An assessment of the use of Implanon® in three community services

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Abstract

Aims. *The aims of the study were three-fold, namely to assess continuation rates with Implanon® fitted in clients from three contraception and sexual health services; to identify factors associated with early removal of Implanon®; and to assess clinician compliance with recommended practice in counselling and insertion*

Methods. *Retrospective review of client records, and comparison with audit criteria. Postal survey.*

Main findings. *One hundred and ninety women had Implanon® inserted in the study period. Continuation rates were between 84% and 88% at 6 months and 67% and 78% at 12 months. There were no pregnancies or procedure complications. The main reasons for removal were identified as intolerance of recognised side effects or a change of mind about wanting contraception. Younger women were more likely to have the device removed early. There was evidence of excellent or good recording of many criteria for best practice in counselling and insertion. The assessment highlighted certain issues around counselling and insertion that services needed to consider further.*

Conclusions. *The three services have been reassured that they are providing a good standard of care to clients requesting Implanon® and that their 'real life' 6- and 12-month continuation rates are reasonable.*

Key message points

- Implanon® is a highly effective method acceptable to the majority of women who chose it.
- 'Real life' 6- and 12-month continuation rates were reasonable compared with the research studies for this device.
- Prior to insertion, adequate assessment of motivation and counselling on the advantages and disadvantages of the method, plus management of side effects, is recommended.

Introduction

The single rod, progestogen-only contraceptive implant, Implanon®, delivers highly effective contraception over 3 years.[1,2] Studies indicate that it is well tolerated by users and that continuation rates are high.[2,3] Although it has a high initial cost it is cost effective based on continuation rates in clinical trials subjected to sensitivity analysis.[4]

Implanon® was introduced into three community services informally linked by the authors soon after the official UK release. A year later clinicians raised concerns about the perceived frequency of early Implanon® removals.

An audit was initiated across the three services to assess the early removal rate and identify any factors recorded in the notes associated with early removal of the device. The audit also aimed to assess clinician compliance with recommended practice in counselling, insertion and removal.

Methods

With reference to the available literature on recommended practice,[5] clinicians in each service drew up compatible guidelines for counselling and administration of Implanon®.

Using the guidelines and literature review,[2,3,5–7] standards for effectiveness, continuation, and procedure complication rates were set and a list of criteria that clinicians counselling and administering Implanon® need fulfil were drawn up. Characteristics routinely recorded in clients' notes that could be checked for an association with early removal were identified.

The notes of service users who had undergone an Implanon® procedure between the date when Implanon® was introduced into each service and 31 December 2000 inclusive were reviewed after 30 June 2001 and assessed against the standards and criteria. This ensured that there was a minimum of 6 months' data for each user.

In addition to information about continuation of the method obtained from follow-up visits detailed in the notes, subjects whose notes indicated correspondence home was acceptable were contacted by letter after 30 June 2001 and asked whether or not they had continued with Implanon®. A freepost envelope was provided for their response.

A pilot on five sets of notes was initially undertaken in North Derbyshire and the record sheet was modified accordingly.

Coded data were analysed with the assistance of Excel software. Additionally, rates of continuation were computed on SPSS using survival analysis (Kaplan Meier) techniques[8] and associations between the time to removal of the device and other factors were investigated using Cox regression analysis.[9] These methods enable as much information from previous follow-up appointments as possible to be used from those subjects where it was not known at the end of the study whether or not they had continued with Implanon® (censored observations).

Results

Service and client characteristics

A total of 190 clients had Implanon® fitted during the study period, 100 in North Derbyshire clinics, 63 in Central Nottinghamshire clinics and 27 in Doncaster. Clients' ages ranged from 13 to 51 years with a median of 24 years. Eighty-six women were nulliparous (55 nulligravid). Parity

was unrecorded in three cases, and ranged from one to eight with a median of two in the other 101 women.

Most women (173) self-referred. Eleven were formally referred by their general practitioner (GP) and six by another health care worker.

Current and previous contraception. Information about current method used when transferring to Implanon® was recorded in 187 cases. Most clients were using either condoms 46 (25%), injectables 42 (22%), the combined pill 36 (19%) or Norplant® 25 (13%).

Information about the previous method used was recorded in 174 cases. One hundred and thirty-eight women (79%) had used another method previously, most frequently the combined pill 76 (55%).

Reason for choice of Implanon® recorded in notes. The main reason for choosing Implanon® given to the clinician was recorded in 105 cases. Twenty-three (22%) were previous happy Norplant® users, 21 (20%) wanted a method that required no personal intervention, and 14 (13%) wanted a long-term method. Other less frequent reasons for choosing Implanon® included client choice, hidden method, effectiveness, recommendation by a friend, less chance of weight gain and fewer clinic visits.

In 23 (22%) cases the reason recorded implied an element of choice by default: either no alternative was perceived as suitable or they had experienced problems with other methods.

Number of days between counselling and insertion. The number of days between the initial counselling session at the community clinic and the insertion varied from between 0 to 350 days with a median of 14 days. One-third of clients (61/190, 32%) had the implant inserted on the day of their first counselling visit.

Effectiveness, continuation, and procedure complication rates

Pregnancies. There were no method failures. One client was found to be pregnant at first follow-up. Gestation calculation revealed that she must have been pregnant before the implant was inserted.

Procedure complications. There were no known procedure complications. Two infections occurred: one a wound infection in a client who had an Implanon® inserted through the same incision as a difficult Norplant® removal and the other a suspected infected Implanon® site occurring 6 months after insertion.

Continuation rates. One hundred and seventy-one women were sent the postal survey. Seventy-five women responded (44%).

At 6 months 97 clients had definitely continued with Implanon® and 22 had definitely had their implant removed. The implant status of 71 was unknown. Assuming none had Implanon® removed elsewhere the 6-month continuation rate would be 88%. Survival analysis gives a 6-month continuation rate of 84%.

By the end of the study period 95 clients had the Implanon® fitted at least 12 months previously. At 12 months 40 had definitely continued with Implanon® and 21 had definitely had their implant removed. The implant status of 34 was unknown. Assuming none had Implanon® removed elsewhere the 12-month continuation rate would be 78%. Survival analysis gives a 12-month continuation rate of 67%.

Factors associated with early removal

At the end of the study period 43 implants had been removed, 40 (93%) in the three services and three (7%) by the clients' GP. The main reasons for removal recorded in the notes (known in 41 cases) are detailed in Table 1.

No significant relationship was found between time to removal of Implanon® and parity, current contraception or gap between counselling and insertion. A relationship was found between age and time to removal. There was an 8% decrease in the risk of removal for every year increase in age (p = 0.001; hazard 0.92; 95% CI 0.87–0.97).

Comparison with audit criteria identifying best practice in counselling and administering Implanon®

There was evidence of a good level of recording in the notes of:

- Counselling session 171/190 (90%).
- Blood pressure (BP) prior to insertion 162/190 (85%).

Table 1 *Reason for Implanon® removal in 41/43 removals*

Reason	Frequency (n)			Total (%)
	First reason	Second reason	Third reason	
Bleeding problems	13	1		14 (34)
Mood swings	2	7	1	10 (24)
Headaches	4	2	1	7 (17)
Weight gain	4		1	5 (12)
Wishes to get pregnant	3	1		4 (10)
Depression	1	1	1	3 (7)
Acne	1	1	1	3 (7)
Infected injection site	2			2 (5)
Patient or partner sterilised	2			2 (5)
Pain in arm	1		1	2 (5)
Abdominal pain		2		2 (5)
Breast tenderness		1	1	2 (5)
Low sex desire			2	2 (5)
Tiredness		1	1	2 (5)
Other[a]	8	2	1	11 (27)

[a]Includes perceived swelling in arm, urticaria, generally unwell, diarrhoea, pregnant, breast lump, nausea, hair loss, joint pain, or a wish for user-controlled method.

- Batch number of inserted device 179/190 (94%).
- Arm of insertion 153/190 (81%).
- Follow-up appointment within 3 months given in appropriate cases 183/184 (99%).
- General enquiry recorded at first follow-up 114/121 (94%).

Issues that the services needed to consider further were as follows:

- Only 34% (120/190) had recorded evidence of a medical history check within the past 12 months.
- Only 31% (58/190) had recorded evidence of the expiry date of the inserted device.
- A total of 56% (73/130) had recorded evidence that the '7 day rule' for additional contraception for 7 days after insertion was explained when appropriate.
- The default rate from first follow-up was 49% (90/184)
- BP was recorded in 50% (61/121) at first follow-up.
- A total of 66% (80/121) had recorded evidence of an injection site check at first follow-up.

Discussion

Service and client characteristics

The number of insertions in each service will be influenced by differences in the date of introduction of Implanon®, the number of implant trained staff, the clinic population (annual attendance) and financial considerations.

A prospective study would provide more robust information regarding reasons for choosing Implanon®.

Effectiveness, continuation, and procedure complication rates

The effectiveness and procedure complication rates found in our study were comparable to those in clinical trials.[5,7]

Continuation rates in clinical trials with high follow-up rates are between 94.75% and 90% at 6 months and between 88.3% and 80% at 12 months.[2,3] In common with other 'real life' estimates of continuation rates our results have suffered because of the high default rate from follow-up.[10]

Our survival curve continuation rates are lower than those found in these trials. Most local Implanon® trainers were working in the three services. It is, therefore, unlikely that many of the defaulters from follow-up had their implant removed elsewhere and the true continuation rates are likely to be higher. Excluding the defaulters from the analysis would also give an underestimate of continuation rates. It is feasible that clients who returned for follow-up and/or who responded to the postal survey included more who had problems, and that defaulters were happy with the method and perceived no reason to return to the clinic or find time to answer the survey. Defaulters also include those that have moved out of the area. If time and financial considerations permitted, reanalysis of this cohort after 3 years' potential use would give more accurate continuation rates. More of the defaulters from first follow-up and those who had returned for initial follow-up but had not returned since would probably have attended. Our continuation rates are reasonable, given that they represent 'real life' use of the method free from the rigorous exclusion criteria and follow-up in clinical trials.[2,3]

Factors associated with early removal

As identified in prospective studies, the main reasons for removal in the present study were recorded as intolerance of recognised side effects or with a change of mind about wanting contraception.[3,11] Mood swings were particularly poorly tolerated in our population.

The present study is retrospective and descriptive so there is no evidence to indicate that the association between younger age and early removal is causal. However, it is unsurprising that some relationship was found. Compliance with contraceptive usage in younger women is often poorer than in older women.[12] It is affected by many determinants, which include attitudes to sexuality, socioeconomic and environmental factors, access to sex education, confidentiality, cycle control of contraceptive method, adverse publicity about methods and misconceptions about side effects.

Studies indicate that continuation and user satisfaction rates are high among those who have undergone detailed pre-insertion counselling, in spite of the fact that users report a significant incidence of side effects.[6] Although most records in the present study contained evidence that a counselling session had occurred, it was impossible to assess the content and effectiveness of such counselling, which would require a qualitative study of perceived and actual effectiveness. These facts do, however, highlight the importance of assessing motivation, the requirement for 2–3 years' contraception, stressing the advantages, and careful counselling on possible bleeding patterns, side effects and symptomatic treatments available for unacceptable bleeding patterns.[13] It must be acknowledged that people's personel circumstances may change and even perfect counselling about possible side effects cannot take the place of the actual experience of them.

Although clients having Implanon® inserted on the day of their counselling session were not more likely to have it removed early, a gap between counselling and insertion will enable clients to reflect on the information they had been given and to read an appropriate leaflet. However, the possible benefits of a gap between counselling and insertion need to be balanced against the risks of an unplanned pregnancy during such a gap.

Comparison with audit criteria identifying best practice in counselling and administering Implanon®

The results were presented and discussed in the respective services.

Each service is reviewing ways to assist staff in recording pre-insertion history checks.

Although not a legal requirement, it is considered good practice to record the expiry date of any inserted device. The services also decided that it should be usual practice to record that the '7 day rule' has been explained in appropriate situations. Discussion and dissemination of the guidelines resulting from this audit could resolve differences between doctors in what should be explained and documented, in different situations.

The high rate of default from follow-up raised the issue of wasted appointment times. Although a formal, cost-effectiveness analysis of this policy was not performed, services decided that best practice would be to continue to arrange follow-up to allow for discussion, reassurance and management of minor problems before they potentially became troublesome enough to lead to a request for early removal. The other issue raised was the possibility that a significant proportion of women may not return at 3 years for scheduled removal. Taking into consideration the response rate of the postal survey, the individual services are currently deliberating whether to proactively contact those who do not return for removal after 3 years or to leave the responsibility to the client.

Because Implanon® does not appear to have any clinically important effect on BP,[2,14] the services decided

that BP should continue to be checked prior to insertion but only annually at follow-up, unless specifically indicated.

In view of the number of removals associated with complaints of weight gain, the services decided to add to their guidelines that a baseline weight and body mass index (BMI) should be recorded prior to insertion.

Conclusions

This assessment has confirmed Implanon® to be a highly effective choice. Implanon®'s long duration of action and freedom from user intervention help to make it acceptable to most women who choose it.

The 'real life' 6- and 12-month continuation rates are reasonable in comparison with those found in clinical trials prior to the introduction of Implanon®.

The results have reassured the three services that they are providing a good standard of care to clients requesting Implanon® and have highlighted areas for improvement.

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A study on the knowledge and practice of contraception among men in the United Arab Emirates

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Abstract

Objective. *To determine the knowledge and practice of contraception among United Arab Emirates (UAE) men.*

Design. *Cross-sectional survey.*

Participants. *Four hundred UAE monogamously married men with children.*

Method. *The participants were randomly selected from the community and interviewed about knowledge and practice of contraception using a structured questionnaire.*

Results. *A total of 348 men (87%) gave consent to participate in the study. Two hundred and ninety-four participants (84.5%) were aware of the availability of male contraceptive methods but only 94 (27%) were currently using these methods; 39 (41.5%) used condoms, 30 (31.9%) practised coitus interruptus, 24 (25.5%) practised the rhythm method and only one (1.1%) had been sterilised. Male contraception was accepted by 116 (33.3%) subjects of the total study population. The reasons for the objections*