Specific Aims

Violence is a public health crisis, with 30 million hospital and emergency room visits incidents in the US and estimated 1.6 million worldwide deaths annually. Hospital Based Violence Intervention Programs (HVIPs) show promise in using a public health based approach, providing support services to victims of violence. Through relationship-based mentoring and case management, Trauma Outreach Workers engage at-risk individuals during hospitalization, providing individual support and community service navigation. Key to this model is the recognition that risk of violence is rooted in modifiable risk factors that often represent social determinants of health, and that mitigating these factors mitigates the risk for violent re-injury and improve overall population health. These programs, are, however, expensive, and complicated to manage and sustain.

While limited single center studies have reported successes in decreasing recidivism, little is known about the population level effects of these programs, as noted in a recent EAST evidence-based review. This conclusion was reached in part because there is a paucity of high-quality evidence to support HVIPs as a global violence reduction strategy. While this review did not make a strong recommendation for these programs, it did highlight the need for additional research, in particular the need for measurement of intermediate psychosocial and health outcomes. There is a gap in scientific evidence and understanding of how to deploy and refine these programs to be effective in violently injured populations. There is a need for such evidence to support program development and investment, as these programs may be promising but are costly and complex to manage. Evidence in support of these programs would prompt widespread adaptation, evidence against would support the adaptation of an alternate strategy.

To date, no study has been performed that is multicenter, nor has any been done that uses a cohort to compare program participants to non-participants. Studies have been variable in their outcome measures, between intermediate health and social outcomes (return to school or work, establishment of safe housing) and recidivism, which is difficult to fully assess due to the time in which recidivism may occur. Due to the intensive nature of the programs and the general lack of financial support, individual programs do not typically have numbers of enrollees to support statistical significance when reporting their results. This study, therefore, aims to address these complex issues with the following aims.

Specific aim 1 is to develop a multicenter trial allowing large-scale input of prospective, observational information from both centers with HVIPs and centers without HVIPs, creating a cohort of participants and non-participants and comparing early health and social outcomes among participants and non-participants.

Specific aim 2 will create a subset analysis of HVIP disengagers, or patient who are offered program enrollment but disengage and are lost to follow up within the first month. These individuals' early and late outcomes will be compared with HVIP participants and non-participants.

Specific aim 3 will create a create a unique latent dataset in which individuals enrolled in all study arms will be either searched in hospital records or contacted in 5 years to ask about their rate of recidivism. This will allow us to compare both the recidivist rate in HVIP participants versus non-participants and allow us to look retrospectively at individuals to identify which demographic markers or early successes are indicative of a sustained decreased in recidivism.

The proposed study will determine if participation in public health based psychosocial programming that modifies social determinants of health also changes intermediate health and social outcomes in these patients, effectively changing their social determinants profile. Demonstrating the value HVIP participation will improve evaluation, prompt program quality benchmarking, and demonstrate value of HVIPs. This work will provide the first rigorous, multicenter scientific study of these programs. As the trauma surgery community continues to recognize violence as a public health problem, many individuals across the spectrum of providers have shown interest in managing HVIPs. This bold study will create a body of evidence that may support these individuals as they seek the necessary funding and hospital buy-in to create successful and sustainable strategies.

Significance

Violence is a public health problem prevalent in urban trauma centers. Recent literature demonstrates, violent crime and firearm violence follow similar patterns to infectious disease(1). Research has identified populations at risk, and violent trauma and trauma recidivism remain major public health crises affecting trauma centers (2, 3). Chronic exposure to trauma in the urban population and hospitalization for violent injury are associated with symptoms of PTSD, which can lead to an increase in violence perpetration in affected individuals (4). This cycle of violence leads to injury recidivism, adding additional burden to already overwhelmed urban trauma centers (5, 6).

Patients who are victims of interpersonal violence are often offered lifesaving medical care, but may not be offered violence prevention services during this critical time to prevent repeat episodes of violence. Trauma best practice guidelines discuss a unique experience following a traumatic event, in which individuals are more receptive to intervention immediately following an injury. However, there is little evidence that physicians are effective messengers (5). Much more evidence supports trauma outreach workers (TOWs) who are relatable individual from the community as essential credible messengers for prevention following trauma(7). This is based off of the widely evidence-based "Cure Violence" model(8). Key to this model is the recognition, in a public health model, that risk of violence is rooted in modifiable risk factors that often represent social determinants of health, and that mitigating these risk factors, we can mitigate the risk for violent re-injury and improve overall population health(9). While all are based in public health principles, HVIPS differ from Cure Violence, Cease Fire and other replication type programs in that they capitalize on the presumed "teachable moment" that happens in the hospital. During this time, it is thought, individuals are more receptive to understanding their own social determinants and risk profile, rather than before being injured. This is similar to a cardiac patient who refuses to quit smoking or exercise until he has actually had a heart attack.

It is with this knowledge that trauma centers have invested in Hospital-Based Violence Intervention Programs (HVIPs)(10). A successful HVIP requires community based workers to be embedded in the trauma team, often supervised by trauma surgeons and nursing leadership(11). When victims of violence are enrolled in HVIP programs, positive outcomes are reported, such as return to work and school, decreased retaliatory violence, decreased substance abuse, and decreased trauma recidivism(12). Individual programs have reported decreased healthcare resource utilization and spending (13, 14). As HVIPs become more ubiquitous in hospitals nationwide that serve victims of violence, the more clear it becomes that social determinants of health can be modified through the utilization of a TOW using case management based model(15).

An increasing body of literature supports HVIPs as an effective strategy for achieving violence reduction and the reduction of recidivism in urban trauma centers. However, despite initial promise from early reported results of HVIPs, a recent Eastern Association for the Surgery of Trauma evidence-based review made no strong recommendation for implementation of HVIPs, owing to a paucity of high quality evidence rather than making a referendum on these programs based on specific evidence of ineffectiveness(16). While formal evidence based review did not make a strong recommendation for these programs, it does highlight the need for additional research, in particular the need for measurement of intermediate outcomes, health outcomes, and qualitative analysis(17). The ensuing conversation both in the literature and among leaders in the field suggested that additional study is necessary to demonstrate program effectiveness, portability and best practices. Simply put, the humanistic trauma surgeon wants to believe these programs to work, and initial data suggests that they do, but ***we simply do not know if this is an effective strategy suitable for widespread adaptation, which is a critical barrier to the dissemination of this strategy***. Without high quality evidence, it is difficult for HVIP champions to convince hospital administrators, legislators and private funders to make the large-scale investment needed to create an effective and sustainable program.

When considering the history of surgery, it is impossible not to notice that trauma is frequently at the forefront of movements that are then adopted across the house of surgery. The American College of Surgeons Committee on Trauma was among the first to develop as a committee, and the trauma community was among the first to develop national education courses like ATLS and quality programs like TQIP. We are now at an exciting forefront of surgical care, where surgeons across disciplines and subspecialties recognize the privileged platform they hold in many of their communities, from which they may influence the social determinants of health that lead to surgical disease. It is from this platform that interest is growing in HVIPs. This age of "surgical public health" will require population-level data to show efficacy of strategies, and multicenter trials will the only way in which to adequately demonstrate results. ***If the aims of this project are achieved, we will have a high quality, multicenter trial that will indicate whether HVIPs should become part of the framework of all trauma centers who manage violently injured patients. Additionally, subset analysis will provide data about the best practices that may change the model in which HVIPs are***

deployed to be more uniform across centers (18). Currently, HVIPs are widely variable in their approach, population served, funding, and service provision.

Innovation

While several single centers have had remarkable accomplishments in developing their HVIP, and have been able to publish positive outcomes, they represent a small number of programs that may have specific factors contributing to their success. Therefore, most data reported on HVIPs has been single center, retrospective, and before-and-after comparisons. In addition, studies have used variable outcomes. Some studies report improved early health and social outcomes, and others report long-term recidivism. One major pitfall to the HVIP body of research is that it is unknown if early social and health outcomes are predictive of decreased recidivism, nor if recidivism is, in fact, the proper tool to define "success."

The coordinating site in this proposal has collected intermediate health and social outcome data from its first 18 months managing an HVIP in Newark, New Jersey, which will be scientifically presented in September, 2019. In this study, 120 patient records were reviewed in prospective observational fashion. 11 (9%) were lost to follow up. 50% of enrollees were scored as "moderate risk" or "high risk" by initial caseworker assessment. Ninety (75%) patients received information or referral, 102 (85%) obtained personal advocacy and 54 (44%) successfully applied for Victims of Crime Compensation funds. Of the initially identified needed services, 7 (29%) achieved education goals, 23 (35%) obtained stable housing, 13 (14%) became employed, 19 (17%) obtained health insurance, 13 (35%) obtained assistance with the criminal justice system and 65 (66%) obtained mental health services. Seventeen (11%) of participants completed the program when all personal goals were attained. Nine (53%) had more than one accomplishment. The accomplishments were: gaining employment (n=10, 59%), finishing high school, trade school or GED (n=7, 41%), enrolling in mental health services (n=10, 59%), and obtaining health insurance (n=4, 23.5%). This data, while interesting, suffers from being a single center experience without a comparison cohort, historical or contemporary.

In another single center study, the early outcomes that were most closely associated with success in decreasing recidivism were the achievement of stable housing and the attainment of appropriate mental health services(15). Still other programs use psychosocial metrics to determine "success," often measured by self-reported outcomes or validated tools for psychosocial stress, mental health or substance abuse as surrogates, believing that the most valuable aspect of the program is the improvement in mental health outcomes. The urban population suffers from pre-existing Post-Traumatic Stress Disorder (PTSD) at higher rates than the general population and also frequently suffers from PTSD related to their injury (19). It is therefore vital to screen individuals at program initiation for PTSD to understand their baseline level of PTSD to better understand the prevalence at time zero for comparison at later times.

All of this data is interesting and promising, but we are unable to know if various programs have similar success rates or are collecting the same outcomes, as no uniform data collection tool, outcome measure or quality metric has been developed or agreed upon. "Success" in HVIPs has been somewhat arbitrarily predetermined to be a decrease in recidivism, as the program is, by definition, secondary prevention and decreased recidivism is of greatest interest to funding stakeholders due to the high cost of a second event of hospitalization. A more holistic, public-health based approach would instead measure patient-centered indicators related to quality of life, health and social determinants, rather than individual events that may be the result of ecologic factors outside of the patient or caseworkers' control. Consider the example of a patient who had achieved stable housing and employment, but was shot a second time when a former contact was angry over a disagreement from years prior(17). This patient is considered a program failure, as he was a recidivist, but from a patient centered approach was a success in that he had achieved stable housing and employment, and improved life for his family. ***There is considerable disagreement in the HVIP community about what constitutes a "successful outcome," which we seek to unify with this study.***

To date, no HVIP study has attempted to use a cohort mechanism. The investigator in this proposal is familiar is in the process of collecting single center cohort data which will be valuable, but is low fidelity in terms of its single-center nature. Additionally, that study is specifically focuses on the mitigation of substance abuse and PTSD, rather than on which social determinants are indicative of decreased risk of recidivism.

This study will seek to mitigate the above problems by using the power of a multicenter analysis to develop uniform outcome metrics, and determine which, if any, early outcomes are more predictive a reduction in recidivism, It also will demonstrate if there is value of including mental health outcomes as a primary measure of program success and if these measures correlate with other social outcomes or recidivism. In short, ***rather than continuing to depend on single center studies reporting a single variety of outcome metric, we will ask multiple centers to report on demographics, intermediate outcomes, recidivism and***

mental health in order to create a rich dataset from which to abstract a proposed "recipe" for predicting and measuring success. We will additionally add a contemporary matched cohort of centers without HVIPs and as them to contact enroll violently injured patients. While the individual metrics are not novel to the field, the combination of them and the application to multiple centers is, as is the use of a propensity matched cohort. This will create a powerful study, which additional programs can cite and build upon as they develop and expand their own programs and seek sustainable funding from stakeholders.

An increasing group of researchers and practitioners are interested in the work done by HVIPs nationwide. There are currently over 50 members of the national network of hospital based violence intervention programs (NNHVIP), and this group is receiving applications at an astonishing rate such that it may double in size in the next year. This incredible interest in developing these programs nationally means we are at an interesting and important inflection point in the history of these programs and this work. ***The time to do a large multicenter trial is now***, while in the window where many programs are available to sample and have sustained funding through the study period. Many of the directors of these programs are EAST members, some of whom serve on the EAST Injury Prevention and Control Committee, indicating there is a community of individuals who would be eager to participate if the proper investment and infrastructure were in place.

Approach

This study will ask EAST members to participate in a prospective, observational, multicenter trial in which they will enter data centrally to a RedCap platform through Rutgers University. We will enroll patients starting January 1, 2020 and complete on December 31, 2021. We will invite both hospitals with HVIPs and those without HVIPs to participate in the study. Hospitals with HVIPs will prospectively consent patients for deidentified data entry into the study, and offer a gift card incentive on study completion at 2 years. Community based participatory research best practices as well as experience in ecological studies in urban populations suggest that compensation is a necessary requirement for participation in a vulnerable population. Therefore, ***this study cannot be done without financial support, prompting this application for support.*** Five-year follow up will be voluntary for logistical reasons.

The principal investigator and research mentor for this study are co-directors of the American College of Surgeons Committee on Trauma Injury Prevention Committee's HVIP workgroup and Dr. Dicker serves on the board of directors of the NNHVIP(20). These roles make these investigators uniquely suited to recruit programs for participation, and although no formal agreements yet exist, there has been wide discussion of undertaking this study among leaders in the field, should resources become available to do so. We expect 15-20 participating programs, who each would be expected to enroll 25-50 patients, for a total HVIP cohort of 500-1000 patients, far exceeding the number needed for statistical significance. Rutgers University will remain the IRB of record for this project, with individual site approvals necessary. Dr. Bonne has ready access to IRB support and the Rutgers Office of Corporate Contracts (OCC) as a stipulation of her role in the New Jersey Gun Violence Research Center, as well as two full time research assistants, one MPH graduate and the second with a PhD in Epidemiology. Rutgers (OCC) will manage all data use agreements with participating sites. Dr. Bonne is currently managing two smaller multicenter retrospective reviews and therefore has some experience in the execution of the necessary regulatory agreements.

The NNHVIP already hosts a central data service online to create a national database of HVIPs. This database, however, is not universally used by all HVIPs due to the costs associated with the platform, and does not collect the specific variables of interest to our specific aims. It does, however, collect some important data and therefore for programs both participating in our study and in the NNHVIP data system, our data use agreements will be written such that these programs can release their data to Rutgers directly without duplicating data entry.

HVIPs can be highly variable in their implementation and approach. To control for program-level factors, we will ask some basic questions of the programs, such as age demographic served, limitations on enrollment, types of violence served, and trauma center designation. This will be valuable to subset analysis, as programs may be broadly separated into groups by metrics such as funding, age restrictions, volume, TOW caseload and other factors that might globally affect outcomes in the patients served by these programs. From this, we can learn about program level factors that affect patient outcomes.

In order to accomplish our specific aims, we will ask programs to abstract both demographic and follow up data on patients. Demographic data will be used for post-hoc propensity matching as well as retrospective review of risk factors for future recidivism, during the second phase of data collection (see below). We will collect age, sex, race, injury type (gunshot wound, other penetrating trauma, blunt assault,

sexual assault), presenting hospital, patient zip code, patient insurance status (zip code and insurance status will be used as surrogate indicators of socioeconomic status), Injury severity score (ISS), hospital length of stay, ICU length of stay, any permanent disability (spinal cord injury, amputation, traumatic brain injury, palsy), immigration status, highest education level, and employment status on enrollment. We will then ask about early health and social outcomes tracked at 6 and 12 months, specifically, the achievement of stable housing, mental health, if needed, employment, education goals, substance use and several Likert-scaled global quality of life questions. We will also collect the PCL-5, which is a validated, easily administered, multilingual tool used to screen for PTSD. The data collection can occur at a regularly scheduled medical follow up, via contact with a case manager, or by telephone. The tools used, including PCL-5 are specifically designed to be multilingual, easily administered by staff, and require very little time.

One of the hallmarks of a successful HVIP is the unique, somewhat personal, relationship that caseworkers have with patients. We expect this relationship to be beneficial to the abstraction of data on our HVIP participant cohorts. Due to the difficult nature of ecological study on urban populations, however, we expect the non-participants and HVIP disengagers to be a more difficult group to contact at longer time points. As such, we will seek to enroll a disproportionately high level of centers without HVIPs in order to oversample our non-participants 3:1. This will allow for post-hoc propensity matching by age, race, sex, ISS, hospital LOS, injury type and socioeconomic status (to be assessed by primary insurance as a surrogate). Propensity matching will be accomplished using the XL Stat plug-in for Microsoft Excel.

The sample size is based on the lowest threshold measure, which is the PCL-5, and will require the most patients to demonstrate statistical significance. Previously published data suggests that PTSD rates are 40%-50% in violence victims vs. non-violently injured victims of trauma (20%). Power estimation was completed with G-Power, yielding a prediction of 160 patients total in the intervention group and the cohort. The intermediate group will be a convenience sample of necessity. Most HVIPs report retention rates of 70%, meaning that 230 HVIP patients would need to be enrolled prospectively, with an expectation of 90 of those patients entering the intermediate group. To oversample the cohort 3:1, we would need 480 victims of violence from non-HVIP centers. For discreet and binary variables such as achievement of employment, stable housing, or education goals, chi-square analysis will be used to determine significant differences between HVIP and non-HVIP patients, and one way ANOVA for three-group analysis when adding the disengagers. Students T-test will be used to evaluate continuous variable such as age and ANOVA for scaled variables such as PCL-5 or any Likert scaled questions asked in our survey.

Phase 2 of data collection will be longer term. The study will enroll patients from January 1 2020 through December 31, 2021. In 2026, we will ask center in both the HVIP and non-HVIP cohorts to revisit the data by opening their linking document and searching for each patient in their medical record system for events of recidivism. We will also ask that they search the vital statistics records for their state for any interim death that may not have presented to the hospital. For patients that are non-recidivists in each of these systems, we will ask centers to reach out for a brief 5-question survey to each participant, simply asking if they had any interim victimization events, the nature of these events, and the continuation of any personal goals or social determinants initiated during the program, such as finishing school or maintaining work.

Data from this second phase of data collection will allow comparison across several domains. We can, once again, compare HVIP participants to disengagers to nonparticipants in terms of long-term recidivism rate. Recent data suggests that thought widely variable, the T50, or time at which half patients who will experience recidivism already have is about 4.25 years, making the 5-6 year window for follow up a reasonable time to expect an event of recidivism if one were to occur. Again, chi-squared analysis will be performed to compare level of incidents across groups. Data from the second phase will also address the predictive factors for future recidivism. A subset analysis on all recidivists will retrospectively evaluate how many, and which, intermediate outcomes were achieved by future recidivists versus non-recidivists. There are a number of ways to analyze this data, comparing HVIP participant-future recidivists to HVIP non-participant-future recidivists, etc.

A known limitation of this phase of data collection will be the loss of follow up. Patients in the urban population frequently change phone numbers, move, are incarcerated, or are otherwise easily lost to follow up. We recognize this limitation as a significant one but feel that it is still valuable to attempt this important aim in order to receive valuable longitudinal information that has never been attempted elsewhere. Due to the richness of this dataset, we hope to make it available to all researchers involved in the project for a variety of subset analyses, including program features indicative of success, individual quality metrics for programs, and any other questions the investigators may be able to use.

In summary, although challenging and large in scale, this project represents a vision of work regarding outcomes, quality, and metrics to bring rigorous scientific study to the field of HVIP research. We believe this

work to be integral to our role in trauma centers as pillars of the community and dedicated to the prevention of injury and violence.

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