

Communicating Contraceptive Effectiveness

Markus Steiner¹, James Trussell,² Neha Mehta,³ Maxine Wedderburn,⁴ and Sumathi Subramaniam⁵

1. Family Health International, P.O. Box 13950, Research Triangle Park, Durham, NC 27709, USA. Telephone: 919-544-7040, ext 346; fax: 919-544-7261; email: msteiner@fhi.org
2. Office of Population Research, Wallace Hall, Princeton University, Princeton NJ 08544, USA. Telephone: 609-258-4949; fax: 609258-1039; email: trussell@princeton.edu
3. Family Health International, P.O. Box 13950, Research Triangle Park, Durham, NC 27709, USA. Telephone: 919-544-7040, ext 487; fax: 919-544-7261; email: nmetha@fhi.org
4. Hope Enterprises, Ltd., 7-7a Tangerine Place, Kingston 10 Jamaica. Telephone: 876-968-4976, email: maxwed@cwjamaica.com
5. Family Health International, G-101 Adarsh Palace, 47th Cross, 5th Block, Jayanagar, Bangalore-560041 India. Telephone: 91-80-26631548; email: s.subramaniam@tfgi.com

Abstract

Only with accurate understanding of risk of contraceptive failure can people make informed contraceptive choices. The main objective of this research study is to evaluate how well three simplified approaches of communicating contraceptive effectiveness increase understanding for women in two developing countries (Jamaica and India), and to compare the approaches. In each country, 450 subjects will be randomly assigned to receive one of three simplified charts presenting contraceptive effectiveness: (1) methods ranked on a continuum, (2) methods grouped by average effectiveness, and (3) methods grouped by average and “best-case” effectiveness. Secondary objectives include but are not limited to: (1) determining the importance of method effectiveness relative to other factors in deciding which contraceptive method to use, (2) determining the importance of provider counseling about contraceptive effectiveness on subsequent understanding of these concepts, and (3) evaluating how well women understand the effectiveness of barrier methods for STI/HIV protection.

1. INTRODUCTION

1.1 Background

Only with accurate understanding of risk can people make informed choices. This is especially true in the field of contraception with the wide selection of methods with differing pregnancy risk, contraindications and side-effect profiles. For labeling of contraceptive devices, the US Food and Drug Administration (FDA) recommends the use of a table with two columns presenting the numeric annual risk of pregnancy (e.g. 15%) for each method during typical use and during cycles when the method is used correctly and consistently.² For the labeling of medical products, a European Union (EU) guideline recommends the risk of side effects be communicated using verbal categories (very rare, rare, uncommon, common, very common).¹

A systematic review of decision aids to help prepare people facing medical decisions found 24 randomized controlled trials (RCT),³ but none in the field of contraception. This Cochrane review concluded that when compared to standard care, decision aids: 1) improve knowledge and realistic expectations of risks and benefits; 2) reduce passivity in decision-making; and 3) lower decisional conflict stemming from feeling uninformed. However, decision aids have little impact on anxiety or satisfaction with the decision-making process and have varying impact on choice of options depending on the therapeutic area. Interestingly, more detailed decision aids compared to simple decision aids improved knowledge only marginally.

An earlier Family Health International(FHI) randomized controlled trial (RCT) conducted in the United States evaluated which of three approaches best communicated the relative effectiveness of contraceptive methods: 1) chart with perfect and typical-use rates (FDA table); 2) table with only categories; and 3) table combining rates and categories (WHO table)⁴ We evaluated women's knowledge before and after being shown her assigned table. The most important reason for choosing a contraceptive was "how well it works" (53%), followed by "ease of use" (13%) and "protection against STD/HIV" (11%). Before looking at the tables, about half the participants knew that hormone shots are more effective than pills (48%) and pills are more effective than condoms (57%). For these two key comparisons, the category table compared to the FDA table with numbers improved knowledge significantly more (37% vs. 20% and 27% vs. 14%; both $p < 0.05$). Significantly fewer participants assigned to the category table compared to those assigned to the FDA table said the table was difficult to read (6% vs. 19%; $p < 0.01$). The majority of participants in all three groups said their assigned table provided enough information to choose a contraceptive method.

1.2 Rationale

Results from this earlier study were used to draft three simplified tables at a meeting in Baltimore in March 2004. The purpose of this current study is to evaluate these three simplified tables and guide the development of improved counseling messages. The ultimate goal of this research is to provide women with the right decision making tools to make informed choices about their contraceptive use.

2. STUDY OBJECTIVES

2.1 Primary Objectives

The main objective of this research study is to evaluate how well three simplified approaches of communicating contraceptive effectiveness increase understanding for women in two developing countries (Jamaica and India), and to compare the approaches.

2.2 Secondary Objectives

Secondary objectives include but are not limited to: 1) determining the importance of method effectiveness relative to other factors in deciding which contraceptive method to use; and 2) determining the importance of provider counseling about contraceptive effectiveness on subsequent understanding of these concepts; and 3) evaluating how well women understand the effectiveness of barrier methods for STI/HIV protection.

3. TRIAL DESIGN

3.1 Primary End Points

Participant knowledge about the relative effectiveness of two sets of contraceptive methods will be assessed pre- and post-intervention with an interviewer-administered questionnaire. The two key questions are:

What method works better to prevent pregnancy: I) birth control pills or male condoms; and II) injectables or IUDs?

3.2 Study Design

We will recruit a convenience sample of 450 women aged 18-45 in at least 5 public areas (e.g. markets, parks, malls, beauty salons, garment factories etc.) at each country site. All women meeting study admission criteria will be informed about the study verbally by the interviewer using a prepared script. The interviewer will describe the purpose of the study, the estimated duration of time required, the amount of compensation, the participant's right to refuse to answer any questions, and give an assurance of anonymity.

Women willing to participate and who meet all the eligibility criteria will be randomized to one of three groups. Study staff will administer a background questionnaire and then briefly review the participant's assigned table using a predefined script. A second set of questions will be administered while the woman is looking at her assigned chart. Women will be compensated modestly (\$2-\$5) for their participation in this research study. The study questionnaire is appended.

3.3 Measures to Minimize Bias

3.3.1 Randomization

Randomization and concealment of allocation will be accomplished by the use of sequentially numbered, sealed, opaque envelopes containing the group assignment. FHI

will be in charge of preparing the randomization envelopes. FHI will use a random permuted block scheme stratified by study site. We will instruct study staff never to open an envelope until the participant is fully screened and found eligible for the study.

3.3.2 Allocation concealment

After completion of the screening process, study staff will open the next sequentially numbered envelope to determine group assignment for each woman willing to participate.

3.3.3 Blinding

Neither participant nor site study staff can be blinded to the intervention. Our goal is to blind key FHI staff involved in the analysis throughout the conduct of the study.

3.4 Randomization Codes

The FHI randomization manager will maintain the trial treatment randomization assignment list. The manager will provide this list to the statisticians when they are prepared to unblind after completion of the final blinded analysis of the data.

3.5 Study Duration

This is a pre- / post-test cross-sectional study with data collection expected to last for approximately one month at each country site.

4.0 SELECTION OF PARTICIPANTS

4.1 Eligibility Criteria

A participant who meets the following inclusion criteria will be eligible for the study:

- ⇒ between the ages of 18 and 45 years of age, inclusive
- ⇒ basic literacy in the English language
- ⇒ not participated in this research study previously

Women will be recruited from public areas (e.g. markets, public parks, malls, beauty parlors, garment factories etc.) and attempts will be made to recruit women from a wide range of socio-demographic backgrounds.

5.0 INTERVENTION

The interviewer will briefly review with the participant the general concepts that the assigned table is to convey using a predefined script. The participant will be asked to look over her assigned table for a few minutes. The interviewer will then continue the interview while the participant continues looking at the assigned table in an open-book test format.

6.0 STATISTICAL SUMMARY

6.1 Study Size Justification

At each country site 450 women will be enrolled.

We plan to test the null hypothesis that there is no difference in the improvement pre- / post-intervention of correct understanding about relative effectiveness of the two key comparisons (birth control pills vs. male condoms and injectables vs. IUDs). Each question will be analyzed separately.

We make the following assumptions:

- 50% of participants will have correct knowledge about these two key comparisons pre-intervention.
- Subjects who answer a question correctly on the pretest will also answer it correctly on the post-test.
- The table with both typical and perfect-use categories will improve knowledge by 15% points (control group).
- The other two tables will improve knowledge significantly more. We will consider a 25% point increase or greater to be clinically meaningful.

Administering the questionnaire to 300 participants per group (N=900 in total) will provide us 87% power at a 0.05 significance level to detect a clinically meaningful difference between the three groups with the above assumptions, using the two-sided chi-square test (Lachin, 1977). For each country (N=450), the power will be 57%.

6.2 Analysis Plan Summary

We will conduct analyses that address the following:

- Characterize the population surveyed.
- Estimate the proportion of respondents in each of the three groups who correctly answered the key comparison questions about relative contraceptive effectiveness pre- and post- intervention. (Objective 1). The two key comparisons (birth control pills vs. male condoms and injectables vs. IUDs) will be analyzed separately. Further, the Fisher's Least Significant Difference (LSD) approach will be used to compare the improvement in correct knowledge of the three groups to see if the difference is statistically significant. The chi-square global test will be used first to test the null hypothesis that there is no difference in the pre- / post-intervention of correct understanding about relative effectiveness among these three groups at alpha 0.05 level. If the null hypothesis is rejected, pairwise chi-square tests among these three groups will be performed under the same alpha 0.05 level.
- Explore demographic or other determinants of correct responses.
- Estimate the proportion of participants who list contraceptive effectiveness as the most important characteristic when deciding what contraceptive method to use (vs. other characteristics mentioned) (Objective 2).
- Estimate the proportion of participants who list contraceptive effectiveness as the second most important characteristic when deciding what contraceptive method to use (vs. other characteristics mentioned) (Objective 2).

Explore the association between having received contraceptive counseling from a healthcare provider and correctly answering questions about contraceptive effectiveness (Objective 2).

Explore participants' knowledge about how well barrier methods provide protection against STI/HIV (Objective 2).

7.0 DATA MANAGEMENT PLAN SUMMARY

7.1 Questionnaires

This study will use a short interviewer administered questionnaire. That questionnaire is attached as an appendix.

7.2 Data Transfer

Questionnaires will be delivered to and stored at FHI. Completed questionnaires and databases will be stored at FHI following FHI's established SOPs.

7.3 Data Entry

Data from the questionnaires will be double entered into an Epi-Info (version 6.04B) program by site staff. The data entry screens will be created and verified by FHI staff. The Epi-Info files will be converted into SAS at FHI and all analyses will be performed at FHI. A more detailed data entry plan will be outlined in a separate document.

8.0 STUDY DOCUMENTS

8.1 Site Study Files

The following documents will be in place before participants are contacted and maintained at the study site during the course of the study.

- ✘ Signed protocol and amendments
- ✘ Study questionnaires
- ✘ Financial records
- ✘ Signed agreements between involved parties
- ✘ CV for Investigator and Sub-Investigator
- ✘ Relevant communications
- ✘ Copies of documentation of questionnaire corrections
- ✘ Participant enrollment log
- ✘ Staff signature list

8.2 Site Record Retention

After completion of the study, all of the documents in 8.1 should be retained in the file at the study site.

9.0 ETHICS

9.1 Institutional Review Board Review and Approval

The study questionnaires will contain no information linking the data to individuals. No social risk events are anticipated and adverse events are not relevant to this study. This is an anonymous survey with minimal risk, however, all women meeting study admission criteria will be informed about the study verbally by the interviewer using a prepared script. The interviewer will describe the purpose of the study, the estimated duration of time required, the compensation amount, the participant's right to refuse to answer any questions, and give an assurance of anonymity. Women will be compensated modestly (\$2-\$5) for their participation in this research study.

This protocol has been exempted from a full review by the Protection of Human Subjects Committee due to the minimal risk to participants.

9.2 Participant Confidentiality

Every effort will be made to protect participant confidentiality. Participants will be assigned a unique ID. No names will appear on the questionnaire. Participants will sign a paper stating that they received compensation for being in the trial, but this will not be linked to their ID number. If the results of this research study are published, no names will be used.

In at least one site (India), a convenience sample of participants will be called by site staff after the interview to verify that the data were collected during an actual interview. Site staff will only call participants who agreed to be called during the initial interview.

10.0 TIMELINE

Subject recruitment will be completed by mid-fall, and data analysis will be completed by early 2005..

Communicating Effectiveness Questionnaire - Page 2

Chart: |__|
(A, B, C)

Participant ID: |__||__||__||__| - |__|

Interview Date: |__||__|/|__||__|/|__||__|
mm dd year

12. Please indicate **ALL** of the method(s) of birth control that **YOU HAVE EVER USED**:

*Read each item, check **ALL** that apply. Show Flashcard #1.*

- Male sterilisation (vasectomy)
- Female sterilisation (tubes tied)
- Implants (Norplant)
- Injectables (hormone shots)
- Birth control pills
- IUD
- Male condoms
- Diaphragm
- Vaginal sponge
- Cervical cap
- Female condoms
- Spermicide (foam, gel, film, suppositories)
- Withdrawal (pulling out)
- Natural family planning (rhythm, calendar)
- Other (specify): _____
- Not applicable - Have never used birth control

13. Please indicate your **CURRENT** method of birth control (if no current method, indicate **MOST RECENT** method):

Do not read choices, multiple answers possible. Show Flashcard #1.

- Male sterilisation (vasectomy)
- Female sterilisation (tubes tied)
- Implants (Norplant)
- Injectables (hormone shots)
- Birth control pills
- IUD
- Male condoms
- Diaphragm
- Vaginal sponge
- Cervical cap
- Female condoms
- Spermicide (foam, gel, film, suppositories)
- Withdrawal (pulling out)
- Natural family planning (rhythm, calendar)
- Other (specify): _____
- Not applicable - Have never used birth control

14. What was your **MOST IMPORTANT** reason for choosing the method(s) listed in Question #13?

*Do not read choices, check only **ONE** box*

- How well it prevents pregnancy
- How well it protects against sexually transmitted infections and/or HIV/AIDS
- How easy it is to get (e.g., no doctor's visit needed)
- How easy it is to use
- How many side effects it has
- Sexual pleasure
- How long it works
- How much it costs
- Other (specify): _____
- Not applicable - Have never used birth control

15. What was your **SECOND MOST IMPORTANT** reason for choosing the method(s) listed in Question #13?

*Do not read choices, check only **ONE** box. Offer examples to respondent.*

- How well it prevents pregnancy
- How well it protects against sexually transmitted infections and/or HIV/AIDS
- How easy it is to get (e.g. no doctor's visit needed)
- How easy it is to use
- How many side effects it has
- Sexual pleasure
- How long it works
- How much it costs
- Other (specify): _____
- Not applicable - Have never used birth control

16. If participant did **NOT** choose "**HOW WELL IT PREVENTS PREGNANCY**" for questions 14 and 15, ask: Why is how well a contraceptive method prevents pregnancy not an important factor in your decision?

*Do not read choices, check only **ONE** box*

- All methods work well
- Not concerned about becoming pregnant
- It is not as important as the other reasons
- Other (specify): _____
- Don't know
- Not applicable - Chose "How well it prevents pregnancy"

Communicating Effectiveness Questionnaire - Page 3

Chart: |__|
(A, B, C)

Participant ID: |__||__||__||__| - |__|

Interview Date: |__||__|/|__||__|/|__||__|
mm dd year

17. Indicate **ALL** of the birth control method(s) listed below that provide **PROTECTION AGAINST SEXUALLY TRANSMITTED INFECTIONS AND/OR HIV/AIDS**.

Read each item, check **ALL** that apply.
Show Flashcard #1.

- Male sterilisation (vasectomy)
- Female sterilisation (tubes tied)
- Implants (Norplant)
- Injectables (hormone shots)
- Birth control pills
- IUD
- Male condoms
- Diaphragm
- Vaginal sponge
- Cervical cap
- Female condoms
- Spermicide (foam, gel, film, suppositories)
- Withdrawal (pulling out)
- Natural family planning (rhythm, calendar)
- Other (specify): _____
- None provide protection

For questions 18-24, we want to know what you think. Please make your **BEST GUESS** if you do not know the answer. For remaining questions:

Read all choices, check only **ONE** box, unless otherwise specified.

18. If 100 women were using a **VERY EFFECTIVE** birth control method for one year, how many women do you think would get pregnant in that year?

|__||__||__| (Write in response, between 0-100)

19. If 100 women were using an **EFFECTIVE** birth control method for one year, how many women do you think would get pregnant in that year?

|__||__||__| (Write in response, between 0-100)

20. If 100 women use **NO** birth control method for one year, how many women do you think would get pregnant in that year?

|__||__||__| (Write in response, between 0-100)

21. For average/typical women, which method do you think works better to prevent pregnancy, **BIRTH CONTROL PILLS** or **MALE CONDOMS**?

- Birth control pills
- Male condoms
- They work about the same
- Don't know

22. For average/typical women, which method do you think works better to prevent pregnancy, **INJECTABLES (HORMONE SHOTS)** or **IUDS**?

- Injectables (hormone shots)
- IUDs
- They work about the same
- Don't know

23. How effective do you think **MALE CONDOMS** are at preventing the transmission of HIV and other sexually transmitted infections?

- Very effective
- Effective
- Somewhat effective
- Not effective
- Don't know

24. If you think **MALE CONDOMS** are not effective, why are they not effective?

Do not read choices, check only **ONE** box

- They break or slip off
- They have holes in them
- Other (specify): _____
- Not applicable - Did not choose "Not effective" in Question #23

Communicating Effectiveness Questionnaire - Page 4

Chart: |__|
(A, B, C)

Participant ID: |__||__||__||__| - |__|

Interview Date: |__||__|/|__||__|/|__||__|
mm dd year

After all questions have been answered, interviewer should give the participant their assigned chart to look at and then administer the rest of the questionnaire.

For questions 25-33, please refer to the chart provided and answer the next series of questions based on the chart.

25. According to the chart, which method works better to prevent pregnancy, BIRTH CONTROL PILLS or MALE CONDOMS for average/typical women?

- Birth control pills
- Male condoms
- They work about the same
- Don't know/can't tell from the chart

26. According to the chart, which method works better to prevent pregnancy, INJECTABLES (HORMONE SHOTS) or IUDs for average/typical women?

- Injectables (hormone shots)
- IUDs
- They work about the same
- Don't know/can't tell from the chart

27. How easy was the chart to understand?

- Very easy
- Easy
- Difficult

28. Does this chart give you enough information to help you choose the most effective method of birth control for you to use?

- No
- Yes

29. If NO, what other information would you like to know to help you choose a method of birth control?

- _____
- _____
- Not applicable - Chose "Yes" in Question #28

30. According to the chart, if 100 average/typical women used IUDs for one year, how many would get pregnant?

- None
- 2 or less
- 3 to 9
- 10 to 30
- More than 30
- Other (specify): _____
- Don't know/can't tell from the chart

31. HOW LIKELY do you think YOU would be to get pregnant if you used IUDs as your only method of birth control for one year?
Show Flashcard #2.

- Less than 2%
- 3% to 9%
- 10% to 30%
- Greater than 30% chance
- Don't know
- Not applicable - Can't get pregnant

32. HOW LIKELY do you think YOU would be to get pregnant if you used MALE CONDOMS as your only method of birth control for one year?
Show Flashcard #2.

- Less than 2%
- 3% to 9%
- 10% to 30%
- Greater than 30% chance
- Don't know
- Not applicable - Can't get pregnant

33. CHART C GROUP ONLY: Which method do you think works better to prevent pregnancy, BIRTH CONTROL PILLS or MALE CONDOMS if used CORRECTLY & CONSISTENTLY?

- Birth control pills
- Condoms
- They work about the same
- Don't know/can't tell from chart
- Not applicable - Assigned to Chart A or Chart B

Communicating Effectiveness Questionnaire - Page 5

Chart: |__|
(A, B, C)

Participant ID: |__||__||__||__| - |__|

Interview Date: |__||__|/|__||__|/|__||__|
mm dd year

Interviewer please take the chart from participant and continue with Question #34.

34. Having seen the chart about pregnancy protection, have you changed your mind about how effective **MALE CONDOMS** are at preventing the transmission of HIV and other sexually transmitted infections?

- No
- Yes, I now think they are more effective
- Yes, I now think they are less effective

35. If a woman has sex **JUST ONCE** and uses a **MALE CONDOM CORRECTLY**, what are her chances of getting HIV/AIDS?
Show Flashcard #3.

- Less than 1%
- 1% to 2%
- 3% to 9%
- 10% to 30%
- Greater than 30%
- Don't know

36. If a woman has sex **JUST ONCE** and uses a **MALE CONDOM CORRECTLY**, what are her chances of getting pregnant?
Show Flashcard #3.

- Less than 1%
- 1% to 2%
- 3% to 9%
- 10% to 30%
- Greater than 30%
- Don't know

The remaining questions are for participants who are currently using birth control.

37. Now that you have learned more about how well the different methods of birth control prevent pregnancy, are you thinking about changing methods?

- No
- Yes
- Not applicable - Currently not using birth control

38. If **YES** to Question #37: what method are you thinking of switching to?

*Do not read choices, check **ALL** that apply*

- Male sterilisation (vasectomy)
- Female sterilisation (tubes tied)
- Implants (Norplant)
- Injectables (hormone shots)
- Birth control pills
- IUD
- Male condoms
- Diaphragm
- Vaginal sponge
- Cervical cap
- Female condoms
- Spermicide (foam, gel, film, suppositories)
- Withdrawal (pulling out)
- Natural family planning (rhythm, calendar)
- Other (specify): _____
- Not applicable - Currently not using birth control/answered "No" in Question #37

END OF SURVEY