

Does the Use of Ovulation Monitors Really Increase Pregnancy Rates? Some Things Women Should Know

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Received: June 9, 2018/Accepted: December 27, 2018/ Published online: December 29, 2018

Abstract

Ovulation monitors are widely used by women wishing to achieve pregnancy. However, there are few data substantiating claims that these devices enhance the probability of becoming pregnant. In one report it is concluded from the cumulative pregnancy rate that the use of the Clearblue Easy Fertility Monitor increased the pregnancy rate. In a second report, it is argued that the use of the Clearblue Digital Ovulation Test reduces the time taken to conceive. We reconsider these previously published data by analysing each cycle and show that use of such devices might have a small effect ($\phi \approx 0.12$, odds ratio = 2.1-2.2, relative risk = 1.9) in the first month of use, but has no significant effect ($\phi \approx 0.01$, odds ratio = 1.2, relative risk = 1.1-1.2) in the second month. However, the subjects recruited for these two trials had single cycle pregnancy rates (7-11%) that were more similar to those of women avoiding pregnancy (about 6%) than women trying to conceive (about 25%). Given this, there is a reason to suspect that the data that are available might not be representative of all women. Further work is required to test whether even this small transient effect can be replicated in women with higher pregnancy rates. Women should be aware of the limitations of these ovulation monitors.

Keywords: Fertility; Menstrual cycle; Ovulation monitor; Pregnancy

Introduction

Ovulation monitors are used by many women to support their efforts to avoid or become pregnant. The basis of this is that a woman is usually fertile for a few days during each menstrual cycle and this 'fertile window' can be identified using the device. In some trials, ovulation monitors have been employed in the contraceptive mode as the only method used [1, 2], despite warnings from health authorities [3], and in others, they have been combined with various fertility awareness methods [4, 5]. Robinson *et al.* [6] provide data for just two cycles, these parameters can only be estimated algebraically (Appendix). This approach yields $\pi \approx 0.15$ and $P(\infty) \approx 0.51$, both of which are lower than any of the corresponding values for other reports. While these values are not particularly reliable as they are based on only two cycles, it does provide some indication of what might be expected had Robinson *et al.* [6] continued to monitor their subjects for more cycles. Some weak support for the low $P(\infty)$ estimated from these data is provided by the results of Zinaman *et al.*

[16] who recruited subjects wishing to conceive in a similar way using the same manufacturer's website. As it was conducted for a different purpose, that study did not include a control group of subjects who did not use an ovulation monitor. Nevertheless, only 42% of these subjects had conceived after six cycles, despite using an ovulation monitor to assist them. This is more than the 32% estimated from the data of Robinson *et al.* [6] but is much smaller than the 75% after six cycles reported by Wilcox *et al.* [24]. That both parameters were so much smaller prompts the speculation that not only was the probability of pregnancy of the subjects decreased ($\pi \approx 0.15$ versus $\pi = 0.35$), but the proportion of women unlikely to conceive was increased ($P(\infty) \approx 0.51$ versus $P(\infty) = 0.82$). We do not pretend that there is a reliable statistical basis for these speculations, but it does seem likely that the subjects recruited for the work of Robinson *et al.* [6] were not necessarily representative of women in general. What the use of an ovulation monitor enhances the probability of becoming pregnant [6], in part, it is argued, because couples mistime coitus if they do not know when the woman is fertile [7]. The timing of intercourse is important because the ovum is viable for only 8-12 hours after ovulation, so the window of opportunity is quite brief. As the manufacturer's current advertising appears to emphasize pregnancy achievement, which is of particular importance to many women [8], and because these devices are relied on by many women who can incur significant financial cost [7], we consider this application of ovulation monitors.

Some ambiguity arises when comparing some of the devices because they have been available for sale with various product names for more than two decades [9-11], but the hormones measured seem to have been consistent. The current tests employ urinary measurements of two reproductive hormones (luteinizing hormone (LH) and the oestradiol metabolite oestrone-3-glucuronide (E1-3G)) to identify days of 'high fertility' during the menstrual cycle. Neither the details of the measurements nor the algorithm used to interpret the data has been published except, in very general terms, in a patent. However, these two hormones (LH and E1-3G) can if measured appropriately, provide information about the onset of fertility and the day of ovulation, but they do not give consistently reliable information about the end of the fertile period [12, 13].

We use the available published data [6, 14] to investigate how well they substantiate the claim that the use of an ovulation monitor enhances a woman's chance of becoming pregnant. While several trials of ovulation monitors are registered, the data are not (yet) available from the CDC trial database. In these circumstances, the usefulness of these devices can only be judged from the published reports.

Material and Method

The data used are those of Jones *et al.* [14] and Tiplady *et al.* [15] who report on the same trial of the Clearblue Digital Ovulation Test (CDOIT) and Robinson *et al.* [6] who stated on a trial of the Clearblue Easy Fertility Monitor (CEFM). We have been unable to identify any other reports of comparable trials, but we make a brief reference to an uncontrolled trial of the Clearblue Fertility Monitor that was conducted for different purposes [16]. It is not clear whether the different product names represent substantive differences in the method or commercial expedience, so caution should be exercised in making direct comparisons of the data. All calculations were carried out using R and, where appropriate, the exact 2×2 package [17, 18]. The power of a statistical test depends mostly on the sample size and the effect size [19, 20]. For example, even a small effect might be statistically significant if the sample size is large, but an effect of that magnitude might be of little practical use. On the other hand, a practically significant effect may or may not be observed by chance. Given this, we report both the statistical significance and several measures of the effect size. While the numbers specified differ, as a guide, the odds ratio can be considered small, medium or large if it is 1.5, 2 or 4, respectively, [19] and ϕ can be considered small, medium or large if it is 0.2, 0.4 or 0.6, respectively [20]. The confidence intervals for ϕ [21] were determined using 1000 bootstrap replicates rather than the theoretical expression [22].

Results and Discussion

The Clearblue Easy Fertility Monitor (CEFM) Trial

Robinson *et al.* [6] enrolled 1000 women in a trial of the CEFM. After excluding nine women who became pregnant before the trial began, 335 women who did not respond and five women who did not match the selection criteria, 309 women were assigned to a group using CEFM and 348 women to a control group that did not use CEFM. Four women (three CEFM users and one non-user) were excluded at the end of the first cycle because they provided no data. During the first cycle, 46 CEFM users and 27 non-users became pregnant. At the end of the trial, after two menstrual cycles, data were available from 302 and 347 women among the CEFM users and non-users, respectively. The number of women becoming pregnant during the second cycle is not stated. However, it can be estimated by subtracting the number of pregnancies in the first cycle from the total number at the end of the trial. By the end of the trial 22.7% of 305 CEFM users and 14.4% of 348 non-users had become pregnant, which corresponds to 69 ($\approx 0.227 \times 305$) and 50 ($\approx 0.144 \times 348$) pregnancies, respectively. If these numbers are correct then 23 ($= 69 - 46$) CEFM users and 23 ($= 50 - 27$) non-users became pregnant during the second cycle. In Table 1 the data are summarised for each cycle, following the approach of Wilcox *et al.* [23, 24], rather than presenting the cumulative data as Robinson *et al.* [6] did.

The data in Table 1 indicate that Robinson *et al.* [6] observed a small ($\phi = 0.11$), but significant ($p = 0.004$), effect in the first cycle. However, there was no significant effect ($\phi = 0.02, p = 0.617$) in the second cycle. In the first cycle, the relative pregnancy rate associated with CEFM use was 1.9, indicating that the device did not quite double a woman's chance of becoming pregnant on average, and was only 1.2 [95% CI: 0.7, 2.1] in the second cycle. Note that the probability of pregnancy among non-users in this trial was less than 0.08 in both cycles (Table 1).

Table 1. Summary of the single cycle data of Robinson *et al.* [6] and Jones *et al.* [14] for users of CEFM and CDOT, respectively. The ranges in square brackets are 95% confidence intervals.

	Robinson <i>et al.</i> [6]		Jones <i>et al.</i> [14]	
	cycle 1	cycle 2	cycle 1	cycle 2
Non-users				
Entering cycle	348	320	82	54
Pregnancies	27	23*	9	6
Exclusions	1	0	19	5
Pregnancy rate (%)	7.8 [5.2, 11.1]	7.2 [4.6, 10.6]	11.0 [5.1, 19.8]	11.1 [4.2, 24.5]
Users				
Entering cycle	305	266	93	55
Pregnancies	46	23*	20	7
Exclusions	3	0	18	4
Pregnancy rate (%)	15.1 [11.2, 19.6]	8.6 [5.5, 12.7]	21.5 [13.6, 31.2]	12.7 [5.3, 24.5]
odds ratio	2.1 [1.3, 3.6]	1.2 [0.6, 2.3]	2.2 [0.9, 5.5]	1.2 [0.3, 3.9]
relative rate	1.9 [1.2, 3.0]	1.2 [0.7, 2.1]	1.9 [0.9, 4.0]	1.1 [0.4, 3.2]
χ^2	8.06 ($p = 0.004$)	0.25 ($p = 0.617$)	2.8 ($p = 0.096$)	0.0 ($p = 1.000$)
ϕ	0.11 [0.03, 0.18]	0.02 [0.00, 0.10]	0.12 [0.00, 0.26]	0.00 [0.00, 0.19]
ϕ/ϕ_{\max}	0.17	0.04	0.16	0.00

* An estimate that is explained in the text.

The Clearblue Digital Ovulation Test (CDOT) Trial

Jones *et al.* [14] enrolled 210 women who wished to become pregnant in a trial of the CDOT. The women were randomly assigned to either a group using CDOT or a control group that did not use any fertility awareness aids (such as observations of basal body temperature or cervical mucus). By

the start of the trial 35 women had become pregnant and were excluded from further participation, leaving 93 and 82 women in the CDOT and control groups, respectively. Both groups were followed for two menstrual cycles. At the end of the first cycle, 20 women in the CDOT group and 9 women in the control group had become pregnant. At the end of the second cycle, 27 of the women remaining in the CDOT group and 15 of the women remaining in the control group had become pregnant. Unlike Robinson *et al.* [6], Jones *et al.* [14] are explicit about the number of pregnancies and the data for each cycle are summarised in Table 1.

In this case, the use of CDOT had no statistically significant effect on the probability of pregnancy ($p = 0.096$ and $p = 1.000$ in cycles one and two, respectively (Table 1)). Nevertheless, the odds ratio, relative risk and ϕ were similar to the corresponding measures reported for CEFM, which might indicate some similarity between the two devices. The lack of significance in this trial is probably due to the smaller number of subjects (Table 1). For example, assuming type 1 and type 2 error rates of $\alpha = 0.95$ and $\beta = 0.8$, respectively, standard power analysis [25] indicates that 255 subjects (without accounting for attrition) are required to detect a difference of 10.5% in the pregnancy rate. It is, perhaps, unfair to observe that the same calculation for cycle two indicates that about 8500 subjects are required to detect a difference of 1.6% of the pregnancy rate. This simply reinforces the small effect on the probability of pregnancy associated with the use of such ovulation monitors.

Discussion

The data show that the use of an ovulation monitor may have a small effect in the first cycle, but that it has no effect in the second cycle (Table 1). By reporting the cumulative pregnancy rate rather than the rate for each cycle, Robinson *et al.* [6] made the difference between the first and second cycles less apparent. Women contemplating the use of these ovulation monitors to assist them to conceive should be aware of this.

It might be argued that it is inevitable in a trial like this that the pregnancy rate would decline as the trial progresses. This is correct, but a decline to the control rate (about 8%) in the proportion of women conceiving after a single cycle is unexpected. In work involving fewer subjects, Wilcox *et al.* [23, 24] observed a higher pregnancy rate (about 25%) which was maintained for the first three cycles before a gradual decline. The pattern in the data of Robinson *et al.* [6] is quite different. Tiplady *et al.* [15], working with the same data as Jones *et al.* [14], employed Kaplan-Meier analysis and concluded that a "possible reduction in time to pregnancy" was associated with the use of CDOT, although this became "did not negatively affect time to conception" in the abstract. The simple analysis employed here makes the point very clearly: in the CDOT trial there was no significant effect in either cycle, and in the much larger CEFM trial there was no significant effect in the second cycle.

A second concerning feature of the data is that the pregnancy rates among the non-user control groups are low in both trials (Figure 1). The control group pregnancy rate reported by Robinson *et al.* [6] is only 7.8% in the first cycle and, based on the foregoing calculations, 7.2% in the second cycle. This is much lower than the corresponding rates for women who wanted to become pregnant (about 24.0% [95% CI: 18.5% to 30.2%] and 25.5% [18.9% to 32.9%] in cycles one and two, respectively, of their trial) reported by Wilcox *et al.* [23, 24] (Figure 1) and others in which the mean cycle one rates range from 29% to 38% [26-28]. None of these latter rates is significantly different from the rates observed arising from coitus during the fertile period by Barrett and Marshall [29]. On the other hand, Robinson's control group rates are similar to the overall single cycle rate reported by Barrett and Marshall [29] for women who wished to avoid pregnancy (6.6% [6.0% to 7.3%]) and to the value specified by Evers [30] as characteristic of 'moderately subfertile' women. In contrast, the control group pregnancy rate of Jones *et al.* [14] is about 11% for each cycle which is not significantly different from either the rate reported by Wilcox *et al.* [24] for either of the first two cycles ($p \geq 0.135$) or the control group rates of Robinson *et al.* [6] (Figure 1). The subjects recruited through the company website [6, 14] appear to have differed materially from those recruited through newspaper advertisements 30 years earlier by Wilcox *et al.* [23, 24]. Further work is required to determine whether the small effect demonstrated in cycle one of the CEFM trial can be expected from other cohorts of women.

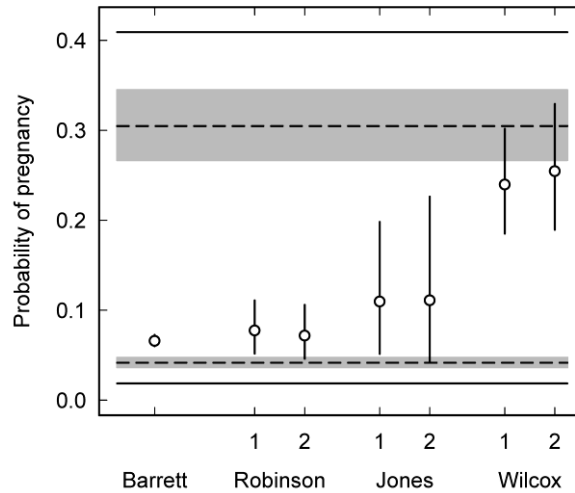


Figure 1. The probability of pregnancy in a cycle of women not using an ovulation monitor. The data (and 95% confidence intervals) are those of Barrett and Marshall [29] for women avoiding pregnancy (Barrett), Wilcox *et al.* [24] for the first two cycles of women who did wish to become pregnant (Wilcox) and for both cycles in each of the trials of Robinson *et al.* [6] and Jones *et al.* [14]. The grey zones represent the 95% confidence intervals for the average probability (indicated by the dashed lines) based only on days in (upper zone) or outside (lower zone) the fertile period (days -5 to +1 relative to ovulation) calculated from the data of Barrett and Marshall [29]. The horizontal solid lines are the maximum and minimum daily probability of pregnancy reported by Barrett and Marshall [29] the larger of which is very similar to the value Gnath *et al.* [27] give for the single cycle pregnancy rate of 'truly fertile' couples.

The differences in the probability of pregnancy shown in Figure 1 are compounded over time (Figure 2). According to several reports, the cumulative probability of pregnancy increases from about 30% in the first cycle and exceeds 80% within about ten cycles [24, 26, 27] (Figure 2). If the probability of pregnancy in a cycle (π) is constant and the cycles are independent, then the probability that women do not conceive $(1 - \pi)$ in $n - 1$ cycles and then do (π) in the n th cycle is

$$P(\text{pregnancy in cycle } n) = \pi(1 - \pi)^{n-1} \tag{1}$$

and the corresponding cumulative probability function is

$$P(n) = P(\text{pregnancy in } \leq n \text{ cycles}) = \pi + \pi(1 - \pi) + \dots + \pi(1 - \pi)^{n-1} = 1 - (1 - \pi)^n \tag{2}$$

[31]. However, only a fraction $(P(\infty))$ of women can conceive, so a more realistic expression for the cumulative probability of pregnancy in n cycles or fewer is

$$P(n) = P(\infty)(1 - (1 - \pi)^n) \tag{3}$$

In this case, the probability of pregnancy in cycle one is just $P(1) = \pi P(\infty)$, so $\pi \geq P(1)$. This can be tested by applying (3) to data reported in the literature. For this purpose, we take the data of Wilcox *et al.* [24] as a reference because (a) only 5% of their subjects had been taking oral contraceptives, which are known to extend slightly the time required to conceive after ending their use [32], before the monitoring began, (b) their age range is similar to that of subjects involved in the CEFM trial (Table 2) and (c) their subjects were monitored for nine cycles. For these data $\pi = 0.35 \pm 0.04$ (95% CI) and $P(\infty) = 0.80 \pm 0.04$ (95% CI), from which the probability of pregnancy in cycle one is $\pi P(\infty) \approx 0.28$ and about 18% of women are unlikely to conceive (Figure 2). The values of π obtained using the data of Wang *et al.* [28] and Zinaman *et al.* [26] are not significantly different from $\pi = 0.35$ ($p \geq 0.284$), but a lower value ($p < 0.001$) is obtained for women who had recently stopped taking oral contraceptives [33] (Table 2), consistent with their known effect in some women [32]. Similarly, the values of $P(\infty)$ were not significantly different from 0.80 ($p \geq 0.211$), except for the examples of Wiegatz *et al.* [33] and Wang *et al.* [28] ($p < 0.001$). It is not clear why this is the case for the former.

In the latter case, women over the age of 34 and any woman who had tried unsuccessfully to get pregnant for at least a year at any time were specifically excluded. As almost all of their subjects conceived within ten cycles, $P(\infty) = 0.99$.

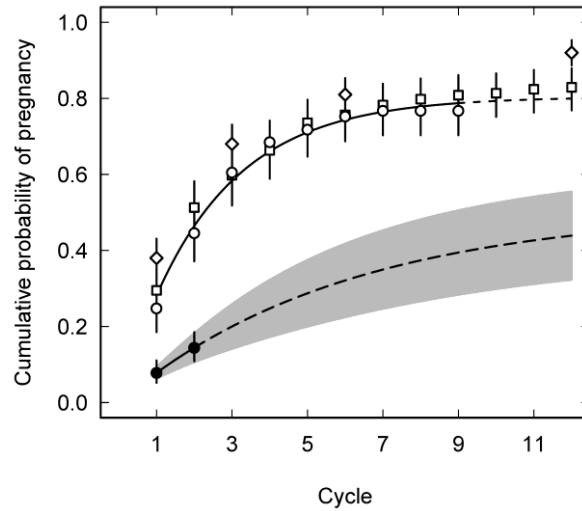


Figure 2. Cumulative probability of pregnancy of subjects not using an ovulation monitor. The data shown are those of Gnoth *et al.* [27] (\diamond), Wilcox *et al.* [24] (\circ), Zinaman *et al.* [26] (\square), and Robinson *et al.* [6] (\bullet). The error bars are 95% confidence intervals. The upper curve is a fit of (3) to the data of Wilcox *et al.* [24]. The lower curve is the algebraically estimated (Appendix) fit of (3) to the data of Robinson *et al.* [6] and the grey zone represents an estimate of the uncertainty based on that of the reported data. Note that the dashed curve section of each curve represents extrapolation. Details of the parameter estimates are given in Table 2.

Table 2. Estimates (\pm 95% CI) of π and $P(\infty)$ obtained from data discussed in the text and some of the relevant details of the subjects. Some of the data are plotted in Figure 2.

Source	Subjects*	n	π	$P(\infty)$
Gnoth <i>et al.</i> [27]	20-44 y, using NFP to time intercourse	340	0.39	0.89
Robinson <i>et al.</i> [6]	21-40 y, excluded if had been trying to conceive for more than 2 y, not using ovulation monitor	348	0.15	0.51
Wang <i>et al.</i> [28]	20-34 y, excluded if had ever tried unsuccessfully to conceive for more than 1 y	518	0.33 ± 0.01	0.99 ± 0.01
Wiegatz <i>et al.</i> [33]	16-41 y, based on time from ending oral contraceptive use	706	0.24 ± 0.02	0.90 ± 0.03
Wilcox <i>et al.</i> [24]	21-42 y, 5% of subjects ended use of oral contraceptives when trial began	221	0.35 ± 0.04	0.80 ± 0.04
Zinaman <i>et al.</i> [26]	21-37 y, from 0-5 months of ending contraceptive use, type of contraceptive not specified	200	0.36 ± 0.02	0.82 ± 0.01

* NFP is natural family planning

As Robinson *et al.* [6] provide data for just two cycles, these parameters can only be estimated algebraically (Appendix). This approach yields $\pi \approx 0.15$ and $P(\infty) \approx 0.51$, both of which are lower than any of the corresponding values for other reports. While these values are not particularly reliable as they are based on only two cycles, it does provide some indication of what might be expected had

Robinson *et al.* [6] continued to monitor their subjects for more cycles. Some weak support for the low $P(\infty)$ estimated from these data is provided by the results of Zinaman *et al.* [16] who recruited subjects wishing to conceive in a similar way using the same manufacturer's website. As it was conducted for a different purpose, that study did not include a control group of subjects who did not use an ovulation monitor. Nevertheless, only 42% of these subjects had conceived after six cycles, despite using an ovulation monitor to assist them. This is more than the 32% estimated from the data of Robinson *et al.* [6] but is much smaller than the 75% after six cycles reported by Wilcox *et al.* [24] (Figure 2). That both parameters were so much smaller prompts the speculation that not only was the probability of pregnancy of the subjects decreased ($\pi \approx 0.15$ versus $\pi = 0.35$), but the proportion of women unlikely to conceive was increased ($P(\infty) \approx 0.51$ versus $P(\infty) = 0.82$). We do not pretend that there is a reliable statistical basis for these speculations, but it does seem likely that the subjects recruited for the work of Robinson *et al.* [6] were not necessarily representative of women in general (Figures 1 and 2).

Finally, we note that Gnoth *et al.* [27], reporting on the use of natural family planning techniques to help couples improve the timing of intercourse, presented data from which it can be estimated that $\pi \approx 0.39$ and $P(\infty) \approx 0.89$ (Table 2). Unfortunately, they employed no control group, but it is interesting to observe that the cumulative pregnancy rates they report are consistently greater over 12 cycles than those of Wilcox *et al.* [24] and Zinaman *et al.* [26] (Figure 2). We cannot know whether a control group might have yielded data closer to those of Wilcox *et al.* [24] and Zinaman *et al.* [26], but it is tempting to speculate that women wishing to conceive might be advantaged by using the techniques described by Gnoth *et al.* [27] rather than an ovulation monitor. More work on these important issues is warranted [12, 13, 34]. The published data indicate that ovulation monitors have limitations that should be made clear to potential users.

Conclusions

The published data underpinning two ovulation monitors promoted for use by women wishing to become pregnant indicate that their use (a) does not affect a woman's chances of becoming pregnant, or, if it does, that that effect is small ($\phi \approx 0.1$) and (b) appears to be limited to the first cycle of use. In the one trial in which the use of an ovulation monitor has been shown to have a statistically significant effect in one cycle, the control pregnancy rate was closer to that of women wishing to avoid pregnancy than those wishing to achieve it. In that case, the effect was to change the rate for a single cycle from about 7.8% to 15.1%. Whether the same small improvement in one cycle could be expected for women has not been established.

Appendix. Algebraic parameter estimates

Robinson *et al.* [6] provide data for only two cycles $((n_1, P_1), (n_2, P_2))$, where the $n_i \geq 1$ are the cycle numbers and $0 \leq P_i \leq 1$ are the corresponding observed cumulative probabilities), so the parameters of (3) can be determined by substituting the data into (3) to obtain

$$P_1 = P(\infty) \left(1 - (1 - \pi)^{n_1} \right) \quad \text{and} \quad P_2 = P(\infty) \left(1 - (1 - \pi)^{n_2} \right) \tag{A1}$$

Eliminating $P(\infty)$ from these expressions yields a polynomial in $(1 - \pi)$

$$P_2 (1 - \pi)^{n_1} - P_1 (1 - \pi)^{n_2} + P_1 - P_2 = 0 \tag{A2}$$

which can be solved for $(1 - \pi)$. The corresponding estimate for $P(\infty)$ can be found by substituting the solution into one of the expressions in (A1). One solution of (A2) is $(1 - \pi) = 1$ (or $\pi = 0$), as can be found by inspection, but this can be discounted because it is inconsistent with the data. For the particular case in Robinson *et al.* [6], $n_1 = 1$ and $n_2 = 2$, so the other solution of (A2) is $(1 - \pi) = (P_2 - P_1)/P_1$, which yields $\pi = 2 - (P_2/P_1)$ and $P(\infty) = P_1/\pi = P_1^2/(2P_1 - P_2)$.

List of abbreviations

CDOT	Clearblue Digital Ovulation Test
CEFM	Clearblue Easy Fertility Monitor
E1-3G	oestrone-3-glucuronide
LH	luteinizing hormone
n_i	number of the i th cycle
P_i	observed probability of pregnancy by the i th cycle
$P(n)$	theoretical estimate of the probability of pregnancy by the n th cycle
$P(\infty)$	theoretical estimate of the fraction of women capable of conceiving
π	probability of pregnancy in a cycle

Conflict of Interest

DC is currently employed by Science Haven Limited, and LB is and SB has been a consultant to the same company. Science Haven Limited is developing assays for monitoring the menstrual cycle, some of these could eventually be used for the same purpose as the ovulation monitors considered here.

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