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The influence of informed consent content on study participants' contraceptive knowledge and concerns

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Abstract

Objectives—Little is known about how the information presented in the informed consent process influences study outcomes among participants. This paper examines how the content of the informed consent document may influence baseline levels of knowledge among study participants.

Methods—We examined the influence of the content of informed consent documents on reported contraceptive knowledge and concerns among two groups of sero-discordant and HIV concordant positive couples enrolled in research projects at an HIV research center in Lusaka, Zambia.

Results—We found significant differences in the reporting of both contraceptive knowledge and concerns between couples viewing consent forms that included detailed information on contraception and those viewing consent forms without the detailed information.

Conclusions—The protection of human subjects is vital. The future challenge, however, lies in creating informed consent documents that can find the balance between ensuring that participants give truly informed consent, and educating participants in ways that compromise the assessment of the impact of behavioral interventions.

INTRODUCTION

The requirement for informed consent of research participants is a fundamental element of all ethical guidelines for research^{1, 2, 3}. While the need for informed consent is widely accepted, debate surrounds the content and delivery of the informed consent process. Many previous studies have demonstrated that for research subjects in developed or high literacy settings, the provision of a written consent document greatly improves participant's recall of information⁴. Low levels of literacy among the research population may limit the use of written informed consent, however, creating challenges for implementing the consent process in resource poor settings. Although many previous studies have demonstrated the positive benefits of written informed consent documents, including increases in participant enrollment, recall of information and reported trust in the research, such research has focused largely on clinical research studies in developed nations⁵. Video-based consent has been used in the informed consent process and is particularly useful in low literacy and multilingual populations^{6, 7}. Video-based informed consenting has been associated with better comprehension^{8–12}, better retention of information^{13, 14} and increased willingness to participate¹⁵ when compared with standard reading of the consent form. There is a dearth of studies that have examined the impact of the content of the informed consent form on participants' knowledge; that is, have attempted to understand the extent to which the information given to participants in the informed consent process may influence their study outcomes. This is particularly relevant when the study is aiming to influence knowledge, attitudes or behavior (rather than a potentially more objective clinical outcome). The current study examines how the content of a video-based informed consent process influences contraceptive knowledge and concerns among cohorts of sero-discordant and concordant HIV positive couples enrolled in two research studies in Lusaka, Zambia. An understanding of the role of the consent process in shaping study outcomes will provide important new information to researchers designing informed consent documents for studies that aim to measure knowledge, attitudes and behaviors.

STUDY SETTING

Zambia is one of sub-Saharan Africa's more urbanized countries, with approximately 36% of the total population living in urban areas¹⁶. Overall HIV prevalence in Zambia among persons 15–49 years is approximately 16%, with higher infection levels among women (18%) than men (13%). In urban areas HIV infection among pregnant women declined during between 1994 to 2004—especially among young people aged 15–24 years from 30% in 1994 to 24% in 2004—yet rates in rural areas of Zambia increased slightly from 11% to 12%^{16, 17}. Zambia's TFR is 5.9 births per woman, and the contraceptive prevalence rate is relatively low with only 23% of women of reproductive age reporting contraceptive use, and only 17% report use of a modern method. Among currently married women the oral contraceptive pill (12%) and withdrawal (5%) were the most commonly used modern and traditional methods¹⁶.

DATA & METHODS

First established in 1986, the Rwanda Zambia HIV Research Group (RZHRG) operates 10 free standing couples voluntary counseling and testing (CVCT) clinics and four clinical research centers in two countries in Africa: Project San Francisco (PSF) in Kigali, Rwanda, and the Zambia Emory HIV Research Project (ZEHRP) in Lusaka and Ndola, Zambia. This study was carried out at the Lusaka, Zambia research site. Couples received joint, same-day HIV counseling and testing at the CVCT clinics, an intervention with proven efficacy in reducing HIV incidence among high-risk populations, namely heterosexual couples in the African setting^{18–22}. Couples meeting eligibility criteria were invited to participate in

ongoing clinical studies based at the research centers. Couples that agreed to be enrolled in studies returned to the research centers every three months for follow-up visits during which time behavioral and clinical data were collected, and health care, referrals, counseling and free condoms were offered to study participants. More detailed information regarding CVCT recruitment strategy and procedures, HIV results and demographic characteristics of RZHRG study participants have been published elsewhere^{18–26}.

The data analyzed come from cohorts of couples from Zambia enrolled in two studies: *Heterosexual Transmission of HIV in Africa* (HT), an observational study aimed at understanding the behavioral, virologic, immunologic, and immunogenetic correlates of HIV transmission in HIV discordant couples; and *Family Planning in Couples with HIV* (FP), a randomized control trial investigating two different video-based family planning interventions with the goal of reducing fertility in concordant HIV positive and HIV discordant couples. The FP interventions provided information on family planning, contraceptive methods, and future planning behaviors (including help in preparing a will and appointing guardians for existing children) in order to encourage contraceptive adoption among sero-discordant and concordant positive couples. Eligibility criteria for couples in both studies included cohabiting for at least 12 months, planning to stay in Lusaka for at least one year from the date of enrollment, and age 18–45 for females, and 18–65 for males. For the HT study only sero-discordant couples were eligible, and for FP both sero-discordant and concordant HIV positive couples were eligible. Additional eligibility criteria for the FP study included no evidence of infertility and no medical contra-indicators to contraception. Enrollment for both studies included medical history, physical exam, and demographic and KAP questionnaires with the same data collection forms used for HT and/or FP participants. Follow-up procedures for the two studies were also identical and included quarterly visits with interim medical and reproductive health (STI, contraception, obstetric) histories. FP study participants had one additional visit between enrollment and the first quarterly visit, during which behavioral interventions targeting family planning behaviors were administered.

Couples attending the clinics for CVCT underwent an informed consent process prior to HIV-testing. Couples who were identified as meeting study eligibility criteria were invited to enroll in the HT and/or FP studies, dependent on couple sero-status and other criteria. Prior to enrollment into the HT or FP studies couples underwent a video-based informed consent process, detailing the scope of the study, their expected participation as well as issues of confidentiality, participant protection and voluntary nature of the participation. The informed consent process for CVCT, HT, and FP began with a videotape of a counselor reading the consent verbatim in the local language, followed by a discussion with a nurse during which key points were reiterated, questions answered, and signatures (or thumb prints in the case of illiterate participants) obtained. Approval for the studies was granted by the Emory University Institutional Review Board, and the University of Zambia Research Ethics Committee. However, the IRBs required that the informed consent form for the FP study include detailed information on each contraceptive method that was to be available to study participants. This included a detailed description of each method and the possible side effects. For example, the consent form included the following information on the IUD: *The third form of contraceptive you may choose in the IUD, a small device which is placed in your uterus by trained personnel. Some women who choose the IUD experience heavier or more painful periods during the first few months after insertion.* The videos were both approximately the same duration (around 25–30 minutes), and aside from the inclusion of family planning information in the FP consent video, both contained the same information in the same order. Topics covered included the purpose of the study, the volunteer nature of participations, rights to withdraw from the study, expected potential harms and benefits of participation, and compensation for participation. The ordering of the information was the

same in each consent video. Thus, the critical difference between the consent forms for the HT and FP studies was the inclusion of detailed contraceptive method information and information on side-effects on the FP informed consent. Although the investigators suspected that the detail included in the informed consent document may potentially influence participants' knowledge of contraception, the studies were pursued as the aims of the studies reached beyond increasing family planning knowledge to include reducing pregnancy and increasing contraceptive adoption, outcomes that were less likely to be influenced by the inclusion of descriptions of family planning methods in the consent document.

After completing the informed consent process, couples completed a baseline questionnaire, which included information on individual knowledge of contraceptive methods: this is referred to as the baseline data. Couples in the FP study were then randomized to one of the 4 study arms: control, video showing information on family planning only, video showing information on future planning only, and video showing both information on family planning and future planning.

Data at baseline were collected by trained counselors at the CVCT centers. Completed data forms were scanned daily on-site with TeleForm software, and data were then transferred into Microsoft Access databases. These databases were uploaded to RZHRG servers on a weekly basis, facilitating the transfer of data to the research headquarters in Atlanta, GA, USA. Statistical analyses were performed using SAS software, version 9.1, [Copyright © 2002–2003 by SAS Institute Inc., Cary, NC, USA]. In total, 2029 couples were enrolled into the HT and FP studies (Table 1): of which 1557 were enrolled in the FP and/or HT studies (either FP only or HT and FP) and 472 in the HT study only; the larger enrollment in the FP study is a product of the higher number of concordant positive couples. For simplicity, we now refer to the studies as FP and non-FP to recognize that some couples may be in both the HT and FP studies; couples could be in HT only, FP only or HT and FP. Because the FP consent document was viewed and FP indicators were collected at the initial enrollment visit, data from clients that dropped out of the study or were lost to follow up after giving consent (n=111) were still included in the analysis.

The analysis considers two sets of outcomes, measuring knowledge of contraception and concerns about contraceptive methods. The baseline questionnaire asked individuals if they had heard of oral contraceptive pills (OCP), injectable contraceptives, implants, intra-uterine device (IUD), emergency contraception, female sterilization (tubal ligation) and male sterilization (vasectomy). For each contraceptive method, respondents who reported knowledge of that method were also asked if they had any worries or concerns about the method that would prevent them using it. The analysis considers method specific binary variables coded one if the respondent spontaneously reports knowledge of the method or concerns about the method, and a variable coded one if the respondent reports knowledge of or concerns about any of the methods. The analysis compares the distribution of reported knowledge and concerns about each contraceptive method by study (FP versus non-FP) using appropriate tests for statistical significance.

RESULTS

Table 1 shows the demographic profile of study participants aggregated by the type of consent form viewed (based on study eligibility and participation). A total of 2,029 couples are included in this study, of which 1,557 viewed the FP consent form and 472 viewed the non-FP consent. The distribution of HIV status among study participants is such that 1,086 couples viewing the FP consent were concordant HIV positive couples, along with 220 HIV sero-discordant couples where the male partner was positive and 251 HIV sero-discordant

couples where the female was positive. Of couples viewing the non-FP consent form only, 195 were sero-discordant where the male partner was HIV positive and 277 were sero-discordant couples where the female partner was HIV positive. The mean ages are 29 for women and 35 for men participating in the FP study, 30 for women and 36 for men participating in the non-FP study (these differences are not statistically significant between couples in the FP and non-FP groups).

Table 2 shows literacy and employment characteristics by gender for couples in the two groups. In both the FP and non-FP groups' men report higher level of literacy and understanding of English, and have higher levels of employment than women. The differences in literacy and employment between genders were statistically significant within both the FP and non-FP groups: but there were no significant differences in literacy and employment between genders across the two groups. There were no significant differences between the couples in the FP and non-FP groups in terms of any other socio-economic or demographic factors (data not shown).

Table 3 shows the reported levels of knowledge of contraceptive methods by study group. Women who were exposed to the family planning consent form reported significantly higher levels of knowledge of injectable, implant and IUD than women who were not exposed to the family planning consent form. The family planning trial aimed to promote longer-lasting family planning methods (e.g. IUD and implant), and it is noteworthy that these methods saw the largest differences in knowledge between the FP and non-FP groups. Similarly, men who were exposed to the family planning consent process also reported higher levels of knowledge of injectable, implants and IUD than men who were exposed only to non-FP informed consent.

Table 4 shows the reported concerns about contraceptive methods. In the aggregate, both men and women exposed to the FP consent form reported overall higher levels of concerns regarding family planning than men and women exposed to the non-FP consent forms. The difference in concerns regarding family planning between women in the FP and non-FP groups was driven by greater levels of concern about OCP, injectable and emergency contraception (the only significant difference was concerns regarding emergency contraception). Figures 1 and 2 show the types of concerns regarding family planning reported by men and women in the FP and non-FP groups. The only significant difference in the types of concerns reported between women in the FP and non-FP is for emergency contraception, where a much larger percentage of women in the FP group reported that they were concerned emergency contraception was bad for their health (Figure 1). Women in the FP group also reported marginally higher levels of concern about OCP, injectable and tubal ligation. For men, there were no clear patterns in the reporting of types of concerns between the FP and non-FP groups; however for vasectomy, emergency contraception and injectable men in the non-FP group reported marginally higher, although not significant, levels of concern.

DISCUSSION

Participants exposed to the FP and non-FP informed consent forms reported very differing levels of both knowledge and concerns regarding family planning methods. These differences exist in the absence of significant differences in socioeconomic and demographic background characteristics between the two groups, suggesting that the differences in reported knowledge and concerns are in some way driven by the informed consent process. However, the study measured only gross knowledge of contraceptive methods; we did not explore specific knowledge about the use and workings of each method and it is possible that further variations in specific knowledge may be observed between the two groups.

Men and women in the FP group reported higher knowledge of IUD, injectable and implant contraceptives than men and women in the non-FP group. Zambia's total fertility rate of 5.9 births per woman is among the highest in the world; the country's contraceptive prevalence rate is relatively low with only 17% of women of reproductive age reporting using a modern contraceptive method and 27% reporting an unmet need for family planning¹⁶. Use of the longer acting methods IUD and implants is virtually negligible; with oral contraceptive pills and female sterilization the most frequently used contraceptive methods¹⁶. Interestingly there were no differences in reported knowledge of oral contraceptive pills or female sterilization between the FP and non-FP groups; hence the addition of detailed family planning information to the informed consent process acted to increase knowledge of the less commonly used, and thus less commonly known, contraceptive methods. As a result, the informed consent process in the FP group essentially contaminated the enrolled cohort of couples; by creating artificially high baseline knowledge of family planning it thus became difficult to measure and identify true changes in family planning knowledge that could be attributed to the effects of the family planning intervention delivered after the baseline questionnaires.

While it may be argued that the detailed informed consent document allowed couples to make informed decisions regarding their decision to participate in the trial, given the impact on knowledge about contraceptives, one of the outcomes of the trial and a critical mediator of long-acting contraceptive use, the primary trial outcome, we argue that such information was not necessary at the informed consent stage of the process. In fact, the consent process acted to create a higher level of concern for about some family planning methods, with higher levels of concern reported for unfamiliar methods such as emergency contraception. After passing through the informed consent and enrollment stages, couples would meet with a counselor who would provide detailed information on their contraceptive options, which provided an ethical mechanism for delivering family planning information without including it in the consent process.

It is possible that there are other study related factors that are driving the differences in knowledge and concerns reported by participants exposed to the FP and non-FP consent forms. Recruiting mechanisms were the same for both studies, and Table 2 shows there are very few socio-economic differences between participants in each of the studies, hence it is unlikely that study selection procedures acted to create differences between the two groups. The main difference between the two groups is that those exposed to the FP consent form were more likely to be concordant HIV positive; it is possible that those who are HIV positive may have more concerns about family planning methods, however, it is hard to see how being HIV concordant positive would create more knowledge of family planning methods.

CONCLUSION

The results clearly demonstrate the potential for the informed consent process to influence knowledge outcomes among study participants. In this case, a consent document acted to create artificially high levels of baseline knowledge, thus contaminating the measurement of true change in knowledge attributed to the intervention that came later. While informed consent is a vital element of the research process, and that the rights of the study participant should be protected, we suggest that the IRB review process consider the nature of the intervention more fully when making decisions on the content of the informed consent document. Both the family planning and heterosexual transmission studies included free contraceptive services to all participants; the FP interventions were designed to increase selection of longer acting methods-in particular IUD and implant. These methods are not well known in Zambia, and improved knowledge about them was a critical mediating step

that was impossible to measure given the contamination resulting from the content of the FP informed consent.

The purpose of the informed consent needs to be considered. Informed consent documents should provide enough information to participants for them to judge the relative risks and benefits of their participation. In the case of the family planning focused intervention presented here, the informed consent need only inform the participant of the nature of the intervention – providing details of the procedures and activities to be conducted. It would have been sufficient to inform the potential participant of the nature of family planning and contraception and to state that they would be provided with access to a trained counselor who would outline all their contraceptive options and associated risks and benefits. By including all this information into the informed consent document the document became an educational tool that influenced the measurement of knowledge outcomes and compromised the goals of the trial.

The provision of quality family planning services requires that couples be provided with full information on all of their contraceptive options and the associated side effects. The provision of effective informed consent requires that potential participants have all the facts that enable them to make an informed choice on their enrollment. In this paper we show that combining these two needs into one document influences knowledge related outcomes, thus contaminating the research process. We suggest that IRBs take steps to discuss with investigators alternative mechanisms for delivering information to study participants, outside of the consent form; in our case, the consent form should have provided enough background to allow the participant to make the decision to enroll, while the information enabling the decision on which contraceptive to adopt should have been left to the post-enrollment counseling session. Our first priority should always be the protection of research subjects. The future challenge, however, lies in creating informed consent documents that can find the balance between informing and educating the potential participant.

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Figure 1.
Distribution of worries or concerns about contraception among women who know about contraceptive type in Lusaka, Zambia by type of informed consent form viewed

Figure 2.
Distribution of worries or concerns about contraception among men who know about contraceptive type in Lusaka, Zambia by type of informed consent form viewed

Table 1

Demographic comparison of research cohort viewing family planning consent form (FP) with cohort viewing other study consent form (non-FP), Lusaka, Zambia, 2003–2005

	Total	FP	Non-FP
Total number of participants	4,058	3,114	944
Total number of couples	2,029	1,557	472
Number of men	2,029	1,557	472
Number of women	2,029	1,557	472
Distribution of HIV status			
Concordant positive	1,086	1,086	0
Discordant male pos, female neg	415	220	195
Discordant male neg, female pos	528	251	277
Age range in years (<i>mean</i>)			
Women	18 – 45 (28.95)	18 – 45 (28.72)	18 – 45 (29.70)
Men	18 – 64 (35.22)	18 – 62 (34.91)	18 – 64 (36.21)
All	18 – 64 (32.09)	18 – 62 (31.82)	18 – 64 (32.96)
Study of participation			
Heterosexual transmission (HT)	472	0	472
Both HT and FP	1557	1557	0

Table 2

Literacy and employment characteristics of female and male study participants by type of consent form viewed ('FP' or 'Not FP'), Lusaka, Zambia, 2003–2005

	FP		Non-FP	
	Women (n = 1,557)	Men (n = 1,557)	Women (n = 472)	Men (n = 472)
Understand English				
Easily	401 (26%)	961 (62%)	112 (24%)	300 (64%)
With difficulty	645 (41%)	542 (35%)	194 (41%)	155 (33%)
No	511 (33%)	54 (3%)	166 (35%)	17 (4%)
Read English				
Easily	349 (22%)	900 (58%)	93 (20%)	288 (61%)
With difficulty	547 (35%)	505 (32%)	160 (34%)	145 (31%)
No	661 (42%)	152 (10%)	219 (46%)	39 (8%)
Employment				
All year	506 (33%)	822 (53%)	141 (30%)	254 (54%)
Part of the year	150 (10%)	413 (27%)	68 (14%)	117 (25%)
Once in a while	65 (4%)	73 (5%)	20 (4%)	27 (6%)
N/A	836 (54%)	249 (16%)	243 (51%)	74 (16%)

Table 3

Distribution of knowledge of family planning method ('yes' or 'no') by gender and type of consent form viewed ('FP' or 'NOT FP'), Lusaka, Zambia, 2003–2005

Contraceptive method	Women			Men		
	FP (n= 1,557)	NON-FP (n=472)	p-value	FP (n= 1,557)	NON-FP (n=472)	p-value
Any method [†]	1,557 (100%)	471 (99.8%)	0.2326 ^I	1,549 (99%)	464 (98%)	0.011
OCP	1,557 (100%)	469 (99%)	0.0125 ^I	1,542 (99%)	458 (97%)	0.0013
Injectable	1,549 (99%)	454 (96%)	< 0.0001	1,476 (95%)	401 (85%)	< 0.0001
Implant (Norplant)	1,347 (87%)	335 (71%)	< 0.0001	1,139 (73%)	134 (28%)	< 0.0001
IUD	1,343 (86%)	325 (69%)	< 0.0001	1,189 (76%)	179 (38%)	< 0.0001
Emerg. Contracep.	246 (16%)	51 (11%)	0.0072	146 (9%)	34 (7%)	0.1457
Tubal Ligation	1,225 (79%)	357 (76%)	0.1625	670 (43%)	202 (43%)	0.9281
Vasectomy	544 (35%)	153 (32%)	0.3118	438 (28%)	123 (26%)	0.378

[†] Any method = indicated 1 (spontaneous) or 2 (prompted) to knowledge of ANY of the contraceptive methods

l Two-sided fishers exact test used because 0 observations in one cell

2 Two-sided fishers exact test used because less than five in cell(s)

Distribution of concerns about family planning methods ('yes' or 'no') by gender and type of consent form viewed ('FP' or 'NOT FP'), Lusaka, Zambia, 2003–2005

Table 4

Contraceptive method	Women			Men		
	FP (n= 1,557)	NON-FP (n=472)	p-value	FP (n= 1,557)	NON-FP (n=472)	p-value
Any method [†]	821 (53%)	223 (47%)	0.0405	739 (48%)	189 (41%)	0.0082
OCP	482 (31%)	132 (28%)	0.2318	466 (30%)	136 (30%)	0.8253
Injectable	352 (23%)	91 (20%)	0.2167	248 (17%)	75 (19%)	0.3638
Implant (Norplant)	87 (7%)	21 (6%)	0.9195	166 (15%)	17 (13%)	0.5645
IUD	221 (17%)	56 (17%)	0.7337	286 (24%)	39 (22%)	0.4794
Emerg. Contracep.	38 (16%)	3 (6%)	0.0766 [‡]	21 (14%)	7 (21%)	0.3777
Tubal Ligation	74 (6%)	18 (5%)	0.4624	131 (20%)	42 (21%)	0.7336
Vasectomy	21 (4%)	7 (5%)	0.6769	98 (22%)	33 (27%)	0.2923

[†]Two-sided fishers exact test used because 0 observations in one cell

[‡]Two-sided fishers exact test used because less than five in cell(s)