Offering extended use of the combined contraceptive pill: a survey of specialist family planning services

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Background: The purpose of this study was to determine attitudes to, and provision of, extended regimens for taking the combined oral contraceptive pill (COC) by specialist contraception practitioners from three contrasting specialist contraception services in London.

Methods: An online cross-sectional survey was administered to all doctors and nurses, who counsel, provide, or prescribe the oral contraceptive pill at each clinic.

Results: A total of 105 clinicians received the questionnaire and 67 (64%) responded. Only one of three clinics initiated and maintained guidelines for extended COC use. In that service, 60% of staff prescribing COC advised more than 50% of patients regarding alternative COC regimens. In the other two services, this was discussed with 20% and 6% of patients, respectively (P < 0.001). The reasons for prescribing extended use included cyclic headaches, menorrhagia, patient request, menstrual-related cramps, and endometriosis, and did not differ between the three different settings. The most common extended regimens were 63 pills or continuous use until bleeding occurs, followed by a hormone-free interval. Concerns highlighted by providers and patients were "unhealthy not to have a monthly bleed", "future fertility", and "breakthrough bleeding". Such comments highlight the need for further information for providers and patients.

Conclusion: There is growing evidence, backed by national guidance, about extended COC use, but routine provision of this information is patchy and varies ten-fold, even within specialist family planning services. Targeted training, use of service guidelines, and implementation research will be needed to extend patient choice of different COC regimens and change clinical

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Introduction

When the combined oral contraceptive pill (COC) was introduced over six decades ago, 1,2 it was designed to be taken in a regimen that mimicked the normal menstrual cycle. This requires active pills to be taken for 21 days followed by 7 days without hormones, resulting in a withdrawal bleed. It has been common practice for many years to prescribe modified pill-taking regimens if unwanted symptoms such as withdrawal headaches³ or painful menstruation^{4,5} occur during pill-free days. These modified regimens entail taking active pills for more than 21 days and/or shortening the hormone-free interval. Such regimens are commonly termed tricyling, extended, or tailored use of the pill.

More recently, interest has focused on tailored or extended COC regimens for reasons of individual preference.⁶ Evidence suggests that many Western European

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women would prefer either amenorrhea or a longer interval between periods.^{6–12} More than 90% of health care providers also support extended pill use.^{13,14} In a previous study where pills were prescribed for 84 days followed by a 6-day, pill-free interval,¹² 82% of the participating women welcomed having fewer periods and many found the regimen easier to follow.

The Clinical Effectiveness Unit of the Faculty of Sexual and Reproductive Health, which publishes guidelines for recommended standards in contraception provision, endorses the prescription of extended COC use in its most recent COC prescribing guideline, ¹⁵ although cautions this as an off-license use of the product. ¹⁶ Whilst extended use is viewed as acceptable, there is no clear consensus over which of the many different extended regimes in use is preferable. It is also unclear what knowledge practitioners hold about extended pill regimes, to what extent these are being used in routine practice, and which various regimens are being used most frequently.

In the UK, contraception is provided by general practitioners and through specialist contraceptive services. The latter are also responsible for training doctors and nurses in contraceptive care, so play a key role in promoting innovation, service improvement, and delivering "gold standard" ¹⁷ contraceptive care. We wanted to ascertain whether extended use was common or routine practice in these specialist settings, and whether there was significant variation in prescribing characteristics across different clinics. To explore these questions, we selected three specialist contraceptive services out of 15 Faculty of Sexual and Reproductive Health registered services providing training in London which are expected to be "early adopters" of innovation in practice, namely, counseling women about extended use of oral contraception. We used purposive sampling (based on known service characteristics) with the intention of revealing a range of clinical practice across specialist services, rather than aiming for a representative sample.

Materials and methods

We selected three contrasting specialist contraception services in London which had varying policies on extended COC use: the Margaret Pyke Centre, chosen immediately following the clinic's involvement in a study of extended COC use; the Enfield clinic, where a guideline on extended pill use had been introduced in association with staff training (2010); and King's College Hospital, which is an example of a newly developed fully integrated and forward-looking

service, but where extended use of the COC has not been formally introduced. In April 2012, we invited all doctors and nurses in the three services who prescribe, counsel, or provide the COC to complete an adapted¹⁸ online survey (https://docs.google.com/spreadsheet/viewform?formkey=d DhTRnUwcmtvS0xXYTF5Q2EzOWZhTlE6MQ). The link was distributed through a designated staff member at each of the three locations. The questionnaire was pilot-tested in the study of Gerschultz et al. ¹⁸ The average intraclass correlation was 0.69 (range 0.30–1.00), showing good reliability.

We asked about frequency of COC prescription, the reasons and conditions for which extended use would be considered, their preferred regimens, and any concerns expressed by patients or staff regarding extended use. We excluded 24/4 or 26/2 regimens (24 or 26 consecutive pill days followed by 4 or 2 pill-free days) as none were available at any of the three clinics at the time of the survey.

Follow-up reminders were sent on two occasions to increase the response rate. We present descriptive analyses of knowledge and provision of extended pill use, and the relationship between participant characteristics and prescribing patterns. All comparisons were made using Fisher's exact test. Odds ratios were calculated to estimate differences between clinics in providing information to patients about the extended use. All analyses were performed using Stata/SE 12 (Statacorp, College Station, TX, USA).

Results

Characteristics of sample

A total of 67/105 (64%) doctors and nurses completed the survey. Out of these, nine of the 38 staff who did not respond were locum doctors, and six respondents could not comment on extended use in the survey because, having come from a stand-alone genito-urinary medicine service, they had not been trained to prescribe oral contraceptives.

Of those who provided COC, 84% had ever provided information to women about extended use. However, only 29% offered this information to more than half of their patients and this proportion varied ten-fold across the three clinics (P < 0.001). There was no difference between behavior of doctors and nurses, but frequent counseling about extended COC use was more likely to be provided by younger clinic staff and in the clinic that had developed specific local guidance. No other factors, such as age, ethnicity, or gender of health care professional were significantly different between those who prescribed extended use compared with those who did not (see Table 1).

Reasons for prescribing extended cycling regimens

Clinicians gave a variety of reasons for prescribing extended pill regimens. These included 62% of clinicians who would prescribe if patients want to miss a bleeding because of a holiday, examination, or for cultural reasons (for patient preference, Figure 1). There was likely to be an overlap between giving patient preference as a reason for prescribing and all the other reasons given in Figure 1. One participant commented that:

"Patients seem to like the option of more than one way to take pills especially when going on holiday, travelling to a hot country, or taking exams and removing the period pain and PMT symptoms.

"Patients are reassured in the knowledge that this is not harmful."

There were no significant differences in the reasons given between the different clinics, and so data from the three clinics were combined.

Types of extended regimens prescribed

A wide range of different regimens was prescribed, of which the most common was taking three pill packets together followed by a pill-free interval, or "tricycling" (Figure 2). However, there was variation in recommended length of the pill-free interval following the 63 consecutive days of pill-taking. Twenty survey participants advised a 3-day, pill-free interval (63/3 cycle) most commonly, 14 recommended a longer pill-free break of

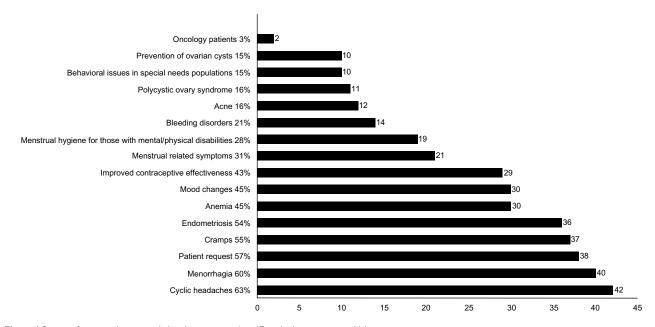
7 days, and three recommended a 4-day or 5-day break, while 12 survey participants did not specify a recommended length of break. The 63/3 regimen was regarded as simple to explain to patients, with the added benefit of greater contraceptive efficacy by shortening the hormone-free interval.

Four of five respondents stated that the lack of a monthly bleed was the most common concern raised by their patients, followed by concerns about fertility (41%) and breakthrough bleeding (38%). Overall, 34% of respondents felt more comfortable prescribing the standard 21/7 regimen for the COC, mostly because of lack of familiarity with other regimens. There was a desire for more evidence on prescribing recommendations, including the long-term effects of extended COC use, and for better information leaflets for users.

Discussion

Our findings show that routine use of extended COC regimens is generally low, but highly variable between settings even in the context of specialist contraceptive services. However, reasons for prescribing extended use were more uniform across the three sites and respondents expressed a desire for more knowledge and guidelines about extended use. Development of local clinic guidance does seem to have had a positive influence on extended COC prescribing in this context, although it is well known that guidelines alone often have little impact on practice.¹⁹

This was a small study of London-based clinicians that limits the generalizability of our findings. The response



 $\textbf{Figure I} \ \ \text{Reasons for prescribing extended cycling regimens (n=67: multiple answers possible)}.$

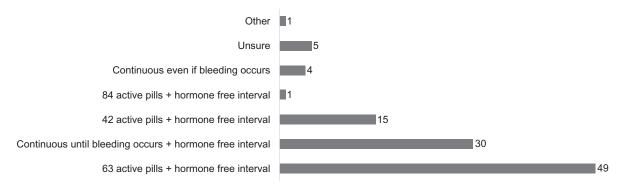


Figure 2 Type of extended regimens prescribed.

rate was lower than expected at 64% (which partly reflects non-response from locum doctors) and varied across settings, which limits the potential for cross-site comparisons especially in view of the small sample size. Furthermore, some clinical staff working in fully integrated services but previously working for a genito-urinary medicine service had not had the training to provide contraceptives.

Despite evidence from other studies that an increasing number of women would prefer to menstruate less frequently,⁶ most clinicians believe that the commonest concern among

Table I Characteristics of the sample (n = 67)

Characteristic	n, (%)
Age, years	
25–39	21 (31)
40–49	14 (21)
50–59	18 (27)
60–74	14 (21)
Sex	
Male	6 (9)
Female	61 (91)
Setting	
Camberwell clinic	
Doctors	12
Nurses	9
Enfield Clinic	
Doctors	10
Nurses	11
Margaret Pyke Centre	
Doctors	15
Nurses	10
Prescribed COC	
Ever	61 (91)
Never	6 (9)
Prescribed COC for extended cycle	
Ever	51 (84)
Never	10 (16)
Proportion of patients offered extended COC use	
≤10%	26 (43)
11%–50%	17 (28)
>50%	17 (29)

Abbreviation: COC, combined oral contraceptive pill.

patients using extended cycles is that "it is unhealthy not to have a monthly period". In a recently completed randomized trial of extended versus standard use of an COC containing 0.03 mg ethinylestradiol and 0.15 mg levonorgestrel,²⁰ we showed that tailored pill use suited some women very well and was an acceptable alternative to the standard pill. Qualitative interviews conducted during the trial²¹ showed that reduced bleeding on extended use clearly suited some women very well, while others disliked the unpredictability of bleeding. To our knowledge, the only study that has analyzed clinicians' attitude to withdrawal bleeding and manipulating bleeding patterns in order to reduce pain or inconvenience associated with menses in the UK was conducted in 1977.¹²

Overall, the respondents in our survey appeared to be more enthusiastic about extended regimens than in 1977 when half of the 24 doctors and nine nurses taking part in a trial of extended pill use preferred to prescribe the standard 21/7 pill regimen, but change has clearly not been rapid.

There are now several published trials and a Cochrane review providing evidence in support of extended or tailored pill use, and this has recently been backed in the UK by national guidance from the Faculty of Sexual and Reproductive Healthcare. The Cochrane review of eight randomized trials showed similar outcomes with respect to participant satisfaction, contraceptive efficacy, and discontinuation rates for women taking a variety of extended regimens compared with traditional 21/7 regimes of COC use.²² Studies also support the safety of extended use.^{15,22,23} Regimens supported by the UK Faculty of Sexual and Reproductive Healthcare include tricycling (63/7), shortened pill-free interval (21/4, or 63/4) extended use (21+) with a shortened (4 days) or regular (7 days) pill-free interval, of which just the 21/7 regimen is licensed in the UK.

Anecdotally, primary care providers are more cautious about prescribing non-licensed contraceptive regimens, but specialist contraceptive services are well placed to lead innovation in clinical practice. To build on evidence from randomized controlled trials, we need health services or implementation research to show how guidance on extended COC use can be incorporated successfully into routine practice in busy clinics. Building on the findings of this targeted survey, we are now evaluating methods for routine implementation of extended pill guidance, including tricycling, and tailored and standard use, for all women requesting COC.

Conclusion

In conclusion, despite growing evidence backed by national guidance, routine provision of information about extended COC use is very variable even within specialist "innovative" contraceptive services. Targeted training, use of service guidelines, and implementation research will be needed to extend patient choice of different COC regimens and increase the pace of change in clinical practice.

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Disclosure

The authors report no conflicts of interest in this work. The authors alone are responsible for the content and writing of the paper.

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