Continuation rates and reasons for removal among 976 Implanon® users accessing two family planning clinics in Queensland, Australia

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Abstract

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Background: This study examined demographic profile continuation rates and reasons for removal among Implanon® users accessing two family planning clinics in Queensland, Australia.

Study Design: A retrospective chart audit of 976 women who attended for for implant insertion over a three year period between May 2001 and May 2004.

Results: Continuation rates showed that at six months after insertion, 94% of women continued, 74% continued at one year, and 50% continued at two years. Metropolitan women were more likely than rural women to discontinue use because of dissatisfaction with bleeding patterns. Cox regression analysis showed that those attending the regional clinic experienced significantly shorter time to removal.

Conclusions: Implanon® continuation rates and reasons for removal differ between clinics in metropolitan and rural locations. A cooling off period did not affect the likelihood of continuation with Implanon®. Pre-insertion counselling should emphasise potential changes in bleeding patterns.

1. Introduction

The progestogen contraceptive implant, Implanon®, became available in Australia in May 2001. Many contraceptive options have historically bypassed the small Australian market, so this new method was rapidly embraced enthusiastically by women and doctors. Its potential advantages over available methods included high efficacy, the need for minimal maintenance, absence of oestrogen and rapid return to fertility after discontinuation. In the two years following its introduction around 10 000 doctors were trained in the use of the implant and almost 160 000 implants were inserted [1].

Although Implanon® is generally well tolerated, clinical trials have indicated that a proportion of women will discontinue use because of unacceptable side-effects, particularly frequent and/or prolonged irregular bleeding; with marked variations between countries. Discontinuation rates within the first 2 years of use were as high as 31% in Europe, Canada, Chile and Hungary to less than one percent of women in South East Asia [2, 3].

Counselling women on expected bleeding patterns has been shown to improve continuation rates for injectable and implantable progestogen contraceptives [4-9]. Acceptability of bleeding pattern changes or other side effects is probably only ever truly evidenced in continuation rates in the real life setting. Several audits [10-13] have examined data from UK clinics and found lower continuation rates than in clinical trials, although the rates were sufficiently high to support the use of implants as a cost effective method of contraception [11]. An Australian study suggested that about one third of users had the implant removed within 12 months of insertion [1].

To date there is only limited published data on the patterns of use and continuation rates of Implanon® users in Australia. This paper determines continuation rates and rationale for discontinuation among 976 clients attending two Family Planning Queensland (FPQ) clinics over a three year period.

2. Methods and materials

This study was designed to assess the demographic profile, the continuation rates, the lost to follow-up rate and reasons for removal among Implanon® users accessing two community based family planning clinics in Queensland, Australia. The study was undertaken as an internal quality assurance project and therefore did not require clearance by a human research ethics committee [14]. In May 2007 a retrospective chart audit was conducted of all clients attending the clinics for implant insertion and/or removal over a five year period between May 2001 and May 2006. The data presented in this paper pertains to the women for whom three years (the recommended duration of use for Implanon ® use) had been completed at the time of audit. FPQ provides around 24,000 sexual and reproductive health services to around 16,000 clients per annum across six centres in the state. The clinics chosen for the audit had the highest number of clients accessing clinical services – one of these is in Brisbane, the state capital (population 1.6 million) and the other is in a regional city (population 90,000) 200 km from Brisbane.

Case notes for all women attending the two clinics during the specified timeframe were reviewed for information relating to age, parity, indigenous status, country of birth, language spoken, weight, baseline menstrual pattern, most recent contraceptive use, date of Implanon® insertion, subsequent clinical consultations, reported side-effects, discontinuation and

rationale for removal. Women are routinely contacted by mail one to three months before the due date of removal and reminded about the need to remove the implant. No other attempt was made to contact women who had not returned to the clinic.

A total of 976 women had Implanon® inserted at the 2 clinics between May 2001 and May 2004. There were 209 women who had not attended the clinic since insertion and these women had only baseline data and were considered lost to follow up. The remaining 767 women were included in the survival analyses. In this group, 597 had a recorded removal. The date of removal was recorded for 580 while 17 had reported dissatisfaction with the implant but the date of removal was not documented. Among these 17 women a date of removal was estimated based on the last clinical visit. The remaining 170 women did not have a recorded removal during the follow-up period but had been seen in the clinic at one or more visits at which time their implant was still in situ and they are therefore included in the survival analyses. These data were used in the analysis as shown in Fig. 1.

Examination of the socio-demographic and clinical information of women for whom complete data was available showed few significant differences compared to the 209 women who were lost to follow up. Specifically, the two groups did not differ by age, country of birth or previous pregnancies. However, differences were noted with regard to baseline contraceptive use and menstrual history. Specifically, women for whom there was complete data were more likely to have regular menstrual cycles (81% compared with 73%) and to have used some other form of contraception at the time of insertion. There was no significant difference in the proportion of women lost to follow up between the metropolitan and regional clinics.

Data were analysed using SPSS version 15.0 (SPSS, 2006). Demographic and contraceptive history information was tabulated for the sample. Differences between discrete variables were tested with χ^2 test while comparisons between normally distributed continuous variables used *t*-test. Continuation rates were analysed using Kaplan Meier survival analysis. Cox regression was used to adjust for age, parity, geographic region and whether the implant was inserted on the day of assessment.

3. Results

Socio-demographic characteristics and other relevant clinical information including previous contraceptive use of the women attending either the metropolitan or regional family planning clinic are summarised in Table 1. Women attending the metropolitan clinic for Implanon® were generally older than women attending the regional clinic (M=27.4, SD=72, M=25.7, SD=8.0, t_{973}=3.48, p <0.01) and less likely to be Australian born. Women from the metropolitan clinic reported fewer pregnancies and fewer live births than women from the regional clinic. The metropolitan sample was also more likely to report contraceptive use prior to commencing Implanon®. The type of contraceptive use by women differed by clinic location. Specifically, regional women were more likely to have used the combined oral contraceptive while women from the metropolitan clinic were more likely to report condom use.

FPQ practice policy is that women requesting Implanon® attend an assessment visit where suitability for the implant method is assessed, information and prescription provided and a suitable time to return for insertion is discussed, allowing a “cooling off” between information provision and insertion. However for a range of clinical and practical reasons, the

implant will sometimes be inserted on the same day as the assessment. The average time between the assessment consultation and insertion was 15 days (SD = 20 days). Just over a quarter (27%; N = 260/976) of women had their implant inserted at the time of the assessment visit.

Kaplan-Meier survival analysis was performed to provide estimated continuation rates to three years, based on those 767 women with follow-up data. The survival curve is depicted in Fig. 2 and both the observed and the estimated cumulative continuation rates are presented in Table 2. At 6 months after insertion, 94% of women had Implanon® in-situ. Continuation rates showed that 74% continued at one year, 61% continued at one and a half years and 50% continued at two years. Only a small proportion of the sample (1.2%) continued beyond the recommended three years after insertion. Nearing the time of removal (2.5 years) around 42% of the sample was still using Implanon®. In over a quarter of known removals (28%; N = 164/597), women continued with the method, that is had a new implant inserted on the day of removal.

Reasons for premature discontinuation (defined as discontinuation at less than 2.5 years after insertion) of Implanon® were obtained from clinical case notes. Data are presented in Table 3. There were no pregnancies recorded in the 767 women who had an implant inserted at FPQ for whom follow up information is available. Metropolitan women were significantly more likely to discontinue use because of dissatisfaction with altered bleeding patterns alone, while regional women more commonly cited multiple reasons (including dissatisfaction with bleeding) for having the implant removed. Other common reasons for removal cited included desiring a pregnancy, contraception no longer being required, mood changes and weight gain. A proportion of women reported a considerable range of single ‘other’ reasons for

discontinuation including low libido, pelvic pain, headaches, mastalgia, arm pain, dislike of hormones or light menstrual flow. These are combined under the category of 'other' in Table 3.

Table 4 shows Cox regression analysis examining the factors associated with survival time. Several variables were examined including the influence of age at insertion, parity (number of live births), clinic (metropolitan vs. regional clinics) and whether or not the insertion occurred on the same day as assessment. The clinic where Implanon® was inserted was the only significant covariate, with a hazard ratio of 0.77 (95% CI: 0.64 - 0.92). In other words, the location of the clinic significantly impacted survival time. Those who attended the regional clinic experienced significantly shorter survival times (or time to removal). However, survival time was not impacted by age, parity or a "cooling off period" between assessment and insertion.

4. Discussion

This study examined continuation rates of the contraceptive implant Implanon® and reasons for early discontinuation. As expected, lower continuation rates for the method were seen than those in clinical trials where overall > 80% were still using the implant at two years [3]. Strict inclusion criteria in clinical trials tend to bias towards a willingness to continue with regular follow up visits, free supplies and health services serving as positive reinforcement to continuation. Implanon® continuation rates in this Australian study of 74% at one year and 50% at two years are consistent with findings from a review of evidence from real use settings in the UK and Europe which concluded that 20-25% and up to 44% of women will

discontinue within one year and two years respectively [15]. Continuation rates at three years are more difficult to determine as implant users are generally advised to have routine implant removal before the three year expiry date. In this study 42% of women still had the implant in situ at 2.5 years and only 13% at three years; removal beyond 2.5 years was not considered early discontinuation. A study of 329 users of Implanon in Scotland [11] used 2 years 9 months as an end point and found a comparable rate of 47% of women continuing with the implant at that point. At one year continuation rates are similar to those reported with intrauterine methods (73-91%) and higher than those for injectable (56%) and oral methods (32-68%) [15]. A detailed cost analysis of all contraceptive methods and concluded that despite their high initial purchase price implants are more cost effective than the combined oral contraceptive pill, even after one year of use [15]. In Australia, the government funds the majority of cost of an implant via the Pharmaceutical Benefits Scheme. The cost to women of the implant purchase is low and the same as, or less than, four months oral contraceptive pill supply; however there is no published cost analysis in the Australian setting of other contraceptive methods.

Bleeding pattern dissatisfaction was the commonest reason for premature discontinuation which is consistent with clinical trials and other audits [4, 13]. There were 168 out of 337 (50.6%) women across both clinics who reported abnormal bleeding as the main reason for premature removal. The difference in recorded reasons for premature removal between the two clinics may explain the overall finding that clinic location was the only variable associated with survival time. In this study a “cooling off period” between information provision at a separate assessment visit and insertion was not found to alter the likelihood of continuation.

This study has several methodological limitations. First, data were collected through a clinical audit and therefore the quality of data relied on information previously gathered during clinical consultations. In this study, data quality and consistency was related directly to the information that was recorded and then able to be retrieved from the clinical chart. Moreover, data relied on patient attendance and in some instances patients did not return after insertion. Overall, one-fifth (21%, N = 209) of the charts contained incomplete information and data from these charts were excluded from the survival analyses. This may have influenced the quality of the data leading to bias [16]. The analysis suggested, however, that women for whom there were complete data, in many instances, did not differ from those who were lost to follow-up. Two exceptions were noted; women who were lost to follow-up were less likely to have regular baseline menstrual cycles or to have used contraception prior to Implanon® insertion.

It is difficult to draw definite conclusions from this audit on the differences found between the two clinics in user demographics, continuation rates and reasons for removal. Whether this reflects differences in the clinic settings more generally, variations in initial counselling provided by the individual service providers, their management strategies with altered bleeding patterns, their clinical record keeping practices or characteristics of women themselves in the two different settings is unclear and could be the subject of further research. Previous studies have found that improvements in continuation rates for long term methods may be associated with both provider characteristics [6, 17] and counselling strategies being tailored to a woman's personal context [8].

Despite the limitations associated with the data collection method, this audit provided an opportunity for Family Planning Queensland to review current clinical practices and the

information provided to patients when considering Implanon® as a contraceptive choice; specifically on expected continuation rates and common reasons for premature removal in the Australian setting. Policies around the timing of assessment and insertion visits will now recognize that if clinically appropriate, inserting an implant on the day of assessment (with no interval "cooling off period" to consider the information) is not associated with premature discontinuation. The audit also provides local data for other doctors in Australia to include in their counselling of women about the method.

Overall, this study found that Implanon® has continuation rates in Australia very similar to settings in Europe and the United Kingdom. These continuation rates are higher than those for injectable and oral hormonal methods, which combined with its low failure rate and minimal maintenance makes it a viable and cost effective method to be offered to women. However, a proportion of women continue to have the implant removed, most often due to altered bleeding patterns. This supports the need for pre-insertion counselling to specifically emphasise the potential changes in bleeding patterns that may be expected from this form of contraception.

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Figure 1. Flow chart showing number of insertions, loss to follow up, and women eligible for inclusion in the survival analysis.

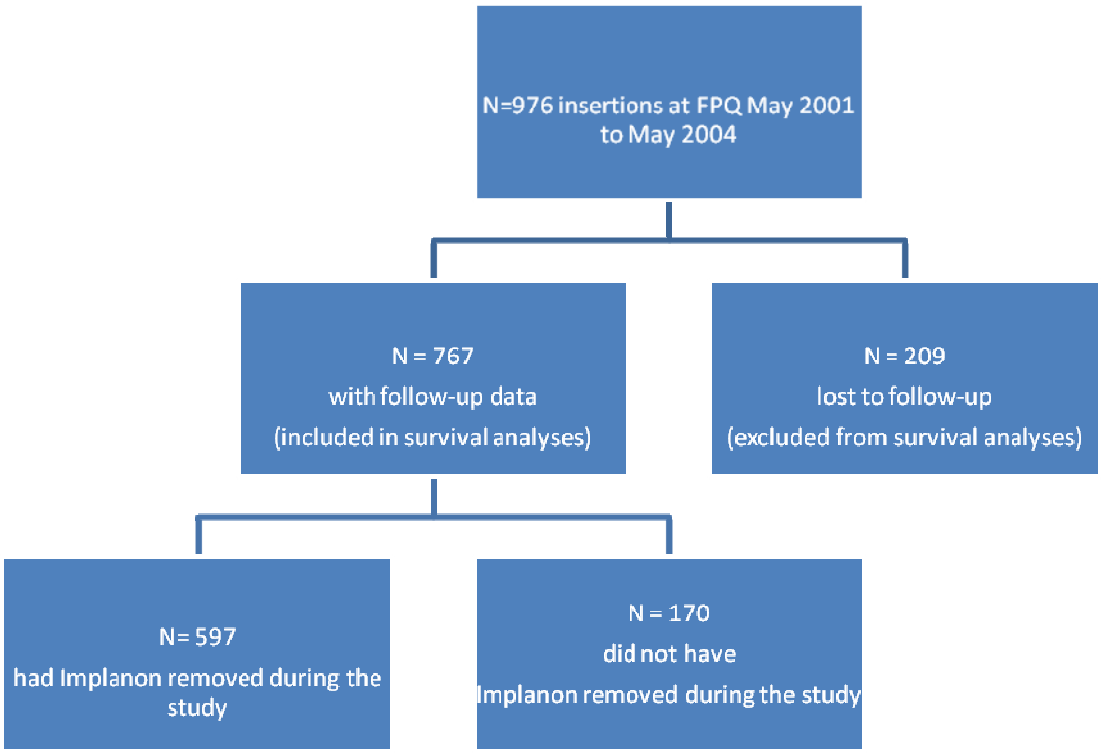

Figure 2. Survival analysis curve for Implanon® users over three years

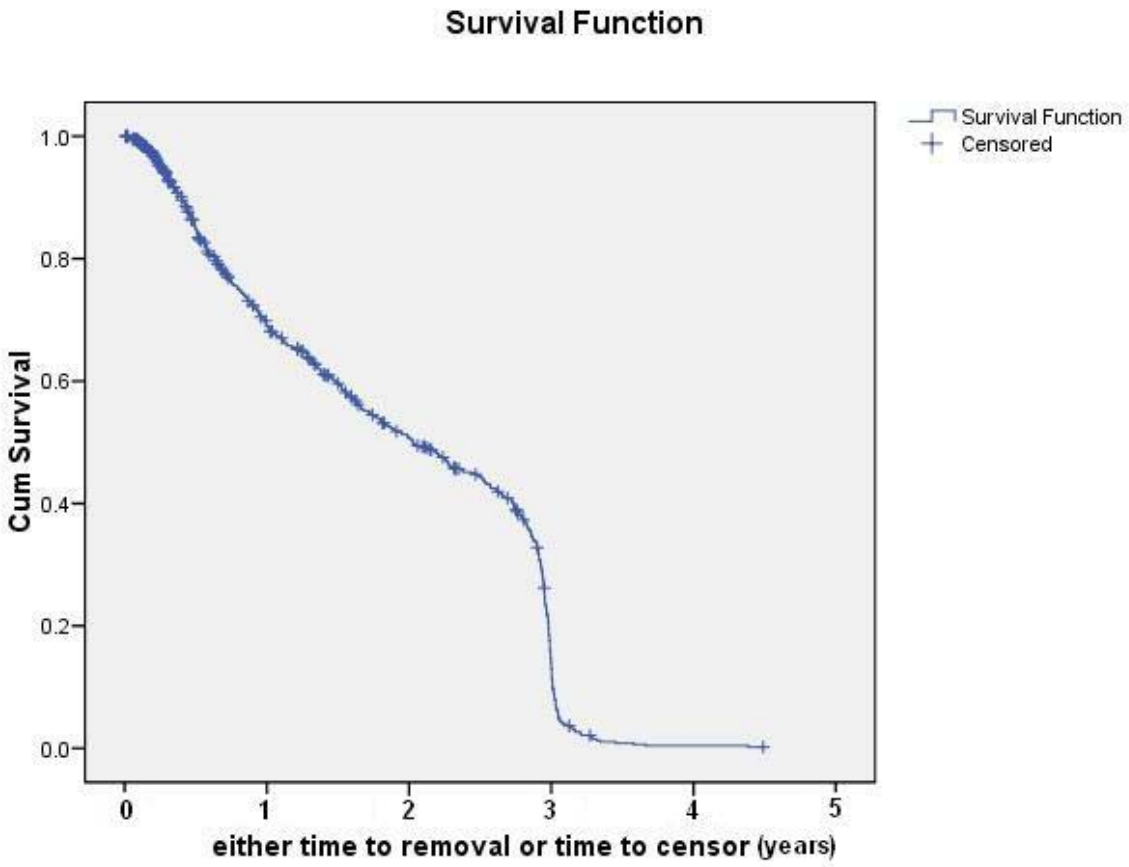

Table 1. Socio-demographic characteristics and past contraceptive use of women attending two different family planning clinics in Queensland, Australia

	Metropolitan (N = 629*)		Regional (N = 347†)		χ^2	p value
	n	%	n	%		
Born in Australia	479	76	330	95	55.61	<0.01
Pregnancies						
0	260	44	137	41	9.67	0.05
1	130	22	56	17		
2	96	16	72	22		
3	53	9	31	9		
4 or more	46	8	38	11		
Live Births						
0	363	62	169	51	15.67	<0.01
1	83	14	48	14		
2	96	16	73	22		
3	28	5	25	8		
4 or more	15	3	18	5		
Regular baseline menstrual cycle	481	79	256	79	0.02	0.90
Contraception at baseline						
COCP	186	31	117	37	12.84	<0.01
Condoms	219	36	86	27		
Other[§]	118	19	53	17		
Nil/Not required	85	14	63	20		

[*] Information on pregnancies and live births missing for 44 women, percentages based on N = 585; information on regular baseline menstrual cycle missing for 23, percentages based on N = 606; information on baseline contraception missing for 21, percentages based on N = 608.

† Information on pregnancies missing for 13 women, percentages based on N = 334; information on live births missing for 14 women, percentages based on N = 333; information on regular baseline menstrual cycle missing for 23, percentages based on N = 324; information on baseline contraception missing for 28, percentages based on N = 319.

[§] includes 3.0% (n = 21) using "withdrawal"

Table 2. Estimated cumulative continuation rates (N = 597*)

Time	Number of discontinuations	Cases remaining with Implanon	Observed cumulative continuation rate	Estimated cumulative continuation rate	Standard Error of the estimated continuation rate
6 months	34	563	0.943	0.848	0.014
1 year	157	440	0.737	0.691	0.018
1.5 years	233	364	0.610	0.596	0.019
2 years	297	300	0.503	0.506	0.020
2.5 years	345	252	0.422	0.444	0.020
3 years	521	76	0.127	0.139	0.015
3.5 years	593	4	0.007	0.008	0.004
4 years	596	1	0.002	0.004	0.003

* Estimated cumulative continuation rates based on Kaplan-Meier analysis of those 767 women with follow-up data.

Table 3. Reasons for early discontinuation[1]

Reason	Metropolitan		Rural		p value
	n	(%)	n	(%)	
Excess bleeding only	109	56.2	57	41.3	0.01
Multiple reasons, including bleeding	12	6.2	34	24.6	< 0.01
Desiring pregnancy only	16	8.2	10	7.2	0.74
Mood changes only	16	8.2	3	2.2	0.02
Contraception no longer required only	9	4.6	7	5.1	0.86
Multiple reasons, not including bleeding	6	3.1	10	7.2	0.08
Weight gain only	9	4.6	4	2.9	0.42
Other	17	8.8	13	9.4	0.84

[1] N=332 women who discontinued early had a recorded reason for removal. Early discontinuation was defined as removal prior to 2.5 years. There were no pregnancies recorded in the women who had an implant inserted at FPQ for whom follow up information is available.

Table 4. Cox proportional hazard regression analysis of discontinuation rates

Variable	**Coefficient**	**Hazard ratio (95% confidence interval)**	**p value**
Age at insertion	-0.01	0.99 (0.98 – 1.01)	0.42
Parity	-0.04	0.96 (0.88 – 1.04)	0.35
Clinic location	-0.27	0.76 (0.64 – 0.92)	<0.01
Insertion on day of assessment	0.01	1.00 (0.99 – 1.01)	0.65