# Risk factors for discontinuation of Norplant implant use due to menstrual problems

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#### Abstract

The objective of the analysis reported here was to examine risk factors for early discontinuation of Norplant implant use due to perceived menstrual problems. Cox's proportional hazard regression model was used to calculate adjusted hazard ratios that would reflect the relationship of selected subject characteristics to the risk of early discontinuation due to perceived menstrual problems. Approximately 13% of the study population discontinued for perceived menstrual problems. At the end of year 2, the gross cumulative life table discontinuation rate for perceived menstrual problems was 9.4 per 100 women and it rose to 16.4 per 100 women at the end of year 5. Women in this study were significantly more likely to discontinue Norplant implant use due to perceived menstrual problems if they had a higher eduction level (>12 years), had used no contraceptives in the month before Norplant implant insertion, or had a relatively long average duration of menstrual flow at admission. Identifying potential risk factors such as these may help providers to counsel and prepare women to use the Norplant implant method.

#### Introduction

The Norplant implant system is approved for general use in more than 30 countries including the United States. The system consists of six Silastic capsules approximately 34 mm in length and containing 35 mg levonorgestrel, a progestin widely used in oral contraceptives. The total steroid release rate into the bloodstream is initially about 85  $\mu$ g daily, decreasing to 50  $\mu$ g/day at nine months and 35  $\mu$ g/day at 18 months, with a further decline thereafter to 30  $\mu$ g/day [1]. Inhibiting ovulation, combined with thickening and decreasing the amount of cervical mucus, and creating a thin, atrophic endometrium are the primary mechanisms of action of Norplant implants [1–3].

The primary side-effect of Norplant implant use is menstrual disturbance [2,4–6]. The influence of levonorgestrel can cause women to experience more frequent onsets and more days of bleeding or spotting than expected for cycling women who use non-hormonal methods [2]. Studies show that menstrual irregularities are particularly noticeable during the first 12 months of use [7,8]. Cycles in women with longer use tend to become more regular, possibly due to a spontaneous decrease in bleeding/spotting days over time. However, this regulation may also be influenced by early discontinuation of women who are most affected by bleeding disturbances. Also, women whose cycles become very different from their pre-Norplant implant cycles are more apt to discontinue use than women whose cycles do not change appreciably with Norplant implant use [2].

Some women who use Norplant implants are more likely to request removal for menstrual disturbance than for any other reason [9,10]; physiological and psychological factors may influence this request. Aside from the physical discomfort menstrual irregularity causes, cultural and religious ramifications of menstrual bleeding exist. Some women may also believe that they have lost the ability to prepare for and predict the onset and duration of their menses. This analysis is designed to examine potential risk factors for early discontinuation of Norplant implant use due to perceived menstrual problems. Identifying these risk factors may help providers better to counsel and prepare women to use the Norplant implant method.

#### Materials and methods

Clinical trials of Norplant implants were conducted by FHI investigators at 31 clinics in 11 countries between 1985 and 1994; the cutoff date for this analysis was August 12 1994. Only countries in which five-year data were available were included in this analysis. The analysis population included 2140 women at 16 sites in seven countries: Nigeria, Pakistan, Bangladesh, the Philippines, Singapore, Sri Lanka and Ghana. The analysis excluded 21 subjects who were reported pregnant with an estimated date of conception prior to implant insertion date or had one or more implants expelled during the study.

Because this multicenter trial was conducted under one protocol and investigator training was uniform, the data were pooled. Standardized data collection forms were used to record information about each acceptor at admission and at regularly scheduled follow-up visits.

Baseline sociodemographic and menstrual data were collected and summarized for women who discontinued Norplant implant use due to menstrual disturbance; discontinued for other side-effects/medical reasons (e.g. weight loss/gain, insertion site complications, etc.); and discontinued for pregnancy (planning pregnancy and/or method failure) or personal reasons. Women who completed the study or were lost to follow-up were grouped separately. Single-decrement, gross cumulative life table discontinuation rates [11] were calculated for perceived menstrual problems. The specific menstrual problems included the following: intermenstrual bleeding (small amount of bleeding at a time other than menses), menorrhagia (heavy or prolonged

bleeding), amenorrhea (no menses in the last 90 days), dysmenorrhea (pain related to menstruation), and polymenorrhea (menstrual bleeding of increased frequency). The categorization was made by the investigators based on the woman's subjective assessment of her bleeding, if available, at admission and follow-up visits. The life table rates were also reported for other side-effects/medical reasons and pregnancy (planned or method failure) and personal reasons.

A percent distribution was used to illustrate specific reasons reported for discontinuation related to menstrual disturbance. Cox's proportional hazard regression model was used to estimate adjusted hazard ratios that would reflect the relationship of selected subject characteristics to the risk of early discontinuation due to perceived menstrual problems, controlling for center location by region (South Asia, Southeast Asia, and Africa). In the initial model, the pairwise interactions between age and education, age and live births, and cycle length and previous contraceptive use were tested at the 0.05 level. These interactions were found to be not statistically significant; thus they were dropped in the final model. Because menorrhagia was the most commonly reported menstrual reason for early discontinuation, similar models were also run for discontinuation due to menorrhagia alone and discontinuation due to other menstrual reasons (excluding menorrhagia) as the dependent variables.

#### Results

A total of 295 (13.3%) subjects discontinued use of Norplant implants due to menstrual problems. As shown in Table 1, women discontinuing for menstrual problems were more likely than other subjects to have used no contraceptives in the month before Norplant implant insertion. They were also less likely to have used other hormonal methods such as oral contraceptives. Subjects discontinuing for menstrual problems had a marginally lower median weight (44.0 kg) than study participants who discontinued for other reasons (data not shown).

Most women in the study had regular menstrual cycle length (21–35 days) at admission (Table 2). Subjects who discontinued early for perceived menstrual problems had a median flow duration at admission that was marginally longer than subjects who continued in the study or discontinued for other reasons. Also, it should be noted that the percentage of women with flow greater than seven days at admission was higher among women who discontinued for menstrual reasons. These women were also more likely to report an excessive amount of menstrual flow at admission. About the same percentage of subjects in each discontinuation category reported intermenstrual bleeding.

Table 3 presents gross cumulative annual life table discontinuation rates per 100 women for Norplant implant use. At the end of year 1 and year 2, discontinuation rates for menstrual disturbance were higher than for any other discontinuation category. At the end of years 3–5, however, cumulative removal rates for menstrual problems were lower than those for pregnancy and other personal reasons. Still, they were higher than those who reported other side-effects and medical reasons.

Table 1. Selected baseline characteristics of women by discontinuation/continuation status of Norplant implants

Characteristics	Menstrual (n = 295) (%)	Other side- effects/medical (n = 153) (%)	Pregnancy/ personal (n = 464) (%)	End of study (n = 1026) (%)	Lost-to- follow-up (n = 202) (%)
Age (years completed)					***************************************
<25	29.5	19.6	42.5	16.8	21.8
25–29	31.9	36.0	33.6	34.9	31.7
30–34	25.1	26.1	16.8	28.8	24.3
≥35	13.6	18.3	7.1	19.5	22.3
Mean (SD)	27.6 (5.17)		26.1 (4.85)	29.4 (5.03)	29.1 (5.74)
Education (years comple	eted)				
None	42.7	34.0	23.9	31.9	41.6
1–6	19.3	20.9	21.8	22.9	21.3
7–12	32.9	38.6	48.1	39.8	31.7
>12	5.1	6.5	6.2	5.5	5.4
Mean (SD)	4.6 (4.80)	5.7 (5.10)	6.5 (4.56)	5.7 (4.70)	4.8 (4.77)
No. live births					
0-1	10.5	7.8	29.5	5.8	11.4
2–3	54.6	52.9	51.9	52.5	45.5
<b>≥</b> 4	34.9	39.2	18.5	41.6	43.1
Mean (SD)	3.3 (1.71)	3.6 (2.18)	2.4 (1.50)	3.6 (1.80)	3.7 (2.19)
Prior contraceptive use <sup>a</sup>					
OCs/injectables	28.1	36.6	31.9	34.8	27.7
IUD	10.2	12.4	9.3	10.8	9.9
Barriers/other	13.2	15.7	18.1	15.1	6.4
None	48.5	35.3	40.7	39.3	55.9
Smoking					
Yes	7.1	9.2	4.5	8.8	9.9
No	92.9	90.8	95.5	91.2	90.1
Weight (kg) <sup>b</sup>					
<40	25.4	15.8	24.6	17.8	11.1
40 <del>-4</del> 9	48.1	43.4	39.2	43.4	43.2
50-59	19.0	21.7	22.2	24.2	24.1
≥60	7.5	19.1	14.9	14.6	21.6
Median	44.0	46.0	45.0	46.0	49.0

<sup>&</sup>lt;sup>a</sup>Contraceptive mainly used in the past month

<sup>&</sup>lt;sup>b</sup>Weight was not recorded for 10 subjects

Table 2. Selected baseline menstrual characteristics of women at admission by discontinuation/continuation status of Norplant implants<sup>a</sup>

Characteristics	Menstrual (n = 293) (%)	Other side- effects/medical (n = 152) (%)	Pregnancy/ personal (n = 463) (%)	End of study (n = 1018) (%)	Lost-to- follow-up (n = 202) (%)
Cycle length					
Regular <sup>b</sup>	93.5	93.4	90.5	91.6°	91.6
Irregular	6.5	6.6	9.5	8.4	8.4
Flow duration (days)					
13	22.5	29.0	25.7	28.1	33.2
4–6	62.5	59.2	66.3	64.0	59.4
<b>≥</b> 7	15.0	11.8	8.0	7.9	7.4
Median	5.0	4.0	4.0	4.0	4.0
Flow amount					
Scanty/moderate	93.9	96.7	94.2	95.3	97.0
Excessive	6.1	3.3	5.8	4.7	3.0
Intermenstrual bleeding					
Yes	3.4	3.3	3.2	2.4	2.5
No	96.6	96.7	96.8	97.6	97.5

<sup>&</sup>lt;sup>a</sup>12 subjects with amenorrhea at admission were not included in this table

Table 3. Gross cumulative annual life table discontinuation rates per 100 women for Norplant implant use

	Discontinuation rates by reason				
Year	Menstrual Mean (SE)	Other side-effects/medical Mean (SE)	Pregnancy/personal Mean (SE)		
1	2.5 (0.34)	1.7 (0.28)	1.6 (0.28)		
2	9.4 (0.66)	3.7 (4.24)	7.6 (0.60)		
3	13.8 (0.80)	6.1 (0.57)	15.9 (0.86)		
4	15.3 (0.84)	8.1 (0.67)	21.8 (1.00)		
5	16.2 (0.87)	9.2 (0.73)	27.5 (1.10)		

<sup>&</sup>lt;sup>b</sup>Regular refers to cycle length between 21 and 35 days

<sup>&</sup>lt;sup>c</sup>One woman did not report cycle length

Reason	n	%	
Menorrhagia	167	56.8	
Intermenstrual bleeding	56	22.1	
Amenorrhea	20	6.8	
Dysmenorrhea	4	1.4	
Polymenorrhea	47	16.0	
Total <sup>a</sup>	294	100.0	

<sup>&</sup>lt;sup>a</sup>One woman who discontinued due to menstrual disturbance did not specify a particular problem

Menorrhagia was by far the most commonly specific reason reported for discontinuation related to menstrual disturbances (56.8%), followed by polymenorrhea (16.0%) and intermenstrual bleeding (13.3%) (Table 4). Amenorrhea accounted for 6.8% of the removal requests for menstrual disturbances, spotting for 5.8% and dysmenorrhea for 1.4%.

Table 5 presents the Cox proportional hazards model regression results. Based on the adjusted hazard ratio, women with higher eduction (>12 years) were significantly more likely than less educated women to discontinue Norplant implant use early because of perceived menorrhagia. However, educational level was not a significant risk factor in the other model with other menstrual disturbances as an outcome variable. It is worth noting that the interaction between education and age was not statistically significant (p < 0.05); however other independent variables included in the model appeared to have modified the effect of education on the outcome variable.

Women who had used no contraceptives in the month before Norplant implant insertion were more likely to discontinue for perceived menstrual problems than women who had used oral contraceptives or injectables. This predictor was significant in women using orals/injectables in relation to those without prior contraceptive use experience for the models with menorrhagia and total menstrual reasons as a dependent variable. Previous IUD or barrier use in reference to those not using contraceptives was not significantly associated with discontinuation due to menstrual disturbances.

Irregular cycle length (<21 days or >35 days), intermenstrual bleeding or excessive bleeding at baseline did not appear to be significant predictors for perceived menstrual-related early discontinuations. However, women who reported having an average flow duration of 1-3 days in the three months before insertion were significantly less likely to discontinue early for menstrual reasons.

Table 5. Hazard ratio results relating the risk of discontinuation due to perceived menorhagia, other menstrual, and total menstrual problems to selected subjects' baseline socio-demographic and menstrual characteristics $^{a,b}$ 

	Menstrual reasons for discontinuation			
Characteristics	Menorrhagia Hazard Ratio (95% CI)	Other menstrual reasons Hazard Ratio (95% CI)	Total menstrual reasons <sup>c</sup> Hazard Ratio (95% CI)	
Age (years completed)				
<25	1.0 (0.58, 1.88)	2.1 (1.01, 4.38)	1.4 (0.90, 2.24)	
25–29	0.9 (0.52, 1.47)	1.2 (0.60, 2.38)	1.0 (0.66, 1.50)	
30–34	0.9 (0.55, 1.51)	1.3 (0.67, 2.52)	1.1 (0.71, 1.57)	
≥35	1.0	1.0	1.0	
Education (years completed		1.0	1.0	
None	0.5 (0.22, 0.96)	0.9 (0.26, 3.14)	0.6 (0.31, 1.05)	
1–6	0.4 (0.18, 0.80)	0.8 (0.23, 2.83)	0.5 (0.26, 0.90)	
7–12	0.5 (0.25, 0.96)	0.8 (0.23, 2.60)	0.5 (0.30, 0.97)	
>12	1.0	1.0	1.0	
No. live births				
0–1	0.7 (0.38, 1.47)	0.6 (0.29, 1.24)	0.7 (0.41, 1.10)	
2–3	1.0 (0.69, 1.58)	0.9 (0.54, 1.37)	1.0 (0.70, 1.31)	
<b>≽</b> 4	1.0	1.0	1.0	
Prior contraceptive use				
Orals/injectables	0.6 (0.41, 0.90)	0.9 (0.60, 1.35)	0.7 (0.56, 0.97)	
IUD	0.7 (0.41, 1.28)	1.1 (0.62, 2.03)	0.9 (0.59, 1.33)	
Barrier/other	1.2 (0.73, 1.82)	0.7 (0.35, 1.33)	1.0 (0.67, 1.41)	
None	1.0	1.0	1.0	
Smoking				
Yes	1.0 (0.58, 1.82)	0.5 (0.22, 1.25)	0.8 (0.50, 1.29)	
No	1.0	1.0	1.0	
Weight (kg)				
<40	1.4 (0.66, 2.98)	1.3 (0.58, 2.80)	1.4 (0.83, 2.45)	
40–49	1.8 (0.92, 3.60)	0.9 (0.43, 1.96)	1.4 (0.82, 2.28)	
50–59	1.7 (0.87. 3.42)	0.8 (0.34, 1.71)	1.2 (0.74, 2.10)	
≥60	1.0	1.0	1.0	
Cycle length				
Irregular	0.7 (0.38, 1.40)	0.9 (0.42, 1.83)	0.8 (0.49, 1.30)	
Regular	1.0	1.0	1.0	

Table 5 (cont.)

208

	Menstrual reasons for discontinuation			
Characteristics	Menorrhagia Hazard Ratio (95% CI)	Other menstrual reasons Hazard Ratio (95% CI)	Total menstrual reasons <sup>c</sup> Hazard Ratio (95% CI)	
Flow duration				
1–3 days	0.4 (0.21, 0.64)	0.5 (0.26, 0.82)	0.4 (0.28, 0.61)	
4–6 days	0.7 (0.42, 1.06)	0.5 (0.32, 0.89)	0.6 (0.43, 0.85)	
≥7 days	1.0	1.0	1.0	
Flow amount				
Excessive	1.2 (0.65, 2.20)	0.7 (0.28, 1.55)	0.9 (0.58, 1.56)	
Scanty/moderate	1.0	1.0	1.0	
Intermenstrual bleeding				
Yes	1.0 (0.39, 2.45)	1.0 (0.38, 2.40)	1.0 (0.51, 1.86)	
No	1.0	1.0	1.0	

<sup>&</sup>lt;sup>a</sup>Numerals in **bold** denote significant findings

#### Discussion

Our results suggest that women with higher education (>12 years) were at a greater risk for discontinuing Norplant implant use early for perceived menstrual problems than those with some or no education. However, this result is not consistent for the model with other menstrual problems as an outcome variable. One other study indicated that less education was associated with a favorable attitude towards Norplant implants [12], and our data suggest the same. Clearly, counseling appropriate to the educational level of a given individual or population is important. Educational level may also be a proxy for other social and economic variables that influence a woman's decision to continue with a certain contraceptive method. Since we did not collect data on the effect of counseling, it is not clear what effect counseling might have had on the subject's decisions to either continue with or discontinue Norplant implant use. Further research in this area could better prepare providers to give adequate counseling appropriate to individual needs.

<sup>&</sup>lt;sup>b</sup>Cox's proportional hazard regression model

<sup>&</sup>lt;sup>c</sup>Controlling for region (South Asia, Southeast Asia and Africa) and for other variables listed in the table

<sup>&</sup>lt;sup>d</sup>Based on 2117 observations (165 events and 1952 censored for menorrhagia, 128 events and 1989 censored for other menstrual reasons, and 293 events and 1824 censored for total)

Our data suggest that women who have experience with combined oral contraceptives (COCs) in the previous month may be somewhat less likely than others to discontinue Norplant implants for menstrual problems. This may be because women were dissatisfied with the estrogenic side-effects or the need for daily compliance with COCs. One study of women using progestin-only oral contraceptives (POCs), Depo Provera or a levonorgestrel-releasing vaginal ring showed that women using POCs or a vaginal ring were less likely to discontinue if they had been using contraception previously, and recent experience of the same or a similar method had a particularly positive effect on the continuation rate [13]. However, in a study of New York City Hispanic women using Norplant implants, prior satisfaction with oral contraceptives did not predict success of failure with Norplant implants [14].

Our ability to interpret the variable in our analysis describing previous contraceptive use is limited, as it reflects the woman's contraceptive use only in the month before insertion. While our data suggest that switching from no previous use of contraceptives to Norplant implants may be one possible risk factor for early discontinuation of Norplant implants, we collected only one month of contraceptive history and did not ask women why they switched to Norplant implants. Therefore, with existing data, we can only speculate about the reasons for the statistical relationship between no previous contraceptive use and early discontinuation of Norplant implants. Further study of previous contraceptive use and Norplant implant acceptability is needed to help providers adequately assess contraceptive needs of their clients.

Women who reported an average menstrual flow duration of 1-3 days at baseline were less likely to discontinue for menstrual reasons than women with a longer average flow. Intuitively, it was believed that the opposite would occur (i.e. women experiencing shorter cycles before insertion would be more likely to discontinue use because of increased flow duration later on). One explanation for why women with longer flow duration were more likely to discontinue early for menorrhagia could be that women who have a longer duration of flow before Norplant implant use may be more likely to experience unacceptable disruptive menstrual patterns than women with regular or very short menstrual flow duration. Providers who counsel women about menstrual pattern changes and Norplant implant use should pay particular attention to women with a history of irregular menstrual flow duration, as they may be more adversely affected by menstrual disturbance than women with a history of regular flow. Another key point to consider is the possible clinical interaction between OCs/injectable use and short cycles. If women with short flow and women using OCs/injectables at baseline were the same group (likely physiological correlation), this finding may be substantiated.

On average, women in this study who discontinued for menstrual disturbance weighed slightly less than the other study participants at baseline. However, this variable was not found to be a risk factor for early discontinuation due to menstrual disturbance in our model. Other studies have reported conflicting data on the correlation between irregular bleeding and weight or body mass index (BMI). In one study, heavier women (65 kg) experienced a higher degree of amenorrhea than lighter women [9], but in another study [7], lighter women were more likely to

experience amenorrhea than heavier women. In a third study [14], lighter Chilean, Sri Lankan, and Filipino women had less intermenstrual bleeding than heavier women in China. Also, one study has shown no association between irregular bleeding and BMI [15]. These data suggest that weight or BMI is not consistently correlated with menstrual disturbance in Norplant implant users.

The Norplant implant system can disrupt normal menstrual cycles, but it is rarely associated with severe bleeding problems. As a side-effect, menstrual disturbance associated with Norplant implants has fewer medical than socio-psychological consequences. Many women have fears of side-effects, long-term health effects, pregnancy or infertility that may influence their acceptance of menstrual disturbance [16]. Unpredictable or prolonged bleeding or amenorrhea may not only be an inconvenience, but it may also frighten women who have had normal, predictable cycles before insertion. In addition, fears of pregnancy or future infertility may be heightened by amenorrhea. Counseling efforts designed to anticipate potential anxiety and to provide reassuring information could lessen fears about this, or any other method. For example, if short-term treatment for irregular bleeding is available at the provider clinic, a woman who is counseled before insertion about the availability of this treatment may tolerate bleeding episodes better. It should be noted that cultural or regional differences in how subjects responded to menstrual disturbance may exist, and that by pooling variables such as 'amenorrhea' or 'prolonged bleeding' from multiple regions in our model, we may have obscured some country differences in attitudes about bleeding.

When a woman chooses to use contraception, her motivation for doing so influences her choice of method and her subsequent compliance and tolerance for continued use [16]. One outcome of the decision to use contraception is how this choice is integrated with a woman's cultural values. Due to various cultural and religious differences seen in this trial, religious constraints on women during their menses may have affected the acceptance of the bleeding disturbances associated with the Norplant implant method.

Another potential effect of Norplant implant use may be how this method influences personal norms. Women who use Norplant implants may find they have forfeited their ability to prepare for and predict the onset and duration of bleeding days during their cycle for the benefits of contraception. For many women, Norplant implant use (or other hormonal use) may not be worth the inconvenience and distress of losing 'control' over their cycle. Some women may believe that an easily identified reason, such as menstrual disturbance, for discontinuation is more 'valid' than other concerns. Although this reasoning is not supported by this analysis, it is the authors' opinion that these issues warrant further study.

This analysis suggests that several factors may exist to predict early discontinuation of Norplant implant use due to menstrual disturbance – educational level, previous contraceptive experience and menstrual flow duration before admission. Other potential discontinuation factors that advocate more study include the following: user expectations/prejudices prior to use; the extent to which the user felt adequately informed about possible menstrual disruption; the availability of short-term treatment and the user's knowledge of this treatment; and the user's need to

prepare for and predict bleeding days. All of these factors could be greatly influenced by comprehensive counseling before insertion.

The results reported represent a hypothesis-generating analysis and require further specific analyses. Certainly, one limitation to the analysis is our interpretation of the results with respect to regional and cultural differences, which inherently introduces a certain degree of complexity. Some of the variables tested may have different connotations for one region or culture as opposed to another. Again, regional and/or cultural variations may have influenced our results, and these will be scrutinized in a follow-up analysis.

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### References

- The Population Council. Norplant levonorgestrel implants: A summary of scientific data. New York: The Population Council; 1990.
- Sivin I. International experience with Norplant and Norplant-2 contraceptives. Stud Fam Plann. 1988;19:81-94.
- 3. Croxatto HB. Norplant: levonorgestrel-releasing contraceptive implant. Ann Med. 1993;25:155-60.
- 4. Akhter H, Dunson TR, Amatya RN et al. A five-year clinical evaluation of Norplant contraceptive subdermal implants in Bangladeshi acceptors. Contraception. 1993;47:569-82.
- Balogh SA, Klavon SL, Basnayake S, Puertollano N, Ramos RM, Grubb GS. Bleeding patterns acceptability among Norplant users in two Asian countries. Contraception. 1989;40:541-53.
- 6. Basnayake S, Dunson TR, Krueger SL, Amatya RN. A five-year clinical evaluation of Norplant subdermal implants in Sri Lanka. Br J Fam Plann. 1994;19:269-74.
- 7. Shoupe D, Mishell DR Jr, Bopp BL, Fielding M. The significance of bleeding patterns in Norplant implant users. Obstet Gynecol. 1991;77:256-60.
- 8. Said AM, Youssef HH, Haroon AH, Souman ME, El-Hoseni M. Experience with Norplant in Zagazig, Egypt. In: Proceedings of the symposium on long-term subdermal contraceptive implants: Egyptian and international experience, February 23–24, 1984. Assuit, Egypt: Assuit University, 1984:28–39.
- 9. Liskin L, Blackburn R, Ghani R. Hormonal contraception: new long-acting methods. In: Population Reports. 1987, Series K, No.3.
- Fakeye O, Balogh S. Effect of Norplant contraceptive use on hemoglobin, packed cell volume and menstrual bleeding patterns. Contraception. 1989;39:265-74.
- 11. Kalbfleisch JD, Prentice RL. The Statistical Analysis of Failure-Time Data. New York: Wiley; 1980.

 Noerpramana NP, Rusbandi. Factors influencing attitudes about Norplant contraceptive subdermal implant. Adv Contracept. 1993;9:215–26.

- 13. Belsey EM. The association between vaginal bleeding patterns and reasons for discontinuation of contraceptive use. Contraception. 1988;38:207-25.
- World Health Organization. Contraceptives and Women's Complaints Preliminary Results from the 'Post-marketing Surveillance of Norplant'. WHO; 1990.
- 15. Pasquale S, Knuppel R, Owens A, Bachmann G. Irregular bleeding, body mass index and coital frequency in Norplant contraceptive users. Contraception. 1994;50:109–16.
- Boque D. Determinants of fertility in developing countries: fertility regulation and institutional influences (Vol. 2).
   Normative and Psychic Costs of Contraception. New York: Academic Press; 1983

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#### Resumé

L'objectif de l'analyse décrite ici était d'examiner les facteurs de risque déterminant l'abandon prématuré des implants Norplant à cause de troubles constatés au cours du cycle menstruel. Le modèle de régression proportionnelle de Cox a été utilisé pour calculer les ratios de risques ajustés qui refléteraient la relation entre les caractéristiques de sujets sélectionnés et le risque d'abandon prématuré dû aux perturbations du cycle menstruel. Environ 13% de la population étudiée avait abandonné les implants à la suite des perturbations constatées. A la fin de la deuxième année, le taux brut cumulé d'abandon dans la table de survie était de 9,4 pour 100 femmes, et ce taux était passé à 16,4 pour 100 femmes à la fin de la cinquième année. Les femmes ayant pris part à cette étude étaient d'autant plus susceptibles d'arrêter l'utilisation des implants Norplant en raison de troubles constatés au cours du cycle menstruel que leur niveau d'éducation était élevé (> 12 ans); elles n'avaient pas utilisé de contraceptifs durant le mois précédant l'insertion des implants, ou présentaient, au moment de l'admission, un flux menstruel de durée moyenne relativement longue. L'identification de facteurs de risque potentiel tels que ceux-là peut aider les services de contraception à mieux conseiller les femmes et à les préparer à l'emploi de la méthode d'implants Norplant.

#### Resumen

El objetivo del análisis presentado aquí fue examinar los factores de riesgo en el abandono temprano del implante Norplant debido a problemas menstruales percibidos. Se utilizó el modelo de regresión de riesgo proporcional de Cox para calcular las tasas de riesgo que reflejarían la relación entre características seleccionadas de sujetos con el riesgo del abandono temprano debido a problemas menstruales percibidos. Aproximadamente el 13% de la población estudiada abandonó el implante por problemas menstruales percibidos. Al final del segundo año, la tasa bruta acumulativa de tabla de vida de abandono correspondiente a los problemas menstruales percibidos fue del 9,4% y aumentó al 16,4% al final del quinto año. Era mucho más probable que las mujeres que participaron en este estudio abandonaran el uso del implante Norplant debido a problemas menstruales percibidos si tenían un nivel de educación más alto (12 años), no habían utilizado anticonceptivos el mes anterior a la inserción del implante Norplant o habían tenido una duración media relativamente larga del flujo menstrual al comienzo del estudio. La identificación de factores potenciales de riesgo como éstos podría ayudar a ofrecer una mejor orientación y a preparar a las mujeres para el uso del método de implante Norplant.