

*This report contains the collective views of an international group of experts and does not necessarily represent the decisions or the stated policy of the World Health Organization.*

WORLD HEALTH ORGANIZATION  
TECHNICAL REPORT SERIES

No. 360

**BIOLOGY  
OF FERTILITY CONTROL  
BY PERIODIC ABSTINENCE**

**Report of a WHO Scientific Group**

WORLD HEALTH ORGANIZATION

GENEVA

1967

© World Health Organization 1967

Publications of the World Health Organization enjoy copyright protection in accordance with the provisions of Protocol 2 of the Universal Copyright Convention. Nevertheless governmental agencies or learned and professional societies may reproduce data or excerpts or illustrations from them without requesting an authorization from the World Health Organization.

For rights of reproduction or translation of WHO publications *in toto*, application should be made to the Division of Editorial and Reference Services, World Health Organization, Geneva, Switzerland. The World Health Organization welcomes such applications.

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the Director-General of the World Health Organization concerning the legal status of any country or territory or of its authorities, or concerning the delimitation of its frontiers.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature which are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

PRINTED IN FRANCE

## CONTENTS

	Page
1. Introduction . . . . .	6
2. Hormonal control of the menstrual cycle . . . . .	6
3. Systemic changes during menstrual cycle . . . . .	7
4. Ovulation and its detection . . . . .	8
5. Menstrual onset intervals (MOI) . . . . .	9
6. The phases of menstrual onset intervals . . . . .	11
7. The shift in BBT . . . . .	12
8. Instruction in use of the method . . . . .	14
9. Duration of the fertile period . . . . .	15
10. Evaluation of periodic abstinence . . . . .	16
11. Methods in use . . . . .	16
12. Use effectiveness . . . . .	18
13. Causes of failure . . . . .	19
14. Research needs . . . . .	20

SCIENTIFIC GROUP ON THE BIOLOGY  
OF FERTILITY CONTROL BY PERIODIC ABSTINENCE

Geneva, 31 May - 6 June 1966

*Members : \**

- Professor G. K. Döring, Municipal Hospital, Munich-Harlaching, Federal Republic of Germany
- Dr C. A. Lancot, Hartford Health Department, Hartford, Conn., USA (*Rapporteur*)
- Dr J. Marshall, Reader in Clinical Neurology, Institute of Neurology, National Hospital, London, England (*Rapporteur*)
- Professor Osamu Nishikaze, Director, Central Clinical Laboratorium, Sapporo, Hokkaido, Japan
- Professor R. G. Potter, Department of Sociology and Anthropology, Brown University, Providence, Rhode Island, USA (*Chairman*)
- Dr Ch. Rendu, Chairman, Centre de Liaison d'Equipes de Recherche, Paris, France (*Vice-Chairman*)
- Dr Anibal Rodriguez, Professor and Head of Department of Gynecology, Hospital El Salvador, Santiago, Chile

*Representatives of Other Organizations :*

*International Planned Parenthood Federation:*

Professor A. S. Parkes, Physiological Laboratory, University of Cambridge, England

*International Federation of Gynecology and Obstetrics:*

Professor G. Tesauro, Chancellor of the University of Naples, Naples, Italy

*Secretariat :*

- Dr Florante P. Gonzaga, Department of Obstetrics & Gynaecology, College of Medicine, University of the Philippines, Manila, Philippines (*Temporary Adviser*)
- Dr R. T. Hill, Chief, Human Reproduction, WHO (*Secretary*)

---

\* Unable to attend : Professor J. Ferin, Department of Gynaecology and Obstetrics, University of Louvain, Belgium

## **BIOLOGY OF FERTILITY CONTROL BY PERIODIC ABSTINENCE**

### **Report of a WHO Scientific Group**

A WHO Scientific Group on the Biology of Fertility Control by Periodic Abstinence was convened in Geneva from 31 May to 6 June 1966. The meeting was opened by Dr J. Karefa-Smart, Assistant Director-General. Dr R. G. Potter served as Chairman, Dr C. Rendu as Vice-Chairman, and Dr J. Marshall and Dr C. Lanctot as Rapporteurs.

In the previous six months, WHO had convened scientific groups on the Clinical Aspects of Oral Gestogens<sup>1</sup> and on the Basic and Clinical Aspects of Intra-Uterine Devices.<sup>2</sup> The published reports of these groups have been well received and it seemed appropriate that WHO should also study a method of fertility control that depends on abstinence from sexual contact during the fertile portion of the menstrual cycle. It is hoped that this report will make the method better understood by those who will be called upon to teach and explain it to others.

The Group wishes to make it clear that this report is not written for self instruction: those couples who wish to use this method of fertility control should seek the best available professional instruction. Those who gain adequate knowledge and understanding of the method and then teach it, should realize that there are in every population those who have neither the ability nor the motivation to make the method effective. Adequate education does much to develop both of these capacities.

However, it is generally conceded that the method of fertility control by periodic abstinence could become much more widely accepted and effective if there were available an accurate, easy, and cheap test that could be used in the home for the prediction of ovulation some days in advance. Such a test does not now exist. The Group noted with favour that WHO is trying to stimulate research that may lead to the discovery of a method for the anticipation of ovulation.

---

<sup>1</sup> *Wld Hlth Org. techn. Rep. Ser.*, 1966, 326.

<sup>2</sup> *Wld Hlth Org. techn. Rep. Ser.*, 1966, 332.

## 1. INTRODUCTION

1.1 This report outlines existing knowledge of the menstrual cycle, ovulation, and fertility relevant to the aim of understanding the mechanism of fertility control by periodic abstinence. The discussion is limited to physiological and arithmetical analyses of the subject and to the relative effectiveness of different methods for determining the necessary period of abstinence. Genital and extragenital changes associated with the menstrual cycle are discussed as possible aids in detecting ovulation and the demarcation of that part of the cycle that is potentially the fertile period.

1.2 It was clearly necessary to use terminology that avoids confusion and facilitates exchange of views. It is not always possible to speak of the interval from the start of one menstrual bleeding to the start of the next as a cycle, because in some cases there may be no ovulation; in others, though ovulation may occur, the follicular or luteal phase may be disturbed or the cycle may be unduly prolonged for unknown reasons. The intervals in some women may be so variable as to lose the semblance of periodicity. For this reason, the term "menstrual onset interval" (MOI) seems preferable to describe the interval between the first day of one menstrual bleeding and the first day of the next. However, the term "menstrual cycle" is at times used in this report in lieu of "menstrual onset interval", although this is not intended to convey a different meaning.

1.3 Certain other terms were discussed by the Group and are used in this report as follows in relation to the female:<sup>1</sup>

*Fertility* is the ability to produce a viable child.

*Infertility* is the inability to produce a viable child.

*Sterility* is the inability to conceive.

No attempt is made to refer to the voluminous literature. Areas where more factual information is needed are indicated and, wherever possible, suggestions are made for future research.

## 2. HORMONAL CONTROL OF THE MENSTRUAL CYCLE

Two predominant hormones of the anterior pituitary, namely the follicle stimulating hormone (FSH) and the luteinizing hormone (LH), are primarily responsible for the growth of the ovarian follicle, its rupture

---

<sup>1</sup> The three terms listed are in need of clarification and definition by some international body.

(ovulation), and subsequent corpus luteum formation.<sup>1</sup> The ovarian follicle that grows as a result of pituitary FSH stimulation is in turn primarily responsible for the elaboration and secretion of ovarian oestrogens, which cause the proliferative growth of the endometrium. This growth of the endometrium, in conjunction with that of the follicle, is known as the follicular phase of the menstrual cycle. Pituitary LH is primarily responsible for rupture (ovulation) of the previously developed follicle. Immediately following ovulation, the corpus luteum begins to develop. The latter is the main source of progesterone which, in combination with oestrogens, is responsible for the development of the secretory phase of the endometrium. In the absence of conception the fully developed secretory endometrium undergoes breakdown and sloughing, which leads to the overt bleeding known as menstruation and which is associated with the histological and physiological involution of the corpus luteum. The development of the corpus luteum and its attendant secretion of progesterone, along with the development of the secretory condition of the endometrium, are known as the luteal phase of the menstrual cycle. Deviations from this described norm are not uncommon and each deviation can be a subject of individual consideration and study. For example, major deviation from this pattern occurs in a cycle in which ovulation fails to take place (anovulatory cycle) and in which an apparently normal menstruation is associated with the absence of normal corpus luteum formation, and the failure of development of the secretory phase of the endometrium.

### 3. SYSTEMIC CHANGES DURING MENSTRUAL CYCLE

3.1 A wide range of extragenital systemic changes which occur in association with the menstrual and ovarian cycles have been studied with the aim of finding a simple, reliable, and easily observed indicator of ovulation. So far, none of the phenomena studied has met these requirements.

3.2 Known systemic changes that reflect one or other phase of ovarian physiology are of such nature that determination can, for the most part, be done only in a specially equipped laboratory or clinic. Among these are changes in the endometrium, cervical mucus, and vaginal cytology and cyclic changes of certain substances in the urine and blood. None of these determinations can be made by unskilled personnel. It seems of paramount importance that research be concentrated on finding an accurate and inexpensive method of predicting the time of ovulation that can be used easily by interested couples.

<sup>1</sup> *Wld Hlth Org. techn. Rep. Ser.*, 1965, 303.

#### 4. OVULATION AND ITS DETECTION

4.1 Ovulation is the release of the ovum from the mature Graafian follicle. The recent literature has contained several comprehensive reviews of various studies of physiological changes that have been used as indicators of ovulation. In most reports ovulation is presumed to have taken place if certain criteria have been fulfilled.

4.2 These criteria of ovulation are either direct or indirect. There are at least two direct proofs that ovulation has taken place : (1) pregnancy and (2) the rare direct observation of the release of an ovum by the mature ovarian follicle. All indirect indicators or tests, e.g., biphasic basal body temperature (BBT) changes, increase in pregnanediol excretion, increased pyknotic index of vaginal cytology, and endometrial changes assessed by biopsy provide at best only presumptive evidence that ovulation has probably taken place. For the most part they reflect the various responses of the organism to the steroids produced by the ovary during an ovulatory cycle. In some women who have been stimulated with exogenous gonadotropins for the induction of ovulation, the basal body temperature has shown a shift (see 7.1), pregnanediol excretion has increased, and vaginal cytology has shown changes, yet on surgical exploration corpora lutea have not been found, but rather a luteinization of the theca interna without ovulation. Thus, the commonly used criteria do not constitute absolute proof that ovulation has taken place.

4.3 The direct observation of a young corpus luteum by culdoscopy, laparoscopy, or laparotomy is good evidence of ovulation. However, neither gross nor histological examination of the corpus luteum is an accurate method of dating ovulation, and, like much other evidence of ovulation, has no practical value. A great amount of additional research must be done with the hope of correlating changing systemic conditions and patterns with the time of ovulation. It is doubtful if there is any method better than the BBT method for home use in determining the general period of ovulation. If there is to be increasing practical application of fertility control by periodic abstinence, increasingly accurate methods must be devised for determining the exact time of ovulation—or, better, for anticipating ovulation by a reasonably precise interval. Such findings would prove of incalculable value in the practice of fertility control.

##### Methods of detecting ovulation

4.4 Each of the indirect indicators of ovulation has some merit, and collectively the accuracy of such indicators is appreciable. However,

it can be said that all current methods have an inherent weakness in that they become positive only after the fact of ovulation; that is, they are retrospective and not anticipatory. Further, there is no existing single method or group of methods that permits accurate estimation of the length of the interval between ovulation and the observed changes. This is not to malign the value of these tests, but rather to point to the urgent necessity for more research on methods that will better and more closely indicate the exact occurrence of ovulation.

#### Methods of anticipating ovulation

4.5 It can be postulated that if methods of predicting the time of ovulation are developed, they will probably depend upon (a) a serum level of LH necessary to cause follicle rupture, (b) some specific relationship, either changing or constant, between the serum levels of LH and FSH that will indicate imminent ovulation, (c) some unique pattern of specific hypothalamic pituitary releasing factor(s), or (d) some yet to be discovered immuno-assay of serum-borne and/or urine-borne materials, probably of peptide hormone nature, or their metabolic products.

### 5. MENSTRUAL ONSET INTERVALS (MOI)

5.1 Data concerning MOI show these to be greatly variable from menarche to the age of about 20 years; from 20 to 45 years the variability is much reduced, but after 45 years it increases rapidly. During the period between 20 and 45 years of age there is a slight but definite tendency for the mean duration and standard deviation of the intervals to fall.

5.2 Most of the data relative to MOI have been obtained from groups of women. As yet there have not been enough studies of variations in the menstrual cycle pattern in individual women, though some data are being collected; still less is there satisfactory information on the factors responsible for differences between individuals.<sup>1</sup>

5.3 When interpreting menstrual history data, one must bear in mind certain points, neglect of which can only lead to confusion. Distinction must be made between the characteristics of data for a group and those for individuals, and it must be clear as to who provided the data; for instance, were they people attending infertility clinics or were they fertile people seeking advice on fertility control? Additionally, it must be known whether all onset intervals have been included in the data (as is the usual practice of biostatisticians) or whether certain intervals have been excluded

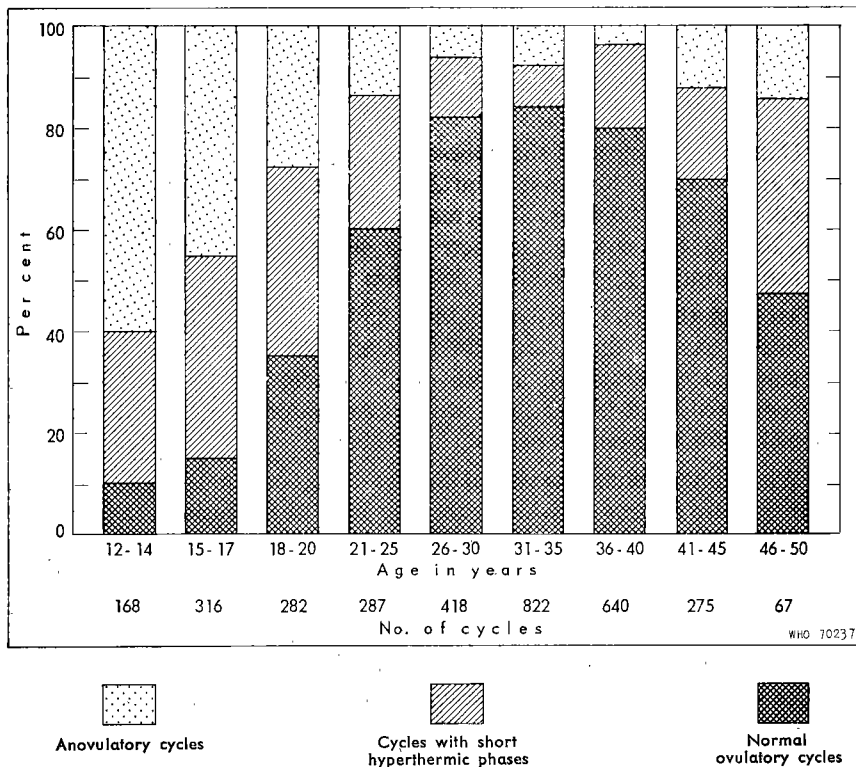
<sup>1</sup> Hartman, C. G., *Science and the safe period*, Baltimore, Williams & Wilkins, 1962.

on the grounds that they are abnormal (as is the practice in certain studies). The age grouping of the persons providing the data must also be clearly stated.

5.4 The mode for the typical menstrual cycle is about 28 days and the frequency distribution curve shows a higher proportion of longer than of shorter cycles.

5.5 There is as yet no precise information available about the relationship between the duration and variability of MOI and the biological characteristics of the cycle. In those age groups where the variability in the MOI is comparatively large, the percentage of those intervals that are anovulatory, or have a short luteal phase, is correspondingly high. Between 20 and 45 years of age the intervals are least variable and the frequency of anovulatory cycles is lowest (Fig. 1). In any case, the occurrence of uterine bleeding at more or less regular intervals, in the presence of follicular growth but in the absence of ovulation, shows that neither the periodicity nor the initiation of endometrial breakdown is essentially

FIG. 1. DISTRIBUTION OF NORMAL OVULATORY CYCLES, CYCLES WITH SHORT HYPERTHERMIC PHASES, AND ANOVULATORY CYCLES IN 3264 CYCLES OF 481 FEMALES



dependent on the cyclic formation of the corpus luteum. This point is of some importance as it might provide evidence of the dependence of menstruation on an extra-ovarian factor.

5.6 Parturition may disturb in some fashion the next two or three MOI but usually not later ones. The disturbance may be associated with anovulatory cycles or with a change in duration of either the follicular or luteal phases. The same may hold true relative to lactation.

5.7 Information is almost totally lacking concerning the influence of ethnic factors, climate, occupation, and nutrition upon the MOI and its variations. There is some evidence, based on case-history reports, that physiological disturbances may affect the interval.

## 6. THE PHASES OF MENSTRUAL ONSET INTERVALS

6.1 The MOI typically exhibits a biphasic body temperature curve. This is true regardless of the method of temperature measurement (oral, vaginal, or rectal) and of the fact that the temperatures will differ slightly depending upon the method used. Each day the temperature should be taken in the same manner, under essentially identical resting conditions, and with a thermometer that has adequate graduations for easy and accurate reading. The body temperature taken under these conditions is commonly referred to as basal body temperature (BBT). The two phases of the biphasic temperature curve relate in a general way to the follicular and luteal portions of the cycle. The follicular phase is the phase of the lower temperature level and is called the hypothermic phase; the higher temperature (luteal) phase is called the hyperthermic phase.<sup>1</sup> The latter is characterized by a slight increase in BBT above normal due to the thermogenic activity of progesterone.

6.2 Both phases of the cycle show ordinary biological variability in duration. The duration of the hyperthermic phase is slightly variable, having an approximately normal distribution, with a mode at 13 days; the duration of the follicular phase is more variable, with a mode at about 15 days. Almost all the data published on the duration of the two phases relate to groups of women and there is a regrettable dearth of statistics on variation in individual women. More research is needed to determine whether most long MOI are characterized by a long hypothermic phase. Fig. 2 and 3, based on previously unpublished data, clearly illustrate variations in duration of both the hypothermic and hyperthermic phases of over 4500 MOI in 512 normal healthy Western European women.

---

<sup>1</sup> It is emphasized that the terms "hypothermic" and "hyperthermic" should not be construed as implying pathological conditions; the biphasic temperature curve is a normal characteristic of the MOI.

FIG. 2. LENGTH OF HYPERTHERMIC PHASES OF 4540 CYCLES IN 512 HEALTHY WOMEN

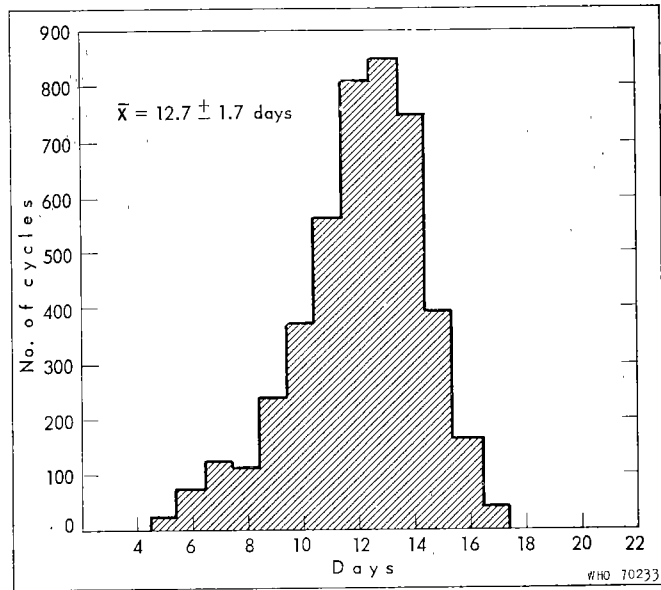
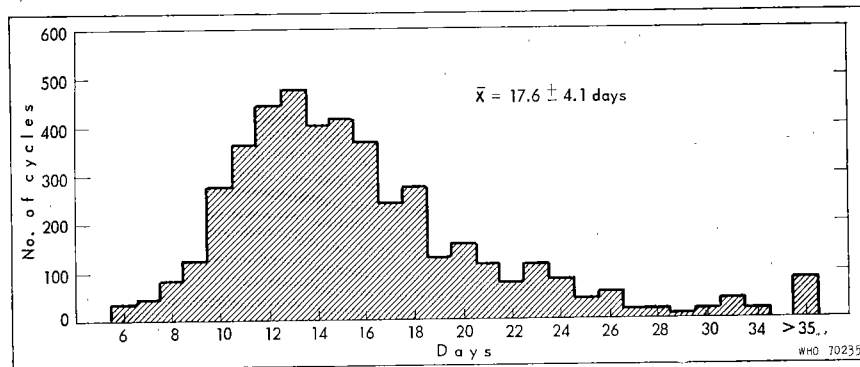


FIG. 3. LENGTH OF HYPOTHERMIC PHASES OF 4540 CYCLES IN 512 HEALTHY WOMEN



## 7. THE SHIFT IN BBT

7.1 The change from the hypothermic to the hyperthermic phase is spoken of as the "shift". A significant shift is one that occurs in 48 hours or less, and in which three consecutive daily temperatures are at least  $0.2^{\circ}\text{C}$  ( $0.36^{\circ}\text{F}$ ) higher than the last six daily temperatures prior to the

start of the shift. This sustained BBT shift is the criterion of the "established hyperthermic phase", and marks the beginning of the hyperthermic infertile period. In some cases it may not be possible to apply this criterion strictly because the relevant recorded temperatures of the two phases differ by less than 0.2° C or because the shift from the hypothermic to the hyperthermic phase takes place during a period of more than 48 hours. These cases are, however, in the minority and perhaps require interpretation by an experienced observer.

FIG. 4. BASAL BODY TEMPERATURE (BBT) CURVE TYPE 1

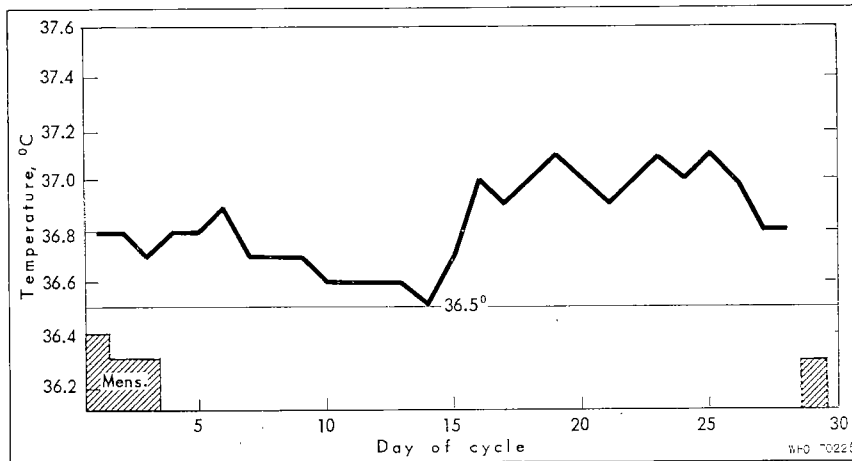


FIG. 5. BASAL BODY TEMPERATURE (BBT) CURVE TYPE 2

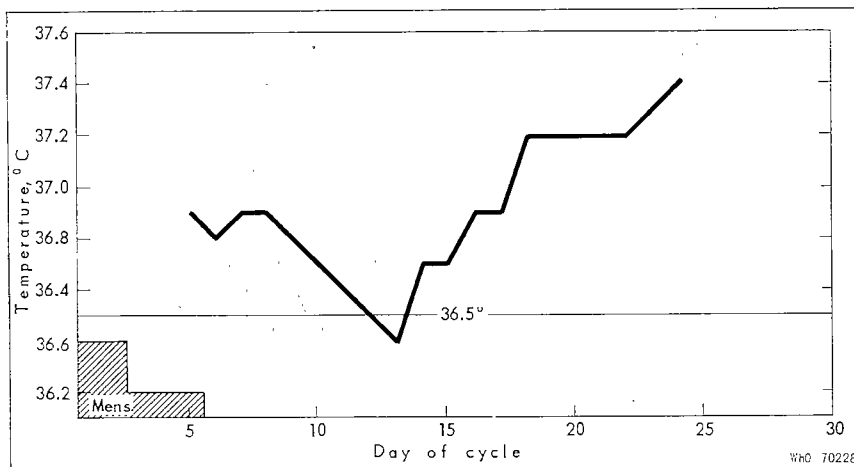
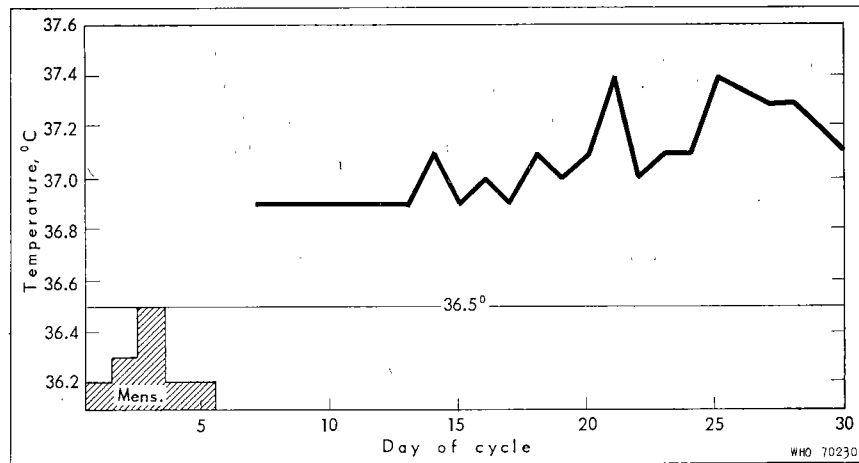


FIG. 6. BASAL BODY TEMPERATURE (BBT) CURVE TYPE 3



7.2 Fig. 4-6, inclusive, are representative BBT curves, based on temperatures taken and recorded by married women practising the BBT method of fertility control. It can readily be seen that the curve in Fig. 4 exhibits a distinct temperature shift, and it easily conforms to the criteria set forth above (see 7.1). The curves in Fig. 5 and 6 are at variance with the characteristics of the curve in Fig. 4 and with the criteria set forth as indicating a clear temperature shift. Curves of the latter two types may have to be interpreted by an experienced observer.

7.3 When analysing the effectiveness of this method of fertility control it is essential to know (a) the nature of the individual or population studied (i.e., whether the fertility of individual or population is high or low), (b) the age distribution of the population, and (c) the quality and extent of the education given to those using the method.

## 8. INSTRUCTION IN USE OF THE METHOD

8.1 The quality of teaching is of paramount importance. Some investigators have reported that only 45% of a Western European population were able to take temperatures accurately and record them in the form of a technically satisfactory temperature curve; others have indicated that satisfactory data can be recorded by 95% of a group. The willingness and competence of the educators to instruct women or couples in the technical and psychological aspects of the method are of critical importance.

8.2 In one study of a population of normal fertility within the 20-40 year age group, who had received careful and adequate instruction, 95% were able to procedure BBT curves that could be interpreted. Of this 95%, 82% showed a clearly defined shift of BBT occurring within 48 hours, while 18% showed a slow or step-like change over several days. These figures indicate the existence of biological variations of BBT curves (in approximately one fifth of the population of this study) and such curves are more difficult to interpret than others.

## 9. DURATION OF THE FERTILE PERIOD

9.1 The term "fertile period" as used in this report indicates that part of the menstrual cycle during which insemination may lead to conception. Conception (fertilization) is dependent on the availability of a freshly extruded viable ovum and on the presence of recently deposited viable spermatozoa in the proper environment (fallopian tube) and sufficiently close to the ovum. Knowledge of the length of the fertile period in the human is not complete; such information as is at present available indicates that the ovum may remain susceptible to fertilization for about 12 hours, probably for a maximum of 24 hours. In the case of the spermatozoon, the duration of viability is greatly influenced by the environment encountered in the female genital tract; spermatozoa that remain in the vagina die within a few hours while those that enter the cervical canal may remain motile for 48 to 72 hours or more if the condition of the mucus is favourable. In this report the period of viability of a spermatozoon is considered to be that interval during which it can fertilize an ovum, and this is most probably much shorter than the duration of motility. These figures suggest that the fertile period has a maximum duration of 4 days, but the average is probably much less. Mathematical models that are based on certain assumptions about the chance of conception per unit of time, and about coital frequency, tend to support the latter conclusion.

9.2 Rare cases of conception following a single act of coitus several days before the presumed time of ovulation have been described. The interpretation of these cases is difficult because data on human sexual behaviour are subject to both forgetfulness and the unwillingness of some individuals to divulge freely information on frequency of coitus. These same human elements make it virtually impossible to differentiate accurately between failures of use effectiveness and of biological effectiveness of any of the three methods (see 11.2). Interpretation is made more difficult because there is no way of knowing whether such failures arise from unusually long survival periods of one or both gametes or incorrect

determination of the time of ovulation. In any case, evidence from such isolated cases cannot be used to formulate general physiological principles.

## 10. EVALUATION OF PERIODIC ABSTINENCE

10.1 A consistently and significantly shortened hyperthermic phase is usually associated with sterile cycles (see Fig. 1).

10.2 More adequate information about the relationship between the length of the luteal phase and that of the entire menstrual onset interval could be incorporated into a formula that might give a better estimate of the time of ovulation than the current Ogino and Knaus formulae. However, at the clinical level the advantage of greater scientific accuracy (i.e., more precise formulae) might be outweighed by the increased difficulty in applying it.

10.3 The fact that menstruation is related to the preceding ovulation, and not to the subsequent one, is the underlying principle in the prediction of the probable ovulatory period from menstrual interval data. The accuracy of this prediction depends largely upon the amount of data on which it is based, as shown in the table. These data are of great importance in the application of the calendar method (see 11.2) of fertility control.

CONSISTENCY OF MENSTRUAL INTERVAL DATA

No. of women	No. of past cycles recorded	Proportion of three subsequent cycles within the range of past cycles <sup>a</sup> (%)
381	3	64
264	6	82
172	9	87
113	12	90

<sup>a</sup> Note that from 36% to 10% of subsequent cycles have a calendar pattern dissimilar to the past 3 to 12 cycles, respectively. This variability can be, and probably is, the basis for some conceptions that occur in those individuals using the calendar method of fertility control.

## 11. METHODS IN USE

11.1 A variety of methods have been employed in the hope of determining the part of the menstrual onset interval during which abstinence should be practised in order to avoid conception. Some methods predict future events on the basis of past data while others are based upon the record-

ing of a specific event in each interval. As these two approaches are fundamentally different it is essential, in making any evaluation of periodic abstinence, to state clearly which method is under consideration.

11.2 There are three currently accepted methods :

(a) The calendar method determines the time for abstinence solely on the basis of data from past records of menstrual cycles. To these data a variety of formulae may be applied including the well known ones of Ogino, Knaus and Farris, and various modifications of these. In one accepted calendar method, 18 is subtracted from the number of days of the shortest and 11 from the longest of the last six MOI. Thus, if the shortest and the longest MOI are 26 and 31 days respectively, days 8 ( $26 - 18 = 8$ ) to 20 ( $31 - 11 = 20$ ), inclusive, are considered as "fertile days". By the use of certain modifications of this formula, the suggested number of possible fertile days can be increased, thus increasing the chances for success of the method. There are also some formulae without scientific merit and of uncertain derivation, such as the "rule of 10" (10 days sterility, 10 days fertility, and 10 days sterility counted from the first day of the menses).

(b) The second method employs the basal body temperature curve as the basis for determining the time of ovulation and fertility, and its usual application restricts coitus to the part of the MOI that follows three consecutive daily readings of raised body temperature (see 7.1).

(c) In a third approach a combination of the basal body temperature method (which indicates the infertile part of the luteal phase of the cycle) and the calendar method is used to predict the infertile days during the follicular phase. This prediction may be based on the average of temperature curves recorded during the previous six or more MOI. The infertile part of the follicular phase of the cycle is determined as follows :  $D$  is used to indicate the earliest beginning day of the BBT shift in the previous six or more MOI. Then  $D$  minus 6 is the first day of the fertile period. Thus it is suggested that for fertility control purposes, coitus should be abstained from during the period beginning six days before the start of the predicted shift and ending with the establishment of the hyperthermic phase (see 7.1). Alternatively, the infertile part of the hypothermic phase may be determined by the formula  $S$  minus 19, where  $S$  is the number of days in the shortest menstrual onset interval experienced by the woman in the previous 6 to 12 months or more. For example, if the previous six onset intervals were 30, 27, 26, 31, 30, and 27 days, respectively, the shortest interval was 26 days. Since  $26 - 19 = 7$  the woman would be considered infertile up to day 7 of the menstrual onset interval and again after the third recorded elevated temperature after completion of the shift. If the Ogino calendar method only were used,

it would call for abstinence for an average of 12 days for the menstrual onset intervals cited above.

## 12. USE EFFECTIVENESS

12.1 Studies of the use effectiveness of the calendar methods have given failure rates varying from 14 to almost 40 pregnancies per 100 woman-years of use. The difference in these results is due to a variety of facts, including variations in the intelligence, knowledge, and motivation of the user, and in the selection of subjects (e.g., studies limited to women whose range of menstrual onset intervals is below a certain level), the adequacy of instruction, and the specific calendar formula employed.

12.2 Data from four studies in Western Europe of the use effectiveness of the temperature method, in which coitus had been restricted to the infertile period of the hyperthermic phase, were available for consideration. Three of these studies were retrospective and contained an unknown percentage of non-respondents to the questionnaires. One was a prospective investigation, still in progress, with a known but negligible number of drop-outs to date. In these four studies the failure rate was 0.8 to 1.4 pregnancies per 100 woman-years of use.

12.3 The same four studies included some couples who had combined calendar with temperature methods as described above. Use effectiveness in this group varied from 3.2 to 8.0 pregnancies per 100 woman-years.

12.4 When assessing such results it is important to ascertain exactly how the failure rates have been computed. Distinction must first be made between (a) the calendar method, (b) the calendar and temperature method combined, using both hypothermic and hyperthermic phases, and (c) the temperature method using the hyperthermic phase only. A further distinction must be made between biological effectiveness and use effectiveness. If the temperature shift necessarily means that ovulation has taken place, and if the survival of the gametes is as brief as supposed, then after the third elevated daily temperature of the shift the woman would be biologically infertile. In practice there are other considerations. The failure rate of fertility control methods is expressed in pregnancies per 100 woman-years of use (Pearl formula). Though this report uses the same reference to failure rate, it was pointed out that the success of fertility control by periodic abstinence introduces the element of no sexual intercourse (i.e., no exposure) for a large portion of each menstrual onset interval. Accordingly, actual exposure per woman year is reduced by the interval of abstinence, which, depending on the individual and method employed, may be more than half of the MOI.

12.5 Biological effectiveness studies consider only those failures that occur when the instructions appropriate to a particular method or combination of methods are followed accurately.

12.6 Use effectiveness studies consider all conceptions that occur during cycles in which couples purport to use a certain method, irrespective of whether they have followed instructions accurately or not. Thus if a couple are purporting to use the temperature method with coitus restricted to the hyperthermic phase, but in fact have coitus in both hypothermic and hyperthermic phases, any conception that results must be counted against the use effectiveness of the method. This must be the case irrespective of whether coitus in the hypothermic phase was due to misunderstanding of instructions, to difficulty in reading the temperature chart, or to difficulty in maintaining abstinence. All these factors must be taken into account when assessing the use effectiveness as opposed to the biological effectiveness of any given method.

### 13. CAUSES OF FAILURE

13.1 The most common causes of failure (i.e., pregnancy) with the various forms of fertility control by periodic abstinence are probably lack of accurate knowledge about the method employed and lack of motivation. In one interrogation and questionnaire survey, only 68% of a general probability sample of wives using any one of several formulae for periodic abstinence were correct in their knowledge of where the fertile phase was situated within their menstrual cycle. Such ignorance may be due to lack of instruction, failure to comprehend the instruction given, or—not infrequently—to inaccurate and inadequate instruction.

13.2 It is sometimes suggested that a pregnancy in a woman who uses the temperature method only, and who confines coitus to the normally infertile portion of the hyperthermic phase, might be due to a second ovulation occurring during the hyperthermic phase of a cycle. The evidence on which this suggestion is based is not well founded. Moreover, practical experience with the temperature method shows that conception after the third successively recorded high daily temperature in the hyperthermic phase is very rare indeed.

13.3 In this connexion it should be pointed out that the failure rate of either the BBT or the calendar method, or of some combination of the two, will probably be much higher in the case of a large population than in that of a small, carefully studied group that has frequent contact with a competent observer. Such differences must be, in large part, responsible for the great range noted in the failure rates of the several methods (see 12.1, 12.2, and 12.3).

#### 14. RESEARCH NEEDS

After evaluating the biological basis of fertility control by periodic abstinence the Group considers that there is need for further studies on the problems listed below. No attempt has been made to place these problems in order of priority. The references in parentheses indicate the relevant paragraphs in the body of the report.

(a) Variations in the menstrual cycle pattern in individual women (5.2, 5.5).

(b) The causes of individual differences in the menstrual cycle pattern (2, 6.2, 7.2).

(c) The relative frequency of ovulatory and anovulatory cycles that are not complicated by pathological conditions (frequency polygon) (6.2).

(d) The influence of ethnic factors, climate, occupation, and nutrition upon menstrual onset intervals (5).

(e) A formula that may give a better estimate of the time of ovulation than the current formulae (4, 10.2).

(f) More precise determination of the correlation of ovulation with BBT (6.1).

(g) Simple tests for the accurate prediction of ovulation (4.2, 4.3, 4.4, 4.5).

(h) An immuno-assay technique for determination of pituitary hormones or breakdown products in serum or urine (4.5).

(i) The duration of the periods of viability and fertilizing capacity of sperm and ova (9.1, 9.2).

---