Feasibility of a self-completed history questionnaire in women requesting repeat combined hormonal contraception

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Abstract

Objective To measure agreement between the client's and the clinician's responses to questions regarding client history as answered on a questionnaire based on the *UK Medical Eligibility Criteria for Contraceptive Use* (UKMEC) for combined hormonal contraception (CHC).

Methods Clients aged 18 years and over, attending a central London community contraceptive clinic requesting a repeat supply of CHC, completed a history questionnaire and an evaluation form. Clinicians then completed their copy of the same questionnaire during the consultation. Percentage agreement and the Kappa statistic were used to assess the level of client–clinician agreement.

Results Data from 328 client–clinician pairs were analysed. Agreement was above 93% for all identified risk factors. There was complete agreement for thrombosis, diabetes, stroke, cancer and liver problems. Least agreement was noted in the recording of migraine and abnormal bleeding. For all risk factors except smoking, the proportion of clients reporting a risk factor was more than the proportion of clinicians reporting a risk factor. No clinically important information relevant to a particular client's use of CHC was missed and none of them would have been wrongly prescribed the CHC based just on their self-completed questionnaires. Most women (97%) were happy with this method of history taking.

Conclusions A self-completed history questionnaire is acceptable to women and can potentially replace traditional routine medical history taking for continuing CHC. Women completed the questionnaire with a high degree of reliability. There was complete client–clinician agreement on UKMEC Category 4 criteria. Overall, clients reported more risk factors than clinicians, which increases the safety of the questionnaire.

Keywords client history, hormonal contraception, questionnaire survey, risk factors

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Introduction

The combined hormonal oral contraceptive pill (COC) is the most commonly used method of contraception in the UK, used currently by 24% of all women aged 16–49 years.[1] Women requesting repeat prescriptions of the COC constitute the major part of contraceptive workload in primary care, both in community contraceptive clinics and in general practice.[2] Ways of improving the management of COC users' care are needed to ensure safe, efficient and accessible service provision.

The World Health Organization *Medical Eligibility Criteria for Contraceptive Use* (WHOMEC) provides clear evidence-based recommendations on the selection of the most appropriate method of contraception. Services can use these criteria to develop guidelines for delivery of contraceptives locally.[3] Family Health International have used them to develop checklists to initiate COCs in community-based programmes to increase the quality of services and care and to increase women's access to contraceptives.[4]

The *UK Medical Eligibility Criteria for Contraceptive Use* (UKMEC) were developed from the WHO document in 2005.[5] These criteria are classified into four categories, ranging from UKMEC 1 – a condition for which there is no restriction for the use of the contraceptive method (e.g. parity) to UKMEC 4 – a condition which represents an unacceptable health risk if the contraceptive method is used (e.g. thrombosis). History taking and appropriate examination allow clinicians to assess medical eligibility for COC use. The medical and family history should alert the clinician to conditions or risk factors that might be a strong or absolute contraindication to COC use. A woman with multiple risk factors may need to avoid COC use, although individual risk factors would not necessarily contraindicate use. Blood pressure and body mass index (BMI) should be documented for all women before a first prescription of COC[6] and at follow-up.

In this article we describe the use of a history questionnaire for established users of combined hormonal contraception (CHC), which includes COCs and the contraceptive patch. The aim of this study was to determine

Key message points

- **A self-completed history questionnaire is a reliable and acceptable method of recording client history prior to continuing combined hormonal contraception.**
- **Except for smoking, clients reported more risk factors than the clinicians.**
- **Questions on a clinical outcome or disease that generate discrete responses yield a greater agreement between the client and the clinician than do questions on behaviour.**

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whether a self-completed history questionnaire was a safe and acceptable way of obtaining relevant information from clients before continuing their CHC.

Methods and analysis

This study was carried out at a central London community contraceptive clinic. During the study period of 1–31 October 2006, all women who were existing service users established on CHC and requesting repeat supplies were approached to participate in the study. To evaluate the accuracy of a self-completed history, a one-page questionnaire was designed for the women to complete prior to seeing the clinician (Figure 1). This questionnaire was informed by the UKMEC.[5] A short evaluation of the self-completed history method was included in their questionnaire. A questionnaire with the same history checklist was also designed for the clinicians. The clinician's questionnaire formed part of the client's case notes. This included documentation of the client's blood pressure and BMI. Any specific comments or documentation of any other service provided at that visit was done on the back of the clinician's copy of the questionnaire.

Clients aged 18 years and over requesting repeat supplies of their CHC, and who were proficient in English and able to complete the questionnaire without the help of an interpreter, were given an information sheet describing the study by the reception staff. Following their verbal consent to participate, clients were asked to complete the questionnaire and return it to the receptionist. The client was then seen by the clinician, who took their history, completed their copy of the questionnaire and performed the consultation as usual. The clinician was unaware of the responses the client had made. The clinician's questionnaire was photocopied and linked with the client's copy for comparison. The client's clinic number was on both questionnaires so that their notes could be examined if there were any inconsistencies between the client and clinician questionnaires.

Questionnaire data were entered into and analysed using SPSS (v.12) (SPSS Inc., Chicago, IL, USA). Univariate descriptive statistics were created to describe the proportions of the client and clinician responses to each of the risk factors. Agreement between the client and the clinician was measured using percentage agreement and the Kappa statistic. The Kappa statistic allows us to measure agreement above and beyond that expected by chance alone. A Kappa value of one is where there is complete agreement and a value of zero is where there is no more agreement than would be expected by chance alone.[7] A negative Kappa statistic can result if agreement occurs less often than predicted by chance alone. Agreement was defined as either a yes–yes or a no–no client–clinician response to each question. In order to assess safety, we wished to obtain 100% agreement for UKMEC 3/4 criteria and over 90% agreement for UKMEC 1/2 criteria.

Question	Yes	No
1. Have you read and understood the information sheet given?	☐	☐
2. Are you aged 35 years or over?	☐	☐
3. Do you smoke?	☐	☐
4. Do you have any abnormal vaginal bleeding, for instance after sex or at a time when you should not bleed?	☐	☐
5. Have you had or do you currently have any of the following medical conditions:		
Migraine	☐	☐
High blood pressure	☐	☐
Thrombosis (blood clots in legs or in lungs)	☐	☐
Diabetes	☐	☐
Stroke	☐	☐
Heart disease	☐	☐
Cancer	☐	☐
6. Do you currently have or have you had since your last visit any of the following conditions:		
Liver problems or jaundice	☐	☐
Breast problems	☐	☐
Abnormal smear (Pap) test	☐	☐
Any other serious illness	☐	☐
7. Have you had a pregnancy since your last visit here?	☐	☐
8. Have your mother, father, brother or sister had stroke, heart attack or thrombosis when they were under the age of 46?	☐	☐
9. Do you have more than one relative (any type) who has had stroke, heart attack or thrombosis when he/she was under the age of 46?	☐	☐
10. Are you taking St John's wort or any other regular medications?	☐	☐
11. Have you ever been advised not to use the combined pill/patch?	☐	☐
12. Would you like to discuss other methods of contraception such as long-acting methods that you do not have to remember to take each day?	☐	☐
13. Do you want to see a doctor or nurse for any other reason apart from more pills/patches?	☐	☐
Evaluation Form		
1. Were the questions easy to understand and answer?	☐	☐
2. If not, which question was difficult?		
3. Would you be happy with this method of recording your history?	☐	☐
4. Comments:		

Figure 1 Questionnaire for clients requesting repeat supplies of combined hormonal oral contraceptive pill/patch

Ethical approval

The study proposal was reviewed and approved by the Camden and Islington Community Local Research Ethics Committee. This research study was also registered with the North Central London Research Consortium (NoCLoR).

Results

During the study period, 370 clients met the inclusion criteria and were given the information sheet describing the study. One client declined to participate. Forty-two questionnaires were excluded from the analysis for the following reasons: five women left the clinic before being seen, four client-completed questionnaires were lost, nine women attended the clinic for other reasons therefore the clinician did not complete a questionnaire and in 23 cases the clinicians used routine notes to document the consultation instead of completing the questionnaire. The results are therefore based on the analyses of 328 pairs of client–clinician questionnaires.

Table 1 shows the frequency of risk factors identified by clients and clinicians and their level of agreement. Ten percent of clients were aged 35 years or more. The risk factor most commonly reported was smoking. UKMEC 4 criteria were less reported, as would be expected of established CHC users. There was complete agreement in risk factors of thrombosis, diabetes, stroke, cancer and liver problems. Agreement was above 93% for all the identified risk factors. Migraine and abnormal bleeding were the risk factors where the proportion of client–clinician agreement was the least. For all risk factors except smoking, the proportion of clients reporting a risk factor was more than the proportion of clinicians reporting a risk factor.

Where the client reported a risk factor but the clinician did not, it was unlikely to affect the repeat prescription of the CHC as these clients would be seen by the clinicians to discuss their history further. However, where the client did

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Table 1 Risk factors identified by combined oral contraceptive users and clinicians

Risk factor	Valid pairs[a]	Clients reporting risk factor [*n* (%)]	Clinicians reporting risk factor [*n* (%)]	Client marked yes, clinician marked no [*n* (%)]	Client marked no, clinician marked yes [*n* (%)]	Agreement[b] [*n* (%)]	Kappa
Age ≥35 years	328	33 (10.0)	34 (10.4)	0	1 (0.3)	327 (99.7)	0.98
Smoking	325	72 (22.1)	77 (23.7)	1 (0.3)	6 (1.8)	318 (97.8)	0.939
Abnormal bleeding	324	35 (10.8)	32 (9.9)	8 (2.5)	5 (1.5)	311 (95.9)	0.784
Migraine	326	39 (11.9)	23 (7.0)	19 (5.8)	3 (0.9)	304 (93.3)	0.611
High blood pressure	319	3 (0.9)	3 (0.9)	2 (0.6)	2 (0.6)	315 (98.7)	0.327
Thrombosis	321	0	0	0	0	321 (100.0)	NA[e]
Diabetes	322	1 (0.3)	1 (0.3)	0	0	322 (100.0)	1
Stroke	322	0	0	0	0	322 (100.0)	NA[e]
Heart disease	322	1 (0.3)	0	1 (0.3)	0	321 (99.7)	NA[e]
Cancer	322	0	0	0	0	322 (100.0)	NA[e]
Liver problems	324	0	0	0	0	324 (100.0)	NA[e]
Breast problems	323	2 (0.6)	1 (0.3)	1 (0.3)	0	322 (99.7)	0.665
Serious illness	322	0	1 (0.3)	0	1 (0.3)	321 (99.7)	NA[e]
Pregnancy	323	0	1 (0.3)	0	1 (0.3)	322 (99.7)	NA[e]
Immediate family history[c]	326	10 (3.0)	6 (1.8)	4 (1.2)	0	322 (98.7)	0.744
More than one relative[d]	326	9 (2.7)	4 (1.2)	6 (1.8)	1 (0.3)	319 (97.8)	0.452
Medication	323	9 (2.8)	6 (1.9)	5 (1.5)	2 (0.6)	316 (97.8)	0.523
Ever advised not to use COC	325	9 (2.8)	5 (1.5)	6 (1.8)	2 (0.6)	317 (97.5)	0.417

[a]Number of cases where the question was answered by both (i.e. the client and the clinician).
[b]Agreement on these questions was based on the number of yes–yes/no–no client–clinician responses.
[c]Have your mother, father, brother or sister had a stroke, heart attack or thrombosis under the age of 46?
[d]Do you have more than one relative (any type) who has had a stroke, heart attack or thrombosis under the age of 46?
[e]Kappa cannot be calculated if the table is not balanced, for example, either the client or the clinician never uses one of the categories (either yes or no).
NB. Although the number of clinicians and clients reporting a risk factor may be similar they may not be matched pairs and hence the Kappa.
COC, combined oral contraceptive; NA, not available.

not identify a risk factor but the clinician did, a risk factor could be missed if the self-history method were to be adopted. In these cases, we looked into any comments made by the client or the clinician and at the client's case notes to establish the cause for disagreement. In all such cases no clinical contraindication to CHC for that particular client was missed. The disagreement was noted to be more in subjective or open-ended questions. For example, clinicians identified women who smoked occasionally as 'smokers' while the clients had not identified themselves as a smoker. Similarly, in cases of abnormal bleeding the client did not identify occasional breakthrough bleeding with late or missed pills as abnormal. Removal of a benign spinal tumour was marked as a serious illness by the clinician but not by the client. Referral for termination of pregnancy at her last visit was reported as a pregnancy by the clinician but not by the client. One client taking Roaccutane® did not report this as taking medication.

Nine clients were not prescribed their CHC. This was for reasons such as wanting other contraceptive methods or having side effects associated with the use of CHC.

Table 2 shows the results of the clients' evaluation of this method of history taking.

Discussion

Our study sample included clients already established on CHC. This is an important population to study, as new health problems can develop over time and can affect the safety of ongoing contraceptive use. In our study, critical medical history questions that would affect the prescription of the CHC such as stroke, thrombosis, diabetes, cancer and liver problems obtained 100% agreement. All risk factors had more than 93% client–clinician agreement. Women could understand the questions and found this method of recording history acceptable. Overall, clients were more likely to report a risk factor than the clinician, which increases the safety of the questionnaire. In all cases of disagreement it was confirmed from the client's case notes that no clinically important information relevant to that particular client's use of the COC was missed. None of these 328 patients would have been wrongly prescribed the COC based just on their self-completed questionnaires.

Table 2 Clients' evaluation of method

Client response	Valid (*n*)	Yes (%)
Read and understood information sheet	319	99.7
Questions easy to understand	322	98.4
Happy with method	319	96.9

Subjective questions like smoking, migraine and abnormal bleeding generated more disagreement. Whilst this may not prohibit CHC use for most women (in this study it did not affect any of the respondents getting the CHC), it will be relevant to some women, particularly if they have other risk factors.[5,8] Six clients who smoked only occasionally did not identify themselves as smokers. Similarly, three clients did not report a history of simple migraine. This may have been because of the way the questions were worded. This illustrates that questions need to be carefully worded to identify all women with any of the risk factors. For example, a better wording for the question on smoking may be: 'Have you smoked at all in the last year?' A better way of asking a question on migraine may be to actually describe a migraine headache.

A study done in the USA on self-completed questionnaires amongst women aged 15–45 years attending family planning clinics for a variety of reasons has reported similar areas of disagreement. In the USA study, questions that in general generate discrete responses (e.g. presence or absence of gall bladder disease) yielded the highest agreement. Conversely, questions regarding more subjective queries such as menstruation patterns or smoking habits generated greater disagreement.[9]

We did not collect any sociodemographic data such as the level of education, income and parity as our aim was to

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assess use of this questionnaire in routine practice, amongst all clients attending the service, rather than to investigate the effects sociodemographic data have on the levels of agreement. The USA study, however, found no statistical difference in agreement between the responses in subgroups of age, income, education and prior contraceptive use.[9]

Another important consideration is to ensure there is standardisation of what is being measured. For example, clinicians may differ in their criteria for a diagnosis of hypertension.[10] Surprisingly, despite clear local guidelines, both the cases in our study where the clinician reported high blood pressure as a risk factor had neither a history of hypertension nor elevated blood pressure readings documented in the client case notes.

As the questionnaires were linked to and part of the case notes, the person responsible for data collection and analysis (JSD) was not blinded to which clinician saw each client. This is a limitation of our study as, for example, assumptions could be made on the accuracy of risk factor identification depending on the level of a clinician's experience.

Benefits of a self-completed questionnaire include increased client participation during the history taking process, more complete client records, standardisation in the recording of client information, minimal interview bias and the clinician identification of additional medical problems that may not be noted during a consultation.[11] It can make it easy to audit the service guidelines and enable a long-term research study on changes in health in long-term CHC users. For women established on CHC with no risk factors, a self-taken history can speed up consultations. There is also scope to develop roles for health care assistants. They could record the client's blood pressure and BMI, check the self-completed history questionnaire, and if there is no indication to refer to a doctor or a nurse, then they could issue the CHC to clients under patient group direction. Our study showed that it is feasible to record history this way and that it is acceptable to clients.

Conclusions

A self-completed history questionnaire could be a valuable tool to potentially improve the care given to established CHC users in contraceptive clinics. Our study has shown that clients can complete a history questionnaire with a high degree of reliability. Discrete questions that ask about a clinical outcome, a disease or whether an event has occurred (e.g. thrombosis) rather than a behaviour (e.g. smoking) or a symptom (e.g. menstrual bleeding patterns) yield a greater agreement between the client and the clinician. In further research, subjective history questions should be worded in such a way as to obtain an unambiguous yes/no answer. Further work needs to assess the impact the questionnaire has on service delivery, such as the effect on consultation times. Use of this tool could be explored in other settings such as general practice and pharmacies, as well as for clients requesting CHC for the first time or for clients established on CHC in other services.

Statements on funding and competing interests
Funding None identified.
Competing interests None identified.

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BOOK REVIEW

Stolen Tomorrows: Understanding and Treating Women's Childhood Sexual Abuse. S Levenkron, A Levenkron. New York, NY: W W Norton, 2007. ISBN: 0-393-06086-1. Price: £16.99. Pages: 288 pages (hardcover)

It's always worth celebrating an addition to the coverage of therapy for abuse survivors. When this addition is written well, sensitively and by an experienced expert in the field, that's even more cause for celebration.

Steven Levenkron, already known for his work on self-harm and eating disorders – his celebrity patients included Karen Carpenter – now focuses his attention on the issue of abuse. *Stolen Tomorrows*, written with his wife Abby, also a therapist, fulfils all of the above criteria, and consists of a series of 19 extended case histories with comment, with supporting sections on the causes, progression and treatment of female childhood abuse. It's an insightful work, and therapists both new to and working in the field will find it useful, particularly if they wish to have a window into what happens in the counselling room. Non-therapists who work with abuse survivors will also benefit from that window, as well as gaining a good overview of what can be done in a therapeutic context were they to refer on.

So where's my flinch, for flinch there is. I have no doubts about this book's appropriateness to the professional reader. But then I turn to the back cover – and I read the advertising blurb on several bookstore websites and the reviews quoted on the author's own site – and that's where I have my reservations. For the book claims to be appropriate for the abuse survivor, and that it will help such 'victims' seek help for 'their secret shame'.

That may have been the book's aim, but it's not what it has achieved. The case histories are moving, but accompanied by objective and entirely therapy-aimed commentaries that might well frighten any but the most informed, educated and therapeutically advanced client. At the end of the 276 pages, the four and a half pages aimed at such clients seem like – and perhaps are – an afterthought, and though compassionate, by no means comprehensive or sufficient. None of this would matter had the book been advertised as being for a therapy market. But to major on its use to survivors of abuse seems to me to be inaccurate and unfortunate.

Final verdict? If you are a therapist, absolutely buy it for your own library and recommend it to colleagues. But on no account give it to your clients until the work you are doing with them is complete and they can take a long view.

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