EHR-BASED SCREENING AND INTERVENTION FOR INTIMATE PARTNER VIOLENCE: STUDY PROTOCOL FOR A STEPPED WEDGE CLUSTER RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Intimate Partner Violence (IPV) is a frequently occurring condition (25% lifetime prevalence) for which screening in primary care is recommended. However existing screening tools often lack sensitivity due to high rate of nondisclosure, privacy, and safety concerns.

Methods/Design: A stepped wedge cluster randomized trial across the 28 clinics in three blocks of 8-12 sites will be used to assess the impact of an electronic health record (EHR)-based multifactorial intervention screening for Intimate Partner Violence in primary care practice for women aged 18 to 49 years. Our EHR intervention will promote IPV screening and risk management in primary care and will consist of three components: (1) a non-interruptive EHR alert; (2) confidential screening using the 3-item Partner Violence Screening (PVS) instrument and (3) confidential assessment and referral of high-risk patients using decision-support templates. Efficacy of each of these components will be assessed separately. The trial will be conducted in the setting of a control intervention of screening for IPV using nurse interviews and an electronic checklist.

Discussion: This paper describes the use of a stepped wedge cluster randomized trial to evaluate a privacy preserving screening approach.

BACKGROUND

Intimate Partner Violence (IPV) is a frequently occurring condition (5.9% annual rate of IPV reporting in women in US [1]) for which screening in primary care is the United States Preventative Service Task Force recommended service [2]. The lifetime prevalence of IPV is reported to be 25% of all women [3].

Screening for IPV is conducted much less frequently in primary care than screening for other conditions such as depression [4]. IPV is stigmatizing to its victims and concerns about confidentiality are a recognized barrier to disclosure [5]. Self-administered computer questionnaires are an effective but underutilized, privacy-preserving approach to screen for IPV [6]; alternatively, many healthcare providers often screen for IPV and other issues with oral questions. In IPV, asking questions in an overly routine or uncaring way is a barrier to a forthright response [4]. Further complicating matters, IPV screening also generates electronic health record (EHR) documentation that can compromise privacy, particularly if the perpetrator of the violence has access to a patient's screening results, EHR summaries, or claims data. An EHR diagnosis may also become widely available to personnel within a health system, creating concerns that may further inhibit disclosures [4, 7]. Many women, even in emergency department settings with evidence of injuries, choose not to disclose abuse because of privacy and safety concerns [8]. Therefore, maintaining patients' privacy in screening for IPV in healthcare settings is of paramount importance. A lack of expertise of primary care providers in the assessment of risk and difficulty linking patients to needed resources may also pose significant barriers for providers in screening processes.

One of the most widely used approaches to change provider behavior is an alert or prompt in an EHR for a specific task. These alerts come in two general flavors: interruptive which presents a popup alert that blocks a user from further actions on the computer screen until resolved and non-interruptive, which has more diverse implementations but often highlights an action on the screen. Blocking popup style alerts are the most common type of decision support alert in EHR systems; however, this approach has been overutilized, and as a result, providers frequently

ignore these alerts. A recent review of non-interruptive alerts found these were an effective means to alter provider behavior [9]. However, to the best of our knowledge, this method has not been previously applied in IPV screening.

A lack of expertise of primary care providers in the assessment of risk and difficulty linking patients to needed resources may also pose significant barriers for providers in screening processes. Integrated tools for risk assessment and referral for follow-up of positive IPV screening, including reminders of legal conditions that may mandate disclosure (for example, children witnessing IPV events), may help providers feel more comfortable with screening tasks [5, 10], and thus encourage compliance with screening guidelines. While screening and counseling for IPV is a billable activity, the desire to keep discussions private may result in a provider not using IPV-related billing codes and losing potential credit for time spent counseling in provider productivity calculations. An approach to document time spent in confidential activities that a health system might *choose not to bill for* because of privacy concerns may be important positive reinforcement for provider screening behaviors for IPV.

The objective of this paper is to describe the protocol of a stepped wedge cluster randomized trial for evaluating the effectiveness an IPV screening workflow consisting of three major components:

1. a non-interruptive alert for annual IPV screening;
2. PVS confidential screener;
3. Provider risk assessment of PVS screening results and patient referrals.

Stepped wedge study design was chosen for several reasons [11]. Firstly, we had a background control condition present (nurse-led screening) in all clinics. Secondly, because each cluster acts as its own control we need a limited set of clusters to reach the desired level of statistical power. We also needed time to do staff trainings and intervention support, and make sure that they follow our intervention protocol, with stepped wedge design we could do trainings in 5 clinics at a time. In addition, this design gives us control over temporal trends in the data.

METHODS/DESIGN

Study design/Participants

The protocol for this study is based on a stepped wedge cluster randomized controlled trial design [12].

28 clinics (14 Family Medicine, 12 Internal Medicine Primary Care and 2 women's health clinics) are grouped into 3 blocks each holding 8-12 clinics based on number of eligible patients seen in 2018-2019 and the number of full-time employees in clinics to assure that each block has similar population and employee size. We then use random number generator to randomize the starting time for 3 blocks. The target population is all women aged 18-49 who visit the clinics during the whole study period. Multiple screenings of the same patient can be made as it is described in the Intervention section. The blocks are shown in Figure 1.

Control (nurse-led screen)	Intervention Start (nurse-led and confidential screen)		
Time Period 0	**Time Period 1**	**Time Period 2**	**Time Period 3**

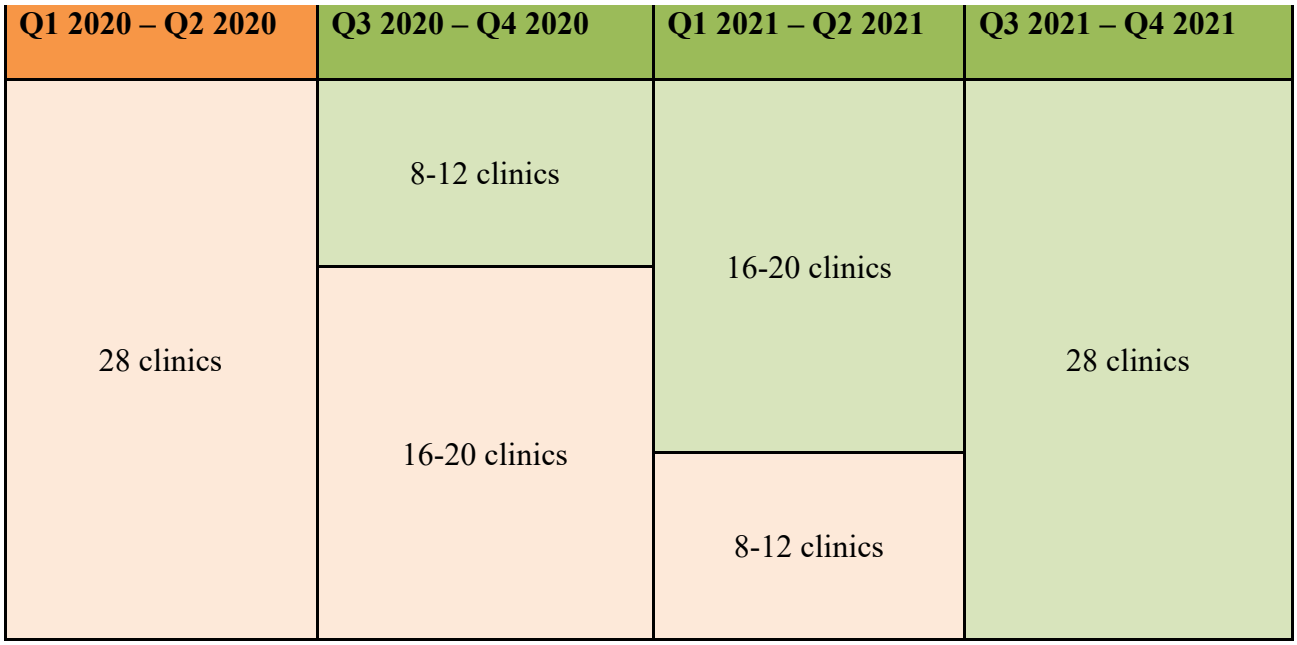

Figure 1. Randomized Stepped Wedge design with 28 clinics.

The control condition is a nurse-led screen developed by MUSC and deployed in 2019. When patients are roomed in all outpatient clinics, nurses complete a checklist where they, based on professional judgment (e.g., without asking standardized questions), screen for a variety of factors. One of those factors is Abuse/Neglect. Clicking on this item in the Epic EHR user interface, opens a second menu for nurses to document either the absence of any evidence of abuse/neglect or the presence of different risk factors. Selecting the "caregiver degrades or threatens patient", "abuse/neglect suspected", "evaluation for abuse", "excessive fear/withdrawn or guarded behavior" or "has unexplained injuries or bruises" was considered a positive screener for spousal abuse risk. It is important to note that control screening is always present (though not necessarily completed) when patient is eligible for confidential screening intervention, thus two screens are working at the same time during intervention period.
IRB determined that this was a quality improvement effort which did not require consent identifying and managing IPV is part of current practice the intervention was the Epic automatic fielding and special protection approaches used that decreased patient risk of disclosure.

Intervention
Working with key stakeholders (i.e., providers, patients, IPV survivors, IPV experts) we will adapt an existing program for IPV screening with both paper-based and computer-based components used within Northern California Kaiser Permanente Health System [13] to be fully implemented within the EHR by Epic Systems *in a privacy-preserving way*.
The EHR workflow will use this registry to present an in-menu, non-interruptive alert which notifies medical assistants to screen a patient for IPV on an annual basis. Responding to the (non-interruptive) alert converts the exam room computer to a kiosk-like mode for use by a patient to self-administer an IPV screening questionnaire.
At a population level, screening will be tracked for the entire eligible clinic population using a combination of decision support alerting rules. The non-interruptive reminder for medical assistants to screen patients will remain active until a patient is screened. In screener negative

patients, the non-interruptive reminder for medical assistants is turned off for one-year. In screener positive patients, the reminder for medical assistants to screen remains active for one-year to encourage repeat screening. In addition, in screener positive patients, providers will continue to receive pop-up alerts reminding them of the presence of hidden IPV data on an ongoing basis in subsequent primary care visits and to allow providers to trigger re-screening of patients.

The self-reported questionnaire approach is to maximize potential patients' willingness to report for IPV [14]. Because of the difficulties in ensuring a tablet computer or other device will be available in all primary care settings and in ensuring the privacy of responses after patient use, we will develop the kiosk-style approach: the medical assistant assures the patient is alone by removing another adult-age family from the room, so that the patient can use exam computer to give response to a 3-item PVS initial screening questionnaire [15], which if positive, will cascade to an additional questionnaire administered to assess risk levels of future harm [16]. The approach provides the maximum feasible level of protection for the privacy of patients' responses. Completion of the questionnaires results in a lock screen for the computer while awaiting the provider's portion of the visit. If the patient has screens positive for IPV, a popup alert notifies the provider. Clicking on the "IPV navigator Activity" in the alert takes the provider to an electronic form that provides decision support for IPV care.

The IPV Visit Navigator is a decision support tool that displays patients' responses to screening questions, helps the provider further evaluate a patient's risk level, offers recommended follow-up questions with examples of scripted responses, supports documentation of an IPV specific physical examination, and of counseling. It also allows the provider to record time spent on this issue during the visit to allow potential credit for this time in resource valuation units (RVUs) without billing, which might compromise privacy. The results are stored in an electronic flow sheet hidden from other visit records. Providers then complete reassessments of risk, physical exam findings, and document follow-up recommendations. On return visits, a Blocking BPA reminds providers to access the Navigator to review data. All patients screened positive are automatically reassessed on their next clinic visit for risk.

Referral for IPV further care will be managed in two ways. In settings of immediate risk to the patient there will be immediate outreach to hospital security and a nurse specialist providing IPV support to the Emergency Department. For lower-risk cases, patients are provided psychoeducation and offered a referral to a national hotline for counseling and support for IPV victims. In cases where the abuse of the victim is observed by children, the provider is reminded in the documentation tool to immediately refer the case to state child protective services, as required by law, and contact information was given.

To prepare clinics for participation, we will work with the Primary Care Service Line Director, clinical leaders in clinics and staff to implement the study. We will provide manuals, trainings and online education for clinic staff and providers. Online training will be integrated with MUSC's MyQuest staff education system. Educational materials will include tip sheets on intimate partner violence and how to implement screening procedures, video demonstration of EHR use, as well as videos demonstrating suggested scripting for interactions with patients. During the initial week of the roll out, Epic research support personnel will be available in the clinics to help providers learn to use software modifications and to answer questions. Provider support for in-person individual IPV-related training and case consultations will be provided by two experts in IPV training and management through-out the implementation and operation of the study.

Data Sources/Collection
All data will be collected within the Epic EHR system.

Outcome measurement
The primary outcome measure for the study is the rate at which patients were screened for IPV across the clinics. This outcome is calculated as the share of patients who completed PVS questions from all eligible patients. The secondary outcome is the rate at which patients at risk for IPV are detected by screening procedures. The patient is flagged positive if they are positive on one of the three PVS questions (Table 1). Other outcomes are the severity of risk (using Danger 5 risk assessment, ranging from 0 to 5) observed in patients, physician compliance with IPV management tools (measured as the rate of completion of follow-up decision templates, and the rate of referrals for post-visit counseling to a national hotline (a share from screened positive patients).

Table 1. How IPV Positive patients were identified using both screens.

Screen type	IPV Positive	IPV Negative
Nurse-led screening	One or several of the following answers is selected by during assessment for Abuse/neglect: • Has unexplained injuries, bruises, cuts • Caregiver degrades or threatens patient • Abuse/neglect suspected • Being evaluated for suspected abuse	One or several of the following selected: • No suspicion of abuse or neglect • Poor hygiene, dirty/unkept inappropriate clothing • Excessive fear, withdrawn, or guarded behavior • Non-compliance with plan of care
Confidential screening	In case one of the following answers was given: • Have you been hit, kicked, punched, pushed, shoved, or otherwise hurt by someone at home in the past year? **Yes** • Do you feel safe in your current relationship? **No** • Is there a partner from a previous relationship who is making you feel unsafe now? **Yes**	In case when the following answers were given: • Have you been hit, kicked, punched, pushed, shoved, or otherwise hurt by someone at home in the past year? **No** • Do you feel safe in your current relationship? **Yes, or Not applicable.** • Is there a partner from a previous relationship who is making you feel unsafe now? **No**

Power Calculations

This study will involve a total of n=28 clinics which will provide two years of data on approximately 68,000 patient visits. Of these, we expect 34,000 to occur during the non-screening steps and 34,000 visits during the intervention period.
Based on our current practice visit patterns for unduplicated visits by women between age 18 and 49 years, we will have approximately 34,000 eligible visits during the non-screening steps and 34,000 during the screening steps. We have assumed an annual IPV prevalence of 5.5% within the preceding year, based on rates reported by the CDC for SC [17], a screening completion rate of 95%, a 75% counselling rate for women who screen positive, and a 50% referral rate to the Hotline. Studies report the ability of screening to increase patient referral to services from a 2.5 percentage point to an 8.0 percentage point increase based on current referral rates between 0% and 3.6% [18]. Based on an analysis of our archival data, we expect that our current referral rate for IPV for women aged 18-49 seen in our clinics is no more than 0.14% and that this rate will increase to 3.9% with screening.
With about 600 relevant patient visits over 6 months per clinic, 8-12 clinics per wedge, and 3 wedges, we estimate that we will have 97% power to detect an increase in screening (i.e. 0.14% vs. 5.5%), and 89% power to detect a difference in the rate of referral for counseling and/or calls to the Domestic Violence Hotline (i.e. 0.14% vs. 3.9%). While we may be somewhat overpowered for our primary analysis, these numbers of clinics and patients will also allow us to make very precise estimates of the treatment effects within relevant patient subgroups (e.g. whites vs. blacks, urban vs. rural) and to determine whether there are any differential impacts of the intervention on those subgroups. These power calculations are conducted using PASS15 (NCSS, Kayesville, UT) and verified using the 'steppedwedge' function in STATA (StataCorp, College Station, TX), assumed an intraclass correlation coefficient of 0.05 (to account for a moderate level of clustering of patients within clinics), along with an alpha of 0.05 and two-sided testing.

Statistical analysis
We will use a generalized linear mixed model with a logit link controlling for block set and a fixed effect for each step, as discussed by Hussey and Hughes [19], to compare active screening accounting for the cluster design with a random clinic effect. Primary analyses will also adjust for patient characteristics (age, race) since these have been associated with risk of IPV. Models will be estimated with interaction terms to assess subgroup effects for specific patients, and to examine the effect of practices' characteristics on the heterogeneity of the estimates.
The intraclass correlation coefficients will also be estimated and reported for screening and counselling to assess the assumptions made for the sample size analyses so that this information will be available to future investigations using similar designs and outcomes.
Analysis for the other outcomes will be largely description. Frequency tables with patient demographics, including race, insurance, ethnicity, age, and marital status will be reported. Responses to individual PVS questions will also be presented in the form of frequency tables. Danger 5 risk assessment will be presented using histogram showing counts of patients that scored 0 to 5 of the risks [16]. Physician compliance will be measured as percentage of screened positive patients for whom decision-support templates have been based. Rates of referrals will be reported as percentage from total of patients screened positive.

In addition, we will perform sensitivity analyses to assess the effects of early vs. late randomization, potential "learning" effects that may occur as the screening becomes better integrated in practice routines, the effect of the practices' presence of a IPV champion prior to the study, and the effect for practice-specific screening refusal and rate of counselling acceptance on the overall estimate. Sensitivity analyses for the primary and secondary outcomes will be conducted using several methods, which have different missing data assumptions: 1) Complete case analyses which assumes missing data are completely at random; 2) Multiple imputation using M=10 imputations, which assumes missing at random; and 3) Assigning contrasting age group, race and income category classifications for missing values differentially by intervention group, which aligns with non- ignorable missingness (the data missingness is nonrandom and related to the actual values.)

Follow-up interview

A subset of patients, after providing informed consent, will participate in a follow-up telephone qualitative interview to gather information on acceptability of this self-report IPV screening approach within their primary care visit.

DISCUSSION

This paper outlines the study design and data analysis process to measure efficiency of our IPV screening intervention. Intervention consists of three components, efficiency of each of them will be assessed separately. The first component is the use of a non-interruptive alert to remind providers to screen for IPV on an annual basis. The second component of the intervention is confidential screening by self-report. The third component of the intervention is a physician-decision support system for assessment of risk and management.

This kind of dissemination research is needed because, despite strong recommendations for IPV screening at a national level, evidence for the overall effectiveness of screening on health outcomes is inconsistent and may be a barrier to adoption. Specifically, evidence for the impact of EHR-based IPV screening in primary-care settings on rate of initiation of counseling is an undeveloped area. Understanding of the link between screening and initiation of counseling has been identified as a critical evidence-gap by the USPTF and US Dept. of Health and Human Services [20, 21]. In addition, a recent review of IPV referral programs and processes strongly recommended the further evaluation of the effectiveness of referral processes for IPV in health care settings [22].

Our main technical innovations will be addition to Epic support of administration of the PVS questionnaires to patients on a recurring basis. This application uses a novel workflow developed at MUSC that tracks what questionnaires a patient needs to complete on a given visit and allows the exam room computer (i.e., the doctor's computer) to be safely used by patients to complete self-administered questionnaires. This allows screening without purchase and maintenance of additional hardware (a tablet may be used optionally if required by clinic layout). This workflow operates completely within the Epic system—no additional software or web service interaction is required. Questionnaires for IPV screening appear automatically in the workflow on an annual basis. The workflow is well-validated at MUSC, having been used in thousands of patients.

A second technical innovation is the automatic protection of information for patients who screen positive for IPV in a confidential department in Epic. This segmentation of information prevents inadvertent disclosures of information about IPV to a patients' partner, which could provoke violence to the patient. A novel alerting system helps link the routine care in each clinic with the

confidential department. In settings where providers are less focused on IPV care, this innovation may increase patients' safety by reducing provider effort to maintain security while making them more cognizant of the need for it through EHR alerts.

Our approach to screening has some limitations. We think that there might be some barriers for older patients to use the kiosk-based screening. Non-interruptive alert, while reducing alert fatigue, can lead to physicians ignoring the IPV screening more often. Provider incentives for compliance with screening and counseling process may be important in future dissemination efforts.

The study protocol does require significant effort by clinic staff and assessment of its impact on clinic productivity may be warranted. However, the elimination of non-scientifically-based screening programs that are ineffective may yield sufficient time to allow more effective ones to be performed in practice.

LIST OF PUBLICATIONS AND PRODUCTS

Software
https://comlib.epic.com/

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