METHODS OF FAMILY PLANNING BASED ON AUTOOBSERVATION AND SELF-EVALUATION OF THE OVARIAN CYCLE

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Methods aiding conception or contraception based on autoobservation make use of identifying the effects (directly noted or indirectly measured) of the various physiological changes in the organism of a woman preceding accompanying and following ovulation. A good understanding of the ovarian (menstrual) cycle will help in understanding some underlying principles related to human reproduction. The following text hopes to be of use to medical professionals as well as to anyone interested in this broad and evolving topic.

To date known cyclic signs are [1]:

CHANGES IN THE REPRODUCTIVE ORGANS:

RELATED TO THE UTERUS:

- **Endometrial** cycle classified as menstrual, proliferative and secretory phases marked by periodical menstrual bleeding, changes in the thickness and morphology of the endometrium, sonographic characteristic (by means of transvaginal sonography the changes of the endometrium may be demonstrated in quantitative and qualitative parameters), histological changes of the epithelium (allowing for accurate dating), histochemical changes (with cyclic changes of many substances: glycogen, ascorbic acid, alkalic phosphatase, beta-glucuronidase, nucleic acids and mucopolysacharides. The endometrium is also equipped with estradiol specific receptors, The number of

cytoplasmic and nucleolar receptor sites markedly rises until ovulation, from which it again decreases.

- **Myometrial** changes consisting of spontaneous myometrial contractions (more frequent in the proliferative phase and culminating at ovulation).

- **Cervical** cycle with biophysical and biochemical changes. The complex of biophysical properties sometimes called the cervical factor consists of changes in the volume of the mucus (reaching 200-700mg/24 hours during ovulation, while nonovulatory levels reach a maximum of 60mg/24 hours). Transparency and index of refraction is highest at ovulation (1.33 as compared to 0,01 in other phases of the cycle). The viscosity is lowest at ovulation, while the Spinnbarkeit (capability to pull out a filament from the mucus) is highest (10-15 cm as opposed to 1-2 cm in other periods of the cycle). During the late follicular phase the phenomenon of arborization (crystalization, ferning) can be evaluated upon microscopic examination of air-dried mucus smear. This is caused by a relative increase of sodium chloride content of the mucus (the absolute value remains constant, as the cervical mucus is isosmotic at all times). The sodium chloride content is roughly the same during the cycle (isotonic solution containing 0.93% NaCl), but the air dried specimen during ovulation shows the salt content of 40-70% as compared to 2-20% otherwise. Other parts of the cycle show microscopically only amorphous structure with the presence of cells. Peak Arborization is seen on the day of the peak LH levels (one day following peak urinary levels of estrogens). The content of many macromolecular substances (IgA, IgG, lactoferin), enzymes and their activators (alkalic phosphatase, aminopeptidase, esterase, amylase, lysozyme and other) follow a similar cyclical pattern with their low coinciding with the preovulatory estrogen peak. The lowest viscosity and greatest Spinnbarkeit is achieved one day before the ovulatory LH peak (on the day of the peak levels of estrogens in the urine). The peak of plasmatic levels of estrogens also causes the maximal mucus production (for more information refer to the chapter on the ovulation method - Billings method). The pH is predominantly alkalic (ranging from 6.5 to 8.0) with maximal values during ovulation. The changes in the cervical epithelium are less marked than in the endometrium. Changes of the muscle tone and tone of the external cervical os (hypotonic during the ovulation and presenting a picture of a fish-eye) is influenced by changing levels of chondroitinsulphate (lowest periovulatory). From a practical point of autoobservation, the beginning of the cycle is characterized by a closed vaginal portion of the uterine cervix with a consistency

resembling the nasal cartilage. nearing to ovulation due to the elevating level of estrogens the cervical portion usually elevates from the posterior vaginal fornix to mid-vaginal position and is so soft around ovulation, that may not be palpated at all, with the external cervical os opening widely. The consistency is often likened to the softness of the lower lip. Following ovulation, the external os closes again, and the cervix hardens and resumes its usual position pointing into the posterior vaginal fornix (in cases of the anteverted, anteflect uterus).

FIG. 1. PLACED HERE

RELATED TO THE VAGINA:

- **Vaginal** cycle is best assessed by vaginal cytology. The early proliferation phase is marked by the presence of basophilic large and small intermediate cells. Nearing to ovulation large and intermediate eosinophilic and basophilic cells with pyknic nuclei are observed. Postovulatory phase is marked by the presence of characteristic cell clumping and aggregation due to the shedding of the superficial layer of the squamous vaginal epithelium. These changes can be quantified according to several indexes (karyopknotic, eosinophilic and index of maturity). Also the acidity of the vaginal milieu has a cycle. Menstruation is marked by a neutral or even slightly alkalic pH. Proliferative phase by pH 5.7, periovulatory the value reaches a pH neutral value, the second day post ovulation they fall again only to rise just 1 to 2 days preceding the menstruation to neutral pH again. The underlying changes of lactic acid (produced by Lactobacillus metabolizing glycogen) follow the above mentioned pattern.

RELATED TO THE OVARY:

- The sellection of the dominant **follicle** from a kohort of follicles of certain maturity and its linear growth untill preovulatory size (volume), vascularization and preovulatory disappearance of the oocyte-cumulus complex may be indirectly visualized. This is followed by follicular rupture at the time of ovulation in a physiological cycle. More subtle changes in the ovarian morphology will be discussed in the section reserved for sonographic assessment of the cycle.

RELATED TO BREASTS:

- The **mammary gland** becomes hyperemic and hyperplastic with intralobular oedema and alveolar dilatation, proliferation of the epithelium of the ducts and signs of secretion in the premenstrual period. The volume of the breasts is smallest in the follicular phase with a rapid increase after ovulation peaking premenstrually, but declining before the onset of menstruation.

SYSTEMIC CHANGES DURING THE MENSTRUAL CYCLE:

- The body **temperature** changes are best recorded at basal conditions (awakening after adequate sleep) follow the same pattern when recorded vaginally, orally or rectally. The characteristics of this basal body temperature curve have been described many times. The elevation of this biphasic curve lasts approximately 14 days (for the normal function of corpus luteum 9 -17 days is a prerequisite) The elevation of basal body temperature is caused by the thermogenic effect of progesterone mediated by excessive norepinephrine (noradrenaline) secretion in the CNS, which acts upon the hypothalamic thermoregulator centers. This effect may be blocked by barbiturate and salicylate medication.

- The body **weight** grows in about 1/3 of the women in periovulatory and premenstrual phase. The retention of fluids, sodium and chlorides as a result of elevated levels of estrogens is usually considered as the underlying cause.

- Changes in **blood** show a periovulatory fall in the number of eosinophilic and basophilic leucocytes. Thrombocytes reach the maximum number during ovulation. Norepinephrine (as well as other plasmatic catecholamines) shows a marked and rapid serum level increase coinciding or preceding the preovulatory rise in the serum level of LH. The likely mechanism for this is the activation of the hypothalamic dopaminergic neurons by the elevated level of circulating estrogens during the positive feedback leading to elevated secretion of LH-RH. ACTH is low during the follicular phase with a sharp rise coinciding with the LH peak followed by a lower and relatively stable level in the postovulatory phase. The hGH (somatotropin) secretion peaks during ovulation, whereas alpha-tocoferol reaches it's lowest levels in this phase of the cycle.

- **Capillary** changes include elevated fragility and permeability coinciding with menstruation presumably owing to a relative estrogen deficiency. Estrogens are known to strengthen the capillary wall by depositing acid mucopolysaccharides there. Capillary fragility also sometimes coincides with periovulatory spotting.

- Changes detectable in the **urine** have been studied excessively. All of the terminal metabolites of hormones may be detected and follow closely the serum concentration levels.

- The superficial **cells of mucosal epithelium** (buccal, pharyngeal, urethral and vaginal) undergo characteristic changes during the menstrual cycle, which forms the basis of functional vaginal exfoliative cytology.The **mucus secretions** (nasal epithelium, salivary glands secretion, tears and most markedly of the uterine cervix) also change in several characteristics.

- In the **skin** as opposed to perspiratory glands the activity of the sebaceous glands stimulated by androgens is increased in the luteal phase, while estrogens in the follicular phase suppress it.

- Changes of the **nervous system** include the elevation of the tone of the sympathetic system during menstruation with a decrease until a minimum preceding ovulation by several days followed by gradual elevation towards the time of menstruation. The parasympathetic behaves inversely (Fig.2). Also the central nervous system shows signs of being influenced by the cycle. The premenstrual and menstrual period is marked by more frequent suicidal and aggressive moods, while periovulatory is characterized by emotional relaxation with a decrease of anxiety and hostility. Copulatory activities of the female show certain variations during the cycle with a higher coital frequency in the follicular and preovulatory phase.

FIG. 2. PLACED HERE

As has been shown, there are MANY SIGNS of CHANGE during the menstrual cycle influenced by the cyclic changes of the hormonal status (Fig. 3.). Out of these but a FEW are so well defined and constant, that they MAY BE USED FOR the PREDICTION OF THE FERTILE and INFERTILE PERIOD of the cycle. These form

the base of the so called "natural family planning methods", or methods for the regulation of fertility based on autoobservation. For didactic reasons the methods used for defining the limits of the fertile period of the cycle can be divided into methods based upon the evaluation of a single indicator, the so called "single-index methods" and methods based upon the several indicators, the "multi-index methods.

FIG. 3. PLACED HERE

SINGLE-INDEX METHODS are the calendar method, thermal method and the mucus method.

CALENDAR METHOD: is sometimes referred to as the **rhythm** or **Knaus-Ogino** method after its authors Knaus [2, 3] and Ogino [4, 5]. The periodicity of the menstrual cycle was always a reason for speculations about its significance in relation to reproduction. Already in the Bible (III. Book of Moses[6]). Jews were to abstain for 7 days after the end of the menstrual bleeding (roughly till the time of the conception optimum). Another interesting statistical study was published in 1844 by Raciborski [7]. This author studied pregnancies concepted shortly after marriage and found, that marriages soon after the termination of the menstrual bleeding led in a high percentage to pregnancy, as opposed to marriages celebrated 10 - 12 days later where pregnancy occurred usually only after several cycles. Out of his observations he concluded that the conception optimum was limited at ten days after the end of the menstruation. The breakthrough in ovulation timing was made by the Japanese Ogino in 1923/24 on his clinical laparotomic findings that ovulation can be spaced between the 12$^{th.}$ to 16$^{th.}$ day before the beginning of the next menstrual cycle in a regular 28 day cycle. As he counted with the fertilizing potential of sperm for 3 days, he calculated the fertile period to be between the 19$^{th.}$ to 12$^{th.}$ day before the following menstruation. In 1927 another approach to this problem was made by the Austrian Knaus. He was studying the response of the uterus to contract when stimulated by Oxytocin. This was possible until the time, when the uterine muscle was densensitized by progesterone. In this way he was able to determine the length of the luteal phase of the cycle and so predict the probable time of ovulation. He placed the ovulation of healthy women to be on the 15$^{th.}$ day preceding the next menstruation. He also already knew, that the luteal phase is more or less constant in

length, as opposed to the follicular phase. Knaus demanded a 12 month period of observation to determine the individual variations in cycle length, before a woman should use his method of calculating the fertile and unfertile period of her cycles.

PRACTICALLY CALCULATED:

According to Ogino the fertile period is calculated by subtracting 18 days from the number of days in the shortest cycle and 11 days from the number of days of the longest cycle. A minimum of 12 cycles must be evaluated. In this way the user gets to know the last and first fertile day. Example: the last 12 cycles evaluated showed the shortest cycle to be 25 days and longest 31 days.

Calculate: 25 - 18 = 7 (first day of the fertile phase of the cycle)
31 - 12 = 20 (last day of the fertile phase of the cycle)
(the fertile phase is day 7 to day 20 of the cycle)

According to Knaus, the fertile phase is determined:

Calculate: 25 - 17 = 8 (first day of the fertile phase of the cycle)
31 - 13 = 18 (last day of the fertile phase of the cycle)
(the fertile phase is day 8 to day 18 of the cycle)

The length of the menstrual cycle is often influenced by many factors (physical and psychical state, climate, hours of sunshine, physical activity, time shifts, irregular lifestyle, age etc.), which poses a serious limit to the use of the Knaus - Ogino calendar method. Controversy also exists as to the time span of fertilizing ability of the gametes. According to Royston[8] the maximal survival time for the ovum is probably less than 48 hours. This contrasts with the possible fertilizing potential of spermatozoa in the cervical mucus after intercourse, which may reach up to 6 days.[9] For practical use most authors adhere to the fertilizing potential of sperm for 3 days and fertilizability of the oocyte for 2 days. Because of the above limitations, a high percentage of failure obscured the effectives of natural family planning methods as a whole for many years. Never the less, the scientific determination of relationship between menstruation and ovulation pioneered by Knaus and Ogino, which were the first to relate ovulation with the subsequent (and not preceding) menstruation together with studies about ovum and sperm fertilizability put a sound basis for the use of "natural" methods of fertility awareness. Data available show, that the Pearl index (PI) of the calendar method lies between 2.2 - 8.0. The use of the calendar

method is definitely obsolete by today's standards and any counseling about these methods must be considered as irresponsible and potentially harmful.[10] Still, this method even today for some, presents the only known method of contraception.

BBT (BASAL BODY TEMPERATURE) THEORY:

The body temperature of homoiothermal creatures is kept at a relatively constant level, with slight inter-individual variations. The Homo Sapiens hypothalamic thermoregulator center keeps the body temperature at roughly 37 degrees Celsius. The temperature varies with the location where it is measured, with the most constant being the rectal (which is minimally influenced by external changes) and reflects well the internal body temperature. The normal internal body temperature shows a diurnal variation of 0.5 - 0.7 degrees Celsius.[11] With individuals that are awake during the day and asleep at night (though they may be at a 24 hours bed rest during the whole 24 hours), the temperature is lowest (nadir) at 6:00 AM and reaches the peak during the evening. The lowest temperature is during the sleeping state, a little increase is observed on awakening and at bed rest and elevates with physical activity. Several studies have addressed the relation between the body temperature upon awakening while observing bed rest and the time of waking Royston[12]. The so called weekend effect, in which BBT temperatures registered are higher than their neighbors on Friday and Monday is well recognized by gynecologists. In the above cited paper when temperature measurements upon waking between 05:30 and 11:00 were used a highly significant temperature-time regression slope of 0.086 degrees Celsius/hour was found (individually estimated slopes varied between 0.05 and 1.15 degrees Celsius/hour. A rounded adjustment factor of 0.1 degrees Celsius/hour is usually used for simplicity of application. The elevation of the BBT is caused by the thermogenic effect of progesterone, as described previously.

Thermal or temperature or BBT - the practical use of the method:

This method was advocated by Ferin[13] and Döring.[14] For observing good practice, the measurement of BBT should be done by the same thermometer (when electronic thermometer is used, the battery must be replaced every year). The temperature may be taken vaginally or rectally (as soon as possible after awakening, insertion depths at least 50 mm). Oral measurements are less useful, axillary measurements are useless. For correct evaluation of the temperature elevation we must define the baseline of lower temperatures Arbeitsgruppe NFP.[16] This baseline temperature is

postulated as being the highest temperature of six measurements preceding the temperature elevation. In defining the **Peak of the temperature elevation** (and thus the beginning of the infertile period) three situations may be encountered.

1/. - three consecutive temperatures are higher than the baseline, the third temperature is at least 0.2 degrees Celsius above the baseline (this is the peak of the temperature elevation) (Fig. 4.).

2/. - if the third elevated temperature doesn't reach as high as 0.2 degrees Celsius above the baseline, a fourth measurement is necessary. To count this measurement as the day of the peak of the temperature elevation, its value must be above the baseline, but does not necessarily have to reach the 0.2 degrees Celsius above the baseline (Fig. 5).

3/. - If during the elevation one of the measurements falls bellow the baseline, the temperature must be measured until a measurement reaches a value of at least 0.2 degrees Celsius above the baseline. This measurement is then considered as the peak of the temperature elevation (Fig. 5.). According to Döring the ovulation takes place 1-2 days before the temperature rise. Starting from the evening of the day considered as the Peak of the temperature elevation conception is impossible (Döring[17], Peel[18]). The following days till the beginning of the next menstruation are defined as the absolutely safe part of the cycle. Cases, where the temperature-curve shows a slow step-wise rise in temperature in the span of 5-6 days can be explained by insensitivity of the diencephalon to the thermogenic effect of the progesterone. <u>The most common interference with the measurements are:</u> illness (even a slight influenza, headache etc.), use of various medicaments, insufficient sleep (less than 6 hours), physical activity before the measurement (eg. when a weaning mother is not able to observe at least 1 hour of bed rest after feeding the baby), alcohol consumption during the preceding evening, intensive stress (eg. exams), traveling or heavy work and use of a different thermometer. All of these events should be marked in the chart, which is usually used to keep track of the BBT. When only the unfertile phase of the cycle after the temperature rise is used for intercourse, we refer of this method as the "<u>strict form of the temperature method</u>". The Pearl index of this form of contraception is 0.8.[19] This method of contraception can be used already in the first monitored cycle with success. The effectives of the above discussed BBT method is usually accredited a Pearl index between 0.8 - 3.0.

FIG. 4, 5, 6 PLACED HERE

With regards to the BBT theory, electronic devices to aid the woman using this method have been constructed and tested. One of these, an automated electronic device (Rite Time) was evaluated in a total of 140 menstrual cycles.[20] It gave the signal for the start of the infertile period in 117 cycles, of which 114 (97%) appeared to have occurred at the appropriate time. The comparison with evaluated mercury thermometer recorded data showed, that the device had probably given premature signal in 3% of cycles. This was due to several unusually low temperatures during the baseline period (days 4 - 11), possibly caused by poor technique. An interesting point is addressed, when the subjective evaluation of the temperature rise (as defined previously by rules 1/., 2/. and 3/.) is substituted for a statistical method. This has been elaborated by Royston and Abrams who applied a modified CUSUM (cumulative sum) test to detect the BBT elevation. We would like to discuss the method in more detail.[21]

The CUSUM test is applied once reasonably stable preovulatory temperature has bee reached to detect the upward shift. To perform the test, values of the four CUSUM parameters (baseline, preovulatory standard deviation, the magnitude of the BBT shift and the CUSUM decision interval) must be determined. The baseline period in the case of the BBT is defined as the first six valid readings beginning day 5 of the cycle (a valid reading is not influenced by unusual circumstances and is not more than 0.3 degrees Celsius higher than its neighbor values). As preovulatory standard deviations of the BBT show no significant differences between cycles of the same woman (women are consistent from cycle to cycle but different from one another) a 95% confidence interval in S.D. was estimated between women and the mean was found to be 0.123 degrees Celsius. A value of 0.1 is used in practical calculations. The magnitude of the shift in BBT truly representative of ovulation has been recommended by the WHO in 1976 to be not less than 0.2 degrees Celsius. The CUSUM decision interval for woman with cycles from 22 to 35 days has been shown to be 0.35 degrees Celsius by Royston in 1980 on the basis of analysis of 137 charts of experienced BBT NFP users. THE **INFERTILE POSTOVULATORY PERIOD STARTS** THE EVENING OF THE THIRD DAY, AFTER THE BBT REACHES A VALUE GREATER OR EVEN TO THE SUM OF THE **BASELINE TEMPERATURE + 0.1 deg. Celsius** (ONE S.D. which sets the CUSUM REFERENCE VALUE) **+ 0.35 deg. Celsius** (CUSUM DECISION INTERVAL). The day defined in such a way is the day, when

CUSUM exceeds the decision interval thus detecting the upward shift in the measured BBT (Fig. 7.).

FIG. 7. PLACED HERE

The modified baseline for the Rite Time is taken as the mean temperature of 8 days starting at day 4. The reference level used is baseline plus 0.1 degrees Celsius. The CUSUM "shows" a significant rise, when it exceeds 0.25. This can happen before three high temperatures have been recorded. For standardization three consecutive temperatures greater than or equal to the reference value are needed, before the third one of these can be selected as the last day of the fertile period. In Royston's study about one half of the volunteers already using the thermal or symptothermal method, would be willing to replace their conventional charting methods with Rite Time. Another study by Flynn[22] is of the Bioself 110, which is a hand-held electronic device that combines the BBT and calendar methods of fertility regulation for planning or preventing pregnancy. A pilot study was undertaken in three centers in the United Kingdom to evaluate the Bioself 110 as a contraceptive aid introduced to the market in Europe in 1984. This paper deals with 1238 cycles from 131 women. Only one unplanned pregnancy occurred where a volunteer correctly used the Bioself 110 and had intercourse on a supposedly "safe" day. The Bioself 110 was correctly used in 71% of the cycles studied. Eighty-four percent of the volunteers indicated that they were satisfied with the Bioself 110 after six to twelve cycles of use. It was concluded that the Bioself 110 can serve as an effective family planning aid and should be added to the menu of contraceptive methods available to women today. Since 1992 a newer model the Bioself 2000 was introduced onto the market. This microprocessor controlled device keeps the track of the last 64 measured temperatures and the length of the last six menstrual cycles. When connected to a printer, the woman can obtain a readout of her basal body temperatures. This new model was evaluated in a study by Drouin[23] in 745 cycles of Canadian woman. The pregnancy rate was 9.02 per 100 women-years. The discontinuation rate was 32.5%. Again it was concluded, that the Bioself device is an effective contraceptive aid for couples who are aware of the pros and cons of natural family planning.

It is an issue for speculation why with such a detailed knowledge of the rules that need to be observed for correct interpretation of the BBT no mass production of electronic hand held device combining a clock (for time correction of the BBT value),

electronic thermometer and a memory (for corrections in compliance with the calendar method) with an incorporated (possibly EPROM programmed CUSUM test or fuzzy-logic evaluation algorithm) to evaluate (and also for several cycles store) the first day of the infertile period has never been attempted. Especially as it has been shown, that the BBT + 3 rule combined with the calendar rule "shortest cycle -18 days" or appearance of the first mucus (both used for determining the last infertile day of the follicular phase) can define the fertile phase of a cycle on a 90% confidence level (Fig. 8.).[9]

FIG. 8. PLACED HERE

THE CERVICAL MUCUS OR OVULATION METHOD (OM) OR BILLINGS METHOD:

This single-index method was elaborated since 1953 (Billings[24]) and introduced in 1972 by the Billings and collaborators.[25, 26] It is widely recognized especially because of the activities of the WOOMB, World Organization of the Ovulation Method (Billings), Billings Family Life Center, Victoria, Australia. The theory behind this method emerged gradually. The changes of the character of the cervical mucus has been known for a long time and best quantified in the work of Insler.[27] **Cervical mucus and external os changes** were quantified by Insler in the following attributes:

I. External cervical os (closed and whitish 0, semi-opened pink 2, gapping and hyperemic 3).

II. Presence of mucus (absent 0, very limited quantity 1, a shiny drop 2, plentiful outflowing cascade 3).

III. The ability of the mucus to be pulled out into a filament (the so called Spinnbarkeit) (filament length < 1 cm 0, 1 - 4 cm 1, 5 - 8 cm 2, > 8 cm 3).

IV. Ferning (or crystallization or arborization) of a room temperature air dried mucus sample on a microscope slide at HPF 400x magnification (amorphous mass with no crystallization 0, linear single branch crystals 1, primary and secondary branching 2, full branching in tertiary branches or fern-like crystals 3).

V. The presence of cells (cellularity at HPF microscopic magnification under a cover slip viewed in a phase contrast microscope or in a microscope with a lowered condenser enabling the examination of an unstained sample) (>11 cells 0, 6 - 10 cells 1, 1 - 5 cells 2, sporadic or absent cells 3).

Thus the **Cervical (or Insler) Score** may reach values in the range from 0 to 15 points. According to the authors, in 30% the maximal score correlates with the ovulation, in 50% of the cases the maximal score precedes ovulation by 24 hours. The ability of pulling out a filament and ferning indicate the maturation of the follicle, the total amount produced correlates best with the ovulation. A total of 240 observations in 10 patients by two observers were done with almost absolute correlation of the scoring. The above changes reflect very narrowly the production of 17-beta estradiol by the growing follicle (Fig. 9). These signs are of course accessible only to someone able to visualize the cervix and equipped with a microscope.

FIG. 9. PLACED HERE

The contribution of the Billings and their collaborators was in recognizing and describing the personal sensations and feelings (at the vulvar region, not vaginal) accompanying the quantitative and qualitative changes of the cervical mucus. At present we also have electron-microscopic evidence of the changes of cervical mucus structure during various phases of the cycle. Nearing to the ovulation peak, the water content of the mucus grows, and the fibrous web becomes much less dense, allowing the passing through of the sperm. Also the appearing of crypts in the cervical canal intensifies the production of the mucus as well as offering temporal storage places for some of the sperm ascending into the uterus. Studies of the character of cervical secretion have recognized several types of the cervical mucus. The G - mucus of high viscosity is cloudy and tacky (sperm cells in a phase out of ovulation get immobilized and killed in this mucus in 1-2 hours). The L - mucus in pockets of Schorr with Mn^{++} ions modifying it to become wet and slippery at the vulva, not vagina. The S - mucus or ovulatory type of mucus provides channels for sperm ascension and is of low viscosity, constitutes fiber like matrix of stalactite like needles sometimes seen under microscope when evaluating crystallization during the Insler test. A perfect correlation between 17-beta estradiol plasmatic levels and liquid mucus has been demonstrated. When estradiol starts to rise, the woman feels wet sensation at the vulva. Peak L is day -1, peak S is on day 0 of ovulation, lowest G is on day 0. A most important postulate of this method is, that there can be only one ovulation in a cycle (ovulation is the cause of menstruation), anovulatory cycles cannot be referred to as cycles, because there are no cyclic, but only degenerative changes present. Luteinization of the granulosa cells of the follicle leading to the production of

progesterone sharply block the production of the cerIvical mucus (though not to the extent as in some animal species) and at the same time leads to the diminution of the cervical crypts. This abruptly ends the wet and slippery vulvar sensation and the presence of any palpable vulvar secretion.

From a practical point of view, the instructor of the Billings method should lead the woman on the voyage of discovery of herself, listen to her - not talk to her. The woman has to describe what she feels, not be told what to find, or she will try to find it. The woman has to find, what kind of a sensation the mucus produces at the vulva (usually smooth lubricative in spontaneously ovulating fertile women). The last "slippery" day correlates with day 0 of the cycle (ovulation).

The **GUIDELINES** to follow when training in this method or when using it are (when summarized briefly) the following:

1. Menstruation - no intercourse.
2. Follicular phase intercourse every other night if no changes at the vulva occur.
3. When slippery feeling starts no intercourse until 3 days after the normalization ("wait and see one, two, three").
4. Luteal phase intercourse available all the time.
5. After delivery and during lactation apply the early days rule (like follicular phase).

Woman makes a conscious effort to record the feeling in the region of the vulva during the whole day and makes a record of it in the evening. Other signs of ovulation have been described by the Billings and are said to be recognized by 60-70% of ovulating women. In the groin on side of the ovulating ovary when femoral artery is felt by the middle finger, then under the index finger a tender and enlarged lymph node is found. The labia may be more swollen on the ovulating side. With regards to the above mentioner rule number 1. the intercourse is forbidden during menstruation, because the menstrual blood flow may mask the slippery vulvar sensation in a cycle with a very short follicular phase. Rule number 2. - is observed during days of the follicular phase. The intercourse is possible only on evenings or at night to allow the woman a full day to note the basal feeling of dryness at the vulva. The reason for the "every other night" rule is the possibility, that on the day after the intercourse the seminal plasma present in the vagina may mask the appearance of the fertile type of mucus. Rule number 3. - immediately when the basal dry feeling of the infertile period changes, the couple must abstain from any form of genital activities or intercourse until the fourth day after the appearance of the "Peak mucus day" (this is the day of

the wet vulvar feeling immediately preceding the "dry" following day caused by progesterone production of the corpus luteum). Rule number 4. - once ovulation has occurred and luteal phase has been detected no other ovulation can occur until the onset of the menstrual bleeding. This absolutely safe infertile period allows unrestricted sexual activity of the couple. The method is applicable also in women with prolonged cycles (as is the case of premenopausal women, women discontinuing the use of oral contraceptives or women with lactational amenorrhea). In these cases the woman must abstain from intercourse for a period of 14 days to identify basal dry feeling (**basal infertile mucus pattern, sometimes abbreviated as BIP**) of the infertile phase, or when vaginal secretion is present, to identify this as her basal infertile secretion. When the woman experiences no change in her vulvar sensations, the couple may adopt the rule number 2. (intercourse every other evening). Should any change in the vulvar sensation occur, the rule number 3. (sexual abstinence) must be observed. If Peak Day is detected, then rule number 3. "wait and see, one two three" is applied and coital activities can be resumed on the 4$^{th.}$ evening after the Peak Day. If the changes do not evolve to Peak Day, then the appearance of the BIP is waited for and coital activities may be resumed on the 4$^{th.}$ evening after the BIP is observed. Should the woman note any signs of bleeding which has not been preceded by a Peak Day sensation (bleeding in the course of the BIP of the cycle), then rule number 3. should be observed - that means refraining from intercourse on all days of the bleeding and resuming coital activity on the 4$^{th.}$ evening after the return of the basal dry infertile sensation. In the following days rule number 2. (intercourse every other evening) must be observed.

With this method a woman learns to recognize the characteristics of her cervical mucus that identify the fertile phase in her menstrual cycle. She and her partner abstain from sexual activity during a period from the first indication of mucus until four days after the Peak mucus day, which determines the time of ovulation. They also abstain during menses, because mucus can be confused with menstrual bleeding. This method of family planning is used worldwide by many couples seeking a natural, reliable method of contraception, as well as by couples wishing to take advantage of the signs of ovulation to foster a child. Cervical mucus patterns that reflect ovarian hormone levels are shown to be accurate markers of the fertile and infertile phases of a woman's menstrual cycle. Billings ovulation method is based on the scientific observation that by noting the changes in cervical mucus, which is clear, slippery and copious in periovulatory period, it is possible to prevent pregnancy by avoiding

intercourse during this period. Interpretation of these patterns forms the basis of the Billings Ovulation Method of natural family planning. Extensive laboratory and clinical studies have shown this method to be on a sound scientific footing and that it is applicable to all phases of a woman's reproductive life. It has also been shown, that women readily understand and are able to teach other women the meaning of these patterns as experienced by changing sensations at the vulva and changing characteristics of any visible mucus. Simple rules have been formulated for postponing and achieving pregnancy. Field trials of this non-invasive method for fertility regulation in both developing and developed countries show that the rules are readily understood by participants. In the most recent trials, it has been shown that the method-related pregnancy rate is less than 1 per 100 woman years, which compares more than favorably with other contraceptive techniques (Hume[28]).

In 1975 very little objective data was available on the ability of women to detect the above described changes and on the effectives of the ovulation method (OM). For this reason the WHO Task Force on Methods for the determination of the Fertile Period, Special Programme of Research, Development and Research Training in Human Reproduction initiated a well designed prospective multicentric trial study of the OM.[29] The results of this study were published as "A prospective multicentric trial of the ovulation method of natural family planning" in five phases starting 1981 and ending 1987. I. The teaching phase was designed to find out the percentage of 869 women in five countries (New Zealand, India, Ireland, Philippines, El Salvador) capable of being taught to recognize the periovulatory cervical mucus symptom in a setting of a prospective multicentric trial.[29] The women were ovulating, of proven fertility and represented a spectrum of cultures and socioeconomic levels (from illiteracy to postgraduate level). In the first three standard teaching cycles, 93% recorded an interpretable ovulatory mucus pattern. 88% of the subjects successfully completed the teaching phase. 7% discontinued for reasons other than pregnancy, including the 1.3% who failed to learn the method. Forty five women (5.2%) became pregnant during the average 3.1 cycle teaching phase, but only 3 (0.3%) pregnancies could be attributed to the method failure. The average number of days of abstinence required by the rules of the method was 17 in the third teaching cycle (58.2% of the average cycle length). In the majority, the teachers at the centers were married women successfully using this method and having successfully completed a questionnaire devised to test their knowledge of the OM. The subjects of the study were required to be ovulatory women, not lactating and with a menstrual cycle interval between 23

to 35 days with preceding five years in the present union and not using any other contraception in the effectives phase of the study. In addition the women were required to be newcomers to the OM method. Catholics constituted 83% of all subjects. 83% of the women were housewives, and their partners had occupations varying widely between countries. Fifty-two per cent of the subjects did not wish to have any more children "limiters", eight per cent planned another pregnancy "spacers". Only 11 women reported to have an non-interpretable pattern in all three subsequent cycles. The fertile period was longer in Auckland and Dublin than in the other three centers ($P < 0.05$). Continuation rates varied from 75.3% to 93.2% . Two pregnancies occurred even though all the rules of the OM were observed, a third may have been method related. Thirty-two pregnancies occurred when couples chose to have intercourse in the fertile phase of the cycle and eleven (1.2%) more were judged to have resulted from inaccurate interpretation of the results. A striking difference in discontinuation and pregnancy rates emerged when the results of the first three teaching cycles were compared with the results for subject who required teaching extending the 3 months. The former group was made of 2530 cycles in which there were 33 pregnancies (1.3% pregnancy cycles) whereas the later group contained 171 cycles with 12 pregnancies (7.0% pregnancy cycles). The relative discontinuation rates were 3.0% and 13.5% respectively. Calculations of the pregnancy rates by the Pearl index or lifetable analysis is not justifiable when the mean period of observation was 3.1 cycles/subject. It should therefore be emphasized, that transposition of any of the above data can be only to subject similar to the above (monogamous, motivated to use the OM method, with a regular daily schedule, of proven fertility, non-lactating and capable of learning the OM in the first three cycles).

Also in 1981 the results of the II. The effectives phase were published.[30] After successful completion of a teaching phase, 725 subjects entered a 13 cycle effectives phase and contributed 7514 cycles of observation. The overall cumulative net probability of discontinuation for the effectives study after 13 cycles was 35.6%, 19.6% due to pregnancy. Pregnancy rates per 100 woman-years calculated using the modified Pearl index were as follows: conscious departure from the rules of the method, 15.4; inaccurate application of the instructions, 3.5; method failure, 2.8; inadequate teaching, 0.4; and uncertain 0.5. The rules of the OM were those set out in the Atlas of the Ovulation Method (Billings[26]), with the exception that all days of the mucus secretion in the preovulatory phase of the cycle were regarded as days of possible fertility. This again led to abstinence for approximately half of the time of

the cycles. After evaluating the couples records, pregnancies were divided into five categories, more than one category being applicable in some instances. These were: Method-Related pregnancy (typically such a record would have a reported intercourse on days adjourning to the first day of the mucus appearance or on or just after the fourth day following the peak), Pregnancy Resulting from Inadequate Teaching (the forms with their comments indicated, that the subject received inaccurate teaching), Pregnancy Resulting from Inaccurate Application of the Instructions, Pregnancy Resulting from Conscious Departure from the Rules of the Method, Pregnancy Classification Uncertain (no decision on part of the evaluating person could be made regarding the correct classification). Double checking of copies of all forms and final statistical analysis were done at WHO in Geneva. Overall during the effectiveness study 16 pregnancies classifiable as method-related occurred, giving a modified Pearl index rate of 2.8 pregnancies per 100 woman years (1300 cycles). Three pregnancies were classified as "uncertain", with the (unlikely) possibility of method-failure being present - a PI rate of 0.5. Of the remaining 111 user-related pregnancies, 89 resulted from a conscious departure from the rules and 20 from inaccurate applications of the instructions, inadequate teaching could be found in two cases of pregnancies. There were significant differences between centers in reasons for pregnancy. Of the 16 definite method failures 7 occurred in Auckland and 8 in Dublin, the reasons for this were not obvious. Overall continuation rates of the effectiveness phase 64% were also quite high.

Phase III. Characteristics of the menstrual cycle and of the fertile phase was targeted at reporting various phases of menstrual cycles defined by self-recognition of the mucus and also examined the consequences of acts of sexual intercourse occurring outside the defined fertile phase.[31] The mean cycle length of the 6472 "normal" cycles was 28.5 days (standard deviation +/- 3.18). The Peak Day of the mucus discharge was the last day of slippery, raw-egg-white-like mucus and occurred on average on day 15 (+/- 2.6). The fertile period was defined as any day on which mucus was reported before the Peak Day until 3 days after the peak. Its mean length was 9.6 (+/- 2.6) days. The probability of pregnancy was maximal on the Peak Day and declined on the days before and after the peak. All data was derived only from the effectiveness phase of the study. Two types of mucus were classified. The thick, sticky, tacky and/or cloudy - referred to as unfertile, and a clear, stretchy, and/or lubricative or slippery - referred to as fertile. 10% of the women had a standard deviation (SD) in cycle length of < 1 day, over 50% an SD < 2 days, 80% had an SD of <

3 days, and 4.8% had an SD of 5 days or more. As to the cycle length, age groups 18 - 22 years had a mean cycle length of 29.2, group 23 - 27 had 29 days, 28 - 32 had 28.6 and in the 33 - 39 years of age the mean cycle was 27.9 days respectively. The trend towards shorter cycles was statistically significant ($P < 0.001$). The mean length of bleeding was 5.0 days with 4.3 in Manila and 5.9 in Dublin. The two centers with the longest bleeding were the centers in developed countries. The mean duration of preovulatory dry days was 3.5 for all cycles, but varied between 1.5 days in Dublin and 5.1 days in Manila. The mean length of the follicular phase was 15.0 days and of the luteal phase 13.5 days, the 90% frequency interval was 8.7 to 17.2 days. The mean length of the fertile period was 9.6 days and varied between 7.2 days to 10.8 days in Auckland. The 90% frequency interval was 5.3 to 13.8 days. The calculated probability of pregnancy in the presence of sticky mucus was 0.024 on Peak Day (PD) -4 or earlier, but rose to 0.500 on PD -3 to PD -1. In the presence of slippery mucus, the risk was 0.353 on PD - 4 or earlier, and rose to 0.546 on PD -3 to PD -1. There were 9 intercourses recorded on PD which resulted in 6 pregnancies, which gives a pregnancy probability of 0.667. In the post-peak period, the probability declined from 0.444 on PD +1, to 0.205 on PD +2, to 0.089 on PD +3. Outside the fertile phase the probability was 0.004 per cycle. It is important to note, that a substantial probability of pregnancy is, if intercourse occurs in the presence of a sticky, previously called infertile type of mucus (not much different from the situation, when slippery mucus is detected). It appears, that proximity to PD is a more reliable indicator of fertility, than the characteristics of the mucus discharge.

Phase IV. The outcome of pregnancy published in 1984 has strong implications for those seeking to discredit the NFP methods because there may be a higher risk of **aging gametes** coming into contact with unpredictable results.[32] In this study 175 pregnancies occurred, with known outcome in 163. There were 140 live births (86% of known outcome); 2 congenital malformations (1.2%), including 1 stillbirth; 16 spontaneous abortions (9.8%); and 6 induced abortions (3.7%). The rates of congenital malformations, stillbirths and spontaneous abortions do not differ from outcomes in the community or outcomes associated with other fertility-regulating methods. Among the live births, there were 81 males and 59 females, a male proportion of 0.58 and this does not differ significantly from the normal population ratio of 0.51. There were no significant differences in sex ratio from varying intervals between the likely act leading to conception and the estimated day of ovulation. <u>The study does not therefore support the view, that failures of methods based on periodic abstinence</u>

are likely to result in an increased number of abortions or congenital abnormalities. It also does not support the proposal, that the timing of intercourse in relation to the likely day of ovulation has significant effect on the sex of the child. Another group of investigators approached the problem of aging gametes in a study published in 1991.[33] 706 pregnancies from six centers were analyzed. Most subjects practised symptothermal or mucus methods. Preliminary data indicated, that the pregnancy loss is not increased in the NFP population. However a trend towards fewer pregnancy losses is observed among pregnancies conceived by intercourse +/-1 day from the mucus peak compared to those conceived 2 or more days before or after the mucus peak. This trend reaches significance among women having pregnancy losses in previous pregnancies and is independent of maternal age. Preliminary analyses also showed that neither birth length, birth weight or head circumference was correlated with timing of conception.

The last part (V. Psychosexual aspects) of this study published in 1987 addressed the satisfaction, discontinuation and coital frequency of the couples using the OM.[34] During the effectiveness phase substantial differences, particularly between the two developed and three developing countries emerged. Most couples of the developing countries expressed satisfaction with the frequency of intercourse. One third of the women and a half of their partners would have preferred more frequent intercourse in Auckland and Dublin. Cumulative net probabilities of discontinuation due to pregnancy were 1.8%, 18.6% and 54.7% for couples in whom the male partner's degree of satisfaction was described as "no difficulty", "occasional difficulty" and "always some difficulty", respectively. This study appears to have demonstrated important trends and to provide a basis to identify those couples best suited to practice this method of natural family planning. The average weekly frequency of intercourse of the couples in this study was 46.5% 1 acts per week, 45.2% 2 acts per week and in 4.5% 3 acts per week. 88% to 99% of the women and 81% to 99% of their partners reported no "marital-domestic friction" as a result of practising the OM. When asked to describe their overall satisfaction with the method, the rating "good" or "excellent" was used by women in 98.2% of cycles and by partners in 96.7%. It is evident, that much more information is needed about the factors that affect demand, choice and use of these methods, together with the information on their impact on fertility rates.

The sexual activity of the users of various forms of NFP has also been studied by Gnoth.[35] For 10 years, starting 1985, a prospective study has been taking place in Germany to examine the use of natural family planning (NFP). As natural methods are behavioral methods, use-effectiveness, acceptability and continuation rates are very much influenced by patterns of sexual behavior. Therefore the authors performed an analysis of the sexual behavior of NFP users. Out of the data base of 1211 clients and 21591 cycles they could identify a group of 300 women, all NFP beginners, with 5900 contraceptive cycles, who contributed at least 12 cycles with reliable recording of their sexual activity. Different groups were analyzed with methods of analysis of variance and regression models to find out significant differences in their sexual behavior with respect to sociodemographic structure and time of use. Nearly half of all the women systematically combined the fertility awareness part of NFP with other family planning methods. They used barriers in more than 60% of their cycles. The other half never or only in about 7% of their cycles used additional barrier methods. The latter showed a clear decrease in barrier use in the course of time, whereas the frequent barrier users constantly combined the advantages of two family planning methods. Regarding the frequency of intercourse they were the sexually more active ones and show distinct sociodemographic characteristics. The existence of three groups of NFP users could be confirmed, which differ significantly in their use of NFP as a family planning method. Despite these differences the low pregnancy rates indicate the conscious and risk-related sexual behavior of the group members.

In a more recent study by Xu between July 1988 and May 1990, 688 couples of child-bearing age, most of whom were parous, used the Billings method for contraception in China.[36] Five hundred and fifty of these couples used the method for more than 12 months. Efficacy, continuation rates, and discontinuation rates were analyzed using life-table analysis for 10175 woman-months of data collected. The net cumulative discontinuation rates per 100 women at 12 and 18 months were 19.85 and 34.58, respectively, resulting in continuation rates of 80.15 and 65.42. The discontinuation rates per 100 women for method-related reasons at 12 and 18 months were 1.61 and 2.84, respectively, while the discontinuation rates for unintended pregnancy were 1.02 and 1.18.

Because of the necessary high level of patient education required to undertake the Billings method correctly, Dorairai has developed a simpler method based on the cervical mucus method, called the modified mucus method (MMM).[37] The MMM has a

simple set of rules and requires fewer days of abstinence per cycle. In her study from India Dorairai reported a Pearl index of 2.04 over 24.702 cycles. But in a comparative multicentric study from Indonesia the OM had a lower overall pregnancy rate than the MMM. As with all methods of natural family planning, success rates depend upon the quality of instruction given by the trainers, together with the compliance and motivation of the couples, who are using the method.

In certain parts of the world another NFP method is or can be used very effectively. This is the so called Lactational amenorrhoea method (LAM). With the objective of formulating guidelines which would be of practical help to breast-feeding mothers, Family Health International organized a consensus meeting in 1988 sponsored by the WHO, Rockerfeller Foundation and US AID at Bellagio, Italy. On the basis of data from 13 studies in 8 countries, the Bellagio consensus statement concluded that "breast-feeding provides more than 98% protection from pregnancy during the first 6 months postpartum if the mother is fully or nearly fully breast-feeding and has not yet experienced vaginal bleeding after the 56th. day postpartum".[38] On the basis of the Bellagio statement an algorithm for the LAM method has been prepared by Labbok[39]:

Ask the mother:
Is your baby less than 6 months old?

yes

Are you amenorrheic?
(no vaginal bleeding after 56 days post partus)

yes

Are you fully or nearly fully breast-feeding your baby?

yes

TELL the mother:
there is only about a 2% chance of pregnancy; she does not need a complementary family planning method at this time

WHEN the answer to any one of the above asked question **is NO:**
TELL the mother her chance of pregnancy is increased. She should not rely on breast-feeding alone. Use another family planning method, but continue to breast-feed for the child's health.

The contraceptive efficacy of LAM has lately been addressed by a work of Kennedy.[40] The data were collected from nine prospective studies with sites ranging from Bangkok and Birmingham. Cumulative probabilities of ovulation during lactational amenorrhea were 30.9 and 67.3 per 100 women at 6 and 12 months, respectively, compared to 27.2 at 6 months when all three criteria of the LAM were met. Cumulative pregnancy rates during lactational amenorrhoea were 2.9 and 5.9 per 100 women at 6 and 12 months, compared with 0.7 at 6 months for the LAM. The probability of pregnancy during lactational amenorrhea calculated from these studies is similar to that of other modern contraceptive methods. The authors conclude, that the natural contraceptive effect of lactational amenorrhea is substantial and women experienced 3% and 6% cumulative probabilities of pregnancy by 6 and 12 months respectively, post partum. The original Bellagio guideline that women must be fully (or nearly fully) breast-feeding seems to be the least important feature of the LAM. It though remains important that women attempting to use the LAM acquire good breast-feeding skills and start another method of contraception immediately when menstruation resumes.

A considerable amount of space has been devoted to the thermal and mucus method as to methods classified as "Single Index" methods. This can serve for a quicker comprehension of the following "Multi-Index" methods.

MULTI-INDEX METHODS are calculo-thermal, muco-thermal and symptothermal.

CALCULO-THERMAL: preovulatory infertile period is calculated according to the rules devised by Knaus and/or Ogino (statistically from the last 12 cycles), postovulatory infertile phase is evaluated according to the rules of the thermal (BBT) method.

MUCO-THERMAL: the preovulatory infertile phase ends with the appearance of the mucus (rules of the Billings OM), postovulatory infertile phase is evaluated according to the rules of the thermal (BBT) method and by evaluating the mucus signs as with the OM method.

SYMPTOTHERMAL (STM) "double check" method (for a reliable prediction of the infertile phases of the cycle at least two independent signs of such a phase must be present). This form is advocated by the German group of NFP methods. The first set of rules for this method were set by the work of Rotzer[42], and was elaborated into todays accepted version by the Bonn Workgroup for NFP.[43] Preovulatory infertile phase is evaluated using calendar statistics in relation to the BBT elevation and the onset of the mucus signs as in the OM (and optionally also by evaluating the changes of the position and consistency of the vaginal portion of the uterine cervix), postovulatory infertile phase is evaluated according to the rules of the thermal (BBT) method, by evaluating the mucus (and optionally also changes of the cervix). Auxiliary signs accompanying ovulation (lower abdominal tenderness and pain, breast tension, intermenstrual bleeding-spotting...) can also be charted and used as a help in instances, where some of the main signs are absent. This method appears as of todays knowledge to be the most effective version of the NFP methods based on autoobservation.[44,45] We would like to devote the next paragraphs to a brief introduction to the principles and practise of this form of NFP.

All rules in the following paragraphs presume the fertilizing capability of sperm to be 3 days and take into account the fertilizability of the oocyte to be a maximum of 1

day after ovulation. A safety factor of 1 day is always used in the calculations to provide for additional contraceptive safety.

The GUIDELINES to follow when training in this method or when using it are (when summarized briefly) the following:[45,46]

1. For the determination of the INFERTILE DAYS OF THE FOLLICULAR phase of the cycle, one of the three following rules is applied.
A/. Rule of the "First Five Days" - the first five days of the cycle (counted from the first appearance of menstrual bleeding) can be usually considered infertile. This method of calculation is used in cases, where the user does not have a sufficient amount of previously charted cycles. The rule may not be applied, if there is a history of cycles shorter than 25 days.
B/. Rule "Minus 20" - if the woman has charted the length of 12 consecutive cycles 20 days are subtracted from the number of days of her shortest cycle and the result we obtain is the last infertile day of the follicular phase of the cycle.
C/. Rule "Minus 8" - from the 12 consecutive charted cycle s where BBT was measured we find the earliest occurrence of the day of the first elevation of the BBT (using the rules set by the BBT method). From this day we subtract 8 and the result is the last infertile day of the first phase of the cycle. (NOTE: The rule -8 is always the rule of choice. If the user has charted the BBT in 12 cycles, then the information about ovulation calculated from the elevation of the BBT is always more accurate, than the presumed time of ovulation estimated from charting only the cycle length. This rule is also used in situations, where after the charting of some cycles the 1st day of the elevation of the BBT occurred before the 13th. day of the cycle even if the number of charted cycles has not reached 12). In rare situations, where the onset of the mucus sign is observed during the menstruation, the fertile period for this respective cycle commences with the onset of the mucus sign. All above mentioned rules are disregarded for this cycle. The first three cycles after delivery, after the termination of oral contraceptive medication or after a significant weight reduction (diet or illness) cannot be used for the above statistics and are not incorporated into the 12 charted cycles.

At the SAME TIME the MUCUS sign is evaluated as the second check. This sign may be perceived as
A/. vulvar feeling

B/. felt by hand
C/. seen.
From a PRACTICAL point of view the:
A/. Vulvar feeling or sensation should be consciously assessed by the woman during the day. The sensation can be described as dry, sometimes even as a feeling of burning or itching. It may also be a feeling of dampness and wetness, some women may have a feeling of something flowing from the vagina or they have a sensation like when a few drops of urine pass away.
B/. If the woman feels the vulva with a piece of toilet paper or with her finger, usually in some days she finds this more slippery than on other days. In some days this vulvar feeling can be described as slippery, oily or likened to fingers sliding on one another when covered by soap or detergent.
C/. Assessing the mucus by direct visualization is possible, when the woman notices some mucus adherent to her palpating finger or to the toilet paper. When this is the case, she should try to describe its looks and consistency. The mucus can be white, yellowish or on the contrary transparent like glass sometimes with a pink shade or with traces of blood. The consistency can be lumpy, creamy or jelly-like as opposed to a mucus resembling raw egg-white, and can be pulled out into a fibre / filament. The ability of the mucus to be pulled out into a thread sometimes as long as 12 centimeters is best assessed when a drop of mucus is squeezed between the thumb and the palpating finger and then the fingers are slowly taken apart (Fig. 10). Useful is also the "toilet paper test", which is best performed by a plain coarser type of toilet paper without extreme absorbability. It is best done just when the woman registers the wet vulvar sensation. The beginner with this method should try to observe the mucus every time she goes to the toilet just before voiding. The paper is first used to wipe the vulva (vaginal introit), not the vagina, as the vagina is almost always wet, and repeated palpation may easily lead to irritation of the vaginal mucosa. If mucus is noted, then the paper is folded and slowly opened out in the effort of pulling out the mucus filament (Fig. 11).

FIG. 10, 11 PLACED HERE

The changes of the mucus have been described in the chapter on OM. Only the mucus of the "most fertile" character observed throughout the day is recorded in the chart each evening by the user. Thus the changes that are recorded can range from a feeling of dryness through -> "no sensation noted" -> wet or damp feeling -> wet

feeling with white/yellowish lumpy/creamy mucus to a -> wet/watery sensation with a clear raw egg-white like mucus that can be pulled out into a fibre. These signs are evaluated to determine the PEAK DAY of the mucus. The **Peak Day is DEFINED as the last day of a mucus of a "more fertile" character followed by a day with a mucus of a "less fertile" character**. From this definition it is obvious, that the Peak Day is assigned to a day in the users chart retrospectively, only when a decline in the "fertile quality" of the mucus is noted. It has to be emphasized, that it is not the quantity, but the quality of the mucus, that determines the Peak Day of the mucus in the cycle. If in some cycles the woman doesn't observe the "fertile mucus", then the Peak Day is defined as the day preceding the disappearance of any mucus, if no mucus at all is found in a cycle, then the Peak Day is defined for that cycle as the day preceding the disappearance of the wet vulvar feeling.

The option of evaluation of the changes of the position and consistency of the vaginal portion of the uterine cervix is helpful in those rare cases, where the mucus sign is badly assessable. It also helps when the symptothermal method is used by lactating and climacteric women. By cervical palpation the second sign of the phase of the cycle is obtained. The **self-palpation of the cervix** is done by a washed hand with trimmed nails either when lying down, or when squatting, or with one leg knee-bent and positioned on a chair (Fig. 12).

FIG. 12 PLACED HERE

The cervix undergoes changes that have been described previously. The main notable change is the change in cervical consistency resembling the nasal cartilage in infertile phases of the cycle to periovulatory softness, which is often likened to the softness of the lower lip. Following ovulation, the external os closes again, and the cervix hardens and resumes its usual position pointing into the posterior vaginal fornix. Therefore as signs of the fertile phase of the cycle the mid-vaginal position, opened (gaping) external cervical os and soft consistency are used as opposed to the infertile characteristics of a cervix pointing into the posterior vaginal fornix, closed external cervical os and hard consistency. Sometimes mucus can by found on the finger palpating the cervix, which otherwise goes unnoticed at the vulvar region. The same indices of fertility for this mucus apply, as for mucus found at the vulvar region.

For determining the INFERTILE DAYS OF THE LUTEAL (POSTOVULATORY, ABSOLUTELY SAFE INFERTILE) phase of the cycle, a combination of following rules is used. The **infertile postovulatory phase begins:**

A/. On the evening of the 3rd. day following the Peak Day of the mucus.

B/. On the evening of the 3rd. day, when the BBT rise was detected. Using the "double check" method means, that the safe infertile postovulatory period sometimes starts later than on the 3rd. evening of the Peak Day of mucus, sometimes later, than on the 3rd. evening of the elevated BBT. Decisive for the determination of this contraceptive safe period is the sign (mucus or BBT rise) which onset appears later in the cycle, from this moment onwards the 3rd. evening is calculated. In the absence of one of the previous signs, the following sign may be used as the other parameter for the "double check" - the postovulatory infertile phase starts:

C/. On the 3rd. evening on which the cervix is repeatedly found hard, closed and low in the posterior vaginal fornix.

All the above mentioned signs and any irregularities are marked by the woman into a chart, which is used as an aid in determining the onset and end of the fertile phase of the cycle. One modification of such a chart is presented in (Fig. 13.), a sample of a filled STM method chart is shown in (Fig. 14).

FIG. 13. PLACED HERE

FIG. 14. PLACED HERE

Specific situations arise in some cycles which will now be discussed.

Irregular cycles:

The Symptothermal method is applicable to a woman with irregular cycles. The method is, as has been said, based upon the determination of ovulation, the length of a cycle is just secondary information and is used as a help for beginners with the method and only for the determination of the infertile period of the follicular phase (rule minus 20). With the symptothermal method earlier ovulation is detected by the mucus sign or by the changes of the cervix, ovulation later in a cycle is determined from the evaluation of the BBT chart.

Monophasic cycles:

If no BBT elevation is recorded in a cycle, the couple CANNOT rely on the preovulatory safe infertile phase in the following cycle. The menstrual bleeding could be at a time, when the woman will be ovulating. (The BBT measurement is a precise tool to distinguish a true menstruation from pseudomenstruation or intermenstrual bleeding. The true menstrual bleeding must be preceded by a period of elevated BBT).

Lactation:

In the postpartum period the return of fertility may start as soon as after 4 weeks in a non-lactating woman, after 6 weeks in a partly breast-feeding woman and in 10 weeks in a fully breast-feeding woman. The following rules are applied <u>for a breast-feeding woman using the Symptothermal method.</u>

1/. A woman is infertile so long, as she feels a sensation of dryness or no sensation at all in the vulvar region and does not register any feeling of wetness.

2/. From the moment, when she detects a a wet feeling of the vulva or presence of mucus the fertile period starts.

3/. The fertile period lasts from the onset of wetness or presence of mucus until the evening of the 4$^{th.}$!! day of the Peak Day of the mucus (if no more mucus has been detected on this 4 $^{th.}$ day).

4/. Any bleeding that was NOT preceded by elevation of the BBT is classified as the onset of the most fertile period.

5/. From the detection of the first rise of BBT the usual rules of the Symptothermal method are used. In the first cycle the infertile postovulatory phase starts from the 4$^{th.}$!! evening after the detected BBT elevation. Some lactating women witness a persisting presence of a mucus of "less fertile" character due to general fatigue or stress in this period. If the above mucus persists without any change for at least 3 weeks, the period can be considered as infertile until a mucus of a "more fertile" character appears.

After the termination of use of oral contraceptive medication:

The first five days of the following cycle are considered infertile. After that, the following days are classified as fertile until the 4$^{th.}$ evening of the BBT rise (with observing of the rules of "double check" - 3$^{rd.}$ day after the Peak Day of mucus, or 3$^{rd.}$ evening the cervix hard, external os closed, cervix pointing into the posterior vaginal fornix).

Climacteric women:
In this phase of life due to hormonal changes (depletion of estrogens and progesterone, elevation of FSH and LH) the cycles tend to be irregular. Following rules of the Symptothermal method are used.
A/. A woman of 40 years or older with documented 12 months amenorrhea can be considered as no more fertile.
B/. When the BBT elevation is still detectable, the usual rules of the Symptothermal method are observed.
C/. If no feeling or a dry feeling is observed in the vulvar region, the woman is in a infertile phase of a cycle and may have intercourse every other day (for the semen not to mask the onset of a wet vulvar sensation).
D/. The feeling of wetness or the presence of mucus of any type is always considered as the beginning of a fertile period. This period lasts until the evening of the 4$^{th.}$ day after the Peak Day of the mucus. (Because no BBT elevation is detectable, the principle of "double check" cannot be applied. This is the reason, why the infertile period starts only on the 4$^{th.}$!! evening after the Peak Day of the mucus).
E/. Any bleeding NOT preceded by a BBT rise is considered as a sign of the onset of the fertile period. The infertile period starts on the evening of the 4$^{th.}$ day after the end of the bleeding, of course only when this day can be classified as a "dry day".
F/. If the woman uses also the self-palpation of the cervix, any change of the cervix signals the onset of the fertile period, which lasts until the 3$^{rd.}$ evening of a "infertile type" of a cervix.

With regards to the reliability of the symptothermal methods the **contraceptive effectiveness is evaluated** mostly in two ways.
1/. The failure rate is expressed as the number of pregnancies per 100 women or womanyears of exposure. This may be calculated as the **Pearl index (PI)**, whereby the number of unplanned pregnancies is divided by the number of months of exposure and multiplied by 1200.
2/. The failure rate may also be calculated by the **cumulative life table** technique, an approach that is most often used to evaluate the first 12 months of use. The Life table rates are cumulative net pregnancies at 1 year or 13 cycles per 100 women. Several papers have been published. Deleizaolacordonnier[47] reports a study to check the symptothermal method in a European environment, the practical efficiency and the acceptability. Average age of the women was 32 years. Average fertility was 2 children/woman. Fifty-nine percent of the participants had a professional occupation.

The same percentages were found in those accepting a contraceptive method (oral contraceptives or intrauterine devices). 1240 cycles (103 woman-years) of experience have been gathered. The average participation was 17.5 cycles/woman. No method failure has been reported. One unintended pregnancy due to unprotected sexual intercourse during the fertile phase occurred (user failure). Overall Pearl Index (PI) was 0.96. In 84% of the cycles, no protected intercourse was reported (NFP only). According to PI, practical efficiency of the NFP method analyzed was 1.31. Sexual abstinence during the fertile phase was found in 71.4% of the cycles. Another study by Döring[48] reports the evaluation of 2,276 cycles in 439 patients who had been employing the double-check family planning method. The average length of the hyperthermic phase was 12 days. A tendency to longer hyperthermic phases was recorded in case of cycles of longer duration. In 74% of all cycles, the mucus peak was observed 1 to 3 days previous to the temperature rise. In 2,242 cycles, 3 pregnancies occurred which had not been planned, which corresponds to a Pearl index of 1.6. The temperature curves were also assessed according to Roetzer's criteria. This analysis also yielded 89.8% evaluable temperature curves according to Roetzer. Another study was conceived following the German public opinion pool in 1985, that showed about 4% of fertile women using NFP. Published 1991 the 255 women with 3174 cycles that used only the NFP for family planning and the 274 women with 3995 cycles that used the barrier methods occasionally in the fertile phase had a Pearl index for unplanned pregnancy 2.3 and 2.1 respectively.[44] Most of the pregnancies resulted from unprotected intercourse in the fertile phase, and the use of the barrier methods did not reduce risk-taking. The educational level of NFP clients was found higher, than in the general population. The dropout rate because of dissatisfaction was very low at 7.1%. With further consistent better and ever increasing use of the symptothermal method, especially in the more industrialized countries, the resulting data is more and more encouraging for the method. One of the last efforts at evaluating the method could be found during the 3rd. Seminar on Natural Family Planning held June 1995 in Münich and organized by the 1. Woman Clinic in Munich together with the Bavarian Medical Chamber and with the Workgroup for NFP.[45] The evaluation of the effectiveness of the "double control" was performed on 9639 cycles. The calculations for the determination of the start of the fertile period correlate with the onset of the mucus sign (or precede this sign) in 90.5%, in 9.5% of the evaluated cycles the onset of the mucus sign preceded the calculations that were to define the onset of the fertile period. With regards to the termination of the fertile period the study used 9075 cycles. The coincidence of the

BBT elevation and the 3rd. day after the Peak Day of the mucus was found in 21.1% of the cycles, the confirmation by BBT rise was delayed after the 3rd. day of the Peak Day of mucus in 51.8% and the 3rd. day of the Peak Day of the mucus defined the end of the fertile period later than the BBT rise in 27.1% of the cycles. The mucus sign (expressed as a feeling - damp, wet, dry, and by observation - yellowish, whitish, sticky, watery, transparent) recorded in 9411 cycles was present for less than 5 days in 5.5% of the cases, 5-10 days in 61.5% and for more than 10 days in 33% of the cycles. In the 48 sonographically assessed cycles it was shown, that under normal circumstances only one Peak Day of the mucus occurs and this day precedes ovulation by 1 day in 31% and coincides with the day of the ovulation in 38% of the cycles. Under situations of stress, several Peak Days were observed in 7.6% of the 9411 studied cycles. In the 87 cycles where LH (serum and urine values) and folliculometry was performed, the serum LH peak preceded the ovulation by 27 to 36 hours, the urinary LH peak preceded ovulation by 21 to 30 hours with the ovulatory follicle size lying between 18 to 24 mm, which is in good correlation of other authors.[49] The reliability of the contraceptive effect of the German study was following: with 2798 regular menstrual cycles (cycle length variations less than 5 days) the Pearl Index (PI) = 2.6 in 1928 irregular cycles (more than 5 days variation of cycle length) the PI = 4.3. The "Mix STM" (when barrier methods were used in the fertile phase) in 5018 regular cycles PI = 1.7 and 3577 irregular cycles PI = 2.3. Current ongoing "European Study" (as of June 1994 15 NFP Workgroups from 10 European countries participate) the 17218 cycles of 1271 women show a PI = 2.2 for the STM and a PI of 2.9 for the "Mix STM" methods. When the length of the fertile phase was assessed, less than 8 days wee found in 1.2% of cycles, 9-10 days in 10.2%, 11-12 days in 22.4%, 13-14 days in 22.5% of cycles, 15-16 days in 15.2% and 17-18 days in 10.2% of the evaluated cycles. The excessive experience of the German Workgroup on counseling about NFP can be briefly summarized:

1/. Four couples counseled 4 times during three cycles.

2/. Explaining of the principles of self-assessment, explication of the charting.

3/. Evaluation of the charts, explanation of the "exceptions" to the STM rules, defining the end of the fertile period.

4/. Confirmation of the onset and termination of the fertile period, self examination of the cervix.

5/. Various types of cycles, confirmation of a pregnancy.

As has been discussed in the previous paragraphs, the **symptothermal method appears to be a very reliable method applicable to practically all couples desiring regulation of fertility.** It's greatest advantage seen by many seems to be in the adjective "natural". Opponents often criticize the necessity of long periods of sexual abstinence. This has so far been most objectively studied in the WHO study which we have previously cited. As of today's knowledge, no strict correlation between the libido, phase of the cycle or cyclic hormonal changes has been found, and libido is shown to be more a result of the psychical situation than hormonal status.[44] As each new method of family planning is developed, it is only a mater of time until major and minor drawbacks are recognized. The STM is no exception. Certainly it has its drawbacks, including the requirement for selfobservation and the need to adjust behavior to meet fertility intentions. In short, the drawbacks of any user-dependent family planning method. If couples are exposed to accurate data on this method, it will become attractive for many. It may be on my part speculative, but the favorable PI rates and overall acceptability of the STM or "Mix STM" method by some couples requiring daily but 3 to 5 minutes to measure and chart the BBT and mucus symptoms can be the reason for the slow increase in use and small interest generated by some of the other methods devised and available to monitor the ovulation for the purpose of NFP we would like to mention.

FURTHER METHODS FOR THE MONITORING OF THE CYCLE that show a potential to be used as an aid in family planning based on the observation of the ovarian cycle are:

1/. Measuring the fluid volume in the posterior vaginal fornix.
2/. Measuring electrical resistance of the cervical mucus or conductivity changes of the vaginal secretions.
3/. Measuring the urinary level of 17-beta estradiol and progesterone metabolites (urinary steroid glucuronides) and of the luteinizing hormone. Measuring cervical mucus enzymes.
4/. Direct visualization of the follicle by transvaginal sonography (sonographic tracking of follicular growth).

1/. An approach to ovulation timing using the **measuring of the volume of the cervicovaginal secretions** has been explored and published in 1983 by Usala.[50] The authors devised a modified long syringe, looking rather like the vaginal applicator of some brands of vaginal tablets with a rounded perforated end which is graded in 0.1 mL steps. Women were instructed to position this device upon awakening into the posterior vaginal fornix and aspirate the full volume of the cervicovaginal secretion accumulated there overnight and record the volume in a chart. Good correlation was found in predicting the time of ovulation. Flynn in 1988 has also tested the volumetric self sampling mixture of cervical mucus and vaginal transudate in a pilot study to ascertain its reliability to demarcate the fertile phase of the cycle.[51] Results show that in all cycles tested, it is possible using the Rovumeter aspirator to detect the beginning of the fertile phase by rapidly increasing volumes of CVF; this volume reaches a peak approximately 1 day before ovulation detected by ultrasound and demonstrates an abrupt fall after ovulation and the onset of the infertile phase. From the results of this pilot study, the authors believe that, by the use of suitable algorithms and larger studies, it should be possible to develop a CVF volume method which could be offered as an objective alternative method for users of natural family planning and programs. As in the NFP methods the fertile period is defined as the period of 4 days preceding ovulation and the two days following ovulation, this method so far found limited use in aiding couples that are trying to define this unfertile period. The method should receive more attention than it has, especially in view of updates on the cyclic changes of the human cervical mucus. Indeed, initial physiochemical studies by Wolf[52] and electron microscopical and rheological studies by Katz[53] suggest that the principal determinant of cyclic changes in mucus is its water content or hydratation (which influence the networking of the glycoprotein mucin that represents the main constituent of the solid phase of the cervical mucus). Because on removal from the cervix the mucus begins to evaporate rapidly, the logical way of monitoring is by the proposed volumetric self sampling. In view of this, the method seems to hold some potential for couples desiring pregnancy for the evaluation of the impeding ovulation rather than for the use by couples using NFP.

2/. Changes in the conductivity of the vaginal secretions and saliva have also been evaluated for their potential use in family planning. An independent assessment of the CUE Monitor (Zetek, Aurora, Colorado) as an ovulation predictor was made with emphasis on its potential role in "natural family planning".[54] The device provides a

digital measurement of the electrical resistance of saliva and vaginal secretions. Twenty-nine menstrual cycles from 11 regularly cycling women were monitored with basal temperatures, urinary LH, pelvic ultrasound and the CUE monitor. Patterns of peak salivary electrical resistance were able to predict ovulation on average 5.3 (+/- 1.9 SD) days in advance. Despite variations in total length of the follicular phase from cycle to cycle, the within-subject variation of this predictive interval was quite small. Nadirs in the electrical resistance of vaginal secretions occurred within 2 days of ovulation in all but one patient. Variation in this interval from cycle-to-cycle was small as well. An algorithm for the use of these intervals in "natural family planning" that could safely reduce the monthly abstinence period of present methods has been proposed. The simplicity, objectivity and consistency of this device could result in greater general acceptance of NFP methods.

3/. Home tests to monitor fertility on the basis of **measuring the changes of urinary estrone glucuronide** (metabolite of plasma estradiol) **and pregnanediol-3alpha-glucuronide** (a metabolite of plasma progesterone) have been developed. The requirements for a home kit for monitoring ovarian function are formidable. Such a kit must have the following characteristics: 1/. It must be able to measure estrone glucuronide at levels of 25-50 nmol/24 hours (total estrogen value of 7-14ug/24 hours), and pregnanediol glucuronide at levels of 3 umol/24 hours (0.7 mg/24 hours). 2/. It must be able to distinguish daily increases in levels of estrone-,B,D-glucuronide. 3/. It must be simple, rapid and robust. 4/. Its results must be easily interpretable. 5/. Its cost must be low. 6/. It must not contain any hazardous chemicals. 7/. Its results must be as good as the best laboratory assays. 8/. It must be absolutely reliable: errors lead to pregnancy. Much work to bring the above specified into reality has been done in Australia by James B. Brown and his collaborators and the technical underlying facts published in 1988.[55] After several decades of work, starting 1955, a homogenous enzyme immunoassay based on the principle that the enzymatic activity of conjugates of certain enzymes with a hapten is inhibited by antibodies raised to the hapten. The enzyme used is egg-white lysozyme and the haptens are estrone-3-glucuronide and pregnanediol-3-glucuronide. The substrate is micrococcus lysodeikticus. The reaction is measured in a thermostated rate colorimeter by the change of light transmission through the micrococcus suspension. The change of transmission is directly proportional to the amount of the respective urinary glucuronides. This system was cross-tested with

laboratory readings in situations ranging from normal ovulating women, hyperstimulated patients in a program of assisted reproduction, climacteric and lactating women and in anovulatory patients treated for hyperprolactinemia. In all tested situations the correlation was excellent. This led to the development of the home "Ovarian Monitor" system by Thornton and collaborators.[56] It consists of a palm size thermostated rate colorimeter, the Ovulation Meter (Juno Electronics, Hepburn Springs, Victoria, Australia) and an assay tube (colorimeter cell) with a dried anti-serum , conjugate spot, micrococcus spot and a glass bead for mixing coated by buffer salts. The dried spots are in different levels of the plastic tube, enabling that all reactions can be performed in this single plastic cell. The home kit also includes a urine-collecting jug, 4 syringes for measuring urine and water, test tube rack and airtight storage tins containing silica gel (the tubes are stable for 7 years when freezed and for 5 months when stored dry at room temperature). The woman collects timed specimen of urine (usually overnight or for at least 3 hours) into a plastic jug calibrated in hours of collection. The urine is diluted with tap water to 100 mL/hour and a 10 mL sample is pasteurized in near boiling water and then cooled. A 50 uL of urine is placed in the bottom of the appropriate test tube for the first stage of the reaction. this dissolves the antiserum and the mixing bead is freed. The volume is then made up to 350 uL with distilled water, this reaches the enzyme hormone conjugate which dissolves instantly. The tube is then warmed in the colorimeter to 40 degrees. Celsius for 5 to 10 minutes, and the micrococcus spot (placed near the top of the colorimeter cell) is then suspended by shaking. The light transmission registered by the colorimeter is then read immediately (transmission 1). The remainder of the measurement is performed automatically by the rate colorimeter, which at the end of 5 (for pregnanediol-3-glucuronide) or 20 minutes (for estrone-3-glucuronide) holds the final transmission reading (transmission 2). The change in transmission is calculated by subtracting value 1 from 2 and provides a direct measurement of the respective urinary hormone metabolite. The time spent physically by the woman doing each test is about 10 minutes per assay. In a later paper the use of the Home Ovarian Monitor was tested for three years as an aid in pregnancy avoidance by periodic abstinence.[57] During the first cycle tested (as described in the previous paragraph) the estrone-3-glucuronide (E_1G) baseline and the first rise is determined essentially the same mathematical way as when defining the baseline values and the onset of rise of the BBT (the CUSUM method). The rise is usually quite defined. In particularly long cycles several rises may occur before the ovulatory rise takes place. In such cases the day of the rise was the one that proceeded directly to the E_1G

preovulatory peak and fall, immediately followed by the pregnanediol-3-glucuronide (PdG) rise, that reached the "cutoff". A cutoff of 6.3 umol/24 hours of PdG after an estrogen peak and fall was used, as previously it has been shown in over 100 cycles, that no woman that has reached this cutoff ever showed evidence of ovulation later in the cycle. This is also good validation of the confidence now placed in the definition of the postovulatory infertile days (late safe days) used in NFP. The "three-quarter" rule was introduced for breastfeeding and perimenopausal women, who have a deficient luteal phase and whose PdG values never reach cutoff. General rules observed during the use of the Home Ovarian Monitor for pregnancy avoidance were the following:1/. Low E_1G (baseline), low PdG = infertile. 2/. Raised E_1G, low PdG = fertile. 3/. Raised PdG = infertile. For normal cycling women this ment the establishment of a baseline E_1G before resuming intercourse (the basic infertile mucus pattern /BIP/ was used as a backup). Sexual abstinence when E_1G rises or the BIP changes. When E_1G rises, peaks and falls, watch for the day of the fall, that marks the ovulation and the most fertile day in the cycle. Change to the PdG measurement, watch for the PdG rise to cutoff (7 umol/24 hours) and resume intercourse immediately, no further measurement or observation needed in this cycle. For breastfeeding mothers a set of rules to measure the E_1G once a week until the $6^{th.}$ month and twice a week between the $6^{th.}$ and $11^{th.}$ month. All days of persistently low baseline E_1G are available for intercourse. BIP is observed for additional information. If E_1G rises, testing is done more frequently and sexual abstinence is required. If E_1G reach peak values and fall, start testing for PdG, resume coital activities if cutoff or 3/4 (75%) of the cutoff value is reached. From this point on, monitor all subsequent cycles as normal ovulatory cycles. The Monitor was used for pregnancy avoidance for a total of 661 months (55 women-years). There were 4 unplanned pregnancies (one of them resulting from a inappropriate use of the 3/4 rule during breastfeeding). This gives a Pearl index of 7.3. No women had problems performing the tests. Most of the users considered the test a nuisance and they would like the work load to be reduced, although this was not a sufficient reason for stopping because of the sense of security it provided. 75% of the women used the late safe days immediately after the PdG cutoff was reached and 25% of the women in this study added several days according to the mucus rules for additional safety. The close correlation between the hormone values and the mucus symptoms the women can now observe provides them with important reassurance that both are correct. Interesting facts resulting from a more widespread use of the device after

the end of this study emerged. 5-day sperm survivals to conception are not uncommon, 6-day survival is less common, the largest interval encountered was 8 days (1 in 4000 cycles). The last E_1G baseline and BIP is still the problem day, and most unwanted pregnancies result from intercourse on these days. Women are highly fertile during the second and third ovulatory cycles after 10 months or more of breastfeeding. Appreciations of these findings is making unplanned pregnancies in Australian groups using the Home Ovarian Monitor a rarity.

A pilot study has been undertaken to test a noninstrumented enzyme immunoassay assay (NEIA) for urinary estrone conjugates (E_1C).[58] The test has been adapted from an instrumented microtiter plate enzyme immunoassay assay (EIA). The end point of the assay was the color change from green to clear, which was visible to the naked eye. The microtiter plate was substituted for high binding test tubes as a solid matrix for the assay. To maximize the color change during the midfollicular phase (early follicular phase E_1C concentrations ranged from 35.9 +/- 6.8 to 70.4 +/- 14.7 ng/mL) the estrone conjugate enzyme label was altered to maximize the dose response dynamic by eliminating the glucuronide moiety. This steepened the slope and provided the "all-or-none" or "binary" signal to be generated over a small change in concentration. The 50% binding point of the standard curve of the E_1C NEIA with estrone horseradish peroxidase as the enzyme competitor was 400pg/tube or 80 ng/mL on the basis of a sample size of 6.5 uL of urine of estrone-3-gucuronide. Small Whatman No.1 filter paper disks (7.5 mm diameter) were used to measure and transfer the 6.5 uL urine samples with reliability comparable to micropipettors. The test is performed in a test tube coated by antibody. The filter paper disk is soaked in the urine for 1 to 3 minutes, blotted dry and placed into 0.5 mL of conjugate solution added to the precoated test tube. After a 60-minute incubation the contents of the tube are discarded and 0.5 mL of substrate is added. The visual color change occurs at approximately 70 to 80 ng/mL. Under these conditions early follicular phase concentrations exhibited dark green coloration, late follicular phase and ovulatory concentration were indicated by no color. In general the dark green color progressively lightened over two or three samples 3 to 4 days before the LH peak and was nearly colorless in all cycles on the day of the E_1C peak. The visual color change could also be evaluated quantitatively by measuring the optical density of 0.1 mL of the substrate transferred to a microtiter plate read on a spectrophotometer at 405

nm. CUSUM analysis described by Royston[21] for the determination of the onset of the BBT rise was used to describe the pattern of urinary estrogen concentrations before ovulation. This accurately predicted the fertile period beginning preceding ovulation by five days or the LH peak by four days in five of the six studied cycles. When compared to serum 17-beta estradiol measurements, the urinary E_1C EIA lagged behind only by 0.7 days. The analysis should not be performed on urine with either too high or too low osmolality to avoid false-positive or false-negative results.

SUMMED UP: The use of the evaluation of the urinary metabolites of estradiol and progesteron in pregnancy avoidance is possible, though still offers some degree of personal discomfort in everyday use. It can provide additional safety (double check) to women lacking good observability of one of the signs of the symptothermal method. It is advantageous in long and irregular cycles, where if the cutoff of the PdG is correctly used, it may prolongate the interval of the contraceptive safe postovulatory phase of the cycle. Due to considerable variations in the concentrations of the voided urine (which is compensated for in regular laboratory by indexing each hormone value by creatinine concentration), it is good to advise the users of these and similar testing methods (home tests for hCG or LH) about regular and stable fluid uptake habits. It seems likely, that this type of monitoring will require the development of a noninstrumented test for urine osmolality in the near future. Further simplification in the handling of the urine will be searched for, but it is unlikely that a dip-stick method (like the currently available over the counter tests for urinary LH or hCG) will be revealed, due to the very nature of the hormonal information in relation to ovulation (the value of E_1G or the amount of total urinary estrogens for which tests are sought does not have a universal cutoff value predicting ovulation like the LH). This in turn cannot be used for contraceptive purposes because of a too short interval (from 27 to 57 hours) between the onset of the rise of LH and following ovulation). Other biochemical markers of impending ovulation have been sought, and a simple visual test has been devised to determine the activity of the cervical mucus peroxidases by Tsibris.[59]

4/. Direct visualization of the follicle by **transvaginal sonography** (sonographic tracking of follicular growth) could become a very reliable method aiding in the prediction of ovulation in NFP, same as it is used today in infertility treatment. With ovaries in their normal position (fossa ovarica) the ovarian follicle is a well

recognizable structure, especially with transvaginal sonography. The nature of the follicle (a vesicle filled with follicular fluid) makes direct measurement of the follicle growth (roughly 1.5 mm each day) possible by even the most basic ultrasound equipment. Several authors have correlated the follicle size and onset of the LH surge. In a paper published by Randall[49], the authors have found the follicle size at the time of the LH surge onset to be 21.6 mm (ranging from 14.4 to 31.2 mm). With todays sophisticated sonographic equipment, even more subtle changes preceding ovulation may be detected, as has been summarized in a work by Collins.[60] A structure resembling the detached cumulus and oocyte is often seen before the follicle has started to rupture. Blood vessels start to be visible in the inner layer of the follicle (the granulosa layer) at the time of the LH peak. Concurrently, the wall of the follicle becomes less clear, crenated, thicker and more echogenic. When ultrasound with color mapping is used, blood flow velocity waveforms are observed clearly at the time of the rise of the LH. If there is a possibility to measure the blood flow, the regular envelope of the peak systolic blood velocity waveform present at the time of the onset of the LH surge becomes fuzzy at the time of imminent ovulation, possibly indicating the presence of broken blood vessels. The reduction of the follicular size and disappearance of the follicle are sure signs of ovulation. Sonography may in the future bring into reality an exciting prospect of a hand-held LCD display device enabling the direct visualization of the growing follicle for self assessment by a woman using NFP, much in a way as she today uses the electronic thermometer vaginally to measure her BBT.

The **ECONOMICS OF NFP CONTRACEPTION** have so far not been discussed in this chapter. The fact of methodological problems associated with such studies limits their availability. A well designed study designed to throw some light on the economical side of contraception has been published by Trussell and collaborates on data valid for USA in 1994.[61] All 15 types of studied contraceptive methods (ranging from oral contraceptives to withdrawal and periodic abstinence) saved the public or private health insurance plans from 8933 to 12239 US dollars over the time span of five years in prevented unwanted pregnancies and complications associated with pregnancy. Even the "periodic abstinence" with a horrendous 20% failure rate saved the public health care payer 4963 USD and the private health care payer 11213 USD over a five year span, when compared to couples where no contraception was used at all. This shows another of the major advantages of contraception based on autoobservation of the cycle and periodic abstinence. That is minimal or no cost after

the initial introduction of the couple to the proper use of the method. Studies like this could also answer the question, where to look for funding of research of NFP methods. It has been shown Kambic[62], that without greater commitment of resources, it is likely that NFP will continue to be a marginal method of family planning in the United States. On the other hand commitment of the German Ministry for Youth, Family, women and Health (Project No. KAP 1502, Title 68402-511270651) has led to ever increasing numbers of couples correctly using this form of natural family planning (4% of the women between 15 and 45 years of age in 1985). The impact of a decline in the duration of breastfeeding and its concomitant effect on lactational amenorrhea has also been highlighted by several authors with relation to economics. For example in Senegal, where the average duration of breastfeeding and lactational amenorrhea is 19 and 15 months respectively, a 50% reduction in the duration of breastfeeding (which is often seen when the baby food supplements flood the market) would require an increase in contraceptive use from 11% to 35% to maintain the current fertility rates.[63]

IN THE PREVIOUS CHAPTER, SOME OF THE CONTRACEPTIVE METHODS BASED ON AUTOOBSERVATION OF THE OVULATION CYCLE AND PERIODIC ABSTINENCE DURING THE FERTILE PHASE OF THE CYCLE HAVE BEEN ADDRESSED. Many questions and problems still require to be studied and explained in the quest to further refine these methods. From yet the largest and most complex WHO study of NFP methods and large studies from Germany and other European countries it seems likely, that a profile of a successful user of the family planning methods based on periodic abstinence in the fertile phase of the cycle should be matched with the potential new users. Some of the more evident favorable traits which could identify a successful user are a relatively stable cycle with minimal variations of the cycle length, a woman not suffering from civilization hyperestrism, with a relatively short menstrual period, a well defined and sharp 17-beta estradiol preovulatory rise onset, with a regular non-stressful life and daily schedule and an average weekly coital frequency requirement between 1 and 2 intercourses. About the compliant and successful male partner even less is known, apart from the fact of the average coital frequency in the range from 1 to 2 times per week and work in such a profession, that does not require repeated long periods of stay away from home. Due to reports of longer than average sperm survival in some cases (Brown[57]) we propose, that a standardized performed spermiogram, preferably with strict

morphology staining and count, should be a part of an evaluation of the couple before they embark on using any of the contraception methods based on the autoobservation of the cycle. An even better test addressing the sperm vitality would be a the sperm-cervical mucus interaction test as described in the WHO laboratory manual for the examination of human semen and sperm-cervical mucus interaction (WHO[64]), with a modification allowing observation of the preparation not only after the standard 30 minutes, but on several consecutive days with the mucus held in darkness at room temperature and in a wet chamber to hinder its evaporation. A reanalysis of the contraceptive failure of the OM was published in 1991 by Trussell, who found a probability of 3.1% failure of the method during perfect (correct and consistent) use versus a 86.4% failure rate during imperfect use. [41] The authors also advise not to use the method during periods of stress (with observing all the other rules of the OM). Conception rates per cycle day are much higher in the big WHO trial, than in other studies, which is probably due to the underreporting of intercourse during the fecund phase. Couples should be always advised, that the OM is quite effective at preventing pregnancy when used perfectly, but that it is extremely unforgiving of imperfect use. Little information is traceable in literature as to the profile of the successful users, which can most probably be attributed to the tendency to evaluate a method negatively (in terms of failure) rather than in a more positive vein (in terms of success). Interesting enough, most of the texts intended as textbooks of NFP methods tend to be biased and declare the NFP methods as an option, that is suitable (with but a few exceptions) for all couples. With a serious review of available data, the author of this chapter holds a strong opinion, that the use of any contraception method and a NFP method even more so, must relate to the users health, life-style and mentality. This could be the key to a successful use of any method, that offers a multiple choice of options serving the same end purpose. It is a part of the wisdom of the advisor on a contraceptive alternative, to take the time and present all the options and drawbacks of today available methods of contraception and to lead the user to a satisfactory choice. Natural family planning is the only option for many couples and the preferred option for some. NFP has many advantages but the main limitation to its effectiveness is the high frequency of risk-taking during the unrecognized fertile phase. More studies are necessary to determine the extent to which this risking is due to problems in evaluating the fertile signs, misunderstanding about the rules or voluntary decisions of the users.

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Fig. 1.

Cyclic changes of the cervical mucus

Amount Viscosity Cellularity Sperm penetration

Mucin pH Albumin% Arborization

Globulines% Spinnbarkeit cm

Fig. 2.

Changes of the vegetative nervous system during the cycle

Menstruation Menstruation Ovulation

Follicular phase Luteal phase

Tone of the Parasympathetic

Tone of the Sympathetic

Fig. 3.

Cyclic changes of gonadotropins and ovarian steroids

milli IU FSH and LH/mL of serum

Ovulation LH FSH Estradiol Progesteron

Plasmatic levels of progesteron ng/mL

Plasmatic levels of estradiol pg/mL

day of cycle

BBT charts evaluation

Baseline temperature Baseline temperature Baseline temperature

Peak of the temperature elevation Peak of the temperature elevation

Peak of the temperature elevation

Fig.4. Fig. 5. Fig. 6.

Fig. 7.

Application of the CUSUM test to a basal body temperature chart

CUSUM BBT (°C)

Menstrual cycle day number

CUSUM exceeds decision interval
(day 16)

Baseline
(36.22 °C)

CUSUM reference
value (36.32 °C)

CUSUM decision interval
(0.35°C)

Fig. 8.

The means and 90% observed ranges for days of 7 signals relative to day of LH peak

Mean and 90%
observed range
n=58

Peak mucus +4 BBT shift +3 Peak E_1-3-G +4

First fertile mucus Defined rise in E_1-3-G

First mucus Shortest cycle -18

Fertile phase of the cycle

Fig. 9.

Uterine cervix with mucus of a low Insler Score

Uterine cervix with mucus of a high Insler Score

Transvaginal ultrasonography of the patient with the high Inlser Score showing a single dominant praeovulatory follicle of 2.68cm and a triple line type of endometrium 1.15cm thick (day 11 of a 25 day cycle)

Fig. 12.

Self-palpation of the uterine cervix

Fig. 13.

Chart used for cycle follow-up when using the symptothermal method

Circumstances influencing the BBT

Menstrual period

Time of BBT taking

Abdominal pain

Breast tension

Character of mucus

Cycle day

Date:

Bleeding

MUCUS

Subjective feelings

Appearance

UTERINE CERVIX

Position of cervical os

Consistency

Intercourse
Fertile days

Aid for determining the last day of the infertile preovulatory phase (fill out after charting 12 cycles)

Length of the shortest cycle

minus 20

Day of the

earliest
BBT rise

minus 8

Fig. 14.

Filled out sample chart of a user of the symptothermal method

Fig. 10.

Testing the character of the cervical mucus

Fig. 11.

The “toilet paper test” of the cervical mucus