ICCR - IRB Proposal
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Screening for Intimate Partner Violence

1. Study Purpose & Rationale

Background

Intimate partner violence (IPV) is defined as actual or threatened physical or sexual violence or psychological and emotional abuse directed toward a spouse, ex-spouse, current or former boyfriend or girlfriend, or current or former dating partner.[1] Common terms used to describe intimate partner violence are domestic abuse, spouse abuse, domestic violence, courtship violence, battering, marital rape, and date rape.

Although there is extensive literature on intimate partner violence, there are few studies providing data on its detection and management to guide clinicians. As a result, clinicians confront difficulties fulfilling their role in preventing and treating the adverse health effects of violence.

Epidemiology of Intimate Partner Violence

Findings from the National Violence Against Women Survey in 2000, funded by the Centers for Disease Control and National Institute of Justice, report that approximately 1.5 million women are physically assaulted and/or raped by an intimate partner each year.[2] A 1998 Commonwealth Fund Survey of Women's Health[3] asking women nationwide, through telephone interviews, about their lifetime experiences with abuse and violence found high rates of violence and abuse. This survey found that 39% reported experiences with childhood abuse, rape or assault, or domestic violence. Thirty-one percent of women reported that she had been kicked, hit, punched, choked or otherwise physically abused by a spouse or partner in their lifetimes. Three percent of women, or 3 million women nationwide, reported experiencing domestic abuse in the past year. Prevalence rates of abuse in clinical samples range from 4% to 44% within the past year and from 21% to 55% over a lifetime.[4,5, 6, 7, 8]

Health Conswequences of Intimate Partner Violence

IPV is associated with both short-term and long-term harms, including physical and psychological injury and illness, economic costs, and death. There is significant risk of injury to women in IPV as victims are punched, punched, kicked, strangled, assaulted, and verbally abused causing pain, injury, and psychological distress. These injuries are the short-term consequences that most health care professionals associate with IPV. Studies have shown that IPV is the most common cause of nonfatal injury to women in the U.S.[9,10] The lifetime risk of severe injury as a result of IPV has been estimated to be 9% for women, with a lifetime risk of 22% for any type of injury from domestic violence.[11] The incidence of acute cases in emergency care settings ranges from 2% to 7%.[12] The health care costs of IPV exceed $5.8 billion each year, of which $4.1 billion is for direct medical and mental health services.[13] Moreover, there is a considerable risk of death from IPV. One-third of homicides of women in the U.S. are committed by a spouse or partner.[14]

Aside from direct physical injury, there is mounting evidence that IPV has long-term health consequences for victims as well as survivors of violence. The long-term effects of injuries as well as the fear and stress associated with having an abusive intimate partner can result in long-term health problems. These include pain and discomfort from recurrent central nervous system symptoms such as headaches, back pain, fainting, or seizures.[15] Victims also suffer from more illnesses associated with chronic fear and stress, such as functional gastrointestinal disorders and appetite loss, viral infections, and cardiac problems, such as hypertension and chest pain. Moreover, women experiencing IPV are more likely to have gynecologic symptoms, such as pelvic pain, vaginal bleeding or infection, sexually-transmitted infections, urinary tract infections, and fibroids. These findings translate into lower quality of life, lower health status, and higher utilization of health services for victims of IPV.

The Commonwealth Fund Survey of Women's Health found strong links between abuse and a wide range of negative health effects, including higher rates of depression, reports of fair or poor health, and problems obtaining access to health care. While 22% of women who have been victims of domestic abuse rated their health as fair or poor, the same was true for only 15% of women without a history of violence. Fifty-three percent of women reporting a history of any abuse or violence had a high level of depressive symptoms compared with 30% of women who said they had not been abused or experienced violence. Moreover, 27% of women with a history of abuse or violence had a diagnosis of anxiety or depression compared to 10% of women without a history.

Risk Factors

The USPSTF state that the factors associated with intimate partner violence include young age, low income status, pregnancy, mental health problems, alcohol or substance abuse by victims or perpetrators, separated or divorce status, and history of childhood sexual and/or physical abuse.[16] As stated before, witnessing IPV as a child or experiencing violence from caregivers as a child increases one's risk of both perpetrating IPV and becoming a victim of IPV.[17] The Commonwealth Fund Survey of Women's Health found that violence and abuse rates varied little geographically by whether women lived in cities, suburbs, or rural areas, and by region of the country in which they live. The survey also found little variance by race, ethnicity, or education. Women living on low incomes did tend to be at a higher risk for various types of violence, although rates remained high across incomes. Overall, 47% of women with incomes of $16,000 or less reported at least one incident of violence or abuse in their lifetime as compared to 34% of women with incomes of more than $50,000.

The Commonwealth Fund Survey found that while 75% of women surveyed who were victims of domestic violence had discussed their problem with a friend or relative, less than one-third had done so with a their doctor. Among abused women who discussed their abuse with a doctor, only 20% reported that the doctors raised the subject. Moreover, among the women surveyed who had been victims of assault, rape, or other violent crimes, only 28% sought medical attention. Of those who discussed their abuse with a doctor, 44% were referred to support services.

Does screening for IPV work?

It is important to distinguish between asking about IPV during the diagnostic evaluation of a patient versus routine screening for IPV in a primary care setting. It is important for clinicians to be alert for signs and symptoms that could be associated with IPV during any medical assessment of a patient in which there is suspicion for IPV. Theoretically, routine screening is a low-risk, low-cost procedure with reliable screening tools and effective treatment which improves outcomes. However, it is currently unknown whether routine screening leads to a decline in IPV. From 1993 through 1998 after several medical organizations, including the American Medical Association and the American College of Obstetricians and Gynecologists, recommended screening female patients for IPV, rates of violence against women by their intimate partners declined by 21% according to the U.S. Department of Justice.[18] However, since Department of Justice data do not include information on screening, it is not possible to make conclusions about the effects of screening. In a systematic review examining nine studies of screening compared with no screening in healthcare settings, screening detected more abused women than no screening.[19] In this same systematic review, 43% to 85% of women respondents found screening in healthcare settings acceptable while two surveys of health professionals' views found that only one-third of physicians and half of emergency department nurses favored screening. Moreover the evidence on how to screen and effectively intervene once problems are identified is limited, and few clinicians routinely screen patients who do not have apparent injuries.[20,21]

U.S. Preventive Services Task Force recommendations

In March 2004, the U.S. Preventive Services Task Force (USPSTF) reviewed the evidence for screening women for intimate partner violence.[22] In summary, the USPSTF found insufficient evidence to recommend for or against routine screening of women for intimate partner violence. They found no studies that directly addressed the effectiveness of screening in a health care setting in reducing harm from intimate partner violence or the adverse effects of screening and interventions. They stated that several instruments have been developed for intimate

partner violence screening with some demonstrating fair to good internal consistency and some that have been validated with longer instruments. However, none had been evaluated against measurable intimate partner violence outcomes. Moreover, in regards to interventions, the USPSTF summarized that few intervention studies have been conducted and these fair studies focused on pregnant women with limitations in study design and inconsistent results that restricted their interpretation.

In addition, the USPSTF review found that no studies were identified that provided data about the adverse effects of screening or interventions. They speculated that possible adverse effects include hindering identification of those who are truly at risk by false-negative tests, inappropriate labeling and punitive attitudes by false-positive tests, psychological distress, escalation of abuse and family tension, loss of personal residence and financial resources, erosion of family structure, loss of autonomy for the victim, and loss of time from work.

Although the USPSTF found insufficient evidence to recommend for or against screening, they did state that all clinicians should be alert to physical and behavioral signs and symptoms associated with abuse. Furthermore, they recommended that patients in whom abuse is suspected should receive proper documentation, treatment of physical injuries, arrangements for skilled counseling by a mental health professional, and telephone numbers of local crisis centers, shelters, and protective service agencies.

The Canadian Task Force on Preventive Health Care has also concluded that the evidence is insufficient to recommend for or against routine screening for violence against women.[23] However, the American College of Obstetricians and Gynecologists and American Medical Association recommend that physicians routinely inquire about abuse and domestic violence. Indeed, these organizations may advocate for such screening on the basis of prevalence alone or the value of this information in caring for the patient and the influence that this information may have in the assessment and treatment of health problems.

Although there is evidence that screening instruments are available to identify women who have been abused, no studies have evaluated the effectiveness of screening to reduce violence or to improve women's health. The effectiveness of routine screening in primary care remains unclear since screening studies have not evaluated outcomes beyond the ability of the screening test to identify abused women. Indeed it appears that the conclusions of the USPSTF, CTFPHC, and several other systematic reviews[19,24] has shown that there is a lack of evidence regarding the effectiveness of screening where the end point was improved health outcomes for women. There is a need for the development of primary care screening approaches for IPV.

In IPV, the primary health outcomes of interest are those related to physical and psychological morbidity of abuse. However, many studies have used self-reported incidence of abuse as the primary outcome in many of these studies.[24] There is debate as to whether incidence of reabuse is the appropriate measure for evaluating treatment interventions. Many authors argue that reabuse is an inappropriate measure because women have no control over whether they are abused again, and they are often forced to return to an abusive relationship for economic or other reasons. Other types of outcomes suggested in the literature include the impact of screening or counseling on the patient-physician interaction and subsequent physician action if women are identified as abused,[25] whether women revisit emergency departments,[26] and whether women's mental health improves. However, these measures are often lacking in studies. Moreover, some studies do not examine outcomes for abuse per se, but include main outcome measures such as amount of social support, use of safety behaviors or safety planning, or use of community resources. However, the link between these surrogate outcomes and subsequent abuse or health status has not been established.

2. Study Design and Statistical Procedures

We will conduct a clinical trial at a general internal medicine clinic at the Columbia University Medical Center. The study design will be formulated to address the following primary question/end point:

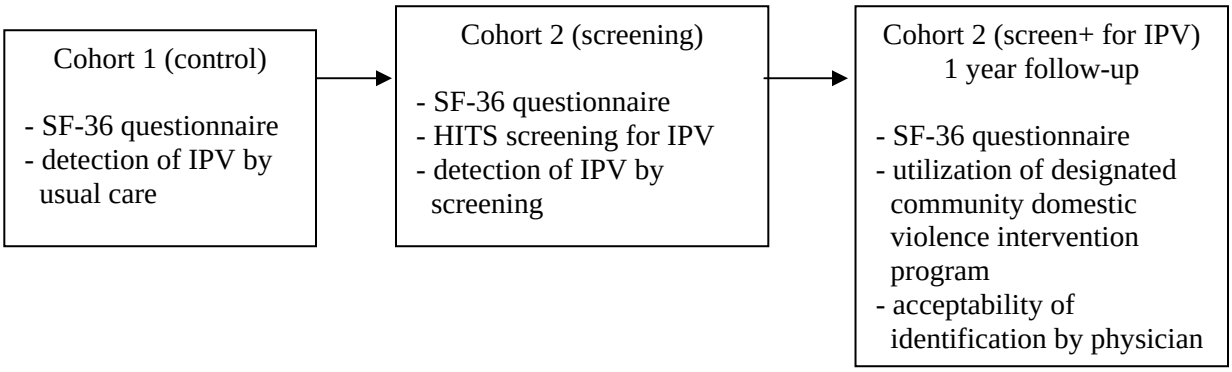
Does screening for intimate partner violence by written questionnaire in a primary care setting improve health outcomes (physical and psychological health) in women victims?

Secondary end points will assessment of type (psychological/emotional, control, threat, physical, or sexual), frequency, and duration of abuse; detection of IPV using screening versus usual care; utilization of community resources for victims of IPV; and acceptability of screening for IPV by participants.

As for study design, there will be 2 separate cohorts of participants and study participants at both clinic sites will be informed by nurses and support staff that we are conducting a study on women's health issues. . The first cohort will be the control group and will include women participants at a designated general internal medicine clinic that will be administered a written health questionnaire by nurses to assess physical and psychological health. The questionnaire that will be used will be the Medical Outcomes Study Short Form-36 (see Study Questionnaires section below for details). This cohort will represent a "usual care" scenario and clinic staff will not be trained to actively screen for intimate partner violence. After assessment of the first cohort, a second cohort will enroll in the study after physicians, nurses, and support staff will undergo skills and knowledge training regarding the importance of recognizing domestic violence in primary care and will be informed of the screening instrument to be utilized. Those who provide consent to participate in the second cohort will be administered a written health questionnaire by nurses assessing physical and psychological health. Embedded within in the health questionnaire will be 4 questions used to screen for IPV (HITS instrument, see Study Questionnaires section below for details).

For those participants in the second cohort that screen positive for IPV by questionnaire, physicians will be notified of the screening results by nurses. Women who are found to be victims of domestic violence, either through screening or usual care, will be appropriately referred to a designated community domestic violence intervention program which provides health assessment and care, advocacy, counseling, case-management, and community referral for victims of IPV. Those participants in the first cohort who are identified as victims of IPV will also be appropriately referred.

At a follow-up visit one year later, participants in the second cohort that screened positive for IPV will be re-administered health questionnaires along with the questionnaire completed one year previously as reference. Additionally, they will be administered a questionnaire to explore whether victims had utilized the designated community domestic violence intervention program or other intervention programs as well as acceptability of screening for IPV.



Mean scores and standard deviations for the Medical Outcomes Study Short Form-36 (see Study Questionnaires section below) will be calculated to compare health outcomes. Statistical analysis will be performed by t-test to compare baseline health of Cohort 1 compared to Cohort 2 at 1 year follow-up. In addition, t-test will be used to compare health of victims of IPV at screening compared to one year follow-up.

Power analysis: Unpaired t-test, approximations for 80% power, testing at p=0.05

n (in each group) = 1 + 16 (std devn/effect)^2
n = 1 + 16 (20/10)2
n = 65

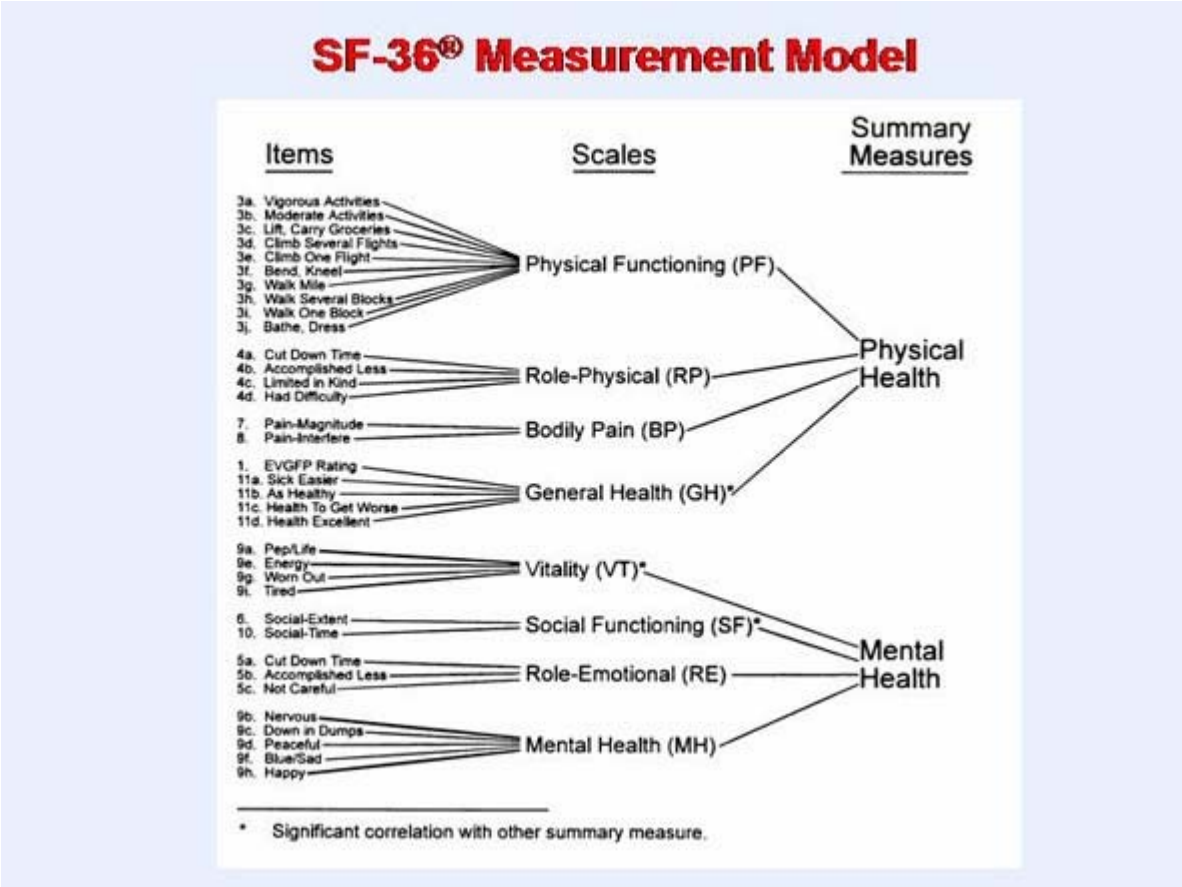
3. Study Drugs or Devices

No drugs or devices will be used in this study.

4. Study Questionnaires

Several instruments have been developed for intimate partner violence screening and have demonstrated good internal consistency.[27, 28, 29, 30] In addition, several have been validated with longer instruments although none have been evaluated against measurable violence or health outcomes. We chose the HITS (Hurt, Insulted, Threatened, and Screamed at) instrument to screen for domestic violence as it demonstrated fair internal consistency and its results correlated with previously validated 19-item Conflict Tactic Scales which is a screening tool for domestic violence used since the 1970s. In addition, it is a good screening tool in this study as it was originally tested in an outpatient setting, is a brief screening tool, and has an easily memorable mnemonic for practical use. This instrument is a 4-item questionnaire that asks respondents how often their partner physically Hurt, Insulted, Threatened with harm, and Screamed at them, making the acronym HITS. Each question is answered on a five point scale ranging from 1 to 5 for never, rarely, sometimes, fairly often, and frequently, respectively. The total scores range from a minimum of 4 to a maximum of 20. The patients who fall in the 11 to 20 range are the ones will be recognized as screening positive and will be offered information regarding community resources.

We will use the Medical Outcomes Study Short Form-36 (SF-36) to assess health-related quality of life.[31] The SF-36 was designed for use in clinical practice and research and includes 36 questions that assesses eight health concepts: 1) limitations in physical activities because of health problems; 2) limitations in social activities because of physical or emotional problems; 3) limitations in usual role activities because of physical health problems; 4) bodily pain; 5) general mental health (psychological distress and well-being); 6) limitations in usual role activities because of emotional problems; 7) vitality (energy and fatigue); and 8) general health perceptions. It yields a profile of functional health and well-being scores as well as a psychometrically-based physical and mental health summary. Scoring is based on an algorithms that will generate a score 0 to 100 representing poorest health and best health, respectively. The SF-36 has been used in a previous study addressing the relationship between IPV and health.[32]



5. Study Subjects

Women aged 18-65 years were eligible for the study. Women presenting to the clinic for any type of visit (e.g., annual physical exam, follow-up visit, acute care) were included in the study. Patients who were known to be victims of domestic violence as documented in the medical chart were excluded from the study.

6. Recruitment

Subjects will be recruited at time of presentation to clinic for any type of visit.

7. Confidentiality of Study Data

Oral consent will be provided by participants and written consent will be avoided in order to protect a link to identifying subjects in the administered questionnaires. All questionnaires will be coded numerically with identifiers linking number to name kept safe in a locked box.

8. Potential Risks

Risks include potential discontinuation of medical care by women who may feel that screening is unacceptable once they are enrolled in the study. However, participants will be reassured that all information will be kept confidential and can choose to discontinue from the study if they choose. Another risk may include increased violence towards women if partners are aware of their participation in a study involving IPV. To minimize this risk, all information will be kept confidential and follow-up appointments will be made on the basis of needing follow-up medical care.

9. Potential Benefits

Benefits to participants include identification of IPV by screening and utilization of community services which may lead to improved health outcomes in women victims as well as decreased episodes of violence. Benefits to medical staff include increased knowledge regarding IPV and community resources for victims of IPV.

10. Alternatives (to participating in the study for the pt)

Patients may choose not to participate in the study at time of recruitment but will have access to community services for IPV if they so choose.

11. Attachments

Medical Outcomes Study: 36-Item Short Form Survey Instrument

1. In general, would you say your health is:	
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

2. **Compared to one year ago**, how would your rate your health in general **now**?	
Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

(Circle One Number on Each Line)

	Yes, Limited a Lot	Yes, Limited a Little	No, Not limited at All
3. **Vigorous activities**, such as running, lifting heavy	[1]	[2]	[3]

objects, participating in strenuous sports			
4. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	[1]	[2]	[3]
5. Lifting or carrying groceries	[1]	[2]	[3]
6. Climbing **several** flights of stairs	[1]	[2]	[3]
7. Climbing **one** flight of stairs	[1]	[2]	[3]
8. Bending, kneeling, or stooping	[1]	[2]	[3]
9. Walking **more than a mile**	[1]	[2]	[3]
10. Walking **several blocks**	[1]	[2]	[3]
11. Walking **one block**	[1]	[2]	[3]
12. Bathing or dressing yourself	[1]	[2]	[3]

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

(Circle One Number on Each Line)

	Yes	No
13. Cut down the amount of time you spent on work or other activities	1	2
14. **Accomplished less** than you would like	1	2
15. Were limited in the **kind** of work or other activities	1	2
16. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

During the **past 4 weeks,** have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

(Circle One Number on Each Line)

	Yes	No

17. Cut down the **amount of time** you spent on work or other activities	1	2
18. **Accomplished less** than you would like	1	2
19. Didn't do work or other activities as **carefully** as usual	1	2

20. During the **past 4 weeks,** to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

(Circle One Number)

Not at all 1

Slightly 2

Moderately 3

Quite a bit 4

Extremely 5

21. How much **bodily** pain have you had during the **past 4 weeks**?

(Circle One Number)

None 1

Very mild 2

Mild 3

Moderate 4

Severe 5

Very severe 6

22. During the **past 4 weeks,** how much did **pain** interfere with your normal work (including both work outside the home and housework)?

(Circle One Number)

Not at all 1

A little bit 2

Moderately 3

Quite a bit 4

Extremely 5

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks** . . .

(Circle One Number on Each Line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

32. During the **past 4 weeks,** how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

(Circle One Number)

All of the time 1

Most of the time 2

Some of the time 3

A little of the time 4

None of the time 5

How TRUE or FALSE is each of the following statements for you.

(Circle One Number on Each Line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

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