efficacy

major issue in family planning choice in European countries

representative public opinion poll (Freundl 1985)

Quality criteria of STM-Development in Germany, NFP-Vlaanderen and NFP-Nederland

• Decision-making only by Scientific Committee (acknowledged by the German Association of Obstetrics and Gynaecology as an expert group for “Natural Fertility”)

• ST methodology: effective and evidence-based

• Practicability (only necessary rules)

• Standardized teaching materials (NFP-DAG)

• Standardized teacher training courses with permanent evaluation

• Own Database to study NFP use (EBM – peer reviewed)

• Continuous systematic review of international research (>1500 references)

Determination of the fertile phase according to the STM NFP-DAG

1. Cervical mucus
2. Earliest temperature rise out of 12 preceding cycles minus 8
   whatever comes first

1. Peak of the cervical mucus symptom plus 3
2. Third higher temperature reading
   whatever comes later

Onset of the fertile window
End of the fertile window

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To get interpretable cycle charts:

- Chart should allow documentation of
  - different symptoms
  - the time of temperature measurement
  - and disturbances

- Disturbed temperatures have to be excluded

- Use of a suitable thermometer

- Observation of the cervical mucus externally (!) at the vulva

Temperature observations
Mucus observations
Cervix observations

Note the date
The 1st day of the bleeding is the 1st cycle day

Start measuring temperature 1st day of menstruation
Indicate temperatures by dots, link following temperatures to each other; missing ones are left open
e.g. travel, illness, shift services,…

The way of measurement indicated
Daily charting mucus observations at the evening
Daily charting the cervix observations
Noting the fertile days
The beginning of menstruation is charted and a new chart taken
Indicate amount of bleeding
The 1st higher temperature is written down
The cycles are numbered

Learning NFP-DAG

- NFP is as driving a car.
- Once the client has learned it, it becomes a second nature…
- … ideally, it is learned out of a book and by an experienced instructor.
Learning NFP-DAG

- **User**: 4 x 2 hours (3 cycles)
  - Individualized teaching
  - A few minutes a day (observation and charting)
  - Until end fertile phase

- **Teacher**:
  - 50 hours teacher training course
  - Practice (3 couples)
  - Yearly accreditation

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NFP methods today

- Still too many variations of methodology
- Often historically grown
- Lack of scientific selection/rejection of rules
- Controversial discussion of effectiveness

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Effectiveness of the end of fertile phase by TM/STM

<table>
<thead>
<tr>
<th>Method</th>
<th>Prospective Studies</th>
<th>Retrospective Studies</th>
<th>Method Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TM</strong></td>
<td>(method-related pregnancy rates)</td>
<td>(method-related pregnancy rates)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vincent 1967 (0.1)</td>
<td>Döring 1967 (0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Marshall 1968 (1.2)</td>
<td>Volmar 1975 (0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vollmar 1975 (9)</td>
<td>Rice et al. 1977 (0.3)</td>
<td></td>
</tr>
<tr>
<td><strong>STM</strong></td>
<td>(method-related pregnancy rates)</td>
<td>(method-related pregnancy rates)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Psycho 1968 and 1978 (8)</td>
<td>Johnston et al. 1978 (OM)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Barbato and Bertolotti 1986 (9)</td>
<td>Frank-Herrmann et al. 1988 and 1997 (9)</td>
<td></td>
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<tr>
<td></td>
<td>European Multicenter Study 1993 (9)</td>
<td>European Multicenter Study 1993 (9)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Irish 1981 (OM)</td>
<td>WHO 1981 (OM)</td>
<td></td>
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<tr>
<td></td>
<td>New zealand 1981 (OM)</td>
<td>WHO 1981 (OM)</td>
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</table>

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Beginning of fertile phase: mucus only

- Ball 1976 (OM)
- Klaus et al. 1976 (OM)
- Johnston et al. 1978 (STM/OM)
- WHO 1981 (OM)
- Ireland
- New Zealand
- Barbato et al. 1988 (STM)

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Beginning of fertile phase: Döring rule, shortest cycle rule

Prospective studies

- Vollman 1975 (minus 20, 12 cycles) 0.1
- Rice 1981 (-19, -20, 12 cycles, -21, 6 cycles) 0.5
- European Study (double-check) 0
- German Database 1997, 2007 (double-check) 0.2

⇒ Double check, 12 cycles minus 8 or 5 days!

Population Surveys

e.g. National Survey of Family Growth (USA)

- at the moment not suitable to estimate the effectiveness of NFP methods, because of two limitations:
  - the most effective NFP method (STM) is not mentioned in the questionnaire
  - outdated and ineffective methods are mentioned and counted as NFP methods

- Interesting approach for the future!

Efficiency: prospective studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Women Cycles</th>
<th>UP Method failure</th>
<th>User failure</th>
<th>Dropout</th>
</tr>
</thead>
<tbody>
<tr>
<td>Döring</td>
<td>291</td>
<td>3.370</td>
<td>5</td>
<td>0.7</td>
</tr>
<tr>
<td>Freundl</td>
<td>1 046</td>
<td>16 860</td>
<td>34</td>
<td>0.5</td>
</tr>
<tr>
<td>Frank-Herrmann</td>
<td>900</td>
<td>17 638</td>
<td>22</td>
<td>0.4</td>
</tr>
</tbody>
</table>

German STM effectiveness study (NFP-DAG)

- 900 NFP beginners, 17,638 cycles (collected prospectively)
- 19 – 45 years of age
- no postpartum, no breastfeeding, no postpill
- cycle length 22-35 days (80 % of the cycles of a woman)
- 63 % < 30 years
- 52 % no child
- 81 % spacer
- 64 % medium level of education
- the option achieve or avoid pregnancy was clear
- lost-to-follow-up rate = 6.3% after 13 cycles
Measures of effectiveness

Use-effectiveness

- Life-table / Kaplan-Meier (actuarial curve) acc. to Tietze, Potter et al.

Method-effectiveness

- Perfect/imperfect use-approach acc. to Trussel and Grummer-Strawn

(no parametric models)

Pregnancy rates in relation to perfect and imperfect use

<table>
<thead>
<tr>
<th>Method-effectiveness</th>
<th>Pregnancy rate</th>
<th>95% CI lower</th>
<th>95% CI upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstinence</td>
<td>0.03</td>
<td>0.05</td>
<td>1.55</td>
</tr>
<tr>
<td>Protected intercourse</td>
<td>0.59</td>
<td>0.07</td>
<td>2.13</td>
</tr>
<tr>
<td>Unprotected intercourse</td>
<td>0.46</td>
<td>0.49</td>
<td>2.72</td>
</tr>
<tr>
<td>Total</td>
<td>1.62</td>
<td>1.2</td>
<td>12.43</td>
</tr>
</tbody>
</table>

Frank-Herrmann P et al., Hum Rep, 2007

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NFP meets Gynaecological Endocrinology

Infertility

- Hormonal disorders
- Hyperprolactinemia
- Hyperandrogenemia (adrenal)
- Polycystic ovaries syndrome (PCOS)
- Postpill amenorrhea
- Amenorrhea after eating disorders
- Amenorrhea due to premature ovarian failure
- Dysmenorrhea
- Contraindication for oral contraceptives
- Turner syndrome
- Mosaics and others

The infertility patient determines the day for the diagnostic measures (ultrasound, blood sample, postcoital test) herself acc. to her observations
Infertility study at the University of Heidelberg

Luteal blood sample on day 7 of elevated temperature

NFP-teaching in Gynecological Endocrinology

1. Avoiding pregnancy:
   symptothermal method with complete methodology

2. Trying for pregnancy / infertility
   cervical mucus and temperature charting, peak fertility, sexual behavior

3. Hormonal disorders / Oligo-Amenorrhea
   cervical mucus observation, bleedings, temperature charting during mucus phases + 4 days afterwards

Take home messages

• Women/couples are able to develop a high degree of reproductive competence
• Effective family planning is possible without medical intervention
• Women/couples have a right to get informed about effective FAM \( \rightarrow \) informed choice / cafeteria approach

Take home messages II
The Symptothermal Method (NFP-DAG*)

• is the recommended FAM for our countries
• double-check to determine the beginning and the end of the fertile window (non STM with mucus only to determine the onset of fertile phase)
• low pregnancy rate with correct use
• can be as effective as oral contraception

Take home messages III
Gynaecologists may use FAM / NFP-DAG much more than is currently the case:

- method of family planning for motivated couples
- management of infertility
- greater efficacy of diagnostic tests (hormones, US)
- assessment of degree and development of hormonal disorders (extent of ovarian insufficiency)
- better involvement of patient and her partner

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Take home messages IV

- FAM has to be taught at university level and to midwives, GP and ObGyn
- = clinical decision making

Thank you very much for your attention