HHS/CDC/NCIPC
SUPPORTING STATEMENT FOR
OMB INFORMATION COLLECTION REQUEST

(OMB #0920-0761)
Revision

Part B

Randomized Controlled Trial of Routine Screening for Intimate Partner Violence

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B.1. Respondent Sampling frame and Sampling Methods

Sampling frame. All women at least 18 years of age attending a women's health clinic in Cook County Bureau of Health Services are eligible. The following table provides our exclusion criteria and rationale:

Exclusion Criteria	**Rationale**
Non-English or Non-Spanish speaking	Audio programming and video clips in multiple languages is cost-prohibitive
Women accompanied by a child >3 years of age who don't have adequate provision for child care	Older children may compromise the privacy of the kiosk and for security reasons, they should be with their caretaker
Visually- or hearing-impaired women	They will be unable to use either the A-CASI or the touch-screen monitor
Women who are accompanied by their partner and the two can't safely be separated	Patient privacy is essential for the safety of participants
Women who do not have access to a telephone	Unable to complete study task - CATI follow-up at one-year (Main Study)
Severe Mental impairment	Unable to give Informed Consent and complete study tasks

Sampling methods: Eligible participants will be enrolled every day in participating clinics until the sample size is reached. Research assistants (RAs) will approach potential patient-participants in the clinic's waiting room.

Sample size: OMB Clearance No. 0920-0761 approved a sample size of 3876 women for the Main Study. This sample size was based on previous studies' findings of a prevalence of 13% of women in primary care clinics reporting IPV in the past year. However, the Pretest showed that about 20% of women attending the clinics where participants are being recruited report exposure to IPV in the past year. With this higher prevalence, only 2675 women will be required for the Main Study. This sample size will allow us to detect a standardized effect size of .4 (considered a small to moderate effect size[i] in Quality of Life score means among women exposed to IPV at a significance level of .05, power of 80%, factoring in a 30% lost-to-follow-up rate. [ii]

B.2. Procedures for the Collection of Information

Sample size estimates and sample selection have been described in Part A.

A standardized questionnaire with a total of 33 questions have been developed for the baseline and follow-up assessment, respectively (Attachments E and F). All questions on the baseline questionnaire have been based on existing scales or surveys as follows:
- *Quality of Life*: will be measured with the SF-12[iii] at both baseline and at follow-up (section A of baseline and follow-up). This measure has shown acceptable reliability and validity and summary scores of the SF-12 can be used to derive a utility value for the health state reported through an established algorithm. This transformation of the SF12 score represents what the general population believes is the quality of life associated with each woman's health state and allows comparisons with other conditions similarly standardized. This tool has been successfully and extensively used to assess QOL in clinical trials.
- *Disability* will be assessed at both baseline and follow-up utilizing two items that have been used successfully in the WorldSAFE IPV study.[iv]
- *Mental health* will be measured using the Self-Report Questionnaire (SRQ-20[v]) developed by an international team of mental health experts convened by the World Health Organization. The measure has been translated and validated in over 20 countries around the world showing acceptable criterion validity and internal consistency.
- *Partner Violence Screen* (PVS) will be used to assess the presence of current IPV (past year) and women's perception of being 'safe' from IPV among all participants in the Pretest and in Arm 1 of the Main Study. This 3-item screening tool has been used in Emergency Room settings where it was validated using the much longer IPV research instruments – Index of Spouse Abuse (ISA) and the Conflict Tactics Scale (CTS) as criterion.[vi] The sensitivity of PVS was .65 (compared to ISA) and .71 (compared to CTS); specificity for the PVS was .80 (ISA) and .84 (CTS).

The baseline questionnaire in the Main Study will also have a symptom checklist for conditions that have been associated with IPV developed specifically for this study. This will allow us to determine the effectiveness of screening among asymptomatic participants given that the US Preventive Services Task Force requires evidence showing that early treatment (during the asymptomatic period) produces better results than waiting for the appearance of symptoms and a diagnosis.[vii-viii]

The follow-up survey will ask the same questions as the baseline except for the Partner Violence Screen. In addition we will ask about:
- *Lifetime and past year* e*xposure to IPV*: will be assessed at follow-up in the Main Study using 10 of the items measuring simple and aggravated assault (threaten and use a gun and threaten and use a knife or other weapon have each been collapsed into 2 items), one of the items measuring sexual assault, and the seven items measuring control utilized in the National Violence Against Women Survey (NVAWS).[ix] Factor analysis of the NVAWS data collected with the seven control items suggested that these items measured one construct reliably (Cronbach α=.70).[x] These nonviolent control items will allow us to distinguish between situational couple violence (resulting when conflict escalates into mutually violent interactions) and so called "intimate terrorism" (male-to-female aggression motivated by the intent to control).[xi] Because these two types of IPV are hypothesized to have a different natural history and outcomes, the impact of any intervention might also differ;

- *knowledge of the prevalence and seriousness of IPV and of available services* with questions developed for this study as these might be other potential benefits of screening;
- any potential *adverse effects* as a result of their responding to our questions or receiving information as a participant in the study.

This baseline assessment will be conducted with A-CASI technology. A search of the literature identified the utility of computer assisted surveys in exploring sensitive health issues. The literature suggests that computer assisted surveys achieve higher disclosure rates than self-administered questionnaires or face-to-face encounters for many sensitive health issues[xii,xiii,xiv,xv,xvi], including IPV[xvii], are acceptable to patients and health care providers, and may increase solicitation and recall of health advice.[xviii] Based on this evidence, we have chosen this technology for use in our RCT of routine screening.

The follow-up questionnaire will be administered with CATI technology. The questionnaires have been tested for comprehension in 8 patients utilizing the A-CASI or CATI system. Revisions were not deemed necessary.

Questionnaires are at the seventh grade reading level. However, a research assistant will be available to assist participants who may have difficulty reading or understanding the questionnaires as well as utilizing the touch screen format at baseline. The follow-up questionnaire will be administered by a trained interviewer who will be able to handle potential questions participants may have over the phone.

After completion of the A-CASI in the clinic, a research assistant (RA) will meet with the participant she enrolled to "wrap-up". During this wrap-up, the RA will try to establish some rapport and negotiate telephone appointment dates/times for the one-year follow-up interview. She will ask participants to provide a preferred contact number, two alternate contact numbers, and the names and contact numbers of two people with whom she maintains regular contact. During this negotiation, the RAs will emphasize the woman's convenience and safety. Times not to call will be recorded in the RAs' log, as well as notes including agreed to safety signs (i.e., a safe word, identified by the woman to indicate if the woman is not able to safely answer the question). Additionally, during the wrap up, the RA will negotiate a safe message to leave on the participants' voice mail or answering machine. The RAs will give each woman a card with the toll-free number and RA's name noting the preferred time and two alternate times for the follow-up interview. The participant will be encouraged to inform the project of changes in her contact information by calling this 24-hour toll-free number.

Follow-up. Participants will be contacted at least once by phone and possibly one or two more times by mail to remind them of the phone interview and verify contact information and plans for the next few months, and to review strategies agreed on at baseline for contact and ensure that these methods remain safe and appropriate. Eleven months after completion of the baseline interview, efforts will begin for the follow-up of participants and will continue up to 4 weeks after the one-year date. As much as possible, the same RA that enrolled the participant will be responsible for follow-up of that participant. RAs will schedule calls based on days and times participants' reported preferring at baseline.

All information, except selected demographics and health care utilization, will be collected at the one-year follow-up using a computer-assisted telephone interview (CATI). The RA will open the CATI application and enter the study identifier, log the date and time of contact. For patients who cannot be contacted on the initial attempt, the interviewer will attempt a follow-up call to each of the numbers the participant provided up to 4 times on 3 consecutive days during times specifically negotiated with the women at enrollment, including calls during evening hours. After successful or failed follow-up contact, the patient will be removed from the report and considered as a failed contact. For partially completed or refused follow-up interviews the participant will be asked about the reason for termination of the interview (e.g., safety concerns or time pressures). The CATI program will create an automatic record of all dialings, track the outcome of each contact/interviewing attempt, and document reasons for refusal and the place of termination.

Once contact with participants is established for the follow-up, the interviewer will either proceed with the interview or schedule the interview at a time convenient to the respondent. For patients who are unable to complete the interview, but who request the opportunity to resume the interview at a later date, work will be saved and the interviewer and interviewee will have the option of resuming the interview without repeating questions.

CATI follow up interviews will be conducted in the Collaborative Research Unit at John H. Stroger Hospital -CATI office (Room 1608) following CRU protocol for attempts, response to disconnect, script for call answered by other, etc.). The CATI program will include the text of the question wording, response category wording, and the programming of the skip patterns, and range checks and other on-line consistency checks and procedures during the interview as well as a system to help eliminate the problem of key entry error as a result of accidentally hitting the wrong key. For quality control, these activities will be supervised or reviewed by the study coordinator.

B.3. Methods to Maximize Response Rates and Deal with Nonresponse

Women in the clinics' waiting room will be invited to participate in this study, including the follow-up telephone interview. The RA will give women a copy of the consent form and will also read it aloud to her. Those not wishing to participate will receive the standard of care. RAs will keep a log of women who do not wish to participate to determine non-response rates. Participants in the study will be compared to what is known about women attending women's health clinics in the Cook County's Health and Hospitals System as to age, race, and insurance coverage to determine potential non-response bias.

Those consenting will be asked to go to a computer kiosk with the RA and respond to the questionnaire. In the Main Study, participants will be offered a $20 certificate upon completion of the questionnaire and mailed a $15 certificate after the telephone interview in one year.

All interviewers hired by the subcontractor (Dr. Laura Sadowski in the Collaborative Research Unit of John H. Stroger Hospital) will be thoroughly screened and their interviewing abilities tested prior to their being employed by the Collaborative Research Unit. For this study, interviewers will receive approximately 8-12 hours of project-specific training. The content of training will include: eligibility determination, recruitment, informed consent, enrollment, A-CASI operations, and CATI follow-up. In addition, interviewers will also receive information on IPV and its consequences and will be given a comprehensive set of questions and answers that will provide encouraging responses to questions that respondents may ask.

Telephone interviewing techniques will be modeled utilizing the study questionnaire and practiced by trainees through role-play. Trainees will be observed and given feedback during simulations of the interview until they are able to perform each skill to the PI's satisfaction.

B.4. Test of Procedures or Methods to be Undertaken

The feasibility and acceptability of the questionnaires and procedures were tested in the Pretest. This request for approval of Revisions with an extension of the approval time is based on the findings from the Pretest.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

All instruments and procedures have been reviewed extensively by CDC/DVP and the Collaborative Research Unit staff at Cook County Hospital. The following individuals have worked closely in developing the instrument and procedures that will be used, and will be responsible for data analysis:

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REFERENCES

[i] Cohen, J. Statistical power for the behavioral sciences (2nd edition). Hillsdale, NJ: Erlbaum (1988).

[ii] Hulley, SB & Cummings, SR. Designing Clinical Research (pp. 216, 219). Baltimore, MD: Williams & Wilkins; 1988.

[iii] Ware JE, Kosinski M, Keller SD. A 12-item short-form health survey: construction of scales and preliminary tests of reliability and validity. Med Care 1996;34(3):220-233.

[iv] Sadowski, LS, Hunter, WM, Bangdiwala, SI, Muñoz, SR. The world studies of abuse in the family environment (WorldSAFE): a model of multi-national study of family violence. Injury Control and Safety Promotion 2004; 11: 81-90.

[v] World Health Organization: A user guide to the Self-Reporting Questionnaire. Geneva: WHO; 1994 Available at: http://whqlibdoc.who.int/hq/1994/WHO_MNH_PSF_94.8.pdf

[vi] Feldhaus, KM, Koziol-McLain, J, Amsbury, HL, Norton, IM. Accuracy of 3 Brief Screening Questions for Detecting Partner Violence in the Emergency Department. JAMA 1997; 277: 1357-1361.

[vii] Campbell J, Jones AS, Dienemann J, et al. Intimate partner violence and physical health consequences. *Arch Intern Med* 2002; 162:1157-1163.

[viii] Coker AL, Smith PH, Bethea L, et al. Physical health consequences of physical and psychological intimate partner violence. *Arch Fam Med* 2000;9:451-457.

[ix] Tjaden, P. & Thoennes, N. Full Report of the Prevalence, Incidence, and Consequences of Violence Against Women. Findings from the National Violence Against Women Survey. Washington, DC: National Institute of Justice, 2000.

[x] Johnson, MP & Leone, JM. The Differential Effects of Intimate Terrorism and Situational Couple Violence. Journal of Family Issues 2005; 26: 322-349.

[xi] Johnson, MP & Ferraro, KJ. Research on domestic violence in the 1990s: Making distinctions. Journal of Marriage and Family 2000; 62:948-963.

[xii] Gerbert, B, Bronstone, A, Pantilat, S, McPhee, S, Allerton, M, Moe, J. When asked, patients tell: disclosure of sensitive health-risk behaviors. Medical Care 1999; 37: 104-111.

[xiii] Des Jarlais, DC, Paone, D, Millikenm, J, Audio-computer interviewing to measure risk behavior for HIV among injecting drug users: a quasi-randomised trial. Lancet 1999; 353: 1657-1661.

[xiv] Gribble, JN, Miller, HG, Cooley, PC, Catania, JS, Pollack, L, Turner, CF. The impact of T-CASI interviewing on reported drug use among men who have sex with men. Substance Use and Misuse 2000; 35: 869-890.

[xv] Turner, CF, Ku, L, Rogers, SM, Lindberg, LD, Pleck, JH, Sonenstein, FL. Adolescent sexual behavior, drug use and violence: increased reporting with computer survey

technology. Science 1998; 280: 867-873.

[xvi] Newman, JC, Des Jarlais, DC, Turner, CF, Gribble, J, Cooley, P, Paone, D. The Differential Effects of Face-to-Face and Computer Interview Modes. American Journal of Public Health 2002; 92: 294-297.

[xvii] Rhodes KV, Lauderdale DS, He T, Howes DS, Levinson W. "Between me and the computer": Increased detection of intimate partner violence using a computer questionnaire. Ann Emerg Med 2002; 40: 476-484.

[xviii] Rhodes, KV. The Promise and Problems of Using Information Technology to Achieve Routine Screening for Intimate Partner Violence. Family Violence Prevention and Health Practice 2005; (3): 1-14.